

An empirical study series to investigate the research synthesis of complex health care interventions and related methodological issues

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Abstract

Purpose: This thesis aimed to evaluate how theory-orientated approach to research synthesis of complex health care interventions may facilitate better understanding of intervention mechanisms. Thesis intended also to evaluate how qualitative research compliments a systematic review and meta-analysis of complex health care interventions, especially what participants' perceive as effective intervention features and how this compares with systematic review and meta-analysis evidence. By combining these different approaches thesis aimed to improve reporting of reviews of complex health care interventions by providing more detailed information about intervention mechanisms that appear to be associated with a successful intervention.

Methods: The thesis was built on a series of empirical studies. Multiple bibliographic databases and references of retrieved articles were searched for relevant review articles, randomised controlled and qualitative studies. Random-effects meta-analyses were conducted to estimate effectiveness of psycho-educational smoking cessation interventions, while behaviour change techniques used in the studies and their suitability to change behavioural determinants were evaluated using a framework by Michie et al. (2008). Thematic analysis was conducted to explore qualitative studies, while narrative analysis was used to bring the different case studies together.

Results: Psycho-educational interventions significantly increased point prevalent and continuous smoking cessation, and despite superficial differences, interventions appear to deploy similar behaviour change techniques. Qualitative research suggested considerable variation in patients' expectations and experiences of psycho-educational interventions, but combined results suggested that many of the techniques used in psycho-educational interventions appear to be well matched with patients' experiences of successful interventions.

Conclusions: Although questions remain about how to distinguish characteristics of an effective intervention, the theory-orientated approach to systematic review and meta-analysis was able to provide a detailed analysis of the intervention techniques to help in the design of future interventions. This approach, however, is labour intensive in its present form.

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Chapter 1

Introduction to this thesis

1.1 Interventions in health care

Healthcare and health care policy making is a rapidly developing field with a variety of interventions now available for preventing and treating illnesses. As the amount of available interventions grows, policy and decision makers in healthcare increasingly demand research evidence of the effectiveness, suitability, and unintended outcomes of interventions' to help in deciding the allocation of resources (e.g. Mays et al., 2005). However, conclusive evidence of the effectiveness of interventions is not always available, often because of a lack of research, but, also as the Medical Research Council (2000, Craig et al., 2008) has highlighted, the complexity of an intervention may also be an important barrier to evaluating its effectiveness. The aim of this project is to evaluate how examining intervention theories and mechanisms as a part of systematic reviews of complex health care interventions could help understanding intervention complexity and practical application of research results.

While the term “intervention” is commonly used as a general term to describe a clinical intervention delivered on an individual level, it should be noted that “intervention” may also be used to describe methodologically-diverse initiatives. Thus, a variety of quite distinct things may be called an intervention, from a clinical treatment to a health care programme, or a health service delivery, which, again, are all distinct from health policy (Pawson et al., 2005). Although the term “intervention” is often associated with a clinical treatment, health care interventions can function on several levels, from targeting individual patient care, to the structure of organisations or services, to health professional practice, and to whole populations (Medical Research Council, 2000).

Traditionally, in health care, systematic reviews are used to clarify questions about the overall effectiveness of an intervention when primary studies offer unequivocal answers of intervention effectiveness (e.g. Higgins and Green, 2011). Reviewing the overall effectiveness of complex health care interventions, may, however, face

several challenges ranging from locating of studies to the interpretation of results in practice (Armstrong et al., 2008, Higgins and Green, 2011, Jackson et al., 2004). Although there are no precise figures about the prevalence of complex health care interventions within particular health care systems, it could be assumed that they are likely to be widely used, even if their effectiveness and mechanisms may not be fully understood.

1.2. Complex interventions in health care

Although even a relatively straightforward intervention, such as a medication, can present complexities, an intervention can be described as complex when its different components, usually behaviours, and relationships between the different components are difficult to define (Medical Research Council 2000, Craig et al., 2008). Campbell et al. (2000) argue that complex health care interventions can target service delivery and organisation (e.g. stroke units), health professionals' behaviour, community, groups, and individuals. However, Hawe et al. (2004) point out that the definition of complex intervention brought forward by Medical Research Council (2000) can be problematic, as it can be equally consistent with both a poorly thought through intervention and a complex intervention. Hawe et al. (2004) argue that instead of standardising a complex intervention by precisely defining its components, such as an information pack and thus simplifying the intervention, it would be more appropriate to define the steps in the process that facilitate change and the key purposes of these steps.

1.3 Understanding how complex health care interventions work

Intervention theory could be described as a general principle or a collection of related principles that aim to explain a set of known facts or empirical evidence (Reber, 1995). Complex health care interventions are based on theories or assumptions of through which mechanism they produce expected outcomes (e.g. Pawson et al., 2005), though these may not always be explicitly stated. Many interventions, such as a pain relief medication after surgery, are well-established with a sound evidence base for practice and well-understood intervention mechanisms (e.g. Derry et al., 2010). However, for some interventions, such as for psychological interventions in

the management of chronic pain (e.g. Turk et al., 2008), intervention mechanisms are not well-established. Understanding how complex health care interventions work, is hampered by the difficulty of defining intervention components and interactions that may be expected between components (Medical Research Council, 2000, Craig et al., 2008), which may restrict, how well an intervention mechanism can be explored and conclusions drawn about the effectiveness of an intervention. The investigation of mechanisms informing an intervention may be easier in the cases where complex health care interventions have clear standard processes, as suggested by Hawe et al. (2004). However, given the complexity of factors that might affect outcomes of any health care intervention, it is not surprising that the findings of research on complex health care interventions can be confusing and mutually conflicting, which, in turn, may limit its application to practical decision making.

1.4 Evaluating the effectiveness of complex health care interventions

Although randomised controlled trials are designed to offer an unbiased estimate of the effectiveness of an intervention, complex health care interventions can face challenges in applying all the requirements of randomised controlled trials within their methodology. Among the potential challenges facing randomised controlled trials of complex health care interventions are difficulties in blinding participants and providers to the treatment conditions. (e.g. Medical Research Council, 2000). To help in improving the design and the evaluation of randomised controlled trials of complex health care interventions, the Medical Research Council (Medical Research Council, 2000, Craig et al., 2008) launched a guidance on how to improve the planning and the evaluating of randomised controlled trails of complex health care interventions.

However, developing an evidence base for complex health care interventions and understanding how they function not only depends on the availability and quality of primary research, but also on how that research is brought together and conclusions drawn from the material. Combining primary research results helps in evaluating the overall effectiveness of interventions, summarising the existing evidence, exploring gaps in knowledge, advancing the development of a research area, and in supporting the primary research (e.g. Petticrew and Roberts, 2006). The increasing need for

utilising evidence from all the primary research to support the best possible care and treatment for patients has been highlighted. The use of evidence from the existing studies has been further stimulated because, due to current ethical and research governance requirements, primary research in the NHS is becoming increasingly restricted Hewison and Haines (2006).

Combining research, or rather synthesising research, is often understood to mean reviewing literature, though research synthesis better describes the process of making systematic and transparent research summaries of the best available evidence (EVIPNet, 2009). In the health care settings the widely applied approach to research synthesis is a systematic literature review of available randomised controlled trials, which is often accompanied by a meta-analysis to estimate the combined effectiveness of an intervention compared to a control condition (Petticrew and Roberts, 2006). The conventional systematic literature review, accompanied by a meta-analysis, has, however, been criticised of its overt orientation towards evaluating the effectiveness of quantitative research and especially of randomised controlled trials. This had led to calls for research synthesis methods that are able to accommodate more diverse evidence. (e.g. Britten et al., 2002, Dixon-Woods et al., 2005, Mays et al., 2005).

Although research synthesis tends to be associated with the assembly of evidence to support decision-making and policy formulation, it has other functions outside this rather narrowly defined role. Research synthesis may be used in summarising, pooling, aggregating, and replicating the research results. These approaches to research synthesis are sometimes described as a “knowledge support” (Mays et al., 2005) or as an “integrative synthesis” (Dixon-Woods et al., 2005), which requires comparability between data. While the integrative approaches for research synthesis are perhaps more widely-known and used, research synthesis may be equally used for purposes of an “interpretive synthesis” (Dixon-Woods et al., 2005), or a “decision support synthesis” (Mays et al., 2005). This kind of synthesis aims to build and test theoretical constructs, investigate associations between variables, and interpret primary studies in a new context. Traditionally, the integrative synthesis has been considered more suitable for the quantitative evidence, whereas the interpretative synthesis is seen as more suitable for the qualitative research evidence (Dixon-

Woods et al., 2005, Dixon-Woods et al., 2006). Divisions between the integrative and the interpretative synthesis, however, have become blurred with the increasing application of the conventional research synthesis methods, such as the meta-analysis, in investigating intervention mechanisms and theories (e.g. Dixon-Woods et al., 2006, Yang, 2002).

Including the consideration of theory and mechanisms of complex interventions in the research synthesis has been recently suggested (e.g. Shepperd et al., 2009). However, there is a need to conduct a comprehensive review of the relevant methodological studies to evaluate how an examination of intervention mechanisms and underlying theories as part of a research synthesis can be achieved. In addition, there is a very limited experience and empirical evidence on the consideration of underlying theories or mechanisms in the research synthesis for evaluating complex healthcare interventions.

1.5 Aim of this project

This project therefore aims to evaluate research synthesis methods for the complex health care interventions. The purpose of this project is to examine how including theoretical considerations in the review process may be used to strengthen reviews of the complex health care interventions and application of their results to health care practice. In this thesis, the inclusion of theoretical considerations means examining how theories underpinning interventions are used in the primary studies and how intervention mechanisms could be systematically examined within a systematic review, without using a statistical method. Therefore, a series of empirical studies is conducted to examine ways to improve understanding of the theories and mechanisms underpinning interventions.

This thesis follows a structure in which each of the chapters have their specific research questions while building on one another to form a coherent investigation of theories and mechanisms underpinning interventions in a systematic review of complex health care intervention. In the background chapter, the discussion touches on a number of relevant issues for this thesis: complexity of interventions; challenges faced in the design and the evaluation of complex health care intervention;

methodological issues in systematic reviews of complex health care interventions; as well as giving an overview of a selection of methods for reviewing complex health care interventions. The background chapter does not aim to provide a systematic review, but aims rather to set the background for the thesis. Although this thesis begins with health psychological concepts, a considerable amount of the material comes from public health research problems. However, this thesis does not primarily aim to contribute to the public health discussions, but to evaluate how the theories and mechanisms underpinning interventions may be better understood as a part of review of complex health care interventions as often found in public health.

In this thesis, a series of empirical studies are presented to examine the contribution of theory in reviews of complex health care interventions: a review of reviews of psychological cardiac rehabilitation interventions; a scoping review of psycho-educational cardiac rehabilitation interventions; a systematic review and meta-analysis of psycho-educational smoking cessation interventions for coronary heart disease patients; an examination of intervention mechanisms in psycho-educational smoking cessation interventions for coronary heart disease patients; a systematic review of qualitative studies examining participants expectations and experiences; and finally a synthesis of results from the qualitative review and review of psychological cardiac rehabilitation interventions. A centrepiece of this thesis is trialling a new and innovative approach to investigating intervention mechanisms, using a framework developed by Michie et al. (2008). Another important addition to the knowledge that this thesis aims to make is to examine whether and how qualitative research can add to, confirm, or explain previous analysis results of effective intervention features and mechanisms. The empirical studies are not conducted in isolation from one to another, as findings from the earlier studies are used to modify the research questions in the later studies. The combined experience from the empirical studies is used to draw conclusions about how and whether the theory-orientated approach to systematic reviewing of complex health care interventions pursued in this project may have improved the understanding of the mechanisms informing the intervention and the applicability of their results to the practice. Finally, as many of the tables and figures included in this work are extensive, these are presented together at the end of the chapter to which they are relevant

Chapter 2

Methodological issues posed by complexity in interventions in primary and secondary research on complex health care interventions

2.1. Introduction

Health care is a rapidly developing field with a variety of interventions available for prevention, diagnosis, and treatment of illnesses, though conclusive evidence of effectiveness of interventions is not always available. Lack of evidence of an intervention effectiveness may be due to multiple factors, not least by the lack of research, but, the Medical Research Council (Medical Research Council, 2000, Craig et al., 2008), has highlighted complexity of an intervention as an important factor that can hinder the evaluation of its effectiveness. The purpose of this chapter is to provide an evaluative overview of the present challenges facing the reviews and synthesis of complex health care interventions, and discuss the available guidance for reviewing complex health care interventions. A further aim of this chapter is to critically examine and compare the methodological issues raised by some of the methods suggested for reviewing and synthesising complex health care interventions. This chapter also aims to identify limitations in the current guidance on developing and reviewing complex health care interventions, discuss the role of theory in the reviews of complex health care interventions, clarify which methodological issues need further research, and how the research question of this thesis fits into the wider field of the research on reviewing complex health care interventions.

This chapter presents an overview of the current issues and guidance from key papers and publications, without attempting a systematic review of all the relevant methodological literature of reviewing complex health care interventions. As the purpose of this chapter was to provide an overview, rather than a systematic presentation of literature, a non-systematic review was judged as the best approach in this instance. Adopting a non-systematic approach allowed evaluating selection of relevant and related issues in developing and reviewing complex health care interventions. The strategy for this review included searching electronic databases

(MedLine, PsycINFO) with the generic search words “complex intervention”, hand searching references from identified articles, and asking experts from the field about relevant articles. The chapter begins by identifying issues relevant for the design and evaluation of complex health care interventions before going on to examine the issues relevant for reviewing complex health care interventions, and finally evaluates number of methods suggested for reviewing complex health care interventions.

2.2 Defining complexity in interventions

In general usage “complexity” tends to describe something that is characterised by multiple parts in intricate arrangement (Wolfram, 2002). In the research of complex health care interventions definitions of complexity aim to explain, what factors or components cause intervention complexity and how the complexity affects the evaluation of an intervention effectiveness. Examples of different definitions of a complex intervention are shown in Table 2.1, which shows the type and range of the approaches to defining complexity in interventions. Bradley et al. (1999) suggested defining a complex intervention on what he described as three levels; in relation to the target population, service provision, and management of behavioural change. According to Bradley et al. (1999) the first level comprises the theory and evidence underlying the intervention; the second level includes the tasks and the processes that are essential for delivering the intervention; and the third level comprises the different people with whom and the contexts within which the intervention is operationalised. Bradley et al. (1999) argue that this three level definition of a complex intervention enables not only mixed methods evaluation of complex health care interventions, but also explaining the study findings within the three different levels.

In 2000, the Medical Research Council published a definition of a complex intervention that defined it as consisting of several components that can act both “independently and inter-dependently”. The guidance by Medical Research Council argued that the evaluation of a complex intervention is difficult due to problems of developing, identifying, documenting, and reproducing the intervention. (e.g. Campbell et al., 2000). Superficially the definitions of complex health care interventions promoted by the Medical Research Council (Campbell et al., 2000) and

Bradley et al. (1999) appear dissimilar. However, the both definitions do emphasise that complexity in an intervention is characterised by the intervention's acting on different levels, and that the interaction between the different levels of the intervention complicates any evaluation of its effectiveness.

Hawe et al. (2004) point out several potential problems associated with the guidance developed by the Medical Research Council (2000). According to Hawe et al. (2004) one significant problem with the way the Medical Research Council (2000) defines a complex intervention is that the definition can equally be consistent with both a poorly thought through intervention and a complex intervention. In contrast to the Medical Research Council's definition (Campbell et al., 2000), Hawe et al. (2004) argue that instead of standardising a complex intervention by defining its components, and thus simplifying the intervention, it would be more appropriate to define those steps in the process that facilitate change and the key purposes of these steps. Hawe et al. (2004) argue that Mullen et al. (1985 in Hawe et al., 2004) have shown that interventions are more likely to be effective when they meet certain behaviour change criteria, such as tailoring an educational programme to fit with participants needs. Therefore, Hawe et al. (2004) argue that the theory underpinning the intervention and functions of the key elements of the intervention were driving the improvements rather than the elements in themselves. This would imply that the key to evaluating a complex health care intervention is not in standardising the components of the intervention, but in standardising the function(s) of the intervention so that regardless of variations in the intervention over time and place, the function of an intervention will remain the same. (Hawe et al., 2004, Hawe et al., 2008). Further, Hawe and Shiell (2009 in Mackenzie et al., 2010) also argue for a shift from considering interventions as packages to see interventions as "events in systems".

However, Blackwood (2006) points out that while defining the components of a complex health care intervention, as Hawe et al. (2004) suggest, may seem straightforward, this may not always be the case. According to Blackwood (2006), the definition offered by Hawe et al. (2004) implies that all components of a complex intervention can be defined according to their form and function. However, Blackwood (2006) argues that defining an intervention components according to

their function may not be unproblematic either, as this approach tends to overlook related components that also have an impact to outcomes, such as the characteristics of people delivering and receiving the intervention. Blackwood (2006) argues that these components are not always easily defined and can be neglected in reports.

Shiell et al. (2008) point out that although many health researchers use the term ‘complexity’ to describe the problems faced when evaluating non-drug interventions, complexity has actually two specific meanings. In the first meaning, as used in the Medical Research Council’s guidance, complexity can mean complicated. As a complex intervention is built on multiple components, it is difficult to know which of the components or the combination of components is important. (Medical Research Council, 2000, Shiell et al., 2008). However, the second view considers complexity as a property of a system, not of an intervention. Complex systems are built on other complex systems (such as the human body), which can accommodate changes in their local environment, and do not behave in a linear fashion. An example of a complex system is a hospital, in which interventions themselves can be complex or simple. (Rickles et al., 2007, Shiell et al., 2008). Therefore, Shiell et al. (2008) argue that distinctions between these two views of complexity can be easily blurred, especially when complicated interventions can readily take on characteristics of complex systems, as it is not feasible to isolate the human agency needed to deliver an intervention from the intervention itself.

The Guidance from the Centre of Reviews and Disseminations (Centre for Reviews and Dissemination, 2009) has not developed its own definition of complex interventions, but describes complex interventions as a “package of components”, such as interventions that include diet, exercise and counselling for weight loss. The guidance of the Centre of Reviews and Disseminations (Centre for Reviews and Dissemination, 2009) relies primarily on the definitions of the Medical Research Council (e.g. Craig et al., 2008) in defining complex interventions. This, nevertheless, may not be surprising, as May et al. (2007) argue that the Medical Research Council Guidance for evaluating complex health care interventions is an internationally accepted definition of complex health care interventions. Examples of context-specific definitions of complex health care interventions can be found, such as the definition by May et al. (p.3, 2007) of a complex intervention as

“...deliberatively initiated attempt to introduce new, or modify existing, patterns of collective action in health care.”. However, it seems that the approach to defining complex intervention by the Medical Research Council (Campbell et al., 2000, Craig et al., 2008) is the most widely used in the literature (e.g. Bird et al., 2011, Evans and Higginson, 2011).

This overview of the current literature suggests that regardless of the widespread use of the MRC definition of complex health care interventions (Campbell et al., 2000, Craig et al., 2008), defining complexity in interventions continues to be a topic for debate. Two main approaches for defining a complex health care intervention emerged from the literature. Firstly, the task of defining a complex intervention may be approached by defining and attempting to standardise complex intervention's components (e.g. Campbell et al., 2000, Craig et al., 2008), thus seeing interventions as a package of components. Secondly, defining a complex intervention may be attempted by specifying and standardising intervention aims, thus seeing intervention more as an event in a system (e.g. Hawe et al., 2004). Available literature also suggested that how a complex intervention is defined influences in how the evaluation of the effectiveness of an intervention may be approached. For example, if a complex intervention, as suggested by Hawe et al. (2004), is defined by the aims of the intervention, it is possible to evaluate the overall effectiveness of the interventions with the same aim, but, investigating intervention mechanisms common to these interventions may be complicated, as the interventions may be too dissimilar for meaningful analysis. On the other hand, using the approach argued for by the Medical Research Council (e.g. Campbell et al., 2000, Craig et al., 2008), ensures that the complex interventions are defined within stricter lines, which may improve comparability between the interventions. However, this approach may limit the number of potentially relevant studies. Therefore, it appears that the decisions about how a complex health intervention should be defined are dependent on the type of an intervention and the purpose of the evaluation. In addition, the literature on defining complex health interventions does not clarify how defining a complex health care intervention links to what is being evaluated in an intervention.

2.3 Conceptual frameworks for evaluating complex health interventions

Ideally, evaluation of the complex health care interventions should assess the effectiveness of an intervention and the efficacy of the intervention components (Landau, 2011). Several frameworks are proposed for enabling the best design and evaluation of the complex health care interventions. A key difficulty for these frameworks is a lack of clarity in defining what should be evaluated. For example, although the MRC's framework (Campbell et al., 2000) for developing and evaluating complex health care interventions discusses methodological issues relevant to the different phases of development and evaluation of a complex intervention, and what should be evaluated in each phase. The guidance highlights the importance of a "pre-clinical" or a theoretical phase, which should establish the theoretical basis for the intervention, i.e. how an intervention is assumed to cause its desired effects. (Campbell et al., 2000). However, the guidance is less clear on how the evaluation of theories underpinning interventions should be approached. Although the guidance for developing and evaluating complex health care interventions (Medical Research Council, 2000, Craig et al., 2008) is successfully used in the practice (e.g. Bonetti et al., 2005, Faes et al., 2010, Bradshaw et al., 2011 In Press, Kirkevold et al., 2011 In Press), it has been, however, criticised for its emphasis on RCTs and failing to take into account the complexities of policy related programmes and contextual variation (e.g. Hawe et al., 2004, Mackenzie et al., 2010, Craig et al., 2008).

In 2008 (Craig et al., 2008) an updated framework for developing and evaluating complex interventions was published by the MRC, which addressed a number of points criticised in the earlier framework (Medical Research Council, 2000). According to the updated guidance, developing and evaluation a complex intervention has several phases, though these need not be linear. The updated guidance notes the need to use and understand the theoretical basis of an intervention planning, and argues that having a coherent theoretical basis for an intervention and using the theory systematically in developing the intervention is helpful in specifying intervention mechanisms. In addition to having a clear theoretical basis for an intervention, the Medical Research Council Guideline (Craig et al., 2008) recommends that the studies of complex health care interventions describe

interventions fully so as to facilitate the implementation, replication, and the process of evaluation. A recent research on complex social interventions has indeed suggested that information on the implementation of the intervention is often insufficient or unclear, and that this impairs understanding how the implementation of a complex intervention may have influenced its results (Egan et al., 2009).

According to the MRC, a complex intervention is characterised by a number of components that can act independently or co-dependently (Campbell et al., 2000). The updated guidance continues to emphasise that clearly formulated theoretical background of how an intervention works enables understanding of which parts of the intervention work independently or together co-dependently (Craig et al., 2008). However, the guidance still lacks detailed guidance on how the evaluation should be done in the practice. The guidance in the development and the evaluation of complex health care interventions links with the definitions of complex health care interventions by the Medical Research Council (Campbell et al., 2000) and by Bradley et al. (1999). As complexity is seen by these authors as caused by interaction between the intervention components, participants, and providers, the complexity is best evaluated, as suggested by the guidance of the Medical Research Council (Craig et al., 2008), by examining the different parts of the intervention and how they interact together. According to this framework, successfully evaluating intervention mechanisms requires a clear theoretical formulation of what and how different parts of an intervention are planned to achieve. (e.g. Craig et al., 2008).

The updated MRC guidance emphasises that while understanding the processes is important, this cannot replace evaluation of outcomes (Craig et al., 2008). The updated guidance points out that though experimental designs are not suitable in all circumstances, they should be preferred to observational methods, and that instead of complete standardisation, complex interventions may work best if adapted to the local conditions (Craig et al., 2008). A typical example of complexity in the implementation process of a complex health care intervention is the intervention's dependency on many individuals, who may not share the same ideas and assumptions about the process. Interactions between people who deliver and those who receive the intervention may also be unexpected, and different stakeholders with diverse agendas may want to influence the intervention direction. In addition, social

systems that surround a complex intervention are multiple, making it difficult to evaluate interactions between a circumstance, a context, and an intervention. Therefore, even apparently straightforward interventions have inherent complexities that complicate investigation of the effectiveness of an intervention. (Pawson et al., 2005, Medical Research Council, 2000, Craig et al., 2008).

However, in a letter to the BMJ, Kernick (2008) argued that the MRC's (Craig et al., 2008) guidance for developing and evaluating complex health care interventions conflates 'complex' with 'complicated'. According to Kernick, complex systems and interventions should be viewed as a non-linear, implying that they cannot be reduced to their component parts. In this way of thinking, outcomes are not endpoints, but reiterations of an on-going process with emphasis on the interactions between system variables that may cause unexpected results. Kernick suggested that the example of a realistic review (Pawson et al. 1997 in Kernick, 2008) provides an alternative methodological approach for evaluation of complex interventions. Kernick (2008) argued that reducing a complex intervention to its components is not meaningful, thus implying that evaluating how the different components of a complex intervention interact or function may not be achievable. Therefore, it appears that Kernick argued, similarly to Hawe et al. (2004) (Hawe et al., 2004), that a complex intervention should be defined in the terms of the aims of an intervention rather than in the terms of its components. However, the argument by Hawe et al. (2004) for defining complex interventions by their aim is reflected in the updated MRC guidance of the development and evaluation of complex health care interventions (Craig et al., 2008), which recognises that in some cases a complex intervention works best when it is adapted to the local conditions. Thus the currently published guidance (e.g. Craig et al., 2008) is sensitive to accommodating different ways of defining complex interventions.

Mackenzie et al. (2010) argued that some complex interventions, as with national policy initiatives, face considerable challenges for being evaluated as they may not easily accommodate the recommendations in the MRC guidance (Medical Research Council, 2000, Craig et al., 2008) nor be standardised by means of the intervention functions or the theorised mechanisms (Hawe et al., 2004). Mackenzie et al. (2010) pointed out that some national policy initiatives can vary in form and function across

different research sites, highlighting the problem that there are no evaluation approaches which can suit all purposes. Mackenzie et al. (2010) suggested a number of reasons why standardising, in this case a national policy initiative, may not be feasible. Standardisation, according to Mackenzie et al. (2010), does not accommodate differences between a policy as a statement of intent and the actual practice. Complex organisations are not stable, but are characterised by contextual variation and adaptive learning, meaning that practices can change within a trial period. A further difficulty is keeping an intervention separate from its policy context, making it difficult to keep control groups unaware of what is going on. Mackenzie et al. (2010) suggested that in the evaluation of the public health programmes or other complex interventions that do not easily yield to a randomisation, evaluators, policy makers and commissioners should encourage robust data collection, and theoretically-driven questions about what works in which context. In a letter to BMJ, however, Bond et al. (2010) argued that Mackenzie et al. (2010) misrepresent the MRC guidance (Medical Research Council, 2000, Craig et al., 2008). Bond et al. (2010) argued that the MRC guidance aims to be pragmatic and recognises that rigid protocols are often impractical while emphasising the need for the process evaluation to be theoretically-informed.

The MRC framework (Craig et al., 2008) for developing and evaluating complex health care interventions has also been criticised for its lack of a specific guidance on how authors should comprehensively and transparently report a complex intervention to ensure reliable replication of both the study results and the intervention (Möhler et al., 2012). According to Möhler et al. (2012), a transparent reporting of an intervention means researchers clearly describing the intervention's underlying theoretical considerations and components, a rationale for selecting intervention the components, anticipated interactions between the components, and how contextual factors may influence the intervention. Additionally, Möhler et al. (2012) emphasise a clear reporting of implementation process and any deviations to this as well as reporting of unexpected interactions between intervention's components. A 16 item criteria has been developed by Möhler et al. (2012) to facilitate the reporting of complex interventions. Although Möhler et al. (2012) argued that adopting this checklist would improve understanding of intervention mechanisms, presently there

is limited evidence on applying the suggested criteria successfully in reporting of research studies.

Paterson et al. (2009) argued that the research on complex health care interventions may also need to reconsider how an outcome is defined. In medical research, an outcome is often interpreted as a single endpoint with a linear cause-and-effect link to an external intervention. Paterson et al. (2009) pointed out that defining an outcome, as in a rehabilitation and health promotion research, may be problematic. Instead, an outcome could be conceptualised as a health-related change that results from the interaction between an intervention, a process, and a context over time. In this particular framework, both a patient and an intervention are defined as causal factors, as the effectiveness of the intervention is dependent on the patient's own motivation to change, for instance, or their physical health. (Paterson et al., 2009). Apart from need to evaluate how a complex intervention is defined, Howe et al. (2009) argue for a shift from seeing preventive interventions as packages of activities to understanding them as an events in systems. Evaluation of complex preventive interventions may be improved if they are understood as a part of complex systems that are not influenced only by the intervention designs but also by their setting, social networks that connect an intervention and participants, and how an intervention changes over time.

Although the guidance published by the MRC (Campbell et al., 2000, Craig et al., 2008) offers a good overview of the methodological issues affecting the planning and evaluation of complex health care interventions, Mackenzie et al. (2010) argued that complexity in complex health care interventions can have very different expressions, depending on the purpose and the setting of an intervention. The MRC guidance (Campbell et al., 2000, Craig et al., 2008) recognises that a complex health care intervention may function on different levels, such as policy initiatives or individual level interventions. However, the guidance nevertheless appears to be more relevant for developing and evaluating individual level complex health care interventions. In addition, while the guidance recognises the need of understanding how an intervention works, it emphasises the importance of evaluating outcomes (Campbell et al., 2000, Craig et al., 2008). The MRC guidance (Campbell et al., 2000, Craig et al., 2008), however, does not clearly define what should be evaluated as intervention

outcomes or as part of understanding how a complex health care intervention works. Therefore, while some attempts have been made (e.g. Paterson et al., 2009) to set guidance on how an outcome of a complex health intervention should be defined, guidance on defining those outcomes and evaluating mechanisms in interventions, is lacking.

2.3.1 Evaluating process of complex intervention

The need to evaluate how an intervention works is noted in the MRC's guidance on developing and evaluating complex health care interventions, though the guidance is not explicit how this should be done in practise (Craig et al., 2008). Similarly, Oakley et al. (2006) argued that including the process evaluation in trials of complex health care interventions could improve the explanatory power and generalisability of the results. Likewise, Doyle et al. (2008a) stressed the importance of reporting on the process variables to ensure that reviews can report on what actually happened within an intervention, which parts of the intervention functions or not and why they function or not, and what resources are needed to reach the desired outcomes. Oakley et al. (2006) suggest that the process evaluation within a trial may, for example, explore participants' reception of the intervention or investigate why effects vary between subgroups. Further, Oakley et al. (2006) see process evaluation especially important in distinguishing between interventions that are inherently faulty and those that are badly delivered, and in multisite trials, when same intervention may have been implemented and received differently. As a further benefit for combining the process and outcome evaluation in to a trial design Oakley et al. (2006) highlight the possible methodological developments such as a more theory-based approach to intervention evaluation.

May et al. (2007), similarly to Oakley et al. (2006), argue that process evaluation of complex interventions can be crucial in understanding of how intervention outcomes were reached and what factors may inhibit or promote reaching specific outcomes. A normalisation process model, according to May et al. (2007), provides a theoretical framework for understanding complex interventions. The normalization process model suggests that apart from measuring the outcomes and the effectiveness of an intervention, complex interventions should also be evaluated in the terms of the

processes that make them workable and integrated in an everyday practice. The normalization process model aims to explain, by especially referring to collective social actions, those factors that inhibit or promote the implementation of complex interventions. May et al. (2007) argue that a deliberate initiation imply that an intervention is sanctioned by an institution, is formally or informally defined, purposefully planned and intends to change an outcome. Those that initiate a complex intervention may aim to influence the ways people act, think, or organise themselves in the health care. Apart from aiming to influence people's behaviours, a complex intervention may equally seek to initiate a new process with an aim of creating a new outcome.

At the present the guidance on evaluating complex health care interventions do not emphasise the potential benefits of a systematic examination of intervention processes, even though role of theory in planning of complex interventions is recognised (e.g. Campbell et al., 2000, Craig et al., 2008). In the evaluation of complex health care interventions, more emphasis may be need to be placed in the evaluation of causes for an intervention effectiveness, and how an intervention effectiveness may be associated with the underlying intervention assumptions of how it works. In addition, concentrating too much only on the effect outcomes may not adequately inform new primary studies of potentially important variables to be included in the design, or about issues in an intervention design itself, as implementing unclear results in the practice is difficult, if not meaningless.

2.4 Choosing the appropriate research design for primary evaluation of complex health care interventions

Number of study designs can be adapted in the evaluation of complex health care interventions. As the guidance from Centre of Reviews and Disseminations (2009) for Systematic Reviews points out, due to the complexity of public health interventions, a range of study designs have been used to answer different research questions. Sackett and Wennberg (1997) argued that a research design should be determined by the research question, not by a tradition, experts or different paradigms. According to Sackett and Wennberg (1997) arguing about respective merits of the different research designs approaches the problem of study design from

a wrong perspective. A study design should be influenced by considerations of what kind of a research strategy and tactics succeed in collecting and describing material that is essential in answering the particular research question. Sackett and Wennberg (1997) suggested that it is irrelevant whether a research approach is called for example an outcome research or an effectiveness research, as what matters is that are the methods appropriate in answering the particular sort of questions.

The existing research designs can be approximately classified between a quantitative and a qualitative research methods, both of which contain a distinctive set of methods designed to be applied to various research settings. The quantitative research methods can be further divided between an experimental and an observational study designs. Observational studies can be further divided between analytical studies, that feature a comparison group, and descriptive studies without a comparison group. (e.g. Bowling, 1997, Fink, 2005, Grimes and Schultz, 2002). The observational studies are widely used in health care to investigate, for example, variables that predispose to diseases. For example, in a cohort study, a group of people that share some common characteristics are observed over a time, either prospectively or retrospectively, and potential predictor variables and their association between outcomes are investigated. A case-control study is also often used retrospectively in the health care research to explain why a phenomenon currently exists in one group but not in another. In a case control study histories of two groups of participants, one with and one without the phenomenon e.g. coronary heart disease, are compared to explore any variables that may be associated with the occurrence of the phenomenon.

A snapshot of information from a group or groups can be collected by cross-sectional surveys and descriptive studies, which typically use questionnaires and interviews to collect data. The cross-sectional designs are commonly used in investigating associations between variables, describing study populations, and comparing different study groups. While the cross-sectional studies may suggest associations between different study variables, they cannot infer causality without data that are collected longitudinally in a different time points, though then the study would effectually become a cohort study. (e.g. Bowling, 1997, Fink, 2005, Grimes and Schultz, 2002). In the evaluation of complex health care interventions, the controlled

studies may not always be a feasible choice for intervention evaluation. Using the observational designs, especially when they include a comparison group, enables meaningful evaluation of an intervention, and allows further development of an intervention and methods used in the evaluation.

In an experimental study, the intervention environment is manipulated and controlled by a researcher, whereas an observational study relies on the existing conditions and activities. The experimental trials can be further divided between randomised, or “true” experiments, which randomly allocate participants between experimental conditions and non-randomised, or quasi-experiments, which allocate already existing groups as different experimental conditions. (e.g. Bowling, 1997, Fink, 2005, Grimes and Schultz, 2002). The randomised controlled trials (RCT) are considered the gold standard for intervention design, as they are designed to be effective in minimising bias in the estimations of the effectiveness of an intervention (e.g. Grimes and Schultz, 2002). A CONSORT statement (Schulz et al., 2010, Moher et al., 2010) sets widely accepted standards for reporting randomised controlled trials, which are used by scientific journals to evaluate the quality of a randomised controlled study. However, the CONSORT statement did not specially address some issues that face especially trials of non-pharmacologic treatments, such as surgery, rehabilitation, psychotherapy, and behavioural interventions. Therefore, an extension to CONSORT statement has been published that aims to improve the reporting of non-pharmacological interventions that often test complex interventions consisting of several components. The statement aims to improve the reporting of interventions that are difficult to describe, standardise, reproduce, and deliver consistently to all patients by offering additional guidance on reporting standards (Boutron et al., 2008).

For the purposes of evaluating the quality of evidence the US Preventive Services Task Force (in Grimes and Schultz, 2002) has suggested a rating system for quantitative clinical data. According to this assessment system evidence from at least one properly designed randomised controlled trial provides the highest quality of evidence, whereas a well-designed non-randomised controlled study provides a higher quality evidence than a poorly designed randomised trial, though this offers better quality evidence than a cohort or a case-control study. Although evidence from

a time series study provides a less quality evidence than a cohort or a case control-study, a time series study offer better quality evidence than opinions of respected authors. (Grimes and Schultz, 2002).

Although a number of study designs can be used in evaluation of complex health care interventions, it is argued that the randomised controlled trials have an important role in the evaluation of complex health care interventions. For example, Oakley et al. (2006), considered it important that sceptics of randomised controlled trials in the evaluation of complex health care interventions should be persuaded not to discard the RCTs in a favour of other study designs. Further, Hawe et al. (2004) argued that using randomised controlled trials to evaluate complex health care interventions is feasible if, instead of aiming to standardise the intervention components, the function of a complex intervention is standardised so that even when the intervention varies over a time and a place, the function of the intervention remains the same. However, O'Mullane et al. (2012) pointed out that it should be acknowledged that complexities in some public health interventions mean that a randomised controlled trial may not be an appropriate design.

Sackett and Wennberg (1997) pointed out that in many times answers to research questions generate further research questions, answering of which may require shift in appropriate research methods. According to Sackett and Wennberg (1997), it should also be noted that many research questions can be answered using different research strategies, such as an expert opinion or data collected for other purposes, even though this may not provide an optimal answer to the question. Sackett and Wennberg (1997) argued that instead of focusing in criticising of shortcomings in other's choices of a research approach, attention should be paid on how a research question can be answered so that it will provide the most valid and useful answer.

2.5 Implementing complex health care interventions in practice and implications to policy development

Thomson (2009) suggested that an implementation of complex interventions in the practice faces major challenges. Apart from the challenges associated with the design and evaluation of the complex health care interventions, Thomson (2009) argued that

there is a recognised problem of implementation of complex interventions, which persist even when there is evidence of an intervention's effectiveness. Bero et al. (1998 in Thomson, 2009) suggest that to overcome the problem of the intervention implementation, combined approaches are needed. The implementation of a complex intervention is dependent on many factors and, for example, the term knowledge translation, or KT, has lately emerged to describe practices involved in how an evidence is generated and used by policy makers, practitioners, and communities. In health sector researchers have recognised that the practice of the evidence based public health requires reciprocity between researchers, practitioners and policy makers. (Armstrong et al., 2006).

The knowledge translation can be defined as an acceleration of natural transformation of knowledge in to a practice (e.g. Armstrong et al., 2006). Armstrong et al. (2006) argue that the KT is based on several theoretical perspectives, which, for example, see knowledge as changing understandings that are shaped both by those who use and generate research. Although it is expected that practitioners and policy makers use research evidence in decision making, several barriers exist that impede this process. A Lack of personal contact between the researchers and the policy-makers and practitioners, a lack of correctly timed research, power and budget battles, a lack of good quality research, political climate, and disagreements of what counts as an evidence have been cited as barriers to the evidence based policymaking and practice. (Armstrong et al., 2006).

In order to improve the evidence use in policy and practice decisions, Armstrong et al. (2006) suggested applying a framework developed by The Prevention Group of the International Obesity Task Force to improve a translation of evidence in to action across the public health. The five key components of the framework are: "building a case for action, identifying contributory factors and points of intervention, defining opportunities for action, evaluating potential interventions and selecting a portfolio of specific policies, programmes and actions." (Armstrong et al., 2006, p.386). Armstrong et al. (2006) argued that at the present knowledge translation is under-developed part of the research process, which hinders the implementation of an evidence based policy and practise in public health, preventive medicine and health promotion.

2.6 Reviews and systematic reviews in evaluation of complex health interventions

Clinicians and health care policy makers face many challenges to stay abreast of the amount of available research information, as thousands of relevant studies are published yearly (Mallett and Clarke, 2003). An old scientific joke “For every expert there is an equal and opposite expert” reflects the difficulties of deciding, which of the available primary studies offers the best evidence (Petticrew and Roberts, 2006). Therefore, literature reviews and research syntheses have become a favoured method to summarise the available research material for practitioners and policy makers (e.g. Lavis et al., 2005). While literature reviews may be conducted by well-known experts on the field, Petticrew and Roberts (2006) argue that the high profile of the reviewer in itself is a poor indicator of the review’s ability to provide an unbiased summary of the results. While the traditional literature reviews can have considerable shortcomings, with unrepresentative samples that are unsystematically evaluated (Petticrew and Roberts, 2006), Petticrew (2009) argues that a literature review can be a useful tool in providing a broad overview of a topic, in discussing a range of evidence, and contributing to debates of what might work in particular settings.

Though the terms “literature review” and “research synthesis” are at times used interchangeably, they refer to different aspects of the research process. A literature review describes a process bringing together a body of literature to answer a specific research question, whereas research synthesis refers to a mechanical stage of a review where evidence is combined (Dixon-Woods et al., 2005, Mays et al., 2005). More broadly, however, research synthesis, can be understood as a review process that utilises existing research data and includes a literature review. What research synthesis does not mean, however, is a secondary analysis of data by re-analysis of individual level data, or just a mechanical process of combining data. Rather, research synthesis should be seen as a means of drawing new conclusions from the data and advancing the research field. (e.g. Dixon-Woods et al., 2005, Mays et al., 2005).

The term systematic review is relatively new, and has become widely used only in the late 1990's (Chalmers et al., 2002). A systematic literature review shares many common features with primary research, and differs from a traditional literature review in number of ways. Systematic literature reviews commonly aim answering a specific research question or testing a hypothesis. A systematic review, similarly to a primary research, also clearly sets out review methods in advance. However, while the aim of the primary research is to summarise and explain variation in single responses, systematic literature review aims to do this across the studies included in the review (e.g. Fink, 2005, Petticrew and Roberts, 2006).

The growing need for research reviews has led to a development of organisations dedicated to producing high quality reviews. For example, the Cochrane Collaboration (<http://cochrane.co.uk/en/index.html>) for reviews of clinical studies, the Campbell Collaboration for systematic reviews in education, crime, justice, and social welfare (www.campbellcollaboration.org), and EPPI Centre (<http://eppi.ioe.ac.uk/cms/>) for reviews of social science and public policy have been established. The task faced by these organisations is considerable, as it has been estimated for example by Mallett and Clarke (2003) that the minimum number of systematic reviews that would cover all the relevant studies for health care interventions would be 10,000. Nevertheless, the task is further complicated by the need to update the reviews when new research is published.

A Cochrane handbook for systematic reviews of interventions (Higgins and Green, 2011) is the official guidance of Cochrane Collaboration that describes in details how systematic reviews of effectiveness of health care interventions for publication in Cochrane Collaboration should be prepared, but can be used as a general guidance in planning a systematic review. In general, systematic reviews handle large bodies of literature, and aim to offer an unbiased estimation of an intervention effectiveness (e.g. Khan et al., 2001a, Sutton et al., 2001, Higgins and Green, 2011, Higgins and Green, 2008). Systematic reviews aims to answer range of questions by setting a well-defined review question, and by a comprehensive identification, appraisal, and a synthesis of all relevant studies on a given topic. (Petticrew and Roberts, 2006). It is suggested that systematic reviews are particularly useful in situations where there is some uncertainty about the answer to the research question and therefore need to

review all the available evidence. Therefore, before a decision about doing a systematic review is reached, it should be carefully considered whether such a review is needed and if it is an appropriate way to address the particular research question, (Petticrew and Roberts, 2006).

Systematic literature review methods have been developed to control systematic errors in the reviews (Petticrew and Roberts, 2006, Higgins and Green, 2011, Higgins and Green, 2008, Centre for Reviews and Dissemination, 2009). Therefore, a crucial aspect of a systematic review is its ability to locate all the relevant studies needed to answer the specific question. Another common concern in systematic reviews is introducing systematic error due to publication bias. The systematic error is created when, for example, more studies with significant than non-significant results are published, though statistical methods such as funnel plots are available to evaluate this. An important part of any systematic review is a methodological appraisal of the included studies, which enables reviewers to evaluate possible biases in primary studies that may introduce a bias in the review conclusions. The purpose of a methodological appraisal, however, is not necessarily finding methodologically weaker studies for exclusion, but to estimate what kind of limitations should be recognised and taken into account in discussing the results of a review. (Fink, 2005, Petticrew and Roberts, 2006, Higgins and Green, 2008).

Although systematic reviews can be a wholly descriptive, they often involve synthesis of material at some level. In principle, a systematic literature review can handle any type of research design. However, it is widely assumed that a systematic review is more effective when combining evidence from studies that share some commonalities such as outcome measures. (Chalmers et al., 2002, Fink, 2005, Petticrew and Roberts, 2006). A hierarchy of evidence is also typically emphasised in systematic reviews so that experimental studies, especially the randomised controlled studies, are considered the best possible available evidence for evaluation of treatment effect and therefore preferred in study selection (e.g. Khan et al., 2001a, Higgins and Green, 2011). Systematic reviews are considered as the gold standard in the effectiveness research and the international collaborations of systematic reviews such as Cochrane and Campbell have further emphasised the importance of systematic reviews in the evidence based practice (e.g. Petticrew and Roberts, 2006).

The narrow focus and emphasis of systematic reviews on this hierarchy of evidence can, however, limit their capability to answer questions about complex health care interventions. However, Petticrew (2009) argues that while some misconceptions of the scope, flexibility, and type of intervention design in systematic reviews continue to emerge, in reality many reviews need to make use of all the available research, regardless of the design of the studies.

Although the Cochrane handbook (Higgins and Green, 2011) promotes especially systematic reviews or randomised controlled trials with detailed guidance of how to conduct the review, the Cochrane handbook (Higgins and Green, 2011) also provides guidance of including non-randomised studies and qualitative research in to reviews. Although the Cochrane handbook points out that randomised controlled trials provide the best estimate of an intervention effectiveness, (Higgins and Green, 2011) it also recognises the challenges faced by, for example, reviews of public health and health promotion interventions. This guidance is very important in highlighting the issues around selecting an appropriate research strategy for each situation (Sackett and Wennberg, 1997), as randomised controlled trials may not be available or, if available, may not be providing the best possible evidence for certain interventions.

2.6.1 Issues in systematic reviews of complex health interventions

Systematic reviewing of complex health interventions is feasible, though inherently complex (Sheik, 2009, Wong, 2009, Jackson et al., 2004, Higgins and Green, 2011, Shepperd et al., 2009). Some of the challenges facing systematic reviews of complex health care interventions have been identified as; defining intervention within a review, locating and searching studies, standardising the selection of studies, and data synthesis (e.g. Shepperd et al., 2009 in Shepperd et al., 2009). The Cochrane Handbook (Higgins and Green, 2011) points out that locating studies for the reviews of public health questions may be a complex task as evidence may be widely spread, and located to a variety of bibliographical tools (Jackson et al., 2004) or outside of traditional health care domains (Shepperd et al., 2009 in Shepperd et al., 2009, Armstrong et al., 2009). Further, the systematic search of studies may be complicated by imprecise and varying use of terminology and indexing in different databases (Greyson, 2003 in Higgins and Green, 2011, Jackson et al., 2004, Armstrong et al.,

2009), which may require additional search methods to locate these studies. In cases where there is uncertainty about type of study designs that have been used in an intervention evaluation, a scoping review may be needed in identifying the types of study designs that have been used (Higgins and Green, 2011, Jackson et al., 2004, Armstrong et al., 2009). After locating relevant studies, reviewers of public health interventions need to consider how study quality would be best assessed. Additional difficulty in the evaluation of study quality is the actual quality of interventions, as an intervention may not have been implemented as initially planned (Jackson et al., 2004). However, for example the Cochrane Handbook (Higgins and Green, 2011) offers resources for appraisal of studies with varying designs.

In addition of the actual effect size, reviews of complex interventions should consider context of an intervention and the processes through which the effects of the interventions were delivered (Sheik, 2009 in Shepperd et al., 2009). These improvements in understanding the complex interventions' descriptions and conceptual content could be achieved by using typologies to guide classification of the interventions or using supplementary evidence such as qualitative or descriptive data (Shepperd et al., 2009 in Shepperd et al., 2009). Typologies may be predefined or developed by consensus. Supplementary evidence may (e.g. a qualitative study alongside of the main trial) or may not (e.g. qualitative evidence unrelated to trial data) be collected together with the quantitative data. Theory may also be used as a supplementary evidence to help explaining how an intervention is related to similar interventions in the field. (Shepperd et al., 2009 in Shepperd et al., 2009).

Reviewers of the public health and health promotion interventions also have to deal with heterogeneity of studies. Heterogeneity may be caused, for example, by variations in the study populations, methodological diversity of the studies, or the different contexts that an interventions operates (Jackson et al., 2004). The notion that key definitions used in primary studies are not consisted (Doyle et al., 2008a) may increase heterogeneity between the studies. Shepperd et al. (2009 in Shepperd et al., 2009) suggested that defining studies can be improved by using iterative process to defining intervention, contacting study authors for further information, recording the intervention components during data extraction, and being explicit about disagreements during the selection process. The reviews of complex interventions

need to balance between narrow intervention definitions that limit heterogeneity in results but limit generalisability of the results. Shepperd et al. (2009 in Shepperd et al., 2009) suggest that categorising interventions by their key variables, for example by intervention intensity, and retaining the grouping in the analysis can improve synthesis of data. Categorisation of intervention variables can be used both in a statistical (e.g. meta-analysis) and a non-statistical analysis (e.g. narrative analysis). For example, Song et al. (2009), used categorisation in their systematic review and meta-analysis of complex psycho-educational interventions for prevention of smoking relapse to investigate effect of participant motivation. Based on their subgroup analyses, Song et al. (2009) concluded that coping skills training was effective for motivated community quitters.

Methodologies of synthesising data from complex interventions are still being developed (Shepperd, 2009 in Shepperd et al., 2009), and reviews may need to consider different strategies to combine research findings to deal with the complexity (e.g. Armstrong et al., 2009). Possible methods include combining findings from a range of studies using different methods but similar outcomes (Mazerolle et al. 2007 in Armstrong et al., 2009), or the effects of an intervention can be analysed within different study designs (Goss et al. 2008 in Armstrong et al., 2009). Difficulties in data synthesis are reflected in difficulties of extracting and interpreting the study findings, especially when key definitions in the primary studies are not consistent (Doyle et al., 2008a). Reviews face also the challenge of how to separate the effect of an intervention from the effects of an intervention context, how an intervention context and characteristics may be utilised in evaluating the sustainability of an intervention, how an intervention effects different groups, and how to make the results of the review relevant to different users. (Jackson et al., 2004, Higgins and Green, 2011). However, as for example the Cochrane Handbook (Higgins and Green, 2011) points out, these issues cannot be solved without a more systematic reporting and examination of an intervention context.

Although a number of methods to improve reviews of complex health care interventions have been identified, these methods appear not to be consistently applied in the practice (Shepperd et al., 2009 in Shepperd et al., 2009). Possible causes for an infrequent use of these methods have been identified as a lack of

knowledge of theoretical underpinnings of an intervention, a lack of information of characteristics of complex interventions, and technical difficulties in providing an adequate description of a complex intervention (Shepperd et al., 2009 in Shepperd et al., 2009). Further, Wong (2009 in Shepperd et al., 2009) argued that successful reviewing of complex health interventions requires a paradigm shift in how complex interventions are conceptualised. Outcomes in complex health care interventions should not be seen as deterministic or regular, but as something that can be predicted by middle range theories, which can predict demi-regular pattern of interaction between the components of complex health care interventions (Wong, 2009 in Shepperd et al., 2009). Therefore, Wong (2009 in Shepperd et al., 2009) argued that theory driven reviews, for example, the realist review, are a “best bet” to make reviews of complex health care interventions more feasible.

Further, for example Jackson et al. (2004) argued that public health reviews should not only answer questions of an overall intervention effectiveness, i.e. does intervention work, but reviews should additionally answer a question about why does intervention work or not work? To achieve these aims intervention descriptions need not only be accurate but to describe what changes and modifications have been made during the implementation of the intervention (Sheik, 2009 in Shepperd et al., 2009). Sheik (2009 in Shepperd et al., 2009) also stressed the importance of exploring likely mechanisms through which the intervention effects are delivered. For the systematic reviews of complex interventions to be meaningful, they need include relevant theoretical and qualitative work and when relevant, include data from a broader range of study designs as is currently habit in the most Cochrane reviews. (Sheik 2009 in Shepperd et al., 2009). As Sheik (2009 in Shepperd et al., 2009) argues, it is important not to exclude even very complex interventions that cannot be evaluated using randomised controlled trial designs.

Number of examples and challenges facing reviews of complex public health intervention can be found in the literature. For example, a review of culture specific interventions for children and adults from minority groups with asthma faced difficulties in establishing strong links between the asthma management and the impact of culture (Bailey et al. 2008 in Doyle et al., 2008b). Doyle et al. (2008b) identified that this review was complicated by how social determinants were defined,

and how reviewing social determinants was further complicated by different authors using varying definitions to describe and explain similar concepts. In another review Lucas et al. (2008 in Doyle et al., 2008b) evaluated how additional financial benefits to socially and financial disadvantaged families may improve child health and educational achievements in the developed world. In this review Lucas et al. (2008 in Doyle et al., 2008b) explored complex interactions between the many factors relating to disadvantage by extracting information of intervention characteristics and using this information in subgroup analysis to examine heterogeneity in the findings. In this review, the judgements made regarding appropriate outcomes that determine the effectiveness of complex interventions were highlighted.

2.7 Inclusion of qualitative research in randomised controlled trials and some implications for reviews of complex health care interventions

Instead of quantifying data, qualitative research is concerned with describing a phenomena, participants' experiences and feelings, and understanding processes (e.g. Mason, 2002). Depending on the research question, qualitative research may be used solely to examine complex health care interventions or to supplement and explain results of quantitative evaluation. Selecting an appropriate qualitative research approach depends on the research question and the available research material and access to that material. In comparison to the quantitative research methods, the qualitative research methods require researcher to become more subjectively involved with the research participants and settings, making qualitative research vulnerable to the criticism of lacking objectivity and transparency. (Mason, 2002, Silverman, 2005).

The qualitative research commonly uses interviewing, observation, and a text analysis as research methods. The qualitative interview is usually built around a thematic, a topic-centred, a biographical or a narrative method to lead discussion in a relatively informal exchange of dialogue. The role of the researcher is to construct knowledge of the phenomena under investigation from the interview accounts. (Mason, 2002, Silverman, 2005). Observational techniques are also commonly used in qualitative research, either in the form of direct participant observation or by observing a specific phenomenon. Observation can be active or passive, so that in a

passive observation researcher stays remote, while in an active observation researcher becomes involved in the social world of those researched and takes part in functions of the setting. Observational research can be very time- and resource consuming, but is commonly used to investigate actions and behaviours and their interpretation by others. (Mason, 2002, Silverman, 2005). Documents, court proceedings, letters, memos etc. can serve as material for a textual analysis. Textual analyses are used in answering questions of processes in which documents have been produced and consumed, and in offering a meaningful representation of the social world as seen in documents. (e.g. Mason, 2002).

In the qualitative research, the choice of research method and material is linked to how the social world is seen to be constructed and meaningful to investigate. Qualitative research contains numerous different approaches to how the social world is constructed, which, in their turn, influence assumptions underlying research methods, data and questions. (Mason, 2002, Silverman, 2005). Ethnographic qualitative approaches encompass a wide range of perspectives and activities that have been influential in the development of qualitative research. Despite such variety, ethnographic approaches share the assumption that culture can be known only through the social and cultural settings. Ethnographic approaches prefer the use of observational methods in different cultural settings, which are used as data sources. In contrast, interpretivist approaches construct the social world through participant's interpretations, perceptions, meanings and understandings. Interpretivist approaches do not require researcher immersion within social settings, preferring interview methods to explore individuals' perceptions, reasoning and social norms. Biographical, humanistic and life history approaches share similar views of people as social actors. These approaches use verbal, visual or documentary data to investigate people's life stories. These approaches have also tended to use interpretive techniques in data analyses. The approaches lastly mentioned here are conversation analysis and discourse analysis, both characterised by their emphasis on discussion and text as sources of data, but with distinct purposes and methods. While the conversation analysis is concerned with how people produce social interactions, especially through natural talk, the discourse analysis aims to construct the social world not from actions, but through the discourses to be found in text and talk. (Mason, 2002; Silverman, 2005).

Using qualitative research alongside randomised controlled trials has become more common, but problems still exist in integrating the results. For example, a review in trials on interventions aiming to change a professional practice or an organisation of care indicated that out of 100 identified trials 30 had linked qualitative work (Lewin et al., 2009). Although most of the qualitative studies were carried out before or during the trial, in most cases there was no evidence of integrating the qualitative and the quantitative results either in an analysis or in interpreting the results. Another considerable shortcoming in the qualitative studies was their variable quality, with many studies having significant methodological problems. (Lewin et al., 2009). This, however, does not mean that qualitative studies cannot be successfully combined with randomised controlled trials as demonstrated, for example, by Bird et al. (2011). In this example the qualitative study by Bird et al. (2011) was conducted within a randomised controlled trial of a complex intervention that evaluated the effectiveness of a rehabilitation program for promoting recovery after stem cell transplantation. The qualitative study evaluated participant and staff experiences of participating in this trial, and results from the study highlighted the difficulties of developing and standardising a complex rehabilitation intervention so that it would be acceptable to participants with various needs and preferences (Bird et al., 2011).

Although Lewin et al. (2009) emphasised the various methodological problems in the qualitative studies conducted in association with the randomised controlled trials, these studies should not be discarded as unimportant. Perhaps surprisingly, Lewin et al. (2009) suggest that those randomised controlled trials that include qualitative research appear to be linked to increased reporting of explicit theoretical basis for intervention. However, Jackson et al. (2004) and Lewin et al. (2009) point out that uncertainty remains about whether interventions based explicitly on a specific theory are more effective than interventions designed pragmatically. Other authors, such as Attree and Milton (2006), also emphasise the possibility of a qualitative research to add in the understanding of intervention mechanisms. Attree and Milton (2006) argue strongly for including qualitative research evidence in systematic reviews, as qualitative research can yield insights into social phenomena and into those processes that underlie the effectiveness of health care and social interventions, such as capturing participants' perspectives of the interventions.

A guidance for incorporating qualitative evidence in systematic reviews and meta-analyses of effectiveness studies has also been published, for example, by the Centre of Reviews and Dissemination at the University of York (2009), and by the Cochrane Collaboration (e.g. Higgins and Green, 2011). Important methodological issue raised in the guidance concerns the searching of qualitative studies, and overcoming difficulties in identifying qualitative research. Currently recommendations suggest that a search strategy should enable sensitive searching of a number of sources. Although this approach is likely to maximise the amount of relevant records identified, the downside of this approach is the number of records identified that may not be relevant (Shaw, 2004 in Higgins and Green, 2011). In addition, the Cochrane Handbook (e.g. Higgins and Green, 2011) does not recommend that a search strategy should apply study design filters, as currently indexing terms used for qualitative research in bibliographic databases may not be accurate. However, the Cochrane Handbook recognises the need for doing pragmatic decisions regarding the time and other resources needed while conducting a thorough search, and judgements that needs to be made to balance between identifying relevant and non-relevant studies. To ensure the transparency of a search, limitations such as using design filters should be reported and described as a part of the search strategy. (Higgins and Green, 2011).

2.8 Role of theory in reviews of complex health care interventions

2.8.1 Theories, models, and frameworks

Models and theories are commonly used in social sciences to explain, predict and control empirical world (Becker, 2001, Yang, 2002). Although the terms ‘framework’, ‘model’ and ‘theory’ may become mixed in a common language, they define and distinguish different levels of abstraction from the broad conceptualisation of a framework to the more focused presentation of a model (Carpiano and Daley, 2006). Conceptual frameworks can be used to identify a set of variables and relationships between them that are assumed to describe a phenomenon. Frameworks can be used as an aid to a theory development, but frameworks do not in themselves, explain outcomes. A theory is different from a conceptual framework by being more compact and logically coherent. A theory

specifies variables, relationships, and directions between the variables, and how the variables may be expected to co-vary. Theories can be built within a specific framework, but unlike a framework, a theory can be used to explain a phenomenon and to predict outcomes. (Carpiano and Daley, 2006).

Theories present abstract ideas (e.g. health behaviour) that can be inferred from observable phenomena (e.g. change in eating habits) and are not fixed, but constantly developed, operationalised, tested, and applied to practice. (Yang, 2002). In comparison to a theory, a model has a more limited focus. Models are developed to investigate predictions made from a limited set of parameters and variables, which can be empirically tested. Models are not limited to a one particular theory, but can combine different theories or be developed to investigate a specific phenomenon. (Carpiano and Daley, 2006, Yang, 2002, Becker, 2001). While, strictly speaking, theories, models, and frameworks, may be differently defined, it is not always possible or important, to separate them in practice. Therefore, though the terms theory, framework, and model define different constructs, the term theory will be used in this thesis as a general term to describe how interventions describe the mechanisms through which the changes in outcomes are achieved.

2.8.2 Using theory in design and evaluation of complex health care interventions

In a design of a complex intervention, knowledge and beliefs about how the desired changes can be achieved are used to guide planning an intervention (e.g. Pawson et al., 2005, Jackson et al., 2004). Knowledge and beliefs about how an intervention causes the desired changes, can be expressed in the statement of those theories that may have been used implicitly or explicitly in an intervention design (e.g. Jackson et al., 2004). A theory can be explicitly used in two ways in designing an intervention. First, an existing theory (e.g. the theory of Planned Behaviour) can be used to inform the intervention design, and the outcomes are assumed to be achieved through the mechanism described in the theory. Second, while there may not be a specific, published theory that can be applied to the intervention design, the assumed intervention components and mechanisms are nevertheless articulated. An implicit use of theory in an intervention design, on the other hand, refers to a situation where the intervention is designed without a reference to any existing theoretical work or

where the assumptions about how the intervention causes the aimed changes are not articulated.

The guidance from the Centre of Reviews and Disseminations (2009) emphasises the importance of using a theory to guide the development of complex health interventions. According to the guidance, a theory has a potential to predict success and explain why intervention was not effective as planned. Theories have also the power to explain behaviour and a behaviour change at the individual level, as well as explain a change at the organisational or community level. Moreover, having a clear theoretical base for an intervention may allow reviewers to decide for intervention's inclusion and exclusion based on a particular theory. Interventions deploying different theoretical backgrounds can, of course, be included in a review, but a theoretical background of interventions can be collected as part of the data collection. The theories underpinning interventions can be used to group interventions within a review for further analysis. (e.g. Centre for Reviews and Dissemination, 2009)

Theoretical models are increasingly applied to an intervention design (e.g. Petrie et al., 2002, Wyer et al., 2001b). However, theories or mechanisms underpinning interventions are not systematically considered in evaluating the effectiveness of an intervention, though recent research reports statistical developments in evaluating mechanisms of complex health interventions, especially those of complex mental health interventions (Emsley et al., 2011, Farrin and Collinson, 2011). Michie et al. (2009) and Welton et al. (2009) argue that systematic reviews of complex interventions may be improved by the effective evaluation of intervention components, techniques, and theories. The difficulty of evaluating an intervention mechanism is highlighted in the example of evaluating psychological interventions using standard, meta-analytical methods that use direct, head-to-head comparison of evidence about two interventions. Using this method causes psychological interventions to be grouped together and make pair-wise comparisons between “all psychological interventions” and, often, “usual care”. (Welton et al., 2009). What such comparisons do not accommodate, however, is that psychological interventions are usually complex and consist of several components, leading to a situation in which none of the interventions included in the meta-analysis will be exactly alike (Welton et al., 2009).

As a possible solution to this problem of disparity, Welton et al. (2009) have developed a framework that enables exploration of different components of complex interventions using specific statistical methods. Within the framework all interventions are evaluated together for primary outcomes, but more detailed analyses calculate a separate effect for each intervention component, allowing an investigation of which component affects which outcome (Welton et al., 2009). As another possible method to improve understanding of effective intervention mechanisms and how theoretical assumptions are supported by evidence, Michie et al. (2009) suggest applying a meta-regression in identifying effective individual techniques. Using this approach Michie et al. (2009) were able to distinguish between those techniques that increased the effectiveness of an intervention from those that did not. Furthermore, analysis suggested that the theoretically-driven intervention techniques were linked to an intervention effectiveness (Michie et al., 2009). Although Michie et al. (2009) have shown that the meta-regression can be used effectively to investigate intervention techniques, this approach will not be used in this thesis to investigate intervention mechanism, because this thesis aims testing a non-statistical framework for evaluation of intervention mechanisms.

At present, systematic reviews of complex healthcare interventions do not, as standard, evaluate intervention mechanisms or underlying theoretical assumptions of interventions. As highlighted by e.g. Shepperd et al. (2009) and Jackson et al. (2004), this may cause difficulties in the review process, leaving reviews of complex interventions struggling to provide clear conclusions about the effectiveness of an intervention or to effectively investigate possible factors contributing to the achieved results. Transparency of the systematic reviews may also be improved by investigating the theoretical assumptions of interventions.

The lack of examination of an intervention mechanism or a theory as a part of a systematic review of complex health care intervention can lead to problems for interpreting the results of the review, if questions remain about what actually happened within an intervention and which elements of the intervention functions, and why this happened (e.g. Doyle et al., 2008a, Jackson et al., 2004). The effective implementation of an intervention and the production of robust results of a systematic review also requires that it is well understood why and how an

intervention is effective and what limitations the intervention will have, such as contextual factors that may have affected the effectiveness of an intervention (e.g. Jackson et al., 2004). Increased understanding of the mechanisms of an intervention could enable the development of more effective interventions, as, if the intervention principles are better known, this can be translated, for example, into a more specific guidance for practitioners of those intervention techniques that are associated with the effectiveness of intervention within certain populations and contexts.

Using a theory-orientated approach in the systematic reviews could have many potential benefits, and could function on several levels and stages of the review process. Lewin et al. (2009) and Jackson et al. (2004) point out that a controversy remains concerning whether interventions that explicitly include theory in planning are more effective than pragmatically-designed interventions. Using a theory-orientated approach does not mean necessarily examining any specific theoretical model, but rather how a review may approach the investigation of mechanisms of an intervention alongside research on its effectiveness. Theoretical considerations may direct the review question setting and, for example, decisions made about study inclusion criteria. Theoretical underpinnings of interventions can be evaluated as a part of the review process, as in identifying whether and how theories are used in intervention design and whether, if expressed, theoretical claims are borne in the actual intervention design and results. (e.g. Song et al., 2009, Welton et al., 2009).

Although including the investigation of any theory-related issues in systematic reviews can have many advantages, this may not be true in every case. Compared to the traditional systematic review, a theory-orientated systematic review is likely to require considerably more time and effort, which may increase the costs of the review. There is also the question of what material is available, especially about how well theoretical assumptions are covered in primary research (e.g. Welton et al., 2009). A theory-orientated systematic review will also not be practicable or suitable in every context, but may be more useful in the context of complex health care interventions that are largely built around behaviours. A theory-orientated systematic review can also be a useful approach when there is uncertainty about the effectiveness of an intervention, especially if this proved contrary to expectations. There is also a problem in selecting an appropriate methodology for how to

investigate the mechanisms and theories underpinning interventions. The productivity of a theory-orientated systematic review is also an open question, and needs to be further clarified. Given the possible resources that the approach can require, it should be carefully considered whether the benefit from including theory in systematic reviews does outweigh the associated costs.

2.9 Research synthesis and review methods for evaluation of complex health care interventions

2.9.1 Meta-analysis

In the health and medical sciences, a meta-analysis is commonly employed to estimate the overall effectiveness of a given intervention, usually after several primary studies have been published, which do not give an unequivocal answer about intervention effectiveness. Meta-analysis is often, but not necessarily, done as a part of a systematic review to statistically synthesise quantitative studies, and can be defined as a statistical technique that allows combination of findings from numerous studies that test the same hypothesis while reducing statistical imprecision in the results (Chalmers et al., 2002, Petticrew and Roberts, 2006). In the health care research, the meta-analysis is recognised as useful not only as a powerful data pooling tool to estimate the real effect size of an intervention, but also as a tool to summarise research findings and identify gaps in knowledge. (Miller and Pollock, 1995, Petticrew and Roberts, 2006). One of the significant strengths of the meta-analysis is its ability to detect small effects from combined studies, which might have been overlooked in the individual studies. In addition, a meta-analysis enables making more accurate estimations of the overall effect size of an intervention than traditional literature review. A meta-analysis can be also applied to exploring a variation between studies that investigate similar hypotheses, and, its results can provide a basis for drawing conclusions about whether the variation between studies is due to a chance or other factors. (Petticrew and Roberts, 2006, Sutton et al., 2001).

The main criticism, especially of the early meta-analyses, concentrates around the analyses combining too dissimilar studies (Eysenck, 1994). As the meta-analysis is designed for the situations where the review literature addresses conceptually

identical hypotheses, its power as a research tool and comparative easiness to use in practise have at times encouraged pooling of rather dissimilar studies, yielding meaningless results (Petticrew and Roberts, 2006). Heterogeneity between studies can be statistically evaluated to help in decision making whether a particular set of studies is suitable for a meta-analysis or not (e.g. Song et al., 2001). Statistical evaluation of heterogeneity between the studies, alone, however, is not enough to indicate whether a set of studies are suitable for the meta-analysis. For example, a meta-analysis is also likely to be inappropriate in cases where control groups between studies receive very different treatments, even if the treatment groups would receive similar intervention. (Petticrew and Roberts, 2006, Sutton et al., 2001). Interpretation of meta-analytic review results requires caution and methodological scrutiny, not least because all methodological and analytical issues surrounding meta-analysis are not resolved (e.g. Marsh et al., 2001, Petticrew and Roberts, 2006, Song et al., 2001). Another issue with a meta-analytical synthesis of research is that it requires data to be in a numerical form. Therefore, for any qualitative research to be included in a meta-analysis, it has to be transformed into some comparable quantitative form, which has attracted criticism from qualitative researchers, for example in relation to loss of relevant information and appropriateness of the transformation (e.g. Dixon-Woods et al., 2005, Mays et al., 2005).

Three distinct approaches to meta-analysis can be distinguished, namely, a vote counting, a combined test and estimated magnitude of effect size test, and a test of interaction effects (Yang, 2002). The first of these, the vote-counting, is a descriptive approach to the meta-analysis, based on tallies between positive significant, non-significant, and negative significant results from individual studies, and its use is no longer recommended. The next two approaches to a meta-analysis, the combined test and estimation of the magnitude of effect size, are closely related approaches. The combined test is used to investigate the statistical significance of the combined effect size between primary studies that test the same research hypothesis, while the estimation of magnitude of the effect size aims to establish the overall magnitude of the effect across studies investigating similar hypothesis. The third major approach to a meta-analysis explores possible interactions between variables that may explain variation in the effect sizes across studies. (Yang, 2002).

Variables that may be associated with the different effect sizes and that can be used to explain different effect sizes between studies are commonly called moderator and mediator variables. These variables affect the direction and the strength of a relationship between independent and dependent variables. Interaction, or a moderator effect, happens when the conditions for an independent variable's (e.g. exam anxiety) operation are defined by a moderator variable (e.g. gender). Therefore, a moderator can be defined as a variable that affects the strength of the relationship between two variables. A mediator variable, on the other hand, is defined as a variable that accounts for a relationship between independent and dependent variables. A mediator variable (e.g. education) will have a significant association with both the independent (socio-economic status) and the dependent (healthy eating) variables, and can explain the relationship between the two variables. (Baron and Kenny, 1986).

While a meta-analysis is perhaps the most commonly used in synthesising effectiveness studies and answering the questions of an intervention effectiveness, a meta-analysis can also be used in research syntheses that aims to build a theory (Yang, 2002), test a theory (Miller and Pollock, 1995), and examine a theoretical model (Becker, 2001). However, using a meta-analysis as a theory-testing and building tool requires conceptualising the meta-analysis as an experimental method, not just as a statistical technique. Therefore, as a meta-analysis can be employed in different contexts, it is important that researchers are explicit about their research aims, and in what capacity the meta-analysis will be used to avoid confusion about research methodology and how decisions regarding included studies and research outcomes have been decided.

For example Yang (2002) and Marsh et al. (2001) argue that a meta-analysis should not only be used in evaluating combined intervention effectiveness, but also as a theory-building tool in applied sciences. It is common for the social and behavioural sciences to form theories and models that contain several theoretical constructs as main components with explicitly-stated constructs boundaries and relationships between them. These theories and models are often presented in a form of a diagram that specifies interrelations (paths) between variables and constructs. Constructs present general abstract ideas (e.g. health behaviour) that can be inferred from

observable phenomena (e.g. change in smoking habits). A meta-analysis can contribute to the theory building by a conceptual development, confirming and disconfirming theoretical constructs and hypotheses, and by continually refining and developing a theory. (Yang, 2002, Marsh et al., 2001, Becker, 2001). Similarly, Becker (2001) argues that a meta-analysis can be used as a tool to test existing theoretical models representing a phenomenon. Models can be conceptualised, or build, from various sources of information like empirical research and theory, and for any phenomenon more than one explaining model can be created and empirically tested. According to Becker (2001) a model-driven meta-analysis has two distinct aims. First, the model-driven meta-analysis may aim establishing the extent of which the present research has examined all suggested parts of the model and, second, to investigate whether the research supports the hypothesised relationships between the variables and their respective relationships. The model-driven meta-analysis may also help in identifying gaps in the research evidence and in developing new theoretical models based on the empirical research.

The processes of using a meta-analysis in theory building and testing resemble each other. The theory building and testing meta-analyses can be done as a part of a systematic review that may or may not include a meta-analysis of combined study effectiveness. At the beginning of the review the theory and variables of interest according to the theory need to be clarified, and the initial research question formed. At the next stage, as with any other systematic review, relevant empirical studies need to be systematically identified, appraised and the variables of interest coded. In the theoretical meta-analysis variable coding refers to how abstract theoretical constructs are related to observable indicators at the empirical level, such as self-efficacy and smoking cessation. After the variable coding is finished, the next step involves examining potential variation in the effect sizes between the studies, or a group of studies. Significant variations in the effect sizes indicate presence of one or more moderator variables, which may not be accounted for by the theory in its present form. Additional statistical tests can be used in investigating if any of the variables of interest in the studies can account for the variation in the effect size (if present), and whether a new explanatory variable needs to be added to the theoretical model. The goal of theoretical meta-analysis is to draw conclusions about how well the current theory can explain the observed variations in the dependent variables and

whether new variables are needed to explain the observed variations. (e.g. Becker, 2001, Yang, 2002, Marsh et al., 2001).

While the theoretical meta-analysis can be a useful tool in testing and building complex theories with multiple variables, these meta-analyses are not without their problems. The theory-building approach to a meta-analysis can analyse only those variables that have been explored in the existing research, meaning that the analysis cannot exclude the possibility that another, as yet not-researched variable, may be responsible for the observed results. An additional difficulty is that there is no guarantee that the parameters in the existing research explain or describe the phenomenon accurately, although a confirmatory meta-analysis can be used to explore this. Therefore, the theory-building meta-analysis cannot be used to confirm or disconfirm theoretical frameworks outside existing research. (Becker, 2001, Yang, 2002, Marsh et al., 2001). Further, as a theory-building meta-analysis is confined within the limits of the existing research, it is better suited to a research-then-theory than a theory-then-research approach. Yang (2002) argues that despite the limitations to the theory building meta-analysis, it has potential to make novel connections between variables that may greatly advance the theory and understanding of a phenomenon.

Becker (2001) argues that while theoretical models can be incorporated into each stage of a review to provide guidance, theoretical models should not be assumed to be infallible guides, as they may omit important theoretical constructs. Using theoretical models in a meta-analysis may also become restrictive in a review process, especially if the used models unduly limit the selection of constructs and variables that may be explored in the review. Furthermore, practical considerations of incorporating investigation of theoretical models in the meta-analysis should also take into account that the empirical evidence available may not be sufficient to examine all proposed paths and constructs in a model. Also, crucially, when a theoretical model is either investigated in a meta-analysis or used to guide the review process, it is important to recognise that the proposed or found associations between the different variables in a model cannot be automatically assumed to be causally related. (Becker, 2001). Despite the problems and limitations associated to exploring theoretical models in meta-analyses, Becker (2001) and Yang (2002) argue that a

theory testing meta-analysis can be a valuable tool in investigating theoretical and empirical models suggested in the literature.

Though a meta-analysis is quantitative research method and is often used in the integrative research, the theory building and testing approaches to a meta-analysis are seen, for example, by Marsh et al. (2001) more as an interpretative form of synthesis. Interpretative synthesis is characterised by building and testing theoretical constructs, investigating associations between variables, and interpreting studies (e.g. Dixon-Woods et al., 2005), and from this perspective, the theory building and testing approaches to a meta-analysis fulfil all characteristics of an interpretive synthesis. While the meta-analysis is associated with quantitative research, the interpretive synthesis is traditionally related with qualitative rather than with quantitative research (e.g. Mays et al., 2005), which suggests that considering a meta-analysis only as a quantitative research tool may exclude some potentially important applications of meta-analysis.

Several examples of meta-analyses can be found that investigate both combined intervention effectiveness and the theories underpinning interventions of complex health care interventions. For example, Dusseldorp et al. (1999), used the meta-analysis successfully with a systematic review to investigate the overall effectiveness of interventions on cardiac and physical health outcomes, testing the hypothesis that success in proximal targets (e.g. health behaviour, stress level) contributes to cardiac and health outcomes, and finally in examining moderator variables that could explain some of the variations observed between the studies. In another example, meta-analysis has been used effectively for investigating both the effectiveness and intervention mechanisms of HIV-prevention trials. In this example, Albarracín et al. (2005) tested assumptions of eight different behaviour-change theories that had been used in the HIV prevention interventions. Analyses did not support theoretical assumptions about fear and about treatment of HIV mediating behaviour change, but supported theoretical assumptions that attitudes, behavioural control, skills, and motivation, mediate behaviour change. The capacity of the meta-analysis as a structured and transparent analysis method makes it a potential choice to the theory-orientated research synthesis, as these qualities enable critical scrutiny of the analysis results.

2.9.2 Research synthesis methods for diverse evidence

Methods for synthesising diverse evidence differ in the types of data they can handle, the purpose of the synthesis i.e. whether integrative or interpretive, and whether the method is originally developed for primary or secondary research. Not every method, however, has been extensively tested and there are concerns about methodological robustness in some. In addition, as new or modified syntheses methods for diverse evidence are continually developed, empirical evidence on the effectiveness of a synthesis and its wider applicability to practice is often limited. While it is not within the scope of this chapter to discuss all the available methods, or their variations, in synthesis of diverse evidence, the following discussion aims to consider some of those syntheses methods that are especially applicable in health care research and that may be used in the complex intervention research.

Mays et al. (2005) and Dixon-Woods et al. (2005) argue that the conventional research synthesis methods, and especially meta-analysis, tend to favour quantitative research on effectiveness, a tendency emphasised by the influential systematic review collections such as the Cochrane Library. The emphasis on the effectiveness research, according to Mays et al. (2005) and Dixon-Woods et al. (2005) considerably limits the inclusion of diverse evidence in systematic literature reviews. The term “diverse evidence” can be used to describe evidence in differing ways: when there is a considerable heterogeneity between the included studies; or when the research has used methods other than quantitative. While qualitative research is usually seen as encompassing diverse evidence, other possible sources of diverse evidence are different types of documents, legal papers, and policy statements. It is argued that in research on interventions, diverse evidence is especially useful in answering complex questions of the nature, scale, acceptability and mechanism of the intervention. However, as qualitative research has become increasingly accepted, the need has increased to review qualitative research and to use qualitative research to complement reviews of quantitative research. (Dixon-Woods et al., 2005, Mays et al., 2005, Thomas et al., 2004, Lewin et al., 2009).

2.9.3. Narrative Methods

2.9.3.1. Narrative review

A narrative review is often used in traditional and systematic literature reviews to create an account of evidence by summarising, explaining and interpreting data. A narrative review does not use specific statistical methods, and can investigate both qualitative and quantitative research. While narrative review is often applied in reviews that include diverse literature that is either too heterogeneous to be synthesised by meta-analysis or otherwise not suitable for a statistical analysis, narrative review should not be seen as a fall back option, but as a synthesis method of choice. Within a narrative review, synthesis of results may take a form of a simple recounting or describing material, or reach higher levels of abstraction by an interpretive and reflexive review of the material. (Dixon-Woods et al., 2005, Mays et al., 2005, Pawson, 2002b). Pawson (2002b), however, cautions that a narrative analysis may risk of becoming a list of “an annotated bibliography”, unless a common analytical framework is applied to each of the studies included in the review.

Narrative review is similar to a literature review, and the differences between these two approaches may become blurred and combined in practice (Dixon-Woods et al., 2005, Mays et al., 2005). Pawson (2002b) suggests that in an evidence-based research, a narrative analysis is used in a similar way to numerical approaches, such as meta-analysis, in investigating the most effective approaches to the issue. Narrative review is, however, an informal approach without explicit guidance on how it should be conducted, which leaves decisions about study inclusion, comparison, combining largely to researchers, leaving narrative review open to criticism of lack of transparency. (Dixon-Woods et al., 2005, Mays et al., 2005, Pawson, 2002b).

2.9.3.2. Narrative synthesis

A framework for the narrative synthesis was developed by the ESRC Methods Programme (Popay et al., 2006) in order to improve the guidance on a narrative

synthesis and to describe techniques and tools that may be used in a narrative synthesis. It is argued that a narrative synthesis is especially useful in three distinct situations; conducted before meta-analysis; conducted instead of meta-analysis when material included in the review is insufficiently similar; and in situations where it is known from early on that the material will be diverse and not suitable for other synthesis methods. While a narrative synthesis can accommodate even statistical manipulation, the synthesis aims to create explanations for study findings by exploring, describing, and interpreting the studies involved. A narrative synthesis aims to be transparent by documenting decisions and rationales behind the decisions during the analysis. Narrative synthesis tries to increase the potential for generalising the results by limiting biases in the study selection and inclusion, and to move beyond describing studies by providing explanations for reported outcomes when evidence is available. (Dixon-Woods et al., 2005, Mays et al., 2005, Popay et al., 2006).

The steps of narrative synthesis are similar to those of a systematic review, but the framework for narrative synthesis emphasises that the synthesis should not be seen as separate stages, but rather as iterative process. The four main elements to the narrative synthesis are described as; developing a theoretical model of how interventions work; developing a preliminary synthesis; exploring relationships in the data; and assessing the robustness of the synthesis product. (Dixon-Woods et al., 2005, Mays et al., 2005, Popay et al., 2006). The principles of the narrative synthesis have been used successfully in evaluating the effects of interventions that promote the use of domestic smoke alarms (Rodgers et al., 2009), and evaluation of evidence of implementation of interventions that promoted the use of domestic smoke alarms (Arai et al., 2007). Results indicate that in comparison to a narrative analysis, a meta-analysis offers better information about moderator variables but the narrative synthesis provided more extensive advice regarding future research (Rodgers et al., 2009), while enabling systematic synthesis and transparent approach to synthesis (Arai et al., 2007).

2.9.3.3 (Systematic) narrative review

A variation of the narrative review was suggested by Jones (2004), who argued a need for a “(systematic) narrative review” for a synthesis of qualitative research. A systematic narrative review is based on a group working, where the review group participants come from diverse backgrounds and immerse themselves to the selected literature. The participants in the review group should not exclusively be researchers, but service providers, policy makers, and service users. Selecting studies for the review against checklists should be discouraged and the applicability of qualitative studies to research question and evaluating study quality is covered during team discussions. The review question itself is not fixed, but may be reformulated in the review process. Synthesis of the material is done through analytic induction in reflective team discussions to interpret the material. (Jones, 2004). At the present there appears to be little or no research material available that has tested this approach to synthesis of qualitative studies. In addition, this approach also appears to have considerable problems with transparency, especially when the use of checklists for study evaluation is discouraged, which may lead to a biased study selection. Another considerable difficulty with the suggested approach is its requirement to include both policy makers and service users. While including policy makers and service users may improve some aspects of the review, it is not clear how intensively they are expected to take part in the review process and how differences between researchers and the lay members of the research team, in understanding research methodology, for instance, are solved. Jones (2004) does not also consider the potential resource requirements that extensive group work in this particular setting may require.

2.9.4 Thematic analysis

A thematic analysis was originally developed in primary research to enable the research material to be identified and then arranged under thematic headings. However, this approach may be used in secondary research in identifying prominent and recurrent themes in literature. Thematic analysis has been described as both flexible and structured, because it can be used in integrating not only qualitative research studies, but both the qualitative and the quantitative research studies, and

offers a structured approach to dealing with the evidence. (Dixon-Woods et al., 2005, Mays et al., 2005). Dixon-Woods et al. (2005) and Mays et al. (2005) argue that a thematic analysis can be adopted either as a data- or theory-driven approaches to synthesis. In the data-driven thematic analysis, themes identified within the studies drive the analysis, whereas in the theory-driven analysis themes that have been decided beforehand are evaluated through the included studies.

Dixon-Woods et al. (2005) and Mays et al. (2005) argue, however, that the transparency of a thematic synthesis depends on researchers identifying which of the approaches to the data analysis is taken. A failure to distinguish between the data- and theory-driven approaches causes uncertainty about how the results were arrived at. Lack of transparency resulting from the uncertainty of how the analysis results have been achieved is one of the biggest limiting factors with a thematic analysis. The problem of transparency in a thematic analysis is aggravated by the uncertainties of what it precisely involves and how it should be conducted. Further problems identified with a thematic analysis concern whether it is more integrative or interpretative approach, and whether the aim of the analysis should be in summarising and quantifying themes or in creating new explanations. (Dixon-Woods et al., 2005, Mays et al., 2005). Thematic analysis is often integrated within a narrative review as a method of synthesis, and is seen as a relevant synthesis approach where review question requires wide inclusion of material (Mays et al., 2005). For example, Beswick et al. (2005) has applied thematic synthesis instead of meta-analysis in summarising diverse research about successful methods to improve effectiveness of cardiac rehabilitation programmes. However, the analysis by Beswick et al. (2005) did not make clear whether it was a data- rather than a theory-led, and a lack of clarity about how the synthesis was done, made the results less transparent and open to criticism.

2.9.5 Realist synthesis

A realist synthesis, suggested by Pawson (2002c) is a relatively new approach to research synthesis, and has been specifically developed for a synthesis of secondary research and policy evaluation. The realist synthesis is aimed at evaluating complex social interventions and programmes, when traditional review methods struggle to

handle the often diverse evidence (Pawson et al., 2005). The realist review could be described as a theory-orientated method in that it starts with a theory that underlies an intervention, and systematically searches for evidence to test whether available material supports or disproves the theory under scrutiny, and aims to develop the intervention theory according to the emerging evidence (Pawson et al., 2005). Pawson (2002c) and Pawson et al. (2005) suggest that the realist synthesis is better suited to investigating a theory underpinning an intervention than, for example, a meta-analysis. In a realist synthesis, causality is understood as a generative model in which causality is established when the underlying mechanism that connects two events and the context is understood. This is in contrast to a successionist model, which typically underpins clinical trials, where causality is established when cause X is followed by effect Y. (Pawson et al., 2005).

According to Pawson et al. (2005), the hallmark of the realist synthesis is in understanding causality in complex interventions. Although the initial review steps of the realist review are broadly similar than those of a systematic literature review, Pawson et al. (2005) argue that the realist review, rather than being a review techniques, is a review logic. The aim in a meta-analysis is in estimating the effectiveness of an intervention, while the aim of a realist synthesis is to refine theory and provide practical recommendations for practitioners and policy makers about considerations and caveats of the intervention. (Pawson, 2002c, Pawson et al., 2005). Some of the potential advantages of a realist synthesis are its pluralist and flexible approach to synthesis, and its capability to accommodate both qualitative and quantitative research. However, as a realist review is not a protocol-driven approach, there are potential problems with the transparency and replicating the review results. Moreover, as a realist review can be very inclusive, concerns have been raised about the potential implications of differences between the study quality and appraisal of study quality. The results of a realist review can also be tentative and contextual, which requires that the review audience spend time to absorb and understand them. (Pawson, 2002c, Pawson, 2002a, Pawson et al., 2005). Dixon-Woods et al. (2005) argue that, apart from the issues of study quality, the realist synthesis in its present form, does not address clearly the issues of whether the chain of evidence created during analysis can reliably show causal relationships, and how the robustness of the theory under investigation may be established. An example of realist synthesis can be

seen in a complex evaluation of consequences of introducing law in the United States to protect children from convicted sexual offenders (Pawson, 2002a). Although not able to evaluate the effectiveness of the intervention, its results suggested that basing a law on a public opinion and assuming that the public will conform to the assumptions behind the law, is inadvisable (Pawson, 2002a).

2.9.6 Grounded theory

Grounded theory is an influential qualitative primary research method developed by Glaser and Strauss (1967 in Dixon-Woods et al., 2005), which may potentially be adapted for a synthesis of primary studies. Grounded theory is an interpretative approach to the data analysis, which describes methods for qualitative sampling, data collection and analysis. The main goal of an analysis using grounded theory is developing theory by generating explanations for a social phenomenon. (e.g. Dixon-Woods et al., 2005, Forbes and Griffiths, 2002). In the grounded theory, emerging theory in the analysis is grounded in the data, not on previous theoretical constructs (Strauss and Corbin 1994 in Cutcliffe, 2000). According to Eaves (2001), the grounded theory methodology assumes that examining the processes of social life is a process in itself, and that data collection and analysis are parallel processes shaped by an emerging theory and not by preconceived ideas. This feature is reflected in the data collection and analysis process, in which the theoretical sampling is used to refine, elaborate and exhaust theoretical categories that emerge from data. In the grounded theory analysis, the further the analysis progresses the more abstract the analytical interpretations are expected to become. These aspects of grounded theory make it more suitable for developing theory from data than testing theory according to the data. (Eaves, 2001).

Dixon-Woods et al. (2005) argue that the grounded theory has many potential advantages if applied in the research synthesis of qualitative or diverse evidence. (Dixon-Woods et al., 2005, Thorne, 2000). Firstly, grounded theory can deal with sampling issues by using theoretical sampling and saturation to limit the number of studies included in a review. Secondly, the grounded theory enables synthesis of primary studies by considering every individual study as a data unit. Thirdly, the grounded theory methodology may be used to generate higher order themes while

preserving underlying data's interpretive properties. Finally, the grounded theory methodology may also be able to deal with quantitative data by using a narrative process to transform quantitative data into qualitative data. However, while the grounded theory approach has a potential to be used in a research synthesis, Dixon-Woods et al. (2005) point out that using the grounded theory methodology in analysing primary studies poses also several problems. The main disadvantage of the method is, as with many other interpretive methods, its lack of transparency. Grounded theory also does not offer explicit guidance about study appraisal or inclusion, and therefore results are dependent on the status and credibility of the included primary studies. Finally, grounded theory has not been extensively tested in practice for reviewing and synthesising primary research. The principles of grounded theory have been used by Kearney (2001) to analyse domestic violence research and to develop a theory of "enduring love", where women were found to go through different definitions of their relationship with a violent partner.

2.9.7 Meta-ethnography

Meta-ethnography is a systematic research synthesis method that has been developed for the qualitative secondary research (Doyle, 2003). There are three major stages in a meta-ethnographic review and synthesis, which are: a case selection, an analysis, and a synthesis. The case or study selection for the review is purposive, as selection process is based on conceptual, not on representative, merits of the studies. Analysis techniques used in a meta-ethnographic synthesis involve a reciprocal translational analysis (RTA), a refutational synthesis, and lines of argument synthesis. (Dixon-Woods et al., 2005, Mays et al., 2005). The reciprocal translational analysis technique aims identifying key themes and concepts from studies, which are then translated into each others in a process similar to that of a content analysis. In the refutational synthesis contradictions between identified key themes and concepts are attempted to explain. The lines of argument synthesis describes a process of building general interpretations based on findings from the different studies. (Doyle, 2003, Mays et al., 2005). Although the meta-ethnography is primarily an interpretive approach to synthesis, it separates between need of accurate portrayal of original papers (hermeneutical aspect) and need to contrast and compare the original findings

to generate new explanations (dialectic aspect) and theories. (Dixon-Woods et al., 2005, Mays et al., 2005).

Britten et al. (2002) applied meta-ethnography in a review and synthesis of qualitative research studies that explored patients' medicine taking behaviour and communication with health professionals. Interpretations that emerged from the analysis concentrated to a self-regulation in medicine taking, especially of using alternative coping strategies to medication, which was found to flourish when sanctions (by health professionals) were perceived not severe. However, patients perceived that alternative coping strategies were not deemed medically legitimate, and fear of sanctions and guilt produced a selective disclosure of strategies in reflecting the review process and results. While meta-ethnography in the example of Britten et al. (2002) was successfully applied to research synthesis, the approach is not without its problems. Meta-ethnography methodology touches on sampling issues, but there is no explicit agreement about how study sampling and appraisal of study quality should be approached, as meta-ethnography is meant as a synthesis, not as a review, methodology (Dixon-Woods et al., 2005, Doyle, 2003). There are two further limiting factors for using the meta-ethnography in a study synthesis. First, it is comparatively unknown and a little-understood approach to a synthesis among policy makers and practitioners, so limiting its impact on wider decision making and practice. Second, it lacks of transparency and uncertainty on the quality of included primary research (Doyle, 2003). Therefore, while a meta-ethnographic approach to a synthesis might be able to incorporate both qualitative and quantitative material by transforming quantitative data into qualitative form (Dixon-Woods et al., 2005), its potential may be limited (Mays et al., 2005).

2.9.8 Meta-study

“Meta-study” describes an overview of theory, method and data, and can be divided in three distinct components, namely a meta-theory, a meta-method and a meta-data analysis, which are brought together in a meta-synthesis (Paterson 2001 in Dixon-Woods et al., 2005, Thorne et al., 2002). A critical evaluation of studies and their underlying assumptions is essential in the meta-study. The meta-theory analysis looks the different disciplinary and theoretical perspectives that researchers have

used and their effects on the results. The meta-method analysis concentrates on how different kinds of qualitative research methods have affected the results and on how methodological assumptions and constructs shape the research findings. Finally, in the meta-data analysis, different interpretations and conceptualisations are combined (Paterson 2001 in Dixon-Woods et al., 2005, Thorne et al., 2002), using a synthesis method that is considered the best for the occasion (Dixon-Woods et al., 2005). Although, for example Thorne et al. (2002) have used the meta-study successfully in reviewing and synthesising qualitative research of chronic illness experience, Dixon-Woods et al. (2005) argue that a meta-study is laborious, and its conceptualisation is not original, but relies heavily on the rigour of underlying methods, such as meta-ethnography. In addition, Dixon-Woods et al. (2005) argue that another difficulty with the meta-study is a lack of guidance on how it should deal with quantitative data.

2.9.9 Cross-case techniques

Case studies were originally developed as a research approach to examine complex social phenomena, investigation of which could be based either on a single or multiple cases. The case study technique is not clearly a quantitative or qualitative analysis technique, but can include and deal with both types of data. A cross-case technique may be used to combine studies, or cases, from diverse methodological backgrounds, which may enable researchers to explore similarities and differences between diverse studies and suggest generalisations from the findings. (Dixon-Woods et al., 2005, Mays et al., 2005). In general, two phases characterise synthesis process in a cross-case analysis; within case analysis, during which each case is examined alone, and the cross case analysis, when similarities and differences between studies are explored. (Dixon-Woods et al., 2005). Research synthesis by the cross-case analysis contains various analytical techniques, which can be adapted to various data. For example, Miles and Huberman (1994 in Mays et al., 2005) differentiate between a variable and a synthesis orientated analyses. The variable orientated analysis concentrates on investigating a specific part or aspect of the cases enabling examination of themes that cut across the cases. The case synthesis orientated strategy examines cases as a whole, using techniques such as meta-

ethnography (e.g. Yin, 1984 in Mays et al., 2005). However, the case- and variable-orientated approaches can be combined (Mays et al., 2005).

Some reservations over the cross-case analysis concern whether data can be transformed into a more qualitative or quantitative forms without losing its defining properties. This may be especially problematic when there is insufficient either quantitative or qualitative data for synthesis, or when the purpose of the analysis is to synthesise qualitative and quantitative research together (Mays et al., 2005, Dixon-Woods et al., 2005). The cross-case analysis techniques are widely used in health care related research (e.g. Boulus and Bjorn, 2009, McNaughton, 2000). Some of the reasons for the apparent popularity of the cross-case analysis methodology may be its argued transparency and systematic way to deal with data, as well as its ability to deal with both quantitative and qualitative data. (e.g. Dixon-Woods et al., 2005, Mays et al., 2005). While cross-case analysis has many qualities that make it an attractive choice for a synthesis method, it has its limitations. A cross-case analysis does not offer explicit guidance to a study selection, sampling, or appraisal (Dixon-Woods et al., 2005). In addition, Dixon-Woods et al. (2005) point out that while the cross-case analysis is seen as a transparent method, it may be perceived as too disciplined and strict by some qualitative researchers.

2.9.10 Content analysis

Content analysis is a replicable, systematic and powerful technique for a data reduction (Stempler, 2001) that uses explicit coding rules to compress a text into fewer content categories (Stempler, 2001, Graneheim and Lundman, 2004). While the content analysis was originally developed for analysing primary data, it can be adapted to the secondary research, as it enables a systematic investigation of a large amount of material, drawing inferences, and examination of trends and patterns from the data. (Stempler, 2001). While the content analysis involves techniques that use data categorisation to determine frequencies, thus quantifying data, theoretical knowledge and qualitative skills are needed for adequate data categorisation and recognising underlying theoretical assumptions. (Mays et al., 2005). Categories that are used for data coding can be decided a priori or be emergent (Stempler, 2001). Content analysis aims to be a replicable and a transparent method to data analysis

and therefore concepts of validity and reliability of the results and synthesis are emphasised, and the synthesis is achieved by a systematic categorisation and organisation of the data that are mutually exclusive, thus reducing the ambiguity of how the synthesis is achieved. (Dixon-Woods et al., 2005, Stempler, 2001). Some criticisms of the content analysis concentrate on its similarity to the thematic analysis, and its tendency to be reductive, which may diminish the complexity of content. While qualitative researchers may also find that the content analysis may not be able to preserve the qualities of the underlying qualitative data, this is less of a problem with quantitative materials. (Dixon-Woods et al., 2005, Mays et al., 2005). However, perhaps the most considerable drawback with the content analysis is that the results of a synthesis may become over simplified, if absence of evidence is regarded as evidence of absence. (Dixon-Woods et al., 2005).

2.9.11 Qualitative comparative analysis method

A qualitative comparative analysis method (QCA) aims to explain how complex causal pathways lead to an outcome (Ragin, 1999). According to Ragin (1999), causal complexity in the social sciences is caused by the fact that outcomes of interest can be caused by several different combinations of conditions, and therefore causation should be understood in terms of sufficient necessary conditions for an outcome to happen. By a “necessary condition”, Ragin (1999) refers to a condition that is required for an outcome to emerge, whereas a “sufficient condition” refers to a cause or a causal combination that precedes an outcome. Truth tables, which show all logically possible combinations of independent variables associated with an outcome, have a central role in the QCA. The qualitative comparative analysis uses processes of elimination and grouping to decrease the number of causal combinations, so that the remaining set of explanations forms a logical model explaining associations between variables and outcomes. However, this may lead to a situation where causal combinations resulting from the analysis are contradictory, though a probabilistic test may be applied to determine a likelihood of a specific outcome, and results should be considered in the light of how well understanding of different cases is advanced. (Dixon-Woods et al., 2005, Ragin, 1999).

The qualitative comparative analysis may be applied to both primary and secondary research, and to both quantitative and qualitative research. (Dixon-Woods et al., 2005, Ragin, 1999). The qualitative comparative analysis is a transparent approach that has a well-defined framework for synthesis but it cannot effectively deal with qualitative studies that cannot be quantified. (Dixon-Woods et al., 2005). Applying the qualitative comparative analysis to a synthesis effectively requires also knowledge from the particular research field to enable decision making about combinations of causal conditions to be explored, as the analysis may become overly complicated when the number of causal conditions increases. (Ragin, 1999). There is, however, some doubt about the capability of the qualitative comparative analysis to infer causality, as association is seen as equal to causation, raising questions about the validity of the causal arguments based on this approach (e.g. Seawright, 2005).

2.9.12 Bayesian approaches

The Bayesian theory is usually understood as a method to determine how a scientific belief should be used to modify data (e.g. Goodman, 1999). In the Bayesian approach beliefs are formally expressed as probability distributions and modified as new evidence emerges. For example, experimental results are interpreted in the connection of available external evidence and plausibility of the hypothesis prior the experiment was commenced. A familiar example of a practical application of the Bayesian theorem is a diagnostic test, which can modify a doctor's prior beliefs on whether a patient has a disease or not. Using a Bayesian theorem allows a formal expression of scepticism and caution when, for example, test results appear to be exceptionally good. (Spiegelhalter et al., 1999).

The Bayesian approach can be incorporated in both the primary and secondary research, as well as applied to reviews that use a meta-analysis (Goodman, 1999). In the Bayesian approach to the meta-analysis, data from diverse backgrounds can be combined together. While the Bayesian method of meta-analysis is still under development, in broad terms the Bayesian approach to a meta-analysis starts from the beliefs that logically and temporally precede data, called probability distribution. These beliefs are updated and modified as the analysis progresses and evidence

emerges. (e.g. Dixon-Woods et al., 2005, Goodman, 1999, Mays et al., 2005). The Bayesian approach can incorporate both qualitative and quantitative research by using qualitative research to identify potentially relevant variables for the synthesis and their prior probability distribution, while quantitative studies are combined using meta-analysis, which results are used to modify prior probabilities to form posterior probabilities for the data. (Dixon-Woods et al., 2005, Mays et al., 2005).

Factors influencing childhood immunisation uptake have been investigated by Roberts et al. (2002), who applied their own pre-existing subjective beliefs to formulate the probabilities of important factors affecting the immunisation uptake. The researchers' prior beliefs were modified by factors that qualitative studies had identified as potentially important explanatory variables. Bayesian approaches, however, have limitations. A Bayesian meta-analysis is difficult to use in a practice (Dixon-Woods et al., 2005), and Roberts et al. (2002) argue that that a Bayesian meta-analysis methodology would need to be further developed to enable more effective synthesis. Mays et al. (2005) noted further that inclusion of studies with weak designs may undermine the validity of analysis. Mays et al. (2005) also question the feasibility of the Bayesian approach and argue that a Bayesian synthesis may not be able to accommodate biases and differences between studies that may make synthesis unpredictable. In addition, there is no certainty about how the Bayesian approach copes with multiple stakeholders with diverse agendas, and how well models created through a Bayesian meta-analysis may be communicable to a wider audience. (Mays et al., 2005).

2.10 Review and synthesis methods for complex health care interventions – Discussion

Systematic reviews offer the best estimate of intervention effectiveness, and have a well-tested and described methodology (Centre for Reviews and Dissemination, 2009, Higgins and Green, 2011). However, qualitative research has become increasingly included alongside of quantitative evidence in systematic reviews (Attree and Milton, 2006). Even though the foregoing discussion may have unintentionally suggested that only one research synthesis method may be used in a review and that researchers may have to compromise between the data and synthesis

method, in practice, a review can be flexible. For example, Thomas et al. (2004) have successfully combined qualitative and quantitative research, by synthesising them parallel and bringing together at the later stages of the review. The guidance for reviewing qualitative research alongside systematic reviews of quantitative studies has also been published (e.g. Centre for Reviews and Dissemination, 2009). The review of potentially relevant methods for the review and research synthesis of complex health care interventions has suggested that numerous methods may be available as alternative research synthesis methods for diverse evidence, such as the narrative approaches and the meta-ethnography. However, these methods are generally less well-known and tested than the systematic review and meta-analysis methods. This, nevertheless, is not to assert that the methods for reviewing and synthesising diverse research evidence should be simply dismissed as less important, but rather that their application to a research synthesis and the interpretation of the results of the synthesis may require more caution. Applying the review and research synthesis methods for diverse evidence is also likely to be more fraught with difficulties than that of more traditional methods, as there are fewer available examples of practical application and such more novel methods of synthesis may not be well established and tested.

Many of the research methods directed to the diverse evidence may also be relatively unknown to potential target groups, such as health care professionals and policy makers, which may adversely affect how well the results can be disseminated. If the review audience struggles to understand how the review conclusions have been arrived at, the review may not be given due consideration, and might even be disregarded as an irrelevant to the decision making. This practice-relevant problem may be exacerbated by the often-cited concern that many synthesis methods for the diverse evidence lack transparency in how their results have been achieved, in contrast with the systematic review and meta-analysis which offer clear guidelines and expectations that deviations from the guidelines will be well documented and justified (e.g. Higgins and Green, 2011).

Though, for example, Pawson (2002c, 2002b) and Pawson et al. (2005) have criticised the capability of the meta-analysis to explain mediator and moderator variables and the potentially unending list of variables that may need to be tested,

alternative strategies to a meta-analysis, such as the realist synthesis (Pawson, 2002c, Pawson et al., 2005), can also be subject to some of this criticism. As with the meta-analysis, the realist synthesis is confined to variables that are investigated in included studies, and thus it is also limited in its ability to recognise and explain mediating and moderating variables. In addition, synthesis methods such as the realist synthesis are often aimed at situations where there is limited amount of experimental research evidence available, and these synthesis methods may therefore not be suitable for situations where a considerable amount of experimental studies exist. One purpose of a meta-analysis is to produce a replicable synthesis, in which results can be repeated. However, many suggested methods of a synthesis for diverse research evidence struggle to provide a replicable synthesis, which may affect how well the results can be generalised. This in itself may not be seen as a major problem, if the review and synthesis aims to consider a very specific research area or a question, rather than aiming for overarching conclusions about, for example, the effectiveness of a policy or patients' experiences of a treatment.

While a research review and synthesis that includes and has a method to manage diverse evidence may face considerable difficulties and criticism, these reviews and methods employed in them should not be compared directly with, for example, reviews that use a meta-analysis. The Review and synthesis methods for diverse evidence are designed for a variety of purposes, have differing underlying philosophical perspectives, and are directed at different research materials, which makes a direct comparison between the methods complicated. It is also important to separate between the review methodology and the synthesis methodology. For example, neither a narrative nor a literature review offer any guidance on how to conduct a synthesis, but depend on external synthesis methods. However, while a review can be conducted without a formal synthesis of included material, conducting synthesis without first conducting some form of a review is hardly feasible. Therefore, some synthesis methodologies, such as meta-ethnography, can be criticised for their lack of a guidance on study sampling and appraisal. While checklists have been developed to assist in appraising different primary research methods and studies that use these methods, there appears to be less controversy and more consensus on the usefulness of the checklists among quantitative researchers than among qualitative researchers (e.g. Barbour, 2001, Attree and Milton, 2006).

The lack of explicit appraisal of the included studies may, however, be seen as a part of the research methodology or as a considerable shortcoming with the method. Another often-criticised feature of synthesis methods for diverse evidence is the perceived lack of guidance on study sampling. While inclusion of all available studies or material may not be possible, the lack of guidance on how the study numbers should be limited makes evaluating the results' reliability and validity difficult, as well as hinders the replication of the review.

The lack of transparency in synthesis methods for diverse evidence may derive from the interpretive qualities of the many alternative synthesis methods that aim to generate new insights from the material rather than reaching conclusions. Finding a balance between a transparency and interpretive qualities of an analysis is also a contested issue. For example, both the grounded theory and the meta-ethnography, which primary purpose is a theory development, have been criticised for the lack of transparency (e.g. Dixon-Woods et al., 2005, Mays et al., 2005). On the other hand, potential synthesis methods that are more methodologically transparent, such as the content analysis, are criticised for being too rigid and stifle the interpretative qualities of the data (e.g. Dixon-Woods et al., 2005, Mays et al., 2005). Therefore, there appears to be a real conflict between the needs for a clarity and for a flexibility in a synthesis, especially among the synthesis methods for diverse evidence. Another debated issue is whether and how, qualitative and quantitative research can be synthesised. Of the research synthesis methods discussed above, the majority require available data to be transformed to either a quantitative or qualitative form before it can be analysed and synthesised. This however, raises questions of how such data transformation should be done and whether they can then offer any accurate presentation of the original data in a transformed form. In addition, there is not enough available research evidence to reliably evaluate how different synthesis methods would cope with the transformed data and of the effects of transformed data on the results of the synthesis.

2.11 Conclusions

Literature on evaluating complex health care interventions shows that combining systematic reviewing with meta-analysis provides an estimate of the effectiveness of

an intervention (e.g. Higgins and Green, 2011, Moher et al., 2009). The systematic review methodology, however, can shape the results of the review considerably, as often only randomised controlled trials are included in the review. As a consequence, for reviews of complex health care interventions, this may limit the number of available research studies of complex interventions for inclusion, as practical considerations may have prevented the gold standards of randomised controlled trials from being fulfilled (e.g. Doyle et al., 2008a). The challenges to evaluating complex health care interventions are well recognised in literature, and the Cochrane Handbook provides specific guidance for systematic reviews of public health interventions, where randomised controlled trials may not be available (Higgins and Green, 2011, Higgins and Green, 2008). Similarly, guidance is available on how diverse evidence may be incorporated in systematic reviews and how methodological challenges facing such systematic reviews may be solved (Higgins and Green, 2011, Jackson et al., 2004). In short, the present guidance on reviewing complex health care offers comprehensive guidance on issues and challenges facing research in this area.

This literature review showed that there are a variety of methods available for reviewing and synthesising even very diverse research on complex health care interventions. Therefore, there is no need to develop a new method of review or of analysis in this area (e.g. Pawson, 2002c). However, unlike guidance on reviewing complex health care interventions, guidance on which synthesis methods should be used is more fragmented. The selection of synthesis methods for diverse evidence is partially complicated by the limited evidence about the practical application of the many of the methods and partially by unsolved methodological issues within some of the suggested methods (e.g. Bayesian meta-analysis). This literature review appears to suggest, however, that using meta-analysis as a synthesis method offers well tested and widely used method. Available literature, however, pointed out that reviews of complex health care interventions may be improved by further incorporation of an investigation of intervention mechanisms in the review process (Sheik, 2009 in Shepperd et al., 2009).

Although many authors such as Michie et al. (2009), Welton et al. (2009), Möhler et al. (2012), and Sheik (2009 in Shepperd et al., 2009) have emphasised the need to

understand intervention mechanisms and have offered methodological discussion on how to achieve this, there is no commonly-accepted framework for examining intervention mechanisms. Different techniques, such as meta-regression (e.g. Michie et al., 2009, Higgins and Green, 2011), have been mentioned in guidance and used in practice, but there is still limited empirical evidence or practical experience of using these methods in practice. Similarly to Michie et al. (2009), Welton et al. (2009), and Sheik (2009 in Shepperd et al., 2009) this thesis argues that more in-depth evaluation of an intervention mechanism may be needed to enable understanding of how interventions function and may improve how results are reported. Therefore, the present thesis aims to contribute to this methodological discussion by testing a new, innovative, and non-statistical method, to evaluate intervention mechanisms as a part of a systematic review and meta-analysis of complex health care interventions.

This project aims to build on existing systematic review and meta-analysis methodology, as systematic review and meta-analysis are recognised the best practice for investigating combined intervention effectiveness (e.g. Petticrew and Roberts, 2006, Higgins and Green, 2011). This project will also build on the approach tested by Thomas et al. (2004) of reviewing qualitative research alongside a systematic review and meta-analysis. Thomas et al. (2004) demonstrated that a review may include both qualitative and quantitative research, which may be synthesised in parallel and only brought together in the later stages of the review. The purpose of this thesis is to evaluate how systematic review and research synthesis for complex health care interventions may be improved by investigating mechanisms of the interventions as part of the review.

The present chapter aimed to identify and examine the methodological issues relevant to primary and secondary research on complex health care interventions as well as review methods either developed or adaptable for reviewing complex health care interventions. Systematic review and meta-analysis continue to be the dominant methods for synthesising complex health care interventions, as these are well-developed, tested, and widely accepted (e.g. Higgins and Green, 2011). In the recent years the contribution of qualitative research to a theory development and accumulation of knowledge in health care research has been increasingly recognised (e.g. Lewin et al., 2009, Mays et al., 2005), even though synthesis methods for

diverse evidence continue to be less-developed and tested than conventional research synthesis methods such as meta-analysis. Recent research in reviewing and synthesising of complex health care interventions has emphasised the need to improve understanding of mechanisms in interventions (e.g. Michie et al., 2009, Shepperd et al., 2009, Welton et al., 2009). The purpose of this thesis is to answer the question of whether an innovative approach to investigating intervention mechanisms alongside systematic review and meta-analysis, can improve understanding of intervention mechanisms and practical applicability of the results of review.

Author	How complexity should be understood	What this means in practice
Bradley et al. (1999)	On Three levels: 1. The target population 2. Service provision 3. Management of behavioural change	Levels: 1. Intervention theory and evidence 2. Tasks and processes needed to deliver intervention 3. People and contexts within which intervention is operationalised
Campbell et al., (2000)	Complex interventions consist number of components that may act “independently and inter-dependently”	Problems of developing, identifying, documenting and reproducing the intervention causes difficulties in evaluating
Hawe et al. (2004)	Different components of a complex intervention can be defined according to their form and function, i.e. by defining the process that facilitates change.	Instead standardising the intervention function instead of components, so that despite of variations in the intervention over time and place, the function of remains the same.
Shiell et al. (2008)	1. Complexity as complicated 2. Complexity as a property of a system	1. Complex intervention is built on several components, so knowing which of the components or combination of components is effective is difficult 2. Complex systems are built on other complex systems and can accommodate changes in its local environment, and do not behave in linear fashion

Table 2.1: Defining complex health care interventions

Chapter 3

The basis for selecting the intervention topic for empirical case studies and the results of the review of reviews, which examined methodological issues, encountered in previous reviews of psychological cardiac rehabilitation interventions

3.1 Introduction

Reviews of complex health care interventions, as discussed in the previous chapter, can face a number of challenges during a review and data synthesis (Armstrong et al., 2009, Jackson et al., 2004). Difficulties encountered in the reviews of complex health care interventions include problems in; defining intervention (Paterson et al., 2009), locating relevant evidence (Armstrong et al., 2009, Shepperd et al., 2009), deciding what counts as an evidence (Jackson et al., 2004), synthesising results (Armstrong et al., 2009), and interpretation and reporting of results (Jackson et al., 2004). A series of articles by the Cochrane Public Health Review Group has recently highlighted (Armstrong et al., 2009, Doyle et al., 2008b, Doyle et al., 2008a) key issues faced by reviewers of complex public health interventions, such as difficulties in the search of primary studies and examining intervention mechanisms. However, in the reviews of complex health care interventions the role of complexity is not always explicitly identified, which may hinder evaluation of how complexity of an intervention has affected the review methodology or results of the review (e.g. Rees et al., 2004).

This chapter has two distinct aims. Firstly, discussing a rationale for the selection of psycho-educational cardiac rehabilitation interventions as a topic for the empirical studies, and secondly, examining how previous reviews have approached a number of methodological problems that reviewing complex health care interventions may entail. Therefore, the specific research questions for this chapter are as follows. Firstly, what approaches adopted by reviews have approached the methodological problems that reviewing complex health care interventions may cause? And, secondly, whether and how previous reviews may have explored theories underpinning interventions?

3.1.1 Selecting a topic for the empirical studies

In the process of selecting a suitable topic for these empirical studies, several criteria needed to be considered. The intervention must be clinically important, for instance, an intervention that may be widely used, but, where there may nevertheless be a lack of clarity about how the intervention delivers its outcomes. The intervention needed to have relevance to this thesis, i.e. able to be easily characterised as a complex intervention, having features such as complex interactions between participants, intervention, and in its organisation, and posing difficulties for defining which components of the intervention, if any, may have caused the desired outcomes (e.g. Medical Research Council, 2000, Craig et al., 2008). While all complex interventions have their specific characteristics, it would be of a benefit if some of the results of this thesis could be generalised to other complex health care interventions. Another intervention characteristic targeted in the selection was having identified methodological challenges in conceptualising how the intervention functions. Finally, the intervention selection was influenced by the author's professional background in psychiatric nursing and research background in health psychology, especially in psychological interventions in health care and improving the understanding of how these interventions function.

While considering the possible topics for the planned series of case studies, non-pharmacological psychological interventions for people suffering of psychiatric disorders were initially considered. Such interventions are likely to be complex, thus offering particular challenges for understanding how they work, and accessible to the author's professional experience. Also, recent reviews in this area appeared not to have investigated intervention mechanisms, although, for example, Curran and Brooker (2007) found that in the UK, mental health nurses are involved in delivering a wide range of interventions, which often appear to have a positive impact. However, psychological interventions for persons suffering psychiatric disorders are likely to pose such substantial complexities that these may hinder the testing and drawing conclusions about intervention mechanisms using a new approach. And, relatedly, hinder the scope of this thesis to generalise the results to any other context. Reviewing interventions for people suffering from psychiatric disorders, whether in community or in hospital settings, can, as for many other complex health care

interventions, be complicated by the complex interactions between intervention providers, participants, environments, and social interactions within and outside the immediate intervention. However, the complexity of these interventions can be further increased by barriers to distinguishing the effects of psychological interventions from those of medication, differences between compulsory and voluntary treatment, and challenges of diagnosing psychiatric disorders.

Therefore, psycho-educational cardiac rehabilitation interventions were appraised in terms of whether they might instead fulfil all the above requirements. No recent review is available that has evaluated effectiveness of psycho-educational cardiac rehabilitation interventions, even though recent reviews have investigated psychological interventions in cardiac rehabilitation (Rees et al., 2004). Psycho-educational cardiac rehabilitation interventions can be defined as complex interventions using both definitions by Hawe et al. (2004) and the Medical Research Council (Craig et al., 2008). These interventions are characterised by complex interactions between participants, personnel and context, and can be defined by their function if needed. Psycho-educational cardiac rehabilitation interventions operate in complex environments, such as hospitals with number of different professionals involved in participants care, and interactions between participants, environment and intervention personnel can be unexpected. Therefore, the psychological cardiac rehabilitation interventions contain a number of complexities. However, these interventions are still a reasonably well defined group, as participants have a common underlying health condition, i.e. a coronary heart disease with known disease mechanism, and though interventions may measure different outcome variables, interventions have a common function.

Previous reviews of psychological cardiac rehabilitation interventions have indicated uncertainty about the intervention mechanisms (e.g. Rees et al., 2004). However, even though the National Service Framework for Coronary Heart Disease (Department of Health, 2000) highlights the uncertainty regarding the evidence of mechanisms with which psychological cardiac rehabilitation interventions cause their outcomes, these interventions are recommended in the treatment of coronary heart disease patients. Therefore, psycho-educational cardiac rehabilitation interventions are not only complex and a relevant topic, but also clinically important interventions

offering a potential to apply the thesis results to other relevant contexts. Finally, by being on the interface of psychological and health, the topic of the psycho-educational cardiac rehabilitation interventions matches the background and interests of the author.

A difficulty faced by many reviews of a complex health care intervention was raised at this stage, as it emerged there was no clear, agreed definition of what a “psycho-educational” intervention contains. As Doyle et al. (2008b) point out, reviews can be complicated by different authors using varying definitions to describe and explain similar concepts. For example Goldman (1988) has used a term “psychoeducation” to describe an education of psychiatric patients about their condition, and defines psycho-education as an education or training that helps a person with a psychiatric disorder to better accept the illness and therefore promoting active cooperation with the treatment and rehabilitation. In addition, Goldman (1988) argued that psycho-education can strengthen coping skills that can then balance deficiencies caused by a mental health illness. This definition was used as a basis for defining psycho-educational intervention for the present review. Psycho-educational intervention is defined as a primarily non-pharmacological intervention that aims to modify behavioural, physiological and psychological outcomes by increasing knowledge, teaching skills, and changing attitudes towards behaviour change that will help reduce the likelihood of further manifestations of the coronary heart disease. Here, ‘psycho-educational intervention’ is not used to refer to an intervention that is aimed purely at improving the mental health of the participants. Psycho-educational cardiac rehabilitation interventions can be either stand-alone interventions, or be combined with exercise training and pharmacological therapies.

3.1.2 Coronary heart disease and cardiac rehabilitation

Coronary heart disease (CHD) is one of the major causes of death and disability in the UK with estimated prevalence, for example, in England 6.5% in men and 4.0% in women in 2006 (British Heart Foundation, 2006). The creation of a National Service Framework (NSF) for Coronary Heart Disease in 2000 established clear standards for the prevention and treatment of coronary heart disease (Department of Health, 2000), aiming to reduce mortality and life limiting disability caused by the CHD in United

Kingdom. While this NSF focuses on the primary prevention and treatment of the CHD, it recognises the importance of the secondary prevention and rehabilitation of CHD patients. As a comprehensive programme to help recovery from a heart attack (myocardial infarct or MI), revascularisation (percutaneous transluminal coronary angioplasty/PTCA or coronary artery bypass graft/CABG), or other cardiac event, the NSF recommends that a cardiac rehabilitation should be available to all eligible patients. A cardiac rehabilitation may consist of frequent exercise training on low to moderate intensity for a period, psychological and educational interventions without an exercise component, or a combination of exercise training and psychological and educational interventions, which is the recommended form by the national guidelines (SIGN, 2002, Department of Health, 2000). A coronary heart disease can have an impact on physical, psychological and behavioural aspects of patients' and their families lives, and national guidelines suggest that a multidisciplinary approach to the cardiac rehabilitation would be the most effective format to address the different areas of concern (SIGN, 2002, Department of Health, 2000). While recommendations for the cardiac rehabilitation are evidence-based, there is controversy about the features of an effective psychological intervention, which, Taylor et al. (2004) observed, may be due to the difficulties in observing and measuring psychosocial compared with physiological variables.

Cardiac rehabilitation is divided in four phases, the phase I being integrated in the hospital stay or activated by a change in a patient's cardiac condition. This first phase should include review of medication, correction of cardiac misconceptions, reassurance, risk factor assessment, and discharge planning. The guidance also recommends that, when possible, the patient's carer and family should be involved throughout the rehabilitation process. The early post-discharge period, when many patients may feel isolated and insecure, covers the phase II of cardiac rehabilitation. During this phase, patients may benefit from professional support through home visits or telephone calls. Over this time patients' cardiac risk and need for rehabilitation should be evaluated and patients offered lifestyle advice and psychological interventions and support from a cardiologist. Phases II and III of cardiac rehabilitation are closely linked, and while the phase III offers structured exercise training at an appropriate level, patients should continue to have access to psychological and educational interventions and support. The phase IV cardiac

rehabilitation is consist of the long-term maintenance of achieved behaviour changes. Unlike the phases I to III, which are often hospital-based, the phase IV is situated in a primary care and the rehabilitation focus is on maintaining the lifestyle changes achieved during earlier rehabilitation. Cardiac rehabilitation personnel should be appropriately trained, capable of advising and supervising exercise, delivering lifestyle interventions, providing psychological treatments, and trained in life support and defibrillation. (Department of Health, 2000, SIGN, 2002).

According to the NSF for Coronary Heart Disease (Department of Health, 2000) every hospital should ensure that following discharge, 85% of the patients whose primary diagnose is an acute myocardial infarct or a coronary revascularisation are offered a cardiac rehabilitation. The NSF defines aims of the cardiac rehabilitation so that a year after discharge half of those patients admitted to a cardiac rehabilitation should not be obese, should exercise regularly and should be non-smokers. Available information, however, suggest that at the present only 43% of eligible patients receive cardiac rehabilitation (British Cardiovascular Society, 2009). Research has also established that certain patient groups, such as ethnic minorities, women, and older persons are less likely to attend cardiac rehabilitation even when invited (Beswick et al., 2005).

Cardiac rehabilitation is an important part of the national strategy of secondary prevention and rehabilitation of patients with a coronary heart disease. Official guidelines recommend psychological and educational interventions as an integral part of a programme alongside physical and pharmacological therapies. Psychological and educational interventions, especially in the context of recovery from life a threatening illness and a need for behaviour change, can be seen as complex health care interventions. It is unclear, however, through which mechanisms psychological interventions deliver their outcomes and which components of interventions cause the desired changes. Therefore, examining psycho-educational cardiac rehabilitation interventions as a topic for empirical studies provides adequate level of intervention complexity with clinical relevance. The first empirical study, described in this chapter, is a review of previous reviews that have evaluated psychological cardiac rehabilitation interventions. For the purposes of this chapter, 'psychological intervention' is used as a blanket term that covers psycho-educational,

psychological, educational, and stress management interventions that form a part of cardiac rehabilitation. The aim of this review of reviews is to examine how previous reviews have approached methodological problems that reviewing complex health care interventions entail. Therefore, a pragmatic decision was made to include all reviews that have investigated psychological cardiac rehabilitation interventions. This means that reviews evaluating educational, psycho-educational, psychosocial, stress management, and other psychological interventions are included, as this was judged to offer the best possibility for examining the methodological issues facing reviews of complex health care interventions.

3.2 Methodological issues in reviews of psychological cardiac rehabilitation interventions

3.2.1 Introduction

Despite the national guidelines (Department of Health, 2000, SIGN, 2002) recommending the use of psychological interventions as a part of a cardiac rehabilitation, and many reviews of psychological interventions having been undertaken, uncertainty persists both about their effectiveness and also what characterises an effective intervention (e.g. Dusseldorp et al., 1999, Rees et al., 2004). Rodgers et al. (2005) argued that reviews of complex psychological interventions face methodological difficulties that hamper both the evaluation of an intervention effectiveness and improving an intervention planning. Uncertainty about the effectiveness of an intervention and its characteristics may be partly due to the complexity of the psychological cardiac rehabilitation interventions, as it is typically difficult to define precisely those components of an intervention that cause the change and how they might relate to each other (Medical Research Council, 2000, Craig et al., 2008). Comparing interventions and estimating their combined effectiveness is further complicated by the often context-specific nature of interventions. While the national guidelines (Department of Health, 2000, SIGN, 2002) propose some principles for the psychological cardiac rehabilitation interventions, many interventions are locally-tailored to fit into a specific programme or are experimental interventions, making the comparison of interventions a challenging enterprise.

If future reviews try to address the potential methodological difficulties encountered in the reviews of complex health care interventions, it would be important to know if and how the previous reviews have addressed methodological difficulties. Therefore the primary purpose of this review of reviews is not to evaluate evidence of overall intervention effectiveness, but to investigate how reviews have approached the methodological problems that reviewing complex health care interventions may cause. This review also aims to examine whether and how the previous reviews have explored theories underpinning interventions. The overall effectiveness of psychological cardiac rehabilitation interventions has been examined by Rodgers et al. (2005), who investigated reviews of psychological cardiac rehabilitation interventions in terms of what they added to the knowledge about interventions effectiveness. Rodgers et al. (2005) also examined the scope and the quality of the reviews, intervention characteristic, and mediating and moderating variables. Therefore, there is no immediate need to replicate this research. Nonetheless, what Rodgers et al. (2005), did not explore in depth was how the reviews had dealt with methodological problems associated with reviewing a complex health care intervention (e.g. Jackson et al., 2004), and if reviews considered theories underpinning interventions and their effects on planning and evaluation of interventions.

In this review, although it is recognised that these terms have their own distinct meanings, ‘theory’, ‘intervention theory’ and ‘intervention mechanism’ are used to describe theoretical considerations in reviews, especially in describing how an intervention causes outcomes. This approach was selected owing to the uncertainty about how theoretical considerations may have been presented in different contexts and to avoid confusion. Examining theoretical considerations does not necessarily mean explicitly investigating how a theory can predict and explain results, or whether a specified theoretical model or framework has been mentioned, but also exploring whether intervention mechanisms or variables can be found that advance general theoretical understanding of how an intervention causes desired changes.

3.2.2 Methods

3.2.2.1 Identification of studies

A review of psychological cardiac rehabilitation intervention reviews was undertaken to provide a case study of methodological issues foremost to complex health care interventions. The review was not systematic, and relevant reviews were identified first by a checking reviews included in the existing review of Rodgers et al. (2005) and by an additional literature search of MEDLINE, PsycINFO and Cochrane databases. The search strategy was developed to be broad and the review by Rodgers et al. (2005) was used to help in development of the search terms. Only limited number of search words were used, which included following terms; review, intervention, meta-analysis, cardiac rehabilitation, rehabilitation, psychological, psychoeducational, psychosocial, education, risk factor, coronary heart disease, myocardial infarct, MI, heart disease, angina, and coronary artery bypass graft or CABG. Search was limited to English language papers only and databases were searched from 1970's onwards. While including reviews only written in English is recognised as a potentially biasing factor, available resources did not allow more inclusive selection. Both systematic and non-systematic reviews were included, and there was no specific requirement for any data synthesis method, or a time limit for minimum length of intervention or follow-up.

3.2.2.2 Inclusion criteria of reviews

Reviews were considered if they included controlled or randomised controlled trials of secondary preventive psychological interventions, either alone or combined with an exercise training. Review protocols only were excluded. No time limit was set for how long before the start of an intervention the cardiac event had occurred. Reviews could be either systematic or non-systematic, no particular criteria for review methodology was set. There were no specific limitations set on how the studies for a review had been selected or appraised, which kind of a synthesis method was used, or which outcome measures were investigated. Interventions in the selected reviews were classified as 'psychological' when the review described including psycho-educational, psychosocial, educational or risk factor modification interventions that

used one or more of the following techniques: education; risk factor management; behaviour modification; stress management; support; coping skills training; and information transfer. No particular criteria were specified for the length or intensity of an intervention in a review or the personnel involved in the delivery of an intervention. Patients participating in an intervention had to have a confirmed coronary heart disease. Review quality was not appraised as part of this review.

3.2.2.3 Evaluation checklist

A checklist containing several questions was prepared for examining methodological problems posed for the reviews of psychological cardiac rehabilitation interventions. Criteria for evaluating methodological challenges reflected points raised by Jackson et al. (2004) and Armstrong et al. (2009) about methodological issues in reviewing complex health interventions, and challenges in evaluating complex health care interventions highlighted in papers by the Medical Research Council (2000, Craig et al., 2008) and Campbell et al. (2000). The review questions were designed to examine how some problems and solutions highlighted for the design and evaluation of a complex intervention have been recognised and dealt with in the reviews of psychological cardiac rehabilitation interventions.

1. How were psycho-educational, psychosocial, psychological interventions defined?
2. What were inclusion / exclusion criteria for studies?
3. How were the included studies categorised / classified?
4. How were the results from individual studies synthesised?
5. Were theories or mechanisms of interventions explicitly considered in the reviews?
6. What was the impact of theories in reviews?
 - a. Was the definition of an intervention theory-informed?
 - b. Were the inclusion criteria, classification of studies and evidence synthesis theory-guided?
7. How and what did the reviews contribute to a future intervention planning?

The first question examined how reviews have approached the problem of defining their target interventions from seemingly-similar but not the same interventions. Relevant information for this question was extracted from the methodology sections of the papers, and information was recorded on how the target intervention was defined or what kind of a system was in place to identify the relevant interventions. The second evaluation criteria examined how an intervention complexity had been reflected in inclusion and exclusion criteria, and how inclusion and exclusion criteria mirrored the specific objectives of the review. Information was extracted from the methods section including the type of study (RCT, comparison group etc.), participant characteristics, intervention type (e.g. psychosocial), and what were the primary outcomes of the study. The next question investigated how interventions were categorised within a review, as more than one format of an intervention may have been included in the review, or the review might have been interested about distinct characteristics of interventions that separate them from each other. From the results section information was extracted on which study or intervention characteristics were used to classify studies into different groups. Investigating how interventions had been categorised may suggest possible points at which intervention complexity was managed by means of a classification.

The fourth and fifth evaluation criteria examined how the results from the individual studies had been synthesised and whether and how the reviews investigated theories underpinning interventions. From the methods sections relevant information was extracted about what was the main method of an analysis, and if additional analyses were performed. Information about theories underpinning the interventions was searched from all parts of the paper. Information was recorded if the paper discussed a specific intervention mechanism or a theoretical construct that it aimed to test, if the discussion section included a discussion of how the results fitted in with theoretical constructs or intervention mechanisms, or any other reference to theories underpinning interventions or mechanism in primary studies that may be relevant for the results of the review. Information was also recorded if a lack of theories underpinning interventions or mechanism was discussed.

The sixth review criterion was designed to examine the impact of theories underpinning interventions in the reviews. Relevant information for this question was

if any parts of the review process were reported to have been influenced by theoretical considerations. Relevant material for this question included any information about influence of a theory in guiding research question setting, data collection or analyses, such as investigating certain intervention mechanisms, or mediator and moderator variables to understand how an intervention works. Papers did not need to specify any particular theory. As one of the main aims of this project is to explore how the understanding of intervention mechanisms may be improved, it was considered important to know if and how the previous reviews had examined intervention mechanisms. The final review criteria examined how the reviews contributed to the future intervention planning, and evaluated whether and how the reviews were related to each other and had changed over the time. Information was extracted from the conclusions of what future interventions developers should consider when planning a new intervention, such gender issues, intensity of an intervention or possible intervention techniques such as stress management.

3.2.2.4 Data extraction and analysis methods

Data were extracted using data extraction sheets designed and piloted for this study. Two sets of data extraction sheets were used, first of which collected information about review questions and the second collected information about which primary studies were included in the reviews and in how many different reviews each study was included. Data was extracted by the author alone, as resource limitations prevented duplicate data extraction or double-checking of the data. Authors of the original reviews were not contacted for additional information. After the data collection was finished, data-analysis was done using techniques from narrative and thematic analysis methods.

The data from each of the reviews was collected under specific headings, which, in this case, were the review criteria. Themes for the analysis did not emerge from the data as they were pre-defined, and data was extracted to answer the specific questions within each of the review criteria. The thematic analysis compared data within each of the review criteria and examined discrepancies and commonalities between the reviews in their responses to methodological challenges. The narrative analysis was used to describe both the individual and overall findings, and how they

fitted in with previously described challenges and solutions to reviewing complex health interventions. Finally, the number of different papers included in each review was calculated.

3.2.3 Results

Out of the 4561 identified citations fifteen reviews were identified as potentially suitable for the review (Figure 3.1), but after a full text review five of these were excluded (Table 3.1). Shortly, Reasons for exclusion were as follows:

- investigating interventions for depression in heart failure (Lane et al., 2006),
- review did not consider cardiac rehabilitation interventions, but interventions for psychological management of angina symptoms (McGillion et al., 2004),
- review concentrated on exercise only interventions or included exercise only interventions (Lear and Ignaszewski, 2001, Jolly et al., 2006), or
- gender differences in participation to cardiac rehabilitation (Grace et al., 2002).

Therefore, ten reviews were included in the review of reviews, and all but one (Linden, 2000) of these reviews were also included in the review by Rodgers et al. (2005). All reviews, with exception of Linden (2000) that included both primary and secondary research, investigated the effectiveness of primary studies (Dusseldorp et al., 1999, Godin, 1989, Hill et al., 1992, Linden et al., 1996, Moore, 1997, Mullen et al., 1992, Nunes et al., 1987, Rees et al., 2004, Sebregts et al., 2000). The inclusion criteria of the reviews are shown in the Table 3.2. Also, in the Table 3.2 includes review authors' descriptions of whether their review was a systematic, a non-systematic, or a meta-analytic review. If a review is defined as systematic when it has a clear set of objectives, pre-defined inclusion criteria, detailed search strategy that is applied to at least two different databases, a systematic appraisal included studies, and well defined outcomes measures (e.g. Centre for Reviews and Dissemination, 2009), seven of the reviews were evaluated as systematic. Those reviews not evaluated as systematic, either reported searching only one database, or selected only large well known studies or reviews.

The reviews predominantly included studies with control or comparison group designs, and in total 151 papers were included between the reviews to demonstrate

intervention effectiveness. Out of the 151 individual papers included in the reviews 67% (101) were included in only one of the reviews (Table 3.3.). Primary studies that were included in two of the reviews presented 21% (31) of the total number. Eleven (7%) of the primary studies were included in three reviews, while six (4%) were included in four reviews and two (1%) in five reviews. None of the listed primary studies was included in all of the reviews. Studies included in three or more of the reviews were usually reports from a large-scale, well known trials, such as the ENRICH study with multiple published articles. Of the identified reviews, Rees et al. (2004) included largest number of individual primary studies (n=55). Individual papers are listed in the Table 3.3.

For the purposes of this study, papers were listed individually, even when reporting results from the same, large-scale study. Whether to include all the papers or only all the studies in the comparison depends on the purpose of the study. If the purpose of this study is a meta-analysis, only studies, not papers, should be included. On the other hand, evaluating issues related to publication bias may require all the papers to be included. However, in this particular study the aim was to chart the variety of papers that had been included in the different reviews, thus highlighting the complexity of comparing the reviews. Reporting only the studies finally included might have led to confusion, as, especially in relation to long-running studies, a review could have been conducted when the final publication of a study may not yet have been published. Listing the individual papers instead of the studies also helped in charting when a review may have included multiple papers from a same study, as earlier papers may have offered complementary information, such as fuller description of an intervention and control conditions. Using more than a one paper to gather information may be especially relevant for reviews that need to ensure the fullest possible information about intervention characteristics. The results of this review, however, indicated that generally, reviews did not report including multiple papers from the same study, leaving open the question of whether reviews had not located these publications or did report only one paper per study.

3.2.3.1 How have psycho-educational, psychosocial, and psychological interventions been defined?

While the reviews included broadly similar interventions, every review had, nevertheless, its own specific objectives, which were reflected in the study selection. Many of the reviews did not use terms psychosocial, psycho-educational or indeed even psychological intervention to define intervention, even when one of the terms was used in the review title and elsewhere in the article. Rather, interventions were often defined in terms of their forms and functions. For example, a review may have required any included interventions to have an educational component, such as patient education about the outcomes of coronary heart disease, or aiming to reduce risk factors such as lack of exercise or unhealthy diet. Some of the reviews had clearly defined what kind of interventions they were including (Dusseldorp et al., 1999, Rees et al., 2004, Sebregts et al., 2000, Hill et al., 1992, Godin, 1989, Linden et al., 1996). These covered a considerable variety of interventions, with each review concentrating on one or more distinct groups of interventions. These covered health education, stress management, psychosocial, psychological, and non-pharmacological interventions. Only two reviews appeared to have overlap across groups of interventions included (Dusseldorp et al., 1999, Rees et al., 2004). Dusseldorp et al. (1999) included both health educational and stress management interventions, while Rees et al. (2004) included stress management and psychological interventions.

Instead of using the methods described above to define intervention characteristics, Nunes et al. (1987) and Mullen et al. (1992) appeared to use either a categorical or a coding system to describe and classify interventions. For example, Nunes et al. (1987), classified interventions either as an education about coronary heart disease and type A behavioural pattern, or an intervention that used relaxation training, cognitive therapy, or behaviour modification. Finally, two reviews did not clearly define intervention features or a type of group that may describe the interventions broadly (Moore, 1997, Linden, 2000). Linden (2000), did refer to interventions included in the earlier reviews. In Moore (1997) intervention characteristics were not explicitly restricted as the review aimed to explore what kind of interventions are

available that promote recovery following a coronary artery bypass graft (CABG), rather than reviewing these interventions.

3.2.3.2 How were the included studies categorised or classified?

Every review used a different system to organise the included studies, to reflect the review objectives, such as planned comparisons between groups. In the most cases, study classification criteria and system were decided before data collection, but in some cases, as in Linden (2000), the methods needed to be modified after the data collection, to fit the available material. Dusseldorp et al. (1999) and Rees et al. (2004) classified studies according to an intervention type, for example, between stress management and educational interventions. Godin (1989) and Sebregts et al. (2000) classified studies according to the risk factors the studies had investigated. Hill et al. (1992) and Moore (1997) classified studies according to interventions, target population, and location. Nunes et al. (1987) considered the effect of treatment modalities on outcomes, and Mullen et al. (1992) used a coding system which included, for example, contact frequency. In contrast to other reviews using experimental conditions to help in classifying studies, Linden et al. (1996) classified studies according to control conditions, i.e. according to the usual care that participants in the control conditions received. Only Linden (2000) did not appear to use any specific categorisation system, but studies and reviews were considered and discussed case by case.

3.2.3.3 What were inclusion / exclusion criteria for the studies?

Apart from Linden (2000), who appeared to include large, well-known studies and reviews, other reviews had specified inclusion criteria according to the study methodology, participant groups, intervention type, and primary outcomes. The Reviews included predominantly randomised or non-randomised controlled studies. Mullen et al. (1992) also listed studies with weaker designs, such as pre-test-post-test, but these studies were not included in any further data analyses.

All reviews included only those studies that provided evidence that participants had a confirmed coronary heart disease (CHD). However, reviews differed considerably in

how a CHD was defined, or rather, which manifestation of the CHD or treatment was used as a defining factor, depending on the particular interests in the review. While some of the reviews only stated that participants with a CHD were included (Godin, 1989, Linden et al., 1996, Nunes et al., 1987), other reviews used CHD as a main category, then further defining specific conditions (Dusseldorp et al., 1999, Hill et al., 1992, Mullen et al., 1992, Rees et al., 2004, Sebregts et al., 2000). For example, Dusseldorp et al. (1999) included studies that investigated participants with a cardiac event defined as a MI, CABG or PTCA. One review by Moore (1997) was very specific in regarding the participant population and included patients having only a CABG operation. (Table 3.2).

The definition of interventions was included in all reviews except Linden (2000). While Moore (1997) left the intervention definition purposely vague, other reviews had clearly defined interventions to be included. However, where the reviews differed most was the targeted outcome variables. As all the reviews included different sets of outcome variables, this made the comparison of the review results challenging. The reviews investigated a variety of physical (e.g. blood pressure, lipids), behavioural (e.g. diet, smoking), and psychological (e.g. stress, anxiety) outcome variables and combinations of these outcomes. (Table 3.2.).

3.2.3.4 How were the results from individual studies synthesised?

Data synthesis methods varied markedly between the reviews, ranging from a meta-analysis to a counting the number of effective studies to a narrative synthesis. A meta-analysis was the most commonly used statistical synthesis technique (Dusseldorp et al., 1999, Linden et al., 1996, Mullen et al., 1992, Nunes et al., 1987, Rees et al., 2004). A narrative synthesis was used by Hill et al. (1992), Linden (2000), and Sebregts et al. (2000). Narrative methods were used in the cases where the review aimed to describe and summarise available research, whereas using statistical methods was favoured when the aim of the review was to establish average effectiveness of the interventions.

As well as performing a meta-analysis or a narrative synthesis, most of the reviews had explored heterogeneity. The reviews commonly combined meta-analysis with

other statistical techniques to investigate, for example, intervention effects on proximal and distal targets, and for effect moderators (Dusseldorp et al., 1999). Of those reviews that used narrative methods, for example, Hill et al. (1992) used the narrative synthesis to consider interventions for a myocardial infarct and CABG patients separately. Narrative synthesis was also used by Rees et al. (2004) to offer a qualitative overview when statistical methods were not suitable. Godin (1989) counted the number of successful and non-successful interventions, while Moore (1997) coded intervention outcomes as effective, non-effective and partially effective, which were then used to consider interventions' effectiveness for a range of outcomes.

Although it appeared that reviews had used appropriate synthesis methods, when used synthesis methods were analysed according to earlier evaluation of whether review could be classified as systematic or not, picture became more complex. Linden et al. (1996) and Nunes et al. (1987) used meta-analysis in combining intervention effects, but if a review is classed systematic only when two or more databases have been searched, these reviews were not systematic and therefore using meta-analysis might not have been appropriate. On the other hand, Sebregts et al. (2000) though doing a systematic review, opted for a narrative analysis as it was considered that the studies included in the review were too heterogeneous for statistical synthesis. Similarly, Hill et al. (1992) used a narrative synthesis in their systematic review to combine individual study results.

3.2.3.5 Were theories or mechanisms of interventions explicitly evaluated in the reviews?

Three of the included reviews did not mention theories underpinning interventions in any form (Hill et al., 1992, Rees et al., 2004, Sebregts et al., 2000). Only two of the reviews explicitly investigated theories or mechanisms underpinning interventions as one of the review objectives (Dusseldorp et al., 1999, Linden, 2000). Many reviews made references to a intervention theory, or a lack of it, in the discussion (Godin, 1989, Linden et al., 1996, Moore, 1997, Mullen et al., 1992, Nunes et al., 1987). Dusseldorp et al. (1999), while not specifying a particular theoretical model, suggested that interventions were based on assumptions that emotional distress,

cardiac risk factors and related behaviours were contributing factors to cardiac mortality and morbidity. Similarly, the review by Linden (2000), explored rationales underlying interventions, but concluded that there was no clear explanation of how interventions worked.

Those reviews that mentioned theories underpinning interventions in the discussion section appeared to see theoretical considerations as important, though did not actively pursue these theoretical issues in the review. For example, Moore (1997) considered inclusion of theory in an intervention planning as a strength and suggested that future research should consider intervention mechanisms. Linden et al. (1996) suggested that while it was not possible to answer questions of why psychological intervention works, for example, psychotherapy outcome literature proposed mechanisms such as hope, support and sense of control that may help to explain the effectiveness of interventions. Nunes et al. (1987), though not directly mentioning theories underpinning interventions, expressed interest to know via which modalities interventions are effective. Godin (1989) considered, in the review discussion, the compatibility of interventions with the assumptions of theoretical models, whereas Mullen et al. (1992) discussed the lack of explicit references to theoretical models as one of the weaknesses of the studies included in their review.

3.2.3.6 What was the impact of theories in reviews?

One objective of this review of reviews was to consider whether and how theoretical considerations impact on, for example, study selection, review questions, analysis methods, or any other aspect of the review. The results suggested that in most of these reviews there was no explicit evidence that theoretical considerations had affected the decisions about intervention definition, selection or analyses. None of the reviews appeared to use theoretical considerations in a study or, rather an intervention, selection. Though for example Mullen et al. (1992) did examine specifically educational methods used in the included interventions, even there was otherwise no evidence of the use of theoretical considerations. While not mentioning any specific theoretical background, one of the main objectives in Dusseldorp et al. (1999) was to investigate process variables that may explain intervention mechanisms. In this sense, theoretical interest in intervention mechanisms was used

to decide analysis strategy. Linden (2000) did not combine individual study results statistically, but explored how rationales for interventions differed between research groups in this field, offering interesting insight into possible mechanisms of different interventions.

3.2.3.7 Contribution of reviews to future intervention planning

3.2.3.7.1 Evidence and suggestions from the reviews of features of an effective intervention

Available evidence from the reviews suggested that targeting a desired behaviour change, e.g. smoking cessation, as a primary target of an intervention appears to be more effective than targeting behaviours as peripheral targets, e.g. exercise programme with a smoking cessation advice. Evidence also suggested that those interventions that concentrated on one specific behavioural risk factor e.g. smoking or diet changes were judged more effective than more general interventions without specified behaviour change goals. Although Godin (1989) suggested that multi- and uni-component interventions appear to be equally effective, later reviews have suggested that multicomponent interventions are more effective (e.g. Rees et al., 2004).

The review evidence also suggested that the effectiveness of an intervention may be increased by a selective patient referral, e.g. the most motivated or the most distressed patients, screening for those patients with risk factors targeted by the intervention, considering patients' resistance to change, and by maintaining attendance motivation. However, intensive treatments, such as psychotherapy, were considered effective only in cases of an extreme psychological distress. A group format with an adequate staff support was also suggested as a format for an effective intervention. Many reviews also considered effective intervention techniques to influence targeted outcomes, and, in addition to tailoring an intervention to an individual's needs, these techniques were suggested: re-enforcement; longer intervention duration; feedback; skills; stress management; additional resources; knowledge; information; education; and considering patients language competency.

3.2.3.7.2 Reviews contributions to understanding of intervention mechanisms

Process variables can be used to explain and examine mechanisms of an intervention. While most of the reviews considered process variables in some capacity (Dusseldorp et al., 1999, Linden, 2000, Linden et al., 1996, Moore, 1997, Nunes et al., 1987, Sebregts et al., 2000), the reviews differed considerably in their estimation of what were considered as process variables and what as end-point measurements. Reviews had evaluated both biological and psychological process variables and their effects on outcomes. Biological process variables, e.g. blood pressure and cholesterol, were considered in connection with mortality and morbidity, and how they may explain intervention effectiveness to reduce cardiac mortality. Psychological process variables were less-often investigated, but Nunes et al. (1987), for example, considered effects of a type A-behaviour on cardiac risk factors.

3.2.3.7.3 Development of the reviews over time

The reviews, from the earliest to the most recent, were evaluated for possible indicators of how these reviews of psychological cardiac rehabilitation intervention had changed over time. Comparing the reviews was challenging, as although they broadly investigated similar interventions, there were considerable differences in foci and what studies were seen as relevant. No review was an actual update or replication of a previous review, so it was not feasible to evaluate review development in terms of how adding a new research evidence develops review conclusions, either strengthening or weakening the results. Although not included to this review, the review by Rees et al. (2004) has been updated lately (Whalley et al., 2011). While it was not possible to consider how the emergence of new research has affected review conclusions, available information was used to investigate a few points of methodological development over time.

Earlier as well as the more recent reviews were very similar in their requirements for study methodology, with minimum requirements of comparison group and well-defined participant population. A wide variety of definitions was used to describe eligible interventions, and there was no evidence of any emerging consensus in the later reviews. Apart from the general statistical advances, there was also no clear

pattern found in the methods used to estimate combined intervention effectiveness. Both more recent and earlier reviews had used statistical and descriptive methods to synthesise evidence. In one of the early reviews, Godin (1989) argued that future primary studies should improve both intervention design and evaluation, such as measurement of intervention components and outcomes. This, however, appears not to be a recurrent issue in the later reviews. Whether this is due to methodological improvements in primary studies, or investigating different pool of primary studies, or emergence of other methodological problems could not be explored.

No clear pattern emerged from the reviews of how they, collectively, have contributed to the development of an intervention design or in understanding of intervention mechanisms. It was also unclear how much influence recommendations made in the reviews have had in the primary research. For example, Mullen et al. (1992) suggested that an apparent weakness of the primary studies is that they are designed without an explicit reference to theoretical frameworks. Whether or not these recommendations have influenced primary research is difficult to assess. Only a few later reviews, namely Dusseldorp et al., (1999) and Linden (2000), systematically examined theories underpinning interventions, but they did not explicitly examine how primary research in the field has changed in relation to theoretical developments.

3.3 Discussion

Reviewing reviews of complex health care interventions poses a number of specific challenges. For example, Jackson et al. (2004) and Armstrong et al. (2009), point out that reviews of complex health interventions need to solve problems regarding defining intervention, locating relevant research, assessing a study quality, selecting an appropriate data synthesis method, and evaluating the impact of contextual variables in intervention effectiveness. The aim of the present review was to examine how reviews of psychological cardiac rehabilitation interventions have acknowledged and solved some of these challenges. This review did not directly investigate whether interventions in the reviews were as complex or had explicitly discussed methodological issues that they may need to solve. Indeed, as many of the reviews were published prior to the publications of the guidance from the Medical

Research Council (Campbell et al., 2000) and the Cochrane Group (Higgins and Green, 2008), this would not have been meaningful. Instead, this review aimed to elicit if and how the previous reviews have pragmatically aimed to solve methodological challenges commonly faced in the reviews of complex health care intervention. However, the results indicated similarities between the reviews in approaching and solving some methodological problems in reviews of psychological cardiac rehabilitation interventions. The review results also affirm that systematic reviewing and meta-analysis of psychological interventions is feasible. Apart from this, this review examined if and how evaluation of theories underpinning interventions and mechanisms has been approached in the previous reviews.

Results from this review indicated that although none of the included reviews tested how a formal theory, such as the theory of planned behaviour, can be used to predict and explain results, intervention mechanisms or theories were either tested or discussed in number of the reviews. For example, Dusseldorp et al. (1999) showed that interventions were effective in influencing distal targets such as cardiac mortality and morbidity when they were successful in proximal intervention targets such as lowering cholesterol or blood pressure. What, however, the reviews did not examine in detail was the kind of intervention techniques deployed to achieve the observed changes. The lack of testing of formal theoretical constructs was perhaps not surprising, as many of the primary studies were unlikely to provide information that would have supported the analysis. Also, reviews seemed to have taken an approach that rather than testing how a certain theory might fit the findings, it is more useful to understand those mechanisms that facilitate changes

Results from this review suggests that, rather than explicitly discussing what is meant, for example, by psycho-educational intervention, reviews have taken a pragmatic approach to defining interventions. This is usually done by describing the features of an intervention e.g. 'educational', but not specifying intervention components e.g. personal contact. Evidence also suggested that the reviews commonly used categories to classify included studies. The intervention definitions appear to concentrate on intervention techniques and functions, such as specifying educational technique or risk factor reduction function. Although some reviews such as Dusseldorp et al. (1999) and Rees et al. (2004) did specify that they include e.g.

health educational or stress management interventions, this was nevertheless accompanied by descriptions of what features an intervention has to fulfil before being considered as e.g. a stress management intervention. In this sense, for example, stress management was seen as a category, under which interventions were classified. Considering against this background, it is perhaps not surprising that the reviews had included over 150 different papers.

The inclusion and exclusion criteria in the reviews were generally well-defined, and apart from Linden (2000), who included both primary and secondary research, reviews expected primary studies to have at least a comparison group. While reviews were similar in their requirements of primary study methodology, there were differences in their requirements for participant populations, considerable differences in intervention definitions and, importantly, in what outcomes were of interest. The available data suggested that perhaps the predominant factors in explaining why reviews of complex health care interventions are difficult to compare, are the differences in exact participant populations (e.g. what subgroups have been included), interventions of interest, and the measured outcomes. It may be difficult to move on from this situation, as many of the reviews already included studies with considerable problems of heterogeneity. The reviews had used variety of methods to synthesise the research evidence. There was no evidence that synthesis methodology was linked to the time point when the review was conducted, but rather to review objectives. The reviews did not only summarise the evidence of an intervention effectiveness, but both narrative and statistical methods were used to explore available data of intervention mechanisms, and the differences between subgroups.

Only a few reviews explicitly examined theories underpinning interventions or mechanisms, though rather more mentioned theories underpinning interventions or mechanism in discussion. Those reviews, however, that had investigated intervention theory in some capacity appeared not only to find theory as an important tool in understanding intervention mechanisms but also as a useful guide in planning the interventions. However, most reviews nevertheless added little to the theoretical understanding of intervention mechanisms. It was not clear from the available material that why some reviews did discuss theories and mechanisms underpinning interventions without actually formally investigating them in some form. Examining

theories underpinning interventions or intervention mechanisms may help understanding not only differences in the effectiveness of an intervention, but also differences and similarities between interventions, which may otherwise not have been apparent.

Apart from considering theories underpinning interventions and mechanisms in connection with intervention effectiveness, influence of theories in the review planning was considered. While some reviews did investigate intervention mechanisms, and in this sense, review question and analysis decisions were influenced by theoretical considerations, study selection did not appear to be influenced by theoretical considerations in any of the reviews. Whether using theoretical considerations in the study selection process, e.g. deciding what kind of interventions will be included, improves reviews is still an open question. Considering theoretical aspects of interventions from study selection process onwards may improve theoretical understanding of intervention mechanisms. This approach, however, has its practical problems, as it may not always be clear how to include a theory in a review. Theory can be included in a review process at many levels, and in many forms. A review can, for example, investigate effects of a specific theory on intervention effectiveness, investigate if specific theoretical assumptions are concurrent with the review evidence, or investigate intervention mechanisms without reference to a specific theory. New methods are also developed to apply theory to evidence synthesis especially in the reviews of behaviour change interventions (e.g. Gardner et al., 2010). The availability of primary studies with a relevant theoretical information, e.g. explicitly considering theoretical issues and investigating process variables, however, appears to be limited at the present. Theoretical considerations in the effectiveness research must also fit the systematic review methodology, which means that a lack of explicit theoretical considerations cannot easily be used as an exclusion criterion.

The present review indicates that reviewers face weighty challenges in interpreting the results of a review. The complexity and diversity of underlying rationales, treatment techniques, and risk factor models adds to problems of interpreting the review results. While suggestions for a future intervention planning were not always consistent, these reviews contributed considerably to better understanding of possible

features of effective interventions. Some of the review evidence suggested that multi-modal interventions that concentrate on a specific risk factor appear to be more effective than interventions that aim to influence several risk factors. For, example, an intervention that uses education, coping strategy training, and potentially pharmacotherapy to increase smoking cessation is more likely to succeed than an intervention where many other risk factors are simultaneously targeted. In addition, reviews argued that future interventions may find the following intervention techniques effective; re-enforcement; longer intervention duration; feedback; skills; stress management; knowledge; information; education.

3.4. Conclusions

Reviews of complex health care interventions face unique methodological problems, many of which, however, were not explicitly recognised in the reviews. Number of methodological challenges appeared to stem from difficulties associated with defining complex health care interventions and diverse participant populations. Reviews had solved some difficulties related to intervention definitions by concentrating on defining features of an intervention, and by detailed descriptions of patient populations. While reviews, in general, examined overall intervention effectiveness at some level, less attention, however, was paid to more detailed examination of intervention components such as length, or a mechanism of an intervention. Those reviews that examined a mechanism or components of a potentially effective intervention were best placed to provide practical guidance for designers of future interventions.

Author	Review	Reason for exclusion
Lane et al. 2006	Psychological interventions for depression in heart failure	<i>Review did not identify psychological intervention RCTs for the review</i>
McGillion et al. 2004	A systematic review of psychoeducational intervention trials for the management of chronic stable angina	<i>Review did not consider cardiac rehabilitation interventions, but interventions for angina patients. Purpose of the studies appeared to be psychological management of the angina symptoms.</i>
Jolly et al. 2006	Home-based cardiac rehabilitation compared with centre-based rehabilitation and usual care: A systematic review and meta-analysis	<i>In addition to interventions with psychological components, exercise only and predominantly exercise interventions included</i>
Grace et al. 2002	Cardiac rehabilitation I: review of psychosocial factors	<i>Review considers gender differences in participation to cardiac rehabilitation with focus on anxiety, self-efficacy and social support</i>
Lear et al. 2001	<i>Cardiac rehabilitation: a comprehensive review</i>	<i>Considers primary and secondary research from both exercise only and comprehensive cardiac rehabilitation programs</i>

Table 3.1: Reviews excluded from the review of reviews

Review	Study design	Participants cardiac diagnosis	Intervention	Outcomes	Systematic or non-systematic review
Dusseldorp et al. (1999)	Studies with comparison or control group	Cardiac event (MI, CABG, PTCA) within 6 months	Health education, stress management, exercise training	Cardiac and physical health outcomes (risk factors, related behaviours)	<i>Systematic (Authors)</i> <i>Systematic (Meets criteria)</i>
Godin (1989)	Quasi-experimental, experimental and evaluative research with factorial design	Individuals with coronary heart disease	Interventions that provided information about diet, smoking, exercise behaviours.	Changes in diet, smoking, exercise or combinations of these	<i>Systematic (Authors)</i> <i>Systematic (Meets criteria)</i>
Hill et al. (1992)	Studies with control or comparison group	Appears to MI and CABG patients	Replicable global psychosocial intervention.	Mental health outcomes (mood, emotional symptoms)	<i>Systematic (Authors)</i> <i>Systematic (Meets criteria)</i>
Linden et al. (1996)	RCTs with one or more control conditions	Documented Coronary Artery Disease	Psychosocial treatment in addition to the treatments offered to patients in usual care group	Anxiety, depression, biological risk factors (BP, Heart rate, Lipids), mortality and recurrence of cardiac events.	<i>Meta-analysis (Author)</i> <i>Non-systematic (Does not meet criteria)</i>
Linden (2000)	No specific study inclusion criteria. Large, well known, studies and reviews included				<i>Non-systematic (Author)</i> <i>Non-systematic (Does not meet criteria)</i>
Moore (1997)	Experimental studies with control or comparison group	CABG	Interventions that promote recovery in adults following CABG surgery	Not specified. Outcomes reported in the studies included mood states and physical functioning	<i>Systematic (Authors)</i> <i>Systematic (Meets criteria)</i>
Mullen et al. (1992)	RCT, quasi-experimental comparison-group design, one-group pretest-posttest design	Myocardial infarct, angina, CABG, diagnosed coronary artery disease	Psychosocial or educational intervention	Exercise, diet, smoking, stress, drug adherence, morbidity, return to work, death, blood pressure	<i>Systematic (Authors)</i> <i>Systematic (Meets criteria)</i>
Nunes et al. (1987)	Controlled studies	Coronary heart Disease, Type A Behaviour	Psychological treatment for Type A Behaviour Pattern	Not specified	<i>Meta-analysis (Author)</i> <i>Non-systematic (Does not meet criteria)</i>
Rees et al. (2004)	RCT with parallel group design	Adults of all ages with CHD (MI, CABG, PTCA, angiographically diagnosed CHD)	Non-pharmacological psychological & stress management interventions	All-cause and CHD mortality, MI, CABG, PTCA, anxiety, depression, type-A behaviour, stress	<i>Systematic (Authors)</i> <i>Systematic (Meets criteria)</i>
Sebregts et al. (2000)	<i>RCT, one or more control conditions</i>	<i>Patients with established CHD (angiographically defined, PTCA, CABG, AMI)</i>	<i>Treatment condition had to offer non-pharmacological intervention focusing particularly in one or more risk factor</i>	<i>Smoking, serum cholesterol, physical exercise, type A behaviour</i>	<i>Systematic (Authors)</i> <i>Systematic (Meets criteria)</i>

Table 3.2: Inclusion criteria of reviews included in the review of reviews

Review	Dusseldorp -99	Godin -89	Hill -92	Linden -96	Linden -00	Moore -97	Mullen -92	Nunes -87	Rees -04	Sebregts -00
Study										
Adsett -68				X						
Aiken -71			X							
Allen -96						X				
Allison -00									X	
Anderson -87			X			X				
Arntzenius -86							X			
Baer -85			X							
Barbarowicz -80						X				
Barnard -83							X			
Barnason -95						X				
Barnason -95						X				
Beckie -89			X			X				
Bengtsson -83	X						X			
Black -98									X	
Bohachich -84				X		.				
Brown -93									X	
Burell -94				X						X
Burell -95									X	
Burrell in Allen -96										X
Burgess -87									X	
Burt -74		X					X			
Chubb -74							X			
Clark -92				X						
Cowan -01									X	
Cupples -91						X				
Daltroy -85		X					X			
Debusk -94	X								X	
DeBusk -85							X			
Dracup -84	X									
Dracup -82						X	X			
Ehsani -81							X			
Elderen -94									X	
Engblom -92	X									
ENRICHD -00									X	
Louis -02										
ENRICHD -03										
Erdman -83		X							X	
Erdman -86										
Fielding -80				X			X			
Fielding in Oborne -79	X									
Frasure-Smith - 91					X					
Frasure-Smith - 85	X						X		X	
Frasure-Smith - 89			X	X						
Frasure-Smith - 87										
Frasure-Smith - 97	X				X				X	

Table 3.3: Primary studies included in the review

Review	Dusseldorp -99	Godin -89	Hill -92	Linden -96	Linden -00	Moore -97	Mullen -92	Nunes -87	Rees -04	Sebregts -00
Study										
Freedland -96					X					
Friedlund -91	X								X	
Friedman -84				X	X			X	X	X
Friedman -86	X							X	X	
Friedman -82										
Mendes-de Leon -91										
Powell -84										
Powell -88										
Gallacher -97									X	
Gilliss -93	X					X				
Gortner -88						X				
Greenstain -82							X			
Gruen -75				X						
Gutschker -82									X	
Guzetta -89				X						
Hart -84								X		
Healy -83							X			
Heath -87		X								
Hedbäck -87	X									
Hertanu -86							X			
HofmanBang -99									X	
Lisspers -99										
Horlick -84	X		X	X						
Ibrahim -74	X	X					X	X	X	
Jenni -79								X		
Johnston -99									X	
Jolly -98									X	
Jones -96	X				X				X	
Kallio -79	X	X								
Karvetti -81	X									
Kavanagh -73							X			
Langosh -82							X	X		
Levenkron -83								X		
Lewin -92									X	
Friedlund -92									X	
Lidell -96										
Linde -79							X			
Linden -95	X									
Maelund -87							X			
Marshall -86	X					X	X			
Mayou -83	X	X								
Mayou -81		X					X			
McHugh -01									X	
Miller -88							X			
Mitsibounas -92	X								X	
Moore -96						X				

Table 3.3: Primary studies included in the reviews

Review	Dusseldorp -99	Godin -89	Hill -92	Linden -96	Linden -00	Moore -97	Mullen -92	Nunes -87	Rees -04	Sebregts -00
Study										
Munro -88	X			X						
Nordman -01									X	
O'Callaghan -84							X			
Ockene -92										X
Oldenburg -85	X		X						X	
Oldenburg in Lovibond -89	X									
Oldenburg -95									X	
Oldridge -83		X					X			
Oldridge -78							X			
Ornish -93					X					
Ornish -89									X	
Ornish -90					X					X
Ornish -83										X
Owens -82						X				
Penckofer -89						X				
Perk -90	X									
Pimm -84			X							
Pozen -77	X			X						
Rahe -75	X			X				X	X	
Rahe -79		X					X			
Rice -92						X				
Rigotti -94										X
Rosenberg -71							X			
Roskies -79								X		
Rovario -84							X			
Saint -91									X	
Salonen -85	X						X			
Scalzi -80		X								
Schindler -89			X			X				
Schulte -86				X						
Shaw -89						X				
Shaw -81							X			
Singh -92										X
Sivarajan -83	X						X			
Steele -87						X				
Stern -83	X		X	X					X	
Stransky -86	X									
Suinn -78								X		
Taylor -88										X
Taylor -90	X									X
Theorell -82	X									
Thompson -89				X					X	
Thompson -91										
Thompson -90			X	X						
Thompson -90										
Toobert -98									X	
Turner -95				X						

Table 3.3: Primary studies included in the different reviews

Review	Dusseldorp -99	Godin -89	Hill -92	Linden -96	Linden -00	Moore -97	Mullen -92	Nunes -87	Rees -04	Sebregts -00
Study										
Van Dixhoorn -90					X					
Van Dixhoorn -90				X					X	
Van Dixhoorn -89	X									
Van Dixhoorn -87										
Van Dixhoorn -99										
Van Elderen -94	X									
Van Elderen -94	X									
Vermeulen -83									X	
Waites -83							X			
Watts -92										X
Wilhelmsen -75		X					X			
Woodward -72		X								
Young -82	X						X			

Table 3.3: Primary studies included in the reviews

Notes:

- Only first author listed
- Some papers are presented in non-alphabetical order when they report findings from the same (usually) large trial
- Blue letters show papers from one trial
- Only papers reporting Reviews by Linden (2000) and Sebregts et al. (2000). However, this may have caused omissions
- Only papers evaluating effectiveness of psychological interventions has been included in the table from reviews by Linden (2000) and Sebregts et al. (2000)

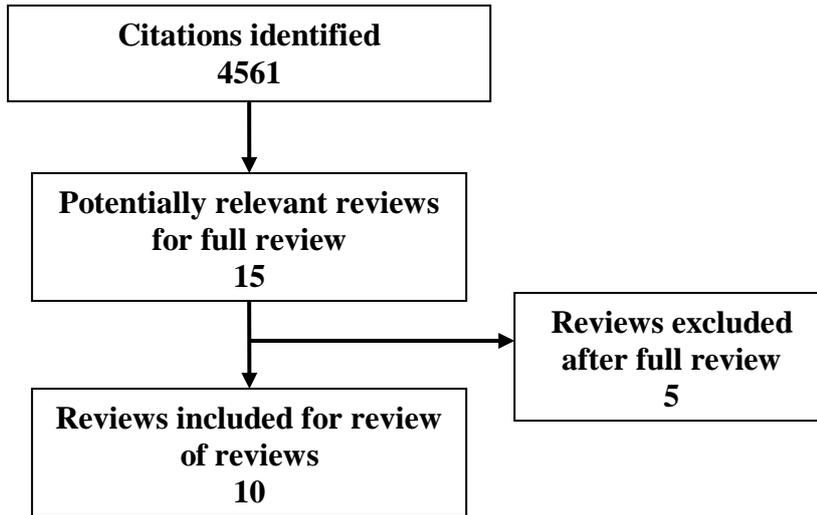


Figure 3.1: Flowchart of studies included in the review of review

Chapter 4

A scoping review of psycho-educational cardiac rehabilitation interventions

4.1 Introduction

The findings of the review of reviews (Chapter 3) showed that interventions, which target modifiable coronary heart disease risk factors, have been investigated in many reviews. However, while some of these reviews support the effectiveness of interventions to modify behavioural risk factors (e.g. Mullen et al., 1992, Sebregts et al., 2000, Moore, 1997, Dusseldorp et al., 1999), others have not found evidence of this (e.g. Godin, 1989, Rees et al., 2004). The main question of the review in the Chapter 3 was to examine how previous reviews of complex health care interventions have dealt with methodological problems associated with reviewing complex health care interventions. Further, it examined how previous reviews contributed to the understanding of how a complex intervention works. Results of the review indicated that a whole variety of methods had been used in reviewing and synthesising primary studies, but mechanisms of complex healthcare interventions have not been explicitly investigated in most of the reviews. Although some reviews referred to complexities of psychological interventions, none of the included reviews explicitly and appropriately discussed implications of complexity on reviewing complex interventions. None of the review formally tested particular theoretical frameworks, even though some mentioned theories or mechanisms underpinning interventions. The selected reviews offered only limited discussion about intervention complexity and its implications on evidence synthesis methodology. This, however, is in keeping with the notion that most of these reviews were completed before the publication of guidance on developing and reviewing complex health interventions, such as the MRC and the Cochrane Collaboration guidance (Campbell et al., 2000, Higgins and Green, 2008).

In summary, an examination of intervention techniques and mechanisms was limited in the previous reviews. Apart from challenges to interpreting results of studies of complex interventions, reviews capability to inform practice of potentially effective

intervention mechanisms and techniques was limited. In this thesis it is argued that a systematic examination of intervention mechanism and techniques used would improve systematic reviews of complex health care interventions.

The review of reviews in Chapter 3 did not identify any recent systematic reviews that had focused on the effectiveness of psycho-educational interventions for cardiac rehabilitation only. Therefore, the evaluation of psycho-educational rehabilitation interventions for patients with coronary heart disease was a relevant topic of further systematic reviews. Before embarking to a new systematic review and investigation of intervention mechanisms, a scoping review was done. As described by Armstrong et al. (2011) a scoping review can be used, for example, to explore the extent of the literature; to identify scope and costs of a review; and to refine review questions and methods. Arksey and O'Malley (in Armstrong et al., 2011) proposed a framework for conducting scoping reviews; identifying the research question and relevant studies; study selection; charting data, summarising and reporting studies; and an optional consultation.

This chapter presents findings from a scoping review of psycho-educational cardiac rehabilitation interventions. For this scoping review, a tentative review question was formulated as: “how effective are psycho-educational cardiac rehabilitation interventions in reducing mortality and morbidity from coronary heart disease?”. This scoping review loosely follows the framework proposed by Arksey and O'Malley (in Armstrong et al., 2011), with the following specific questions.

- What is the extent of the research literature on psycho-educational cardiac rehabilitation interventions?
- Does the suggested review question for evaluating the effectiveness of psycho-educational cardiac rehabilitation interventions need focusing?
- Does the proposed definition of psycho-educational interventions for the purposes of this thesis require revising?
- What are the main characteristics of the relevant interventions?
- Do inclusion and exclusion criteria developed for this review require revising?

As the purpose of this thesis is to examine how systematic reviews of complex health care interventions may be improved, an important step in this process is to demonstrate how a systematic review of complex interventions is undertaken. Although the intervention complexity would not be directly examined in this chapter, findings from the scoping review were used to guide a systematic review in which the complexity of psycho-educational interventions was investigated. Research questions in this scoping review are also relevant to the complexity of interventions, as they are important for framing the systematic review of complex interventions (in Chapter 5). As the purpose of this thesis is to examine how systematic reviews of complex health care interventions may be improved, an important step in the process is to demonstrate how a systematic review of complex interventions is undertaken.

4.2 Scoping review methodology

4.2.1 Identification of potentially relevant studies

The purpose of this scoping literature search was to locate and estimate the number of relevant research papers of psycho-educational cardiac rehabilitation interventions. In the development of the search strategy for the scoping review following sources were consulted; previous systematic reviews, study reports; and health care professionals. The general search are included in the Appendix 1. The following databases were searched for citations of studies with a parallel running control group that investigated non-pharmacological psycho-educational interventions among patients with coronary heart disease: Cochrane Controlled Trials Register (CCTR), PsycINFO, MedLine, CINAHL, and Dissertation and Abstracts. These databases were selected because of their predominant orientation towards health and psychological research. EMBASE was not searched as only studies written in English were included. Studies with non-randomised control group designs were searched along randomised controlled trials as literature of reviewing complex health interventions suggests that randomised control trials may not be appropriate in every setting (e.g. Higgins and Green, 2011). The search was designed to locate both randomised and non-randomised control group designs. This was done to allow for later refining of inclusion criteria depending on the number of identified studies.

The databases were searched from 1970s onwards for non-pharmacological psycho-educational interventions for cardiac rehabilitation. In the context of this thesis, it was considered appropriate to define a psycho-educational intervention as a primarily non-pharmacological intervention that encourages the modification of behavioural risk factors, such as quitting smoking, by increasing knowledge, teaching skills, encouraging behaviour changes, and changing attitudes towards unhealthy behaviours. Studies that used only, for example, pharmacological smoking cessation aids without adjacent intervention were excluded. The search terms included words such as “myocardial ischemia”, “rehabilitation”, “lifestyle” and “RCT”. Reference lists of previous reviews of psycho-educational cardiac rehabilitation interventions were also scanned for relevant citations. Because of resource limitations, only material written in English was considered.

4.2.2 Selection of potentially relevant citations for further review

In this scoping review decisions about inclusion and exclusion were made according to retrieved titles and abstracts. Information on titles and abstracts was often limited, and therefore a citation was tentatively included at this stage if it indicated that some participant, intervention type and study design criteria appeared to have been met. However, citations were not included if any available information clearly contraindicated inclusion, such as an observational design without a control condition. From the initially-identified citations studies with a parallel running control group that investigated non-pharmacological psycho-educational interventions among patients with coronary heart disease were selected. To be considered for inclusion the citation needed to indicate that the study participants were adults (≥ 18 years) with coronary heart disease. Coronary heart disease was defined as one of the following conditions; myocardial infarct (MI), heart failure due to MI, coronary surgery (coronary artery bypass graft i.e. CABG, percutaneous transluminal coronary angioplasty i.e. PTCA), angina, or angiographically defined coronary heart disease. Interventions had to match with the following criteria; primarily non-pharmacological; included a substantial psycho-educational component; and had been delivered by healthcare professionals, though they did not need to have specific training for the intervention techniques. Interventions that investigated stress management or the modification of Type A behaviours as well as

interventions that provided exercise training only were excluded. In addition, trials should have a follow-up period of at least six months from the beginning of the study.

4.2.3 Data extraction and analysis methods

Data were extracted from the available citation titles and abstracts, and was done by the author alone. Data extraction was done using different categories that were developed and piloted for this scoping review. Categories were designed to provide information about intervention and study features. Data were extracted for the following categorical variables: which cardiac rehabilitation phase intervention targeted; intervention personnel; intervention location; method of intervention delivery; duration; intervention type; and participant group. Any other relevant information was also extracted. In the Table 4.2 the different data categories with explanations and relevant subcategories are presented. It was not expected that all citations would provide information for every one of the categories. Analyses for the categorical data were done by counting the numbers of citations in each category that had provided relevant information. Descriptive analysis was used to summarise any other collected information. Results for the categorical analysis are presented as the number of studies that provided relevant information. Citations included for the scoping review will be also compared to studies included in the systematic review and meta-analysis by Rees et al. (2004) to compare whether the search strategy was capable in identifying the same studies.

4.3 Results of the scoping review

The database search identified 8026 potentially relevant studies of which 645 were selected for further scrutiny. The breakdown of the number of studies identified in different databases is presented in Table 4.1. Of the 645 studies 397 were found not to fulfil the inclusion criteria. Of the remaining studies, 128 were evaluated as relevant based on their abstracts, while for 120 studies more information was needed to decide eligibility for inclusion (Figure 4.1). After removal of duplicate entries, 178 citations were left for the scoping review. It was decided that at this stage there was

no need to exclude non-random controlled studies from the preliminary analysis. The results of the scoping review are presented together for the both study designs.

4.3.1 Main features of potentially relevant studies

While all the potentially relevant studies appeared to have one or some psycho-educational components, the interventions contents were very different. Interventions commonly included complex and multiple components, for example combining exercise training with counselling. Interventions were also directed at the different stages of cardiac rehabilitation. However, studies in this review appeared to predominantly investigate the Phase 2 interventions, which target the early post discharge rehabilitation period. The second biggest group of studies investigated the effects of the Phase 1 interventions, provided during the in-patient treatment period. The delivery methods of interventions' and their locality were also diverse. Although interventions appeared more likely to involve either a group or an individual face-to-face interaction to deliver the intervention message, telephone contacts and self-help educational materials were also used. Some interventions were also delivered in the environment of patients' homes, though most interventions took place in hospitals, health centres, or other health institutions. Striking differences in the intervention duration were also evident. Some bedside interventions for smoking cessation lasted minutes, whereas other interventions, such as diet modification, took nearly a year to complete. Some interventions were also more selective in patients (such as only depressed) than other studies. Although men were the predominant participant group, some studies included only women.

4.3.2 Comparison to review by Rees et al. (2004)

Studies identified as potentially relevant in this scoping review were compared with the studies included in the most recent Cochrane review by Rees et al. (2004). The number of studies identified at this stage as potentially relevant appeared to be considerably larger than the numbers identified in the earlier review by Rees et al. (2004). However, this difference in numbers appears to be caused by several differences between the reviews. Firstly, the inclusion criteria in the present review is less rigorous than those in the review by Rees et al. (2004), which did not include

non-randomised controlled studies. Secondly, intervention types are differently defined in the reviews; the present review included interventions even when psycho-educational aspects of an intervention were not clearly described, for example diet interventions. Also in contrast with Rees et al. (2004), the present review did not require health care professionals to have a specific training in the intervention techniques, and non-pharmacological smoking cessation interventions were also included.

4.3.3 Results of the categorical analysis

Most of the studies identified as potentially relevant for this review were randomised controlled trials (91) that used participants, treating physicians, or a place of treatment as a unit of randomisation. Trials that used non-randomised design were in the minority. Non-randomised control groups were typically a result of a participant self-selection to different treatment conditions, for example, when interventions required intensive commitment. A majority of interventions (95) investigated the effects of the Phase 2 cardiac rehabilitation programs. The Phase 1 interventions (24) were often pure smoking cessation interventions with a short duration. This appeared to reflect the seriousness of smoking as a risk factor for coronary heart disease and efforts to tackle this when patients were potentially most ready to give up, i.e. while still in hospital after a cardiac incident. It should be noted, however, that many Phase 1 interventions overlapped with the Phase 2 interventions and included follow-up after discharge from hospital, usually by a telephone contact.

The participants of cardiac rehabilitation programs in the studies were male-dominated due to men's greater susceptibility to coronary heart diseases (e.g. Lawlor et al., 2002). However, most of the interventions included men and women participants, five studies included women alone. The largest single diagnostic group in the studies were patients with a myocardial infarction (MI) (62). The second largest group of participants was formed by coronary heart disease (CHD) patients (40). Coronary surgery (CABG & PTCA) patients were investigated in 24 studies. Only two interventions included angina patients. There was a considerable overlap between the participant groups and many studies included patients from more than one group. This may not be surprising, as cardiac rehabilitation has been

recommended for all patients with coronary heart disease. Unlike patients with MI, PTCA, Angina, or CABG, who have experienced severe symptoms, some patients with coronary heart disease may be symptom free. In summary, patients' experiences of the disease and its consequences were very different and such diversity in patient characteristics may introduce biases in the evaluation of rehabilitation outcomes.

Very little information was available about the intervention personnel. Most of the abstracts did not state which professional groups were responsible for the intervention delivery. While the available information suggested that nurses were the most common health care professionals who delivered interventions, doctors were also involved in some studies. It was notable, however, that not a single abstract mentioned any other groups of health care professionals. Information on the intervention location was not offered in some abstract, although the available evidence suggested that most of the interventions were initiated in a clinical setting, usually in a hospital or a community health centre. In nine studies, interventions were delivered at participants' homes, either via home visits or telephone contacts. A telephone contact was also used in other studies as a means of follow-up and as a booster intervention. Few studies used other means of communication technology and only one study used the internet.

There was no great difference between the number of studies where the intervention was explicitly stated to be an individual (35) or a group (38) intervention. This was somewhat surprising, as it was expected that group interventions would be a preferred choice for treating more people with potentially fewer resources. This result, however, may reflect a sense that group interventions were not always appropriate to provide tailored treatments according to individual patient needs. Also, individual interventions may be easier to arrange, be timelier, and more flexible.

Intervention aims and their chosen techniques for reaching the desired outcomes varied widely. Interventions commonly aimed to achieve a combination of different outcomes and deployed a variety of techniques to attain these outcomes, which greatly increased the interventions' complexity. An attempt, however, was made to categorise groups in order to select a cohesive group of studies for a further analysis.

Smoking cessation interventions formed perhaps the best-defined intervention for psycho-educational cardiac rehabilitation. The rest of the interventions were more difficult to group, and a decision was reached to use either the stated primary aim of the study or an intervention technique as a method to group the studies. The reason for this was that although virtually all studies stated the aim of the intervention, e.g. reduced cholesterol, mortality or morbidity or improved quality of life, the intervention techniques were not always explicitly described in study abstracts.

Behaviour change interventions (31) formed a group of complex health interventions that targeted at participants' behavioural patterns and tried to modify these in order to improve cardiovascular health, quality of life and mental well-being. These interventions commonly included diet change, smoking cessation, and exercise. Diet change was sometime quite radical, e.g. full vegetarian diet, and required a lot of personal commitment from the participants. Risk factor reduction interventions (16) were similar to behaviour change interventions, but they were separated from them because of the study authors' specific emphasis on risk reduction instead of behaviour change. Also, risk factor reduction interventions often targeted cardiac risk factors more broadly than behaviour change interventions, and sometimes included psychological risk factors. An interesting feature of both behaviour change and risk factor reduction interventions was that exercise training did not have a central role. Multi-factorial cardiac rehabilitation interventions (22), on the other hand, often included a strong exercise training component that was supplemented with education on risk factors, smoking cessation elements, and counselling. Finally, only a few of the studies were classified as psycho-social (3). Psycho-social interventions had many overlapping features with behaviour change and risk factor reduction interventions, such as emphasis on health education and behaviour change. Some authors, however, considered their interventions especially psycho-social and the decision was made to keep this distinction at this stage. Another somewhat unexpected feature of studies was that quality of life was measured as an outcome in more recent studies. Increased reporting of quality of life may reflect changing attitudes towards measuring "soft" outcomes and recognition that the improved quality of life may be an important individual endpoint of cardiac rehabilitation.

Teaching (26) and counselling (26) emerged as the most used intervention techniques. Both of these techniques are well-tested. While teaching is known to be effective in information transfer, counselling can be used to help people to make their own choices. Only a few abstracts (4) described interventions using psycho-educational techniques, which, however, in closer inspection did not distinguish teaching and counselling approaches. Advice was used in nine of the interventions, to influence participants' lifestyle and habits.

4.4 Discussion

The literature search for psycho-educational cardiac rehabilitation studies yielded unexpected amount of potentially relevant studies (n=645). This result suggested that the scope of the relevant literature was wide. These results also suggested that there was a need to evaluate and refine the systematic review question and define the study inclusion criteria further. Firstly, due to the large number of potentially relevant studies, one possibility would be to include randomised controlled trials only, as the scoping review indicated that randomised controlled trial design was widely used in the evaluation of psycho-educational interventions for cardiac rehabilitation. However, even if only the randomised controlled studies were to be included, there were still over 90 potentially relevant studies identified, which was judged to be too many to handle within the objectives of this project. Piloting a new approach to investigating mechanisms of complex psycho-educational interventions and behavioural change techniques within a systematic review might be unnecessarily complicated with such a large number of studies. Therefore, it was decided to refine the systematic review question, so that a more coherent group of studies could be selected for further analysis.

Classifying studies based on the information available from titles and abstracts was challenging, and the results were interpreted cautiously. Most of the included abstracts did not specify any theoretical framework that was used in the planning of an intervention. This in itself, was perhaps not an unexpected outcome, given the limited information provided in the study abstracts. It is also possible that there may be a tendency for complex interventions in this particular field to be designed without explicit references to theoretical models. Although using explicit theoretical

criteria to sharpen study selection was not feasible in this occasion, results indicated two clear sub-categories of studies. The first group of studies reported using similar intervention mechanisms, so that these studies had based their interventions around the enhancement of participants' self-efficacy. The second group of studies had common theme and aim, namely smoking cessation interventions. Studies that used increased self-efficacy as an intervention mechanism to achieve desired changes in behaviour formed a group with differing types of interventions and intervention aims. Studies of smoking cessation interventions, on the other hand, had evaluated different interventions based on varying theoretical frameworks, for similar intervention aims.

As the aim of this thesis is to examine how an innovate approach to detailed investigating mechanisms may improve a systematic review of complex health care interventions, it was decided to narrow the focus of the systematic review to psycho-educational interventions for smoking cessation in patients with coronary heart disease. Unlike studies that used self-efficacy as an intervention mechanism to achieve the desired outcomes, psycho-educational smoking cessation interventions have similar aims and, according to the scoping review, there are some relevant randomised controlled trials. Psycho-educational interventions for smoking cessation also fulfil the different criteria for complex interventions by having multiple components, and operating in complex social and organisational environments.

Psycho-educational interventions may be defined as any interventions that encourage health behaviour changes. However, it became clear that in practice psycho-educational interventions, as many other complex health care interventions, are often difficult to define. The challenges of defining psycho-educational interventions had been discussed elsewhere, for example by Rodgers et al. (2005), who observed that reviews of psycho-educational interventions did not explicitly define what was actually meant by a psycho-educational intervention. Another difficulty with grouping of the studies was a loss of objectivity. While systematic reviews aim to be objective with clearly set rules and protocols (e.g. Khan et al., 2001a), it was realised that when attempting to group studies of psycho-educational interventions in the scoping review, preserving objectivity was difficult and subjective judgement was often required. This was caused by the fact that only the study titles and abstracts

were used to gather information at this stage, and that very few authors specifically described the intervention as psycho-educational, even when the intervention clearly aimed to change participants' health behaviours at some level. Furthermore, behaviour change tactics could be described for example as 'counselling', 'information', 'advice', 'education' and 'support', making it difficult to judge actual differences between different interventions.

The complexity in psycho-educational interventions had an effect on the results of the scoping review. This was evident by difficulties in defining psycho-educational interventions. Interventions tended to be defined by their aims (for example, behaviour change), and/or potential techniques used (for example, education) to achieve the desired behavioural goal. Intervention complexity also was reflected in the variety of interventions described in the selected citations, which suggested that the inclusion criteria for the systematic review may need tightening in order to decrease heterogeneity across studies and enable meaningful statistical evaluation of intervention.

Based on the results of the scoping review, the research question for the systematic review was modified as below:

- Are psycho-educational interventions for smoking cessation effective in increasing smoking cessation and reducing mortality in patients with coronary heart disease?

Psycho-educational smoking cessation interventions are complex, but have similar and well defined intervention aim. This offers a good case for testing whether and how in-depth examination of intervention mechanisms improves the results of a systematic review of complex health interventions. The scoping review did not clearly indicate any sub-group analysis at this stage, and therefore, any subgroup analyses that would be done as part of the meta-analysis were post-hoc. The next chapter (chapter 5) reported results of the systematic review of psycho-educational interventions for smoking cessation in patients with coronary heart disease, and discussed implications of intervention complexity on the methodology of research synthesis.

4.5 Conclusions

The scoping review identified a large number of potentially relevant but hugely diverse studies of psycho-educational interventions for cardiac rehabilitation. The results of the scoping review suggested that for the purposes of this thesis the systematic review question should be more focused. This could be achieved by selecting a group of studies that would be less heterogeneous and more suitable in this occasion for detailed investigation of theories underpinning complex health interventions. It was decided that the systematic review could focus on the evaluation of psycho-educational interventions for smoking cessation in patients with coronary heart disease. These interventions appeared to have been largely excluded from the previous cardiac rehabilitation reviews, and there appeared no recent reviews that had investigated the overall intervention effectiveness of primarily psycho-educational smoking cessation interventions among coronary heart disease patients. The next chapter will describe the protocol and results of a systematic review of psycho-educational interventions for smoking cessation in patients with coronary heart disease.

Name of the database	Number of citations retrieved	Number of citations selected
MedLine	4149	322
PsycInfo	741	71
CINAHL	1368	105
Dissertation and Abstracts	259	14
Cochrane	1768	147
Total	8026	645

Table 4.1: Number of citations retrieved and selected from different databases in the scoping review

Name of the category	Explanation	Sub-Categories
Phase	Rehabilitation Phase	1, 2, 3, 4
Personnel	Which health care professional group delivers the intervention?	Nurse, Doctor, Allied Health professional, Other
Location	What was the physical location of the intervention?	Hospital, Home, Community centre, Telephone Follow-up
Delivery	How the intervention was delivered?	Group, Individual, Telephone, Face-to-face, Mail
Duration	Length of the intervention	Any
Intervention	What kind of method was used to achieve the wanted change? Intervention Outcomes	Teaching, Risk Factor Reduction, Behaviour Change, Psychoeducation, Counselling, etc. Smoking cessation, diet, exercise, knowledge, etc.
Participants	What kind of diagnosis participants had?	MI, CABG, PTCA, CHD, CAD
Additional Information	Any other relevant information	

Table 4.2: Data Categories used in the scoping review for intervention classification

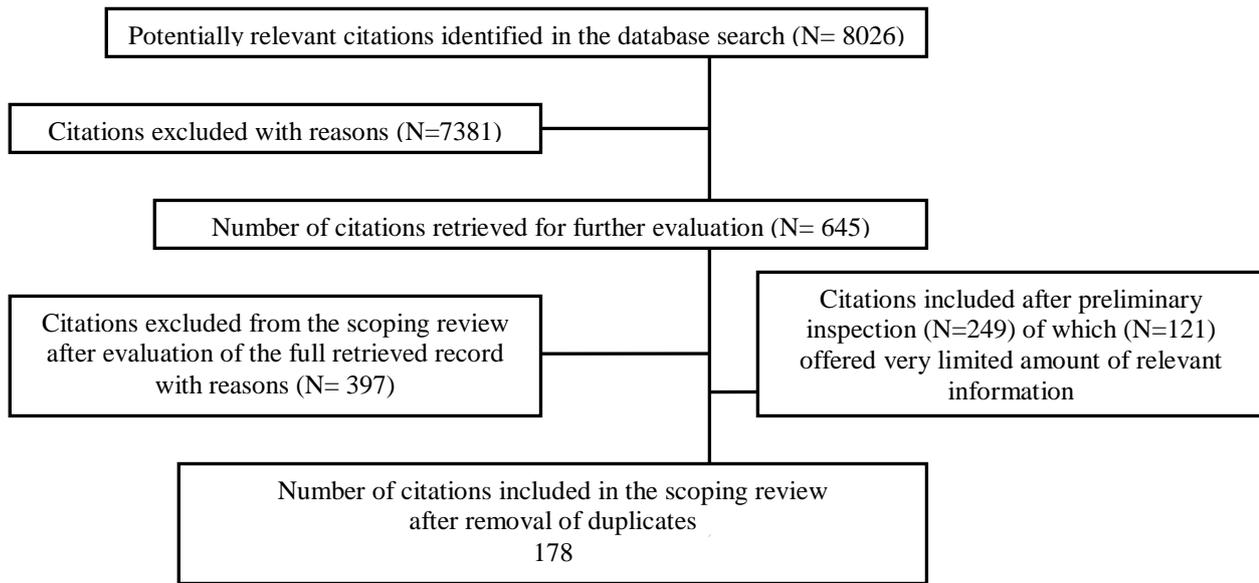


Figure 4.1: Flowchart of study inclusion for the scoping review

Chapter 5

A systematic review and meta-analysis of psycho-educational smoking cessation interventions for patients with coronary heart disease

5.1 Introduction

Alongside medical, pharmacological and surgical interventions, the potential of interventions that target on behavioural risk factors as secondary prevention and treatment of coronary heart disease have been increasingly recognised (e.g. Isles et al., 2002). Patients with coronary heart disease are encouraged to modify unhealthy behaviours such as smoking, physical inactivity and unhealthy diet alongside other treatment. However, changing patients' habits and behaviours may not be straightforward, and interventions have been developed to facilitate behavioural risk factor modification. Interventions that target at modifiable risk factors of coronary heart disease have been investigated in many reviews. While some of the reviews reported findings that support the effectiveness of interventions for modifying behavioural risk factors, other reviews have not found supportive evidence (Dusseldorp et al., 1999, Godin, 1989, Isles et al., 2002, Mullen et al., 1992, Rees et al., 2004).

In the previous two chapters the challenges of reviewing complex health interventions have been approached from two related perspectives. First, the review of previous reviews of psychological cardiac rehabilitation interventions examined how these reviews had accommodated methodological difficulties in evaluating complex health care interventions, such as defining interventions (e.g. Jackson et al., 2004). Secondly, the scoping review of psycho-educational cardiac rehabilitation interventions was concluded to explore how feasible the topic is for a systematic review that could be used to test an innovate approach to examining mechanisms of complex health care interventions.

While a wide range of interventions has been included in the previous reviews of psycho-educational cardiac rehabilitation, smoking cessation-only interventions have

often been omitted. Interventions for quitting smoking can form an important part of the secondary prevention and rehabilitation of coronary heart disease (Isles et al., 2002). While Wiggers et al., (2003) found little evidence that smoking cessation interventions are effective for patients with cardiovascular disease, this may be attributed to decision not to use meta-analysis to estimate the overall effectiveness of the interventions. However, this finding may be due to the fact that meta-analytic pooling was not used to estimate the overall effectiveness of smoking cessation interventions. Available review evidence suggested that behaviour modification interventions could be effective in increasing smoking cessation for hospitalised patients in general (Rigotti et al., 2007), and for patients with coronary heart disease (Van Berkel et al., 1999). These reviews, however, have included studies with mixed participant populations (Rigotti et al., 2007) and mixed intervention aims (Van Berkel et al., 1999). Furthermore, there is a lack of evidence on the main characteristics of effective smoking cessation interventions (Van Berkel et al., 1999), so that the available review evidence has limited use for practical applications. This has been reflected in van Berkel et al.'s (1999) discussion about the diversity of the study characteristics, and how that had complicated the evaluation of complex health care interventions. Rees et al. (2004) also argued that evaluation of psycho-educational interventions is complicated by difficulties in defining psycho-educational interventions.

A recent review has evaluated the effectiveness of psychosocial smoking cessation interventions among coronary heart disease patients (Barth et al., 2008). The findings of this review support the efficacy of psychosocial smoking cessation interventions that last at least one month, but not for short interventions without follow-up. However, this found no evidence of long-term efficacy of the psychosocial smoking cessation interventions. The review by Barth et al. (2008), however, reviewed psychosocial interventions, which did not include-psycho-educational interventions. This included both standalone psychosocial interventions and those delivered as part of cardiac rehabilitation programmes. Although Barth et al. (2008) defined their 'intervention types', they did not explicitly define what is meant by psychosocial intervention, as observed in many reviews of complex health care interventions (Dusseldorp et al., 1999, Godin, 1989, Isles et al., 2002, Mullen et al., 1992, Rees et al., 2004). Barth et al. (2008), however, argued that one way to improve psychosocial

smoking cessation interventions was to gain detailed understanding of effective intervention strategies.

The effectiveness of complex health care interventions is frequently examined in systematic reviews and meta-analyses, using review questions that do not reflect the complexity of each intervention. Similarly, the research questions in the present chapter do not directly relate to the complexity of the intervention, but rather ask about its effectiveness. The specific research questions in this chapter are crucial for understanding intervention effectiveness and those limitations that the complexity of an intervention may bring to the effectiveness of that evaluation. Moreover, without first evaluating overall intervention effectiveness, examining the context of an intervention and the processes through which intervention effects are delivered is not feasible. The systematic review presented in this chapter aimed to evaluate the relative effects of psycho-educational interventions for smoking cessation in patients with coronary heart disease patients. In this systematic review of complex interventions, there are inevitably methodological difficulties caused by complexities in psycho-educational interventions, from defining interventions to interpreting the results. (e.g. Higgins and Green, 2011, Jackson et al., 2004).

This systematic review does not statistically evaluate intervention mechanisms. However, findings of this systematic review and meta-analysis will form a base for further non-statistical investigation of intervention mechanisms and techniques. Complexity in psycho-educational interventions was investigated in this review partly by considering process variables and their relationship to results.

The results of the scoping review, described in the previous chapter, indicated that smoking cessation interventions were often initiated during the early stages of rehabilitation, usually when patients were still hospitalised and potentially more receptive for smoking cessation message. Smoking cessation, even after a serious health scare like a cardiac event, may still be difficult to achieve. It is likely to be a long-term process and require, apart from motivation, considerable behaviour and attitude changes to be successful. Therefore, it would be crucial to acquire better understanding of mechanisms of effective interventions among this group of patients. A further point is that smoking cessation interventions share a common intervention

aim, i.e. increase the rate of smoking cessation, which help investigate intervention mechanisms and how qualitative research may facilitate increased understanding of intervention mechanisms. This chapter reported findings from a systematic review of randomised controlled trials of psycho-educational smoking cessation interventions in patients with coronary heart disease. In addition, issues associated with difficulties in evaluating complex psycho-educational interventions and related problems that arose in meta-analysis will be discussed. Results of this Chapter have been published in Huttunen-Lenz et al. (2010)

5.2 Methods

5.2.1 Identification of studies

The following databases were searched for relevant citations; the Cochrane Controlled Trials Register (CCTR), PsycINFO, MedLine, CINAHL, and Dissertations and Abstracts International. Databases were initially searched from the 1970s onwards until November 2007 to locate any controlled studies that evaluated effectiveness of psycho-educational interventions for cardiac rehabilitation. The initial search strategy did not explicitly search for smoking cessation studies only, though the term smoking cessation was part of the search strategy. This wider search strategy ensured that no relevant studies of smoking cessation would be missed. The search time limits were based on changes that happened around 1970's in reduction of cardiac mortality increased attention to smoking cessation (Shiffman, 1993, Skinner et al., 2007).

In this review psycho-educational smoking cessation intervention was defined as a non-pharmacological intervention that help current smokers to quit smoking by enhancing patients' motivation, increasing knowledge, teaching skills, and changing attitudes towards behaviour changes. The search terms included words such as "myocardial ischemia", "rehabilitation", "lifestyle" and "RCT" (see Appendix 2 for the PUBMED search strategy). The search presented in the in the previous chapter had already identified a number of relevant studies, thus the additional systematic search here was narrowed down by adding smoking related search terms and adjusting the methodological search terms.

In designing the search strategy a decision was needed about which methodological search terms should be included and how the methodological filter should be written. In this case, a methodological filter could be either designed for this study or a published search filter could be used. The advantages of using a published search filter includes increased accuracy in identifying randomised controlled trials. However, though deploying a published search filter can increase the accuracy of the search, it is uncertain how this approach may work in searches of complex interventions. Previous reviews of complex psycho-educational interventions identified have not explicitly reported using published methodological filters. Therefore it was unclear how well these filters might work in searching complex psycho-educational smoking cessation interventions. In addition, deploying published search filters might influence the sensitivity of the search, potentially the search strategy's ability to identify potentially relevant studies with non-optimal randomised design. The search in this review was also aimed to be inclusive, thus allowing identification of as many studies as possible. Therefore, it was decided not to use published filters, but for the purposes of this review methodological search terms were identified from the previous reviews of psycho-educational interventions and modified. It is recognised, though, that using a search with less vigorous methodological filter is likely to increase the number of studies identified.

In addition to the search of bibliographic databases, the reference lists of the previous smoking cessation reviews were hand checked for any relevant studies. Only studies written in English were considered for full text review. However, the number of studies excluded because of language restriction was recorded. Updated study search was done in September 2009 before final writing up to check for any relevant recently published studies.

5.2.2 Study selection

The review included studies that had been published or accepted for publication. From initially-identified citations for research on psycho-educational cardiac rehabilitation interventions, only randomised controlled studies of non-pharmacological interventions for smoking cessation among patients with coronary heart diseases were selected. Study participants had to fulfil the following

requirements. They had to be over 18 years of age with confirmed coronary heart disease that have received medical attention due their disease and were eligible for cardiac rehabilitation. The coronary heart disease conditions included angiographically defined coronary heart disease, angina pectoris, myocardial infarct (MI), coronary artery bypass graft surgery (CABG), percutaneous transluminal coronary angioplasty, and heart failure caused by MI. Participants in the study had either be current users of tobacco products or those who had been regular users of tobacco products, but had stopped earlier. Studies including patients with additional mental health related diagnosis were also eligible. Relevant interventions had to be using primarily psycho-educational methods, including teaching, education, advice, counselling, and information transfer. Interventions that combined psycho-educational methods with stress management or relaxation training were also included.

The review included interventions with various formats, including individual-based, group-based, or a combination of both interventions. Intervention length or personnel were not defined. Intervention personnel were not required to have been formally trained in techniques for smoking cessation. Studies needed to have a follow-up period of at least six months from the beginning of the intervention.

To be considered for inclusion, studies needed to report at least one of the following outcomes: point prevalent or continuous smoking abstinence, and mortality. Study was considered for inclusion regardless of treatments received by the control group. Inclusion of the studies was restricted to those where full text articles were available in English. Studies were selected for full-text review based on titles and abstracts and in unclear cases the opinion of the supervisors was sought.

An intervention was also eligible for inclusion if participants were offered additional pharmacological smoking cessation aids. This approach is similar to that of Barth et al. (2008), who excluded studies where the intervention was based solely on pharmacological or nicotine replacement approach, but not interventions where only the treatment group had been offered pharmacotherapy. It is recognised that including interventions that offer pharmacotherapy in addition to psycho-educational intervention only for the intervention group may be a factor that further complicates

evaluation of effectiveness of psycho-educational intervention. However, it is argued that as nicotine replacement therapies are so widely available, their use may be beyond the control of the study design. This dilemma is also highlighted by Barth et al. (2008) who point out that controlling for the use of nicotine replacement therapy is difficult. In this review it was decided that due to difficulties in controlling use of pharmacotherapy, it would be appropriate to include all studies employing psycho-educational methods. However, effects of pharmacotherapy were examined in the subgroup analyses.

5.2.3 Data extraction

Data extraction sheets were specially designed and piloted for this review. One of the supervisors (FS) independently checked the extracted data. However, no level of agreement was calculated between reviewers for data extracting. Any discrepancies between reviewers were discussed and solved by referring back to original data. Data that was collected from the primary studies included: article information about journal, author/s, country of publication, method of random allocation, description of inclusion criteria, blinding of intervention provider and outcome assessor. Descriptions of intervention and control conditions were extracted in detail and study authors were contacted to ask whether interventions and control conditions were described correctly and what information they would like to add. Information was also extracted about intervention and control condition location, personnel, type, and any theoretical background used in intervention design. Study authors were also contacted to request additional information about any theoretical frameworks used in study design. Information was collected about patient characteristics in both experimental and control groups including diagnosis, participant inclusion and exclusion criteria, and total number of eligible participants, information was collected separately for control and experimental groups about gender and age.

Data were collected about length of the intervention and follow-up period. Data for outcome variables were extracted as follows; point prevalent (number of participants reporting not at the point of measurement), continuous smoking cessation (number of participants reporting not smoking during the whole length of follow-up period), and mortality (number of participants that died for any cause during follow-up). Study

authors were contacted to inquire any unpublished data for these outcome measures. Data were also collected on how smoking status was verified. When smoking cessation was verified either biochemically or by proxy, this information instead of self-reported data was recorded. Data were also collected about any reported process variables in a narrative form, i.e. what process variables had been reported to have been investigated and how these variables relation to results was explained. Data obtained from the authors was included in the analyses.

5.2.4 Assessment of study quality

The methodological quality of the included studies was assessed using a methodological assessment sheet, which was developed and adapted for this review using previously published assessment criteria (Khan et al., 2001b, Petticrew and Roberts, 2006). Full assessment criteria are shown in Appendix 2. Study quality assessment was duplicated so that quality was first assessed by the student and then checked by the supervisor (FS). Agreement levels were not calculated, but only minor disagreements were reported. Assessment of study quality covered; randomisation process (how groups were allocated); similarity of the experimental and control groups; intervention description (procedure, materials, location); participants (inclusion criteria);, blinding of participants, intervention providers and outcome assessors; outcome verification, and completeness of follow-up. It was decided not to rank studies based on the quality assessment, but to record weaknesses in the study methodology using the pre-set assessment criteria.

Study quality was assessed using the information available in the published papers, and no further information was requested from the authors regarding study quality. Information was gathered about how groups were allocated between conditions, such by using opaque envelopes. Similarity of experimental and control group was evaluated based on similarity of participants characteristics, such as participants age, gender and smoking status. Intervention description was used to evaluate intervention planning and implementation. Blinding of intervention participants, providers, and evaluators was based on available information. For example, if methods section stated that participants, providers or assessors were blinded to the

treatment condition, that was recorded. Completeness of follow-up was evaluated in terms of participant dropout rate.

5.2.5 Statistical methods

The study results data were collected from all available follow-up time points, but data were used at the longest follow-up in the main analyses. Relative risk was used as the outcome statistic to calculate effectiveness of the interventions. Relative risk was calculated for three outcomes: point prevalent, continuous smoking cessation, and total mortality. “Point prevalent smoking cessation” describes the number of participants not smoking at the measurement point regardless of their previous smoking status, while “continuous smoking cessation” describes the number of participants not smoking during the whole length of the study follow-up. Studies differed in how participants’ lost to follow-up were reported. In order to avoid over-estimating intervention effectiveness, relative risk was calculated so that cases lost to follow-up and deaths were considered as negative outcomes, i.e. as continuing to smoke. This chapter reports the results of the intention-to-treat analysis.

For smoking cessation outcomes, a relative risk of larger than one indicated a positive outcome, i.e. that the intervention was successful in increasing smoking abstinence. Relative risk for mortality was calculated so that a value of relative risk smaller than one indicated lower mortality in the intervention group. Sensitivity analyses were carried out to investigate any outlying studies; effects of including two studies which methods of randomisation was not optimal (Burt et al., 1974, Johnson et al., 1999); and effects of including one study where there was uncertainty about the diagnosis of some included participants (Mohiuddin et al., 2007); effects of including one study which had both these methodological problems (Bolman et al., 2002b). As described earlier, the decision was made prior to data collection to include those studies with not optimal participant allocation method, and use sensitivity analyses to estimate effects of study inclusion. The number of studies included in sensitivity analyses for different outcome measures will vary, as some studies did not report the relevant outcome. Studies excluded in each of the sensitivity analysis are listed separately for each of the outcomes. Revman v5 (2008) computer programme was used to conduct random-effects meta-analyses and to

graphically present the data. Peters' method was used to test funnel plot asymmetry, which is a regression analysis of association between treatment effect and a variable based on sample size (Peters et al., 2006).

Subgroup analyses (post hoc) were used to investigate possible causes of heterogeneity in meta-analysis. No definitive subgroup analyses were planned prior to systematic review, as the scoping review did not indicate any definitive intervention features that would need to be analysed in sub-group analyses. However, when the review material became familiar and meta-analysis suggested significant heterogeneity between studies, well-defined sub-group analyses offered an opportunity to investigate possible causes of heterogeneity more in-depth. In the first subgroup analysis, the effects of the use of pharmacotherapy in the intervention were investigated, first with all studies that offered pharmacotherapy and then, with the studies that offered pharmacotherapy only for the intervention group. Pharmacotherapy refers to pharmacological smoking cessation aids that had been available to participants, namely bupropion and nicotine replacement treatment (NRT). To explore the importance of theoretical consideration for complex health interventions, the second subgroup analysis investigated effects of studies explicitly using a theory in intervention planning. Intervention complexity has been identified as one of the factors that complicates evaluation of intervention mechanisms (e.g. Welton et al, 2009, Michie et al., 2009). In addition, evidence is unclear whether explicit theory underpinning intervention may improve effectiveness (Lewin et al., 2009). For this analysis, studies were divided between those that explicitly specified a theoretical model and those that did not. The latter group included those studies that mentioned behaviour change techniques.

The third subgroup analysis looked at the effects of intervention intensity, in which the interventions were classified as "intensive", "less intensive" or "could be intensive" interventions. To some extents, the intensity of a psycho-educational intervention may be associated with or determined by its complexity. 'Less intensive' was defined as interventions that included in-patient intervention without written or audiovisual material and possible follow-up contact. 'Intensive' interventions were defined as those interventions that, apart from the inpatient intervention, provided either one-to-one or group-based follow-up after hospital

discharge, or both written and audiovisual material combined with telephone counselling and follow-up. The intensity of “Could be intensive interventions” depended on participants’ response to the initial intervention, so that the intervention input was increased for those participants who failed to stop smoking or who struggled with cessation after the initial intervention. (Table 5.2). Allocation of the studies into different subgroups was not duplicated. Statistical tests of interaction were conducted between independent subgroups (Altman and Bland, 2003). Finally, the effect of follow-up time to intervention effectiveness was investigated. For this analysis three data points were used: six months, 12 months, and 24 months onwards.

5.2.6 Investigation of process variables

The process evaluation may help investigate mechanisms of complex healthcare interventions, and indicate why a complex intervention works or does not work. Process variables reported in the studies were investigated. Process variables are commonly-termed mediating variables that can help describe the process through which, here, changes in smoking behaviour happens. Process variables were not pre-defined, and the main purpose of this analysis was to identify process variables that had been investigated in the included studies and to examine whether they had been used to explain possible intervention mechanisms. Data collected about process variables included authors descriptions of what process variables had been investigated and how these may explain study results. For example, if a study has investigated self-efficacy as a mediating factor between the intervention and outcomes, this information would be recorded, e.g. increased self-efficacy appeared to be associated with increased smoking cessation.

5.2.7 Information requested from study authors

Corresponding study authors were contacted by e-mail for additional information. Questions for additional information were kept short and easy to answer in a return e-mail, should authors wish to reply. Authors were asked for published or unpublished data of patient numbers in each of the outcomes, if not reported. In addition, authors were asked if they had used any theoretical framework in planning of the intervention used in the study.

5.3 Results

The initial search for psycho-educational cardiac rehabilitation interventions identified 8026 citations, of which 249 were potentially eligible studies and 178 of these appeared to be randomised controlled trials. The additional systematic search did not identify new studies. Twenty of the randomised controlled studies were identified as potentially eligible smoking cessation studies. Based on the abstracts, none of the articles not written in English were identified as potentially eligible studies. After scrutinising the full text articles, eight of the articles and one commentary were excluded (Figure 5.1, Table 5.6), and three further articles were added after inspection of the article references and previous reviews (Figure 5.1). In two cases, two of the articles (Ockene et al., 1992, Rosal et al., 1998, Bolman et al., 2002b, Bolman et al., 2002a) reported results from the same study.

Main characteristics of the included studies are summarised in Table 5.1 and descriptions of psycho-educational interventions used in these studies are presented in Table 5.2. Studies included 1792 participants in the intervention condition and 1766 participants in the control condition, ranging from 87 to 789 participants recruited per study. All the interventions were initiated in the hospital, and all apart from Hajek et al. (2002) included some form of home follow-up after hospital discharge. Only one study did not include women among participants, although women were in minority in all studies that included women. Studies differed in their requirements of motivation to stop smoking as well in the availability of nicotine replacement products. There was also a range of approaches taken to define smoking status, so that some studies recruited only current smokers (smoking just before the hospital admission), whereas others also recruited recent quitters.

5.3.1 *Quality of included studies*

The results of quality assessment are summarised in Table 5.3. Randomisation method was clearly appropriate in eight of the 14 included studies. Two studies were cluster randomised trials (Bolman et al 2002; Johnson 1999). One trial allocated patients according to the day of admission (Burt 1974); and the method of patient allocation was unclear in three studies (Mohiuddin 2007, Ockene 1992, Rigotti

1994). Only six studies reported concealment of allocation. However, three of these studies (Feeney et al., 2001, Quist-Paulsen and Gallefoss, 2003, Smith and Burgess, 2009), did not report adequate allocation concealment according to Cochrane guidance (Higgins and Green, 2008). Lack of allocation concealment or inadequate allocation concealment reduces the transparency of the participant allocation process and manipulation of the participant allocation. However, study results indicated that trial participants were generally comparable at the baseline.

Participants in the trials conditions were considered comparable unless study reported statistically significant differences between groups in patient variables, such as age, type of coronary heart disease, and willingness to stop smoking. The descriptions about interventions and inclusion criteria were appropriate in all included studies. Participants, intervention provider, and outcome assessors were not blinded, except the trial by Smith (2009) in which outcome assessor was blinded. Smoking cessation was verified in nine studies biologically or by proxy confirmation, usually a close family member that could confirm participant's smoking status. The proxy confirmation is not as reliable an indication as biochemical confirmation, but is more reliable than participant self-reporting alone. When available, results are based on confirmed smoking cessation rates, either by proxy or by chemical verification. Reported dropouts during the follow-up (including deaths) ranged from 0% to 66%. Results were calculated conservatively so that participants lost to follow-up were classed as non-quitters. Studies with large dropout rates were usually those with long follow-up period, which complicates estimating whether participants had returned to smoking and were unwilling to disclose this or have been lost to follow-up due to other reasons.

5.3.2 Point prevalent smoking cessation

Thirteen included studies provided sufficient data on point prevalent smoking cessation (Figure 5.2). Heterogeneity between studies was statistically significant ($p < 0.0001$; $I^2 = 73\%$). The combined effect size indicated that in comparison to control interventions, psycho-educational interventions were associated with a higher rate of point prevalent smoking cessation (RR 1.44, 95% CI, 1.20 to 1.73). For this outcome, one sensitivity analysis was conducted by excluding four studies: Bolman

et al. (2002b), Johnson et al. (1999), Burt et al. (1974), and Mohiuddin et al. (2007). The result remained statistically significant (RR 1.28, 95% CI, 1.07 to 1.52) with significant heterogeneity between the studies ($I^2= 60\%$).

5.3.3 Continuous smoking cessation

Again, there is statistically significant heterogeneity across studies (Figure 5.3). The pooled relative risk for the 10 studies that reported this outcome indicated that psycho-educational interventions were more effective in increasing continuous smoking cessation than interventions in the control group (RR 1.51, 95% CI, 1.18 to 1.93). For this outcome, two sensitivity analyses were performed: first excluding Mohiuddin et al. (2007) and Bolman et al. (2002b), and then Feeney et al. (2001). The results of these sensitivity analyses were similar to the result of the main analysis using all included studies.

5.3.4 Total mortality

Heterogeneity across 10 studies that reported total mortality was not statistically significant (Figure 6.4). Pooled relative risk indicated a tendency for a lower total mortality in the psychological intervention group, although the difference was not statistically significant (RR 0.73, 95% CI, 0.46 to 1.15). After excluding the studies by Mohiuddin et al. (2007) and Bolman et al. (2002b), there were no substantial changes in result (RR 0.58 95% CI, 0.28 to 1.18).

5.3.5 Funnel plot asymmetry

Peters' method was used to statistically test funnel plot asymmetry (funnel plots Figures 5.13-5.15). Tests for the point prevalent ($p=0.38$), continuous ($p=0.51$) smoking cessation and total mortality ($p=0.76$) suggested that the funnel plots were not statistically significantly asymmetric, indicating that studies with smaller sample size are not significantly associated with greater treatment effects. The results of funnel plot testing should be interpreted cautiously because of small number of studies included.

5.4 Subgroup analyses

The results of the subgroup analyses are summarised in Table 5.4, while figures 5.5. to 5.10 list the studies with forest plots. Studies that provided pharmacotherapy for smoking withdrawal symptoms, nicotine replacement therapy (NRT) or bupropion, to the intervention group only or for all participants tended to report greater treatment effects than those studies that did not offer pharmacotherapy (Table 5.4). However, the differences between these subgroups were statistically non-significant.

A test for subgroup differences indicated that there was no statistically significant difference in smoking cessation results between studies that reported or did not report using theory in intervention planning (Table 5.4).

Interventions were evaluated as “intensive” in three studies, “could-be-intensive” in five studies and “less intensive” interventions in six studies (Table 5.2). Analysis for subgroup differences suggested that compared to “less intensive” interventions “intensive” interventions were statistically significantly associated with increased smoking abstinence (Table 5.4). No statistically significant differences were found between the “intensive” and the “could-be-intensive” interventions or between the “could-be-intensive” and “less intensive” interventions, although there was a tendency for the more intensive interventions to be associated with larger treatment effects (Table 5.4).

Follow-up data for smoking cessation suggested that in comparison to control interventions, psycho-educational interventions were effective at six months and 12 months. Non-significant results at 24-60 months for point prevalent cessation, and at 6 months and 24-60 months for continuous cessation may be explained by the small number of studies that provided relevant data for the analyses (Figure 5.11 and 5.12).

5.5 Evaluation of process variables

Process variables are variables that may explain the relationship between two variables or mechanisms how the change was achieved, whereas predictor variables

are variables that predict an outcome. Studies included in this review appeared to report predictor variables rather than process variables and difficulties were encountered in distinguishing process variables and predictor variables. Studies, though reporting variables that could explain how the desired change was achieved, tended not to label these variables as predictor or process variables. However, five of the studies included in the systematic review reported process variables that explained how the intervention caused the desired change. However, it was questioned whether some of these variables were also predictor variables, as changes in these variables, such as increase in self-efficacy, could predict increased rates of smoking cessation. The identified process variables included: stage of change, i.e. readiness to quit smoking, though there was no interaction with intervention group (Ockene et al., 1992); self-efficacy (Dornelas et al., 2000, Reid et al., 2003); signing commitment to stop smoking; and adherence of intervention personnel to procedures (Hajek et al., 2002). Some contradictions were also identified. For instance, Johnson et al. (1999) did not find any difference in self-efficacy between intervention and control group even though the intervention was designed to improve self-efficacy. The included studies had not consistently tested process variables. While we judged that five studies did investigate process variables, there was not enough information available to reliably identify processes underlying successful smoking cessation.

5.5.1 Intervention location, personnel, material, and delivery

In this section, a short summary is provided of those intervention features that may complicate interpretation of the meta-analysis results. Effects of intervention features such as location, material, personnel, and delivery were not formally examined in subgroup analyses. However, some intervention features were briefly described here to indicate similarities and differences between interventions and how they may add to the complexity of interventions. All the interventions were initiated in the hospital and apart from Hajek et al. (2002) interventions included follow-up after discharge, which was commonly in the form of telephone contact. Apart from telephone contact, participants' follow-up was organised via outpatient clinics, which offered contact with a cardiologist, or, in some cases, more substantial group support by intervention personnel. In only one study intervention participants were offered after discharge individual face-to-face contact (Reid et al., 2003). In all studies except

Hajek et al. (2002), follow-up was linked with additional intervention reinforcing the original stop smoking message, and provided further help and advice to those that struggled with smoking cessation. (Table 5.1). While cardiologists did in some studies deliver the initial advice about benefits of smoking cessation, in majority of studies nurses were responsible for delivering and facilitating the intervention either wholly or partially.

Other health care professionals that were specially mentioned to participate in intervention delivery were a counselling psychologist (Dornelas et al., 2000) and a tobacco cessation counsellor (Mohiuddin et al., 2007). The main method of intervention delivery was verbal communication, which was reinforced by additional written materials, and in some cases with audio-visual materials. While the duration of personal contact during the hospital stay varied between the studies, none of the interventions did appear to offer more than three contacts for the participants. Amount of contacts after the hospital stay was considerably more varied between the interventions, so that for example Feeney et al. (2001) offered minimum of eight telephone contacts after discharge while Rigotti et al. (1994) appeared to offer only one telephone contact. It should be emphasised, however, that instead of telephone follow-up, several interventions also offered personal contact (Bolman et al., 2002b, Bolman et al., 2002a, Burt et al., 1974, Mohiuddin et al., 2007, Reid et al., 2003, Taylor et al., 1990). (Table 5.1).

5.6 Discussion

Results of the meta-analysis suggested that psycho-educational smoking cessation interventions for coronary heart disease patients are effective. Psycho-educational interventions significantly increased rates of smoking cessation, and statistically non-significantly reduced total mortality. While the results are in line with the findings of previous reviews and meta-analyses (e.g. Rigotti et al., 2007, Van Berkel et al., 1999), this review concentrated on coronary heart disease patients and psycho-educational interventions. Studies included in this review were assessed against a number of quality criteria, which suggested that in general studies were of good or satisfactory quality. Studies varied in how well allocation concealment was done, with some studies in which the allocation concealment was inadequate. Trial

interventions were well described with clear inclusion criteria in all of the studies, but none of the studies had concealed group allocation from patients or from intervention providers, and only one study used blind outcome assessor. Another issue that the quality assessment highlighted was that in some studies the smoking status was based on participants' self-reporting. Study quality, however, was not associated with the estimated treatment effects in this meta-analysis.

It was found that analysing and interpreting the results posed certain challenges. Apart from the total mortality rate, the results showed high levels of unexplained variation between the studies, which could not be accounted for by chance. Sensitivity analyses suggested that methodological diversity between the studies could not alone account for the variation found. To further explore the possible causes of heterogeneity for smoking cessation outcomes, unplanned post-hoc subgroup analyses were done. However, the results of the subgroup analyses should be treated with caution as the number of studies included in subgroups was usually very small.

Post-hoc analyses were used to investigate the effects of pharmacotherapy, intervention theory and intensity, and length of follow-up to intervention outcomes. Similarly to Rigotti et al. (2007), it was found that adding pharmacotherapy to psycho-educational interventions did not result in statistically significant improvement in smoking abstinence compared to psycho-educational interventions alone. However, the effectiveness of pharmacotherapy in smoking cessation is well established (Stead et al., 2007, Woolacott et al., 2002). Although results from this review suggest that psycho-educational intervention only may be as effective as a combination of psycho-education and pharmacotherapy, the use of pharmacological therapy could not be excluded from control groups, and the available data in the review may not be sufficiently powerful to detect the incremental effects of the additional pharmacotherapy.

Barth et al. (2008) point out that in their review, controlling for the use of nicotine replacement therapy was not possible and the effects of using nicotine replacement therapy could not be evaluated. Although the present review also could not control for the use of nicotine replacement therapy in the primary research, effects of using

pharmacotherapy were nevertheless evaluated. The results of this evaluation should, however, be interpreted with caution, as the analysis included studies that offered nicotine replacement therapy to both experimental and control group or only to experimental group. This was further complicated by the factor that while nicotine replacement treatment may not have been formally offered, participants may have been advised about it if they asked for advice. Furthermore, all studies reported that a number of participants in the comparison groups had used nicotine replacement therapy, even when not offered this.

As theories of behaviour change may guide intervention planning by making it explicit how the desired behaviour change could be achieved, sub-group analysis tested whether the explicit consideration of theory in intervention planning influences the effectiveness of the intervention. However, analysis did not find any statistically significant difference between groups that explicitly mentioned theory in intervention planning and those that did not report using any theory. This results should not be interpreted as suggesting that using a theory in intervention planning would be useless. On the contrary, this result highlights the importance of examining actual theories or mechanisms underlying interventions, rather than simply considering whether theories had been explicitly stated or not. This consideration also highlights the increased need for practitioners and researchers who are involved in intervention planning and report writing to report, not only intervention procedures, but also how they suggest that the intervention causes the desired change.

It was found, similarly to Rigotti et al. (2007) and Barth et al. (2008), that there was a significant difference in rates of smoking cessation between intensive and less-intensive interventions. Regardless of the methodological problems associated with classifying the interventions into the subgroups, results suggested that less-intensive interventions may not have been able to offer enough support especially for those participants who were struggling to maintain cessation. However, as intensive interventions are likely to require more resources, especially in terms of health care professionals' time, they may not be applicable to every situation. It is also worth noting that only three studies were considered as 'intensive', and that regardless of studies' intensity and in contrast to control treatments, most of the studies included

some form of supportive contact after discharge from hospital. Consistent with findings from this review Rigotti et al. (2007) concluded that high-intensity interventions that begin during hospitalisation and provide at least one month's supportive follow-up after discharge increased smoking cessation among participants. At the present, the cumulative evidence for hospitalised patients suggests that a successful smoking cessation intervention should consist of substantial in-patient intervention followed by supportive contact after discharge from hospital.

Estimations of smoking abstinence at different time points show that the effects of psychological interventions were evident only up to 24 months. Results from the different follow-up points should nevertheless be interpreted with caution, as the small number of trials or patients included in the analyses may have caused confidence intervals at certain time points being wide or statistically non-significant. Collecting reliable long-term follow-up data for this kind of psycho-educational intervention is challenging, as it is difficult to evaluate influence of many possible confounding factors that may have influenced the results, such as advice and support received from other sources by the control group participants.

Psycho-educational smoking cessation interventions are complex and can require substantial resources, thus raising the question of their use in long-term support for smoking cessation. NHS Stop Smoking Services guidelines recommend using both pharmacological and behavioural interventions to aid smoking cessation. This review did not evaluate the cost effectiveness of psycho-educational interventions and therefore cannot draw conclusions of how cost effective behavioural smoking cessations interventions are. The main focus of the review was to compare psycho-educational interventions and control conditions without psycho-educational intervention, and the available data was not sufficient for an accurate comparison of psycho-educational and pharmacological treatment. The results of this review suggested that psycho-educational interventions are effective for smoking cessation, as either a stand-alone or additional to pharmacological therapies. These results are supportive of the NICE guidance (2008) of using behavioural interventions as a part of a smoking cessation intervention.

The results of the review indicated that interventions appeared to be largely designed along similar principles. All the interventions were initiated during participants' hospitalisation, which is sensible, as potential participants are thus easily identified and reachable. Also, for example in the United Kingdom, hospitals are designated non-smoking environments, which automatically restrict possibilities for smoking, and may therefore trigger the initial smoking cessation. Another benefit of initiating the smoking cessation intervention during patients' hospital is the possibility of reaching potential participants at their most sensitive stage for attempting change in their behaviour. Hospitalisation due to coronary heart disease may also result in increased willingness to change behavioural risk factors to prevent further illness episodes, and a timely intervention may impact on success of behaviour change. Review findings also suggested that though other health professionals were involved in delivery of intervention, nurses most commonly facilitated the intervention. Reviews did not specify as standard, whether nurses were specialised smoking cessation nurses, research nurses, or ward nurses. However, nurses, who have the most frequent contact with patients during their hospital stay, are often ideally placed to facilitate the intervention. Finally, the results of the review suggested that the materials used in the interventions could be described as conventional, as materials consisted mainly written booklets and leaflets describing the main points of the interventions. Only few of the studies provided used audiovisual materials to reinforce the intervention message. It was estimated that the intervention material did not require special skills or effort to use by both participants and intervention facilitators. The only exception to this was Reid et al. (2007), who, though using conventional intervention material, used interactive voice response telephony technology for follow-up.

Although the differences in the included studies between this and other reviews (Rigotti et al., 2007, Van Berkel et al., 1999, Barth et al., 2008) may be caused by search strategies used, differences observed between the similar reviews also highlights challenges in reviewing complex interventions. As pointed out by Jackson et al. (2004) and Armstrong et al. (2009), some of these challenges relate to specific difficulties in defining interventions and locating relevant research. When comparing the present review to the review by Barth et al. (2008), for example, this shows how

despite the two reviews having similar research questions, decisions made regarding intervention definition and inclusion criteria influence the final and differing selection of studies. For example, this review included only stand-alone psycho-educational smoking cessation interventions, while Barth et al. (2008) included both stand-alone smoking cessation interventions and multiple risk reduction interventions that had smoking cessation as part of the programme. Reviews of complex interventions do not also generally discuss whether they have used published methodological search filters and whether and how this may influence the identification of studies relevant to the review. Future research in this area may be needed to examine how different search strategies work in the evaluation of complex health care interventions.

Challenges of reviewing complex health care interventions means that comparing the strengths and weaknesses of this review with other related reviews should be made cautiously. Though, for example, it appears that there is a relatively good match between the present review and the review by Barth et al. (2008)s in the included studies, two studies included in the present review (Bolman et al., 2002; Johnson et al., 1999) were not included in the review by Barth et al. (2008). Also, Barth et al. (2008) included studies written in languages other than English. Similar kind of differences can be observed when comparing studies included in this review to other recent reviews (e.g. Rigotti et al., 2007, Van Berkel et al., 1999) in this area. Another concern over the search strategy is that it did not use published search filters, but rather limited amount of search terms to maximise identification of relevant studies. Future research in this area may be needed to examine how different search strategies work in evaluation of complex health care interventions.

Although the differences in the included studies between this and other reviews may be caused by search strategies used, differences observed between the similar reviews also highlights challenges in reviewing complex interventions. As pointed out by Jackson et al. (2004) and Armstrong et al. (2009), some of these challenges relate to specific difficulties in defining interventions and locating relevant research. When comparing the present review to the review by Barth et al. (2008), for example, this shows how despite the two reviews having similar research questions, decisions made regarding intervention definition and inclusion criteria influence the

final and differing selection of studies. Reviews of complex interventions do not also generally discuss whether they have used published methodological search filters and whether and how this may influence the identification of studies relevant to the review. Future research in this area may be needed to examine how different search strategies work in the evaluation of complex health care interventions.

This systematic review has shown that quantitative meta-analysis methods may not be suitable to explore mechanisms of complex health interventions. Complexity of psycho-educational smoking cessation interventions did effect on systematic review and meta-analysis. Defining intervention was challenging, as well as ensuring that the search strategy captured all variations of potentially relevant interventions. Large between-study variation raised also questions about the appropriateness of meta-analysis, but it was felt that the observed heterogeneity was an important part of the results, indicating the complexity of the interventions included in the review. During the review, information was collected about any potential process variables reported in the studies. No evidence was found of systematic testing of process variables, and in many cases it was problematic to decide whether an identified variable should be considered as a predictor or a process variable, as in many cases, such as with self-efficacy, a variable could have both functions. While, in the authors' opinion, there was some indication that five studies did investigate process variables, there was not enough information available to reliably identify processes underlying successful smoking cessation intervention.

Although the review results add to the growing literature on the effectiveness of psychological interventions in smoking cessation, these results should nevertheless be interpreted with caution. Although it appears that the search strategy was successful in identifying relevant studies, the possibility that the search strategy may have missed studies cannot be completely dismissed. Another limitation of the review is the inclusion of studies that offered pharmacotherapy to the intervention group only. However, as nicotine replacement therapy is so widely available, restricting study selection based on offered pharmacotherapy was felt to be impracticable. Possibilities of separating effects of nicotine replacement therapy from effects of psychological interventions may, however, need to be examined in future reviews.

5.7 Conclusions

The results of the meta-analysis indicated that psycho-educational smoking cessation interventions were associated with increased rates of smoking cessation. The results of post-hoc subgroup analyses suggested that intervention intensity was associated with intervention outcomes. Meta-analysis indicated a high level of heterogeneity and interventions appeared to be very different from each other, even though there appeared notable similarities in intervention design, personnel, and use of materials.

This systematic review has shown that quantitative meta-analysis methods may not be sufficient for investigating mechanisms of complex health interventions. Complexity of psycho-educational interventions results in considerable challenges in systematic reviews of complex health interventions. The current systematic review had only very limited success in exploring mechanisms of complex psycho-educational interventions. Even though interventions had similar purpose, the variety of intervention techniques and combinations of different techniques used in the studies to influence participants' smoking behaviours further emphasised the difficulties in reviews of complex intervention to offer clear guidance of how an effective intervention should look like. In order to further investigate intervention mechanisms a new and innovative approach based on the work by Michie et al. (2008) will be tested, results of which will be reported in the Chapter 6.

Study	Setting, Country	Intervention theory and intensity	Sample size (Intervention / Control)	Diagnosis, smoking status before admission	Age Male (%)	Follow-up (Months)
Bolman et al. (2002a) Bolman et al. (2002b)	Hospital & outpatient clinic Netherlands	Social Learning Theory, ASE Model Less intensive	388 / 401	MI, Angina Pectoris, Other. Smoking in the seven days before admission	Mean 57 (11) Male (78%)	12
Burt et al. (1974)	Hospital UK	Not specified Intensive	125 / 98	MI. Smoking at the time of MI attack	Not specified Male (100%)	>12
Dornelas et al. (2000)	Hospital & community USA	Transtheoretical model, Marlatt-Gordon's relapse prevention techniques Less intensive	54 / 46	Acute MI. Smoking during the month before admission	From 27 to 83 Male (77)	12
Feeney et al. (2001)	Hospital & outpatient clinic Australia	Not specified Could be intensive	96 / 102	Acute MI. Smoking or using tobacco products during the week before admission	Mean age: 53.9 (11) Male (64%)	12
Hajek et al. (2002)	Hospital UK	Not specified Less intensive	274 / 266	MI, CABG. Current or recent smokers; not smoking since admission; motivated to stop smoking	under 76 Mean age: 56 (10) Male (77%)	12

Table 5.1: Main characteristics of the included trials

Study	Setting, Country	Intervention theory and intensity	Sample size (Intervention / Control)	Diagnosis, smoking status before admission	Age Male (%)	Follow-up (Months)
Johnson et al. (1999)	Hospital Canada	Stages of change Less intensive	50 / 52	Medical and/or surgical cardiac diagnosis. Self-reported smokers in the contemplation stage to stop smoking.	Over 19, Mean age: 55 (13) Male (75%)	6
Mohiuddin et al. (2007)	Hospital & community USA	Stages of change (author inf.) Intensive	109 / 100	Acute coronary syndrome, de-compensated heart failure. Daily smokers for at least five years	Aged 30-75 years Mean age: 55 (11) Male (63%)	24
Ockene et al. (1992) Rosal et al. (1998)	Hospital USA	Behavioural multicomponent approach Could be intensive	135 / 132	Patients with one or more arteriographical coronary artery lesions . Smoking at least 5 cigarettes/day anytime during the last two months before admission	Aged 30 - 75 years Mean age: 53 Male (75%)	60
Quist-Paulsen & Gallefoss (2003)	Hospital & community Norway	Fear arousal Could be intensive	118 / 122	MI, CABG, unstable Angina. Daily smokers until start of the present coronary symptoms	under 76 Mean age: 57 (9) Male (75%)	12
Reid et al. (2003)	Hospital & community Canda	Transtheoretical model (author inf.) Less intensive	126 / 128	PTCA, MI, CABG. Five or more cigarettes per day during the month before admission. Motivation to quit was inquired	over 18 Mean age: 54 (9) Male (80%)	12

Table 5.1: Main characteristics of the included trials

Study	Setting, Country	Intervention theory and intensity	Sample size (Intervention / Control)	Diagnosis, smoking status before admission	Age Male (%)	Follow-up (Months)
Reid et al. (2007)	Hospital & community, Canada	Not specified Could be intensive	50 / 50	CHD. Five or more cigarettes per day	Over 18 Mean age: 54 (9) Male (67%)	12
Rigotti et al. (1994)	Hospital & community USA	Not specified Less intensive	44 / 43	CABG. Smoked one or more packs of cigarettes in 6 months before admission	Mean age: 59 (8) Male (77%)	66
Smith & Burgess (2009)	Hospital & community Canada	Marlatt and Gordon's relapse prevention model Intensive	137 / 139	MI, CABG. Smoking in the month before the admission	Over 18 Mean age: 54 (10) Male (83%)	12
Taylor et al. (1990)	Hospital, outpatient clinic & community USA	Social learning theory Could be intensive	86 / 87	Acute MI. Smoking during the last six months before admission	Under 70 Mean age: 58 (9) Male (86%)	12

Table 5.1: Main characteristics of the included trials

Study	Intervention theory and estimated intensity	Experimental group	Control group
<p>Bolman et al. (2002b) Bolman et al. (2002a)</p>	<p>Social Learning Theory, ASE Model (<u>the attitude-social influence-efficacy model</u>), theories of relapse prevention, the Stage of Change Theory, and motivational interview strategies</p> <p>Intervention intensity: Less intensive</p>	<p>Cardiologist provided stop smoking advice, which was followed by 15-30 minutes standardised individual counselling and provision of self-help material by a nurse. Counselling was tailored to patient's stage of change and included assessment of smoking behaviour, motivation to quit, consequences of quitting, barriers to quitting, and encouragement to set a date for quitting. Aftercare was provided by cardiologist at the first outpatient appointment, which addressed various aspects of smoking. Patients GP was informed of the intervention and asked to note smoking behaviour.</p> <p>Pharmacotherapy not offered</p>	<p>Usual care, no special stress on smoking cessation.</p> <p>Pharmacotherapy not offered</p>
<p>Burt et al. (1974)</p>	<p>Not specified</p> <p>(Harmful effects of smoking)</p> <p>Intervention intensity: Intensive</p>	<p>A consultant explained effects of smoking and advised patients to stop smoking. Participants were informed that smoking cessation was likely to reduce occurrence of another MI. If participants failed to stop smoking, further advice was provided and reinforced by leaflets and advice booklet. After discharge participants were followed in a clinic and smoking cessation advice was extended to family members. Community nurse visited at home and gave advice regarding smoking and other risk factors.</p> <p>Pharmacotherapy not offered</p>	<p>Participants received standard hospital advice (unclear about details), without follow-up at hospital. A community nurse visited patients at home one or more years later to seek information on smoking.</p> <p>Pharmacotherapy not offered</p>

Table 5.2: Description of experimental and control interventions

Study	Intervention theory	Experimental group	Control group
Dornelas et al. (2000)	<p>Transtheoretical model, motivational intervention, and Marlatt-Gordon's relapse prevention techniques (coping skills training); depending on the stage of change.</p> <p>Intervention intensity: Less intensive</p>	<p>A 20 minutes bedside smoking cessation counselling by psychologist who evaluated participants' current stage of change and based the counselling context on that stage. After discharge participants were contacted by telephone after weeks 1, 4, 8, 12, 16, 20 and 29. Bedside and telephone counselling combined aspects of motivational interviewing and relapse prevention.</p> <p>Pharmacotherapy not offered</p>	<p>Participants received a short intervention lasting about 10 minutes from a psychologist. Intervention consisted verbal and written recommendation to watch an on-line educational video while in hospital. Participants were also referred to local American Heart or Lung Association's smoking cessation resources.</p> <p>Pharmacotherapy not offered</p>
Feeney et al. (2001)	<p>Not specified</p> <p>Relapse prevention: coping skills training.</p> <p>(Self-efficacy, Bandura's social cognitive theory 1986)</p> <p>Intervention intensity: Could be intensive</p>	<p>Stanford Heart Attack Staying Free programme. Participants were advised on smoking cessation and medical implications of cessation.</p> <p>Participants received a manual, which identified high-risk relapse situations and exercises to manage these situations. Audio tapes reviewed program's main points and provided progressive muscle relaxation. After discharge telephone contact was initiated weekly for 4 weeks and at 2, 3, 6 and 12 months with additional support and advice given when necessary.</p> <p>Pharmacotherapy: Informed that NRT available outside of hospital. No use of NRT reported.</p>	<p>Participants received usual care offering verbal and written advice about smoking cessation. Included an educational video while in hospital, and review by an alcohol and drug assessment unit (ADAU) nurse. Participants were also offered outpatient counselling and follow-up by ADAU clinic at 3, 6, and 12 month intervals.</p> <p>Pharmacotherapy: Informed that NRT available outside of hospital. No use of NRT reported.</p>

Table 5.2: Description of experimental and control interventions

Study	Intervention theory	Experimental group	Control group
Hajek et al. (2002)	<p>Not specified</p> <p>(Multiple components, including information about health benefits of quitting; buddy support; self-efficacy)</p> <p>Intervention intensity: Less intensive</p>	<p>Participants were given a booklet about smoking and cardiac recovery and carbon monoxide reading was recorded. The booklet challenged beliefs that smoking reduces stress and advised on relapse prevention. A quiz tested participants' knowledge of the booklet, which was also discussed with a nurse. Participants signed a declaration and a sticker on their notes reminded staff of smoking cessation attempt.</p> <p>Pharmacotherapy not offered. Very few appeared to have used NTR</p>	<p>Participants were given both verbal advice to stop smoking and British Heart Foundation Booklet <i>Smoking and Your Heart</i>.</p> <p>Pharmacotherapy not offered. Very few appeared to have used NTR</p>
Johnson et al. (1999)	<p>Stages of change; problem solving, reinforcing the patient's self-efficacy</p> <p>Intervention intensity: Less intensive</p>	<p>Participants received a booklet and were shown a video about effects of smoking, importance of smoking cessation, cessation process, and smoking triggers. The video encouraged discussion of smoking habits and to set a quit date. On the second visit smoking cessation skills were reviewed in a video and participants developed a smoking cessation plan and strategies to manage smoking triggers. Six telephone contacts during the first 3 months after discharge encouraged and reinforced cessation efforts.</p> <p>Pharmacotherapy not offered</p>	<p>Participants in the control group received routine care, which included stop smoking advice, but not a systematic intervention.</p> <p>Pharmacotherapy not offered</p>

Table 5.2: Description of experimental and control interventions

Study	Intervention theory	Experimental group	Control group
Mohiuddin et al. (2007)	<p>Multiple components: relaxation training, contingency contracting, social support, coping skills, stimulus control, nicotine fading.</p> <p>Intervention intensity: Intensive</p>	<p>Prior to discharge all participants received a standardised counselling (30 minutes) and self-help material on smoking cessation.</p> <p>Participants in the intervention group were asked to meet a tobacco cessation (60 minutes) weekly for 3 months in small groups or individually. Counselling included relaxation training, contingency contracting, social support, coping skills, stimulus control, nicotine fading and risk factor modification such as diet and exercise.</p> <p>Pharmacotherapy offered, used by 75%.</p>	<p>Prior to discharge all participants received a standardised counselling (30 minutes) and self-help material on smoking cessation.</p> <p>No additional intervention provided in the control group.</p> <p>Pharmacotherapy not formally offered; 17% reported use of NRT or bupropion.</p>
Ockene et al. (1992) Rosal et al. (1998)	<p>Behavioural multicomponent approach: including motivational support, behavioural self-management strategies, relaxation, and coping skills training.</p> <p>Intervention intensity: Could be intensive</p>	<p>All received standardised initial (10-15 minutes) advice to stop smoking, including a review of health risks of smoking and the benefits of quitting, and a list of community treatment programmes.</p> <p>Participants in the intervention group received a 30-minutes inpatient counselling session, an individual outpatient counselling visit, and follow-up counselling telephone calls. Participants also received intervention manual, relaxation tapes, maintenance training, and self-help material.</p> <p>Pharmacotherapy not offered</p>	<p>All received standardised initial (10-15 minutes) advice to stop smoking, including a review of health risks of smoking and the benefits of quitting, and a list of community treatment programmes.</p> <p>No additional intervention provided in the control group.</p> <p>Pharmacotherapy not offered</p>

Table 5.2: Description of experimental and control interventions

Study	Intervention theory	Experimental group	Control group
Quist-Paulsen (2003)	<p>Fear arousal; relapse prevention coping skills</p> <p>Intervention intensity: Could be intensive</p>	<p>Participants were offered group sessions with a nurse, with a video shown and a booklet about CHD and advice about quit smoking.</p> <p>Participants in the intervention group received a specially produced booklet about health benefits of quitting smoking, information about smoking cessation, relapse prevention, nicotine replacement products, high risk relapse situations and action plans. Participants were told in a fear arousal message that if they continued smoking they were likely to have another heart attack. Spouses who smoked were also asked to quit. Telephone contact was initiated after discharge and participants had consultation in outpatient clinic.</p> <p>Pharmacotherapy: use of NRT recommended for those with strong withdrawal urges. 36% used NRT.</p>	<p>Participants were offered group sessions with a nurse, with a video shown and a booklet about CHD and advice about quit smoking.</p> <p>No additional intervention provided.</p> <p>Pharmacotherapy not explicitly offered. 28% reported using NRT</p>
Reid et al. (2003)	<p>Positive reinforcement, problem solving, social support</p> <p>Intervention intensity: Less intensive</p>	<p>All received brief bedside, 5-10 minute individual counselling by a nurse counsellor; and a self-help booklet and information on additional support from primary care physicians provided.</p> <p>After hospital discharge, participants in the stepped-care group received three 20-minute face-to-face counselling sessions with a nurse-counsellor over 8 weeks. If participants reported abstinence they received positive feedback and were reminded about the relapse prevention information in the booklet. If participants reported smoking, counselling was started and NRT made available.</p> <p>Pharmacotherapy: NRT provided for 4 weeks after relapse (26.2% relapsed after initial smoking cessation).</p>	<p>All received brief bedside, 5-10 minute individual counselling by a nurse counsellor; and a self-help booklet and information on additional support from primary care physicians provided.</p> <p>No additional intervention provided.</p> <p>Pharmacotherapy not offered. 6 reported using NRT and 4 bupropion.</p>

Table 5.2: Description of experimental and control interventions

Study	Intervention theory	Experimental group	Control group
Reid et al. (2007)	<p>Not specified</p> <p>(Self-efficacy, social support, problem solving, development of coping strategies)</p> <p>Intervention intensity: Could be intensive</p>	<p>All received standard usual care, included personalised advice to stop smoking and NRT if necessary, brief bedside counselling by a nurse-counsellor, self-help guide, and information about outpatient and community smoking cessation programmes.</p> <p>Participants in the treatment group received Interactive Voice Responsive Telephony (IVR) intervention. After discharge an automated telephony system contacted participants on days 3, 14, 30 post-discharge. Calls inquired smoking status and assessed risk of relapse. Those participants that reported either relapse with willingness to further smoking cessation attempt or low confidence to stay smoke free, were flagged in the IVR system software. Nurse-specialist contacted these participants to offer additional assistance. Additional interventions included up to three 20-min counselling sessions over 8 week-period counsellor-led telephone sessions, encouragement, help in identifying situations that were undermining their confidence and possible solutions, access to pharmacotherapy.</p> <p>Pharmacotherapy: NRT offered in hospital & after relapse. Used by 70% in hospital and by 14% after discharge</p>	<p>All received standard usual care, included personalised advice to stop smoking and NRT if necessary, brief bedside counselling by a nurse-counsellor, self-help guide, and information about outpatient and community smoking cessation programmes.</p> <p>No additional treatments provided.</p> <p>Pharmacotherapy: Access to NRT during hospitalisation if required. NRT was used by 58% in hospital and by 14.3% during follow-up.</p>

Table 5.2: Description of experimental and control interventions

Study	Intervention theory	Experimental group	Control group
Rigotti et al. (1994)	Behavioural and cognitive methods Intervention intensity: Less intensive	Based on the American Lung Association's "In Control" program, the intervention was a standardised counselling programme, included edited video tape, patient manual and three 20-min sessions to individual patients by a research nurse. Family members were also encouraged to participate. Within two weeks of discharge participants were contacted by telephone to offer support and short counselling. Pharmacotherapy not offered	Participants received standard post-operative care; including brief advice not to smoke as part of a group lecture. Pharmacotherapy not offered
Smith & Burgess (2009)	Marlatt and Gordon's relapse prevention model Intervention intensity: Intensive	Nurse reviewed two pamphlets with the patients, which contained information about how to quit and where to find help. Nurse placed a note to patients' charts to remind their physicians to deliver scripted non-smoking message at bedside. In the intervention group participants received bedside counselling (45-60 min) and educational materials to take home (video, work book, audiotape), and 7 telephone counselling sessions (at 2, 7, 14, 21, 30, 45, 60 days after discharge). Educations consisted personalised risks associated with smoking, benefits of quitting, and help to develop strategies to stay smoke free. Telephone counselling focused on relapse prevention by developing cognitive, behavioural and social support strategies for situations identified as high risk situations. Pharmacotherapy not part of intervention, but available if requested. 34% used.	Nurse reviewed two pamphlets with the patients, which contained information about how to quit and where to find help. Nurse placed a note to patients' charts to remind their physicians to deliver scripted non-smoking message at bedside. Pharmacotherapy not part of intervention, but available if requested. 34% used

Table 5.2: Description of experimental and control interventions

Study	Intervention theory	Experimental group	Control group
<p>Taylor et al. (1990)</p>	<p>Social learning theory, relapse prevention coping skills training</p> <p>Intervention intensity: Less intensive</p>	<p>A nurse counsellor reviewed benefits of smoking cessation, provided a manual and audio tapes for identifying high risk relapse situations, and provided exercises to cope with these situations. After discharge telephone contact was initiated to monitor relapse and offer support and advice for 4 months. Outpatient appointment was offered when needed. NRT was available and patients signed a contract to quit smoking.</p> <p>Pharmacotherapy: NRT available for strong withdrawal urges</p>	<p>Participants received no specific smoking cessation help, but were free to attend hospital's stop smoking classes.</p> <p>Pharmacotherapy not offered</p>

Table 5.2: Description of experimental and control interventions

Study	Random allocation method	Allocation concealed?	Trial arms similar at baseline?	Interventions clearly described?	Inclusion eligibility criteria set?	Outcome assessor blind?	Intervention provider blind?	Participants blind?	Cessation verified?	Total dropout rate
Bolman et al. (2002b); Bolman et al. (2002a)	Random selection and assignment of hospitals 7 randomly assigned, 4 self selected condition	No	Some diff.	Yes	Yes	No	No	No	No	28%
Burt 1974	By the day of admission	No	Unclear	Yes	Yes	No	No	No	No	0%
Dornelas 2000	Drawn from envelopes	No	Yes	Yes	Yes	No	No	No	No	20%
Feeney 2001	Sealed envelopes	Yes	Yes	Yes	Yes	No	No	No	Bioch.	66%
Hajek 2002	Serially numbered, opaque, sealed envelopes	Yes	Yes	Yes	Yes	No	No	No	Bioch.	11%
Johnson 1999	By admission unit (cluster RCT)	No	Some diff.	Yes	Yes	No	No	No	No	14%
Mohiuddin 2007	UC – without block assignment	No	Some diff.	Yes	Yes	No	No	No	Bioch.	4%
Ockene 1992; Rosal 1998	UC	No	Yes	Yes	Yes	No	No	No	Bioch.	40%
Quist-Paulen 2003	Serially numbered, sealed envelopes	Yes	Some diff.	Yes	Yes	No	No	No	Bioch.	9%

- Bioch= Biochemical verification of smoking status

Table 5.3: Assessment of study quality of included trials

Study	Random allocation method	Allocation concealed?	Trial arms similar at baseline?	Interventions clearly described?	Inclusion eligibility criteria set?	Outcome assessor blind?	Intervention provider blind?	Participants blind?	Cessation verified?	Total dropout rate	Follow-up (months)
Reid 2003	Using a random numbers table, stratified by reason for admission	UC	Yes	Yes	Yes	No	No	No	Bioch. A sample only (n=25)	15%	12
Reid 2007	Third party, computer generated list	Yes	Yes	Yes	Yes	No	No	No	No	16%	12
Rigotti 1994	UC	No	Yes	Yes	Yes	No	No	No	Bioch.	24%	66
Smith 2009	Envelopes containing computer generated random-number, random permuted blocks of 10, stratified by acute MI and CABG	Yes	Yes	Yes	Yes	Yes	No	No	Proxy	11%	12
Taylor 1990	Serial numbered, sealed envelopes, opened by a trial coordinator	Yes	Yes	Yes	Yes	No	No	No	Bioch.	25%	12

- Bioch= Biochemical verification of smoking status

Table 5.3: Assessment of study quality of included trials

<i>Theoretical subgroup analysis</i>	Theory subgroup			No theory subgroup		Statistical subgroup difference			
Point prevalent smoking cessation	RR 1.54 (1.27 to 1.87)			RR 1.28 (0.91 to 1.83)		Z=0.908, p=0.364			
Number of studies	8			5					
Number of participants Treat/Cont	1068/1075			628/589					
I^2	61%			81%					
Continuous smoking cessation	RR 1.64 (1.11 to 2.77)			RR 1.30 (0.74 to 2.31)		Z=0.763, p=0.445			
Number of studies	6			4					
Number of participants Treat/Cont	892/895			549/543					
I^2	40%			83%					
<i>Intervention intensity subgroup analysis</i>	Less intensive	Intensive	Statistical subgroup difference	Could be intensive	Less intensive	Statistical subgroup difference	Could be intensive	Intensive	Statistical subgroup difference
Point prevalent smoking cessation	RR 1.17 (0.97 to 1.41)	RR 2.31 (1.39 to 3.84)	Z=2.463, p=0.014	RR 1.45 (1.18 to 1.79)	RR 1.17 (0.97 to 1.41)	Z=1.502, p=0.133	RR 1.45 (1.18 to 1.79)	RR 2.31 (1.39 to 3.84)	Z=1.662, P=0.096
Number of studies	6	3		4					
Number of participants Treat/Cont	936/936	371/337		389/391					
I^2	56%	79%		23%					
Continuous smoking cessation	RR 1.20 (0.85 to 1.70)	RR 3.67 (1.86 to 7.23)	Z=2.875, p=0.004	RR 1.78 (1.08 to 2.94)	RR 1.20 (0.85 to 1.70)	Z=1.269, p=0.204	RR 1.78 (1.08 to 2.94)	RR 3.67 (1.86 to 7.23)	Z=1.681, p=0.093
Number of studies	4	1		5					
Number of participants Treat/Cont	760/756	109/100		435/443					
I^2	78%	n/a		79%					

Table 5.4: Results of subgroup analyses

<i>Use of pharmacotherapy</i>	Pharmacotherapy offered	Pharmacotherapy not offered	Statistical subgroup difference	Pharmacotherapy offered only for treatment group	Pharmacotherapy not offered or offered to both groups	Statistical subgroup difference
Point prevalent smoking cessation	RR 1.65 (1.14 to 2.40)	RR 1.35 (1.09 to 1.67)	Z=0.917, p=0.359	RR 1.75 (1.11 to 2.77)	RR 1.35 (1.11 to 1.64)	Z=1.023, p=0.306
Number of studies	5	8		4	9	
Number of participants Treat/Cont	489/487	1207/1177		439/437	1257/1227	
I ²	77%	73%		83%	70.8%	
Continuous smoking cessation	RR 1.97 (1.26 to 3.08)	RR 1.34 (1.0 to 1.97)	Z=0.1416, p=0.157	RR 1.97 (1.26 to 3.08)	RR 1.34 (1.0 to 1.97)	Z=0.1416, p=0.157
Number of studies	3	7		3	7	
Number of participants Treat/Cont	313/309	1128/1129		313/309	1128/1129	
I ²	71%	78%		71%	78%	

Table 5.4: Results of subgroup analyses

Study	<i>Reason for exclusion</i>
Chouinard et al. 2005	<ul style="list-style-type: none"> • <i>Participants included patients with peripheral vascular disease</i> • <i>Results were not separated by disease group</i>
Hall et al. 1984	<ul style="list-style-type: none"> • <i>Participants with cardiopulmonary disease</i> • <i>No clear educational or psychological component</i>
Hill Rice et al. 1994	<ul style="list-style-type: none"> • <i>Participants included patients with peripheral cardiovascular and chronic obstructive pulmonary disease</i> • <i>Results were not separated by disease group</i>
Perkins & Scott, 1986	<ul style="list-style-type: none"> • <i>Randomised poster intervention in patients' smoking lounge</i> • <i>Unclear if participants aware of intervention</i> • <i>Exact participant population unclear</i>
Quist-Paulsen et al. 2006	<ul style="list-style-type: none"> • <i>Prospective observational study</i> • <i>Data collected as part of a randomised controlled study</i> • <i>Results not separated according to group allocation</i>
Sivarajan Froelicher et al. (2004)	<ul style="list-style-type: none"> • <i>Participants included patients with e.g. peripheral vascular disease, arrhythmias, and hypertension</i> • <i>Results not separated by disease group</i>
Wiggers et al. 2005	<ul style="list-style-type: none"> • <i>Participants included patients with e.g. peripheral vascular disease</i> • <i>Results not separated by disease group</i>
Wiggers et al. 2006	<ul style="list-style-type: none"> • <i>Patients with both coronary artery and peripheral artery disease</i> • <i>Results not separated by disease group simultaneously</i>

Table 5.5: Studies excluded from systematic review of psycho-educational smoking cessation interventions

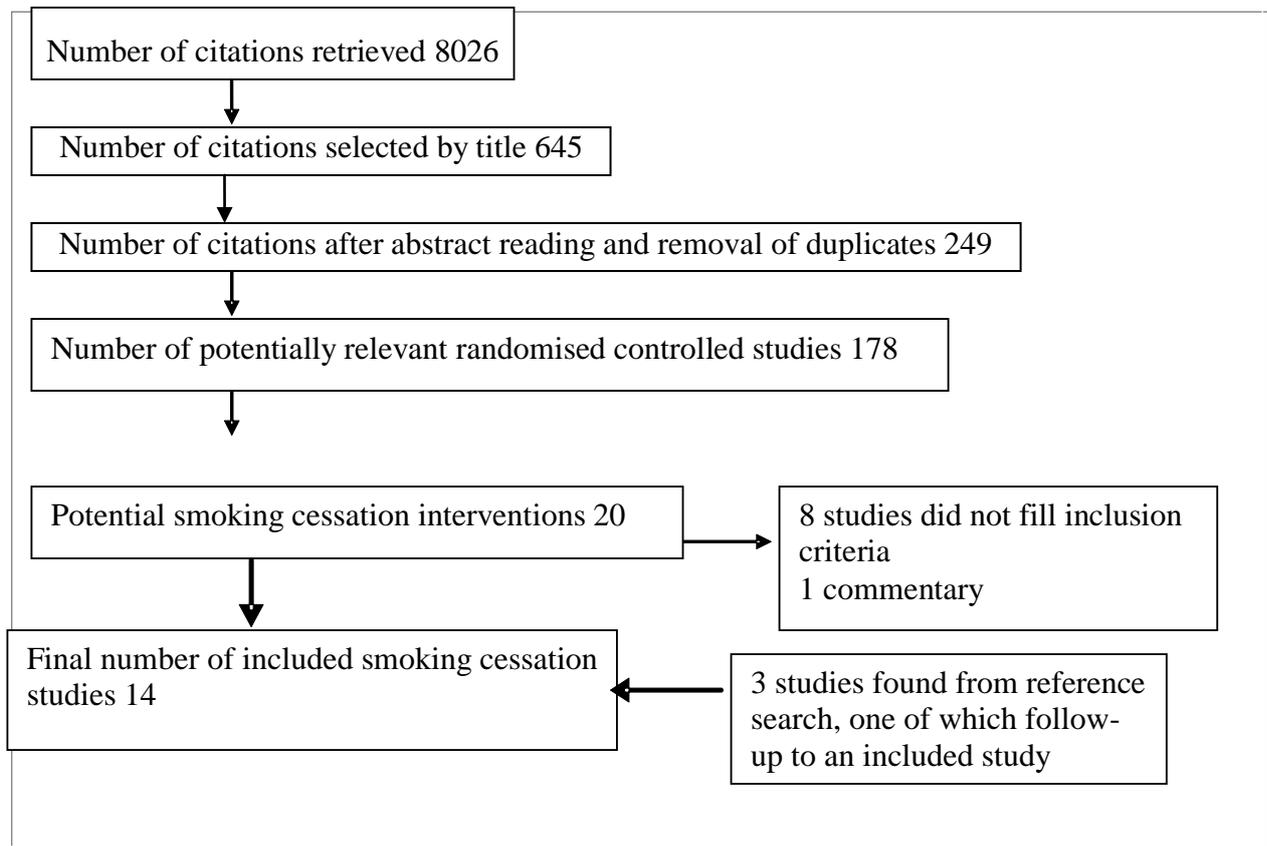


Figure 5.1: Flow chart depicting study selection process for the meta-analysis

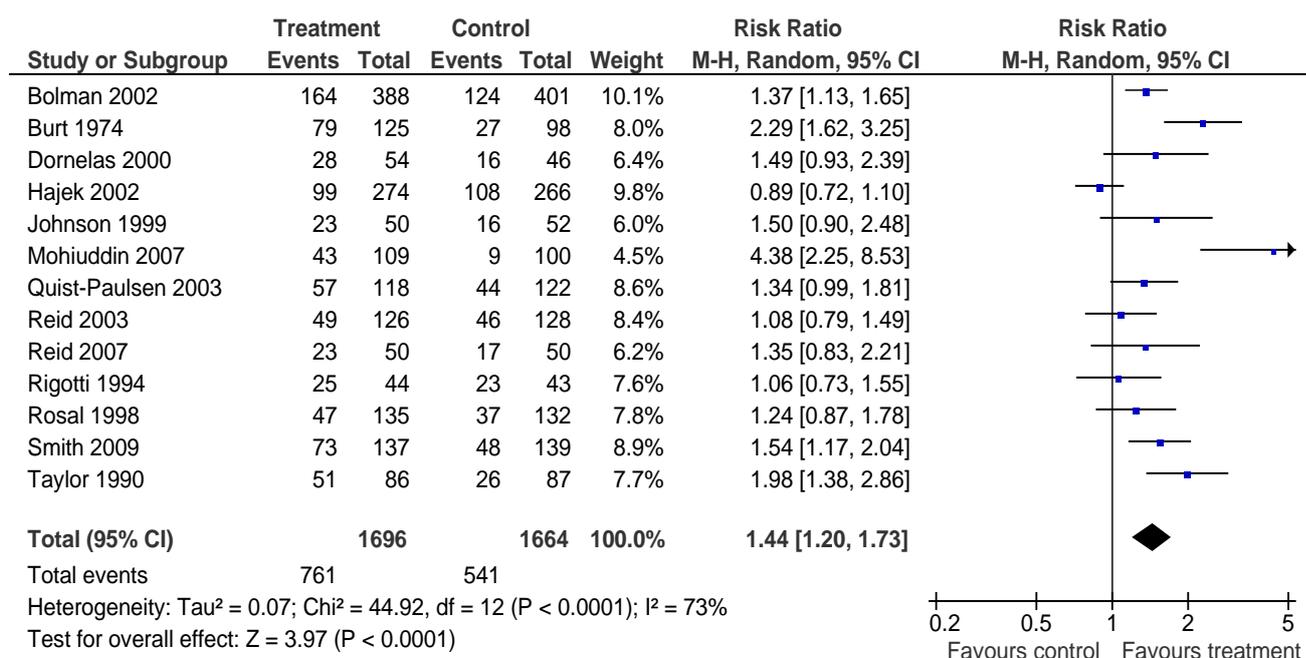


Figure 5.2: Point prevalent smoking cessation outcome comparing effectiveness of psycho-educational smoking cessation intervention to control condition

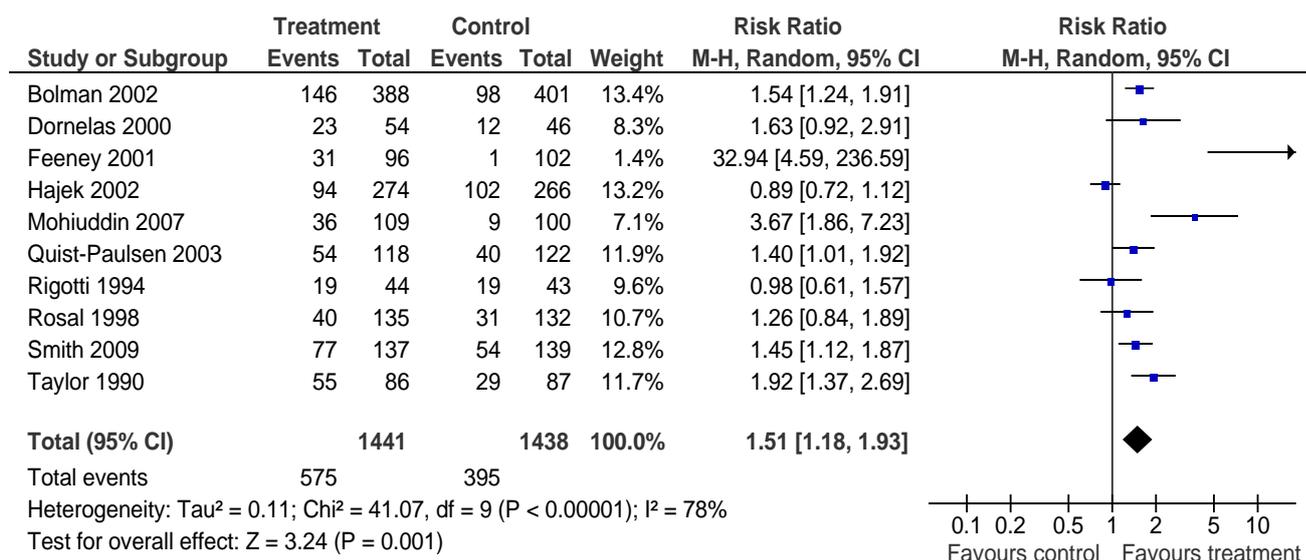


Figure 5.3: Continuous smoking cessation outcome comparing effectiveness of psycho-educational intervention to control condition

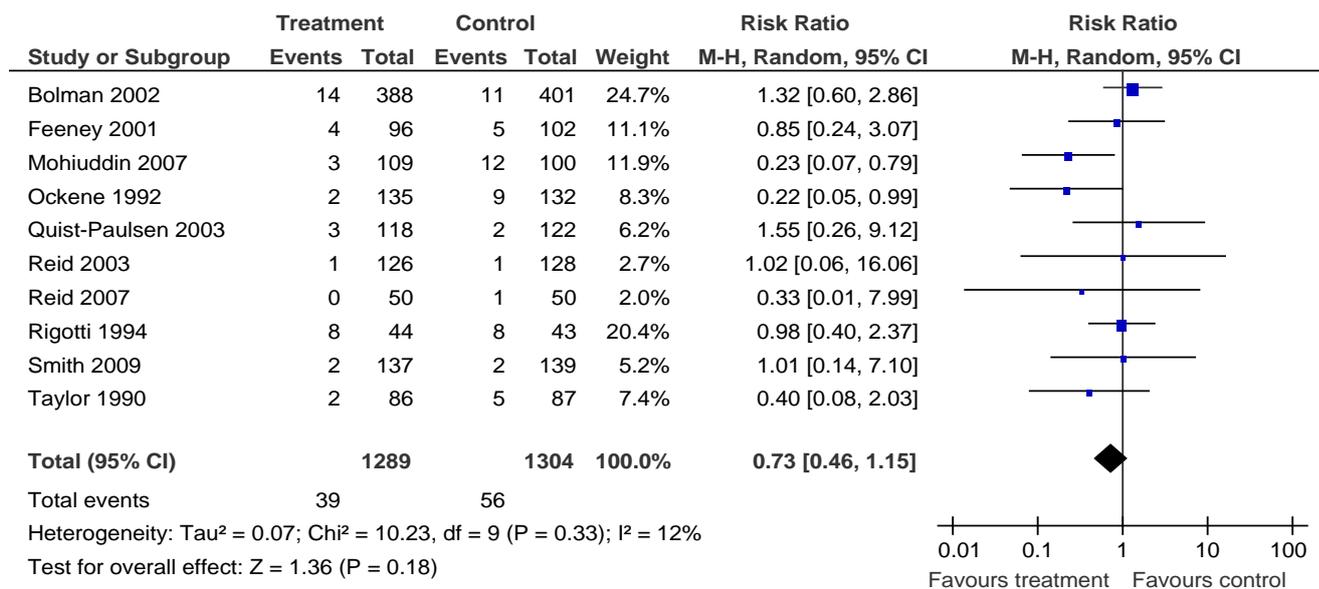


Figure 5.4: Total mortality outcome comparing effectiveness of psycho-educational intervention to control condition

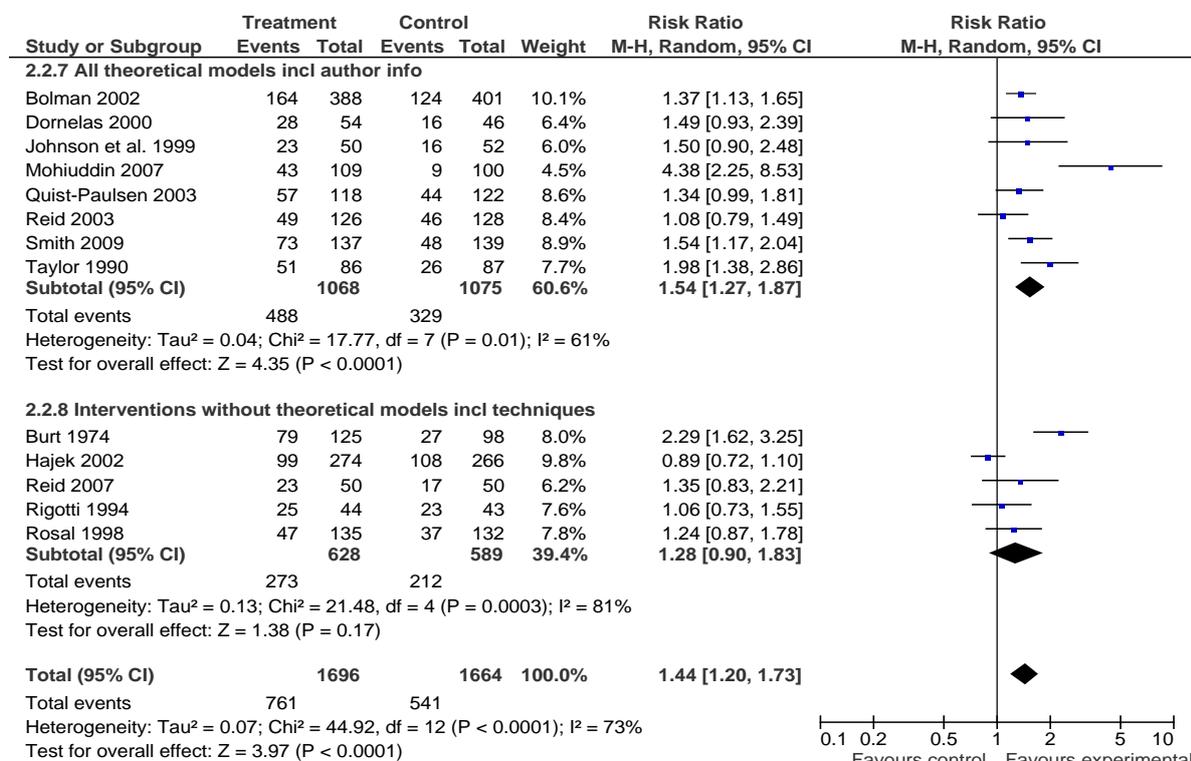


Figure 5.5: Point prevalent smoking cessation intervention theory subgroup analysis

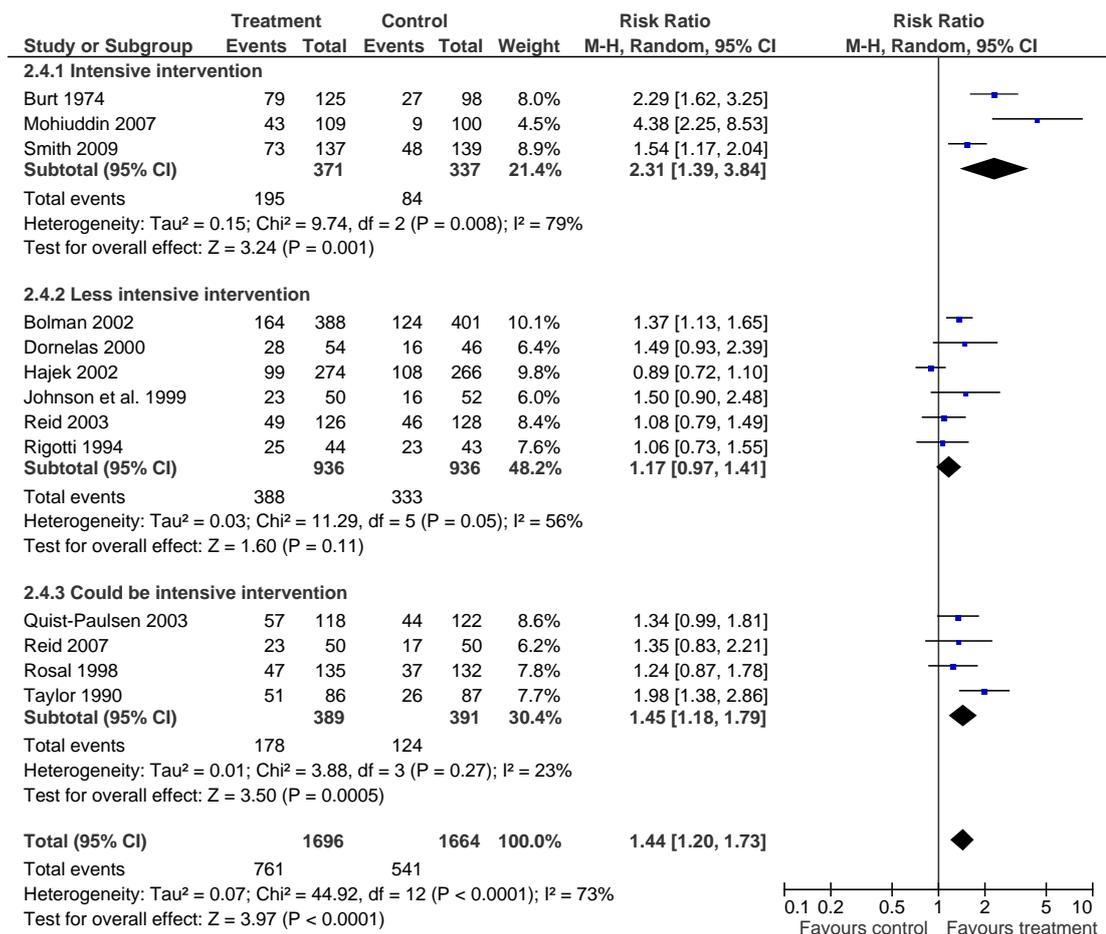


Figure 5.6: Point prevalent smoking cessation intervention intensity subgroup analysis

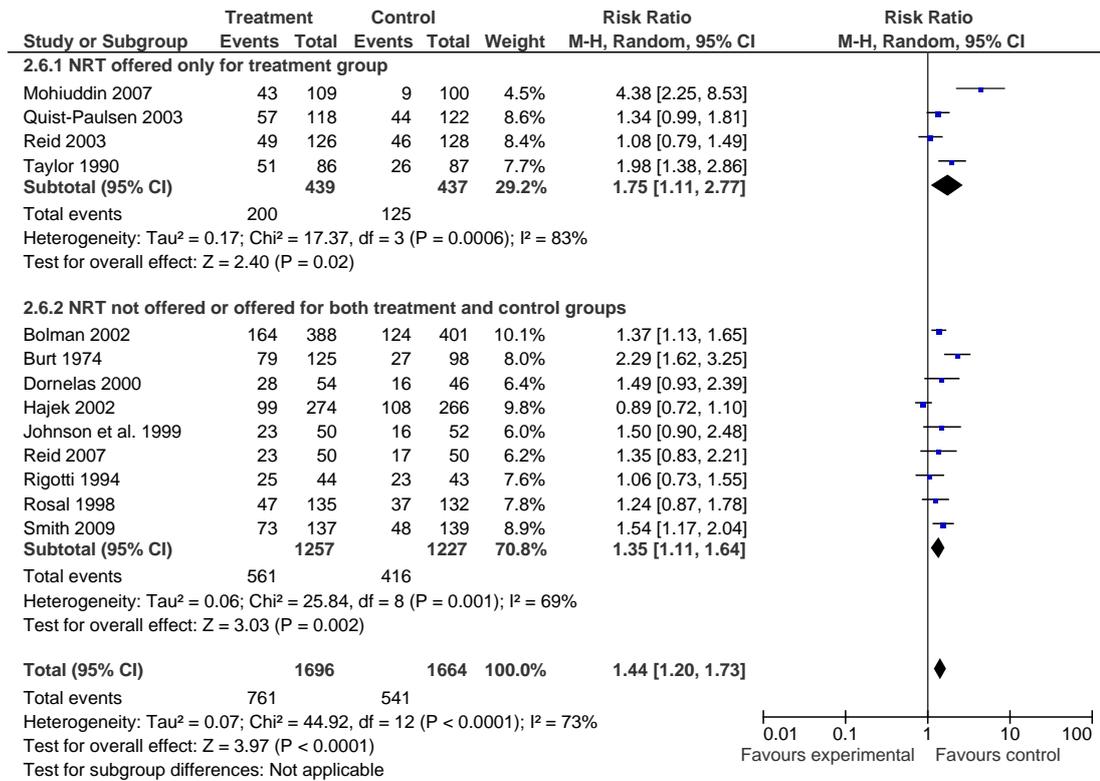


Figure 5.7: Point prevalent smoking cessation use of nicotine replacement products subgroup analysis

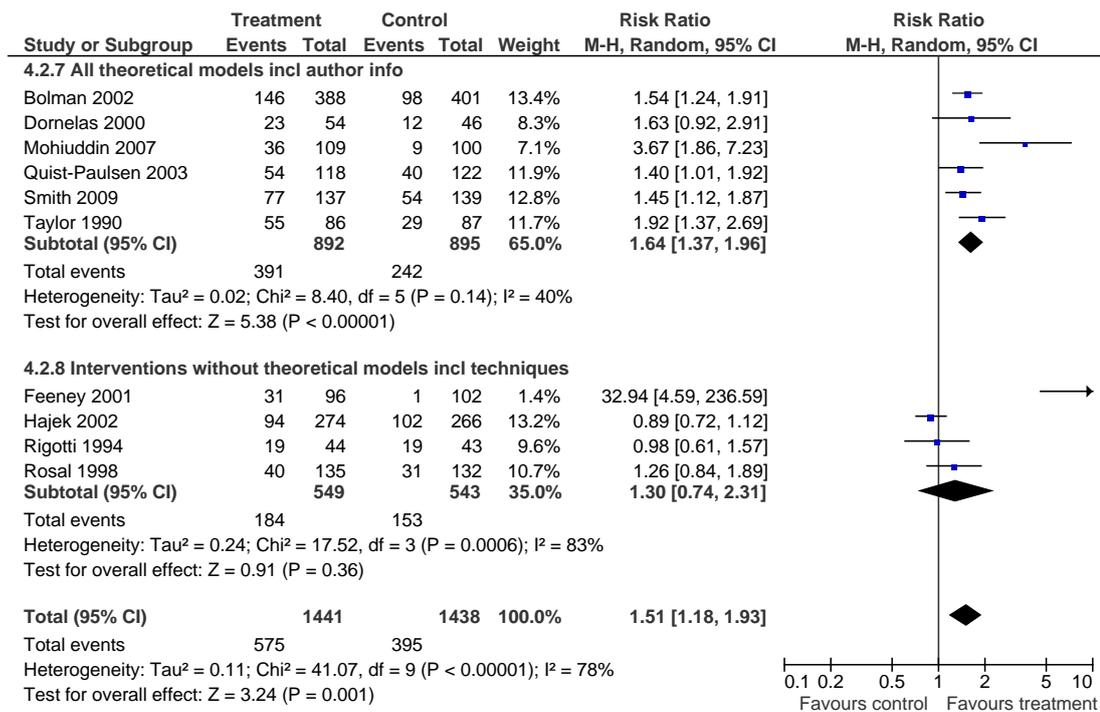


Figure 5.8: Continuous smoking cessation intervention theory subgroup analysis

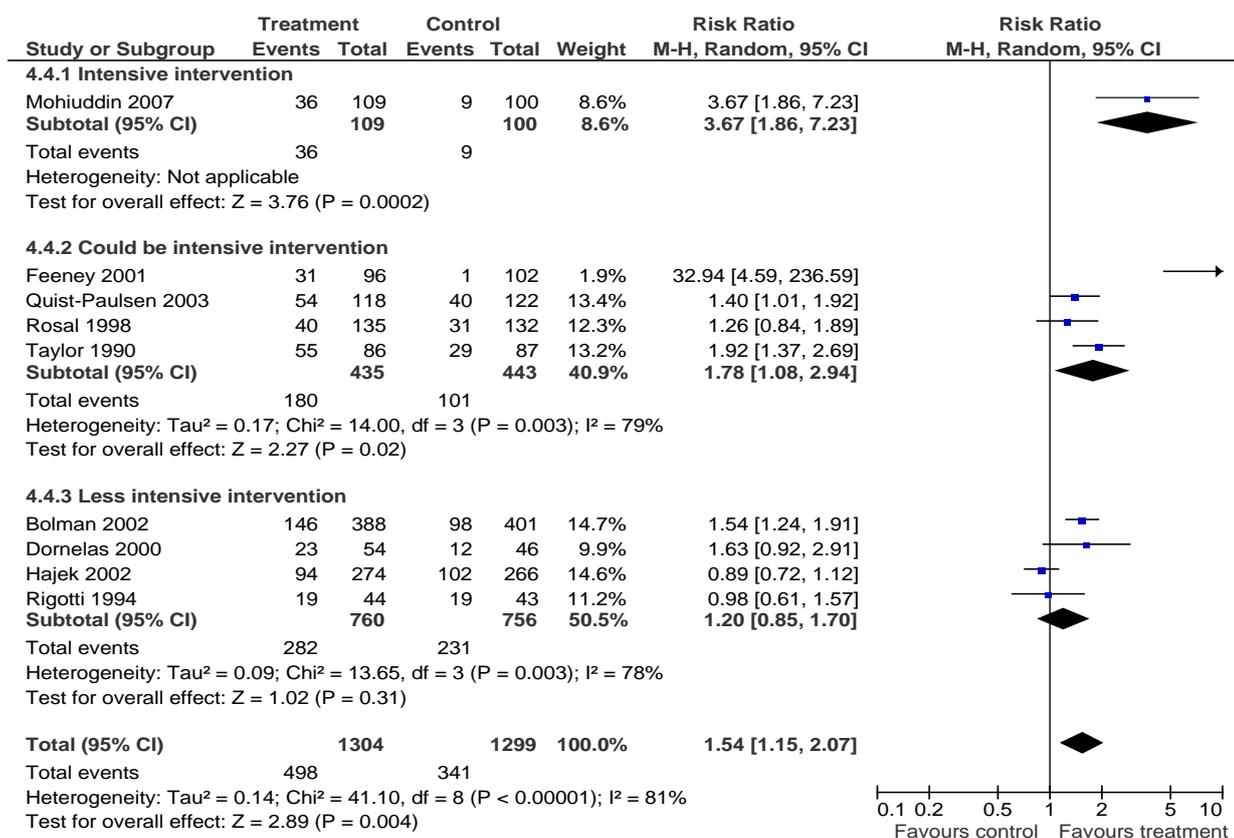


Figure 5.9: Continuous smoking cessation intervention intensity subgroup analysis

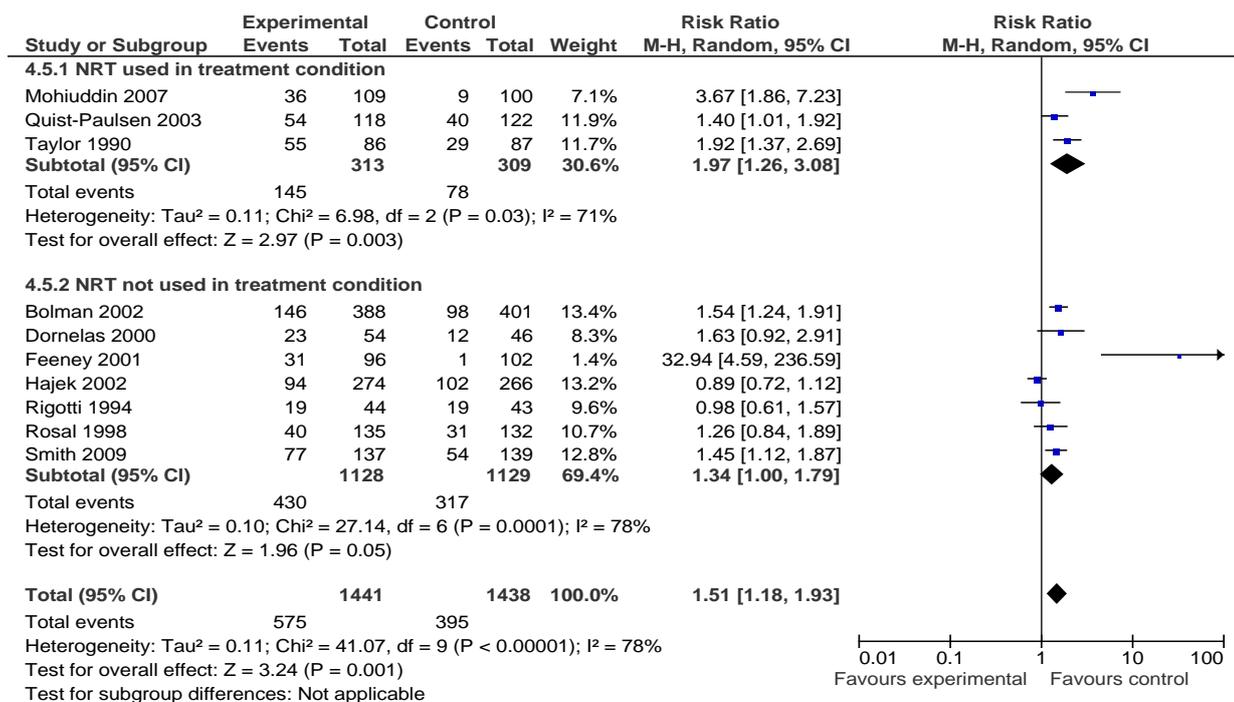


Figure 5.10: Continuous smoking cessation use of nicotine replacement products subgroup analysis

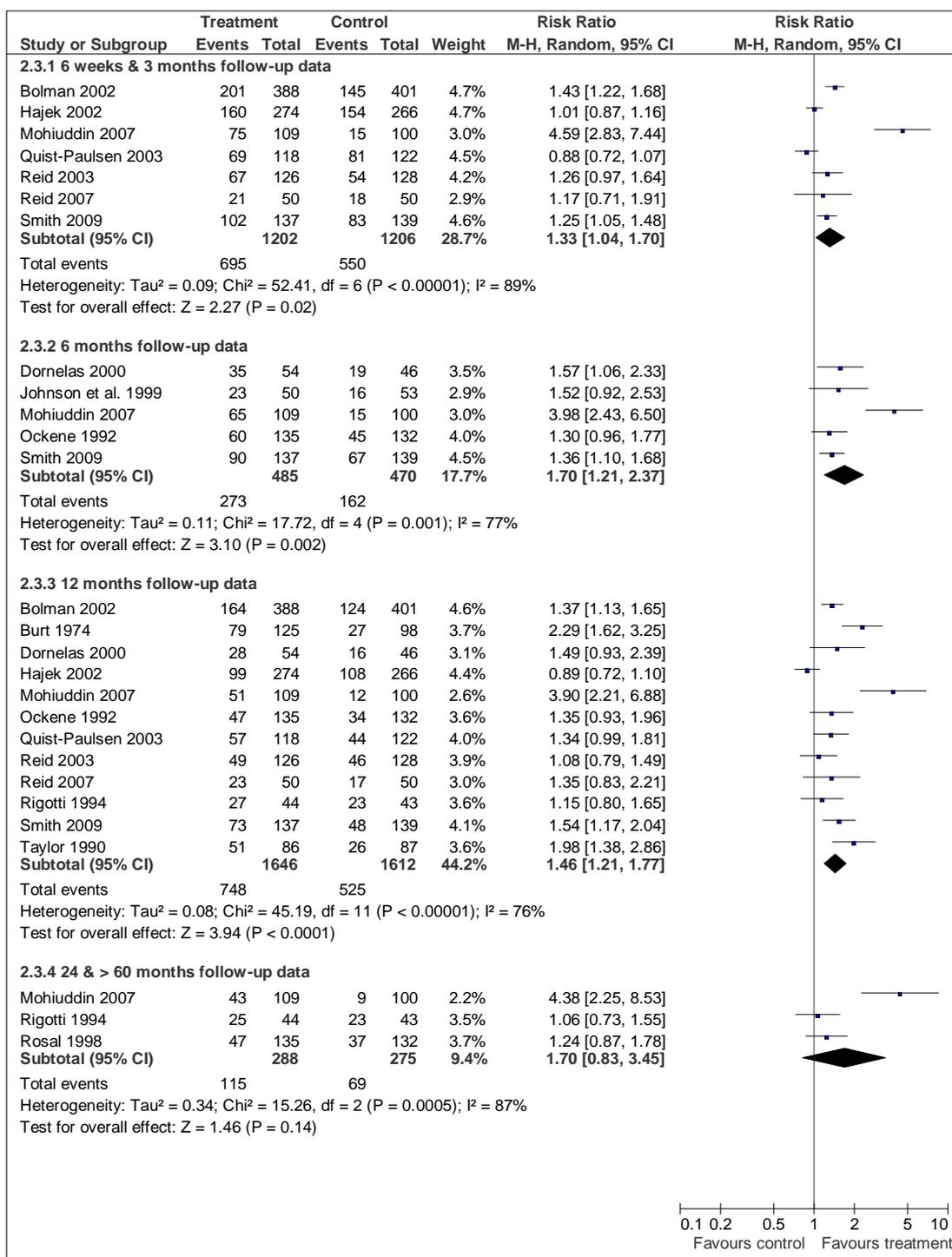


Figure 5.11: Point prevalent smoking cessation analysis results for length of follow-up

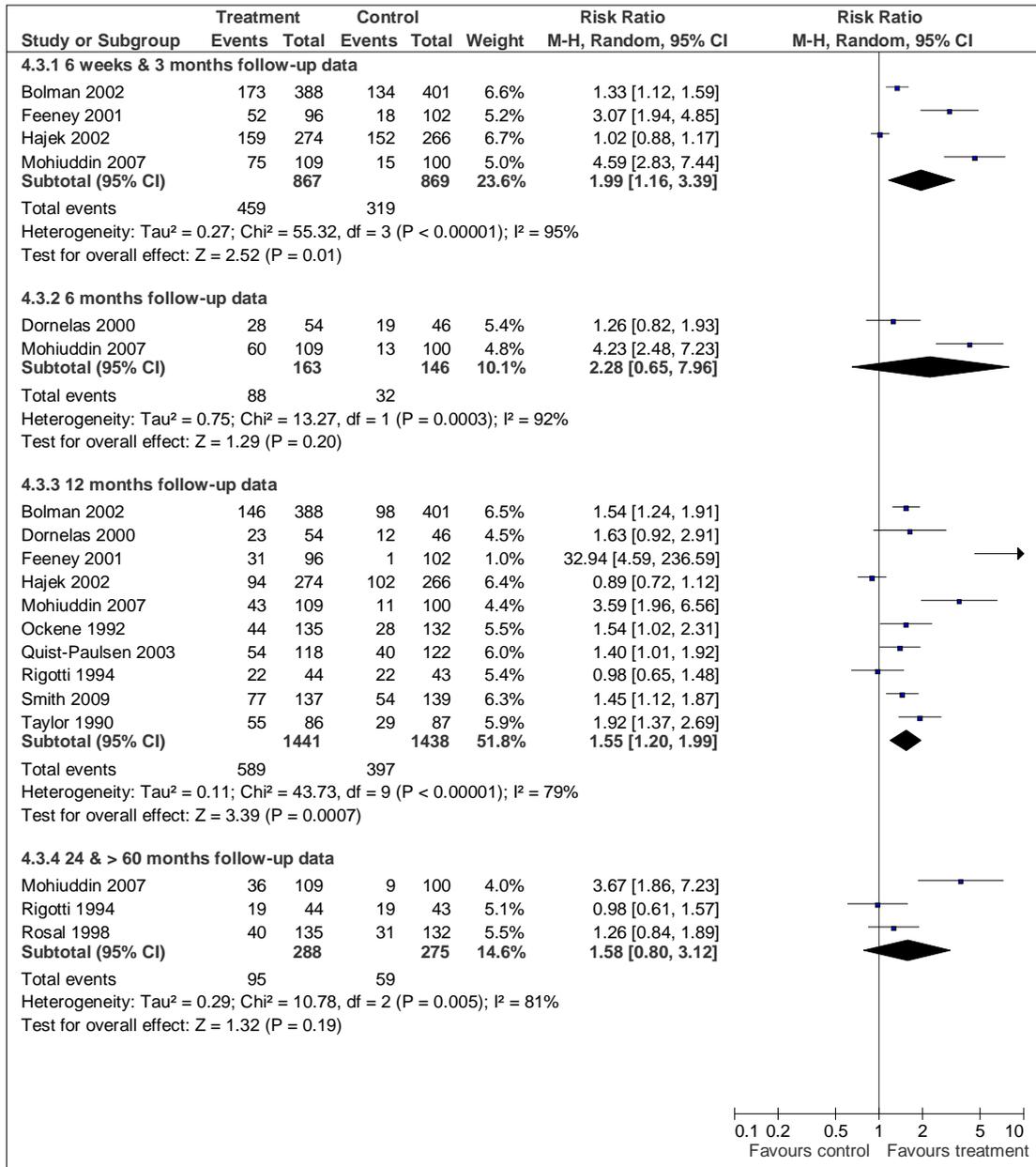


Figure 5.12: Continuous smoking cessation analysis results for length of follow-up

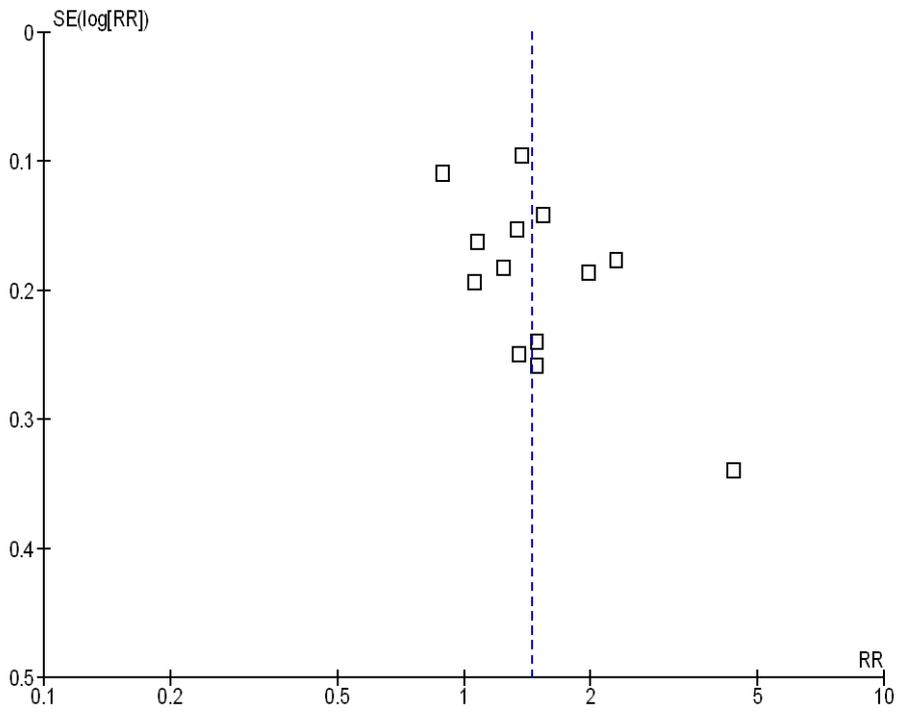


Figure 5.13: Funnel plot for point prevalent smoking cessation outcome

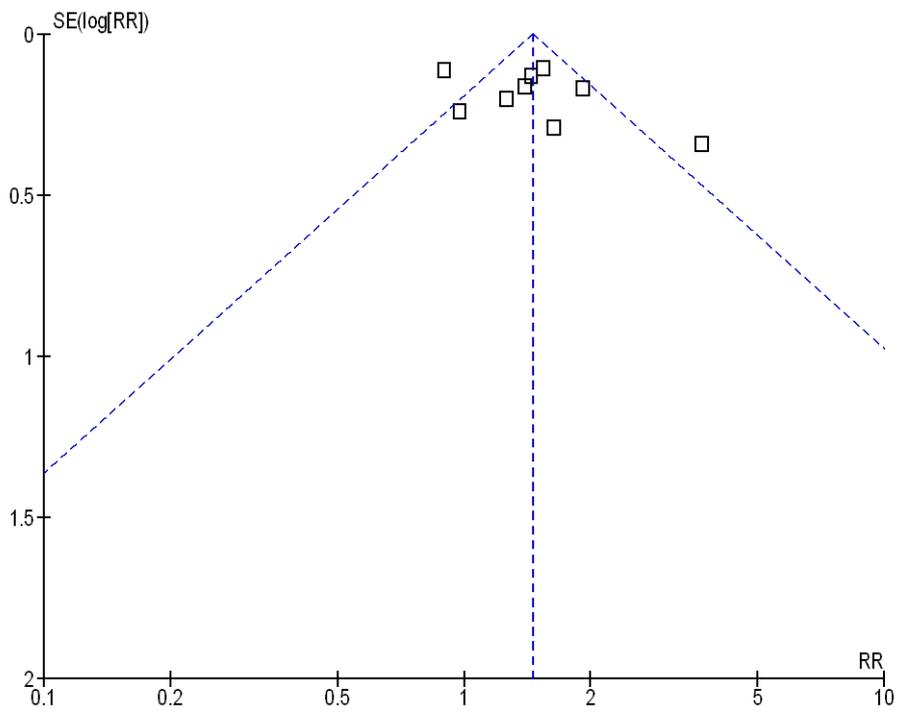


Figure 5.14: Funnel plot for continuous smoking cessation outcome

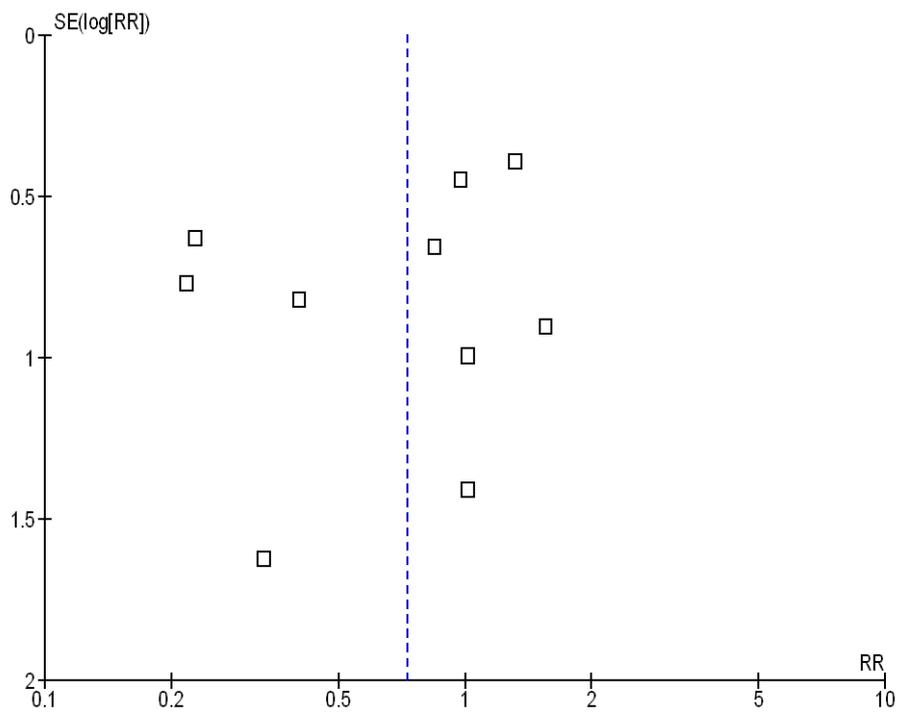


Figure 5.15: Funnel plot for total mortality outcome

Chapter 6

An examination of mechanisms of trial interventions included in the systematic review and meta-analysis of psycho-educational smoking cessation in interventions for coronary heart disease patients

6.1 Introduction

The results from the systematic review and meta-analysis of psycho-educational smoking cessation interventions for coronary heart disease patients showed that interventions increased smoking cessation statistically significantly, and statistically non-significantly decreased mortality. However, the review and the meta-analysis added only a limited amount to knowledge of the intervention mechanisms. The topic of the systematic review and meta-analysis was refined after the scoping review suggested that number of psycho-educational cardiac rehabilitation interventions for coronary heart disease patients and differences between the interventions may unnecessarily complicate testing an innovative approach to investigation of intervention mechanisms. However, even within the more narrowly defined group of psycho-educational smoking cessation interventions for coronary heart disease patients, complexity of these interventions caused difficulties in meta-analysis through significant amount of heterogeneity detected in analysis, which was examined in the post-hoc subgroup analyses.

The post-hoc subgroup analyses indicated that the explicit use of theory in intervention planning was not associated with increased intervention effectiveness. However, it is likely that investigating the mechanisms and techniques related to the intervention instead of the explicitly expressed theories underpinning interventions may be more informative. Complexity in the psycho-educational smoking cessation interventions made it difficult to inform practice of potentially effective intervention mechanisms and techniques, as none of the interventions were the same. Although the results of the meta-analysis indicated that, overall, psycho-educational smoking cessation interventions are effective, it is important to understand the actual causes of the effectiveness of an intervention.

If psycho-educational smoking cessation interventions for coronary heart disease patients are considered from the background of how the Medical Research Council (e.g. , 2008) defines intervention complexity, then, apart from investigating overall intervention effectiveness, different interconnecting parts of the intervention should also be investigated to fully understand how an intervention caused its effects. However, evaluating how interactions between different components of an intervention have influenced intervention outcomes may not be feasible or practical because of the complexity and lack of the relevant data. The results indicated that the studies included in the meta-analysis did not report material that would have facilitated analysing interconnecting parts of the interventions. On the other hand, if psycho-educational smoking cessation interventions for coronary heart disease patients are also considered in the terms of Hawe et al. (2004), so that although interventions differ from each other, they all share a common aim, namely reducing smoking among a specified group of people. Therefore, even though it may not be possible to investigate how different elements outside of the immediate intervention and its implementation may have influenced its outcomes, available information in the research papers allows examination and comparison of intervention components and techniques. Understanding similarities and differences between complex interventions that share a common intervention may improve practical application of meta-analysis result in the form of more detailed advice of potentially effective intervention features.

The analysis described in this chapter aims to investigate similarities and differences between the studies in used behaviour change techniques and targeted behavioural determinants. According to Michie et al. (2008) and Michie et al. (2005), there are 11 key behavioural constructs, or behavioural determinants, that can be used to explain behaviour. These behavioural determinants may be influenced by behaviour change techniques. To achieve a better understanding of mechanisms of interventions evaluated in the meta-analysis, these interventions are re-analysed using a framework developed by Michie et al. (2008). This empirical study includes number of research question as detailed next. The principle question is that does applying the framework developed by Michie et al. (2008) to trial interventions achieve a greater and more in-depth understanding of such intervention mechanisms? If the results from the first

analysis are used as a comparison point, how far may interventions appear as compatible with established theoretical models and how theories have conceptualised how behaviour can be influenced? The analysis aims to test the question of whether, by using this method, it may be possible to achieve findings that might better inform the planning of a complex intervention. This study will also evaluate the practicability of the proposed approach to evaluation of an intervention and discuss issues associated with difficulties in evaluating intervention mechanisms retrospectively and possible implications to practice. Parts of this Chapter have been published in Huttunen-Lenz et al. (2010).

6.2 The analytical framework for linking behavioural determinants to intervention mechanisms and techniques

Statistical methods, such as meta-regression, are available, for example, for testing associations between intervention techniques and outcomes. However, purpose of this study is not to statistically investigate intervention techniques or mechanisms. Instead, it is aimed in systematic examination and comparison of what kind of intervention techniques and mechanism have been used in a set of interventions that, according to meta-analysis results, are effective in achieving desired behaviour changes. As no statistical analysis was planned, the challenge for this study was to find an analytical framework that would allow systematic examination of intervention techniques and theories. In the Chapter 2 several qualitative research methods which may be suitable for investigating complex health care interventions were discussed. However, though for example narrative analysis could be used to describe intervention techniques, none of the earlier described qualitative approaches, offered an analytical framework that would be suited for a replicable secondary analysis of intervention techniques and mechanism.

The framework linking behavioural determinants to intervention techniques described by Michie et al. (2008) was chosen as the analytical framework for this study. In the contrast to other qualitative or quantitative analysis methods, the framework by Michie et al. (2008) was not developed for analytical purposes but to offer guidance for intervention designers on how techniques informing interventions may be linked to theory. Although Michie et al. (2008) pointed out that their work

needs further refinement and is developed for designing interventions, their approach to linking theories to intervention techniques offers a systematic way of retrospectively evaluating the mechanism of complex interventions for behaviour change.

6.2.1 Development and rationale for using the framework by Michie et al. (2008)

Michie et al. (2004) suggested that while including theory in design of behaviour change interventions may be useful, theory in itself offers only limited guidance to designing interventions. They point out that according to the Medical Research Council Guidance for development of complex interventions (Campbell et al., 2000) starts with a theory-building phase and then progresses to a modelling phase. The modelling phase requires both hypothesising and testing what is targeted (i.e. behavioural determinants) and how this is done (i.e. techniques to change behavioural determinants) (Campbell et al., 2000, Michie et al., 2008). Michie et al. (2008) advanced three main reasons for using theory in an intervention design. Interventions are more likely to be effective if they aim for causal behaviour determinants and behaviour change. However, doing this requires that the causal determinants, or theoretical mechanisms of change, are understood. Unless interventions are theoretically informed, it is not possible to develop and test theories underpinning interventions. Further, interventions that are explicitly based on theory better promote understanding of those intervention features that work, and form a basis for developing improved theory across different settings, people, and behaviours.

Michie et al. (2008) argued that apart from the Social Cognitive Theory (Bandura, 1977 in Michie et al., 2008), there exists little information and guidance on how to develop theory-based interventions and progress through the early phases of the Medical Research Council (2000) framework for complex interventions. Hardeman et al. (2005 in Michie et al., 2008) suggested a causal modelling approach in which behaviour change is caused by targeting behaviour determinants, which can be identified from different behaviour theories. Further, evidence-based behaviour change techniques can be directed to identified behavioural determinants, and their effectiveness in changing behaviour tested (Michie et al. 2007 in Michie et al., 2008).

Michie et al. (2008) argue that being able to effectively map theoretical constructs to behaviour change techniques requires addressing the problems of; large number of available theoretical frameworks; specifying the number of available techniques to change behaviour; and advance a system for how the relevant techniques can be mapped to different behavioural determinants.

Michie et al. (2008) suggested that intervention designers should ideally be able to choose a small number of theoretical frameworks that are shown to be able to predict behaviour and interventions that change the specified behavioural determinants, which influence behaviours. However, Michie et al. (2008) argued that lacking such an information, finding a systematic approach to simplifying potential behavioural determinants would be useful. Although based on expert opinions, two independent attempts, which show good agreement, have been published to address this problem (Fishbein et al., 2001 & Michie et al., 2005a in Michie et al., 2008). Table 6.1 is adapted from Michie et al. (2008) and Michie et al. (2005) and shows the key behaviour determinants as suggested by Michie et al. (2005) with descriptions and comparison to those with Fishbein et al. (2001 in Michie et al., 2008).

Building on their previous work, Michie et al. (2008) developed a procedure for selecting appropriate intervention techniques and mapping them to the relevant behavioural determinants. Michie et al. (2008) argued that mapping of appropriate behaviour change techniques to the behavioural determinants is essential for fully achieving the intended benefits of theory-based interventions. Michie et al. (2008) developed a list of techniques and definitions by brain storming (10), reviews (35) and consulting textbooks (92). The agreement between Michie et al. (2008) for the techniques extracted from text books was 74.4%. Using the initial set of 35 behaviour change techniques without definitions, though definitions were later agreed, Michie et al. (2008) independently evaluated would they use the techniques as a part of an intervention to change each of the determinants. Michie et al. (2008) used a rating scale blank = no; 1 = possibly; 2 = probably; 3 = definitively.

Ratings by the researchers were categorised depending on the achieved consensus, resulting behaviour change techniques to be rated as “agreed use”, “agreed non-use”, “disagreement” and “uncertain”. The overall agreement between the researchers was

71%. ‘Agreed use’ and ‘agreed non-use’ designate agreement by Michie et al. (2008) on either the suitability or non-suitability of a technique to influence a behavioural determinant, “disagreement” meant that this technique had been evaluated both suitable and unsuitable, while “uncertain” meant that evaluators were uncertain about a technique’s effectiveness. Table 6.2 is adapted from Michie et al. (2008) and shows the 35 intervention techniques rated by Michie et al. (2008). In Table 6.2, those interventions that were rated as “agreed use” are marked with an X against the appropriate behavioural determinant/s.

6.2.2 Issues arising when using the framework in retrospective evaluation of behavioural determinants and intervention techniques

Michie et al. (2008) develop their framework to improve the effectiveness of an intervention planning by making it explicit which behaviour change techniques are considered effective for changing which behavioural determinants. While this framework is intended to be used for an intervention planning, it is suggested that it may be applied retrospectively to interventions in a meta-analysis, to be used to clarify intervention features and mechanisms. However, using this framework retrospectively raises some important issues that should be considered when interpreting the results of an analysis. Firstly, the work by Michie et al. (2008) is based largely on expert judgements and consensus about the ability of techniques to change the given behavioural determinant, and at present there is only limited empirical evidence about the effectiveness of the techniques. Moreover, the behavioural determinants against which the intervention techniques are evaluated are based on an expert consensus and are a simplification of potential behavioural determinants. Therefore, it is possible that the behavioural determinants as suggested by Michie et al. (2008) may be an oversimplified, or indeed an unnecessarily complicated, representation of behavioural determinants, and thus do not allow adequate evaluation of potentially targeted behavioural determinants.

Another weakness of using the approach by Michie et al. (2008) is that it only makes ratings available for 35 of the intervention techniques that they listed, which means that there is no expert guidance available to help in judging techniques suitability for changing behavioural determinants for the majority of the listed intervention

techniques. However, although not explicitly stated, it appears that the 35 techniques that have been evaluated using expert consensus are frequently and commonly used behaviour change techniques in practice. Michie et al. (2008) reported identifying 35 of the intervention techniques from 2 separate reviews (Hardeman et al., 2000, Abraham and Michie, 2008), which have reviewed available behaviour change techniques. In addition Abraham and Michie (2008), aimed establishing agreed definitions from the literature for number of the behaviour change techniques, whereas Hardeman et al. (2000) systematically reviewed published interventions that aimed to prevent weight gain. Therefore, it appears that the selected 35 behaviour change techniques form an established selection of behaviour change techniques that are frequently used in practice and offer a reasonably well defined group of techniques to form a base of the further work by Michie et al. (2008). However, as Hardeman et al. (2000) pointed out, effectiveness of interventions varied, and as only few of the studies were randomised controlled studies, it was not possible to form definite conclusions of which elements of the interventions were associated with increased effectiveness.

6.3 Overview of three common theoretical models of behaviour change

Michie et al. (2008) have listed a number of behavioural determinants that can influence the forms of behaviour an individual engages with. However, the number of theoretical models that are commonly used in the field of health psychology and more generally among developers of behaviour change interventions, describe how behaviour can be predicted and what determines behaviour. The following three theoretical models are briefly outlined: the social cognitive theory or social learning theory; the transtheoretical or stages of change model; and the protection motivation theory. These three theoretical models were selected because they appeared to have been used in designing some of the interventions included in the meta-analysis.

6.3.1 Social cognitive theory or social learning theory

Social cognitive theory (Luszczynska and Schwarzer, 2005) assumes that an individuals' motivation and actions are regulated by a forethought. Social cognitive theory (Figure 6.1) emphasises the role of self-efficacy and cognitions in behaviour,

and, according to the theory, behaviour change is possible if individuals have a sense of control over the targeted behaviour. Self-efficacy is a central part of the social learning theory, and describes individuals' beliefs of their capabilities to perform a specific behaviour in order to reach a desired goal. In addition to self-efficacy, outcome expectations are the other key construct of social cognitive theory, which are used to refer to beliefs of consequences of actions. The expected outcomes may be physical (e.g. bodily changes), social (e.g. reactions from others) or self-evaluative (e.g. how one feels about oneself). These can be set alongside socio-structural factors that inhibit or facilitate behaviour, self-efficacy and the effect of outcome expectancies on how behavioural goals are set and pursued. (e.g DiClementa and Procheska 1983 in Sutton, 2005).

6.3.2 The transtheoretical or stages of change model

The transtheoretical model (Figure 6.2) is particularly often applied in smoking cessation interventions (Sutton, 2005). The transtheoretical model is constituted from several constructs, which are self-efficacy (confidence and temptation), decisional balance (positive and negative consequences of change), and the process of change itself. These different constructs of the model are organised around the stages of change principle, which means that the transtheoretical model assumes that people process through the stages in a certain order, but that relapses to the earlier stages can happen. Three of these stages, pre-contemplation, contemplation, and preparation are considered as pre-action stages and two of the stages; action and maintenance, as post-action stages. In the transtheoretical model, the process of change describes those activities that people engage in to progress through the stages, such as a stimulus control (e.g. aiming to control smoking triggers) (Rogers, 1975 in Norman et al., 2005).

6.3.3 Protection motivation theory

Protection motivation theory (Figure 6.3) describes how fear appraisals impact behaviour (Norman et al., 2005). As fear and threat are unpleasant emotions, protection motivation theory proposes that communications that induce fear can change behaviour and attitudes toward a behaviour. According to this theory,

behaviour change is based on an individual's aim to lessen the emotional impact of a fear or threat by behaviour change (Hovland et al., 1953 in Norman et al., 2005). A fear appraisal and its effectiveness, however, depend on the impact of three main variables, which are described as magnitude of the fear or threat, the probability of outcome without behaviour change, and efficacy of the proposed solution (Rogers, 1975 and 1983 in Norman et al., 2005). The probability of engaging in a protective behaviour is dependent on beliefs of response efficacy, i.e. perceived effectiveness of the behaviour to lessen the threat, and of self-efficacy, i.e. an individual's perceived capacity to perform the behaviour. Although beliefs of response- and self-efficacy increase the likelihood of the behavioural response, response costs like availability of resources, may hinder the actual performance. Protection motivation, or the actual behavioural intention to perform the behaviour to avoid the feared outcome, is a result of individuals' perceptions of effectiveness of the behaviour and their capabilities of performing it (Norman et al., 2005).

6.4 Methods

The same 14 studies of the effectiveness of psycho-educational smoking cessation interventions for coronary heart disease patients that were included in the meta-analysis described in the previous chapter were included in this analysis. The analysis was based on the available intervention descriptions in the articles, and information received from the authors in the earlier systematic review. Only the experimental interventions were analysed, as it was judged non-productive at this stage to analyse the control interventions or compare them to the experimental interventions. It is recognised that when comparing for example, the effectiveness of one or more drug combined with exercise training, it is important to specify with what this interventions is being compared to. As an example, is it compared to an intervention with no drug or with no intervention? However, the present analysis does not aim to establish the effectiveness of individual interventions compared to control conditions, or indeed the overall effectiveness of interventions, as this was established in the previous chapter. This analysis aims to investigate techniques used in the different interventions, not to compare them with control conditions. Further, even after contacting authors for additional information, limited information of the control conditions would have in many cases prevented a meaningful analysis.

Another problem that also confronts the meta-analyses of complex interventions is the variety of interventions used in both treatment and control conditions, which makes defining what precisely is being compared to what, very difficult. A further difficulty for including control conditions in the present analysis was the uncertainty about how the results of control condition analysis should be included. Should interventions and control conditions be compared, study-by-study, to establish whether there are any differences between the two conditions, and could considering this indicate any reasons for study results being significant or non-significant? Alternatively, should all results be pooled, so as to establish any differences in patterns between control and treatment conditions? In the event, it was judged that due to lack of comprehensive descriptions of the control conditions and a lack of guidance for this kind of an analysis, that at this stage, only treatment conditions would be analysed and compared to each other.

Analyses of behavioural determinants and behaviour change techniques was based on intervention descriptions obtained from published articles and from information provided by the study authors. Initially the analyses were done without any reference to the theoretical frameworks that the studies had used in the intervention planning. In the later stages of the analyses behavioural determinants estimated to have been targeted in the studies were compared to those set out in the three theoretical models described earlier (Figures 6.1, 6.2, 6.3). Data were extracted and analysed by the author only, as there were no resources available for duplicating data extraction and analyses. All stages of the analysis have therefore been done as transparently as possible, and Tables 6.3 and 6.4 show in detail how analyses progressed and their results.

Analyses were done by reading and re-reading the intervention descriptions in the published papers and any additional information provided by authors (Table 6.5). Data collection and analyses were performed concurrently, comparing the intervention descriptions to the Michie et al. (2008) lists of behavioural determinants and behaviour change techniques. A data grid (Table 6.3) was created that specified what if any theoretical model had been used in the intervention design, intervention components as described by the authors, behavioural determinants, and intervention techniques. During the data collection and analysis, it was marked down whether the

available information was judged as offering reasonably clear presentation about potentially-targeted behaviour determinants and behaviour change techniques, or whether the information was derived from the intervention descriptions (Table 6.3).

The data collection and analysis was done in two main stages, so that after extracting the key behavioural determinants from the studies, behaviour change techniques used were evaluated by comparing the intervention descriptions to the 137 potential behaviour change techniques set out by Michie et al. (2008). The extraction of behavioural determinants and behaviour change techniques was undertaken so that if an intervention description stated that health care professionals advised participants about health consequences of smoking cessation, this could be seen to be categorised as targeting knowledge. In the same way, behaviour change technique would be listed as behavioural information (Table 6.3). In order to make the analysis as transparent as possible, in the data grid (Table 6.3.) an intervention component or other relevant feature of an intervention that was used to derive the intervention techniques is shortly described in the brackets. Evaluation does not explicitly include use of pharmacological smoking cessation aids, as pharmacological techniques are not explicitly covered by the Michie et al.' (2008) framework. It should be remembered, however, that the meta-analysis described in the Chapter 5 indicated some benefits for pharmacological smoking cessations aids.

However, it is recognised that as in many cases the evaluation was based only on the information available in the articles, there may be misconceptions and omissions due to this information being incomplete and potential misjudgements of what the study authors' original intentions may have been. Finally, the suitability of the behaviour change techniques to change behavioural determinants was evaluated using the classification from Michie et al. (2008). In this analysis, each of the behaviour change technique evaluated to have been used in a study was evaluated against the expert consensus table produced by Michie et al. (2008) of the techniques effectiveness to change the behavioural determinants (Table 6.3). To simplify the analysis, each technique was evaluated only against one of the Michie et al.'s (2008) ratings, namely the "agreed use", i.e. all of the experts had agreed that the particular technique is effective in targeting the specified behavioural determinant (Table 6.2). In other words, each technique extracted from the intervention descriptions was

classified as (potentially) effective only in cases where all expert ratings in Michie et al. (2008) agreed. In this analysis, each individual behaviour change technique estimated to have been used in an intervention was evaluated against all the behavioural determinants that were estimated to have been targeted by the intervention. This analysis aimed to investigate whether behaviour change techniques used in an intervention can potentially influence any of the behavioural determinants that were targeted. It was not intended to estimate which specific intervention technique/s were designed to influence which behavioural determinants.

After concluding the main analyses, an additional analysis was conducted in eight of the studies to investigate how the theoretical models that had been either reported to have been deployed in intervention planning t, or where the intervention description closely matched a theoretical frame work, may have corresponded with the estimated behavioural determinants (Table 6.4). This analysis was done by comparing the behavioural determinants evaluated in this study to those behavioural determinants specified by the three theoretical models discussed previously (Figures 6.1, 6.2, 6.3). Those studies that did not report using any specific theoretical framework in intervention planning were also evaluated by comparing how estimated behavioural determinants and behaviour change techniques differed between studies that had or had not mentioned an explicit theoretical framework for the intervention.

6.4.1 Contacting authors after completing the analyses

A further attempt to verify the analyses was done by contacting all the study authors after the analyses were completed. The study authors were asked to verify whether or not the analyses of intervention components, behavioural determinants, and intervention techniques reflected their original intentions. Every corresponding study author was sent an e-mail which included descriptions of both the experimental and the control intervention, which had been extracted from the papers and used in the analyses. Authors were asked if they could confirm (yes/no) whether the descriptions were accurate, and add any details that they wished. Finally, the analyses results for intervention components, behavioural determinants, and intervention techniques were presented, and the authors were asked to indicate if they agreed or not with the

analysis results. Information received from authors is included in the appropriate tables and clearly marked as such (e.g. Table 6.5).

6.5 Results

6.5.1 Analysis of behavioural determinants and behaviour change techniques

While a superficial survey of the intervention descriptions suggested that interventions differed considerably from each other's, the analysis of the behavioural determinants and behaviour change techniques indicated some significant similarities between the studies in the methods that were employed to change smoking behaviour. The analysis suggested that the studies appeared to target only eight of the 11 behavioural determinants as listed by Michie et al. (2008). Results indicated that all interventions aimed to influence smoking behaviours through participants' motivation and goals, i.e. by increasing their motivation to stop and by encouraging setting long term smoking cessation as a behavioural goal. Twelve of the interventions were assessed as targeting beliefs about capabilities and skills to be able to succeed in smoking cessation, while 11 of the interventions appeared to target participants' knowledge about effects of smoking, and the positive effects of smoking cessation to health. Social influences were targeted in seven of the interventions, often in form of a family support, while five interventions aimed to influence smoking behaviours through beliefs about consequences of continued smoking. The two least targeted behavioural determinants appeared to be action planning and emotions. Only two of the interventions were assessed to aim to change smoking habits via action planning and only one intervention was evaluated to target participants' emotions. Tables 6.3 and 6.4 presents in detail which studies were assessed as having targeted which behavioural determinants.

It was noted, however, that there were considerable difficulties in evaluating when interventions were targeting action planning instead of skills. This difficulty arose from at least superficial similarities between action planning and skills, when it became problematic to decide whether smoking behaviour was attempted to influence by participants' skills to be able to continue smoking cessation or by planned actions of how to deal with, for example, smoking triggers. Therefore, after

careful consideration, it was decided to record action planning only when it was actually mentioned in the intervention. This, however, does not mean that elements of action planning would not have been present in any of the other interventions, but generally this was not explicitly stated. In addition, none of the studies was assessed to trying to change smoking behaviour through social/professional role and identity, memory attention and decision processes, or environmental context and recourses. However, especially for memory, attention and decision processes, it is very likely that all the interventions have targeted this construct at some level, but this was found to be very difficult to evaluate from available information. Therefore, it was decided not to include memory construct in the analysis, but keep it in the mind that these processes have an important role in successful smoking cessation.

While Michie et al. (2008) listed 137 potential behaviour change techniques, only 15 of these techniques were found to have been used across the studies. This result may be somewhat surprising, as it suggests that interventions may differ from each other less than expected. The results suggest that the most commonly used behaviour change techniques were: standard (e.g. setting behavioural goal such as smoking cessation), monitoring (e.g. following-up participants progress), behavioural information (e.g. information about implications of continuing smoking or quitting smoking), relapse prevention (e.g. preventing return to smoking), and planning (e.g. specific strategies of how smoking triggers can be managed). Less used behaviour change techniques appeared to be: social support (e.g. involving family in the intervention), personalised message (e.g. intervention components tailored to participant needs), feedback (e.g. information of progress), and relaxation (usually muscle relaxation). The analysis showed that the least commonly-used behaviour change techniques were: contract (e.g. written agreement to stop smoking); fear arousal (e.g. causing fear of consequences of continuing smoking); verbal persuasion (e.g. persuasive message to stop smoking usually by a professional); coping strategies (e.g. how to avoid or reduce stressors); and motivational interviewing (e.g. trying to motivate participants to smoking cessation attempt). The results of this analysis study-by-study are presented in the Table 6.2.

As discussed previously in the context of evaluating behavioural determinants targeted in the studies, assessing behaviour change techniques faced similar

difficulties. It was usually complicated to divide planning from coping strategies, as both of these techniques involve forward planning, in this case, how to cope in high risk smoking situations. As coping strategies were not directly mentioned in most of the studies, the decision was reached to assess behaviour change technique as coping strategy only when this was clearly evident from the text. Again, as mentioned previously, this does not indicate that elements of coping strategy training would not have been present in many of the studies, but that this was difficult to evaluate based on the available information.

Although it was aimed to ensure that coding of the interventions was as transparent as possible, it is not possible to conclusively ascertain that the similarities between studies are not result of the way they were coded. Therefore, all corresponding authors were contacted with detailed analyses results of their own study and asked to confirm and comment whether or not the analyses offered fair representation of the original intervention. Six of the authors responded to the information request. One of these authors, Smith (Smith and Burgess, 2009) is on a sabbatical leave, and another, Hajek (Hajek et al., 2002), was not able to recall the information after number of the years. Four of the authors replied with detailed answers to the questions. Hilleman (Mohiuddin et al., 2007), Bolman (Bolman et al., 2002b), and Johnson (Johnson et al., 1999) confirmed that they agreed with the analyses and did not add any further intervention components, behavioural determinants, or behaviour change techniques. Rigotti (Rigotti et al., 1994) reported that regarding intervention components family involvement was not recalled, and did not agree with listing telephone follow-up as an intervention component. Equally, Rigotti (Rigotti et al., 1994) disagreed including telephone follow-up as a form of monitoring in the intervention techniques, but agreed with all the listed behavioural determinants. Information from authors has been also incorporated in the Table 6.3.

One of the study authors, Bolman (Bolman et al., 2002b), added also information to experimental intervention description. Bolman (Bolman et al., 2002b) pointed out that nurses were instructed to call patients two weeks after the discharge to inform about the quit attempt. Further, Bolman (Bolman et al., 2002b) added that not all required steps were carried out, non-adherence occurred especially to the aftercare by both nurses and cardiologists. Table 6.4 includes intervention and control condition

descriptions, with additional information received from authors highlighted. The information received from authors indicated that using the intervention descriptions available in the published papers provided sufficient information for analysing experimental conditions. However, information available for the control conditions was limited, and requests for the authors did provide only limited amount of additional information, casting further doubts to feasibility of analysing the control conditions in this study alongside of the experimental conditions.

6.5.2 Results of the analysis of behaviour change techniques effectiveness to influence behavioural determinants

The potential effectiveness of the behaviour change techniques to influence behavioural determinants in the psycho-educational smoking cessation interventions was evaluated using the expert consensus of techniques effectiveness as reported by Michie et al. (2008). For this analysis behaviour change techniques were evaluated as potentially effective only in the cases where there was an expert consensus of technique's effectiveness to influence behavioural determinant/s (Table 6.2). The main analysis, as discussed above, indicated that all interventions appeared to target a number of behavioural determinants, and used multiple techniques to achieve the desired behaviour change. As there was no possibility to specify which of the techniques would have originally been aimed to influence which behavioural determinants, behaviour change techniques potential effectiveness was evaluated for each of the behavioural determinant that was estimated to have been targeted in the study. This analysis was, nevertheless, able to indicate which techniques may have been more effective across the targeted behavioural determinants than others. The results of this analysis are summarised in the Table 6.4.

6.5.2.1 The most frequently used behaviour change techniques in the interventions

Setting a standard, or a behavioural goal, was used in all interventions and has been evaluated as an effective technique to target the following behavioural determinants: motivation and goals, skills and action planning. A standard as a behaviour change technique appeared easy to use and was often made use of by explicitly stating the intervention aim. Monitoring, which was employed in the majority of studies usually

in form of a follow-up, has been assessed as an effective technique to influence participants skills. Planning has been judged effective to change only one behavioural determinant, namely action planning, which was explicitly targeted in only two of the studies. Interventions appeared to have been using planning as a strategy preparing participants on how to deal with smoking triggers after initial cessation. Behavioural information was also a technique adopted in most of the studies, and tended to contain information about smoking and its effects on coronary heart disease. Offering behavioural information has been evaluated as an effective technique in targeting the behavioural determinants of motivation and goals, beliefs about consequences, and knowledge.

Six of the studies had used social support as a behaviour change technique, which has been judged as an effective technique to influence participants' motivation and goals, beliefs about capabilities and social influences. However, there were differences between the studies in how social support was offered, as some involved participants' family while others offered support from an intervention team. Relapse prevention, which was mentioned in majority of the studies, has not been judged as an effective technique to change any of the behavioural determinants targeted in the studies. Questions were, however, raised about what relapse prevention constitutes of. While studies tended to explicitly mention relapse prevention, this was usually followed by description of what it includes, such as planning how to deal with smoking triggers. Therefore, although the results suggest that relapse prevention as such is not an effective behaviour change technique, it may be productive to investigate what techniques are used to prevent relapse, rather than being restricted to the use of the phrase "relapse prevention".

6.5.2.2 Less frequently used techniques

While a fear arousal was employed in only two of the interventions, both of which emphasised consequences of continuing to smoke for the progress of coronary heart disease, fear arousal has been evaluated as an effective technique to target motivation and goals, beliefs about consequences and knowledge. Feedback, usually information about smoking cessation progress, was used in three of the studies and has been evaluated effective in targeting beliefs about consequences and beliefs about

capabilities. Making a contract, in this case an agreement to stop smoking, was used as a behaviour change techniques in two of the interventions, and is seen as an effective technique to influence the following behavioural determinants: motivation and goals, knowledge, and action planning. A motivational interviewing was used also by only two of the interventions, but has nevertheless been judged an effective technique to influence beliefs about capabilities and consequences, and motivation and goals. Two of the behaviour change techniques, namely verbal persuasion and coping strategies had been used by one study each. It appears these techniques may be effective in targeting beliefs about capabilities and consequences, and apart from coping strategies, motivation and goals. Finally, two of the techniques used, relaxation and personalised message, were not evaluated to be effective techniques to influence any of the behavioural determinants targeted in the studies. No information was available in Michie et al. (2008) about the effectiveness of a buddy-system.

6.5.3 Results of the evaluation of effects of theory use in intervention planning to targeted behavioural determinants and behaviour change techniques

Those interventions that reported using a theoretical model in intervention planning were evaluated to be using one of the three broadly different theoretical approaches to behaviour change. These three approaches were: social cognitive theory, which is also known as the social learning theory; the transtheoretical model or stages of change model; and the protection motivation theory. Both the social cognitive theory and the transtheoretical model are commonly used theoretical frameworks in planning of a smoking cessation intervention. The studies by Bolman et al. (2002a, 2002b), Smith and Burgess (2009) and Taylor et al. (1990) were classified as basing their interventions on the social learning theory. While Smith and Burgess reported that their intervention is based on Marlatt and Gordon's relapse prevention model (Collier and Marlatt, 1995), it appears that the model is based on the theories of social learning and self-efficacy, and could be for the purposes of this analysis to be investigated under social learning theory. Four of the studies were identified as having used the transtheoretical or stages of change model in their intervention design (Dornelas et al., 2000, Mohiuddin et al., 2007, Reid et al., 2003, Johnson et al., 1999). One of studies, Quist-Paulsen & Gallefoss (2003), did not name exact theoretical framework, but reported clearly that the intervention aimed to change

smoking behaviour by fear arousal. On closer evaluation, the fear arousal model used by Quist-Paulsen and Gallefoss is compatible with the protection motivation theory (Bandura 1977, 1997, 1992, 2000a, 2000b in Luszczynska and Schwarzer, 2005), which suggests that fear and threat can have a strong impact on behaviour, and the protection motivation theory was therefore used as a comparison point.

6.5.4 Effect of theory on targeted behavioural determinants

Results of the analysis suggested that overall those studies that had explicitly reported using a theoretical framework in the intervention planning appeared to target behavioural determinants that were compatible with theoretical assumptions of behaviour change. The studies by Bolman et al. (2002a, 2002b), Smith and Burgess (2009) and Taylor et al. (1990) that had reported using the social cognitive theory to guide intervention planning had all targeted motivation and goals, beliefs about capabilities and skills. However, while Bolman et al. (2002b) did not appear to target social influences, the two other studies did. Action planning, which was found difficult to evaluate, was assessed being targeted only in the study by Taylor et al. (1990). In retrospect it is appreciable that while Bolman et al. (2002a) based their intervention to theoretical frameworks that emphasise social influences, in the intervention description this does not clearly come forward. All four of the studies that had based their interventions on the transtheoretical, or stages of change, model targeted motivation and goals, and beliefs about capabilities. However, only Dornelas et al. (2000) did not appear to target either knowledge or skills, and social influences appeared to have been clearly targeted only by Reid et al. (2003). Quist-Paulsen & Gallefoss (2003) were evaluated to have based their intervention on protection motivation theory and so targeted motivation and goals, beliefs about consequences, knowledge, skills, emotion, and action planning, all of which fit relatively well with assumptions of protection motivation theory.

Comparing the studies that had explicitly reported using a theoretical model in intervention planning to studies that had not reported explicit use of theoretical models (or use of one could not be easily inferred) suggested only minor differences between these groups. Some differences were noted in the range of behavioural determinants targeted, so that while the “theory group” was estimated to have

targeted eight of the behavioural determinants the “no-theory” subgroup had been targeting only six of them. As the present analysis was based on intervention descriptions, it is not possible to ascertain why the differences between these groups were found to be minor. Finally, it was estimated which kinds of a theoretical models might be comparable with the interventions in the “no-theory” subgroup. The analysis indicated the intervention by Burt et al. (1974) might be compatible with the protection motivation theory, as the intervention stressed consequences of continuous smoking. As the study by Reid et al. (2003) had similarities to the other study by Reid et al. (2007), it was also in this instance assessed to as potentially compatible with the transtheoretical model. For the other studies (Feeney et al., 2001, Ockene et al., 1992, Rigotti et al., 1994, Hajek et al., 2002), it was not possible to decide whether they would be more comparable with the social learning theory or the transtheoretical model, as the interventions had features that were comparable with the both theories, or they could have been compatible with other theoretical frameworks, not considered in the present work. While these results suggested that including some theory in the intervention planning in this review did not have a major impact on the behavioural determinants targeted, some subtle differences were noticed in the use of behaviour change techniques. It appears that studies that included a theory in the intervention planning used different techniques more frequently and more universally than studies in the no-theory group. For example, social support, behavioural information and personalised message techniques have been used more frequently in the theory sub-group.

6.6 Discussion

While the statistical analysis presented earlier in Chapter 5 offered only limited information about intervention mechanisms and features, this retrospective analysis of behavioural determinants and behaviour change techniques using the framework provided by Michie et al. (2008), suggested there were considerable similarities between features of these interventions. The interventions included in this review tended to emphasise individuals’ responsibility for their smoking and aimed to improve smoking cessation via participants’ knowledge, skills and beliefs about their capabilities to stop smoking and continuing abstinence. Considering the available pool of behaviour change techniques (137) listed by Michie et al. (2008),

interventions deployed a limited number of techniques, all of which were relatively straightforward to apply in practice, to deliver to high numbers of people, and required limited staff training. The present analyses do not permit comment on whether the limited pool of behaviour change techniques in use reflects their comparative practicability or effectiveness. Analysing behavioural determinants and behaviour change techniques, however, raises practical considerations. As the pool of techniques deployed in the interventions was limited, it must be considered whether the results of the meta-analysis are only generalisable to smoking cessation interventions that use similar techniques than the interventions in this review. As this is the first attempt to analyse retrospectively behavioural determinants and behaviour change techniques in interventions, interpreting the evidence should be done with caution. What these results do indicate, however, is that relatively straightforward behaviour change techniques that are also comparatively easy to apply in practice can be effective in changing smoking behaviour. What separated interventions in this review was not so much the behaviour change techniques used or the behavioural determinants targeted but how behaviour change techniques were combined and applied in practice.

Psycho-educational smoking cessation interventions for coronary heart disease patients aimed most commonly to change smoking behaviour by influencing participants' motivation and goals, their beliefs about their capabilities to quit, knowledge about smoking and smoking cessation and improving smoking cessation skills. Fewer studies targeted participants beliefs about consequences of continuous smoking, social influences such as family members that smoked, emotions such as fear of the consequences, and action planning as ways to change behaviour. Results suggest that smoking cessation interventions target similar behavioural determinants, even without any reference to theoretical models. Results also indicate that interventions use very similar behaviour change techniques to increase smoking cessation, some of which appear not to be effective in changing targeted behavioural determinants. However, perhaps the most important finding was that including theory in an intervention planning may be helpful in designing interventions by making it explicit what different parts of the intervention are planned to achieve.

Difficulties were encountered in evaluating both behavioural determinants and behaviour change techniques. Difficulties were met especially in deciding when memory, attention and decision processes and action planning were targeted and in differentiating when the deployed behaviour change technique was planning versus coping strategies. Part of the problem is undoubtedly the limited space routinely available for intervention reporting, which often does not allow discussion of the rationale for how the desired behaviour change is targeted by the intervention, and how it is proposed to be achieved. Apart from the present limitations on an intervention reporting, intervention designers themselves may be reluctant to classify behaviour change techniques too strictly, as many of the reviewed intervention descriptions rather described intervention components than listed specific techniques that would be used to enhance smoking cessation.

As the analyses described in this chapter are based on an as-yet untested analytical framework, the accuracy of the results in presenting what was actually going on in the interventions was difficult to evaluate. Although analyses were aimed to be done as transparently as possible, it was not possible to exclude the possibility that the results of the analyses were actually an artefact of how the interventions were coded. Therefore, all the study authors were contacted with the analyses results for intervention components, behavioural determinants, and behaviour change techniques. Feedback from four of the authors that replied with detailed answers suggested that retrospective analyses were able to relative accurately estimate intervention components, behavioural determinants and behaviour change techniques used in the interventions. Only one of the authors who replied suggested that some parts of the analyses were not accurate. Rigotti (1994) suggested that telephone follow-up was not part of the information. However, the intervention description confirmed by Rigotti (1994) mentions that participants were contacted by telephone to offer support and counselling. This discrepancy raises an important issue in using this approach, namely the difficulty in interpreting, and remembering, perhaps after several years, exact intervention components and techniques, and how central for the interventions these were. Nevertheless, it appears that when the results are interpreted with caution, the retrospective analysis of interventions as presented in this chapter can be used to detailed investigation of intervention mechanisms and techniques. Another limitation of the analysis was in not explicitly incorporating use

of the pharmacological smoking cessation aids, as the framework developed by Michie et al. (2008) covers behaviour change techniques, not pharmacological techniques that may be used in behaviour regulation.

Michie et al. (2008) argued that not all behaviour change techniques are effective in changing behavioural determinants. In addition to evaluating targeted behavioural determinants and techniques used to influence them, this review also evaluated behaviour change techniques effectiveness to influence behavioural determinants in the interventions based on the expert opinion by Michie et al. (2008). Interestingly, these findings suggested that some commonly used intervention techniques such as relapse prevention and personalised messages may not be effective. From the practical point of view, this result suggests that if the guidance by Michie et al. (2008) is used for planning an intervention for purely practical purposes without research interest, then it could be considered sensible that only those techniques judged effective would be used in the intervention. On the other hand, experimental work needs to look into effectiveness and suitability of those techniques that at the present are evaluated uncertain or where there is disagreement about techniques effectiveness. Also, although most interventions used at least one “agreed technique” to influence each of the targeted behavioural determinants, interventions investigated in some trials, for example Feeney et al. (2001), and Ockene et al. (1992) and Rosal et al. (1998), did not appear to use such “agreed techniques” for all targeted behavioural determinants. While these findings are tentative and open to debate, they nevertheless highlight the need for intervention planners to be explicit about what different intervention components are aiming to achieve.

The effects of explicitly mentioning a theoretical reference point in intervention planning, on behavioural determinants and behaviour change techniques were also investigated. The results suggested only very small differences between the groups in the estimated targeted behavioural determinants, though some differences were observed for the used behaviour change techniques. While it could have been expected that including a theoretical model in an intervention planning would have resulted in more differences in behavioural determinants between the groups, this appeared not to have been the case in this review. Whether this was due to the limited availability of relevant information or to other factors could not be evaluated

This result, however, is similar to Lewin et al.'s (2009) argument about uncertainty in whether interventions based explicitly on particular theory are more effective than those interventions designed pragmatically. Nevertheless, it cannot be ruled out that especially in the “no-theory” group intervention designers may not have consciously been targeting certain behavioural determinants, even if this may appear so in the retrospective evaluation of the intervention. Though the results have several problems connected with them and should therefore be treated with considerable caution, they do offer some points of interests. Investigation into behaviour change techniques comparing the “theory” and “no-theory” groups suggested that including a theory in intervention planning may have resulted in more detailed consideration of what techniques should be used and which techniques are most likely to cause the desired behaviour change. These results highlight yet again the need for the intervention designers to be explicit about what different intervention components are designed to achieve. While this may not have a direct impact on intervention itself, it would enable better testing of intervention mechanisms and increased knowledge of effective behaviour change techniques in different situations.

Although the retrospective evaluation of interventions had several problems, it may hold out the potential to improve the understanding of interventions included in the review. However, perhaps the biggest difficulty that was encountered was, in many cases, the need to second guess the authors original intentions. While in some cases interventions were relatively specific about targeted behavioural determinants and techniques they used to influence the behaviour, this information had to be often derived from intervention descriptions, which cause considerable uncertainty about the results. In addition, the analysis was confronted with various problems while using the approach by Michie et al. (2008) within the process of evaluation, such as when the descriptions of some behaviour change techniques were found to be confusing or inadequate. Michie et al. (2008) had also composed a consensus table of the suitability of behaviour change techniques to influence behavioural determinants. In closer look, however, it appeared that many of the 35 behaviour change techniques included in the consensus table were actually combinations of originally-listed techniques within a new composite description, making the evaluation process more complex. Another difficulty with taking this approach was that assessing the

suitability of techniques was based on expert opinion, rather than on empirical evidence.

Several decisions were also made in developing and implementing the research methodology that may have affected the results of these analyses, and which should be explored in further studies. In this occasion it was decided to investigate the treatment conditions only, meaning that the control conditions and their potential effects were not considered in any of the analyses. However, it was argued that as this was the first attempt to analyse interventions using this approach, including the control interventions in the analyses would have been confusing, as the purpose of the analysis was not to compare the treatment and the control conditions, and it was very unclear how information from the control interventions should have been used. However, as the present analysis has indicated that this approach can be used for in-depth analysis of interventions, further research should not only evaluate the applicability and repeatability of the approach in different contexts, but also evaluate how the investigation of control conditions can be meaningfully integrated in the analyses.

6.7 Conclusions

This chapter addressed the question of whether using an innovative approach (Michie's framework) to retrospectively analyse intervention mechanisms and techniques could offer a better understanding of complex interventions. Several analyses examined behaviour change techniques used to influence behavioural determinants, and effects of a theory inclusion on targeted behavioural determinants and behaviour change techniques. The results indicated that interventions aimed either by design or by accident, to affect several similar behavioural determinants. The interventions also appeared to draw from a limited pool of behaviour change techniques. According to the expert consensus in Michie et al. (2008), some behaviour change techniques used are not effective in influencing the targeted behavioural determinants. The explicit inclusion of theory in intervention planning appeared to have only a limited effect on behaviour change techniques used in these studies. The use of Michie's framework enabled a detailed and in-depth examination of different intervention aspects. Importantly, the results of these in-depth analyses

suggest that meta-analysis results should only be generalised to interventions that use similar techniques included in the review. Information received from authors of the studies was broadly in agreement with the analyses based on the published literature, in terms of intervention components, behavioural determinants, and behaviour change techniques. This feedback indicates that the approach described in this chapter offers a feasible framework for in-depth evaluation of intervention mechanisms and technique. However, several limitations of using this approach were identified during the review process. Identified limitations included retrospective evaluation of interventions, and not including control conditions in the analyses. Furthermore, interpreting results requires caution as the behaviour change techniques identified in the review may be applied to practice differently, which may also affect their success in changing smoking behaviour.

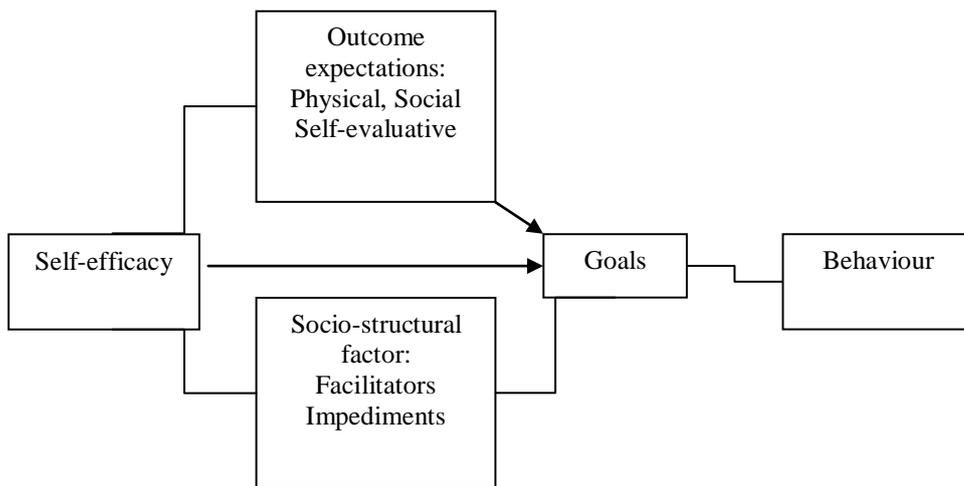


Figure 6.1: Social Cognitive Theory (Bandura, 2000b in Luszczynska &Schwarzer, 2005)

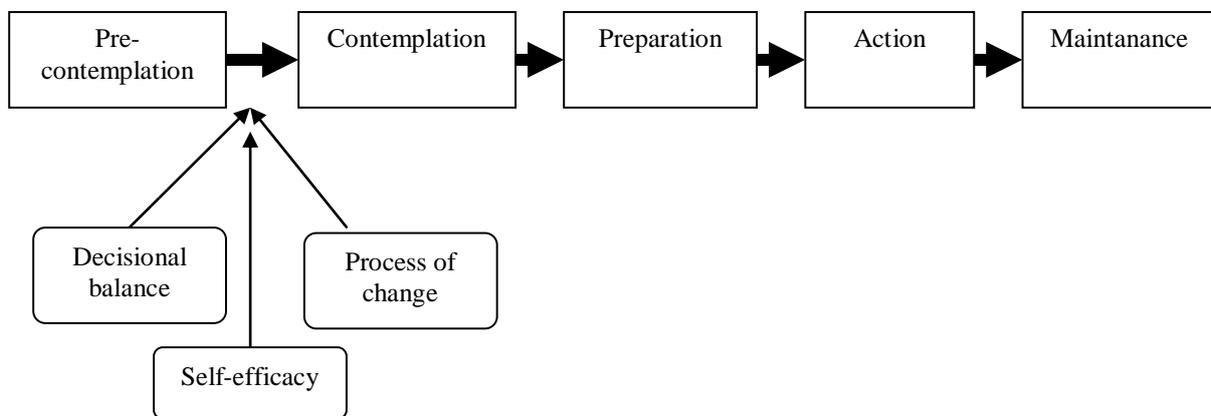


Figure 6.2: The transtheoretical model (Norman et al., 2005)

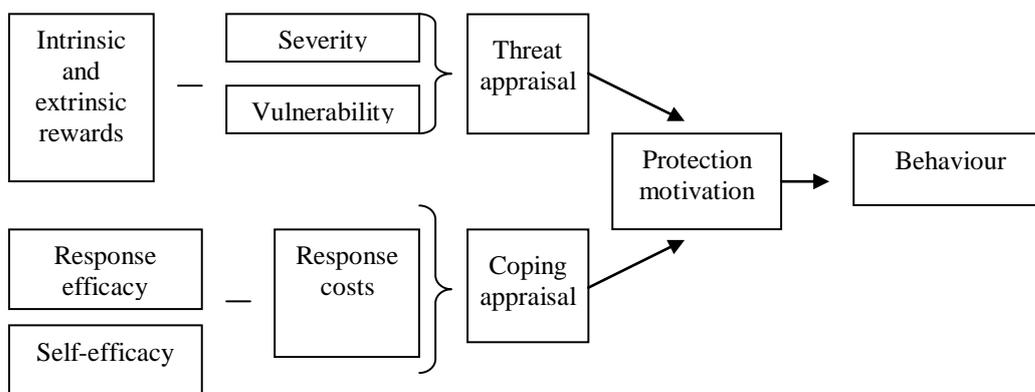


Figure 6.3: Protection motivation theory (Michie and Abraham, 2004)

Behavioural determinants		
Fishbein et al. (2001 in Michie et al., 2008)	Michie et al. (2008) Michie et al. (2005)	Description
Intention	1. Motivation and Goals	Intention, stability of intention/certainty of intention Goals (autonomous, controlled) Goal target/setting, Goal priority Intrinsic motivation, Commitment Distal and proximal goals Transtheoretical model and stages of change
	2. Memory, attention and decision processes	Memory Attention Attention control Decision making
Skills	3. Skills	Skills Competence/ability/skill assessment Practice/skill development Interpersonal skills Coping strategies
Self-efficacy	4. Beliefs about capabilities	Self-efficacy Control: behaviour, material, social environment Perceived competence Self-confidence/professional confidence Empowerment, Self-esteem Perceived behavioural control Optimism/pessimism
Anticipated outcomes/Attitude	5. Beliefs about consequences	Outcome expectancies, Anticipated regret Appraisal/evaluation/review Consequences, Attitudes, Contingencies Reinforcement/punishment/consequences Incentives/rewards, Unrealistic optimisms Salient events/sensitisation/critical incidents Characteristics of outcome expectancies: physical, social, emotional Sanctions/rewards: proximal/distal. Valued/not valued, probable/improbable, salient/not salient, perceived risk/threat
Self-standards	6. Knowledge	Knowledge of condition/specific rationale Knowledge Schemas, mindset, illness representations Procedural knowledge

Table 6.1: Key Behavioural Determinants

Behavioural determinants		
Fishbein et al. (2001 in Michie et al., 2008)	Michie et al. (2008) Michie et al. (2005)	Description
	7. Social/Professional identity	Identity Professional identity/boundaries/role Group/social identity, Social/group norms Alienation/organisational commitment
Environmental constraints	8. Environmental context and resources	Resources/material resources (availability and management) Environmental stressors Person x environment interaction Knowledge of task environment
Norms	9. Social influences	Social support, Social/group norms Organisational development. Leadership Team working, Group conformity Organisational climate/culture Social pressure, Power/hierarchy Professional boundaries/roles Management commitment, Supervision Intergroup conflict, Champions Social comparisons Identity; social identity/group Organisational commitment/alienation Feedback, Conflict: competing demands/conflicting roles Change management, Negotiation Crew resource management Social support: personal, professional, organisational, intra/interpersonal, society/community Social/group norms: subjective, descriptive, injunctive norms Learning and modelling
	10. Emotion	Affect, Stress, Anticipated regret, Fear Burn-out, Cognitive overload/tiredness Threat, Positive/negative affect Anxiety/depression
	11. Action planning	Goal/target setting, Action planning Self-monitoring, Implementing intention Goal priority, Generating alternatives Feedback, Project management Moderators of intention-behaviour gap Barriers and facilitators

Table 6.1: Key Behavioural Determinants

Behaviour change technique	Agreement of techniques effectiveness to change behavioural determinant										
	1	2	3	4	5	6	7	8	9	10	11
Goal/target specified: behaviour or outcome			X								X
Monitoring			X								
Self-monitoring			X	X	X		X				
Contract						X					X
Rewards; incentives (inc. self-evaluation)			X			X					
Graded task, starting with easy tasks			X	X		X					
Increasing skills: problem-solving, decision making, goal-setting			X	X		X					
Stress management										X	
Coping skills				X						X	
Rehearsal of relevant skills			X	X							
Role-play											
Planning, implementation							X				X
Prompts, triggers, clues							X				X
Environmental changes(e.g. objects to facilitate behaviour)								X			
Social processes of encouragement, pressure, support	X			X		X			X		
Persuasive communication					X	X					
Information regarding behaviour, outcome		X			X	X					
Personalised message											
Modelling/demonstration of behaviour by others			X						X		
Homework			X								
Personal experiments, data collection (other than self-monitoring behaviour)											
Experiential: tasks to gain experiences to change motivation											
Feedback				X	X						
Self-talk				X							
Use of imagery											X
Perform behaviour in different settings			X								
Shaping behaviour											
Motivational interviewing				X		X					
Relapse prevention											
Cognitive restructuring											
Relaxation											
Desensitisation											
Problem-solving											
Time management											
Identify/prepare for difficult situations/problems											

1 = Social/professional role and identity, 2 = Knowledge, 3= Skills, 4 = Beliefs about capabilities, 5 = Beliefs about consequences, 6 = Motivation and goals, 7 = Memory, attention, decision processes, 8 = Environmental context and resources, 9 = Social influences, 10 = Emotion, 11 = Action planning

X = Agreed use of technique by Michie et al. (2008) to change behavioural determinant

Table 6.2: Behaviour change techniques and their ratings

Study	Intervention theory/ies	Intervention components (extracted from intervention descriptions)	Behavioural determinants targeted (Estimation of what intervention components target)	Techniques used (mapped to Michie et al. 2008)
Bolman et al. (2002b) Bolman et al. (2002a)	Bandura's Social Learning Theory ASE Model (<u>the attitude-social influence-efficacy model</u>) Theories of relapse prevention Stages of Change model Motivational interview strategies	Stop smoking advice (Auth. Conf.) Assessment of smoking behaviour & addiction (Auth. Conf.) Motivation to quit (Auth. Conf.) Positive and negative consequences of smoking cessation (Auth. Conf.) Addressing perceived barriers to quitting (Auth. Conf.) Self-efficacy (Auth. Conf.) Development of coping strategies to maintain cessation (Auth. Conf.) Encouragement to set a quitting date (Auth. Conf.)	Motivation# (Auth. Conf.) Beliefs about consequences# (Auth. Conf.) Beliefs about capabilities# (Auth. Conf.) Knowledge# (Auth. Conf.) Skills# (Auth. Conf.)	1. Motivational interviewing# (precontemplative and contemplative stages) (Auth. Conf.) 2. Monitoring* (follow-up clinic) (Auth. Conf.) 3. Standard* (Auth. Conf.) 4. Behavioural information* (information given about effects of smoking) (Auth. Conf.) 5. Planning* (how to avoid relapsing in high risk situations) (Auth. Conf.) 6. Personalised message* (intervention tailored to participants stage of change) (Auth. Conf.)
Burt et al. (1974)	Not specified	Information about effects of smoking Professionals advised patients to stop smoking for good No guarantees of better future health given Benefits of smoking cessation in reducing changes of further potentially fatal infarct explained Patients were left to draw their own conclusions Advice on reducing smoking given to those unable to stop Written information provided Motivating patients continued in a follow-up clinic & home visits Advice extended to family members	Motivation # Beliefs about consequences# Social influences# Knowledge#	1. Standard* (non-smoking behaviour/reduction) 2. Monitoring* (follow-up clinic & home visits) 3. Fear arousal * (information about renewal of infarct) 4. Behavioural information* (information given about effects of smoking) 5. Verbal persuasion* (professionals recommended smoking cessation) 6. Social support* (family asked to help in creating smoke free home)

Table 6.3: Data extraction table for the behavioural determinants and behaviour change techniques

<i>Study</i>	<i>Intervention theory/ies</i>	<i>Intervention components</i>	<i>Behavioural determinants targeted</i>	<i>Techniques used</i>
Dornelas et al. (2000)	The Transtheoretical model	Bedside cessation counselling by psychologist Counselling based on participants present stage of change Telephone counselling post d/c based on stage of change	Self-efficacy# (=beliefs about capabilities) Readiness to change# (Motivation and goals)*	1. Motivational Interviewing# (precontemplative and contemplative stages) 2. Relapse prevention# (firm commitment stage) 3. Monitoring* (Follow-up) 4. Standard* (non-smoking behaviour)
Feeney et al. (2001)	Not specified	Health professionals advised participants to stop smoking and informed them about health consequences smoking cessation Program manual identified high risk relapse situations Manual provides exercises to manage potential relapse situations Counselling on specific high-risk relapse situations Progressive muscle relaxation Telephone follow-up after d/c with additional support & advise	Self-efficacy# (=beliefs about capabilities) Knowledge# Skills# Motivation and goals#	1. Planning* (how to avoid relapsing in high risk situations) 2. Behavioural information* (Effects of smoking cessation) 3. Standard* (smoking cessation) 4. Monitoring* (Telephone follow-up) 5. Relapse prevention* (exercises & counselling to prevent relapse) 6. Relaxation*
Hajek et al. (2002)	Not specified	Carbon monoxide reading used to demonstrate benefits of cessation Information booklet: smoking and cardiac recovery beliefs about smoking and stress advice on avoiding relapse Written quiz Nurse discussion to improve information processing Smoking cessation buddy Signed commitment Sticker on notes	Knowledge# Skills# Motivation and goals# Social influences# Beliefs about capabilities#	1. Relapse prevention# 2. Behavioural information* (Effects of smoking cessation) 3. Standard* (smoking cessation) 4. Planning* (how to avoid relapsing in high risk situations) 5. Buddy system# 6. Contract# (signed agreement) 7. Feedback* (quiz to check knowledge)

Table 6.3: Data extraction table for the behavioural determinants and behaviour change techniques

<i>Study</i>	<i>Intervention theory/ies</i>	<i>Intervention components</i>	<i>Behavioural determinants targeted</i>	<i>Techniques used</i>
Johnson et al. (1999)	Stages of change model	<p>Video one Effects of smoking (Auth. Conf.) Importance of smoking cessation (Auth. Conf.) Process of smoking cessation (Auth. Conf.) Smoking triggers (Auth. Conf.) Prompted thinking smoking habits & discussion with nurse (Auth. Conf.) Quit date (Auth. Conf.) Information booklet (Auth. Conf.)</p> <p>Video two Approaches to smoking cessation (review) (Auth. Conf.) Together with nurse smoking cessation plan developed (Auth. Conf.) Plan to manage smoking triggers (Auth. Conf.) Telephone follow-up to encourage & reinforce cessation (Auth. Conf.)</p>	<p>Self-efficacy# (=beliefs about capabilities) (Auth. Conf.)</p> <p>Knowledge# (Auth. Conf.)</p> <p>Skills# (Auth. Conf.)</p> <p>Motivation and goals# (Auth. Conf.)</p>	<ol style="list-style-type: none"> 1. Positive reinforcement# (given in text) Social support* (Auth. Conf.) 2. Feedback* (follow-up and comments of planned behaviours) (Auth. Conf.) 3. Behavioural information* (Information about smoking & cessation) (Auth. Conf.) 4. Standard* (smoking cessation date set) (Auth. Conf.) 5. Planning* (cessation process and smoking triggers) (Auth. Conf.) 6. Monitoring (follow-up) (Auth. Conf.) 7. Personalised message* (intervention tailored to participants needs) (Auth. Conf.)
Mohiuddin et al. (2007)	Stages of change model	<p>Short counselling and advice to stop smoking (Auth. Conf.) Written information (Auth. Conf.) Intensive weekly group counselling (Auth. Conf.) Behaviour modification (Auth. Conf.) Relaxation training (Auth. Conf.) Contingency contracting (Auth. Conf.) Social support (Auth. Conf.) Coping skills (Auth. Conf.) Stimulus control (Auth. Conf.) Nicotine fading (Auth. Conf.) Counselling about other CHD risk factors (Auth. Conf.) Pharmacotherapy (Auth. Conf.) Follow-up meetings & treatment as needed (Auth. Conf.)</p>	<p>Beliefs about capabilities* (Auth. Conf.)</p> <p>Knowledge# (Auth. Conf.)</p> <p>Skills# (Auth. Conf.)</p> <p>Motivation and goals# (Auth. Conf.)</p>	<ol style="list-style-type: none"> 1. Behavioural information* (Information about smoking & cessation) (Auth. Conf.) 2. Standard* (smoking cessation) (Auth. Conf.) 3. Planning* (skills training, stimulus control) (Auth. Conf.) 4. Monitoring* (follow-up) (Auth. Conf.) 5. Coping strategies* (coping skills training) (Auth. Conf.) 6. Relaxation# (Auth. Conf.) 7. Social support# (Auth. Conf.) 8. Personalised message* (intervention tailored to participants needs) (Auth. Conf.)

Table 6.3: Data extraction table for the behavioural determinants and behaviour change techniques

<i>Study</i>	<i>Intervention theory/ies</i>	<i>Intervention components</i>	<i>Behavioural determinants targeted</i>	<i>Techniques used</i>
Ockene et al. (1992) Rosal et al. (1998)	Behavioural multicomponent approach	Counselling + advice to stop smoking & information about smoking Outpatient counselling visits Counselling telephone calls Possibility to attend a group program Self-help material Intervention manual Relaxation tapes Maintenance training	Motivation and goals# Beliefs about capabilities#* Skills#* Knowledge*	1. Standard* (smoking cessation) 2. Monitoring* (follow-up) 3. Relapse prevention* (maintenance training) 4. Behavioural information* (effects of smoking) 5. Personalised message* (intervention tailored to participant needs)
Quist-Paulsen (2003)	Fear arousal	Nurse consultation Information booklet about health benefits of smoking cessation Fear arousing information included in both booklet and nurse consultation Information about relapse prevention Coping with high risk relapse situations, action plans Information about smoking cessation Nicotine replace products Spouses asked to quit smoking were appropriate Telephone follow-up Positive feedback	Beliefs about consequences# Emotion# Knowledge# Skills# Motivation and goals# Action planning*	1. Standard* (smoking cessation) 2. Feedback* (positive feedback) 3. Monitoring* (follow-up) 4. Fear arousal# (fear arousing information) 5. Relapse prevention* (information on how to cope) 6. Behavioural information* (information about effects of smoking) 7. Planning* (how to cope with smoking triggers)

Table 6.3: Data extraction table for the behavioural determinants and behaviour change techniques

<i>Study</i>	<i>Intervention theory/ies</i>	<i>Intervention components</i>	<i>Behavioural determinants targeted</i>	<i>Techniques used</i>
Reid et al. (2003)	The Transtheoretical theory	Brief bedside counselling Smoking cessation information Personalised message Self-help booklet Relapse prevention information Telephone follow-up Positive reinforcement Counselling if smoking Recognise and cope with smoking triggers Social support Nicotine replacement therapy	Beliefs about capabilities (self-efficacy)# Motivation and goals# Skills# Knowledge# Social influences#	1. Standard* (Smoking cessation) 2. Monitoring* (Telephone follow-up) 3. Planning* (cope with smoking triggers) 4. Relapse prevention* (coping with smoking triggers) 5. Behavioural Information* (Information about smoking cessation) 6. Personalised message* (Intervention delivered regarding participant needs) 7. Social support* (support from intervention personnel)
Reid et al. (2007)	Not specified	Brief bedside counselling Advice to stop smoking Personalised message Self-help booklet Telephone follow-up Positive reinforcement Counselling if smoking or low confidence to stay abstinent Recognise and cope with smoking triggers Social support Nicotine replacement therapy	Beliefs about capabilities (self-efficacy)# Motivation and goals# Skills# Social influences#	1. Standard* (Smoking cessation) 2. Monitoring* (Telephone follow-up) 3. Planning* (cope with smoking triggers) 4. Personalised message* (Intervention delivered regarding participant needs) 5. Social support* (support from intervention personnel)
Rigotti et al. (1994)	Behavioural and cognitive methods	Cognitive and behavioural smoking cessation techniques (Auth. Conf.) Video tape, Program manual (Auth. Conf.) Nurse contact (Auth. Conf.) Family members invited to attend (Auth. No Recall) Telephone follow-up (Auth. Non-Conf.) Support (Auth. Conf.) Brief counselling (Auth. Conf.)	Beliefs about capabilities# (Auth. Conf.) Motivation and goals# (Auth. Conf.) Skills# (Auth. Conf.) Social influences* (Auth. Conf.)	1. Standard* (stop smoking) (Auth. Conf.) 2. Monitoring* (Telephone follow-up) (Author. Non-Conf.) 3. Planning* (Behavioural & cognitive techniques) (Auth. Conf.) 4. Social support* (Family involvement) (Auth. Conf.)

Table 6.3: Data extraction table for the behavioural determinants and behaviour change techniques

<i>Study</i>	<i>Intervention theory/ies</i>	<i>Intervention components</i>	<i>Behavioural determinants targeted</i>	<i>Techniques used</i>
Smith & Burgess (2009)	Marlatt and Gordon's relapse prevention model	Personalised message Advice on smoking cessation Nurse contact Information material Information about benefits of smoking cessation and dangers of continuing Counselling to cope with identified high risk situations Coping strategies to stay smoke free Support	Beliefs about capabilities (self-efficacy)# Beliefs about consequences# Skills# Motivation and goals# Knowledge# Social influences*	1. Standard* (Quit smoking) 2. Monitoring* (Follow-up) 3. Planning* (How to deal with smoking triggers) 4. Relapse prevention* (How to cope with smoking triggers) 6. Behavioural information* (effects of smoking and smoking cessation) 7. Personalised message# (intervention tailored partly to participant needs) 8. Social support* (social support strategies discussed)
Taylor et al. (1990)	Social learning theory Addiction models for nicotine	Information about benefits of smoking cessation and dangers of continuing Intervention manual to help to identify and cope with smoking triggers Action planning to cope with smoking triggers Audiotapes Relaxation exercise Counselling to cope with identified high risk situations Written material about strategies to resist triggers Telephone follow-up Support Outpatient follow-up if needed Nicotine gum available Signed contract Set quit date	Beliefs about capabilities (self-efficacy)# Beliefs about consequences# Skills# Motivation and goals# Action planning# Knowledge# Social influences*	1. Standard* (Quit smoking) 2. Monitoring* (Follow-up) 3. Contract# (agreed quit date) 4. Planning* (How to deal with smoking triggers) 5. Relapse prevention* (How to cope with smoking triggers) 6. Behavioural information* (effects of smoking and smoking cessation) 7. Personalised message* (intervention tailored partly to participant needs) 8. Social support* (Support from intervention team) 9. Relaxation# (progressive muscle relaxation exercises)

Table 6.3: Data extraction table for the behavioural determinants and behaviour change techniques

Table 6.3: Notes

- *Author estimate, using Michie et al. (2008) as guidance
- # = Given in the study, or considered fairly accurate description of the intervention aim
- ? = Information not available
- (Auth. Conf.) Conformed by the original study author to be accurate description
- (Auth. Non-Conf.) Not conformed by the original study author to be accurate description

Behavioural determinants targeted Either given or estimated from available information Michie et al. (2008)	Studies that target given behavioural determinant (Only first author listed)	Technique used in the intervention and its appropriateness to influence on targeted behavioural determinant Either given in the intervention description or estimated from available information. Techniques and their appropriateness according to Michie et al. (2008)													
		Standard	Relapse prevention	Monitoring	Contract	Planning	Fear Arousal	Behavioural Information	Verbal persuasion	Coping strategies	Mot. interview	Relaxation	Social Support	Personalised message	Feedback
Motivation and goals	Bolman	Ok	-	Un	-	Dis	-	Ok	-	-	Ok	-	-	Un	-
	Burt	Ok	-	Un	-	-	Ok	Ok	Ok	-	-	Ok	-	-	-
	Dornelas	Ok	Un	Un	-	-	-	-	-	-	Ok	-	-	-	-
	Feeney	Ok	Un	Un	-	Dis	-	Ok	-	-	-	No	-	-	-
	Hajek	Ok	Un	-	Ok	Dis	-	Ok	-	-	-	-	-	-	Un
	Johnson	Ok	-	Un	-	Dis	-	Ok	-	-	-	-	Ok	Un	Un
	Mohiuddin	Ok	-	Un	-	Dis	-	Ok	-	No	-	No	Ok	Un	-
	Ock.&Ros.	Ok	Un	Un	-	-	-	Ok	-	-	-	-	-	Un	-
	Quist-P.	Ok	Un	Un	-	Dis	Ok	Ok	-	-	-	-	-	-	Un
	Reid 03	Ok	Un	Un	-	Dis	-	Ok	-	-	-	-	Ok	Un	-
	Reid 07	Ok	-	Un	-	Dis	-	-	-	-	-	-	Ok	Un	-
	Rigotti	Ok	-	Un	-	Dis	-	-	-	-	-	-	Ok	-	-
	Smith	Ok	Un	Un	-	Dis	-	Ok	-	-	-	-	Ok	Un	-
	Taylor	Ok	Un	Un	Ok	Dis	-	Ok	-	-	-	No	Ok	Un	-

Table 6.4: Targeted behavioural determinants and used behaviour change techniques by the studies and behaviour change techniques' suitability to influence behavioural determinants

Behavioural determinants targeted	Studies that target given behavioural determinant	Standard	Relapse prevention	Monitoring	Contract	Planning	Fear Arousal	Behavioural Information	Verbal persuasion	Coping strategies	Mot. interview	Relaxation	Social Support	Personalised message	Feedback	
Beliefs about capabilities	Bolman	No	-	Un	-	No	-	Un	-	-	Ok	-	-	Un	-	
	Dornelas	No	Un	Un	-	-	-	-	-	-	Ok	-	-	-	-	
	Feeney	No	Un	Un	-	No	-	Un	-	-	-	No	-	-	-	
	Hajek	No	Un	-	No	No	-	Un	-	-	-	-	-	-	Ok	
	Johnson	No	-	Un	-	No	-	Un	-	-	-	-	Ok	Un	Ok	
	Mohiuddin	No	-	Un	-	No	-	Un	-	Ok	-	No	Ok	Un	-	
	Ock.&Ros.	No	Un	Un	-	-	-	Un	-	-	-	-	-	Un	-	
	Reid 03	No	Un	Un	-	No	-	Un	-	-	-	-	Ok	Un	-	
	Reid 07	No	-	Un	-	No	-	-	-	-	-	-	-	Ok	Un	-
	Rigotti	No	-	Un	-	No	-	-	-	-	-	-	-	Ok	-	-
Smith	No	Un	Un	-	No	-	Un	-	-	-	-	-	Ok	Un	-	
Taylor	No	Un	Un	No	No	-	Un	-	-	-	-	No	Ok	Un	-	
Beliefs about consequences	Bolman	Dis	-	Un	-	No	-	Ok	-	-	Dis	-	-	Un	-	
	Burt	Dis	-	Un	-	-	Ok	Ok	Ok	-	-	-	No	-	-	
	Quist-P.	Dis	No	Un	-	No	Ok	Ok	-	-	-	-	-	-	Ok	
	Smith	Dis	No	Un	-	No	-	Ok	-	-	-	-	No	Un	-	
	Taylor	Dis	No	Un	No	No	-	Ok	-	-	-	No	No	Un	Ok	

Table 6.4: Targeted behavioural determinants and used behaviour change techniques by the studies and behaviour change techniques' suitability to influence behavioural determinants

Behavioural determinants targeted	Studies that target given behavioural determinant	Standard	Relapse prevention	Monitoring	Contract	Planning	Fear Arousal	Behavioural Information	Verbal persuasion	Coping strategies	Mot. interview	Relaxation	Social Support	Personalised message	Feedback
Knowledge	Bolman	Un	-	No	-	No	-	Ok	-	-	No	-	-	Dis	-
	Burt	Un	-	No	-	-	Ok	Ok	Un	-	-	-	No	-	-
	Feeney	Un	No	No	-	No	-	Ok	-	-	-	No	-	-	-
	Hajek	Un	No	-	Ok	No	-	Ok	-	-	-	-	-	-	No
	Johnson	Un	-	No	-	No	-	Ok	-	-	-	-	No	Dis	No
	Mohiuddin	Un	-	No	-	No	-	Ok	-	No	-	No	No	Dis	-
	Ock.&Ros.	Un	No	No	-	-	-	Ok	-	-	-	-	-	Dis	-
	Quist-P.	Un	No	No	-	No	Ok	Ok	-	-	-	-	-	-	No
	Reid 03	Un	No	No	-	No	-	Ok	-	-	-	-	No	Dis	-
	Smith	Un	No	No	-	No	-	Ok	-	-	-	-	No	Dis	-
Taylor	Un	No	No	No	Ok	No	-	Ok	-	-	No	No	Dis	-	

Table 6.4: Targeted behavioural determinants and used behaviour change techniques by the studies and behaviour change techniques' suitability to influence behavioural determinants

Behavioural determinants targeted	Studies that target given behavioural determinant	Standard	Relapse prevention	Monitoring	Contract	Planning	Fear Arousal	Behavioural Information	Verbal persuasion	Coping strategies	Mot. interview	Relaxation	Social Support	Personalised message	Feedback	
Skills	Bolman	Ok	-	Ok	-	Un	-	No	-	-	No	-	-	No	-	
	Feeney	Ok	No	Ok	-	Un	No	No	-	-	-	No	-	-	-	
	Hajek	Ok	No	-	No	Un	-	No	-	-	-	-	-	-	Dis	
	Johnson	Ok	-	Ok	-	Un	-	No	-	-	-	-	No	No	Dis	
	Mohiuddin	Ok	-	Ok	-	Un	-	No	-	Dis	-	No	No	No	-	
	Ock.&Ros.	Ok	No	Ok	-	-	-	No	-	-	-	-	-	No	-	
	Quist-P.	Ok	No	Ok	-	Un	No	No	-	-	-	-	-	-	Dis	
	Reid 03	Ok	No	Ok	-	Un	-	No	-	-	-	-	No	No	-	
	Reid 07	Ok	-	Ok	-	Un	-	-	-	-	-	-	-	No	No	-
	Rigotti	Ok	-	Ok	-	Un	-	-	-	-	-	-	-	No	-	-
	Smith	Ok	No	Ok	-	Un	-	No	-	-	-	-	No	No	-	
Taylor	Ok	No	Ok	No	Un	-	No	-	-	-	No	No	No	-		

Table 6.4: Targeted behavioural determinants and used behaviour change techniques by the studies and behaviour change techniques' suitability to influence behavioural determinants

Behavioural determinants targeted	Studies that target given behavioural determinant	Standard	Relapse prevention	Monitoring	Contract	Planning	Fear Arousal	Behavioural Information	Verbal persuasion	Coping strategies	Mot. interview	Relaxation	Social Support	Personalised message	Feedback
Social influences	Burt	No	-	Un	-	-	-	No	Un	-	-	-	Ok	-	-
	Hajek	No	No	-	Dis	No	-	No	-	-	-	-	-	-	No
	Reid 03	No	No	Un	-	No	-	No	-	-	-	-	Ok	No	-
	Reid 07	No	-	Un	-	No	-	-	-	-	-	-	Ok	No	-
	Rigotti	No	-	Un	-	No	-	-	-	-	-	-	Ok	-	-
	Smith	No	No	Un	-	No	-	No	-	-	-	-	Ok	No	-
	Taylor	No	No	Un	Dis	No	-	No	-	-	-	No	Ok	No	-
Emotion	Quist-P.	No	No	No	-	Un	No	No	-	-	-	-	-	-	No
Action planning	Quist-P.	Ok	Un	Un	-	Ok	Dis	Dis	-	-	-	-	-	-	Un
	Taylor	Ok	Un	Un	Ok	Ok	-	Dis	-	-	-	No	Un	Un	-

Table 6.4. Targeted behavioural determinants and used behaviour change techniques by the studies and behaviour change techniques' suitability to influence behavioural determinants

Notes to table 6.4

Ok = Technique appropriate to change behavioural target according to Michie et al. (2008)

Uncert = There is uncertainty about technique's effectiveness/appropriateness to change behavioural determinant according to Michie et al. (2008)

No = Technique not appropriate to change behavioural determinant according to Michie et al. (2008)

Disagree = There is disagreement about technique's appropriate to change behavioural determinant according to Michie et al. (2008)

“-“ = Intervention did not use this technique. Buddy system (Hajek et al.) not included in the list as there is no information available in Michie et al. (2008) about technique's appropriateness or effectiveness.

Study	Experimental group	Control group
<p>Bolman et al. (2002b) Bolman et al. (2002a)</p>	<p>Cardiologist provided stop smoking advice initially (Step 1), which was followed by a ward nurse's assessment of smoking behaviour and degree of addiction, and motivation to change smoking behaviour (Step 2). If patient was not motivated to quit smoking, nurse used strategies derived from motivational interviewing to focus on positive and negative aspects of smoking cessation (Step 3). For those patients motivated to quit, counselling addressed perceived barriers to quitting, and perceived self-efficacy expectations for smoking cessation. Nurse also helped patient to identify problem areas in smoking cessation e.g. withdrawal symptoms, and to develop coping strategies. (Step 4). Depending on patient's motivation and preparedness to quit, nurse encouraged patient to set a date for quitting. Intervention was delivered in one or more short conversation. Before hospital discharge nurse discussed patients' experience and progress while in hospital. Patients were also provided with self-help manual, partly based on American Lung Association's Freedom from Smoking guide (Strecher et al. 1989 in Bolman et al. 2002b). Aftercare was provided by cardiologist at the first outpatient appointment, which addressed various aspects of smoking, in order to prevent relapse or motivate to make a new attempt. Patients GP was informed of the intervention and asked to note smoking behaviour in subsequent visits. For those patients with more severe nicotine addiction or those preferring intensive treatment, nurse made patients aware of possibilities of participating after discharge in a smoking cessation group program at cost of \$45. (Auth. Conf.)</p> <p><i>"Nurses where however also instructed to call patients two weeks after discharge to inform about quit attempt. Furthermore it needs to be mentioned thatnot all required steps were carried out, there was especially non adherence to aftercare (by nurses and cardiologists).</i></p>	<p>Usual care, with occasional attention to patients smoking behaviour. (Auth. Conf.)</p> <p><i>Usual care was delivered by nurses and cardiologist, depending how it was organised in the wards.</i></p> <p><i>Participants were asked only about whether any kind of quit smoking advice.</i></p> <p><i>Participants may or may not have received any stop smoking material, as this depended on normal ward arrangements.</i></p> <p><i>No information was provided about stop smoking services.</i></p> <p><i>Participants were not informed about availability of nicotine replacement products.</i></p>

Table 6.5: Description of experimental and control interventions with author comments

Study	Experimental group	Control group
Burt et al. (1974)	A consultant explained effects of smoking and advised patients to stop smoking, later this message was reinforced by junior medical staff and nurses. Stop smoking message was delivered dogmatically to all eligible patients, and they were told that they should never smoke in any form in their life again. In addition stop smoking message consisted information about consisted information that although no guarantee of future health could be given, reoccurrence of myocardial infarction was less among those that stop smoking. Participants were informed that the purpose of the stop smoking message was to prevent occurrence of second and potentially more serious cardiac infarct and subsequent hospitalisation. If participants failed to stop smoking, further advice and hints were provided about reducing smoking, and at times participants were explained about short and long term effects of smoking. Advice was reinforced by leaflets provided by Scottish Health Education Unit and advice booklet in relation all coronary risk factors. After discharge participants were followed in a clinic and smoking cessation advice was extended to family members. Community nurse visited at home and gave advice regarding smoking and other risk factors.	Participants received standard hospital advice without follow-up at hospital. A community nurse visited patients at home one or more years later to seek information on smoking.
Dornelas et al. (2000)	A 20 minutes bedside smoking cessation counselling by psychologist who evaluated participants' current stage of change using the Transtheoretical Model and based the counselling context on that stage. After discharge participants were contacted by telephone after weeks 1, 4, 8, 12, 16, 20 and 29. Bedside and telephone counselling combined aspects of motivational interviewing and relapse prevention. Motivational interviewing was used for those participants that were assessed in being precontemplative and contemplative stages to help them explore their ambivalence regarding quitting smoking. For those patients who indicated firm commitment to smoking cessation, counselling consisted teaching relapse prevention techniques to anticipate and cope with high-risk situations for relapse. The intervention aimed to reinforce all motivational statements made by patients.	Participants received a short intervention lasting about 10 minutes from a psychologist. Intervention consisted verbal and written recommendation to watch an on-line educational video while in hospital. Participants were also referred to local American Heart or Lung Association's smoking cessation resources.

Table 6.5: Description of experimental and control interventions with author comments

Study	Experimental group	Control group
Feeney et al. (2001)	Stanford Heart Attack Staying Free programme. Cardiologist advised all patients to stop smoking. Nurse management of the program started after transfer from coronary care unit. All participants were interviewed by alcohol and drug assessment physician and medical implications of smoking cessation and the aims of the programme were discussed. Programme included several behavioural components. Participants received a manual, which identified high-risk relapse situations and exercises to manage these situations. After manual review participants filled in a questionnaire to assess confidence to maintain smoking cessation. In cases where patients reported less than 70% confidence to maintain cessation, they were counselled on specific coping strategies. Audio tapes reviewed program's main points and provided progressive muscle relaxation. Manual was worked through during a two week period (before and after discharge from hospital). After discharge telephone contact was initiated weekly for 4 weeks and at 2, 3, 6 and 12 months. During telephone follow-up nurse inquired patients about relapse and confidence to stay smoke free and offered additional support and advice when necessary.	All participants were advised by attending cardiologist to stop smoking. Participants received usual care offering verbal and written advice about smoking cessation. Usual care included an educational video while in hospital, and review by an alcohol and drug assessment unit (ADAU) nurse. Participants were also offered outpatient counselling and follow-up by ADAU clinic at 3, 6, and 12 month intervals.
Hajek et al. (2002)	Participants were given by a nurse a booklet about smoking and cardiac recovery that challenged the belief that smoking relieves stress and provided advice about avoiding relapse. Participants were also asked to fill in a quiz about the contents of the booklet, which was reviewed with a nurse to help in retention of information and understanding of information. Participants had also their carbon monoxide reading was recorded. Participants signed a declaration and a sticker on their notes reminded staff of smoking cessation attempt. Participants were also offered a possibility to be put in contact with another cardiac patient that has recently stopped smoking for mutual support. Intervention took around 20 min to deliver.	Participants were given both verbal advice to stop smoking and British Heart Foundation Booklet <i>Smoking and Your Heart</i> .

Table 6.5: Description of experimental and control interventions with author comments

Study	Experimental group	Control group
Johnson et al. (1999)	<p>Intervention was based on five principles; smoking cessation is a process, smoking cessation cannot be forced, smoking cessation interventions needs to be individual and matched to stage of change, self-efficacy is important in successful smoking cessation, and initially smoking cessation needs to be reinforced by long-term follow-up. Intervention was designed to be brief and consisted of two contacts while in hospital. In the first contact participants received a booklet and were shown a video about effects of smoking, importance of smoking cessation, cessation process, and smoking triggers. The video encouraged discussion of smoking habits and participants were provided a worksheet on which to record their answers. Video encouraged to set a quit date, same day was preferred. Nurse was available to review the answers with the participants and answers any further questions about smoking. Nurse also encouraged setting a quit date. At the end of the first contact, participants were given a booklet developed by American Lung Association (1986 in Johnson et al. 1999) called “A Lifetime of Freedom from Smoking” and asked to review it. On the start of the second visit nurse reviewed material from the previous day, and participants watched second video in which smoking cessation skills were reviewed. Nurse helped participants to developed a smoking cessation plan and strategies to manage smoking triggers and rehearse these plans when appropriate. Six telephone contacts from the nurse that initiated the intervention in hospital during the first 3 months after discharge encouraged and reinforced cessation efforts. Duration of the telephone (5-60 min) calls depended on the needs of the participants. (Auth. Conf).</p>	<p>Participants in the control group received routine care, which included occasional stop smoking advice from physicians and nurses, but not a systematic intervention.</p> <p><i>Only doctors and nurses provided stop smoking advice.</i></p> <p><i>The message given to control group was that “The best thing you can do for your health is to quit smoking.”.</i></p> <p><i>Participants received some stop smoking materials.</i></p> <p><i>No information was given about available stop smoking services.</i></p> <p><i>Participants were informed about availability of nicotine replacement products.</i></p>

Table 6.5: Description of experimental and control interventions with author comments

Study	Experimental group	Control group
Mohiuddin et al. (2007)	<p>Prior to discharge all participants received a standardised counselling (30 minutes) during which advice to stop smoking was given . All participants also received following self-help materials on smoking cessation; Smart Move: A Stop Smoking Guide from the American Cancer Society, and You Can Quit (consumer version) from the Agency for Health Care Policy and Research.</p> <p>Participants in the intervention group were asked to meet a tobacco cessation counsellor (60 minutes) weekly for minimum of 3 months in small groups (typically 3-6 persons per group) or individually if logistically necessary. Counselling included behaviour modification training using relaxation training, contingency contracting, social support, coping skills, stimulus control, nicotine fading and risk factor modification such as diet and exercise. Pharmacotherapy was also offered. Participants that relapsed during the two year follow-up period were retreated if they relapsed. (Auth. Conf.)</p>	<p>Prior to discharge all participants received a standardised counselling (30 minutes) during which advice to stop smoking was given. All participants also received following self-help materials on smoking cessation; Smart Move: A Stop Smoking Guide from the American Cancer Society, and You Can Quit (consumer version) from the Agency for Health Care Policy and Research.</p> <p>No additional intervention provided in the control group.</p> <p><i>The initial counselling was provided by pharmacist or tobacco counselling specialist.</i></p>
Ockene et al. (1992) Rosal et al. (1998)	<p>All received standardised initial (about 10 minutes) advice to stop smoking, including a review of health risks of smoking and the benefits of quitting, and a list of community treatment programmes.</p> <p>Intervention facilitated by master’s-level health educators. Participants in the intervention group received a 30-minutes inpatient counselling session, an individual outpatient counselling visit, and follow-up counselling telephone calls. Participants were also offered a possibility to attend an outpatient group-based program, but as only so few participants took up the offer, they were after 2 months referred to existing group program in the hospital. Counselling calls were scheduled at 1 and 3 weeks regardless of smoking status. Those who successfully quitted were contacted at 3 months, whereas those who continued smoking were contacted at 2 and 4 months. Additional telephone contacts were made if participant relapsed or a participant requested contact. Participants also received intervention manual, relaxation tapes, maintenance training, and self-help material.</p>	<p>All received standardised initial (about 10minutes) advice to stop smoking, including a review of health risks of smoking and the benefits of quitting, and a list of community treatment programmes.</p> <p>No additional intervention provided in the control group.</p>

Table 6.5: Description of experimental and control interventions with author comments

Study	Experimental group	Control group
Quist-Paulsen (2003)	<p>Nurse visited participants during their hospital stay once or twice. The intervention was based on a 17-paged booklet produced specially for the intervention. In the booklet health benefits of smoking cessation after myocardial infarct were emphasised. Two illustrations included in the booklet. The first bar chart showed risk reduction for death five years after smoking cessation and the second linear chart showed percentage of people alive among quitters and non-quitters after 13 years. (Fear arousal message) .Based on these figures, participants were informed that if they continued smoking, they were likely to have another heart attack. In the booklet was also included information about how to prevent relapse, how to stop smoking in case of relapse or if not yet quit smoking. Information consisted advice and action plans how to identify high-risk situations and action plans to cope with these. Participants were encouraged not to smoke during hospital stay. Information was also included about nicotine replacement products. Those spouses who smoke were also asked to quit. Telephone contact was initiated two days, one week, three weeks, three months, and five months after discharge. At six weeks participants had consultation in outpatient clinic with cardiac nurse. Outpatient visit consisted positive feedback of repeat of fear arousal message depending on participant's smoking status, those struggling with cessation were offered additional advice and support</p>	<p>Participants were offered group sessions twice a week with a nurse. At some point during the group sessions a video was shown and a booklet given to participants that contained general information about coronary heart disease and advice to stop smoking. No specific instructions were given about smoking cessation.</p> <p>No additional intervention provided.</p>
Reid et al. (2003)	<p>All received standard brief individual counselling delivered at bedside by a trained nurse counsellor. The counselling lasted 5-10 minutes during which willingness to quit was assessed and personalised advice to stop smoking was given. In addition, participants were given a self-help booklet, and information about outpatient and community smoking cessation programmes.</p> <p>Four weeks after hospital discharge, participants in the stepped-care group were called by the nurse counsellor to inquire about their smoking status. If no smoking was reported, participants received positive feedback and reminded about the relapse prevention information in the booklet. If participant reported smoking, nicotine patch therapy was made available, and participants received three 20-minute face-to-face counselling sessions with a nurse-counsellor over 8 weeks.</p>	<p>All received standard brief individual counselling delivered at bedside by a trained nurse counsellor. The counselling lasted 5-10 minutes during which willingness to quit was assessed and personalised advice to stop smoking was given. In addition, participants were given a self-help booklet, and information about outpatient and community smoking cessation programmes.</p> <p>No additional intervention provided.</p>

Table 6.5: Description of experimental and control interventions with author comments

Study	Experimental group	Control group
Reid et al. (2007)	<p>All received standard usual care, which included brief personalised bedside counselling by a nurse-counsellor that consisted advice to stop smoking. Participants were provided access to NRT if necessary during hospital stay, were given a self-help guide, and information about outpatient and community smoking cessation programmes.</p> <p>Participants in the treatment group received Interactive Voice Responsive Telephony (IVR) intervention. After discharge an automated telephony system contacted participants on days 3, 14, 30 post-discharge. Calls inquired smoking status and assessed risk of relapse. Those participants that reported either relapse with willingness to further smoking cessation attempt or low confidence to stay smoke free, were flagged in the IVR system software. Nurse-specialist contacted these participants to offer additional assistance. Additional intervention consisted up to three 20-min counsellor-led telephone counselling sessions over 8 week-period. Counselling included encouragement, help in identifying situations that were undermining their confidence and possible solutions, recruit social support, and access to pharmacotherapy. When needed counsellor assisted in setting a new quit date and develop strategies to cope with situations that undermined confidence to stay smoke free.</p>	<p>All received standard usual care, which included brief personalised bedside counselling by a nurse-counsellor that consisted advice to stop smoking. Participants were provided access to NRT if necessary during hospital stay, were given a self-help guide, and information about outpatient and community smoking cessation programmes.</p> <p>No additional treatments provided.</p>

Table 6.5: Description of experimental and control interventions with author comments

Rigotti et al. (1994)	<p>Intervention aimed in smoking cessation and relapse prevention using cognitive and behavioural smoking cessation techniques. Based on the American Lung Association's 'In Control' program, the intervention was a standardised three sessions counselling programme, which included edited video tape, patient manual and three 20-min sessions to individual patients by a research nurse. Family members were also encouraged to participate. One week after discharge nurse contacted participants by telephone to offer support and short counselling. (Auth. Conf.)</p>	<p>Participants received standard post-operative care; including brief advice not to smoke as part of a group lecture. (Auth. Conf.)</p> <p><i>Nurse delivered the intervention for the control group.</i></p> <p><i>Stop smoking message was not standardised.</i></p> <p><i>Participants were informed about available stop smoking services.</i></p> <p><i>Participants requiring help to quit smoking were directed to an MHG programs for quit smoking.</i></p>
Smith & Burgess (2009)	<p>Research nurse advised participants to quit smoking by individualising the quit smoking message to each participants' medical condition. Nurse reviewed two pamphlets with the patients, which contained information about how to quit and where to find help. Nurse placed a note to patients' charts to remind their physicians to deliver scripted non-smoking message at bedside.</p> <p>In the intervention group participants received an additional bedside counselling (45-60 min) and education. Participants also received materials to take home (video, work book, audiotape), and 7 telephone counselling sessions initiated by the nurse (at 2, 7, 14, 21, 30, 45, 60 days after discharge). Education consisted personalised risk associated with smoking, benefits of quitting, and help to develop strategies to stay smoke free in high risk situations that they had identified. Telephone counselling was designed to last 5-10 minutes and focused on relapse prevention by developing cognitive, behavioural and social support strategies for situations identified as high risk situations.</p>	<p>Research nurse advised participants to quit smoking by individualising the quit smoking message to each participants' medical condition. Nurse reviewed two pamphlets with the patients, which contained information about how to quit and where to find help. Nurse placed a note to patients' charts to remind their physicians to deliver scripted non-smoking message at bedside.</p>

Table 6.5: Description of experimental and control interventions with author comments

Study	Experimental group	Control group
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<p>Taylor et al. (1990)</p>	<p>A nurse counsellor reviewed benefits of smoking cessation, and dangers of returning to smoking after infarction with the participants. Participants were also provided with an 18-page manual “staying Free”, which contained information how to identify and develop action plans to cope with high-risk situations. Manual also reviewed previous information about benefits of smoking cessation and dangers of continuing smoking. Manual was designed to be completed over two weeks during early stages of recovery. First section of the manual was completed while participants were still in hospital. After reviewing the manual in the hospital, participants were asked to quantify their confidence to stay smoke free in 28 high-risk situation. Participants received counselling in how to cope with those situations they had least confidence to stay smoke free. Additional printed material focusing on high risk situation was provided. After discharge telephone contact was initiated by the nurses one a week for the first 2 to 3 weeks and then monthly for the next four months. Purpose of the telephone contact was to monitor relapse and offer support and advice. Outpatient appointment was offered when needed for those who relapsed or struggled to make a smoking cessation attempt. NRT was available and these patients were asked to sign a contract to quit smoking and save their cigarette butts in a water-filled jar.</p>	<p>Participants received no specific smoking cessation help, but were free to attend hospital’s stop smoking classes.</p>
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Table 6.5: Description of experimental and control interventions with author comments

Notes:

(Auth. Conf.) = Author has confirmed this to be an accurate presentation of the intervention

Cursive text = Information from study author

Chapter 7

Systematic review of qualitative information of patient expectations and experience of cardiac rehabilitation in relation to smoking cessation

7.1 Introduction

The reviews described in the previous chapters evaluated psycho-educational interventions for specific patient populations from three different standpoints. However, the complexity of the psycho-educational interventions included in the different reviews means that the review designs and interpretation of the review results had to accommodate complexity. The findings from the previous studies highlighted difficulties in defining psycho-educational interventions, in interpreting the results of the systematic review and meta-analysis, and in examining intervention mechanisms and techniques in sufficient detail. The results from the systematic review and meta-analysis suggested that psycho-educational smoking cessation interventions appear to be effective in increasing point-prevalent and continuous smoking cessation for at least up to 24 months. *Post-hoc* statistical subgroup analyses suggested that the intensity of the intervention significantly influenced its effectiveness. Further analyses of intervention mechanisms and techniques indicated that interventions were utilising only a limited pool of intervention techniques.

The results of the statistical analyses, alongside those from the analyses of intervention mechanisms and techniques have indicated that reviewing complex interventions and placing the results in the practical context confront various challenges. The meta-analysis of psycho-educational smoking cessation interventions indicated considerable heterogeneity between the interventions, and *post-hoc* subgroup analyses suggested that the intensity of the intervention influenced intervention effectiveness. However, somewhat contrary to the expectations, the detailed analysis of intervention mechanisms and techniques indicated that interventions appeared to use similar techniques to influence behaviour. Therefore, these analysis results underlined the difficulties in designing and evaluating complex health care interventions. The complexity of an intervention was not evident in the

type of behavioural determinants that interventions targeted or the type of behaviour change techniques employed to influence the targeted behavioural determinants. The analysis of the influence of theoretical models in intervention design indicated that only limited differences between studies that used theories in study design and those that did not use any specific theoretical model. Therefore, it appears that at the more abstract or theoretical-level complex interventions in this analysis had similar intervention mechanisms. This means that the complexity of the interventions may stem from other causes, such as interactions between different stakeholders and the implementation of an intervention (e.g. Craig et al., 2008, Egan et al., 2009).

The studies presented in the previous chapters have investigated theories underpinning interventions and mechanism of complex interventions from the intervention perspective. However, the previous studies have not examined how participants' perceptions of complex health care interventions can help in understanding intervention complexity, theories, and mechanisms. The meta-analysis discussed in the Chapter 5 indicated significant heterogeneity between the studies included in the analyses and *post-hoc* subgroup analyses suggested that intervention intensity may be linked with intervention effectiveness. On the other hand, the analysis of intervention techniques and mechanisms suggested that interventions are deploying a relatively limited pool of behaviour change techniques to influence behavioural determinants. Therefore, intervention participants' perceptions of an intervention either before or after participating may help to explain some parts of why seemingly similar interventions differ in their effectiveness, what makes interventions complex, and to further clarify intervention mechanisms.

The previous empirical chapters have shown that though possible causes of intervention complexity, such as complex interactions between different stakeholders (Medical Research Council, 2000), are well understood, traditional systematic review and meta-analysis may not be able to demonstrate what are the causes of complexity within the review. In this project, results from systematic review and meta-analysis indicated that intervention complexity caused significant heterogeneity, but the exact causes of intervention complexity remained unknown. The *post-hoc* analyses suggested that intervention intensity may be associated with effectiveness, indicating that differences in intervention techniques and mechanisms may cause complexity in

interventions. However, detailed analysis of intervention mechanisms and techniques showed that, contrary to expectations, interventions deployed very similar mechanisms and techniques to influence participants smoking behaviour. Thus, in this example, intervention complexity appeared not to be caused by differences in intervention planning.

The foregoing empirical Chapters (5 to 6) have examined effectiveness of complex health care interventions and mechanisms through which intervention effects may be delivered. Though systematic review and meta-analysis in Chapter 5 was able to identify intervention intensity as one of the possible causes for intervention complexity, traditional systematic review and meta-analysis designs have limited scope in examining intervention mechanisms. Chapter 6 presented the results of examining mechanisms of complex interventions, and found that while individual studies may have found differences in the effectiveness of different interventions, those differing interventions were using similar processes through which to effect change. This qualitative review aimed to further examine whether understanding participants' perceptions of complex interventions would help better understand those processes through which interventions may achieve their effects.

The empirical studies reported in this thesis have provided some novel and valuable insights into complex psycho-educational smoking cessation interventions. These interventions, although complex, appear to deploy similar mechanisms through which participants' behaviour changed is aimed to support. Examining participants' perceptions may help in understanding participant related complexities in psycho-educational interventions and why seemingly similar interventions can differ considerably in effectiveness. As discussed earlier (on page 19), complex interventions are characterised by complex interactions between participants, intervention providers and organisations (Black et al., 2000). In this chapter it is suggested that factors relating to intervention participants may explain some of the complexity in these interventions. The complexity of the intervention will be examined from the viewpoint of the participants, to see whether taking their perceptions into account may help understand complexity in interventions. Therefore the chapter aims to examine if participants perceptions may help in understanding causes of complexity in seemingly similar interventions.

The empirical study reported in this chapter poses several questions:

- Can and how may qualitative research on participants' experiences and expectations of psycho-educational cardiac rehabilitation interventions be used to improve understanding of intervention complexity?
- When, taking into account participants' perspectives, what factors may have contributed to the complexity of an intervention?
- In what ways may participants' perspectives further the understanding of intervention mechanisms such as the acceptability of used techniques.

Answers to these questions are sought through the following three specific research sub-questions.

- Firstly, what are coronary heart disease patients' expectations of cardiac rehabilitation?
- Secondly, what participants' experiences and perceptions of cardiac rehabilitation interventions are?
- Thirdly, what may be participants' preferred intervention features and what should an effective intervention include?

In this case study, similarly to the previous case studies in the chapters 5 and 6, if enough studies are found, the review will focus on expectations and experiences of psycho-educational smoking cessation interventions for coronary heart disease patients. This approach was judged reasonable in this present case. As no recent qualitative review of patient experiences of psycho-educational cardiac rehabilitation interventions or smoking cessation interventions for coronary heart disease patients was found, it was difficult to estimate the number of available studies. Some qualitative research is available in assessing the process of smoking cessation (Ritchie et al., 2007), but this examines the process of change rather than participants expectations and experiences. A predominantly qualitative review by Beswick et al. (2005) has investigated cardiac rehabilitation to understand interventions that aim to increase adherence and uptake to cardiac rehabilitation. The question-setting in this systematic review of qualitative research is designed to complement the information gained in the previous reviews and to help evaluate whether or not an addition of a qualitative review succeeds in further clarifying intervention mechanisms and causes for complexity in this particular set of interventions.

The suitability of qualitative research for systematic reviewing and synthesis continues to be debated (Pawson et al., 2005, Sandelowski et al., 2007, e.g. David and Diana, 2002). While this debate is acknowledged, in this empirical study, the view will be taken that systematic reviewing and synthesising qualitative research is both possible and meaningful. Support for this standpoint is also seen in the literature, which indicates increasing recognition, acceptance and use of such methods in health and social care research and policy development (e.g. Pawson et al., 2005, Sandelowski et al., 2007), despite considerable methodological challenges for how this can be best done (e.g. Dixon-Woods et al., 2005, Mays et al., 2005).

This case study therefore takes the stance that qualitative synthesis can provide vital information about how and why interventions work or do not work, from the participants' viewpoint, and therefore is likely to be especially useful in adding to the understanding of reviews of complex health care interventions. The methodology used in this review and synthesis draws on the guidance and literature such as by Petticrew and Roberts (2006) and Lucas et al. (2007), and from a previously published review, by Thomas et al. (2004). The present qualitative systematic review will be following the principles of quantitative reviewing in study search and data extraction, while following qualitative principles in synthesising data. The protocol for this review is included in the Appendix 3.

7.2 Methods

7.2.1 Identification of studies

A search strategy to identify the potentially relevant qualitative studies was developed using guidance from Petticrew and Roberts (2006) and Shaw et al. (2004), and was based partly on the search strategy developed for quantitative studies reviewed in previous studies. As with developing the search strategy for the systematic review, the qualitative search strategy needed a decision about using published search filters. Using published and tested methodological search filters can improve the specificity of the search. Although methodological filters for qualitative research have been published, (e.g. McKibbin et al., 2006), it is uncertain how well they would work in

this type of a review. For example the Cochrane Handbook (e.g. Higgins and Green, 2011) does not recommend that a search strategy for qualitative research apply study design filters. This is because currently indexing terms used for qualitative research in bibliographic databases may not be accurate. Therefore, in the present case it was decided against deploying published methodological filter as part of the qualitative search strategy. Instead methodological search words were derived from the literature.

The search strategy (fully set out in Appendix 3) was designed to be broad, to identify as many potentially relevant studies as possible, and included some of the following words; cardiovascular disease, heart attack, rehabilitation, lifestyle, qualitative, and thematic analysis. Although the search strategy was designed to be broad, it did contain methodological terms, which may limit the number of studies identified in the search. The search strategy was not designed to locate only qualitative research that investigated participants' perceptions of smoking cessations studies, as there was considerable uncertainty of the number of available studies. Studies were searched from 1970s onwards, as the same criteria was applied for the search of the quantitative studies due to changes in cardiac mortality (Shiffman, 1993, Skinner et al., 2007) and the changes that started happening in recognition of qualitative research in 1970' (e.g. Denzin and Lincoln, 2005).

7.2.2 Study selection

The search was limited to published articles written in English, and no record in this occasion was kept of the number of papers excluded due to language restriction. Language restriction was considered necessary due to the lack of resources to fully translate potentially relevant papers, and due to the uncertainty about how accurately the search words could identify non-English language papers. The participant population for this review was the same as in the previous systematic reviews, namely persons over the age of 18 years with confirmed coronary heart disease and eligible for cardiac rehabilitation. As previously, a person with a following condition was defined to have a coronary heart disease; angiographically defined coronary heart disease, angina pectoris, myocardial infarct (MI), coronary artery bypass graft surgery

(CABG), percutaneous transluminal coronary angioplasty, and heart failure caused by MI.

Included studies needed to be able to provide information about coronary heart disease patients' expectations and experiences of cardiac rehabilitation, or information about patient preferences regarding cardiac rehabilitation. For studies that investigated participants' prior expectations of cardiac rehabilitation determining the exact type of intervention offered to participants was not often possible. However, for studies that explored post-participation experiences, the intervention needed to specifically include some psycho-educational components and methods. Psycho-educational components were such as behaviour modification (e.g. smoking cessation) and psycho-educational methods were such as teaching, education, advice, counselling, and information transfer for changing behaviour. Interventions that combined psycho-educational methods with stress management, relaxation training, or exercise training were also included. The format of the intervention was not defined, and the intervention could have been delivered in individual or group format, or as a combination of these. For those studies that researched participants' expectations of cardiac rehabilitation interventions, no criteria were set. In cases where there was uncertainty about applying inclusion criteria, a second opinion was sought from a supervisor. Only studies that used a qualitative methodology and included first-hand information from coronary heart disease patients were considered for inclusion. The qualitative methodology used in a study was not specified, as many different methodological approaches may have been used to research participants expectations and experiences of cardiac rehabilitation. Studies or parts of studies that reported participants' relatives or other close relationships' experiences of cardiac rehabilitation or smoking cessation interventions were excluded. There were no time limits on how long before or after participants' attendance in cardiac rehabilitation programmes the study was conducted. Studies were also included if they explored reasons of non-attendance, but not exclusively barriers to attendance.

7.2.3 Assessment of study quality and data extraction

It is recognised that the area of assessing quality of qualitative research is debated (e.g. Barbour, 2001), but in this study, the stance is taken that the methodological

quality of the papers can be assessed to evaluate the overall quality of the papers. However, methodological appraisal of the papers is not used in deciding inclusion or exclusion of the studies, and it is acknowledged that different researchers will have different views on systematically evaluating qualitative research and how this should be done. Quality assessment criteria were developed for purposes of this review using different published sources (Petticrew and Roberts, 2006, Public Health Resource Unit, 2006), and are included in the Appendix 3. It is noted that as studies to be included for the review are likely to have used different methodological approaches, the quality assessment criteria was necessarily broad and covered; study planning and design, participant description, data collection and analysis, study reporting, and ethical issue reported in the study. Although it is acknowledged that views of what constitutes as weaknesses in a qualitative study are contested (Centre for Reviews and Dissemination, 2009), quality assessment criteria used in this study evaluate the following methodological points: whether the research aim is clear and the study uses appropriate qualitative methodology; is the design defensible and do data collection and analysis methods fit; how well the selection and characteristics of participants are described; is the relationship between participants and researcher/s stated; are data collection and recording methods discussed and is it specified when data collection is complete; is the process of data analysis discussed and are the links between data interpretations and conclusions clear; are findings explicit and backed by the data, and is the credibility of the findings discussed; and their relation to original research question. Quality assessment included also noting how far there was consistency between the offered quotes from the original participant data and the authors' descriptions and analyses of the research material. Studies were not ranked according to their quality assessment, but weaknesses in the study methodology, according to the quality assessment criteria designed for this review, were noted.

The data extraction sheets were developed specifically for this research (Appendix 3). The data collected from the primary studies included data about participants, methods, intervention, and findings. Data collected about participants included information on; inclusion of all or parts of the results, diagnosis, participant inclusion criteria, total number of eligible participants, number of participants approached, participant selection method, number of participants in the study and their gender, ethnicity, age group participant population, research design, data collection and

analysis methods and results. Data collected from the methods section included; type of study, research aim, data collection method, analysis method, if groups were used in data collection how participants were allocated in the groups and time from intervention. Data collected about findings included; theme or narrative component as reported and illustrations for this.

Data were collected mainly from the methods and results sections of the articles, unless it was found, in specific cases, that some relevant additional data was presented in the discussion section, in which case, this was highlighted on the data collection sheet. Data collected included study authors' descriptions and analyses of the research material, not original quotes from research participants to illustrate points made by the authors. In cases where different participant groups were included in the research, such as participants that attended or did not attend cardiac rehabilitation, data were extracted separately for the different groups if possible. If authors had organised the research results under headings, these headings, such as "views of coronary heart disease", were extracted *verbatim* as themes or narrative components. To illustrate the meaning of the themes, data were extracted from the text part of the results. This data included description of how the themes were constructed. This data was not extracted as *verbatim* in most of the cases, but rather in short discretions of different points raised in the results that were used to describe the thematic headings. Data extracted for the illustration section included also any differences within the themes as reported by the authors, such as how different participant group reported different experiences. However, information was not collected about if authors reported a number of participants that gave information to specific themes. In cases where results were not organised under clear thematic headings, but rather presented as continuous discussion, data from the results section of the papers were extracted, and tentative thematic headings or narrative components decided for the data to help in data organisation. Data extraction was not duplicated, as there were no available resources for doing this, which means that it is not possible to verify the correctness of the data extraction, or exclude a possibility that the data extraction and the following analysis of the data may have been influenced by the prior expectations of the author.

7.2.4 Analysis methods

Data analysis drew on the principles of thematic synthesis, which allowed not only exploring identified themes in the studies but new and combined themes to emerge from the research material. Analytic principles were data- not theory-driven, meaning that the themes emerged from the data, rather than the data being used to test predefined themes. This was appropriate because the purpose of the study was to explore the range of patients' experiences and expectations about cardiac rehabilitation, and to investigate similarities and differences between themes that were found in the available research materials. The data collection and analysis pursued the following steps. The research articles, especially methods and results sections of the studies were carefully read, and the available information was used to complete the quality assessment. Data were extracted using the data extraction sheets designed for this review, and result sections of the research papers were used to locate this information. Where results were organised under themes or narrative components, these were extracted in *verbatim* as headings to the data collection sheet. Underneath of the headings data were collated about authors' descriptions and explanations of the meaning of the headings. In cases where materials were not organised within clear themes or narrative components, rough headings were devised to reflect issues considered in the text. Although the themes and narrative components were extracted as written in the text, key points and illustrations about meaning of the headings, rather than explanations and descriptions as whole paragraphs, were extracted. In some cases, however, it was necessary to extract whole paragraphs *verbatim*, which was acknowledged on the data sheet.

After the data extraction was completed, the next step in the analysis consisted reading the extracted themes and meanings of the themes and comparing them to the original texts to ensure that all relevant data has been collected and the information corresponds with the original data. Any discrepancies found at this stage led to correcting the extracted data. The next round of reading aimed to establish how far similar themes could be found in the data. These might include experiences of coronary heart disease or myocardial infarction, expectations of cardiac rehabilitation, and causal attributions of coronary heart disease. Themes were not only identified based on the extracted themes or narrative components, but also using

descriptions and explanations offered by the available data. Data was organised and re-grouped at this stage so that those themes and explanations that discussed similar issues, such as patients' experiences of cardiac rehabilitation, were clustered together. However, the themes or narrative components and their explanations as collected from the original text were kept together within the clusters. At this stage, it was found that the most themes were based on themes, though not identically named, that were explicitly given in the original texts. In the final stage of the analysis, the clusters of narrative themes or components with their adjacent explanations were analysed. The themes for these clusters were decided through combining the existing themes and themes arising from the data. At this stage, the data collected about the explanations of the meaning of the themes were coded and re-organised within the new themes. In some cases, the themes could include subsets of information, such as separating meaning of the themes for those participants that did or did not participate in cardiac rehabilitation. However, meanings of the themes continued to be linked to original authors to ensure that data can be traced and verified if needed. No computer programme was used to assist in the analyses. It should be noted that though the data analysis process is described here as progressing in clearly defined stages, in reality the analyses required moving back and forward iteratively, between different stages. This was notable especially in cases where after initial clustering of the themes or narrative components, the reading of the meaning of the themes suggested that the explanations provided fitted better with an alternative theme or suggested a new theme altogether.

7.3 Results

PsychInfo, Cochrane, CHINAL, and Medline R databases were searched for relevant studies as these databases were known to include healthcare related research, and initially 3345 citations were identified as potentially relevant for the review. The number of citations identified and selected from each database for further review is shown in the Figure 7.1. After scrutinising the potentially relevant citations, 28 studies were selected for the full text review, of which 14 were included in the final review. Reasons for exclusion included, a study not having a qualitative research design, uncertainty about whether the intervention included a psycho-educational component (where applicable), and where a study explored the experience of a

myocardial infarct, but not of a cardiac rehabilitation. It is difficult to estimate whether the search was successful in identifying all relevant qualitative studies available. There was no recent, or indeed later, review identified that could have been used to compare the number of identified studies. The search was also limited to well-established databases, and no grey literature was searched in this occasion, as only published studies were included. Study authors were not contacted for any unpublished papers. Although hand searching the papers for additional articles was attempted, this yielded very limited results, as it was found that the titles of the papers included in the reference lists did not often provide information that was useful for deciding whether or not number of papers should be checked or not. However, although the search for the research papers was challenging, the search was able to locate 28 studies for full text review, which compares with 20 papers selected for the full text review for systematic review and meta-analysis, though the target intervention for these studies was more tightly defined.

Two of the of included studies (Cooper et al., 2005, Hutton and Perkins, 2008), however, did not provide a clear description of the cardiac rehabilitation intervention. After some deliberation these studies were included, as in the study by Cooper et al. (2005), where patients were waiting to start a cardiac rehabilitation programme and in the study by Hutton and Perkins (2008) results suggested strongly that, apart from exercise training, intervention had accommodated some psycho-educational elements, both of which cases comply with inclusion criteria for the studies. During the search, no qualitative studies were found that investigated patients' expectations and experiences of psycho-educational smoking cessation interventions alone, and so the review concentrated on participants' experiences and expectations of cardiac rehabilitation interventions with psycho-educational components.

7.3.1 Description of included studies

The research reported in the included studies was conducted, but not necessarily published, in one of four countries; United Kingdom (8), Canada (3), Ireland (2), and New Zealand (1). Papers were published predominantly in nursing journals, and all apart from two studies, were published after the launch of the National Service Framework for Coronary Heart Disease (2000) in the United Kingdom. All

participants in the included studies had a confirmed coronary heart disease diagnosis; MI, CABG, angioplasty, medically managed coronary heart disease, or established need for cardiac surgery due to coronary heart disease. Overall study quality was found to be good, and all included studies had used either an interview or a focus group method for data collection. Table 7.1 sets out study methodologies and participant characteristics, Table 7.2 provides a short description of the interventions, and Table 7.3 summarises assessment of the study quality.

Although the purpose of this review was to consider research evidence on patients' expectations and experiences of cardiac rehabilitation, what also emerged from the analysis of these articles was a sense of these patients' journey through coronary heart disease (CHD) and, relatedly, how cardiac rehabilitation fitted into their process of recovery. Importantly, these articles have also explored reasons for non-attendance or partial attendance to cardiac rehabilitation, and preferences for certain types of cardiac rehabilitation, such as home-based compared with hospital based rehabilitation. Identifying these provided further insights into why research on psycho-educational cardiac rehabilitation interventions may at times offer contradictory evidence.

7.3.2 How far qualitative review evidence answered research questions of participants' expectations and experiences of cardiac rehabilitation interventions with psycho-educational components?

Thirteen separate themes, listed below, emerged from the data. While all of the themes and evidence from the studies for them are discussed below in detail, not all themes were found to contribute to the research questions. Therefore, after presenting the results and evidence individually for the identified themes, themes are then combined so as to answer the research questions and a short summary of the results for the three questions are presented. In the list which follows, the themes highlighted in italics are those which provided information for the research questions, and, in the list the theme names are followed by the question number in brackets that it has provided information for. Several themes were found to provide relevant information for not just one but for two or three of other questions. In some

cases, however, not all information from the themes was relevant or useful to answer the research questions. It should be also noted that while some of the themes, such as themes numbered 7 and 8 are similar, it was judged that they needed to be listed separately to clarify the information they provided. In addition, the words ‘hospital-based’ and ‘centre-based’ ‘cardiac rehabilitation’, ‘patient’ and ‘participant’, will be used interchangeably in the following text. This decision was taken, as especially in the case of ‘patient’ and ‘participant’, it would otherwise be difficult to differentiate when a coronary heart disease patient become a research participant. Although at points in the following text the terms ‘coronary heart disease’ and e.g. ‘myocardial infarct’ have been used interchangeably, it is recognised that this may not be an entirely accurate description of the participant’s exact condition, but does avoid the potentially confusing listing of differential diagnoses. For the reasons of space and practicability, extracts of the original texts will be only included in the summary answers for the research questions, not in the results of individual themes.

7.3.2.1 Themes extracted from the data

1. Physical, psychological and social effects of myocardial infarct
2. *Living with coronary heart disease, before and after attending cardiac rehabilitation (Q1 & Q3)*
3. *Process of recovery (Q1)*
4. Who influences decisions to attend cardiac rehabilitation?
5. *Factors affecting decision to attend cardiac rehabilitation reported both pre- and post-attendance (Q1 & Q3)*
6. *Seeking causal attributions for heart attack and understanding treatment of coronary heart disease (Q1)*
7. *Beliefs about content of cardiac rehabilitation before and after attending (Q1, Q2 & Q3)*
8. *Experience of cardiac rehabilitation (Q2 & Q3)*
9. *Perceived need for information before and after cardiac rehabilitation (Q2)*
10. *Perceived benefits of cardiac rehabilitation (Q3)*
11. *Process of attending cardiac rehabilitation (Q1 & Q3)*
12. Barriers to cardiac rehabilitation attendance

13. *Participant suggestions for a cardiac rehabilitation programme (Q2)*

1. *Physical, psychological and social effects of myocardial infarct*

Participants described how experiencing a myocardial infarct caused a range of emotions, such as disbelief (Wingham et al., 2006), fear of death (Clark et al., 2004), and feeling body vulnerable (Day and Batten, 2006). Participants described also how experiencing a heart attack had changed their perceptions of their health and the world around them (Tamada and Holmes, 1998, Day and Batten, 2006). Participants also described how a myocardial infarct had affected their individual roles and responsibilities (Wingham et al., 2006), and contributed to loss of confidence (Wingham et al., 2006), particularly in deciding what they were and were not able to do, and how losing confidence had left them feeling anxious (Wingham et al., 2006). In addition, some participants described how family members had lost confidence in them (Tamada and Holmes, 1998).

Qualitative research appears to suggest that experiencing a myocardial infarct or facing a cardiac surgery due to coronary heart disease has major physical, psychological and social consequences for an individual. This was reflected in participants' descriptions of their feelings of fear, loss of confidence, anxiousness, and how roles and responsibilities were felt to change after an illness. Results of the qualitative research indicate that the health care interventions aimed for this patient population can be complicated by the factors outside of an intervention design and implementation. The dynamics of the intervention may be influenced by a patient's individual response to a cardiac event, for example, loss of confidence and how patient expects cardiac rehabilitation help in rebuilding confidence. Therefore, qualitative research indicates that some of the complexity of a complex intervention may be understood by identifying patients' different and specific perceptions of effects of a cardiac incident and how these interact with the intervention.

2. *Living with coronary heart disease, before and after attending cardiac rehabilitation*

Qualitative research described how participants found that coronary heart disease challenged them to engage with new ways of living (Day and Batten, 2006). Available evidence suggested that coronary heart disease can disrupt activities and restrict roles and how patients try to reach “everydayness” with coronary heart disease (Clark et al., 2004). Clark et al. (2004), however, found that experiences of living with coronary heart disease were different depending on participants’ attendance to a cardiac rehabilitation. In their study, Clark et al. (2004) investigated participants with high attendance to cardiac rehabilitation, those with high attrition to cardiac rehabilitation and those who did not attend. Common to all these groups was the experience that coronary heart disease affects every area of life, and feeling a loss of independence. However, after cardiac rehabilitation, the high attendance group talked about effects of coronary heart disease in the past tense, felt able to manage and have an active role in managing the disease. These participants also felt that the coronary heart disease was a warning to change their behaviours. In comparison, participants in high attrition and non-attendance groups felt that disruption caused by the coronary heart disease was on-going, experienced the future as less certain, and reported how feelings of fear persisted as they felt that their bodies were failing them. Further, these participants described a sense of unreality, and continued feeling unwell and helpless to combat the illness.

This qualitative research indicated that suffering coronary heart disease can considerably restrict patients’ roles, and challenge them to re-evaluate their lives. Available evidence suggested that while patients strived to normalise their life, there are considerable differences how well participants adapt to their new life situation and cope with the expected lifestyle changes. The study by Clark et al. (2004) suggested that participation in a cardiac rehabilitation may facilitate normalising life after coronary heart disease and successful lifestyle changes. Leaving aside the continuing negative impact of a cardiac incident for those patients that did not attend cardiac rehabilitation, the qualitative research indicates that participants’ adherence to intervention can have a marked impact on how an intervention works. Results indicate that an intervention may be effective for those participants that regularly attended. However, in order to avoid overestimating the effectiveness of interventions, in effectiveness analyses, all participants, regardless of their attendance records, are usually grouped together. However, qualitative research indicates that

that the evaluation of psycho-educational cardiac rehabilitation intervention appears to be complicated by the different effects of interventions, depending on participants' attendance.

3. Process of recovery

The qualitative research included, indicated that while there appears to be no set timeframe for recovery from coronary heart disease, this is a process that may continue for years (Day and Batten, 2006). Participants have presented the goal of recovery as, for example, gaining "everydayness", which may mean returning to life before coronary heart disease or incorporating changes brought by the disease as part of daily life (Jones et al., 2007). Available evidence also points out that while participants appeared to be aware of the need of lifestyle changes in the face of the coronary heart disease, citing smoking and diet as important lifestyle change targets, they nevertheless often lacked motivation to go through with the changes (Jones et al., 2007). Interestingly, lifestyle changes could be introduced even before the present illness episode if participants themselves or their partners had had previous heart problems (Jones et al., 2007). Jones et al. (2007) also found that family support was important for recovery from the coronary heart disease, as well as for learning to understand the new reality, as reported by Tamada and Holmes (1998). Hutton and Perkins (2008) reported that participants appeared to use behavioural and cognitive mechanisms to cope with the recovery from coronary heart disease. Cognitive strategies such as acceptance, religion, humour, and not thinking about the myocardial infarct were described by participants, as well as moderate changes achieved to diet, exercise, smoking, and avoiding stressful situations. While Hutton and Perkins (2008) noted that, initially, participants tended to limit their physical and social activities, participants gradually increased these activities when their confidence grew.

Taking responsibility for recovery and health was a recurring theme in some of the studies (Murie et al., 2006, Wyer et al., 2001a), which illustrated, for example, how participants emphasised their responsibility for recovery, i.e. 'what can I do' instead of 'what can be done for me' (Murie et al., 2006). It was recognised, however, that not everybody is willing to take responsibility for their own recovery (Wyer et al.,

2001a), and that there appear to be considerable differences in attitudes to recovery between participants (Wyer et al., 2001a). For example, Wyer et al. (2001a) explored the views of three different groups of participants; those who accepted invitation for cardiac rehabilitation and attended (“attenders”), those that accepted invitation to cardiac rehabilitation but did not attend (“accepters”), and those that did not accept invitation to cardiac rehabilitation and did not attend (“non-attenders”). Wyer et al. (2001a) reported how participants in the “attender” and accepter groups felt control over their recovery, whereas the “non-attenders” felt that little could be done to coronary heart disease. Moreover, though all participants regardless of cardiac rehabilitation attendance valued medication as a treatment, the “attenders” were found to hold a psychological model to recovery, whereas the “accepters” and “non-attenders” held a medical model of the CHD recovery. “Attenders” felt responsibility for their own health and felt that recovery requires more than just medication. Participants in the “accepter” and the non-attenders groups considered their recovery responsibility for medical profession and valued medication very highly. Additionally, Murie et al. (2006) found that in their study, participants felt that active participation in decision making about treatment was limited to lifestyle changes, as in many cases, such as cardiac surgery, shared decision-making was considered inappropriate due to the risk of making a wrong decision and therefore best left to professionals (Wyer et al., 2001a).

Research evidence therefore indicates that recovery from coronary heart disease may continue for years while patients aim to normalise their lives. Learning about coronary heart disease and family support were considered important factors in the recovery process. Generally, participants were aware of needs for making lifestyle changes, but at times the lacked motivation to do this. Studies also highlighted differences in participants’ perceptions of whose responsibility the recovery from the coronary heart disease is, which appeared to be also associated with participants willingness to participate in, for example, a cardiac rehabilitation. In some cases, however, participants felt that decisions regarding treatment such as cardiac surgery and about recovery were outside the remit of individuals.

Qualitative research indicates that many coronary heart disease patients are aware of the need for lifestyle changes, but lack motivation in achieving behavioural changes,

such as smoking cessation. Analysis of the intervention mechanisms and techniques reported in the previous chapter suggested that interventions aimed to motivate and help participants to go through with lifestyle changes using number of techniques such as social support, behavioural information, and coping strategies. Interestingly, qualitative research indicated that patients were often aware of the need for changes, whereas the analysis of intervention mechanisms and techniques in the previous chapter suggested that interventions appeared to make considerable efforts to inform participants for the need of change. Therefore, it is unclear whether some of the efforts directed at informing participants of the need for change may be, at least for some participants, more productively directed to achieving the change.

Qualitative research highlighted another aspect that may explain some of the complexity in health care interventions that aim to change behaviour. Wyer et al. (2001a) noted that patients can have very different approaches as to whose responsibility they see for their recovery, which, according to Wyer et al. (2001a), may also impact on their decisions to attend intervention activities. According to Wyer et al. (2001a), cardiac rehabilitation “attenders” saw recovery as their responsibility, whereas those who did not attend appeared to see recovery as the responsibility of the medical profession. The perceived differences between participants about whose responsibility their recovery is, may help to understand some complexity in psycho-educational smoking cessation interventions. The psycho-educational smoking cessation interventions included in the systematic review were initiated while patients were in hospital, which was likely to increase rates of participation. However, the techniques and mechanisms used in interventions appeared to emphasise the role of the individual as an agent of successful smoking cessation, as in making contract, planning, social support, and teaching coping strategies. However, the qualitative research suggested that some participants may not be as responsive to these techniques as they require taking an active role in smoking cessation and recovery from a cardiac incident, which they consider to be the role of the medical profession.

4. Who influences decisions to attend cardiac rehabilitation?

Wyer et al. (2001a) found that although opinions of family and friends appeared to have no marked influence on participants' decisions to attend a cardiac rehabilitation, professional advice had a bearing on their decision making process. Wyer et al. (2001a) noted that recommendations from doctors and carer nurses influenced decisions to attend especially for the participants in the "attender" group, whereas participants in the "accepter" and "non-attender" groups appeared not to mention professional input or advice about attending cardiac rehabilitation. Hird et al. (2004) reported that though a majority of participants in their study reported receiving information about cardiac rehabilitation, still almost third of the participants could not recall receiving any information. While at times participants were unsure who had informed them about cardiac rehabilitation, the most common professional group to be cited by participants as a source of information was physiotherapists, though doctors, nurses, health visitors and even a receptionist were mentioned (Wingham et al., 2006).

While the available evidence is limited, it nevertheless indicates that decisions to attend cardiac rehabilitation appear to be influenced by healthcare professionals, especially by doctors, while family and friends had little influence on attendance decisions. The available evidence does not allow making inferences about whether the reported lack of information was due to participants not being informed about cardiac rehabilitation or their not remembering receiving the information. However, the evidence suggested that information about cardiac rehabilitation was received from various members of health care professionals. Another aspect of a complex intervention appears the difficulty of informing participants of the availability of an intervention and the possible differences in quality and accurateness of the information received by the possible participants. The source of information, as suggested by Wyer et al. (2001a), may have considerable influence on uptake of an intervention, and on expectations placed on the intervention.

5. Factors affecting decision to attend cardiac rehabilitation reported both pre- and post-attendance

Qualitative research indicated considerable differences between participants' expectations of a cardiac rehabilitation. The research indicated that while some participants had firm expectations, for example, that cardiac rehabilitation would help in re-building confidence (Wyer et al., 2001a), others expressed doubts about the benefits of attending cardiac rehabilitation (Wyer et al., 2001a), and others felt uncomfortable regarding some aspects of the rehabilitation (Hird et al., 2004). Hird et al. (2004) also described how just over half of the participants in their study appeared positive about attending cardiac rehabilitation, but many were ambivalent when asked if attendance in a cardiac rehabilitation mattered. The study by Hird et al. (2004) also suggested that participants held a range of attitudes towards exercise and group sessions. While a majority saw benefits in group sessions, such as changes in speaking and comparing progress with others, some concerns were expressed about possible embarrassment if falling behind, conflict between individual and group needs, and dislike of groups (Wyer et al., 2001a).

The study by Wyer et al. (2001a) explored reasons given by the cardiac rehabilitation "attenders", "accepters but not attenders", and "non-attenders" for either attending a cardiac rehabilitation or not. Cardiac rehabilitation "attenders" considered rehabilitation beneficial and helpful in preventing future myocardial infarct. These participants also considered that cardiac rehabilitation must be beneficial, as it would not be offered otherwise in public health care services. "Accepters", on the other hand, had doubts about benefits of cardiac rehabilitation, and the initial acceptance of the invitation appeared to be driven by fear and poor health, but after a good recovery and possible medical procedures e.g. CABG, participants did not see themselves as ill and perceived no further need for a cardiac rehabilitation. "Non-attenders" did not perceive cardiac rehabilitation as relevant or beneficial for them, as commonly this group of participants did not attribute myocardial infarct to long-term lifestyle factors, but events immediately preceding it, such as physical exertion, which should now be avoided. "Non-attenders" also considered avoiding stress important, and as many perceived cardiac rehabilitation as stressful, it was seen best avoided. (Wyer et al., 2001a).

According to Wyer et al. (2001a), their results indicate that cardiac rehabilitation “attenders” perceive myocardial infarction as having consequences and a possibility of recurring, which had led them to approach coping with the disease by seeking information and help from others to inform their decisions of recovery. In this way “attenders” perceive and use cardiac rehabilitation, as a problem based solution to fears caused by myocardial infarct. In contrast, participants in the “accepter” and “non-attender” groups appeared using avoidance as a coping strategy by not considering myocardial infarct as a major event. Participants in these groups tended to see cardiac rehabilitation as a hindrance in returning to normal, and reported wanting to recover without input from health professionals. In addition, Murie et al. (2006) found that participants criticised the existing cardiac rehabilitation materials as not promoting empowerment, while Tamada and Holmes (1998) suggested that participants in their study trusted that the interdisciplinary team would meet their learning needs during hospital stay.

The qualitative research evidence reviewed above suggests that perceptions of usefulness of cardiac rehabilitation may have a marked influence on decisions to accept invitation to participate in a cardiac rehabilitation. Available evidence suggested that participants’ opinions of a usefulness of cardiac rehabilitation were varied, and while some expected definitive benefits from attendance, others were doubtful and ambivalent about the possible benefits of attendance. Participants expressed particularly mixed views about cardiac rehabilitation that included group exercise sessions. Available qualitative research argued that attendance of cardiac rehabilitation appeared to be associated with explanations of causes of coronary heart disease and coping strategies with the illness. Considered as a body, the available evidence suggests that participants’ preconceived views and worries about cardiac rehabilitation as well as their individual coping style may affect decisions to attend cardiac rehabilitation.

Qualitative research suggests a range of issues which may impact on the complexity of an intervention. As with previous themes, complexity appears to arise from participants perceptions of the intervention, and doubts that how a common intervention may be able to respond to individual needs, or indeed doubts about the

need for cardiac rehabilitation. These interactions between intervention and participants make an intervention complex, as intervention cannot influence or indeed often plan for them, as these interactions between participants and an intervention commence before the start of an intervention, but may nevertheless influence the outcomes of an intervention. Qualitative evidence also suggests that although those participants that attend to a cardiac rehabilitation may have different expectations and fears of what the intervention offers, they appear to have in common acknowledgement that cardiac rehabilitation is beneficial for them, and are if needed willing to overcome their initial concerns of participating.

6. Seeking causal attributions for heart attack and understanding treatment of coronary heart disease

Research by Cooper et al. (2005), for example, described how participants expressed need to seek causal attributions for suffering a heart attack. While Cooper et al. (2005) found that none of their participants referred directly to the underlying nature of coronary heart disease, risk factors such as cholesterol and smoking were commonly mentioned. Regardless of participants recognising some of the known risk factors for coronary heart disease, Cooper et al. (2005) noted that participants' explanations of their heart attack included elements of mystification and misunderstanding. As contributing factors to a heart attack participants mentioned stress, worry, and exercise. However, some participants commented on the discrepancy between stress as a contributing factor to a heart attack and on the perceived lack of stress at the moment of their heart attack. The research by Cooper et al. (2005) also suggested that participants' causal explanations for their heart attack influenced their decision to attend cardiac rehabilitation so that those who found little causal explanation for their heart attack were less likely to consider cardiac rehabilitation as beneficial.

As well as the findings from Cooper et al. (2005), Corrigan et al. (2006) suggested that participants especially from socio-economically deprived urban areas emphasised the role of stress in causal explanations of their heart attack. Corrigan et al. (2006) pointed out that these participants also tended to see behaviour change stressful, and therefore best to be avoided. Some participants, however, described feeling internal

stress from knowing that they should exercise, but not feeling able, while others feared that exercise would deteriorate their heart condition even further. In their study Corrigan et al. (2006) found participants also criticised health services for lack of services to reduce the experienced fear and stress.

Wyer et al. (2001a) argued that their findings suggests participants attendance status to cardiac rehabilitation may be linked to how causes and consequences of a heart attack are understood. According to Wyer et al. (2001a), participants in the “high attendance” group consider myocardial infarct as a serious occurrence that has consequences and requires action, whereas participants in the “high-attrition” and the “non-attendance” groups attempt to minimise the consequences of a myocardial infarct, have doubts about having a myocardial infarct at all, and tend to compare themselves with those worse off. While all groups of participants did mention smoking, diet, family history, and stress as risk factors for having a myocardial infarct and recognised themselves having some risk factors, participants nevertheless tended not to consider themselves as candidates for the diagnosis. When the different groups were compared, Wyer et al. (2001a) found that participants in the “high attendance” group considered sedentary life style, alcohol consumption and high blood pressure to lead higher risk of coronary heart disease, whereas participants in the “high attrition” and “non-attender” groups considered stress, shift work, demanding job and busy life style as risk factors for coronary heart disease. In addition, the “non-attenders” and “high-attrition” groups’ participants tended to be sceptical about the role of smoking in development of coronary heart disease.

Day and Batten (2006) suggested that findings from their study suggested that while information attained during cardiac rehabilitation was perceived helpful in identifying possible causes of a heart attack, some participants remained unsure which of their symptoms were related to a myocardial infarct. When participants were unsure about which of the symptoms were attributable to the myocardial infarct, recovering and returning to everydayness was more difficult. Finally, Mooney et al. (2007), found that a pre-cardiac surgery (CABG) rehabilitation programme can be instrumental in helping the participants to accept that cardiac surgery alone does not cure coronary heart disease, and that participants still need to consider life-style changes.

Research evidence indicates that participants actively seek out causal attributions to their illness. While cardiac rehabilitation was at times perceived as helpful in understanding causes of an illness, these illness attributions can also have significant role in participants' decisions to attend or not in cardiac rehabilitation. Even when recognised risk factors such as smoking and diet were widely mentioned as possible causes of a coronary heart disease, many of the participants' explanations for their illness included elements of misunderstanding and mystification. This was especially evident in attributing immediate stress, worry, or exercise as contributing factors to a myocardial infarct. Available evidence also pointed out that those participants who found it difficult to attribute their illness to specific causes appeared less inclined to attend cardiac rehabilitation.

Qualitative research indicates that the mechanisms of an intervention may be complicated by the discrepancies between participants' causal explanations of the causes of an illness and the information about illness provided as a part of the intervention. If participants' causal explanations do not match the intervention rationale, and the intervention is not able early on to shift these illness explanations, participants may struggle to see the purpose and logic of the intervention, which may complicate the intervention. The qualitative research also suggested that an intervention may be complicated by participants' perceptions of what needs to be avoided after suffering a cardiac event, such as worry, stress and physical activity (e.g. Corrigan et al., 2006). Therefore, intervention may be further complicated by mismatched expectations between participants and intervention personnel. Corrigan et al. (2006) also point out that participants from urban socio-economically deprived areas appear to emphasise stress as causal factor for a cardiac incident. This evidence indicates that further complexity in the intervention may be added by participants' socio-economic backgrounds, which, for example, may influence how relevant different participants perceive an intervention.

7. Beliefs about the content of cardiac rehabilitation before and after attending

Research indicated discrepancies between participants reporting knowing the meaning of cardiac rehabilitation (Wyer et al., 2001a) and their actual knowledge of its content (Cooper et al., 2005, Wyer et al., 2001a). Wyer et al. (2001a) described

how comparing prior knowledge of rehabilitation between different participant groups suggested that while uncertainty about programme content did not deter participants in the “attender” group from attending, it worked as deterrent for participants in the “accepter” and “non-attender” groups. When participants were asked about their understanding of cardiac rehabilitation, they tended to describe it as a group-based activity with some social aspects (Hird et al., 2004), and, as participants in the study by Hird et al. (2004) suggested, it was perceived as prescriptive activity and was associated with recovery from heart surgery. Generally, participants associated cardiac rehabilitation with exercise (Hird et al., 2004, Wingham et al., 2006, Wyer et al., 2001a, Clark et al., 2004), even though it was recognised that it may include elements of health education, behaviour modification, counselling, and relaxation (Hird et al., 2004, Cooper et al., 2005). Participants’ emphasis on exercise was highlighted, for example, by Cooper et al. (2005), who described how participants viewed cardiac rehabilitation as an opportunity to learn about exercise, and felt reassured by supervision offered in the programme, safe environment, and tailored level of exercises. Cooper et al. (2005) found also that apart from seeing exercise training as a possible source of embarrassment and worry, participants tended to misunderstand the level of fitness needed to attend, held misconceptions about the role of an aerobic exercise, and some participants perceived attendance as unnecessary, as exercise can be done at home.

Hird et al. (2004) noted that participants in their study were able to name a maximum of two components of cardiac rehabilitation, which was also understood as a series of specific activities rather than a package of treatment. Apart from exercise-related issues, Wingham et al. (2006) reported that participants expected cardiac rehabilitation to help to return back to normal, assist with lifestyle changes, involve family, and offer them a choice of the rehabilitation method. Participants also expressed a strong desire for guidance about what can and cannot be done and need for a professional support. Participants did not always perceive GPs as knowledgeable enough, but expected cardiac rehabilitation professionals to be available and knowledgeable, also about participants as individuals. (Tamada and Holmes, 1998).

After participating in a cardiac rehabilitation intervention, participants described rather different experiences, depending on the timing and content of the intervention. Findings by Tamada and Holmes (1998) suggested that participants perceived passive learning at the acute stages of recovery as adequate, and appreciated the structured programme of teaching, as participants perceived considerable uncertainty about elements of recovery. A teaching programme was experienced as a combination of actions with helpful teaching aids, and understanding of the issues discussed was reported as deepening as the time passed after discharge. In addition, support and care from staff were perceived as important, participants finding nurses good sources of information and experienced inclusion of the family as helpful. (Clark et al., 2005).

Most studies discussed findings relating to cardiac rehabilitation programmes that had commenced after discharge from a hospital. Research findings suggested that after attending a cardiac rehabilitation programme, participants were positive about its content and considered health education bringing new information and reinforcing known information as important, as well as seeing exercise sessions as adequate and safe due to professional supervision (Clark et al., 2005). There appeared, however, to be some gender differences in how cardiac rehabilitation was perceived. Some women participants felt uncomfortable about asking questions during group sessions, and others reported that their questions were answered only because someone else, usually a man, had asked for similar information (Day and Batten, 2006). Cardiac rehabilitation nurses were found by women to have more time for participants than nurses on the wards, even though the support offered by the nurses was not always related to participants' perceived needs (Day and Batten, 2006). Day and Batten (2006) suggested also that cardiac rehabilitation did not always succeed in changing women's perceptions of their symptoms, as their focus was on the classic coronary heart disease symptoms, which not all women experienced. Moreover, women appeared to confuse coronary heart disease symptoms with symptoms of other comorbidities (Day and Batten, 2006). However, many women nevertheless perceived cardiac rehabilitation central to their recovery process, helping them to recognise significance of their symptoms and working out what recovery meant for them (Hutton and Perkins, 2008). In comparison, men experienced content of cardiac rehabilitation generally positive and felt comradeship with other participants (Hutton and Perkins, 2008). Men also reported increased confidence on exercising under

nurses supervision, and valued one to one support and encouragement received in rehabilitation (Hutton and Perkins, 2008). Many men, however, felt that it was impossible to meet everyone's needs in a group, for example, due to differences in fitness levels (Jones et al., 2007).

Some of the available research also offered insight into participants' experiences of hospital-based and home-based cardiac rehabilitation. Jones et al. (2007) found that participants had experienced hospital-based programmes friendly and fun, and giving them a feeling of being cared for (Clark et al., 2005). Participants in the hospital-based programmes found the company, support and shared experience offered by the group to be important (Mooney et al., 2007), as well as support from nurses (Clark et al., 2005). Participants also perceived that cardiac rehabilitation staff had an important role in assisting lifestyle changes (Clark et al., 2005). Some participants described how, before attending to a cardiac rehabilitation, they felt frustrated due to feeling that their physical capabilities were declining, but that exercise training in cardiac rehabilitation benefited them physically and psychologically (Mooney et al., 2007). Cardiac rehabilitation programme was also found to facilitate increased knowledge of cardiac surgery, though participants reported different levels of need for knowledge about surgery, so that for some information decreased fear of surgery, while for others it increased fear of surgery (Jones et al., 2007). In addition to finding the exercise component of cardiac rehabilitation beneficial, participants considered education about medication (Mooney et al., 2007) and talks about relaxation techniques (Corrigan et al., 2006) to be helpful.

Home-based cardiac rehabilitation programmes tended to convey the information for participants mainly through booklets and manuals. In their study, Corrigan et al. (2007) found that participants valued information in a booklet about heart disease, lifestyle changes, and medication, but felt reluctant to complete self-monitoring pages and found it difficult to specify targets related to lifestyle changes. In a study by Jones et al. (2006) participants described the Heart Manual as a good source of information, and reported good use of relaxation tapes provided by the intervention. As a home-based cardiac rehabilitation tends to be based on written information provided to participants, the presentation of the written material appears as an important factor to successful transfer of the information. For example, Murie et al.

(2006) have suggested that important elements of the cardiac rehabilitation materials are their visual appeal and immediate relevance through use of colours and diagrams, and the size of material so that it is easy to carry away. Cardiac rehabilitation material should also give a sense of future, offer unambiguous information about “why me?”, and answer questions about what should be done during recovery, especially when and why (Murie et al., 2006). While it may be difficult to achieve through intervention that is delivered mainly through written materials, participants would nevertheless value personalised targets and treatment plans (Clark et al., 2004).

This qualitative research suggested that there appear to be differences between participants’ perceived and actual understanding of what the aims and content of a cardiac rehabilitation may be. The evidence also indicates that the uncertainty and tolerance of the uncertainty of what cardiac rehabilitation contains may influence participants’ attendance decisions. While the available evidence argued that participants were aware that cardiac rehabilitation contains elements of behaviour modification, counselling, and advice, cardiac rehabilitation tended to be associated with exercise training. Exercise-related concerns and expectations were also prominent in participants’ accounts of what cardiac rehabilitation may mean for them. While some participants welcomed the opportunity to exercise under supervision, others considered exercising as a source of embarrassment, and misunderstandings about the level of fitness needed to attend were common.

Research had investigated participants’ experiences of cardiac rehabilitation during different stages of recovery and of different format of rehabilitation. Available evidence suggested that while passively receiving information might be preferred during acute stages of recovery, participants wished to have a choice of rehabilitation method in later stages. Participants also expected that the programme they attend is led by knowledgeable and supportive professionals who would help them to achieve lifestyle changes and offer guidance on what can and cannot be done. Importantly, present evidence also indicated that participants wished involvement of family in cardiac rehabilitation.

Participants’ opinions of cardiac rehabilitation programmes differed according to the type of intervention they had attended. In general, however, information, health

education and reinforcement of familiar information were considered important, and excise training in safe environment helpful. Many of those who attended perceived participation in a cardiac rehabilitation also as central to their recovery and building confidence. Some differences in experience of cardiac rehabilitation were found between men and women. Overall, men appeared to have had more positive experience than women, who reported at times to struggle especially in a hospital-based cardiac rehabilitation. Some evidence was also available about participants' experiences after participating in either a hospital-based or a home-based intervention. Research suggested that both groups of participants appeared to value aspects of cardiac rehabilitation and for those in a home-based rehabilitation, the importance of the quality of the information provided by the rehabilitation material was highlighted. Participants in both a home- and hospital-based rehabilitation valued information and advice about what can and cannot be done, and appreciated personalised care plans and sense of future.

The qualitative research identified difficulties for evaluating effectiveness of complex health care interventions, as the results of the review suggested that participants' experience of an intervention might vary depending on how an intervention happens to match the needs of an individual. Moreover, some review results suggested that intervention evaluation may be further complicated by some gender differences in what aspects of an intervention male or female participants, in general, may find working for them. Even though many participants appeared to find the intervention beneficial in general, the review evidence appeared to suggest that interactions between participants, intervention personnel, and intervention components added to complexity of an intervention.

8. Experience of cardiac rehabilitation

Clark et al. (2004) explored experiences of and assumptions about cardiac rehabilitation by three different groups of participants; those with "high attendance" to cardiac rehabilitation, those with "high attrition" to cardiac rehabilitation, and those that did not attend, i.e. "non-attenders". Clark et al. (2004) found that participants in the "high attendance" group described how their initial embarrassment of exercising in a group lessened over time with participation and encouragement

from others. Regular attendance to a cardiac rehabilitation group appeared to increase participants' confidence, motivation and fitness, and participants started to feel sense of obligation to help new patients, and found the time after hospital-based cardiac rehabilitation as crucial for a successful secondary prevention. In addition, Clark et al. (2004) found that participants in the "high attendance" group also perceived health care professionals as experts, sources of information, and interested in patients' well-being, and considered not attending to cardiac rehabilitation irrational. In contrast, while participants in the "high attrition" group also described embarrassment when exercising in a group, they saw other cardiac rehabilitation group participants as old, needy and illness-focused, and criticised the exercise programme as too narrow, not taxing enough and unlikely to be beneficial. Clark et al. (2006) also discovered that participants in both the "high attrition" and the "non-attendance" groups saw health professionals as providing inconsistent information, which was often inappropriately timed, coercive, negative, too intense, and poorly organised.

In another study by Wingham et al. (2006) participants' experiences of participating in either home- or hospital-based cardiac rehabilitation were explored. The results of the study suggested considerable differences in participants' expectations and experiences of different type of a rehabilitation. Participants in a hospital-based cardiac rehabilitation found having a professional in control of rehabilitation helpful, as, for example, this allowed exercise training to be supervised and set at an appropriate level. While research indicated that one of the reasons to choose a hospital-based rehabilitation was a perceived lack of self-discipline to exercise at home, participants also expected and experienced group to bring benefits. They expected to be able to draw from group dynamic and described experiencing camaraderie with other group members as well as benefiting from others' similar experiences. Wingham et al. (2006) also discovered that participation in to a group helped reinforce self- discipline and offered an opportunity to go out. In contrast, participants who opted for a home-based cardiac rehabilitation tended to live in more rural locations and found that the home-based rehabilitation guided by the Heart Manual fitted in their lives. These participants did not feel need for supervision and considered self-discipline not a problem. They also tended to dislike being part of a group or did not feel a need to be part of a group. (Clark et al., 2005).

Findings from Clark et al. (2005) described how loss of contact and support of cardiac rehabilitation group had a negative impact on some participants after conclusion of the programme. Some participants, even when they perceived cardiac rehabilitation worthwhile, described it as a false dawn and insufficient, as it did not lead to desired changes. Clark et al. (2005) also discovered that some participants criticised cardiac rehabilitation staff as not being knowledgeable enough of local exercise facilities, and that participation in the rehabilitation did not always increase confidence to exercise or perception of the body limits regarding, for example, exercise. Therefore, for some participants, the years after cardiac rehabilitation were characterised by fear, uncertainty and lack of behaviour change, and their vulnerability continued to be reinforced by other's reactions. (Clark et al., 2005). Similarly to Clark et al. (2005), Day and Batten (2006) concluded that, sometimes, cardiac rehabilitation failed to support a long-term recovery and participants' desire to gain everydayness.

The available evidence indicates that participants' experiences of cardiac rehabilitation are different, and that their experiences appear to be associated with type of a rehabilitation attended and frequency of the attendance. What, however, cannot be evaluated from the available material is whether the frequency of attendance was due to expectations or experience of the cardiac rehabilitation, but the evidence indicated that attendance frequency appeared to be linked to experienced benefits of rehabilitation. Those with a frequent attendance appeared to have predominantly positive experiences of cardiac rehabilitation even if they criticised some aspects of the programme or its delivery. However, participants with a less frequent attendance tended to be more critical and negative about the contents and delivery of a cardiac rehabilitation programme. Not only did the frequency of attending to cardiac rehabilitation but the type of programme attended appeared to have marked influence on participants' expectations of rehabilitation and how the rehabilitation experiences matched the expectations. While participants in a hospital-based rehabilitation appreciated the professional delivery of the programme and group support, participants in a home-based cardiac rehabilitation did not feel need for a group support and found that they were able to manage their rehabilitation with appropriate material. For some participants, however, participation in cardiac rehabilitation, even when experienced useful, was not enough to bring about the

desired changes and withdrawal of the group support after rehabilitation had negative impact on these participants, which, in some cases, appeared to be long-lasting.

Evidence from the qualitative review argues that a health care intervention may be complicated by interactions between patient-experienced benefits from an intervention and participants frequency of an attendance. Interactions between participants and an intervention were also complicated by evaluations of an intervention delivery and content, which, in turn, could be influenced by the attendance frequency. Indeed, in some cases, intervention complexity may stem from participants' finding an intervention beneficial, but not long enough to enable long-lasting change.

9. Perceived need for information before and after cardiac rehabilitation

Based on their results, Davis et al. (1995) suggested that participants appear to be interested in specific information related to recovery, and that many participants in their study had identified specific questions they wanted to have answered before attending a cardiac rehabilitation. Questions that participants had identified as important to have answered, commonly dealt with topics about activity, exercise, medication, how to differentiate symptoms of angina from heart attack, stress management, and smoking cessation. As well as having their own inquiries answered, participants appeared to value information offered during the rehabilitation programme, and hearing answers to other participants' inquiries of specific topics. Interestingly, participants appeared to value information especially from a cardiologist (Day and Batten, 2006). However, research by Day and Batten (2006) pointed out that in some cases provided information lacked practical considerations, for example, on how advice about lifestyle changes may be implemented when a spouse is unwilling to co-operate. Further research suggested that information provided during cardiac rehabilitation should not be limited to participants, but made available for family and carers (Murie et al., 2006). While many participants perceived the information received during cardiac rehabilitation to be beneficial, some had experienced the information load as sometimes too heavy, ill-timed, and inappropriate, such as providing information about returning to sexual activities too early during hospital stay (Cooper et al., 2005).

While the research evidence on participants' expressed needs for information is limited, it nevertheless suggested that participants were not only passively receiving information, but were often actively seeking out information about questions and topics relevant to them. Even when the information received during rehabilitation was in general perceived as adequate, some criticisms were offered about its lack of practical considerations, content, and timing. Yet again qualitative research indicates that complexity in an intervention may be introduced not only by mismatch between participants' needs and intervention, but also by the number information needs that are relevant for participants and how timing of the information is handled. Qualitative research appears to show that complex health care interventions, like in this case psycho-educational cardiac rehabilitation intervention, can face a challenge of providing adequate and timely information to participants and their families, while being sensitive for individual information needs and timing.

10. Perceived benefits of cardiac rehabilitation

Research suggested that a cardiac rehabilitation programme participants could identify several specific benefits from attending, which were often specific to the type of a rehabilitation attended. Even though previously-discussed research has indicated that cardiac rehabilitation is often associated with exercise training, it is also seen as a form of treatment in its own right with potential general and specific benefits that are unrelated to exercise (Tamada and Holmes, 1998). For example, participants in a in-hospital teaching programme that took place before discharge felt that the information received during the intervention helped them to make sense of their experience (Clark et al., 2004). Participants in a hospital-based cardiac rehabilitation programme after discharge found that the intervention facilitated their acceptance that they could put their body under pressure during exercise sessions (Mooney et al., 2007), and increased their confidence, and lessened their fear of exercise (Mooney et al., 2007, Clark et al., 2005). Participants described how cardiac rehabilitation programme not only improved confidence to do more physical activity, but was also successful in increasing knowledge of safe limits of exercise, normalising exercise as part of daily life, and facilitated self-exercise in an unfamiliar group and public settings (Clark et al., 2004, Cooper et al., 2005).

As well as exercise-related benefits, cardiac rehabilitation facilitated learning about angina symptoms, lessened fear of cardiac surgery, helped returning to work and regaining confidence, offered both emotional and psychological support (Davis et al., 1995, Mooney et al., 2007), and contributed with different degrees to reaching “everydayness” (Clark et al., 2004). A longer term cardiac rehabilitation programme was also able to encourage participants continuing changes initiated during the programme, thus providing a basis for health improvements (Jones et al., 2007). Jones et al. (2007) argued also that to gain some of the above listed benefits from cardiac rehabilitation does not necessarily require frequent attendance. According to Jones et al. (2007) even partial participation in either a home- or a centre-based cardiac rehabilitation benefits participants by facilitating acceptance of importance of exercise, increasing confidence to exercise, and participating to exercise activities that fit in with participants’ lifestyles.

Available evidence indicates that cardiac rehabilitation programme can have physical, psychological, and social benefits for participants. Benefits of cardiac rehabilitation may not be limited to those participants that attend frequently, but some of the benefits can be achieved even with less frequent attendance. Research also indicates that both a home-based and a hospital-based rehabilitation programmes appear beneficial, especially when the intervention is relevant for participant’s wishes and needs. While the available research evidence suggests that participants reported especially exercise related benefits from cardiac rehabilitation, it was also experienced as a beneficial intervention to accept life changes caused by the disease.

Yet another aspect that may influence on intervention complexity is number of outcomes that an intervention may influence, all of which may not be anticipated or evaluated. Qualitative research argues that psycho-educational cardiac rehabilitation interventions may influence on number of outcomes, which makes evaluation of intervention difficult, as intervention effectiveness may differ depending on what outcomes are measured. Additionally, qualitative research points out that intervention effectiveness may be linked to participants’ perceptions of an intervention relevance for them. Therefore, intervention complexity may also be influenced by difficulties in establishing which parts of an intervention cause what changes and how this is related

to participant characteristics, such as preferences to the form of rehabilitation. Importantly, qualitative research also pointed out that in some cases in-frequent attendance may nevertheless lead to positive changes, although this may further add to the complexity of an intervention, as different participants may benefit from different length of an intervention.

11. Process of attending cardiac rehabilitation

Some of the available research provided insights into how participants became involved in cardiac rehabilitation, and what considerations weighted in attendance decisions. Some of these considerations are closely related to participants' expectations of cardiac rehabilitation, but it was decided to highlight these in this instance, as they appeared to serve as starting points to participants' decision making. A very limited amount of information was available in the included papers about how participants perceived the invitation to rehabilitation programme. However, for example, Davis et al. (2005) noted that participants who received a telephone call from a nursing staff in advance of attending a cardiac rehabilitation programme perceived this as a sign of caring and support. Clark et al. (2005) found that there appeared to be some element of surprise among participants that cardiac rehabilitation was a group-based activity, which was often initially perceived by participants as a negative feature, due, for example, to dislike of group activities, or fears that a group format would not meet one's individual needs.

Clark et al. (2005) found evidence that after starting a cardiac rehabilitation, participants appeared to go through a process of transition from an outsider to a group member, and that instead of perceiving group activities negatively, participants could come to perceive group-based activities as an advantage through experienced similarities in fears, problems, and needs with the other participants. Moreover, mutual encouragement and support increased participants motivation to attend (Clark et al., 2005), and participants described the atmosphere as friendly and supportive and appeared to developed collected identity from feeling of not being alone (Clark et al., 2005). Research by Day and Batten (2006), however, suggested that especially for some women, assimilation to a cardiac rehabilitation group was very difficult, as they

felt that the group did not meet their needs for support, and felt isolated in the group and as having nothing in common with the other group members.

There is a limited amount of available evidence on the process of attending cardiac rehabilitation, and what there is comes from research that has investigated participants that have attended a group- and a hospital based cardiac rehabilitation. Regardless of the limitations in the available data, research suggests that the initial perception of a group format as disadvantageous may be overcome with participation through the process of transition from an outsider to a group insider, though women were more often found to struggle with this process. Participants also started to see group activities as an advantage and found peer support helpful.

Qualitative review argues that for some psycho-educational cardiac rehabilitation interventions, intervention is not made complex only by participants' expectations of intervention or other factors arising during the intervention, but also, for example, how participants are invited and reminded about the intervention and how this affects perception of an intervention. Although qualitative review as such has not been very successful in elucidating and clarifying intervention mechanisms or theories, data collected for this theme indicates that for a group-based intervention important part of an intervention mechanism appears to be forming of a group identity and social support that that provides. Evidence also suggested that motivation was an important factor in reaching intervention goals. However, qualitative research also suggested some overall gender differences indicating that men experienced social support from group more positively than women did.

12. Barriers to cardiac rehabilitation attendance

The purpose of this review was not to explicitly evaluate barriers to cardiac rehabilitation attendance, but it was found that many of the studies mentioned some barriers to attendance. It was decided include these in the results of review, as they offered additional insights into participants' expectations and experiences of cardiac rehabilitation. The most commonly-cited barriers to attending were either real or perceived; transport difficulties (Hird et al., 2004, Jones et al., 2007, Wingham et al., 2006, Cooper et al., 2005), work commitments (Day and Batten, 2006, Jones et al.,

2007, Hird et al., 2004), caring responsibilities and family commitments (Jones et al., 2007, Wingham et al., 2006), and time of the day classes were being held (Wingham et al., 2006, Day and Batten, 2006). Physical access issues to a venue, and other health problems and co-morbidities were also presented as barriers to attendance (Jones et al., 2007). For some participants, deteriorating health prevented attendance, while for others the heart trouble was the least prohibiting health problem (Jones et al., 2007). Lack of motivation to attend, considering group member composition not suitable for one, unwillingness to participate at all (Hird et al., 2004), preferring not to be with others (Cooper et al., 2005), social interaction (Clark et al., 2004), and a lack of belief in benefits of cardiac rehabilitation (Jones et al., 2007) were also mentioned as barriers to attendance. Some participants also felt that a good recovery made cardiac rehabilitation attendance seem unnecessary (Jones et al., 2007). More study specific barriers to cardiac rehabilitation attendance were randomisation to a not wished for programme, misunderstanding the invitation to the programme, and motivation to exercise at a hospital programme but not at a home-based programme (Corrigan et al., 2006). Participants also appeared to be unwilling to participate if they had to pay the costs of a cardiac rehabilitation themselves, as preventive health care was not always seen value for money if self-financing (Murie et al., 2006).

Participants reported various barriers to attending cardiac rehabilitation, which ranged from physical to organisational difficulties. While some of the barriers, such as unable to leave work, can constitute real difficulties for attendance, others are easier to overcome. Misunderstandings regarding the fitness required to attend, for example, may at least be partially improved by better communication from the side of health care professionals. While practical barriers, such as transport and physical barriers such as access to venue can be improved, health-related barriers as well as motivational barriers may be more difficult to overcome so as to improve rehabilitation attendance. Overcoming motivational barriers may be especially difficult, as they may be expressed indirectly, such as citing transport difficulties, when, for example, patient does not regard cardiac rehabilitation important enough to justify the extra trouble and costs caused by organising a transport, such as taxis. Barriers to attending cardiac rehabilitation are not directly linked to either an intervention complexity or mechanisms. However, available evidence suggests that complex interventions, such as psycho-educational cardiac rehabilitation

interventions, may need to overcome number of difficulties in persuading potential participants of the benefits of an intervention and that attending outweighs difficulties associated in attending.

13. Participant suggestions for a cardiac rehabilitation programme

Only limited information was available citing participants' explicit suggestions for how, from their experiences, cardiac rehabilitation interventions might be improved. In a study by Murie et al. (2006) participants argued that different kind of interventions should be offered at certain time points during recovery. For example, at the discharge from a coronary care unit a leaflet could be given to participants with a relevant information to this time point, which could then be later changed to a new leaflet during a visit to surgery that contains information relevant to later stages of the recovery. These leaflets should also contain questionnaires that would help patients to rank issues that they would like to have additional information from health care professionals. Patients in more advanced stages of recovery could document their own recovery, adverse effects of medication, and risk factor modification, as well as befriend new patients. Separate booklets should be offered to carers and partners, and information could also be offered in a DVD or a CD format. (Tamada and Holmes, 1998).

Tamada and Holmes (1998) found that participants wanted a in-hospital teaching programme to address critical learning needs and explain the activity protocol for recovery. Participants also found the use of models and pictures to explain issues to be helpful, but felt that patients should have been offered checklists to remind them of what had been learned during the sessions, and information about recovery should be available to take home. Participant also felt that an intervention should offer information about available post-discharge support, including contact numbers for different services and help.

In most of the studies, participants were not asked about how they would improve a cardiac rehabilitation programme, but rather to describe their experience of the intervention they took part in. These results have been discussed in the previous sections. The two studies discussed above cannot be described as typical hospital-

based cardiac rehabilitation programmes with exercise training and health educational components. Nonetheless, participants' comments and suggestions offer some ideas about what may be perceived as important components in a programme. Interestingly, participants' comments suggested that interventions should not only offer a number of components to satisfy different aspects of recovery but also offer a substantial amount of information to explain and support the process of recovery. Therefore, available evidence shows some indications that participants' themselves might view complex interventions positively.

7.4 Summary answers to research questions

1. What kind of expectations do coronary heart disease patients have about cardiac rehabilitation before they attend the rehabilitation?

Patients appear to have very different expectations of cardiac rehabilitation before attendance, and indeed, available evidence argues that expectations of cardiac rehabilitation may influence eventual decisions about whether to participate in a cardiac rehabilitation or not. There appear to be variations in opinions about the importance of attending a cardiac rehabilitation, and what those who planned to attend expected cardiac rehabilitation to offer. Some patients were found to expect rehabilitation as a likely to help in recovery and prevention of further episodes of the disease, as well as to offer information about recovery and process of recovery, and help to allay fears and rebuild confidence. Patients also tended to expect cardiac rehabilitation to offer practical advice about what they could and could not do, for example, receive advice about safe limits of exercise. Some patients also expected cardiac rehabilitation to help them understanding the disease and causal attributions of their illness. However, the evidence suggests that patients' causal attributions of the coronary heart disease and myocardial infarct might, in themselves, also affect their willingness to participate in cardiac rehabilitation.

“All nine participants expressed an interest in obtaining specific information related to their recovery. Eight of the nine participants had identified specific questions they had prior to attending the class.”(Davis et al., 1995 p.17)

While patients tended to assert that they knew the meaning of a cardiac rehabilitation, many were nonetheless unsure of the content of rehabilitation programmes. Cardiac rehabilitation was viewed as a series of actions, not as a package that contains different parts, and that it was predominantly linked to promoting exercise, although patients recognised that it might also include health education, relaxation training, and counselling. Exercise-related issues tended to be on the forefront of the participants' perceptions, and they expected cardiac rehabilitation to offer change to learn about exercise, and safe and supervised environment in where to exercise. Some patients, however, perceived exercise as a possible source of worry and embarrassment, and appeared to misunderstand the level of fitness needed to attend.

“Concerns identified were regarding possible embarrassment, ‘falling behind’, and group versus individual needs.” (Hird et al., 2004 p.128)

Encountering a group format for the delivery of cardiac rehabilitation was often surprising to patients. While some saw joining in a group as offering benefits and an opportunity to compare experiences with the other patients, others' dislike of groups appeared to be an inhibiting factor for participating. In addition to individual opinions of participation in group activities, group format was criticised for a potential conflict between group needs and an individual needs. However, apart from the worry of conflict between the needs of an individual and the group, some patients were doubtful about the overall benefits of attending a cardiac rehabilitation, and saw it as a possible hindrance in getting back to normal.

“Support...was identified either as a strong motivator for attending the program or as a benefit that resulted from attending it.” (Davis et al., 1995 p.17)

2. Do coronary heart disease patients express preference for certain kind of intervention or for intervention features?

Because of the diversity of needs and preferences, patients saw it as important to have a choice of rehabilitation programme. Differences between individual needs and preferences were especially highlighted by the comparison of patients that preferred

either a home- or a centre-based rehabilitation. Those who preferred a hospital and group-based rehabilitation appeared to find the rehabilitation group as a source of motivation, and providing a safe environment to exercise which many experienced reassuring and alleviating uncertainties. Patients also expected the group to have a positive impact on the recovery. Those, on the other hand, who preferred home-based rehabilitation, did not experience difficulties in motivating themselves to exercise and found supervision unnecessary. Moreover, these patients found that a home-based rehabilitation allowed them to fit cardiac rehabilitation into their lives, and for those with dislike of group activities, a home-based rehabilitation offered an alternative way to participate.

“This group described two features of their need for their exercise to be supervised by experts. Firstly, they expected to be set exercise at an appropriate level. Secondly, they expected supervision with someone else being in control, who was able to deal with any complications of the activity, for example, any chest pain or breathlessness.” (Wingham et al., 2006 p. 291)

“Some expressed a dislike of being part of a group or did not feel the need to be part of a group.” (Wingham et al., 2006 p. 292)

Further findings suggested that cardiac rehabilitation materials should have relevance for participants, taking into account differences between patients in levels of need for knowledge. Patients suggested that different formats of material might be also made available, such as leaflets and DVDs, and they found it important that such material could relate a sense of future, that life continues after a cardiac event. In addition, patients felt that information should not be restricted to them alone, but be also given to their carers and family members.

*“Patients valued personalised targets and treatment plans.”
(Murie et al., 2006 p.79)*

3. What kind of experiences coronary heart disease patients do have after taking part in an intervention? (Full time or drop-out)

Cardiac rehabilitation appeared often to offer patients the sense of being cared-for, company, and psychological and emotional support from the other participants and staff. Exercising in a group was often described as initially embarrassing, but for some patients, embarrassment diminished with continued attendance and was replaced with an increased confidence in exercising. These participants also described gaining a new sense of fitness and understanding of their body limits. In addition, many patients found it useful to learn new information and having existing information reconfirmed during a cardiac rehabilitation. Number of patients also came to perceive cardiac rehabilitation as a treatment in its own right with benefits unrelated to exercise, such as help with returning to work, and replacing fear with confidence. In addition, patients described how cardiac rehabilitation was helping to learn to live with the coronary heart disease.

“...all participants emphasised the value of having information presented during the program and the benefit of hearing answers to other people’s questions.”(Davis et al., 1995 p.17)

“...a positive attitude or sense of future as key steps to recovery. Patients appreciated unambiguous information addressing ‘why me’, the why, when and what of CHD’ and ‘what should I be doing’ during the inpatient stage and early post-discharge period.” (Murie et al., 2006 p.80)

For some patients, however, exercising in a group continued to be embarrassing. Some patients also perceived other group participants as old, needy, and illness-focused, while exercise programme was experienced as too narrow and sometimes as not taxing enough. This group of patients was also more likely to view information offered as being ill-timed, inconsistent and not appropriate. Cardiac rehabilitation staff were also criticised for not being knowledgeable enough about available local exercise facilities.

“...the emotional impact of this life event, the gravity of which patients felt was underestimated by health professionals, who provided excessive and inappropriate information. Some information, they felt was introduced too early in hospital, in particular relating sexual intercourse and exercise.”(Murie et al., 2006 p.79)

Finally, a group of patients experienced cardiac rehabilitation as worth of attending, but still not adequate for helping them to make changes in their behaviour. These patients appeared to suffer especially from the loss of contact and support of the group after the programme had ended, which had a negative impact on some patients' long-term recovery. Therefore, some patients experienced that cardiac rehabilitation did not always support the long-term recovery. In addition, rehabilitation did not succeed in increasing everyone's confidence or sense of body limits, and for some years after cardiac rehabilitation, these patients could continue to experience fear and a lack of behaviour change.

“Instead CR proved to be a false dawn, an initiative which though initially promising, had not led to change.” (Clark et al., 2005 p. 366)

7.5 Discussion

The present review of the qualitative cardiac rehabilitation studies aimed to investigate participants' expectations and experiences of cardiac rehabilitation, and their suggestions of how the present interventions might be improved. However, it became clear during the data collection and analysis that, while these elements could be separated from the rest of the material, the material accessed described not only how a cardiac rehabilitation may help in the process of recovery, but also how and why a cardiac rehabilitation may or may not fit in with an individual's process of recovery. The qualitative research suggested that a majority of the “attenders” perceived some benefits from attendance. However, the research indicated that those who attended cardiac rehabilitation tended to already be a selected group of patients, who expected and perceived cardiac rehabilitation to have potential benefits, and found the existing intervention format suitable for them. The review evidence supported the argument that illness perceptions, perceptions of cardiac rehabilitation, professional recommendations, and personal circumstances can have a major impact on a cardiac rehabilitation attendance decisions.

The qualitative research included in this review suggests that experiencing a myocardial infarct, severe symptoms caused by a coronary heart disease, or facing a

cardiac surgery due to a coronary heart disease, can have major physical, psychological, and social consequences for an individual. Recovery from the specific manifestations of coronary heart disease, or indeed from a myocardial infarct, may continue for years. Research indicated that while participants appeared to strive to normalise their lives after a cardiac event, there are considerable differences on how participants adapt to the new life situation and cope with the lifestyle changes recommended to avoid further illness episodes. The results pointed out that while participants were aware of the need to make lifestyle changes such as smoking and diet, a lack of motivation often emerged as a barrier to changes. However, the results suggest that participation in a cardiac rehabilitation may both facilitate normalising life after a cardiac event and help participants to succeed in lifestyle changes. In addition to participating in a cardiac rehabilitation, the combined results show that factors such as learning about the coronary heart disease and family support can have an important role in recovery.

The results of the review also highlighted questions about responsibility, how participants differed on their views of whose responsibility recovery from a cardiac event is, and the consequences of accepting or not accepting responsibility for recovery. For example, the results argued that willingness to take responsibility for recovery can affect the decision to attend a cardiac rehabilitation. In some instances, decisions and responsibility for treatment are outside an individual's remit, such as decisions about a cardiac surgery. Although the decision to attend cardiac rehabilitation is ultimately down to an individual, participants reported that their decision making process was influenced by healthcare professionals, especially by doctors, but not by family and friends. This finding was in contrast to reports that family can have an important influence in the process of recovery. The available evidence appears to suggest that while a family support is important in recovery, it does not have such a marked influence on cardiac rehabilitation attendance decisions. Practical implications of this result suggest that health care professionals, especially doctors, may need to ensure that when a cardiac rehabilitation is available and suitable, patients are made aware of the importance of attending, and of how to access the service.

Participants' perceptions of the usefulness and the format of a cardiac rehabilitation can be an important factor in decisions to attend, and while some have firm expectations that a cardiac rehabilitation would be useful, many doubt its benefits and appear ambivalent about its importance. Results indicated as recurring issues participants' mixed views about participating in a group, a group exercise, fears of embarrassment during the group exercise, and expectations of support. Participants tended also to be critical about a group's ability to respond an individual's needs. The review evidence also argues that preconceived images of a cardiac rehabilitation may have a major impact affecting attendance decisions. Moreover, the combined evidence shows that those individuals who see themselves as having less personal responsibility for their recovery may also perceive cardiac rehabilitation more negatively, which means that they are less likely to attend, and have an opportunity to re-evaluate their assumptions of cardiac rehabilitation. While this particular group of participants might indeed benefit from cardiac rehabilitation, health care professionals face considerable challenges in getting this group of patients to consider attending.

Participants appeared to seek causal attributions for their illness, and though they saw cardiac rehabilitation as helpful in understanding causes of illness, it also emerged that the pre-existing causal attributions may influence attendance decisions. Results suggested that while participants commonly quoted such risk factors as smoking and diet as causal attributions, nevertheless many of the explanations included elements of misunderstandings and mystification of the causes of a coronary heart disease. This appeared to be especially a case for those participants who attended cardiac rehabilitation either not at all or only partially. The results indicated that these 'non-attending' participants considered stress and a busy lifestyle as contributing factors, doubted the role of smoking, and even questioned having a myocardial infarct. In contrast, cardiac rehabilitation "attenders" saw lifestyle decisions as contributing factors that required action. These results, however, propose a practical dilemma for health care professionals. While results indicate that cardiac rehabilitation may, up to certain extent, be able to change illness perceptions, results also highlight that illness attributions may influence patients' decisions to attend or not, and which elements of a cardiac rehabilitation they perceive relevant for them. Therefore, available research argues that those patients perhaps most in need of a cardiac rehabilitation may be also

the least likely group to attend, especially if rehabilitation takes place after the hospital discharge.

The results of the review indicate that after participating in a cardiac rehabilitation programme, either at home or in a centre, many of the participants seemed to appreciate exercise sessions, information, and health education that the programme offered. Benefits of a cardiac rehabilitation were apparent for both home- and hospital- based programmes, as well as for participants who participated only partially. Results indicated, however, differences in what aspects of the rehabilitation participants valued. Patients in a hospital-based cardiac rehabilitation valued supervision and safe environment to exercise, while those in a home-based rehabilitation felt content in being charge of their own rehabilitation. Choice of rehabilitation appeared to be an important factor in participants' willingness to participate, and in an ideal situation, every patient should have an opportunity to choose the type of rehabilitation they wish to attend. However, in practice, resource limitations often restrict available choices, leaving health care professionals to find ways to encourage attendance to whatever services are available.

The results also pointed to some gender differences in participants' experiences of cardiac rehabilitation so that in comparison to men, women appeared to struggle more in a centre-based rehabilitation. Results suggested that while number of women experienced cardiac rehabilitation not responding to their needs, men reported generally positive experiences of a rehabilitation, suggesting that women may benefit from gender specific interventions. However, this finding may also reflect the fact that more men than women suffer from a coronary heart disease and need a cardiac rehabilitation, which may have led to a situation where the cardiac rehabilitation programmes tend to be more responsive to men's than to women's needs. Apart from the gender differences, the results also proposed that a proportion of participants found themselves struggling after the cardiac rehabilitation programme ended, which suggests that some participants may need longer support than is available within a formal cardiac rehabilitation programme.

Participants' frequency of attendance appeared to be linked to the experienced benefits of rehabilitation. Results, however, do not allow making conclusions about

whether attendance frequency to cardiac rehabilitation was due to prior expectations or was influenced by experiences during cardiac rehabilitation attendance. Participants with the most frequent attendance perceived cardiac rehabilitation beneficial, offering peer support, motivation, and improved fitness. In contrast, participants who attended less frequently found cardiac rehabilitation less beneficial, and perceived other participants old, needy and illness-focused, and the programme to be too narrow for their needs. Results, therefore, appear to suggest a potentially complex interaction between expectations and experience, which may not only shape patients' willingness to participate but also to inform their willingness to continue attending.

While investigating barriers affecting cardiac rehabilitation attendance was not the primary interest of the review, results nonetheless showed that barriers to attendance were commonly mentioned in these studies. Barriers to attending cardiac rehabilitation found in this review could be divided into four different categories: practical barriers (e.g. transport difficulties), physical barriers (e.g. co-morbidities), barriers specific to cardiac rehabilitation (e.g. lack of belief of benefits), and organisational barriers (e.g. misunderstanding the invitation to attend). Although practical barriers to improve rehabilitation attendance such as transport and physical barriers in accessing the venue can be improved, health-related barriers as well as motivational barriers are more difficult to overcome and would probably need further initial interventions to enable patients to participate in a cardiac rehabilitation.

The combined results showed that only a few of the included studies explicitly explored patients' ideas of what they would like to see in a cardiac rehabilitation intervention. However, the available material showed that patients felt they might benefit from interventions that correspond to their stage of recovery, and which are offered during different time points of the recovery. Further suggestions included providing information about local and national services, and inclusion of family and carers. Many of the participants' suggestions are potentially already incorporated into different cardiac rehabilitation interventions and in locally-available information leaflets. What these results, however, highlight, is that many cardiac rehabilitation interventions may already largely meet the expectations and preferences of those participants that are motivated to attend. The challenge, however, is in how to reach

those patients that are unwilling to attend or do not perceive attendance to be beneficial, and to find out what kind of interventions would motivate them to attend.

The review and its results were successful in answering the questions of expectations and experiences of cardiac rehabilitation interventions. The review, however, was less successful in considering how participants' perspectives of interventions could be used in furthering understanding of intervention mechanisms and theories. Only one of the themes explicitly provided information about possible intervention mechanisms and techniques, namely noting that especially male participants appeared to find group form of rehabilitation as a good source of social support and motivation. Analysis of intervention mechanisms and techniques presented in the previous chapter noted also that social support was used in a number of interventions, and qualitative research appears to support usefulness of social support as a means of behaviour change. The lack of information about intervention mechanisms and theories may be due to research questions asked in original qualitative papers, which concentrated in examining aspects of patient experiences, and not explicitly intervention mechanisms and theories. It is also possible that the question setting for the review would have had to be different, such as asking questions about qualitative process evaluation (e.g. Ritchie et al., 2007), to allow more explicit examination of theories underpinning interventions and mechanisms. Finally, the possibility that at the present there is not qualitative research available to examine intervention techniques and mechanisms cannot be excluded.

However, what the qualitative review was able to highlight was issues related to intervention complexity. As the studies included in this review examined participants' expectations and experiences of cardiac rehabilitation, it was unavoidable that the issues that may explain intervention complexity were participant centred. Nevertheless, results suggested that some aspects of complexity in an intervention may be outside of the control of an intervention design and implementation, and unexpected interactions between participants, intervention, and intervention personnel may make intervention complex. It was also notable that participants' preconceived expectations and assumptions of an intervention appeared to have marked influence on how an intervention worked for certain participants. Moreover, qualitative research suggested that participants' illness perceptions and understanding of causes

of an illness could effect on the complexity of an intervention, especially when the understanding of causes and consequences between a patient and an intervention differed. Finally qualitative research argued that intervention complexity may be further explained by different attendance levels and how intervention outcomes may be dependent on participants' levels of attendance.

Although reviewing qualitative studies and combining the research results can be controversial, it was felt that especially in a review and research synthesis of complex health care interventions this may provide vital information about how or why an intervention work. This qualitative review, however, has its limitations and problems. The qualitative review did not locate any smoking cessation studies, though there was some indication of smoking cessation being evaluated by qualitative methods (Ritchie et al., 2007). Therefore, with hindsight, it should be questioned whether setting different kind of research question, i.e. evaluating process, would have yielded better response. Apart from these challenges, methodological problems in this review were various, ranging from deciding and defining intervention and participant population to applying these criteria to study selection.

Although the study inclusion criteria were piloted beforehand, it was nonetheless noted that in some cases external advice had to be sought to ensure consistent application of these criteria. Search of the studies aimed also to be systematic, but it is difficult to evaluate or ascertain that all the relevant studies were identified, as there was no other review available for comparison. It was also not possible to ascertain how well the search words and the search strategy were able to identify the relevant studies, as qualitative studies may have been indexed differently. It is difficult to evaluate whether deploying a published methodological filter would have improved the search results. Using a published search filter might have improved the specificity of the literature search in terms of study methodology. However, considering the lack of evidence and cautions (e.g. Higgins and Green, 2011) about using these filters, the decision of deploying search filter designed for this review appears justified. Future reviews of qualitative research may need to test whether using a published search strategy improves quality of the search. Additionally, hand searching of the reference lists was found very complicated, and at least in this occasion not workable.

Moreover, the scope of the review had to be additionally restricted by including only studies written in English, meaning that potentially relevant studies in any other language were excluded. However, language restrictions were seen necessary, not least because of the lack of resources to deal with potentially multiply different languages, but also because of a lack of available evidence of effects of including translated qualitative research papers in a review. Therefore, reviewing qualitative research in this example was very language specific, which does limit the overall possibilities of generalising the research results outside of interventions that have been conducted mainly in English speaking countries. Apart from the language related issues, the results should be interpreted with caution in wider context. As qualitative research, in general, tends to be context specific and generalisation of the results requires caution, it is difficult to evaluate how well the results of a qualitative review can be generalised. Qualitative review has the power to bring together and synthesise the results from number of different research papers, and provide an overview of differences and similarities between the results. In the present review, it was noted that although nuanced, number of studies reported similar results, so that data saturation, i.e. no new information was emerging from the added results, did occur for few of the themes.

Interventions and participant populations included in the studies varied considerably, as did how the set research questions. While the diversity in the study methodologies and question setting did complicate evidence synthesis, it was also beneficial in the way that the review was able to include studies that investigated broadly similar topic, but from many different angles. However, it is recognised that intervention complexity was evident in this review similarly than in quantitative systematic review so that interventions included in this review were very heterogeneous. Similarly to quantitative reviews of complex health care interventions, it was found important to recognise intervention complexity, and include complexity as part of the analysis by considering how participants' perspectives may explain some areas of intervention complexity. It was also found that qualitative review allowed in-depth consideration of how participants' experiences and expectations of an intervention may help in understanding how factors related to participants may complicate a health care intervention. However, it is difficult to evaluate how generalisable these results are,

and the present results of potential participant related causes of intervention complexity should be interpreted with caution.

Thematic synthesis was selected as the analysis method because this enabled data presentation under themes that emerged from the primary studies, and enabled presenting differing findings under the wider thematic headings. However, even though the thematic synthesis aimed to be as transparent as possible in how the analysis was done and the results achieved, it can be, nevertheless, criticised for some lack of transparency. Although this review has considerable limitations and caution should be taken in interpreting the results, the results suggest that qualitative research can complement effectiveness research on complex health care interventions by helping to understand patients' perspectives on the interventions and factors that influence attendance decisions.

Using systematic review methodology in reviewing qualitative research did face number of challenges, such as uncertainty about the effectiveness of the search strategy. However, it was found that using the systematic review methodology was helpful in locating published qualitative research. In this review a standpoint was taken that regardless of the original analysis method or indeed of the study type, the results can be meaningfully analysed together. This standpoint was found defensible, as the review was interested in analysing and synthesising the results, and the differences between the studies were acknowledged. The biggest challenge for the qualitative review is perhaps how well the results can be generalised outside of the context of the psycho-educational cardiac rehabilitation interventions included in this review. As the qualitative research included in this study has included psycho-educational interventions with or without exercise component, it could be argued that the results of the review should not be generalised outside of this context, as it cannot be judged whether participants' expectations and experiences are similar to other cardiac rehabilitation interventions.

7.6 Conclusions

This review should be considered in relation to the existing evidence of an effectiveness of psycho-educational cardiac rehabilitation literature, which it aimed to

complement. Its results indicate that the presently-available psycho-educational interventions are considered beneficial by many of the patients who attend. However, there also appears sound reasons to consider the further development of gender-specific services, the availability of hospital- and home-based programmes, and services for patients who may need more intensive and longer-term interventions. The review results also suggest that patients' prior expectations of a cardiac rehabilitation may have considerable influence on their decisions to attend or not. Finally the results indicate that the attendance frequency to a cardiac rehabilitation may well be associated with patients' experiences of the rehabilitation.

The objectives of this qualitative review in the context of this thesis were to examine whether qualitative review can help in examining intervention complexity, theories, and mechanisms underpinning intervention, from participants' perspectives. Qualitative review offered limited insight in to theories underpinning interventions. Qualitative review findings indicated some intervention features and mechanisms that participants found helpful in promoting behaviour change, such as using teaching to inform behaviour change. The best evidence from qualitative review indicated various causes of intervention complexity from participants' standpoint. Participants' perceptions of intervention aims, methods, and understanding of causes of CHD appeared to have considerable effect on how participants received intervention. These results emphasise the complex interplay between participants, intervention content and context, and personnel. As an important finding from qualitative review emerged the complex interaction between participant expectations and understanding of an intervention, which are often outside direct intervention control, and the actual intervention. Therefore, qualitative review findings indicated how participant dependent factors, such as beliefs about intervention effectiveness, could help in explaining causes for varying intervention effectiveness for seemingly similar interventions.

Author	Diagnosis	Participant selection	Participants	Age group	Study type	Analysis method	Data Collection
Clark et al. (2004)	MI, post-CABG, angina	Purposive sampling	Male: 33 Female: 11	51-69	Not specified	Not specified	Focus groups
Clark et al. (2005)	MI, CABG	Random selection	Male: 30 Female: 17	51-84	Realist study	Realist framework	Focus groups
Cooper et al. (2005)	Acute myocardial infarction	Purposive sampling	Male: 9 Female: 4	37 -79	Not specified	Interpretative phenomenological analysis	Semi-structured interviews
Corrigan et al. (2006)	MI, CABG, angioplasty	Maximum variation sampling	Male: 17/11 Female: 6/6	48-74 / 49-80	Sociological theory of symbolic interactionism	Thematic analysis	Focus groups
Davis et al. (1995)	Medically managed cardiac patients	Purposeful sampling of volunteers	Male: 4 Female: 5	51-70	Utilisation-focused approach to program evaluation	Content analysis	Semi-structured interviews
Day and Batten (2006)	MI	Purposive and theoretical sampling	Female: 10	50-89	Grounded theory	Constant comparative analysis	Semi-structured interviews
Hird et al. (2004)	Experienced heart surgery	Convenience sample	Male: 34 Female: 16	Mean age 62.8	Prospective descriptive study	Five-stage process	Semi-structured interview
Hutton and Perkins (2008)	First MI within the last 6 months	Expressed interest to study	Male: 10	40-70	Qualitative exploration	Interpretative phenomenological analysis	Semi-structured interviews
Jones et al. (2007)	MI or revascularisation procedure	Purposive sampling	Male: 33 Female: 16	34-87	Not specified	Technique of charting	Semi-structured interviews

Table 7.1: Study methodology and participant characteristics

Author	Diagnosis	Participant selection	Participants	Age group	Study type	Analysis method	Data Collection
Mooney et al. (2007)	CABG waiting list patients	Purposive sampling	All appears to be male	54-74	Phenomenological approach by Husserl	Frame work by Colaizzi	Un-structured interviews
Murie et al. (2006)	MI, CABG	Geographical selection	Male: 5 Female: 1	45-68	Not specified	Not specified	Focus group
Tamada and Holmes (1998)	MI	Purposive sampling	Male: 5 Female: 1	49-87	Hermeneutic (interpretative) approach, bracketing	Description, thematic interpretation, metaphoric insight	Focus groups
Wingham et al. (2006)	MI	Purposive sampling	Male: 14 Female: 3	46-80	Not specified	Interpretive phenomenological analysis	Semi-structured interviews
Wyer et al., (2001a)	MI	Random selection	Male: 17 Female: 4	39-72	Theory of planned behaviour & self-regulatory model	Interpretative phenomenological analysis	Semi-structured interviews

Table 7.1: Study methodology and participant characteristics

Author	Intervention description
Clark et al. (2004)	12-weeks in-hospital rehabilitation and 1 year follow-up in primary care Health education, smoking cessation advice, exercise programme, blood pressure management, psychological intervention for stress or depression, support from dietician
Clark et al. (2005)	A 12-week long hospital-based programme including exercise, smoking cessation, diet, psychological well-being, after four weeks of discharge or outpatient consultation
Cooper et al. (2005)	N/A, Participants waited to start cardiac rehabilitation
Corrigan et al. (2006)	GP practice based intervention including advice and information, booklet
Davis et al. (1995)	Multidisciplinary program of presentations with time for questions and answers
Day and Batten (2006)	Information about heart disease, risk factor modification, psychological issues, and symptom management
Hird et al. (2004)	Program commences about 6 weeks post-surgery and includes exercise, relaxation, and education.
Hutton and Perkins (2007)	Not specified
Jones et al. (2007)	Hospital rehabilitation: exercise, educational and relaxation components Home rehabilitation: Heart manual, relaxation and information tapes, home visits from nurses and telephone follow-up

Table 7.2: Intervention description in qualitative review

Author	Intervention Description
Mooney et al. (2007)	Exercise, motivational interviewing, behaviour change and risk factor modification, management of misconceptions of CHD and treatment, education of CHD and CABG, preparation for surgery, treatment of psychological disturbances
Murie et al. (2006)	Participants were given to evaluate 46 different intervention including leaflets, manuals, information packs
Yamada and Holmes (1998)	Teaching on one-to-one basis, video tapes, educational booklet, heart model and individualised instructions, interdisciplinary team
Wingham et al. (2006)	Home-based: Heart manual & CDs to provide information and advice, home visits and telephone contact. / Hospital-based: Information and advice, exercise, and psychological care
Wyer et al. (2001a)	Multidisciplinary programme including lifestyle education, exercise and stress management

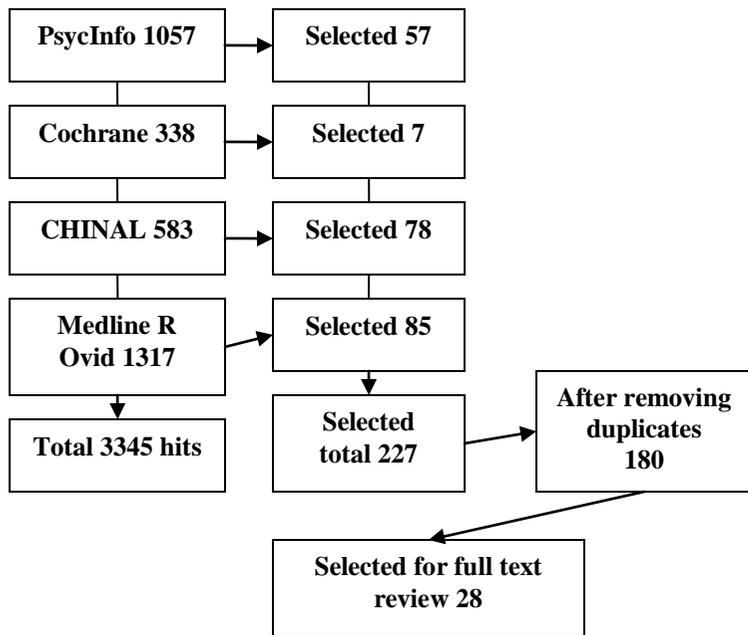
Table 7.2: Intervention description in qualitative review

Study	Research Design			Participants		Data collection & analysis			Findings		Ethics
	Is the research design defensible?	Have theoretical perspectives been considered?	Have data collection & analysis methods been discussed?	Were participants' selection and recruitment processes explained?	Was researcher/s relationship with the field stated?	Was data collection method described?	Was data analysis method and process described?	Were links between data, interpretation and conclusions clear?	Was credibility of findings discussed?	Did findings relate to original research question?	Was there evidence of consideration of explicit ethical issues?
Clark et al. (2004)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Clark et al. (2005)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cooper et al. (2005)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Corrigan et al. (2006)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Davis et al. (1995)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Day and Batten (2006)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hird et al. (2004)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Hutton and Perkins (2007)	Yes	Yes	Yes	Yes	Partially	Yes	Yes	Yes	Yes	Yes	No

Table 7.3: Qualitative study quality assessment

Study	Research Design			Participants		Data collection & analysis			Findings		Ethics
	Is the research design defensible?	Have theoretical perspectives been considered?	Have data collection & analysis methods been discussed?	Were participants' selection and recruitment processes explained?	Was researcher/s relationship with the field stated?	Was data collection method described?	Was data analysis method and process described?	Were links between data, interpretation and conclusions clear?	Was credibility of findings discussed?	Did findings relate to original research question?	Was there evidence of consideration of explicit ethical issues?
Jones et al. (2007)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Mooney et al. (2007)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Murie et al. (2006)	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No
Tamada and Holmes (1998)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Wingham et al. (2006)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Wyer et al., (2001a)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes

Table 7.3: Qualitative study quality assessment



7.1: Flowchart showing selection process for qualitative studies

Chapter 8

Combining the results of qualitative review and review of reviews - A discussion of the contribution of qualitative research in understanding intervention mechanisms in systematic reviews

8.1 Introduction

The purpose of this thesis is to examine ways in which reviews of complex health care interventions might be advanced. However, it is not sought to do this by developing a novel systematic review method, as the existing systematic review and meta-analysis methods for quantitative research are well-established. Novel review methods have also been developed to accommodate diverse forms of evidence including qualitative research (e.g. Pawson et al., 2005). Nonetheless, systematic reviews and meta-analyses of complex health care interventions often lack any in-depth investigation of the features of interventions and the mechanisms through which they aim to effect change. This lack may greatly limit the ability of the review to provide detailed information on what intervention designers may wish to attend in planning a new intervention. At the present, the effects of some specific features and mechanisms of interventions are mainly investigated by statistical sub-group analyses or by investigating moderator and mediator variables. However, the examination of moderator and mediator variables may be impeded if the data to support these are omitted from primary studies.

Using a series of empirical studies, this project has aimed to test one possible method for strengthening the conceptual specificity of systematic reviews of complex health care interventions. As the objective of this project was to elaborate an existing method, a traditional systematic review and meta-analysis methodology was used as its starting point. The overall aim here was to evaluate whether and how, connecting a detailed examination of the underpinning theories and mechanisms of interventions in a systematic review and meta-analysis, would improve understanding of the intervention mechanisms. The core underlying suggestion for this is that understanding of the underpinning theories and mechanisms, and indeed, some causes of intervention complexity, would enable more precise and more practitioner-

orientated, reporting of results. What this means is that, instead of only reporting the overall effectiveness of the interventions compared to the control interventions, reviews could also help pinpoint those intervention mechanisms and features that in a particular review and among a specific patient population, appeared to have contributed to the intervention effectiveness or non-effectiveness. Increased understanding of intervention mechanisms may enable practitioners to decide what they prefer to take in account of in the planning and delivery of an intervention, according to their circumstances.

The series of case studies was carried out to include: a review of reviews of psychological cardiac rehabilitation intervention, a systematic review of psycho-educational cardiac rehabilitation intervention, a systematic review and meta-analysis of psycho-educational smoking cessation interventions for coronary heart disease patients; an examination of intervention mechanisms in the studies included in the meta-analysis, and a systematic review and research synthesis of qualitative studies exploring patients' experiences and expectations of cardiac rehabilitation. While Chapter 7 reported only the results from the review of qualitative studies, the present chapter examines whether and how these findings may corroborate findings from the other types of reviews. This chapter also aims to examine whether this example of adding a qualitative review to a systematic review and meta-analysis can add to the overall results of the review, to the understanding of the mechanisms and features of an intervention, and to the applicability of the results in practice. This chapter, however, will not examine in any depth the different methodological and practical issues raised by including a qualitative review within a systematic review and meta-analysis. It does, however, evaluate how and how far findings from the qualitative reviews (reported in the Chapter 7) may identify complexity, mechanisms and techniques in the intervention. It also seeks to identify how far such findings may corroborate the evidence from the reviews included in the review of reviews.

8.2 What results should be compared and how the comparison should be done

The initially-planned design was intended as a comparison and synthesis of the results from the systematic review and meta-analysis of smoking cessation studies for coronary heart disease patients and the systematic review of qualitative studies

exploring patients' experiences and expectations of cardiac rehabilitation, especially of smoking cessation interventions. Following the steps in the systematic review of quantitative studies, it was planned that the first stage of the qualitative review should search for studies of participants' expectations and experiences of cardiac rehabilitation in general, and from the available pool of the studies, to select studies investigating especially smoking cessation interventions for further analysis. This decision followed the experience of searching relevant studies in the scoping review of psycho-educational smoking cessation studies. The scoping review indicated that using a broader search for psycho-educational cardiac rehabilitation interventions identified successfully psycho-educational smoking cessation interventions. However, while the search for qualitative studies was productive, it did not locate any studies which only investigated smoking cessation. Therefore, in contrast to the originally-planned design focusing on psycho-educational smoking cessation interventions, the qualitative review was instead limited to examining participants' expectations and experiences of psycho-educational cardiac rehabilitation interventions.

The qualitative review results suggested that, overall, this review was able to answer the questions about how participants perceive psycho-educational cardiac rehabilitation interventions and what participants' expectations of participating and of an intervention might be. However, the qualitative review could produce only a very limited range of findings about potential intervention mechanisms and theories. On the other hand, the qualitative review pointed up several issues, from participants' perspective, which may help in understanding reasons of intervention complexity. In this chapter it is asked whether and how qualitative review can further understandings of mechanisms and techniques underpinning interventions. Before any kind of comparison can be made, it needs to be decided with what other review results qualitative review should be compared and what aspects of the results should be compared.

Examining the intervention mechanisms and techniques of psycho-educational smoking cessation interventions provided detailed information about interventions included in the systematic review and meta-analysis. The review of reviews, on the other hand, was considerably more limited in its scope, even though information was

collected about review authors' conclusions and suggestions about intervention techniques and features that might be associated with potentially improved effectiveness of an intervention. It was first thought to be more informative to compare the results of the analysis of techniques and mechanisms used in the psycho-educational smoking cessation interventions with the results of the qualitative review of psycho-educational cardiac rehabilitation interventions. However, because of uncertainty of comparability of these reviews, a decision was reached not to compare these two reviews. Instead, it was seen as more appropriate at this stage, to compare the results of the qualitative review with the partial results from the review of reviews. The main reason for this decision was the uncertainty, discussed in the previous chapter, about how far the results of the qualitative review might be generalisable to other contexts. This is because, while the participant populations in all the reviews were similar, the smoking cessation-only interventions differed in many aspects from the psycho-educational cardiac rehabilitation interventions. Psycho-educational cardiac rehabilitation interventions tended to target multiple behavioural outcomes, while the interventions in the qualitative review often included exercise component, which was also reflected in participants' experiences and expectations of the interventions. Psycho-educational smoking cessation intervention, on the other hand, targeted a single behaviour. Additionally, the time line for the psycho-educational cardiac rehabilitation and smoking cessation interventions was rather different. Whereas smoking-cessation-only interventions tended to start while participants were still in hospital, the time lapse between a cardiac rehabilitation intervention and hospitalisation was longer. Therefore, in this instance, it was judged that comparing the results of the qualitative review with results from the review of reviews would allow some assessment of how qualitative review may advance the understanding of intervention mechanisms, theories, and techniques within similar interventions.

It was decided to compare qualitative research with the review of reviews because of the similarities between the interventions. As no guidelines exist about how this kind of research and comparison should be carried out, a challenge for this comparison was to set out clearly why and how the decisions about comparability were reached in this instance. It is acknowledged that the decision reached here is not the only one possible, and that various comparisons could be made based on alternative

arguments, such as intervention comparability and purpose of the comparison (Sackett & Wennberg, 1997). However, it is not possible within the limitations of this chapter, to go on to evaluate how alternative types of comparisons might affect the results. The review of reviews, presented in the Chapter 3, mainly aimed to identify the methodological issues faced in reviews of complex health care interventions. However, as well as collecting information about methodological issues, data were also collected about authors' conclusions about what, according to the results of the review, they evaluated as being effective and less effective features of an intervention. Therefore, it is suggested that the present analysis should analyse the results presented in the Chapter 7 for the three qualitative review questions in conjunction with the results from the review of reviews, with a particular focus on which features of the intervention were effective.

As well as the main analysis, which compares the results of the qualitative review with the results from the review of reviews, an additional analysis would consider how the intensiveness of an intervention may have affected patients' intentions to attend a rehabilitation programme and their perceptions of the programme. The results of the systematic review and meta-analysis of smoking cessation interventions for coronary heart disease patients showed that intensive interventions can be significantly more effective than less-intensive interventions. The overall aim of the analysis is to examine how evidence from qualitative review and review of reviews may support this finding in the context of more general cardiac rehabilitation interventions. Although the results of the analysis of the intervention mechanisms and techniques are not used as a basis of the comparison, these results will be occasionally referred to emphasise common findings between the reviews.

The results of the review of reviews indicated some disagreement regarding overall effectiveness of psychological interventions (Table 8.1). However, the evidence in the individual reviews indicated that interventions may be effective in having an impact on diverse types of outcome variables: biological, such as mortality and morbidity (e.g. Linden et al., 1996); clinical, e.g. cholesterol (e.g. Linden, 2000); behavioural e.g. diet (Mullen et al., 1992); and psychological, e.g.. anxiety (e.g. Rees et al., 2004). However, some reviews have especially questioned the effectiveness of the interventions for reducing mortality and morbidity (e.g. Rees et al., 2004).

Another area where there is still much uncertainty is on how the observed changes in outcome variables are brought forward. At present, some evidence points to interventions role as stimulating healthy life-styles, which, in turn, may reduce risk factors, or depending on the type of the intervention, interventions aim in reducing emotional stress (Sebregts et al., 2000, Dusseldorp et al., 1999).

The partial findings from the review of reviews (Table 8.1) were compared to the findings of the qualitative review (Table 8.2). The broad framework for making the comparisons can be described as a narrative analysis, meaning that comparisons are made through discussion of the results side-by-side. In building up a coherent framework for the discussion, some features of thematic analysis were used to help in the organisation of the discussion. However, unlike the type of emergent thematic analysis used in the qualitative review, in the present case, data is organised and discussed within given themes, which were derived from the previous reviews presented in the Chapters 3 and 7. This aims to examine whether and how the combined information from the reviews can further explain mechanisms, techniques or complexity in interventions in any way that has not been achieved in the previous chapters. It also aims to evaluate the usefulness of comparing the results of these two types of review in this manner and to identify points where available data from both reviews converges or diverges. In the cases of disagreements between the data, the purpose of this discussion is not to decide the respective accuracy of the data, but to highlight areas where data from different sources may produce similar and divergent findings. Not every finding recorded in Tables 8.1 and 8.2 is discussed at the same level of detail. However, the principles used to prioritise the discussion of findings are explained in the following section.

It is not aimed to discuss and compare all the findings from review of reviews and qualitative review, but to concentrate on evaluating how far participants' perceptions and experiences of psycho-educational cardiac rehabilitation may match previous reviews' findings about the features and mechanisms of an intervention that may improve its effectiveness. It is recognised that the following discussion unavoidably reflects author's opinion of what points should be brought up in the discussion and that alternative approaches for building up the discussion could also have been possible. Although the discussion mainly considers results from the review of

reviews and the qualitative review, some points that arose in the analysis of intervention mechanisms and techniques will be referred to where they prove relevant to the discussion. The discussion that follows, aims to highlight consistencies and inconsistencies between different review sources and to evaluate how and how far combining the results may further improve understanding of complex health care interventions.

8.3 Discussion

8.3.1 Intensive interventions may be more effective but...

A subgroup analysis undertaken as a part of the systematic review and meta-analysis of psycho-educational smoking cessation interventions suggested that intensive interventions were potentially more effective than less intensive interventions. However, the results of the qualitative review underlined some potential problems for patients posed by intervention intensity. While, for example, interventions with longer duration may be more effective (e.g. Linden, 2000), this applies only to that portion of patients who are willing to attend in the first place (Wyer et al., 2001a). Those individuals who do not perceive the recovery as their responsibility may express initial interest in participating in cardiac rehabilitation (Wingham et al., 2006). However without the motivation to commit to a long-term treatment which they may see as unnecessary, even individually-tailored interventions are unlikely to attract these participants. The qualitative review also indicated that patients have very different perceptions about the effectiveness of a rehabilitation, so that while some patients firmly expect to gain benefits from attending a cardiac rehabilitation (e.g. Wyer et al., 2001a), others are more doubtful of the benefits and feel uncomfortable about some aspects of rehabilitation (Clark et al., 2005). Patients who perceive cardiac rehabilitation as beneficial are likely to be motivated to attend regardless of the length and intensity of the intervention. However, for those participants with reservations about attending cardiac rehabilitation, intense and lengthy interventions may further deter attendance, due to level of commitment required.

The combined results from the different reviews suggest that, cardiac rehabilitation interventions are complicated by interactions between patients and specific features of an intervention. While intensive interventions may be more effective than less intensive interventions, as for example the systematic review of psycho-educational smoking cessations interventions implicated, such interventions may deter the less-motivated participants from attending, as they may find it more difficult to engage with the intervention. These results also suggest that an intervention theory, or a mechanism may be also influenced by participant dependent factors, i.e. how participants perceive the intervention. For example, in the case of intervention intensity, an intensive intervention employ social support to reinforce motivated participants' engagement with behaviour change, while trying to get less-motivated participants to engage with the intervention and intended behavioural changes.

8.3.2 How participants' views compare with the review evidence?

The qualitative review indicated that although patients had some knowledge of what cardiac rehabilitation consisted of, they tended to associate it with mainly group exercise combined with some health education. (Hird et al., 2004, Wingham et al., 2006, Wyer et al., 2001a, Clark et al., 2004, Cooper et al., 2005). The qualitative review suggested that participants' motivation, perceptions of the intervention's usefulness, and expectations of its contents influenced not only expectations placed on cardiac rehabilitation but also on how useful participants considered attending to be for their recovery. (e.g. Cooper et al., 2005, Wingham et al., 2006). In addition, for some participants, involvement of family and ability to have a choice of rehabilitation emerged as a feature that they would like to see within cardiac rehabilitation (Hird et al., 2004).

8.3.2.1 What and whom should cardiac rehabilitation interventions target?

The reviews of psychological cardiac rehabilitation interventions identified several intervention features or techniques (Table 8.1) that, they suggested, may improve effectiveness of cardiac rehabilitation interventions. Given the variety of interventions that were included in the different reviews, it is not surprising that the findings and suggestions for potentially effective intervention techniques differ

between reviews. However, the available information nevertheless offers some important pointers about which kind of an intervention or a technique may be employed to improve the effectiveness of an intervention.

Two of the reviews brought up the potential importance of targeting behaviours as the primary goals of interventions, and how interventions that target a specific behaviour, such as smoking, appear to be more effective than an intervention that targets multiple behaviours simultaneously (Godin, 1989, Mullen et al., 1992). Reviews differed in their estimation of the effectiveness of uni- and multi-component interventions (e.g. Godin, 1989, Rees et al., 2004), though a more recent review by Rees et al. (2004) argued that their findings indicated that combined psychological interventions may be the most effective form of an intervention. A number of intervention techniques emerged from the reviews as possibilities to influence effectiveness.

Mirroring the results of the qualitative review, the reviews of reviews highlighted the difficulties faced by cardiac rehabilitation interventions in getting eligible participants to participate and how benefits of participation could be improved. In regarding the improving the participation, possible techniques were suggested as; selective patient referral (e.g. Linden et al., 1996, Linden, 2000) so that certain groups of patients such as most motivated or distressed will be targeted; screening for those patients with specific risk factors targeted by an intervention; and considering patients' existing motivation and resistance to change behaviour (e.g. Godin, 1989). As with the qualitative review results, these results suggested that the existing motivation to attending a rehabilitation can be a major factor influencing attendance decisions (e.g. Sebregts et al., 2000). Therefore, effectiveness of cardiac rehabilitation interventions may be increased by better matching between participant needs and the intervention content.

Intensive treatments, such as psychotherapy, should only be used in the cases of extreme psychological distress. (e.g. Linden et al., 1996, Linden, 2000). The results of the qualitative review suggested that for a proportion of patients, the intensity or the duration of intervention was insufficient. This group of patients may thus benefit from individually tailored longer interventions and perhaps even from intensive

treatments such as psychotherapy (e.g. Linden et al., 1996, Linden, 2000). Gender differences and trends in cardiology should also be considered in improving the effectiveness of an intervention (Linden, 2000). Some of the findings from the review of reviews argued that cardiac rehabilitation interventions should consider possible gender differences in designing the intervention (Linden, 2000). While relatively few qualitative research studies specify the results by the patients' gender, the qualitative review points to subtle differences between the experiences men and women have in participating in a cardiac rehabilitation. Women appeared to experience more troubles than men in rehabilitation and found it more often not responsive to their specific needs, though many still described cardiac rehabilitation as essential to their recovery. Men were also critical of some aspects of the rehabilitation, especially about the ability of a group intervention to cater for diverse needs. Thus, the combination of findings from the reviews points that gender-specific rehabilitation programmes may improve outcomes especially for female participants.(Day and Batten, 2006, Hutton and Perkins, 2008).

8.3.2.2 Intervention techniques – participants' perspectives

The review of reviews noted that several intervention techniques had been judged as a potentially effective in increasing the effectiveness of psycho-educational cardiac rehabilitation interventions. The following techniques were suggested as potentially effectiveness: feedback, reinforcement of information, longer duration of intervention, skills, stress management, additional resources for those who require them, and education (Table 8.1). While the qualitative research suggested that exercise-related issues are often of particular concern, patients' experiences of cardiac rehabilitation appeared to give tentative support to the effectiveness of intervention techniques reported in the reviews. Use of reinforcement, education, improving knowledge about the condition, and support appeared to help patients to regain their confidence and to improve their risk factor profiles.

The findings of the review of reviews (e.g. Linden, 2000) indicated that an intervention may be effectively delivered to participants when the intervention personnel is adequately supported and the intervention follows a group format. The qualitative review results agreed that delivering an intervention in a group can be

effective. However, the qualitative research highlighted the need to consider patients' attitudes towards group interventions, and especially towards exercising in a group. Though a majority of patients saw some benefit in participating group sessions, some were more reluctant to engage in a group intervention. This group of patients cited concerns about possible embarrassment while exercising, conflict between individual and group needs, and dislike of groups. (Cooper et al., 2005, Rees et al., 2004). Therefore, though some evidence indicates that cardiac rehabilitation groups can have benefits for individuals as well as being a sensible way to allocate health care resources, for some patients, the idea of participating in a group may deter attendance in rehabilitation or decrease its benefits. The qualitative research evidence supports the argument that while many find cardiac rehabilitation groups helpful, this is not the case for all. Offering a home-based cardiac rehabilitation appears to answer patients' wishes to have a choice over the method of rehabilitation, thus overcoming the difficulty of group rehabilitation while improving participation. A home-based intervention offers information, education and advice, techniques which reviews have identified as potentially effective for supporting behaviour change.

The qualitative review offered some insights into how patients' perceive the information offered in the cardiac rehabilitation interventions. Although many patients saw the provided information as helpful, some felt that at times the volume of information received amounted to information overload. Further, some participants experienced that information was given at inappropriate times, when they did not feel ready to absorb it (Murie et al., 2006, Davis et al., 1995). The qualitative review evidence appears to support conclusions from the previous reviews that providing information, education, and knowledge about disease and recovery are potentially effective intervention techniques. Only two of the qualitative studies explicitly asked participants' views on the features of a successful intervention (Murie et al., 2006, Tamada and Holmes, 1998). However, as neither of these studies included a cardiac rehabilitation intervention that included both exercise and psycho-educational components, evidence on patients' preferences in a cardiac rehabilitation is rather limited. This evidence, nevertheless, highlights the importance of providing information and knowledge about the disease and recovery as part of an effective cardiac rehabilitation intervention. Patients' comments also reflected the need for information that is relevant to their specific situation, and

having similar information available to their family and carers. In the analysis of intervention techniques (Chapter 6) the intervention technique of providing behavioural information was employed in several studies. The combined results from the reviews suggests that this intervention technique can be effective and well accepted, but that specific consideration need to be given to the format in which the information is given to participants.

Patients who attended formal, usually hospital-based, cardiac rehabilitation, tended to perceive cardiac rehabilitation positive rather than negative. In general, programmes were considered friendly, and the company, support, and shared experience with other participants were seen as important aspects of the rehabilitation. (Mooney et al., 2007, Clark et al., 2005, Wingham et al., 2006). The results of the qualitative review corroborate the results in the Chapter 6, where social support was found to be used as the intervention techniques in a number of studies. The combination of the different results suggests that as an intervention technique, social support may not only be effective but also well accepted by participants. Social support may also stem from a variety of sources. Cardiac rehabilitation staff may have an important role in supporting lifestyle changes (Clark et al., 2005), and support from a rehabilitation group that may motivate attendance (Wingham et al., 2006).

8.3.2.3 Central role of exercise

The qualitative review findings indicated that exercise and exercise-related conceptions can have a central role in the process of deciding cardiac rehabilitation attendance. For example, Rees et al. (2004) suggested that interventions may be improved by using multiple methods to influence target behaviours. However, the qualitative review results strongly supported the argument that while patients recognise that cardiac rehabilitation involves other elements than exercise, exercise-related concepts appear to dominate the image of the rehabilitation, and may be a major factor in preventing or facilitating attendance. The qualitative review, however, adds to the argument for targeting certain patient groups by referring them to specific types of interventions may improve the effectiveness of an intervention. While some evidence from the review of reviews indicated that interventions which

aim changing several behaviours may not be the most effective, they may, nevertheless, match with patient expectations of what a programme should offer. Therefore the combined review evidence suggests cardiac rehabilitation programmes may need to deploy various techniques to deliver a coherent and meaningful intervention that responds to the patients' expectations. For some patients, however, being able to select the type of rehabilitation emerged as an important factor when they were considering possible attendance. Perhaps this group of patients may especially benefit from the rehabilitation programmes that, as suggested in some reviews, target single behaviours, such as smoking, instead of multiple behaviours, as a way to improve intervention effectiveness for this group of patients.

8.4 General discussion

This synthesis of the results from the review of reviews and the qualitative review was limited in its scope due to limitations on available material and the decisions made during the early stages of the analysis about material selection and synthesis methods. However, regardless of the many problems faced during the analysis, combining the results still offered some genuine insights into how qualitative research may contribute to understanding, in this case, the results of the previous reviews. Combining the different types of results here offered an opportunity to evaluate the practicability of this approach and how it may be modified for future research. Perhaps the first and the biggest limiting factor for the analysis and evaluation of the results were the lack of available qualitative research material about coronary heart disease patients' experiences and expectations of smoking cessation interventions. This prevented this approach being tested in combination of the systematic review and meta-analysis of psycho-educational smoking cessation studies for coronary heart disease patients. On the other hand, the observed lack of qualitative research material emphasises perhaps one of the major problems with this approach, namely, the necessity of being able to evaluate beforehand the availability of the research material for a meaningful analysis.

Another substantial challenge faced in the analysis was determining how the research questions set for the qualitative review and the review of reviews might provide information that would be meaningful to discuss together. In the present review, this

problem was resolved not by discussing all the results from the both reviews, but by selecting some results for further discussion. While it is recognised that limiting the number of results included in the discussion does restrict its scope, it also prevents it from becoming unmanageable and potentially meaningless. This approach, however, may attract criticism for some lack of transparency and selective inclusion of the results. Even though an aim in discussing has been to be as explicit as possible about how different decisions were reached and how the discussion was organised, there remains scope for improvement. For the purposes of this discussion, it was decided to compare suggestions about effective features of interventions found in the review of reviews and the findings from the qualitative review. These findings were selected for this discussion as it was judged that they would offer an opportunity to evaluate whether and how patients' perceptions of interventions may converge with the other reviews' findings about successful interventions. Therefore, despite the many reservations about the limitations of the present discussion, such a combined narrative could still be seen to help evaluate whether patients' perceptions of cardiac rehabilitation may match with review evidence of what an effective intervention may look like. This present discussion, however, could not examine intervention mechanisms in any depth, as such an analysis could not be supported by the available material. The available material provided information about intervention characteristics and participants' perspectives, but not about the processes through which the change in behaviour was achieved.

While previous reviews of psychological cardiac rehabilitation interventions discussed both intervention features and techniques that may be associated with an effective intervention, results from the present analysis emphasised how different intervention techniques and features could be used to match patients' expectations of cardiac rehabilitation, and thus to improve the acceptability of intervention and potentially intervention effectiveness. Results from the previous reviews were not consistent in their conclusions about what kind of intervention techniques or features are associated with an effective cardiac rehabilitation intervention. However, similar findings could be seen in a slightly different context through the results of the qualitative review, which showed that patients' expectations and experiences of rehabilitation can vary greatly from each other. The qualitative review results reported in the Chapter 7 suggested that those participants who benefited most of the

cardiac rehabilitation interventions appeared to have the most positive attitudes towards rehabilitation and were those attending regularly. Those participants who attended infrequently tended to have less favourable expectations of cardiac rehabilitation, and appeared not to experience rehabilitation as beneficial. In effectiveness studies, however, these patient groups are usually compared together, which may at least partially contribute to observed inconsistencies between effectiveness studies.

The discussion raised questions about how cardiac rehabilitation programmes may better respond to patients expectations and how patients who are reluctant to access the services could be encouraged to participate. The review of reviews suggested that some of the potential solutions may include, for example, offering interventions that target individual behavioural risk factors, such as smoking, for those patients that are reluctant to participate in a full cardiac rehabilitation. In addition, as reviews suggested, the effectiveness of a cardiac rehabilitation may be increased by more targeted referrals to programmes according to patient needs and preferences. The qualitative research results were largely supportive of these findings, emphasising patients' wish to have a choice over the method of rehabilitation. However, as offering a variety of interventions may be considerably limited by the availability of resources, intervention providers may wish to ensure that those patients eligible for cardiac rehabilitation are well-informed about the importance, rationale for and content of rehabilitation before e.g. hospital discharge. Informing patients of the contents and goals of the rehabilitation may improve their initial acceptance of rehabilitation, especially as findings suggested that many patients expressed concerns relating to a group format of a rehabilitation, even when some evidence argues that such a group format can be linked to the effectiveness of an intervention.

The qualitative review brought up an important issue that has not come up clearly in the effectiveness research in arguing an association between frequency of attendance and perceived benefits from cardiac rehabilitation. Thus, motivated patients with the highest levels of attendance in a cardiac rehabilitation also report the most benefits. Patients with negative perceptions of cardiac rehabilitation appear either to benefit little from rehabilitation, due to partial attendance, or not at all, due to non-attendance. Patients in a partial attendance group appear to find cardiac rehabilitation

as not responsive to their needs, and may benefit from more individually-tailored programmes or indeed from other forms of rehabilitation such as a home-based rehabilitation. Both reviews also identified gender-specific issues, and while not always possible, cardiac rehabilitation programmes may be more effective where they offer the possibility of taking a part in either mixed or single-gender programmes. Findings from the present analysis indicate that considering patients' individual needs and intensity of rehabilitation may have a large impact on the effectiveness of rehabilitation. The qualitative research also highlighted another problem area, which concerns those patients who do not attend at all in cardiac rehabilitation. These patients have no possibility of revising their view of rehabilitation, and pose a challenge to health care professionals to help encourage such patients to reconsider their position, and to offer types of cardiac rehabilitation that would be acceptable to this group of patients.

The discussion and comparison of the different review results continued to underline the complexities faced in developing and evaluating psycho-educational cardiac rehabilitation interventions. Although the techniques used in the different psycho-educational cardiac rehabilitation interventions appeared generally well-matched with participant expectations, the individual variations between participants and interventions mean that matching the right intervention with the right participant to achieve the best possible outcomes would be difficult to achieve within the confines of the health care system. The available combined evidence discussed here argued that some of the complexities faced by the psycho-educational cardiac rehabilitation interventions stem from participants' expectations of the intervention, their personal likes and dislikes, and how participants interact with a particular intervention, which may be very difficult to anticipate in the planning stages. This, however, can cause considerable uncertainty for evaluating the intervention, as the effectiveness or non-effectiveness of an intervention may be caused by factors outside the intervention itself. For example, both the review of reviews and the qualitative review highlighted difficulties in dealing with differently-motivated participants, and how participant motivation can influence intervention effectiveness.

The combined evidence from the reviews of reviews and the qualitative review showed that techniques that have been used in the interventions and evaluated

effective are not only acceptable to participants but also often appreciated. For example, interventions' efforts to educate patients and offer information about coronary heart disease and aspects of recovery, appear to respond to patients' expressed needs to know about their disease and how to prevent and recognise future problems. While some patients criticised the amount of information offered, overall, interventions appeared to be able to effectively transfer the necessary knowledge to patients. Participants also appreciated the support the cardiac rehabilitation interventions offered and felt that the guidance that the interventions offered about the process of recovery and practical help to change risk factor were effective intervention techniques. These results suggest that many of the present techniques used in cardiac rehabilitation are effective and well accepted by the patients.

Employing this approach to considering the results of the reviews together has enabled comprehensive understanding to be gained about the complexities that participants' individual circumstances may engender for the planning, implementation and evaluation of psycho-educational cardiac rehabilitation interventions. However, the approach applied here is time-consuming and not suitable for every situation. Perhaps the biggest benefit provided by this approach was the further understanding of what participants want from this kind of an intervention and how well the present understanding of effective intervention techniques is matched by what participants themselves experience as effective techniques to help in behaviour change.

8.5 Conclusions

This chapter provided a focused evaluation of evidence, the results of which demonstrate that qualitative research could add some conceptual depth to the findings of the review of reviews by identifying some possible causes underlying the results of the review of reviews. While the review of reviews could suggest many features and techniques of an intervention that could affect its effectiveness, the qualitative review was additionally able to show why some of the intervention features and techniques may, from the patients' perspective, increase the effectiveness of the intervention. Equally, qualitative review was able to offer some possible reasons for why the reviews can at times lead to different conclusions. The

comparison of the results showed that cardiac rehabilitation interventions face a difficult balancing act between individual requirements and resource availability, but that many of the intervention techniques presently in use appear to respond well to patients' expressed needs. Although comparing the studies was successful in evaluating the features of interventions features, the evaluation in this form could not be used to identify which intervention mechanisms were effective.

Chapter 9

An overall summary and discussion of main findings and implications

9.1 Introduction

The starting point for this project was to find out how and whether systematic reviews of complex health care interventions may be improved by more detailed understanding of theories underpinning interventions and mechanisms. Methodological challenges faced by reviews of complex health interventions, such as difficulties in searching and interpreting results, are well-documented (e.g. Armstrong et al., 2009, Higgins and Green, 2011, Jackson et al., 2004). The guidance available for reviewing complex health care interventions (e.g. Higgins and Green, 2011) does not explain how theories underpinning interventions and mechanisms might be evaluated in relation to whether it improves the practical application of the review results. In recent years several authors such as Wong (2009 in Shepperd et al., 2009), Sheik (2009 in Shepperd et al., 2009), Michie et al. (2009), and Welton et al. (2009) have highlighted the need for a more systematic evaluation of intervention mechanisms and theories in systematic reviews of complex healthcare interventions. Therefore, this thesis asked whether reviews of complex health care interventions could be improved by a systematic evaluation of theories underpinning interventions or, indeed mechanisms.

In the early stages of the thesis, it was noted that intervention theory and mechanisms were often difficult to separate from each other, as, apart from the formal theories underpinning interventions, both intervention theory and mechanism can be seen as a statement of how the intervention is seen as likely to achieve its stated outcomes. In this thesis, the effects of including and examining intervention mechanisms, or theory, as part of a systematic review of complex health care intervention, were evaluated. This has been tested in a series of diverse but related empirical studies, which began by examining how theory has been considered in existing reviews of psychological cardiac rehabilitation interventions and with what effect it had on reviews. Then inclusion of theory in a meta-analysis of psycho-educational smoking

cessation interventions for coronary heart disease patients was examined. Finally, inclusion of theoretical considerations within a systematic review of qualitative studies of psycho-educational cardiac rehabilitation interventions was investigated. All of the empirical studies approached the research problem with a set of different but related research questions, and ultimately the studies examined what inclusion of theory means, and how examining intervention mechanisms or theory as part of a systematic review of complex health care intervention may improve the systematic review process and the application of the review results to practice.

This project has enabled a series of tests and reflections on the feasibility of including theoretical considerations in a systematic review of complex interventions for advancing the understanding of intervention mechanisms and theories. Apart from examining what identifying theories and mechanisms underpinning interventions may contribute to systematic review and meta-analyses, this project also evaluated how qualitative research may be utilised in this context to advance understanding of theories and mechanisms underpinning interventions. While qualitative research has been previously successfully used in explaining the results of systematic reviews (e.g. Thomas et al., 2004), there is limited evidence available about utilising qualitative evidence in understanding intervention mechanisms and theories within a systematic review. Qualitative reviews have not been extensively applied to the identification of intervention mechanisms in this context. Moreover, there was no previous example of using qualitative review alongside a systematic review and meta-analysis of psycho-educational smoking cessation interventions for coronary heart disease patients. Therefore, it appeared that evaluating the feasibility and usefulness of employing qualitative review alongside quantitative review in examining intervention techniques and mechanisms could add significantly to understanding the potential contribution of qualitative research in this area. The discussion which follows aims to bring together the different case studies, and consider some of the methodological issues that were raised within each of the case study. The discussion will also evaluate whether and how far the case studies presented in this thesis may have been successful in contributing to the understanding of mechanisms and theories underpinning interventions, as a part of a systematic review and meta-analysis, and will also discuss limitations of the different empirical studies. The discussion will start by tracking and explaining the successive

changes of focus taken in identifying the contribution of theories underpinning interventions within reviews. The final part of this discussion evaluates the implications of the results for current guidance on reviewing complex health care interventions and for informing further research directions.

9.2 How examining theories underpinning interventions was approached in this thesis?

Examining what theories may have underpinned interventions appeared a straightforward enterprise at the beginning of this project. However, the results of the review of reviews suggested that though many reviews remarked on the importance of theories underpinning interventions, only a minority of previous reviews had explicitly attempted examining intervention theories or mechanisms in detail (e.g. Dusseldorp et al., 1999). The idea of investigating theories underpinning interventions in systematic reviews is not new, as, for example, Michie et al. (2009) have used meta-regression in investigating effective intervention mechanisms. However, using meta-regression requires that the primary studies provide appropriate data for analysis, and this may not always be possible. A first problem for investigating the theories underpinning interventions in this thesis was to decide what it actually meant for a theory to underpin an intervention. The literature review and the review of reviews suggested that a theory in reviews of complex health care interventions can be examined at different levels and in different forms (e.g. Jackson et al., 2004, Pawson, 2002c, Yang, 2002). The literature review (in Chapter 2) identified two potential major approaches for examining theories underpinning interventions. The first was to assess theories underpinning interventions at “face value” i.e. in the terms in which they are explicitly set out. The second was to evaluate how the intervention may cause the changes desired, i.e. intervention mechanisms, which may or may not be explicitly related to a stated theoretical formulation (e.g. Jackson et al., 2004).

When theories underpinning interventions are considered at “face value”, this means focusing less on the mechanisms of an intervention than on what kinds of theories are explicitly mentioned. Where theories are explicitly mentioned, they can be used for systematic classification of interventions. Interventions can be categorised

according to the explicit theoretical considerations, such as specifying a particular theoretical model in an intervention as a part of inclusion criteria. However, there seems to be little evidence that such categorisation of interventions often happens in practice. Even when it does happen, the scoping review of psycho-educational cardiac rehabilitation interventions indicated that it may prove complicated to use explicitly-mentioned theories as potential inclusion and exclusion criteria. The results of the scoping review showed that many studies did not explicitly mention any specific intervention theory, and that of those studies that did mention an intervention theory, the reported outcomes may be too diverse to allow a meaningful meta-analysis.

In contrast, explicitly-mentioned theories underpinning interventions may be useful in creating subgroups to examine the effects of including theory as part of a meta-analysis. However, the findings from this project indicated that using explicitly mentioned theories underpinning interventions in decisions about what analyses are done requires clarity. In this case clarity was especially required for making it explicit whether analysis that examine theories underpinning interventions were formed before data collection and main analyses, or afterwards. Statistical methods such as sub-group analyses, meta-regression, and analysing mediator and moderator variables to understand intervention mechanism and theories are well-established (e.g. Carpiano and Daley, 2006, Yang, 2002, Becker, 2001). However, the review of reviews and the scoping review suggested that these methods may have only limited usefulness for examining intervention mechanisms in complex psycho-educational cardiac rehabilitation interventions.

Findings from the literature review and the review of reviews suggested that examining the mechanisms informing complex health care interventions was not widely undertaken within reviews of complex health care interventions (e.g. Shepperd et al., 2009). Therefore, the project focus shifted from examining explicitly-stated theories underpinning interventions to examining intervention mechanisms and techniques. Although it could be argued that the terms theories underpinning interventions and intervention mechanisms could be used interchangeably, the results of the thesis were seen to be more informative about the mechanisms and intervention techniques used in the different studies than about

formal theories underpinning interventions. As Jackson et al. (2004) observed, there is still uncertainty about whether including theory in an intervention planning increases intervention effectiveness. Such a view was supported by the results of the subgroup analysis between psycho-educational smoking cessation interventions that had or had not used an explicit theoretical model in the intervention planning, which did not find a difference between the groups. Therefore, as the thesis progressed, its successive studies produced more evidence that evaluating how intervention descriptions matched some specific theoretical model or framework was not as explicative as examining what mechanisms and techniques had been used to achieve the intervention goals.

Doyle et al. (2008b) argued that reviewing social determinants is complicated by the use of varying explanations and definitions of similar concepts. Reviewing the theories underpinning interventions, or the mechanisms informing a psycho-educational intervention is complicated by the uncertainty associated with variability in how similar concepts are defined. For example, 'giving information to patients' can be described as 'education' or 'advice'. Finding ways to specify techniques and mechanisms informing interventions provided a more practical approach than examining how or whether different parts of an interventions may match a specific theoretical construct. Finally, the advantage of investigating intervention mechanisms and techniques rather than explicit theories underpinning interventions was in allowing a detailed examination of the intended action of every intervention, regardless of whether they stated their use of a specific theoretical model.

As the research developed, it became more evident that including evaluation of theories underpinning interventions in a review of complex health care interventions required re-assessing what was actually meant by theories underpinning interventions. This required evaluation in each case of how theories underpinning interventions may have been articulated in the different studies. As the different case studies evolved, it was made increasingly apparent that, within the boundaries of this project, the results of successive studies were successively helping to advance understanding of how interventions may have caused the desired behavioural changes (i.e. mechanisms) rather than improving understanding of explicitly-expressed theories underpinning interventions and how their theoretical constructs

may have been supported by the research evidence. This did not mean that the explicit theories underpinning interventions were not evaluated at all within the analyses, but it was found that the extent of their contribution to understanding of how interventions work were more limited than expected.

9.3 Main findings from the review of reviews

The review of the reviews, presented in the Chapter 3, did not aim in a systematic reviewing all reviews of psycho-educational cardiac rehabilitation interventions. The review of reviews also did not evaluate the effectiveness of interventions, as this had already been done by Rodgers et al. (2005). Instead, the review of reviews asked how previous reviews of psycho-educational cardiac rehabilitation interventions had addressed methodological issues faced by reviews of complex health care interventions, whether theories underpinning the interventions had been evaluated. The review of reviews used a narrative approach to identify whether any theoretical considerations could be seen to be included in the reviews and what intervention features, mechanisms, and techniques that may increase intervention effectiveness could be identified in the previous reviews. As the purpose of the review was to discuss a range of evidence and contribute to the knowledge about challenges faced in carrying out reviews of complex health care interventions, it was judged that a non-systematic review would be best suited to answer the specific, non-statistical, review questions (e.g. Petticrew, 2009).

The earlier findings by Rodgers et al. (2005,) indicated that several of the potentially-relevant reviews were conducted before the publication of the first Medical Research Council guidance for developing complex health care interventions (Medical Research Council, 2000). Therefore, it was not expected that intervention complexity and its potential influence in the review process and results would have been explicitly discussed in the reviews conducted before publication of the MRC guidelines (Medical Research Council, 2000). However, the results from the review of reviews were found to be crucial in understanding how the complexity of psycho-educational cardiac rehabilitation interventions may influence the results of a review and their application to practice.

The results of the review of reviews suggested that complexity of the interventions was recognised in the reviews, either by explicitly identifying the interventions under reviewing as 'complex' or by referring to the difficulties previous reviews had encountered due to the complexity involved in the review process. All the reviews included appeared to investigate the effectiveness of interventions from the same, although broad, field of studies influencing cardiac outcomes by psychological interventions. Individual reviews did focus on their own specific points of interest and research questions. This finding is similar to Jackson et al. (2004), who argued that heterogeneity may be caused by reviews targeting different patient populations, interventions, and investigating different outcome variables, which complicates comparison of the reviews. However, appropriately categorising intervention features in a review may reduce heterogeneity between interventions (Shepperd et al., 2009).

The results suggested that the reviews identified relevant interventions by detailing relevant intervention features and components (e.g. education, males only) that should be common for all interventions. This was often accompanied by exclusion criteria that were identified as not too restrictive (e.g. both group and individual interventions possible), thus allowing flexibility to include interventions with unexpected variations in the design. The results from the review of reviews were also striking in that while a number of reviews specified the target type as, for instance, a psycho-educational intervention (e.g. Dusseldorp et al., 1999), the meaning of psycho-educational was left undefined. Instead of defining a psycho-educational intervention, reviews described what kind of components interventions that are psycho-educational should have. Therefore, some reviews (e.g. Rees et al., 2004) used some form of categorisation based on the defined intervention features, and preserved these categories partly in analyses.

The included reviews may need to consider different strategies to combine research findings to deal with the intervention complexity (e.g. Armstrong et al., 2009), and utilised a range of methods in combining results. Although the included reviews often referred to the previous reviews, none of the included reviews appeared to replicate any parts of the earlier reviews, such as an updated literature search, and consequently could offer no comparison and discussion of how and whether new material strengthened or weakened the results. Some difficulties in comparison

between the results of the reviews may be attributed to a lack of consistency in definitions between primary studies (Doyle et al., 2008a). However, this lack of updating appears to limit the reviews' potential to evaluate how primary research in the area has developed, and to hinder evaluating theoretical developments in the area.

In considering the complexities of interventions that are evaluated in reviews, the suggestion of Hawe et al. (2004) of defining complex interventions in terms of their common aims appears an attractive alternative. Armstrong et al. (2009) have suggested that systematic reviews may need to evaluate the benefits of different complex interventions with similar outcomes. However, even this approach would be problematic. While the interventions may have the same aims, reviews would still need to define participant populations. Without knowing for whom the intervention was designed and why, appropriately evaluating its effectiveness would be impossible. Regardless of the method by which a complex health care intervention is defined, the results of the review of reviews pointed to marked challenges faced by reviews in evaluating intervention techniques and mechanisms.

Several researchers have emphasised the need for reviews of complex health care interventions to report on process variables and examine how interventions function alongside effectiveness evaluation (e.g. Jackson et al., 2004, Shepperd et al., 2009, Doyle et al., 2008a). Indeed, results from the review of reviews indicate that apart from few exceptions (e.g. Dusseldorp et al., 1999, Sebregts et al., 2000), reviews generally did not consider or examine intervention mechanisms, process variables, nor investigate how different intervention and participant characteristics may affect intervention effectiveness and outcomes. This lack of any systematic examination of intervention mechanisms in the reviews may be partly due to limited available information in primary studies. However, of those reviews that did not explicitly investigate theories underpinning interventions, some nevertheless discussed the importance of theoretical considerations and the need for a more central role for them in the future intervention planning. The failure of the reviews to more systematically address possible causes of intervention effectiveness or non-effectiveness contributes to the uncertainty about which features promote effective intervention (Wong, 2009 in Shepperd et al., 2009). Nonetheless, it must be acknowledged that investigating

theories underpinning interventions within systematic reviews of complex health care interventions is likely to be challenging.

Researchers such as Jackson et al. (2004) argued that reviews need to evaluate whether an intervention in itself was effective or whether its effectiveness was influenced by pre-existing factors, such as participant characteristics. As the results from the review of reviews suggested, this may not be always straightforward, as a range of factors such as how the intervention was implemented may have had an impact on the intervention outcomes. Another challenge for excluding pre-existing factors is that, even though participant characteristics may be similar in control and intervention arms, the control conditions, like interventions, tend also to vary greatly, making it difficult to estimate the effectiveness of the intervention.

Results from the review of reviews suggest that the methodological difficulties encountered in reviewing psychological cardiac rehabilitation interventions are very similar to the challenges identified by other reviews of complex health care interventions (e.g. Doyle et al., 2008b, Doyle et al., 2008a). An important finding from the review, however, was the limited theoretical work regarding intervention mechanisms that had been done in the previous reviews. This indicated a need, as Sheik 2009 (Shepperd et al., 2009) argued, to examine how additional theoretical work may improve a review of complex health care interventions. Furthermore, none of the reviews had incorporated qualitative research or tested the usefulness of this addition.

Therefore, reviews of psychological cardiac rehabilitation interventions may be improved using methodologies identified in the literature review (e.g. Armstrong et al., 2009, Armstrong et al., 2008, Jackson et al., 2004, Shepperd et al., 2009). For example, psychological cardiac rehabilitation interventions may be improved by considering theories underpinning interventions, mechanisms, and techniques in primary studies, and how they may help in understanding intervention effectiveness. Secondly, reviews may also be improved by examining intervention characteristics in more details, thus helping to clarify intervention characteristics and how these may relate to intervention effectiveness. Finally, reviews of complex health care interventions may be improved by incorporating qualitative research, which may

complement and help explain why interventions did or did not work, what participants perceive as an effective intervention, and whether such perceptions are congruent with the current research evidence.

The review of reviews was successful in offering an overview of the methodological challenges in the previous research and in deciding the research questions for the further research in this thesis. However, there were several limitations in the review of reviews. First, only a limited literature search was conducted for the review of reviews, which means that potentially relevant reviews may have been overlooked. However, it appeared that when included reviews were compared to the reviews included in the review of reviews by Rodgers et al. (2005), the review was reasonably comprehensive. Question-setting for the review was also unusual in the way that research questions asked about methodological issues in the reviews and about potentially effective intervention features. Although questions were based on the literature, it is difficult to evaluate whether or not a different set of questions may have been better in eliciting information in this particular case. Another limitation was the probing nature of some of the research questions, and lack of relevant data from the included reviews. Therefore, for some of the questions, only indirect data were collected. Data collection was not duplicated, although every effort was made to ensure transparency and accuracy of the data extraction.

9.4 Main findings from the scoping literature review

Instead of conducting a full-scale systematic review and meta-analysis immediately, a scoping review was used to help in formulating the precise review questions and aims. Taking into account the challenges faced by systematic reviews, the scoping review aimed to test the search strategy, functioning of the inclusion criteria, number of potentially relevant studies identified, and through preliminary analyses start to examine how theories underpinning interventions, mechanisms, and techniques may be evaluated. The scoping review was seen as an opportunity to fine tune the review protocol and decide whether there would be any indications for subgroup analyses within meta-analysis. Subgroup analyses were seen as a possibility to examine how, in this context, categorising interventions by key variables, such as intervention

intensity, and retaining the grouping in the analysis may improve the quality of analyses (2009 in Shepperd et al., 2009).

One of the methodological challenges in reviewing complex health care interventions is the lack of consistency in terminology (Doyle et al., 2008a). This problem was evident in developing the search strategy for psycho-educational cardiac rehabilitation interventions. The search strategy had to take in to account that that there is no agreed definition of a psycho-educational intervention or that all relevant interventions do not describe themselves as psycho-educational. Further challenge in developing the search terms for the systematic review was whether search strategy and inclusion criteria should incorporate the theoretical aims of the review. Although researchers such as Wong (2009 in Shepperd et al., 2009) argued that examining intervention theories as a part of reviews of complex interventions is important, there is limited guidance about including theoretical considerations in a search strategy or decisions to include studies.

In this scoping literature review, a decision was reached that theory-related terms would not be included, either in search terms or in inclusion and exclusion criteria for the review, as this was seen to be impractical. The review of reviews indicated that there is uncertainty about how consistently theoretical terminology is used in the research of psycho-educational cardiac rehabilitation interventions (Doyle et al., 2008a), making it difficult to evaluate whether a search strategy would be effective in identifying relevant studies, as key words, abstracts or titles may not contain sufficient information. Further, as the aim of the review was not to investigate any particular theory, the inclusion of theoretical search terms would have been counter-productive, as the number of extra terms needed for the search strategy would have been very great, due to the number of potentially-used theories or other theory-related topics. In addition, it could not be disregarded that even though a study may not have explicitly specified a theoretical framework in the intervention planning, a study may have considered possible intervention mechanism, which can complicate formulation of the inclusion criteria. Theory-related considerations, such as an explicitly stated theory underpinning an intervention, were not incorporated in the inclusion criteria. This review was not aiming to review only interventions with explicit theoretical underpinnings but rather to find out how taking intervention

mechanisms or theories into account may play a part in classic systematic review and meta-analysis.

Although difficulties in locating relevant studies is recognised as one of the methodological challenges facing reviews of complex health care interventions (e.g. Higgins and Green, 2011), the scoping review identified more studies as potentially-relevant than expected. This was despite using the reviews identified in Chapter 3 to help in the design of the search strategy, and having study and intervention characteristics clearly defined in the inclusion criteria. Possible reasons for the large number of potentially relevant studies included the high volume of available research, search terms not specific enough, not strict enough inclusion criteria, and problems in interpreting study and intervention characteristics, i.e. too many interventions being identified as potentially matching inclusion criteria. The preliminary survey of potentially relevant studies suggested a substantial variety in intervention techniques and in combinations of different intervention techniques and methods. Results of the search also indicated that using theoretical terms or components as part of the search criteria would not have been practical, as few studies mentioned in their title or abstract any theoretically relevant terms.

The large number of potentially relevant studies identified in the search was a cause of concern for the systematic review of psycho-educational cardiac rehabilitation interventions. Preliminary investigation of the potentially relevant studies indicated considerable differences in the study and intervention characteristics that were likely to cause marked difficulties in statistical analyses due to increased heterogeneity. Time and resource limitations also made it impractical to conduct a meta-analysis and examination of theories underpinning interventions for so many studies. Therefore, it was decided to select a subset of the studies for a full systematic review and an examination of theories underpinning interventions. Selection of the subset of the studies was done by utilising methods identified in the literature (e.g. Armstrong et al., 2009, Armstrong et al., 2008, Jackson et al., 2004, Shepperd et al., 2009). Categorising interventions according to their features, outcomes, and theoretical considerations was found an effective method to examine similarities and differences between the studies. Two sets of the studies could be distinguished from these analyses. The first set comprised those that named a specific theoretical model for

the intervention. The second set comprised randomised trials of smoking cessation interventions for coronary heart disease patients, which were selected as a refined topic for the full systematic review and meta-analysis. The preliminary analyses did not indicate any clear categories for possible subgroup analyses (Shepperd et al., 2009) for the systematic review and meta-analysis of psycho-educational smoking cessation interventions. Therefore, no planned subgroup analyses were written into the review protocol.

The scoping review effectively demonstrated the number of challenges faced by reviews of complex health care interventions and offered an opportunity to examine how a number of methodological issues could be solved. Without the scoping review, it would not have been possible to adjust the review protocol, or the adjustments would have needed to be made retrospectively, thus lessening the validity of the systematic review and meta-analysis. The scoping review also helped in reflecting how including theoretical considerations in either a search strategy or inclusion criteria may work. The results of the scoping review suggested that including theoretical terms in a search strategy can be challenging, as it is difficult to know how theoretical terms may have been used in research papers. Theoretical considerations, if compatible with a review aims, can, however, be used in determining study inclusion. The scoping review nonetheless had its limitations. As it did not progress to reviewing full articles, it cannot be estimated how many of the studies identified as potentially relevant would have been finally included in the review. Moreover, as only one person was responsible for all the aspects of the review, it can be criticised for the lack of transparency. This is especially true for extracting the preliminary data from the article abstracts to assist in understanding the type of potentially relevant studies.

9.5 Main findings from a systematic review of smoking cessation interventions for patients with coronary heart disease

In this study systematic review and meta-analysis methodology were used to evaluate the effectiveness of psycho-educational smoking cessation interventions for coronary heart disease patients. The work done during the scoping review made it possible to follow the research protocol in respect of search and identification of the studies, and

the main analyses. While this group of studies could be described as more homogeneous than all studies that evaluated the effectiveness of psycho-educational cardiac rehabilitation interventions, statistical analyses nevertheless still suggested considerable heterogeneity between the studies. Despite such heterogeneity, meta-analysis was used, as specified in the review protocol, to evaluate the combined intervention effectiveness. Equally, the marked amount of variation between the studies was perceived as a central feature of the research. The observed degree of heterogeneity indicated that even where studies appeared superficially similar, relatively great variation between them could still exist. As heterogeneity had substantial importance for a theoretical perspective, it was decided to investigate possible causes of the heterogeneity by some post-hoc subgroup analyses. As discussed earlier (Shepperd et al., 2009), grouping studies based on particular intervention features may be helpful in analysing complex health care interventions.

Although the systematic review and meta-analysis in itself did not examine intervention theories or mechanisms, subgroup analyses were seen an opportunity to start examining intervention theories and mechanism as suggested in literature (e.g. Jackson et al., 2004, Shepperd et al., 2009, Doyle et al., 2008a). Planning the *post-hoc* sub-group analyses involved weighing up which intervention features would contribute to a wider understanding of theories or mechanisms underpinning interventions, and in understanding possible causes of heterogeneity within this set of studies. The following set of subgroup analyses were carried out; whether or not explicit mentioning of theory in intervention planning, intervention intensity, and the including of pharmacotherapy.

Results of the subgroup analyses indicated that intervention intensity appeared to have an effect on the effectiveness, with more intensive psycho-educational interventions to be statistically more effective than interventions which were classified as “less intensive” interventions. There were no statistically significant differences in results between other subgroups. While the results of these post-hoc subgroup analyses should be interpreted with caution, they did suggest intervention intensity as a possible intervention mechanism that may affect intervention effectiveness. As previous research has reported similar results (e.g. Alterman et al., 2001), the present subgroup analysis strengthened the argument that intervention

intensity may have a significant impact on effectiveness of psycho-educational interventions for smoking cessation.

Including theory in intervention planning may influence the intervention effectiveness, as inclusion of theory might have made intervention planning explicit by specifying how the change is supposed to happen. This, however, was not borne out by the result of subgroup analysis, which was consistent to the previous evidence that explicit theory underpinning intervention may not necessarily improve intervention effectiveness (Jackson et al., 2004, Lewin et al., 2009). This observation may highlight the importance of understanding intervention mechanisms and techniques regardless of the specific theoretical background. Explicit mentioning of a theory in intervention planning may not be sufficient to reveal how the theory has been applied in the intervention design. In addition, studies that have not explicitly mentioned a theoretical framework may actually have used theoretical principles in the intervention design. However, these results should also be interpreted with caution as some methodological decisions during the subgroup analysis may have affected the results. In this case, studies were also included in the explicit theory subgroup if authors, when contacted for additional information, reported having used a specific theory. Although the analysis in itself was non-significant, it was influential in shifting the direction away from further evaluation of theories underpinning interventions and towards intervention mechanisms and techniques, which has also been suggested by various researchers (e.g. Jackson et al., 2004, Shepperd et al., 2009, Doyle et al., 2008a).

The systematic review of psycho-educational cardiac rehabilitation interventions indicated that such interventions were effective in reducing smoking. As the interventions included in the review were complex health care interventions, it was notable that though the studies had similar aims, the actual interventions appeared very dissimilar, making it difficult to draw conclusions about what actually is happening in the interventions and to provide guidance for intervention designers. A methodological issue in the meta-analysis was the significant heterogeneity between the studies. Although it is suggested (e.g. Higgins and Green, 2011) that significant heterogeneity between the studies may be problematic in meta-analysis, it was judged that in this review of complex health care interventions the heterogeneity was

a reflection of the complexity and rather than being ignored, would need investigating.

Although for this systematic review, locating the relevant research material was not a major obstacle, as for some reviews of complex interventions, this review faced some difficulties in assessing the study quality, which has been noted as a frequent challenge in reviews of complex interventions (e.g. Armstrong et al., 2009, Jackson et al., 2004). Doyle et al. (2008a) highlighted reviews' difficulties in extracting and interpreting study findings when, for example, key definitions in the primary studies are not consistent, such as using different definitions of smoking, smokers and quit attempts (Bala et al. 2008 in Doyle et al., 2008a). The same complexity was evident in this systematic review. Despite piloting the inclusion criteria before and during the scoping review, data extraction revealed several differences e.g. in how smoking status was defined and assessed, the form of the cardiac disease, use of nicotine replacement products, and how intervention was defined. As argued by Sheik (2009 in Shepperd et al., 2009), the present systematic review followed principles of systematic reviewing as closely as possible. However, the systematic review did not stop at evaluating the overall effectiveness of the interventions, but, as Sheik (2009 in Shepperd et al., 2009) suggested, went further so as to evaluate contexts of interventions, and the processes through which the interventions deliver their effects.

In the available guidance for reviewing complex health care interventions (Centre of Disseminations and Systematic Reviews, 2009), Hajek et al., 2002, Higgins and Green, 2011, Higgins and Green, 2008), specific methods for evaluating intervention mechanisms have not been recommended. It has been suggested that intervention mechanisms may be examined using techniques such as meta-regression (e.g. Welton et al., 2009), realist review (Pawson et al., 2005), or examining similarities and differences between interventions in terms of their intervention components, and subgroup analyses (Shepperd et al., 2009). However, this systematic review has shown that quantitative meta-analysis methods may not be sufficient for investigating mechanisms of complex health interventions. Complexity of psycho-educational interventions results in considerable challenges in systematic reviews of complex health interventions. The current systematic review had only very limited success in exploring mechanisms of complex psycho-educational interventions.

Therefore, this thesis (in Chapter 6) tested an innovative approach to evaluate intervention techniques and mechanisms that could be applied to all studies based on the information available in the research papers. The investigation of intervention techniques and mechanisms was based on a framework developed by Michie et al. (2008) that allowed a systematic evaluation of intervention mechanisms.

9.6 Main findings from analysis of intervention mechanisms and techniques

Jackson et al. (2004) argued that public health reviews should aim to answer two principal questions; firstly, whether the intervention works, and secondly, reasons why the intervention may or not may work? The systematic review and meta-analysis in the Chapter 5 answered the first of these questions, that psycho-educational cardiac rehabilitation interventions are effective in reducing smoking. The statistical analyses suggested that complexity in the interventions appeared to stem, at least partly, from the intervention intensity. However, the statistical subgroup analysis offered only limited insight into intervention mechanisms and techniques, and how these may be linked to perceived intervention complexity. Therefore, to answer the question of how the intervention works, (e.g. Jackson et al., 2004) interventions were analysed by innovatively applying the framework developed by (Michie et al., 2008). The results of this analysis suggested that complexity in the interventions appears at least partially to be linked to combinations of techniques used in interventions, rather than to the targeted behavioural determinants. The findings indicated that interventions targeted similar behavioural determinants and that despite the number of possible intervention techniques, only a number of techniques had actually been used in the interventions. Interventions commonly targeted participants' motivation, beliefs about capabilities and consequences, knowledge, and skills as means of causing change in behaviours. Techniques that were frequently used in influencing these behavioural determinant included; behavioural information, planning, monitoring, and social support.

The findings of analysis of intervention mechanisms and techniques provided some support for the argument (Sheik 2009 in Shepperd et al., 2009, Jackson et al., 2004) that examining combined intervention effectiveness alone may not provide sufficient understanding of what is actually reviewed in a review of complex health care

interventions. Reviews of complex health care interventions should consider interventions in more specific detail, and, perhaps, use subgroup analyses to evaluate the effects of different techniques. Reviews may also consider how changes are caused, or to test proposed intervention mechanism in more detail. In general, reviews of complex health care interventions may gain by evaluating whether and how theories are used in intervention planning, and whether this may help to understand intervention effectiveness. Theoretical models and frameworks may improve understanding intervention effectiveness by explaining how an intervention is supposed to work and possible reasons for its working or not. Another indicative finding from the analysis was that explicit mention of theories underpinning the interventions alone may not have a marked influence on the targeted behavioural determinants or behaviour change techniques. This finding adds to the argument that an explicit theory underpinning intervention may not necessarily improve intervention effectiveness (Lewin et al., 2009).

However, examining intervention mechanisms and techniques as a part of a systematic review of complex health care interventions has its limitations. Reviews can only investigate what is included in the primary studies or obtained from the researchers after requests for additional information. Examining intervention techniques and mechanisms becomes especially difficult when primary research does not offer sufficient information to enable thorough investigation and drawing of conclusions. In this thesis, behavioural determinants and intervention mechanisms were evaluated using the framework provided by Michie et al. (2008). To date, however, there is no agreed framework, for example, for classifying intervention techniques. While using the approach offered by Michie et al. (2008) in this context was seen as a feasible method for in-depth examination of intervention mechanisms and techniques, using it raised methodological issues. Perhaps the most considerable difficulty was the reliance placed on the work by Michie et al. (2008). The work by Michie et al. (2008) is based on expert opinions and has not been previously tested, or even aimed directly at the kind of use made of it here.

The process of appraising intervention techniques, mechanisms and theoretical assumptions, however, included considerable subjectivity, even when the framework by Michie et al. (2008) was used to guide the analysis. Statistical techniques such as

the meta-regression and subgroup analyses may provide less subjective evaluation of intervention mechanism. However, even when employing statistical evaluation methods, researchers have to decide what process variables and theoretical frameworks are of interest. Subjectivity is even a greater problem when applying Michie's framework to analysing intervention mechanisms. In the process of evaluation it was necessary to interpret both the Michie et al. (2008) and the intervention descriptions of the primary studies. Although every effort was made to maintain objectivity, it was not possible to ascertain where, instead of drawing from the intervention descriptions the required information, meaning may have been imposed on descriptions. However, analysis results were circulated to authors of the original papers, and author feedback largely confirmed the accuracy of the analyses carried out for this thesis. Despite the success of this approach in enabling the evaluation of intervention mechanisms and techniques, it still faced methodological challenges. Moreover, the review also took rather long to complete when theoretical aspects were addressed alongside overall effectiveness.

9.7 Main findings of systematic review and synthesis of qualitative research

Including qualitative research in systematic reviews has been promoted by arguing that it can capture participants' perspectives of the interventions (Attree & Milton, 2006). While methodology for reviewing and synthesising qualitative studies is debated (e.g. Sandelowski et al., 2007, Pawson et al., 2005), this case study was not a part of this methodological debate. Rather, while it was assumed that qualitative research can be systematically reviewed and results synthesised, it was acknowledged that others may not share this view. The rationale for the qualitative review was its potential to provide information about intervention mechanisms, i.e. how or why interventions work or not, and evaluate any evidence about causes of complexity for these particular interventions. Although intervention mechanisms, techniques, and complexity have been investigated in depth in the previous chapters, this was done against the contextualising background of the effectiveness of the intervention, not against the background of how participants, or potential participants, perceive a complex health care intervention.

Question-setting for the qualitative review was challenging as it was considered unlikely that many, if any, qualitative studies would have directly investigated the theories underpinning interventions, mechanisms, techniques, or indeed complexity. However, review questions still needed to reflect the theory-orientated approach of this project. As asking questions directly about complexity and intervention mechanisms was unlikely to yield enough material, these issues were approached indirectly through a specific set of qualitative research questions. The research questions were designed to explore evidence on patients' experiences and expectations of psychological cardiac rehabilitation interventions. Examining patients' expectations and experiences, while not obviously theoretical questions, offered several advantages. First of all, it was considered likely that this is an area of qualitative research where a number of primary research studies may be available. Specifying expectations and experiences of cardiac rehabilitation may suggest areas where an intervention meets patients' needs, or why even a theoretically sound intervention may fail due to a mismatch between expectations and reality. In addition, this approach allowed evaluation of those intervention aspects, for example intervention techniques, that appeared to be effective and acceptable from patients' perspectives.

Locating relevant studies for the qualitative review was challenging. As the Cochrane Handbook (Higgins and Green, 2011) points out, the search strategy had to balance between pragmatic decisions of available time and resources and thoroughness of the search. Apart from challenges in identifying relevant research, both qualitative and quantitative reviews of complex health care interventions face similar difficulties in defining the target intervention. Though the available guidance in reviewing qualitative research (Centre of Disseminations and Systematic Reviews, 2009, Higgins and Green, 2011, Petticrew and Roberts, 2006) was helpful in formulating search strategy and study quality assessment criteria, more discussion and guidance on formulating exact research questions and inclusion criteria would have been beneficial. However, perhaps the biggest challenge for the qualitative review in this case was that though systematic search indicated several potentially relevant studies, none of these investigated exclusively patients' views and experiences of smoking cessation only interventions.

While the qualitative review was successful in answering the specific review questions, perhaps contrary to expectations, the qualitative review had relatively limited capacity to advance understanding of intervention mechanisms. This finding indicates that the review questions may need to be revised in future reviews. The biggest contribution to understanding the intervention mechanisms was the finding that especially men found social support as an important mechanism to help in recovery. This result was similar to the results of the analysis of intervention techniques and mechanisms, indicating that social support may be an important factor in complex health care interventions that aim to influence participants' behaviour. Although the qualitative review offered only limited insight into intervention mechanisms, the results indicated a number of issues, from the participants' perspectives, that may influence intervention complexity. Jackson et al. (2004) argued that reviews of complex health interventions need to evaluate whether intervention was effective as such or an artefact of pre-existing, and whether results of a review relate to another specific context and situation. The qualitative review indicated that psycho-educational cardiac rehabilitation intervention participants tend to be those who are strongly motivated to participate. Those interventions that managed initially to attract less motivated participants, did struggle to retain this participant group, as this group tended to see interventions as not responding to their needs or as not at all beneficial.

The qualitative review highlighted how intervention effectiveness may be partly understood in terms of the complexities presented by the target patient populations. First, participants' prior expectations of what a cardiac rehabilitation intervention involves and how that matches their understanding of what recovery requires, can have marked impact on the dynamic between an individual and an intervention. Secondly, qualitative review highlighted the complex interactions between participants, intervention personnel and other significant people in participants' life that may have unexpected consequences in the effectiveness of an intervention. Finally, the qualitative review indicated that in these interventions, complexity may result partly from multi-component interventions. As Doyle et al. (2008a) point out, it can be challenging to report on what actually happened within an intervention, which parts of the intervention function or not and why they function or not. However, even though multi-component cardiac rehabilitation interventions are

complex and may not satisfy everyone, the qualitative review indicates that multi-component interventions do appear to address many requirements placed by participants relatively well.

These results emphasise the complexity of evaluating complex health care interventions and the importance of understanding how factors outside an intervention design may influence effectiveness. As Hawe et al. (2009) point out, intervention mechanisms may be better understood when an intervention is seen as a crucial event that leads to the new evolving networks of interaction between person, time and place, changing relationships, displacing existing activities and redistributing resources. Participants' descriptions of how a cardiac event and a cardiac rehabilitation has changed their existing activities, social networks, and relationships demonstrate the impact an intervention can have outside the narrowly defined intervention pathways, but also how participants and context can influence on an intervention, thus making intervention complex.

The qualitative review was not without its difficulties, and though this review was aimed to be systematic, it was difficult to estimate how far all the relevant studies were located. This may be partially due to search terms used and the way that papers have been indexed in the different databases. Further challenges for the review were the transparency of the analysis and linking the analysis results to the wider questions of intervention mechanisms, theories, and complexity. Attree and Milton (2006) argued that qualitative research can yield insights into processes that underlie the effectiveness of interventions, such as capturing participants' perspectives on the interventions. However, in this instance, the results of this qualitative review were not significantly improving understanding of intervention mechanisms, though the review contributed to understanding of complexity in interventions.

Including qualitative research within reviews of complex health care interventions is likely to continue to be debated. While qualitative research may offer valuable insights into intervention mechanisms, the benefits of combining qualitative research in systematic reviews and meta-analyses of complex health care interventions require careful consideration. Here, including qualitative research was both time- and resource-consuming, and while its inclusion was directed by the research questions,

it must be acknowledged that based on this example, including qualitative research within reviews of complex health care interventions should not be automatic. A danger of advocating systematic inclusion of qualitative research in systematic reviews and meta-analyses of complex health care interventions is that including qualitative research may become a token gesture without accompanying in-depth examination of the materials and results of synthesis.

9.8 Main findings of the synthesis between qualitative review and review of reviews

Unfortunately, due to lack of available studies, it did not prove possible to directly investigate how the results of the qualitative review would have complemented the meta-analysis and the analysis of behavioural determinants and intervention techniques used in smoking cessation interventions. Consequently, it was not possible to directly evaluate how qualitative review could complement systematic review and meta-analysis of complex health care interventions. At the point when this was realised, it was decided to compare and combine the results of the qualitative review with some specific findings from the review of reviews. It is acknowledged that other comparisons would also have been possible, but as Sackett and Wennberger (1997) point out, rather than arguing about the merits of different approaches, selected approach should be judged in how well it manages to answer the research question.

In this particular case, it was judged that comparing selected results from the review of reviews and qualitative review was providing the most valid and useful answer. While the review of reviews mainly examined the methodological difficulties to be addressed in undertaking reviews of complex health care interventions, it also gathered information about the reviews' recommendations for planning further interventions. These recommendations were combined in a discussion that used narrative analysis with the results of the qualitative review. Comparing results from the reviews suggested that many issues raised in the qualitative review corresponded with those identified as potentially important or effective intervention characteristics in the review of reviews. This provides some support for arguing that qualitative research could help framing issues for and contextualise findings from reviews of

complex health care interventions. In this case study, the qualitative review was seen to confirm many of the issues that the review of reviews highlighted as possible points for improvement in planning interventions as well as points suggested as mechanisms for improving intervention effectiveness.

Although the results from the review of qualitative research itself were only indicative of the features of an effective intervention, their force was considerably strengthened when combined with the results of the review of reviews. The results emphasised intervention intensity as a factor that could have both positive and negative impact on outcomes, depending on participant preferences. Combining these different review results suggested that qualitative reviews can offer valid information about what features, particularly in terms of acceptability, may be associated with effective interventions. However, the results allowed only limited insights into the nature of intervention mechanisms. While the results were promising in principle, there may be practical and resource limitations on testing the effectiveness of some of the identified intervention features. The most surprising outcome of this comparison was perhaps that, while qualitative review alone did not greatly advance understanding of intervention mechanisms, bringing the results together provided a much clearer picture of some possible intervention mechanisms, such as social support and knowledge.

While combining the qualitative review with the review of reviews was found to be useful in furthering understanding of potentially effective intervention features, it nonetheless demanded considerable effort, thus limiting wider application. The role of the specific qualitative review also needs to be clarified, either as adding new information or as providing a process of confirmation that complements existing knowledge. In this case study, the qualitative review did not add much new information about possible intervention features or mechanisms, but did advance understanding of features of an effective intervention. Apart from the methodological challenges of the qualitative review, another challenge was the question-setting for the review. As the review formed one part of a project, it needed to relate to the other parts. The usefulness of this approach may also be limited by the time and effort it requires. It may also be that no qualitative research is available, and ascertaining this would require some existing expertise in the field. Such findings suggest that

determining whether qualitative review should be included within a systematic review of complex health care interventions should be evaluated in relation to the research goals and questions.

9.9 General discussion

The starting point for this project was to evaluate how systematic inclusion of theory in a systematic review and research synthesis of complex health care interventions may improve review outcomes and the practical application of the review results. Including theory in systematic reviews is not a new idea, as it has been considered in a few previous systematic reviews. The results of this project suggests that at the present including explicit theoretical considerations into search terms or in inclusion criteria of a systematic review may not be practical or productive. In addition, investigation of intervention mechanism and techniques as opposed to evaluating a specific pre-defined theory, appears a feasible choice for reviews of complex health care interventions that wish to evaluate how interventions work in addition to estimating overall intervention effectiveness. In this thesis, an alternative non-statistical method for a systematic evaluation of intervention mechanisms and techniques is presented. This thesis also tested the role of qualitative research in furthering understanding of specific intervention mechanisms and techniques from participants' viewpoint.

Within the previous reviews of psychological cardiac rehabilitation interventions, only a few had systematically examined theories underpinning interventions or mechanism (e.g. Dusseldorp et al., 1999), using both statistical and narrative methods. The reviews reviewed in the Chapter 3 included wide variety of interventions, but the overall impression was that the available information about intervention techniques and mechanisms was fragmented. It was also noticeable, that most of the reviews had not evaluated intervention mechanisms or techniques in detail, or how differences and similarities between interventions may influence recommendations.

In this thesis, the different empirical studies argued that systematic appraisal of intervention mechanisms, or techniques, can improve understanding of what kind of

interventions a review includes. Examining intervention techniques systematically enables detailed survey of how interventions are compiled and how they compare with each other's. In this project framework by Michie et al. (2008) was used in evaluation of both intervention techniques and behavioural determinants (i.e. mechanisms) that the interventions targeted. A major issue with this approach is the necessary amount of subjectivity that is needed in evaluating the interventions in the context of the framework by Michie et al. (2008). Although authors of the original papers found the analysis largely representative of their work, further research should explore reliability and feasibility of this approach in other reviews of complex health care interventions. Intervention complexity was a common challenge in all of the reviews done within this project. However, the results from this thesis indicate that using this theory-orientated approach to complement the systematic review and meta-analysis allowed better understanding of both causes of complexity within particular interventions and common features among the interventions. Detailed examination of the intervention mechanisms indicated that although interventions can appear diverse, they may have more common features than would appear at the surface. Although differences in techniques between interventions may at times be surprisingly few, interventions can differ considerably in number of techniques used, intensity of intervention, and characteristics of participants' that are targeted by the intervention.

The combined results from this thesis indicate that information relevant to understanding mechanisms of complex health care interventions may only emerge through synthesis which addresses diverse research material. In this case, narrative synthesis of results from the qualitative review and the review of reviews enabled some evaluation of how well features of effective interventions matched the views of study participants. Interventions aiming to improve cardiac recovery by educating patients about coronary heart disease and features of recovery appear to respond to patients' expressed needs to know about coronary heart disease, and how to prevent and recognise further illness episodes. While some patients were critical about the amount and timing of information offered, the impression gained from the available research was that interventions were nevertheless effectively transferring the necessary knowledge to patients that would enable them to manage their condition more effectively. Patients also appeared to appreciate support provided by cardiac

rehabilitation interventions and felt that the guidance they were given about process of recovery and practical help to change risk factors constituted effective intervention techniques for them. These results suggest that many of the techniques presently deployed in cardiac rehabilitation are effective and well accepted by the patients.

Although it has been argued that explicit theory underpinning an intervention can improve its effectiveness and evaluation by defining clear links between different intervention parts (e.g. Michie et al., 2008), this was not clearly indicated by the results from this thesis. This result raises the question of importance of an explicit theory in designing of complex health care interventions. One possible way of interpreting these results is to argue that formal and explicit intervention theories may not be important in intervention design. However, that kind of argument does not take into account that pragmatically designed interventions, similarly to theory-based interventions, need to specify how the intervention causes the desired outcomes. Therefore, explicit intervention theories may have an important role in design and evaluation of complex health care interventions, as theories can help in systematic evaluation of how different intervention components interact and are linked to outcomes. Finally, these results emphasise the importance of examining intervention mechanisms and theories regardless of the explicit theoretical background.

Möhler et al. (2012) have suggested that understanding of intervention mechanisms could be improved by more detailed reporting of how an intervention is designed to cause the desired outcomes. The proposed criteria by Möhler et al. (2012) have not been extensively tested in practice, and it is unsure what impact wider application of the criteria would make in understanding of intervention mechanisms. However, Möhler et al. (2012) emphasised the need to understand how intervention components are related to outcomes. It could be argued that the approach presented in this thesis for the retrospective evaluation of intervention mechanisms with the existing information has been successful in demonstrating potential intervention mechanisms without the additional information required by the Möhler et al. (2012) criteria.

Many of the challenges faced in this project stemmed from the difficulties of reviewing complex health care interventions. Existing guidance from Cochrane Collaboration (Higgins and Green, 2011) and Centre of Disseminations and Systematic Reviews (2009) has provided some comprehensive advice on challenges and methods to overcome difficulties when reviewing complex health interventions. However, guidance is less comprehensive on how reviews of complex health care interventions should approach their target audience and how investigation of intervention mechanisms should be approached (e.g. Higgins and Green, 2011, Jackson et al., 2004, Armstrong et al., 2008, Shepperd et al., 2009).

For example the Cochrane Handbook (Higgins and Green, 2011) suggested that reviews of complex interventions should be more relevant to the users of the reviews, so that users could judge which aspects of the interventions are relevant for their specific situation. In this thesis, this recommendation was addressed by not having intervention context in the central place. Instead of trying to evaluate how context influenced the intervention effectiveness, the thesis systematically considered the question, regardless of intervention context, of what kind of intervention mechanisms and techniques were used in effective interventions. Perhaps surprisingly, the analysis suggested that interventions, regardless of the context, used similar mechanisms and techniques to influence participants smoking behaviour. However, unlike many public health interventions, the context of psycho-educational smoking cessation interventions was relatively contained, such as the intervention being initiated in the context of hospitalisation for a cardiac-related complaint, which may have lessened the influence of context in this case. Future research would need to evaluate the interplay between context, intervention mechanisms, and influence on effectiveness.

Although in general it could be argued that the present guidance on reviewing complex health care interventions is comprehensive, such guidance emphasises the methodological aspects of ensuring unbiased estimation of intervention effectiveness. Evaluating intervention mechanisms was approached in this project using an innovative, non-statistical method that has not been previously tested. The successful evaluating of the intervention mechanisms and techniques in this thesis suggests that the method could be applied to other complex health care interventions. The current

available guidance (e.g., Higgins and Green, 2011) has not provided comprehensive recommendations on how to evaluate intervention mechanisms. The present guidance could be improved with more detailed suggestions on methods for investigating mechanisms of complex health care interventions. .

9.10 Conclusions

Methodological challenges in design and evaluation of complex health care interventions have been increasingly recognised in the literature. The growing recognition of the methodological challenges has led to the development of methodological guidance (e.g. Craig et al., 2008) and to debate how the methodological challenges in evaluation of complex interventions could be addressed (e.g. Hawe et al., 2004). Guidance on reviewing complex health care interventions (e.g. Higgins and Green, 2011) offers advice on specific challenges in including complex health care interventions in systematic reviews. Several researchers have pointed out that apart from the challenges in reviewing complex health care interventions, interpretation of the review results can be difficult. Better understanding of mechanisms of complex interventions has been suggested as one possibility to improve systematic reviews of complex health care interventions. (Armstrong et al., 2008, Jackson et al., 2004, Shepperd et al., 2009).

This thesis adds to the present knowledge an example of a systematic evaluation of intervention mechanisms. Further, this thesis adds an example of using a systematic review of qualitative research in examination of intervention mechanisms in conjunction of a quantitative review. The results from this research project add to the knowledge of how including theoretical considerations and qualitative research in the review process may advance the practical application of reviews by improving understanding of intervention mechanisms and techniques, which, in turn, can be used to better understand how and where interventions may be effective. Findings from the case studies suggested that while including theoretical considerations in a review may increase understanding of intervention mechanisms, a considerable range of methodological and resource problems are associated with this approach. Including qualitative research in a review process was initially suggested as a means of improving the understanding of intervention mechanisms, especially from

participants' point of view. However, at least in this case, evidence from the qualitative review was not sufficient to further improve the understanding of the intervention mechanisms. Instead, qualitative review could be used in identifying causes for intervention complexity as perceived from participants' perspective.

9.11 Implications for research and clinical practice

The empirical studies identified many specific weaknesses in the processes of review and synthesis of studies of complex health care interventions. Despite the acknowledged limitations of the empirical studies presented in this thesis, the research did enable the intervention mechanisms of complex interventions to be examined in greater depth and in new ways, and for the implications of the results for clinical practice to be identified. Combined findings from the systematic review, meta-analysis, and evaluation of intervention mechanisms indicated that the more detailed investigation of intervention techniques, mechanisms and theories in reviews of complex health care interventions can improve the application of review evidence in clinical practice. A more detailed understanding of intervention mechanisms and techniques may also help in identifying the effective components of a complex intervention.

The results of the systematic review and meta-analysis suggested that psycho-educational smoking cessation interventions for coronary heart disease patients are effective. These results are in line with the findings of previous reviews and meta-analyses (e.g. Rigotti et al., 2007, Van Berkel et al., 1999), even though there are differences between participant populations and included interventions. Subgroup analyses showed that interventions classified as intensive were significantly more effective than less intensive interventions. The explicit inclusion of theory in intervention planning was not found to affect the effectiveness of interventions. Thus, this result conforms to argument by Lewin et al. (2009) that explicit intervention theory may not translate to increased intervention effectiveness. This finding highlighted the importance of examining the specific theories or mechanisms underlying interventions, rather than simply considering whether theories are explicitly stated or not.

Behavioural determinants and behaviour change techniques were assessed qualitatively using the framework provided by Michie et al. (2008). This analysis suggested many similarities between seemingly-different interventions, which appeared to deploy only a limited number of techniques, all of which were relatively straightforward to apply in practice and to deliver to high numbers of people, while requiring limited staff training. What the analysis indicates is that relatively straightforward behaviour change techniques, which are also relatively easy to apply in practice, can be effective in changing smoking behaviour. While the analysis did not support conclusions about whether the limited pool of behaviour change techniques reflected their comparative practicability or effectiveness, it did raise a question of how well results can be generalised. As the pool of techniques deployed in interventions was limited, it must be questioned whether the results of the meta-analysis are only applicable to smoking cessation interventions that use similar techniques than interventions in this review. Combined evidence from the review of reviews and the qualitative review supported the argument that the techniques commonly used in psycho-educational cardiac rehabilitation interventions, with or without exercise training component, may not only be effective, but appear also to be acceptable and appreciated by patients.

Systematic reviews of complex health care interventions pose specific challenges such as in defining intervention features and populations and in translating these into transparent inclusion and exclusion criteria. Although results from the meta-analysis and subsequent subgroup analysis were able to identify some potentially effective features of interventions, such as intervention intensity, these analyses had limited use for understanding intervention mechanisms. In order to specify the action of intervention mechanisms more precisely, intervention mechanism were examined first, using the framework offered by Michie et al. (2008) and then by synthesising results of the systematic review of qualitative studies. While the results from the examination of intervention mechanisms and synthesis of qualitative studies should be interpreted with caution, two potentially important findings emerged. Firstly, findings from the analysis of intervention techniques and mechanisms of psycho-educational smoking cessation interventions showed that interventions employed only limited number of techniques. This suggests that the results of meta-analysis of psycho-educational smoking cessation interventions may be generalised only to

interventions using similar mechanisms and techniques. Secondly, the qualitative review suggested that some of the variation found in the effectiveness of psycho-educational cardiac rehabilitation interventions may be attributed to participants' different motivations and expectations of an intervention.

Although findings from this project suggested that examining intervention theories and mechanisms in-depth was successful, results nevertheless only indicate of possibly effective intervention mechanisms. Future research would be needed to further evaluate whether the approach used in this thesis can be applicable in other contexts and how comparable the results of any such studies might be.

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Appendix 1

General search strategy, which was modified as needed to respond to requirements of different databases

1. Heart attack (MesH exp)
2. Myocardial infarction (MesH)
3. Cardiovascular disease (MesH)
4. Coronary artery bypass (MesH)
5. Angina pectoris (MesH)
6. Ischemic heart disease (ti.ab.)
7. Coronary artery bypass (ti.ab.)
8. Coronary heart disease (ti.ab.)
9. Coronary angioplasty (ti.ab.)
10. CABG (ti.ab.)
11. Heart infarct (ti.ab.)
12. PTCA (ti.ab.)
13. Myocardial infarct (ti.ab.)
14. Coronary angiograph* (ti.ab.)

((((((((((((#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10) or #11) or #12) or #13) or #14)

15. Counselling (MesH)
16. Rehabilitation (MesH)
17. Lifestyle (MesH)
18. Smoking cessation (ti.ab.)
19. Smoking (ti.ab.)
20. Smok* (ti.ab.)
21. Rehabilitation* (ti.ab.)
22. Behaviour change (ti.ab.)
23. Behavior change (ti.ab.)
24. Health education* (ti.ab.)
25. Psycho-education* (ti.ab.)
26. Psychoeducation* (ti.ab.)
27. Health advice (ti.ab.)
26. Health behaviour* (ti.ab.)
27. Health behavior* (ti.ab.)

((((((((((((#15 or #16) or #17) or #18) or #19) or #20) or #21) or #22) or #23) or #24) or #25) or #26) or #27)

28. Control group
29. Trial
30. Randomised controlled trial
31. RCT
32. Comparison group

((((or #28) or #29) or #30) or #31) or #32)

Appendix 2

Outline for systematic review of psycho-educational smoking cessation interventions for coronary heart disease patients

Background

Medical, pharmacological and surgical interventions are well established in treatment and rehabilitation of coronary heart disease patients (e.g. SIGN, 2002). Role of behavioural risk factors in secondary prevention and treatment of coronary heart disease is also recognised (SIGNIsles et al., 2002, NSF-CHD, 2000) and patients are encouraged to modify behavioural risk factors such as smoking, exercise and diet alongside other treatment. Changing sometimes decades long habits is, however, not always straightforward and interventions have been developed to encourage and help in behavioural risk factor modification. Interventions that target modifiable coronary heart disease risk factors have been investigated in many reviews, and while some of the reviews support interventions effectiveness to modify behavioural risk factors (e.g. Mullen et al., 1992, Sebregts et al., 2000, Moore, 1997, Dusseldorp et al., 1999), others have not found supportive evidence (e.g. Godin, 1989, Rees et al., 2004b). The effectiveness of psycho-educational interventions in reducing cardiac mortality and morbidity is, therefore, unclear. These reviews have included studies with wide variety of interventions and methods, but usually excluded psycho-educational smoking cessation only interventions for coronary heart disease patients. Effectiveness of smoking cessation as a secondary preventive measure for coronary heart disease patients has been well established (e.g. Critchley and Capewell, 2003), and is considered an important part of secondary prevention and rehabilitation of coronary heart disease patients (e.g. SIGNIsles et al., 2002). Smoking cessation interventions are arguably directed to a special section of coronary heart disease patients and may require considerable behavioural effort to be successful, but considering the potential benefits of the cessation, these interventions may have important role in cardiac rehabilitation and secondary prevention.

Effectiveness of smoking cessation interventions among hospitalised patients (e.g. Rigotti et al., 2007) and coronary heart disease patients (e.g. Van Berkel et al., 1999)

have been evaluated. These reviews suggest that smoking cessation interventions have beneficial effects on cessation and maintenance of cessation. The review by Rigotti et al. (2007), for example, suggested that intensive smoking cessation interventions that begin at the hospital and include at least one month's follow-up are effective in reducing smoking among hospitalised patients. In a review by van Berkel et al. (1999) smoking cessation interventions were investigated among coronary heart disease patients and the results indicated that the interventions can be effective in reducing mortality and risk of myocardial infarction. None of the reviews, however, investigated smoking cessation interventions only among coronary heart disease patients. Rigotti et al. (2007) included studies with coronary heart disease patients and other hospitalised patients, while van Berkel et al. (1999) included also studies that targeted multiple risk factors and where smoking cessation was relevant only for a portion of the study participants.

Berkel et al. (1999) noted on the diversity of the study characteristics included in the review, and suggested that this may complicate the evaluation of effectiveness. Diversity in interventions has also been noted among psycho-educational cardiac rehabilitation interventions (Rees et al., 2004b), where diversity between interventions is even greater than among smoking cessation interventions only. This is also reflected in the notion that reviews of psycho-educational interventions have resulted at times in conflicting results, as there is difficulty to define, for example, what is meant by psycho-educational, or rather behaviour modification, intervention (Rees et al., 2004b).

Available review evidence suggests that interventions that promote smoking cessation among coronary heart disease patients can be effective in reducing cessation and mortality rates, but there is still considerable uncertainty about what makes a smoking cessation intervention effective (e.g. Van Berkel et al., 1999). As previous reviews have also used mixed participant populations or included multi-component interventions, there is no recent review available that investigates psycho-educational secondary preventive smoking cessation only interventions among coronary heart disease patients. The present review has been conducted as a part of systematic review of psycho-educational cardiac rehabilitation interventions, from which results smoking cessation only interventions were selected for meta-analysis.

Systematic review aims

The main question of the systematic review is; how effective are psycho-educational smoking cessation interventions in increasing point prevalent and continuous smoking cessation and decreasing mortality. In addition, it is examined if studies have investigated process variables, and whether these variables have been employed to explore intervention mechanism.

Defining Psycho-educational Intervention for the this review

Psychoeducational intervention has been previously defined as an intervention that aims to enhance treatment by increasing people's knowledge of the condition and changing attitudes towards treatment (Goldman, 1988). In this context, psycho-educational intervention was used to refer to interventions that encouraged smoking cessation among coronary heart disease patients using primarily non-pharmacological methods.

Methods

Search strategy

Databases will be searched from 1970 onwards to locate relevant research papers. The following data bases will be searched; the Cochrane Controlled Trials Register (CCTR), PsycINFO, MedLine, CINAHL, and Dissertations and Abstracts International. Reference lists of both previous psycho-educational cardiac rehabilitation and smoking cessation intervention reviews and selected smoking cessation studies will be checked for relevant studies. The full piloted search strategy is included in the Appendix X, but the search words include

Study selection

Both published and articles awaiting for publication will be considered for inclusion. Study with randomised control designs will be included, but studies without optimal

randomisation will also be considered for inclusion. Participant population has to fulfil the following requirements; over 18 years of age with confirmed coronary heart disease and are eligible for cardiac rehabilitation and smoking cessation intervention. The coronary heart disease conditions relevant for the study are; angiographically defined coronary heart disease, angina pectoris, myocardial infarct (MI), coronary artery bypass graft surgery (CABG), percutaneous transluminal coronary angioplasty, and heart failure caused by MI. Participants in the study has either to be current users of tobacco products or those who have been regular users of tobacco products, but have stopped earlier. Studies that include patients with mental health related diagnosis are also eligible. Intervention inclusion criteria are as follows; primarily psycho-educational methods, such as teaching, education, advice, counselling, and information transfer. Interventions that combine psycho-educational methods with, for example stress management or relaxation training, are also eligible. Intervention format is not defined, and intervention could use individual or group format, or combination of both. Intervention will also eligible for inclusion if participants are offered additional pharmacological smoking cessation aids. Intervention length, personnel, or training received by personnel is not defined. Studies with less than six months of follow-up will not be eligible for inclusion. Studies have to report at least one of the following outcomes; point prevalent smoking cessation, continuous smoking cessation, or mortality.

Data extraction

Data extraction sheets that will be designed and piloted for this review. Following data will be collected; journal name, author/s, country of publication, method of random allocation, description of inclusion criteria, blinding of intervention provider and outcome assessor, descriptions of intervention and control conditions, intervention and control condition location, personnel, type, and any theoretical background used in intervention design. In addition, information will be collected separately for control and experimental groups about gender and age, and patient characteristics in both experimental and control groups including diagnosis, participant inclusion and exclusion criteria, and total number of eligible participants, information will be collected. It is planned that after finishing of data collection, authors of the original studies will be contacted to ask whether interventions and

control conditions were described correctly and what information they would like to add. Study authors will also be inquired for existence of any additional information about theoretical frameworks that have been used in study design. Data will also be collected about any potential process variables that have been reported and how authors explain their relationship to results, when applicable. At this stage, it is not anticipated that there will be available resources for doubling the data extraction.

Assessment of study quality

Methodological quality of the papers will be assessed using adapted assessment criteria from previously published criteria (Khan et al., 2001b, Petticrew and Roberts, 2006). The assessment criteria will cover randomisation process, intervention and participant description, and study reporting. Studies will not be ranked based on the quality assessment, but weaknesses in the study methodology will be recorded. It is expected that due potential challenges of designing and evaluating behavioural smoking cessation interventions, studies may not fill all the criteria of randomised controlled trials. Assessment of study quality will not be duplicated.

Statistical methods

Meta-analysis will be used to calculate overall intervention effectiveness. Relative risk will be used to calculate combined effectiveness of psycho-educational smoking cessation interventions. For the point prevalent and continuous smoking cessation outcomes relative risk of larger than one will indicate positive outcome, i.e. intervention was successful in increasing point prevalent and continuous smoking abstinence. Relative risk for mortality will be calculated so that value smaller than one indicated smaller mortality in the intervention group. It is planned that sensitivity analyses will be carried out to investigate effects of inclusion and exclusion of methodologically weaker studies, or those studies in which method of randomisation is not adequate. The results of the scoping review did not indicate that there would be enough research material available to perform subgroup analyses based on reported intervention theories. Scoping review also did not clearly indicate any other potential subgroup analyses. However, when the systematic review material will become more familiar, it is considered likely that sub-group analysis may be needed to investigate

material if it appears later that sub-group analyses are needed, these will be post-hoc. It is planned to use the statistical programme provided by Cochrane Collaboration, currently RevMan 4.2, for meta-analyses.

Search strategy: Systematic review of psycho-educational smoking cessation interventions

1. Heart attack (MesH exp)
2. Myocardial infarction (MesH exp)
3. Cardiovascular disease (MesH exp)
4. Coronary artery bypass (MesH exp)
5. Angina pectoris (MesH)
6. Ischemic heart disease (ti.ab.)
7. Coronary artery bypass (ti.ab.)
8. Coronary heart disease (ti.ab.)
9. Coronary angioplasty (ti.ab.)
10. CABG (ti.ab.)
11. Heart infarct (ti.ab.)
12. PTCA (ti.ab.)
13. Myocardial infarct (ti.ab.)
14. Coronary angiograph* (ti.ab.)

((((((((((#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10) or #11) or #12) or #13) or #14)

15. Smoking cessation (MesH exp.)
16. Counselling (MesH)
17. Rehabilitation (MesH)
18. Lifestyle (MesH)
19. Smoking cessation (ti.ab.)
20. Smoking (ti.ab.)
21. Smok* (ti.ab.)
22. Rehabilitation* (ti.ab.)
23. Behaviour change (ti.ab.)
24. Behavior change (ti.ab.)
25. Health education* (ti.ab.)
26. Psycho-education* (ti.ab.)
27. Psychoeducation* (ti.ab.)

((((((((((#15 or #16) or #17) or #18) or #19) or #20) or #21) or #22) or #23) or #24) or #25) or #26) or #27)

28. Randomised controlled trial (ti.ab.)
29. Randomized controlled trial (ti.ab.)
30. RCT (ti.ab.)
31. Randomised trial (ti.ab.)
32. Randomized trial (ti.ab.)
33. Trial (ti.ab.)
34. Control group (ti.ab.)
35. Comparison group (ti.ab.)

((((((((((#28) or #29) or #30) or #31) or #32) or #33) or #34) or #35)

Study inclusion criteria

Study	Inclusion criteria	
Participants	<ul style="list-style-type: none"> • Adults with confirmed coronary heart disease: angiographically defined coronary heart disease, angina pectoris, myocardial infarct (MI), coronary artery bypass graft surgery (CABG), percutaneous transluminal coronary angioplasty, and heart failure caused by MI. • Eligible for cardiac rehabilitation • No age limitations 	
Intervention	<ul style="list-style-type: none"> • Psychoeducational cardiac rehabilitation intervention • Psychoeducational intervention is defined as an intervention that aims to modify behavioural risk factors by attitude change, providing knowledge, motivation and skills to change behaviours • In- or outpatient intervention • Before or after cardiac surgery, after an acute cardiac event, after diagnosis of coronary heart disease • Hospital or community based 	
Design	<ul style="list-style-type: none"> • Comparison between groups • Patients with the same conditions • Prospective design 	
Outcomes		
<i>Primary</i>	CHD related mortality and total mortality	
<i>Secondary</i>	Morbidity, Quality of life, disability, Smoking, weight, healthy eating habits, exercise, cholesterol, blood pressure, prescribed drug use/adherence to medication, stress, anxiety and depression	
Time line	Minimum of 6 months follow-up after the start of the intervention	
Exclusion criteria		
Participants	Heart failure caused by other reasons than MI, heart transplant patients	
Intervention	<ul style="list-style-type: none"> • Interventions that do not include psychoeducational component • Interventions that concentrate purely on reduction in mental distress using other than psychoeducational interventions • Stress management interventions (specific cognitive behavioural strategies that aim to reduce stress only) • Exercise only interventions or comparisons between different length of exercise programs • Primary prevention interventions • Cost effectiveness studies in cardiac rehabilitation • Interventions that target cardiac rehabilitation providers or the rehabilitation process • Type-A Behaviour modification interventions • Interventions that promote only in-hospital recovery 	
Design	<ul style="list-style-type: none"> • Retrospective design • No comparison condition • If the comparison condition consist other than CHD patients 	
Time line	Follow-up period less than 6 months	

Methodological appraisal of studies

Methodological appraisal of randomised controlled and non-randomised controlled trials
Modified from the Centre for Reviews and Dissemination Handbook, Petticrew & Roberts (2006)

Appraisal questions			
1. Group allocation method			
a. Non-random	Yes	No	Can't answer
b. Random	Yes	No	Can't answer
c. Was the treatment conditions allocation done by persons doing the recruitment?	Yes	No	Can't answer
d. Was allocation open to manipulation?	Yes	No	Can't answer
2. Treatment groups			
a. Were the groups similar?	Yes	No	Can't answer
b. Is there any evidence of matching or otherwise controlling discrepancies e.g. ANCOVA?	Yes	No	Can't answer
c. Do any described variables potentially affect the intervention outcome?	Yes	No	Can't answer
3. Intervention description			
a. Procedure	Yes	No	Can't answer
b. material	Yes	No	Can't answer
c. location	Yes	No	Can't answer
d. personnel & training	Yes	No	Can't answer
4. Participants			
a. Were the participant eligibility criteria specified?	Yes	No	Can't answer
b. Were the criteria of participant inclusion criteria set before hand?	Yes	No	Can't answer
5. Were outcome assessors blinded to the group allocation?	Yes	No	Can't answer
6. Were care providers blinded to the group allocation?	Yes	No	Can't answer
7. Were the participants blinded to the group allocation?	Yes	No	Can't answer
8. Were the measured outcome variables appropriate?	Yes	No	Can't answer
9. Were the used outcome measurement tools reliable and valid?	Yes	No	Can't answer
10. Follow-up period	Yes	No	Can't answer
a. Was the follow-up procedure described?	Yes	No	Can't answer
b. Are the "drop-outs" clearly described?			
c. Could the "drop-out" have caused bias?			
11. Study power and time-line			
a. Does the study have adequate number of participants to detect change in the outcome variable?	Yes	No	Can't answer
b. Is the follow-up period long enough to allow detection of changes over time?	Yes	No	Can't answer
12. Treatment of the groups			
a. Were the two groups treated similarly apart the intervention?	Yes	No	Can't answer

b. Could differences in the treatment cause bias?	Yes	No	Can't answer
c. Was there any evidence for statistical or other ways to control potential bias?	Yes	No	Can't answer
13. Did the analysis include an intention to treat analysis?	Yes	No	Can't answer
<u>Overall comments</u>			

Appendix 3

Outline for the systematic review of qualitative research

Title:

Systematic review of qualitative information of patient expectations and experience of cardiac rehabilitation – emphasis on smoking cessation studies

Background

Meta-analysis of psycho-educational smoking cessation interventions indicated considerable heterogeneity between the intervention, and post-hoc subgroup analyses suggested that intervention intensity influenced intervention effectiveness. However, somewhat contrary to expectations, detailed analysis of intervention mechanisms and techniques indicated that interventions appeared to use similar techniques to influence behaviour. Apparently, intervention complexity was not evident in what kind of behavioural determinants interventions targeted or what kind of behaviour change techniques were employed in influencing the targeted behavioural determinants. Further, analyses of influence of using theoretical models in intervention design indicated only limited influence between studies that used theories underpinning interventions in designing studies and those that did not use any specific theoretical model. This means that the complexity of the interventions may stem from other causes, such as interactions between different stake holders and implementation of the intervention (e.g. Craig et al., 2008, Egan et al., 2009).

The systematic review and meta-analysis of psycho-educational cardiac rehabilitation interventions indicated that regardless of significant outcomes, the results were not conclusive enough to allow recommendations for future improvements of interventions. Post-hoc analyses of the subgroup suggested that inclusion intervention intensity may be associated with increased effectiveness of intervention. However, due to limitations in the available data, firm conclusions could not be made. To complement the information gained in previous analyses a qualitative systematic review of relevant literature will be done to answer the questions of what are coronary heart disease patients' expectations and experiences

of cardiac rehabilitation. Considering the problems encountered in the previous analyses to offer recommendations for future intervention design, investigating patients' expectations and experiences of cardiac rehabilitation interventions, and indeed of smoking cessation interventions, may offer some further insight into successful intervention design. As in the previous analysis, providing that sufficient material will be found, the qualitative analysis will concentrate on patients' experiences and expectations of psycho-educational smoking cessation interventions.

The following research questions are set for the review:

1. What kind of expectations do coronary heart disease patients have about cardiac rehabilitation before they attend the rehabilitation?
2. Do coronary heart disease patients express preference for certain kind of intervention or for intervention features?
3. What kind of experiences coronary heart disease patients do have after taking part in an intervention? (Full time or drop-out)

Methods

Identification of studies

A search strategy was developed to identify qualitative research using guidance from Petticrew and Roberts (Petticrew and Roberts, 2006) and Shaw et al. (Shaw et al., 2004). The search strategy was based on the terms used in the previous systematic review, but modified to capture studies with qualitative design and intervention as cardiac rehabilitation. The search strategy was designed to be broad, so as to identify as many potential qualitative cardiac rehabilitation studies as possible in the search process. The strategy included words like cardiovascular disease, heart attack, rehabilitation, lifestyle, qualitative, and thematic analysis. Studies were searched from the 1970s onwards to coincide with the systematic reviews of quantitative psychological cardiac rehabilitation interventions.

Study selection

The search will be limited to published articles written in English. For studies to be included they had to include adults (age of 18 and over), with confirmed coronary heart disease who were eligible for cardiac rehabilitation. The intervention had to include psycho-educational components such as behaviour modification. Studies that examined participants' expectations of cardiac rehabilitation before participating in a formal rehabilitation programme are also included, as though it may not be possible to ascertain the precise form of rehabilitation, these studies may offer important material about prior expectations of what cardiac rehabilitation offers. Only studies that have used a qualitative methodology and included first-hand information from coronary heart disease sufferers were considered. Included studies also has to be able to provide information about coronary heart disease patients' expectations and experiences of cardiac rehabilitation, or information about patient preferences regarding cardiac rehabilitation. There were no time limits set on how long participants were contacted before or after potential cardiac rehabilitation programme attendance.

Assessment of study quality and data extraction

Methodological quality of the papers will be assessed using pre-set criteria that cover the research planning and design, the participant description, data collection and analysis, and study reporting. In developing quality assessment criteria Public Health Resources Unit(Public Help Resource Unit, 2006) and Petticrew and Roberts (Petticrew and Roberts, 2006) sources are consulted. Studies will not be ranked according to their quality assessment, but weaknesses in the study methodology are noted. Data extraction will be done with data extraction sheets developed specifically for this review. Data collection from primary studies includes information on participant population, research design, data collection and analysis methods, and results. Data will be collected only from the methods and results sections of the articles, unless it is considered in special cases that some relevant additional data may be found in the discussion section, in which case this was highlighted in the data collection sheet. Collected data contains study authors' descriptions and analyses of the research material, not original quotes from research participants illustrating

points made by the authors. However, assessment of intervention quality includes noting how far there was consistency between quotes offered and the authors' descriptions and analyses of the research material.

Analysis methods

Analysis will be done using narrative synthesis, where analysis categories are not predefined but will be emerging from the material. The analysis aims, with the emerging information, answer the questions of what participants expect from cardiac rehabilitation and how experience the rehabilitation after attending, and what would participants consider as important aspects of cardiac rehabilitation programme. For the analyses, results sections of the studies will be read and data will be extracted by hand from the methods and results section. Where results are organised under themes or narrative components, these are used as headings to collate authors' descriptions and explanations of the meaning of the headings. In cases where materials are not organised within clear themes or narrative components, rough headings will be devised according to issues considered in the text. Although themes and narrative components are extracted as written in the text, explanations and descriptions are not extracted as whole paragraphs, but, rather, key points and illustrations will be extracted. In some cases, however, it may be necessary to extract whole paragraphs *verbatim*. After data extraction is complete, the next round of reading will aim to establish similar themes among the data. It is anticipated that themes are not established only on extracted themes or narrative components, but also by using descriptions and explanations offered by available data.

Search strategy: Systematic review of qualitative research

1. Heart attack (MesH exp)
2. Myocardial infarction (MesH exp)
3. Cardiovascular disease (MesH exp)
4. Coronary artery bypass (MesH exp)
5. Angina pectoris (MesH)
6. Ischemic heart disease (ti.ab.)
7. Coronary artery bypass (ti.ab.)
8. Coronary heart disease (ti.ab.)
9. Coronary angioplasty (ti.ab.)
10. CABG (ti.ab.)
11. Heart infarct (ti.ab.)
12. PTCA (ti.ab.)
13. Myocardial infarct (ti.ab.)
14. Coronary angiograph* (ti.ab.)

((((((((((((#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10) or #11) or #12) or #13) or #14)

15. Rehabilitation (MesH exp)
16. Lifestyle (MesH)
17. Counselling (MesH)
18. Behaviour change (ti.ab.)
19. Behavior change (ti.ab.)
20. Psychoeducation* (ti.ab.)
21. Psycho-education* (ti.ab.)
22. Health education* (ti.ab.)
23. Cardiac rehabilitation (ti.ab.)
24. Rehabilitation* (ti.ab.)
25. Psychosocial (ti.ab.)
26. Recovery (ti.ab.)

((((((((((((#15 or #16) or #17) or #18) or #19) or #20) or #21) or #22) or #23) or #24) or #25) or #26)

27. Interview (MesH)
28. Qualitative (ti.ab.)
29. Discourse analysis (ti.ab.)
30. Experience* (ti.ab.)
31. Theoretical sample (ti.ab.)
32. Ethnograph* (ti.ab.)
33. Grounded theory (ti.ab.)
34. Phenomenolog* (ti.ab.)
35. Purposive sample (ti.ab.)
36. Content analysis (ti.ab.)
37. Thematic analysis (ti.ab.)
38. Focus group* (ti.ab.)
39. Constant comparative method (ti.ab.)

((((((((((((#29) or #30) or #31) or #32) or #33) or #34) or #35) or #36) or #37) or #38) or #39)

Qualitative study inclusion criteria

Study		
Inclusion criteria		Comments
Participants	<ul style="list-style-type: none"> • Adults with confirmed coronary heart disease (Incl. angiographically defined coronary heart disease, angina pectoris, myocardial infarct (MI), coronary artery bypass graft surgery (CABG), percutaneous transluminal coronary angioplasty, and heart failure caused by MI) • Eligible for cardiac rehabilitation 	
Intervention	<ul style="list-style-type: none"> • Psychoeducational cardiac rehabilitation intervention • Psychoeducational intervention is defined as an intervention that aims to modify behavioural risk factors by attitude change, and by providing knowledge, motivation and skills to change behaviours. 	
Method	<ul style="list-style-type: none"> • Qualitative study method • First hand reports of persons eligible for cardiac rehabilitation, and those involved in providing or supporting cardiac rehabilitation (should be excluded) 	
Outcomes	<ol style="list-style-type: none"> 4. What kind of expectations coronary heart disease patients have about cardiac rehabilitation (smoking cessation) before they attend the rehabilitation (smoking cessation) intervention? 5. Do coronary heart disease patients express preference for certain kind of intervention or for intervention features 6. What kind of experiences coronary heart disease patients have in actually participating (full-term or part-way) in an intervention? 	
Time line	There is no specified time limit	
Exclusion criteria		
Participants	Heart failure caused by other reasons than MI	
Intervention	<ul style="list-style-type: none"> • Interventions that do not include a psychoeducational component • Interventions that concentrate solely on reducing mental distress using other than psychoeducational interventions • Exercise-only interventions 	
Method	Data collected from other sources than directly from participants	
Outcomes	<ul style="list-style-type: none"> • Coronary heart disease experience • Meaning of coronary heart disease • Experiences of how coronary heart disease influences functioning and everyday life • Experiences of how coronary heart disease affects social role, social functioning and work (without mention of rehabilitation) • Research on outcomes for the relatives and/or social contacts of coronary heart disease patients • Studies that investigate barriers to attending cardiac rehabilitation • Studies that investigate process of CR without including a formal rehabilitation programme • Studies that make recommendations about improving a CR program based on illness beliefs and experiences only 	

Appraisal of Qualitative Studies

Methodological appraisal of qualitative studies

Sources:

Public Health Resources Unit

Petticrew & Roberts (2006) Systematic Reviews in Social Sciences

Name of the study				
Appraisal questions				
				Comments
1. Research Planning				
a. Is the research aim stated?	Yes	No	N/A	
b. Is qualitative research methodology appropriate?	Yes	No	N/A	
2. Research Design				
a. Is the research design defensible?	Yes	No	N/A	
b. Have theoretical perspectives and other assumptions that affect the design been stated?	Yes	No	N/A	
c. Are data collection and analysis methods discussed in context of the research aim (do they fit)?	Yes	No	N/A	
3. Participants				
a. Were participant eligibility criteria stated?	Yes	No	N/A	
b. Was it explained how participants were selected and recruited?	Yes	No	N/A	
c. Was recruitment process recorded?	Yes	No	N/A	
d. Have researcher/s stated their relationship with the research field and participants and its possible consequences?	Yes	No	N/A	
4. Data Collection				
a. Has data collection method been discussed (e.g. interview, semi-structured)?	Yes	No	N/A	
b. Has data collection methods been modified during the research?	Yes	No	N/A	
c. Are data recording methods been mentioned?	Yes	No	N/A	
d. Is it specified when data collection is considered completed?	Yes	No	N/A	
5. Data Analysis				
a. Is formulation and process of analysis described?	Yes	No	N/A	
b. Is context of data discussed?	Yes	No	N/A	
c. Are links between data, interpretations and conclusions clear?	Yes	No	N/A	
d. Is there mention of possible complexity and diversity in the data?	Yes	No	N/A	
6. Reporting				
a. Are findings made explicit?	Yes	No	N/A	
b. Is data used to back arguments drawn from it?	Yes	No	N/A	
c. Is credibility of the findings discussed?	Yes	No	N/A	
d. Do the findings relate to the original research question?	Yes	No	N/A	
7. Is there evidence of consideration of ethical				
	Yes	No	N/A	

issues?		
8. Is there research process documented?	Yes	No N/A
<u>Overall comments</u>		

Data collection sheet

Author	
Journal	
Title	
Country	

Are all or part of the findings included?	
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Participants	
Diagnosis	
Inclusion	
Exclusion	
Total nr of eligible participants	
Nr of participants approach	
Participant selection method	
Number of participants	
Participant gender	
Ethnicity	
Age group	
Comment	

Method	
Type of study	
Research aim	
Analysis method	
Data collection method	
If groups were used, how participants were allocated?	
Timeline	

Intervention	
Description	

Findings	
Theme/ Narrative component	Illustration

