Doctoral Thesis

Meta-Analysis: The Efficacy of Acceptance and Commitment Therapy on Quality of Life in Chronic Health Conditions.

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Abstract

Background and aims: The physical symptoms of chronic health conditions are well documented and understood, the long-term sequelae of chronic conditions are now also more established with a focus on improving quality of life (QoL). Established psychological therapies such as Cognitive Behaviour Therapy (CBT) have aimed to try to help individuals that are suffering with chronic conditions. A relatively new approach, Acceptance and Commitment Therapy (ACT), claims to be transdiagnostic and therefore may be a suitable approach with this population. This thesis aims to explore the efficacy of ACT in improving QoL in chronic health conditions.

Methodology: A systematic literature search and analysis was undertaken utilising a meta-analysis approach.

Results: A comprehensive electronic and manual search yielded a total of 1081 potential articles. Following the implementation of the inclusion and exclusion criteria a total of 12 studies, including 788 participants, were included in the analysis. Data were extracted and studies were assessed for methodological quality. ACT led to greater improvements in QoL compared to control conditions and the effect size (ES) was small to moderate (Hedges g = .33). However, ACT was not significantly better than active control groups when separately analysed (g = .27, p = 0.23).

Conclusions: The findings suggest that ACT does have a positive and significant effect on QoL for individuals with chronic health conditions compared to controls. Furthermore, these improvements in QoL are not diminished after follow-up. The results, theoretical/clinical implications, strengths and limitations and future directions of this thesis are explored in the Discussion.

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Everything I do is all for you, Q6.

Chapter One: Introduction

1.1. Overview

The chapter provides an outline of chronic health conditions and highlights the importance of quality of life (QoL) within this specific population. The aetiology, epidemiology and treatment, both medical and psychological, of chronic pain is explored as an example of a chronic condition. Acceptance and Commitment Therapy (ACT) is described and appraised and consideration is given to how it could provide an alternative or supplementary form of psychological treatment for chronic health conditions. Finally a rationale is presented for why investigating the efficacy of ACT on QoL within a chronic health population is relevant.

1.2. Chronic Health Conditions

In 2012 the World Health Organisation (WHO) proposed that chronic health conditions are the leading cause of death and disability globally (WHO, 2012). Cancer, diabetes and cardiovascular disease accounted for 63% of all deaths worldwide in 2010. The Department of Health estimated that 15 million people in the UK have a chronic health condition. This accounts for £7 of every £10 spent on health and social care (Department of Health, 2012). These conditions do not currently have a cure and primary symptoms are predominately managed with pharmacological interventions. The conditions are enduring, have a poor prognosis and have a pattern of reoccurrence and deterioration. A wide array of conditions can be classified as chronic health conditions. Examples of conditions include; cancer, diabetes, cardiovascular disease, epilepsy, chronic pain, tinnitus, brain injury, HIV/AIDS, irritable bowel syndrome amongst others. Healthcare, given the nature of these conditions, is not targeted towards a cure but instead at improving QoL and managing complex symptoms (Nolte & McKee, 2008).

1.2.1. Definition of a chronic health condition.

Since 1947 there has been a shared definition of health. The World Health Organisation (WHO) defines health as not merely the absence of disease and infirmity but as "complete physical, social and mental well-being" (WHO, 1947, p. 1). This definition is particularly salient for people who suffer from chronic conditions as all three of these domains are affected by the illness. A clear and universal definition of chronic conditions however has not been established. The overwhelming criteria in defining chronic conditions seemed to only involve duration as a means of classification based on a review of literature (O'Halloran, Miller, & Britt, 2004). O'Halloran et al. (2004) highlighted the importance of other factors when considering a definition of a chronic health condition. Their definition includes: the extent to which symptoms recur or worsen over time; an emphasis on maintenance rather than curing the illness; and how sequelae impacts on a person's QoL. O'Halloran et al. (2004) concluded that chronic conditions are multi-faceted and should not be defined solely on their duration. Furthermore, a set of criteria were developed which encapsulated the multifaceted nature of chronic conditions. The criteria include; a duration of at least six months, a pattern of reoccurrence or deterioration, poor prognosis, and sequelae that impacts on QoL (O'Halloran et al., 2004).

1.2.2. Importance of quality of life.

The physical effect of chronic health conditions such as chronic pain, heart disease and cancer is well documented and well understood. Knowledge of the long-term sequelae of chronic conditions is now also more established (Hudson & Chilcot, 2015). The co-occurrence of chronic health conditions and psychological distress is associated with increased mortality, morbidity, increased healthcare costs and poorer QoL (Hudson & Chilcot, 2015). Cancer survivors following invasive treatments are often left with neurocognitive impairments that result in distress such as anxiety,

depression and social withdrawal (Barakat et al., 2015). Lichtman et al. (2008) report that depression is three times more likely following an acute myocardial infarction than compared to the general public. Evidence suggests that people suffering from chronic pain are more likely to report psychological distress due to pain, lack of sleep, diminished social interactions, lack of work and reduced daily activities (McCarberg, Nicholson, Todd, Palmer, & Penles, 2008; Smith et al., 2001). In 2012, it was estimated that there were 4 million people in England with a co-morbid chronic health and mental health condition and that many of them experienced poorer general health outcomes and QoL as a result (Naylor et al., 2012). As such there has been a greater focus on addressing psychosocial distress with the aim of improving functioning, well-being and QoL in chronic health conditions (Livneh, 2014; Naylor et al., 2012; The Department of Health, 2012, 2015).

QoL is often an overused and all-inclusive term that has come to mean different things for different people. There is not a universally shared or agreed definition of QoL which has resulted in a number of different definitions (Barofsky, 2011; Speight, Reaney, & Barnard, 2009). Cella and Tulsky (1990, p. 29) describe QoL as a cognitive appraisal based on satisfaction with a person's current level of functioning compared to their ideal. The WHO defines QoL as a person's perception of their position in life (WHO, 1997, p.1). Bowling (2005, p. 125) describes QoL as a sum of physical, social, emotional and objective dimensions. There is some commonality in these different interpretations that QoL is a multi-dimensional construct which is dynamic, subjective and measures physical, psychological and social well-being (Barofsky, 2011; Cella, 1994; Herrman et al., 1998; Speight et al., 2009; Spilker, 1990).

The primary aim of medical interventions within this population includes reducing the speed of deterioration and the management of symptoms (Naylor et al., 2012). There is also a greater focus on alleviating emotional distress through the use

of psychological interventions (NICE, 2009, 2012). Given the complex nature of chronic health conditions there has been a greater focus in improving QoL as part of treatment interventions (Nolte & McKee, 2008; The Deparment of Health 2012, 2015). By definition a condition is considered chronic based on whether it affects QoL (O'Halloran et al., 2004). Evidence shows that chronic health conditions affect physical symptoms but also on other aspects of a person's functioning/well-being. This has implications for the way outcomes are measured in chronic disease research, with a greater focus on QoL (Arnold et al., 2004). QoL has become an important outcome measure in research, and clinically, in trying to evaluate the effectiveness of interventions within chronic health populations (Department of Health, 2012, 2015). As such there has been a greater focus on psychological based interventions in trying to address QoL. NICE (2009, 2012) recommend psychological therapies for chronic health conditions such as cancer, heart disease, diabetes, musculoskeletal disorders, respiratory illness, and neurological disorders. NHS England have set out a number of outcomes and highlighted the importance of enhancing QoL for patients with long-term conditions (http://www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk/). Given the importance of QoL within this population there is a need to identify evidence based psychological interventions that can improve QoL.

1.3. Chronic Pain

Given the complexity and diversity of the chronic health population an appraisal of the relevant literature for each specific condition focusing on biology, epidemiology, impact, treatment and psychological understanding is beyond the scope of this thesis. This introduction will therefore focus on chronic pain as an example of a chronic health condition and explore the relevant literature. It was also expected that this thesis would include many articles that explore chronic pain as the treatment for this condition has been heavily researched in relation to ACT

(https://contextualscience.org/state_of_the_act_evidence). Furthermore, by focusing on one condition within the introduction it allows the chapter to flow seamlessly between subsections compared to abruptly changing between chronic health conditions resulting in re-orientation for the reader.

1.3.1. Aetiology.

Melzack and Wall (1965) describe pain as "an aversive, personal, subjective experience, influenced by cultural learning, the meaning of the situation, attention and other psychological variables, which disrupts ongoing behaviour and motivates the individual to stop the pain". The International Association of the Study of Pain (IASP) describe pain as an "unpleasant sensory and emotional experience" that is linked to either actual or potential tissue damage (Merskey & Bogduk, 1994, p. 210). Both definitions highlight the importance of an unpleasant sensation but also incorporate the notion of disrupting current behaviour with a compulsion to want to stop the pain. There is also a strong emphasis on the psychological factors of pain as an important factor in the understanding of pain and its subjective experience.

The biological process involved in the sensation of acute pain begins with external stimulation or tissue damage and is described as '*nociceptive pain'* (Flor & Turk, 2015). Receptors known as '*nociceptors*' when activated result in the sensation of nociceptive pain. Damage to nociceptors can occur through three different modalities; thermal stimulation (i.e., noxious heat or cold at different temperatures), chemical stimulation (i.e., contact with bio hazardous substances), or mechanical stimulation (i.e., excessive pressure or mechanical deformation including breaks in the skin). The body's physiological response begins with the transmission of signals through the spinal cord which in turn activate inflammation at the site of the injury. Fast acting messages sent immediately from the spinal cord activate muscles to trigger spams with the intention to avoid additional injury. The cortex is bypassed in this

feedback loop which ensures that the body can respond to the injury quickly. As the injury begins to heal there is a reduction in pain signals and sensations of pain. The pain is generally localised at the injury site and does not result in multiple sensations of pain. However, the experience of pain can be more widespread if it is linked to damage to internal organs.

There is a second category of pain known as '*neuropathic pain*' which is experienced following damage to the somatosensory system (Geber et al., 2009). The initial physiological response from the body includes the one described above. However, in this circumstance there is damage to nerves which results in a different sensation of pain. Damage or disease affecting the somatosensory nervous system can lead to neuropathic pain which can be seen in spinal cord injuries, herpes zoster virus, alcohol abusers, diabetics, post-surgery patients such as cancer survivors (Attal, Lanteri-Minet, Laurent, Fermanian, & Bouhassira, 2011; Bouhassira, Lantéri-Minet, Attal, Laurent, & Touboul, 2008). The experience of neuropathic pain has been commonly described to include tingling, shooting, burning and electrical type sensations. Patients may also experience pain from stimuli that would not normally cause pain known as '*allodynia'*. Neuropathic pain is described as more severe than nociceptive pain and is more difficult to treat (Schmidt et al., 2009).

Neuropathic and nociceptive pain can occur together in conditions such as back pain and cancer pain which can go on to become chronic. In patients with chronic pain, stimulation of nerves and spasms continue as if the body is still reacting to an injury. Traditionally chronic pain has been defined solely on the duration. That is, the experience of continued pain long after the natural rate of recovery from an injury which can range between 3 and 6 months. The continual experience of pain can lead to avoidance of activities (Flor & Turk, 2015) and over time this can lead to disuse or '*deconditioning syndrome'* resulting in loss of muscle strength, mobility and cardiovascular fitness (Bortz II, 1984).

1.3.2. Epidemiology.

The prevalence of chronic pain in the community is varied, between 15% and 48%, based on surveys of the community (Bekkering et al., 2011; Bouhassira et al., 2008; Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006; Elliott, Smith, Penny, Smith, & Chambers, 1999; Reid et al., 2011; Torrance, Smith, Bennett, & Lee, 2006). Chronic pain is more prevalent in women and the elderly affecting approximately 45-80% of older adults in residential settings (Elliott et al., 1999; Maxwell et al., 2008; van Hecke, Torrance, & Smith, 2013). Being retired, out of work or in receipt of a low wage have also been linked with chronic pain (Flor & Turk, 2015; Smith et al., 2001; van Hecke et al., 2013). There is also evidence that chronic pain is an enduring condition with 78% of sufferers continuing to experience pain after a four year follow up (Smith et al., 2001). Back pain is the second main reason for seeking medical advice accounting for almost 7 million GP visits annually. Furthermore, approximately 8.3 million working days were lost as a result of musculoskeletal disorders in the UK between 2013-2014 (Spence, 2014). It has been estimated that healthcare costs for back pain equate to a total of £1.6 billion a year (Maniadakis & Gray, 2000).

Musculoskeletal conditions such as arthritis, herniated/deteriorating discs and back pain have been reported to make up the majority of chronic pain in the community (Breivik et al., 2006). The prevalence of nociceptive pain in the community is greater than neuropathic pain and ranges between 7-8% (Bouhassira et al., 2008) however, neuropathic pain accounts for greater use of healthcare services (Breivik et al., 2006; NICE., 2013). Approximately 33% of patients do not have a formal diagnosis or an obvious injury which has caused them to experience pain (The British Pain Society, 2013). Traditionally, the absence of a medical explanation of pain would lead to the diagnosis of a psychological problem and termed

‘psychosomatic’; it is now recognised that pain can occur without a clear injury (Hadjistavropoulos & Craig, 2004).

The relative subjective experience of pain can differ based on a number of variables, which can be unique to individuals such as, cause, locality of pain and physiological sensations. Despite the unique characteristics of individuals the important factor is how the condition influences everyday life such as performing usual activities which affects QoL. Primary symptoms in chronic pain include the subjective experience of pain however there can be a range of secondary symptoms that arise which are linked to pain. A large community based survey found that; 47% of suffers stated it limited their social life, 54% struggled with household chores, 65% had trouble sleeping, 48% had to change, or were unable to, work, 73% struggled with exercise, 27% struggled to maintain relationships with family or friends and 21% had received a diagnosis of depression (Breivik et al., 2006). These findings describe the immense burden of chronic pain which includes not only physical discomfort but also an illness which highly impacts on psychosocial well-being and QoL.

Research investigating the link between mental health difficulties and chronic pain has been well established in both community and clinical samples (Bair, Robinson, Katon, & Kroenke, 2003; Goesling, Clauw, & Hassett, 2013; Gormsen, Rosenberg, Bach, & Jensen, 2010; Kroenke et al., 2013; Lerman, Rudich, Brill, Shalev, & Shahar, 2015). The prevalence of comorbid chronic pain and psychological distress has been estimated as 35% for anxiety and 40-50% for depressive symptoms (McWilliams, Cox, & Enns, 2003; Tunks, Crook, & Weir, 2008). Researchers have attempted to try to understand this link and Rudy, Kerns, and Turk (1988) suggested that pain and depression are mutually maintaining and do not develop from a common cause. They argue that depression and chronic pain results from a “perceived reduction in instrumental activities along with a decline in perception of control and personal mastery” (Rudy et al., 1988, p. 129). Banks and Kerns (1996) have suggested

a possible role for genetics and highlight a diathesis-stress framework. They argue that certain genes can lead to the expression of both mental health and chronic pain difficulties based on an interaction between genetics and environmental influences. The co-morbidity of mental health difficulties and chronic health conditions lead to worse outcomes. Naylor et al. (2012) found that people with co-morbid mental health difficulties had reduced ability to manage physical health symptoms and poorer clinical outcomes regarding QoL. Bair et al. (2003) found that patients experienced greater, pain complaints, intense pain, amplification of symptoms and durations of pain as a result of co-morbid depression. Future episodes of pain which included lower back pain, chest pain, headache and musculoskeletal complaints were also predicted by the presence of depression. The evidence suggests that overall patients that have co-morbid mental health difficulties experience worse outcomes.

Along with the link of mental health difficulties there is also growing evidence of a link between chronic pain and cognitive functioning. The evidence base for this is still growing and a few domains have been highlighted such as attention, memory and executive functioning.

The experience of pain may involuntarily capture attention and interrupt pain-unrelated cognitive activity. Eccleston and Crombez (1999) have highlighted that chronic pain is attention demanding and that when patients are engaged in attention-demanding exercises there is a competition for limited cognitive resources. Legrain et al. (2009) investigated the effect within a laboratory setting. The effect of pain on attention was investigating by participants undertaking a visual attention task whilst simultaneously experiencing pain via a nociceptive laser stimulus. The study found that pain placed a demand on the attentional system and that simultaneous presentation of both stimuli led to the reduction of attention allocation to on-going cognitive processes. The sample in this study was small and only included healthy controls. Furthermore, the experience of pain was an acute administration and not the

result of prolonged exposure as is true in chronic pain. Dick, Eccleston, and Crombez (2002) found in a sample of 60 patients suffering with rheumatoid arthritis and musculoskeletal pain that scores on the Test of Everyday Attention (TEA) were significantly lower than aged-matched controls. Interestingly the results from the TEA were not correlated to the assessment of pain based on visual analogue scales. It is therefore not possible to conclude that the experience of chronic pain and performance on the TEA are related.

There is evidence to suggest that patients suffering with chronic pain may also experience memory deficits. Weiner, Rudy, Morrow, Slaboda, and Lieber (2006) conducted a large study of older adults suffering with chronic pain. Participants completed a battery of neuropsychological tests which found that chronic pain was linked to deficits in immediate and delayed memory. Despite this finding the sample was an older adult population and therefore it makes it more difficult to generalise the results to a younger population. Interestingly there is evidence to suggest that the relationship between chronic pain and memory could be mediated by anxiety and depression. Munoz and Esteve (2005) found that patients with chronic pain that had complained of impairments with memory and concentration could be explained by symptoms of anxiety and depression. A total of 149 patients suffering with pain completed a battery of scales assessing memory complaints, pain catastrophising, depression and anxiety. The authors found that emotional distress plays an important role with memory in their sample and they highlighted the important factors of rumination and catastrophising as key factors.

Executive functioning can be described as a supervisory attentional system and plays an important role in linking other cognitive resources. Executive functioning is an umbrella term that includes various higher order cognitive processes such as problem solving, planning, multi-tasking, working memory, inhibition control, flexibility and reasoning.

There is evidence to suggest that this important higher order cognitive ability could be impaired in people that suffer with chronic pain. Karp et al. (2006) investigated the relationship between chronic pain and mental flexibility in an older adult population utilising a cognitive battery assessment. The authors found that pain was not associated with impairments in short-term memory or information processing speed but was related to mental flexibility based on a number-letter switching task. Statistical analysis was controlled to account for comorbidity, sleep impairments and years of education. Weiner et al. (2006) described earlier with regards to memory also investigated executive function. A total of 323 older adults, 160 with chronic pain and 163 matched controls completed a battery of tests. The authors reported that participants suffering with chronic pain were impaired on measures of mental flexibility and psychomotor speed compared to controls. Despite the findings from both of the studies it should be noted that they both utilised an older adult sample and that the findings can only be generalised to the older adult population. Furthermore, executive functioning is a complex process and should be measured with a number of different assessments that tap into various aspects of this multifaceted ability. The results from both studies would be more reliable if they had included a wider range of tests that covered more aspects of executive functioning.

The link between cognitive impairments and chronic pain has been highlighted in the research above, however within the wider field of research the understanding of this link is unclear. Research has suggested that the co-morbidity of anxiety and depression experienced by patients with chronic pain could be modulating this relationship. Furthermore it would seem that the difficulties identified may centre on problems with bottom-up processing. Limited attentional resources could be put under strain following the experience of chronic pain. This may have a cascading effect on memory and executive functioning as the attentional system at the lowest level is impaired. The interaction between chronic pain and cognitive impairment is further

clouded with the use of long-term medication. There is evidence to suggest that long-term opiate use may add further cognitive impairment in relation to working memory, information processing and cognitive flexibility (Schiltenwolf et al., 2014). There is a need for further investigation to clarify the cognitive profile within the chronic pain population (Landro et al., 2013).

1.3.3. Theories of pain.

The following section will outline key models of chronic pain. It is beyond this thesis to provide a comprehensive review of all documented models of chronic pain and therefore the focus will be on prominent approaches which will be discussed.

1.3.3.1. Specificity theory.

The specificity theory of pain was first proposed by Rene Descartes in the 16th century (Melzack & Wall, 1965). He proposed that the physical sensation of pain is directly related to the level of tissue damage that occurs. The theory holds true that minor injuries such as pricking your finger results in lower sensations of pain compared to a more severe injury such as severing your finger. The theory postulated that injury results in the activation of specific pain receptors and fibres. These in turn transmit pain signals through the spine towards the brain. It was therefore theorised that the psychological experience of pain was directly related to the extent of external injury. Although the specificity theory is able to explain acute sensations of pain it was not able to explain when patients would experience prolonged chronic pain long after the healing process. Furthermore, the theory was unable to explain patients that would experience increased levels of pain despite no, or limited, external stimulation.

1.3.3.2. Biopsychosocial model.

The most current understanding of how acute pain can become chronic is based on a biopsychosocial model (Gatchel, Peng, Peters, Fuchs, & Turk, 2007;

Lumley et al., 2011). Engel (1977) was the first to introduce the biopsychosocial perspective on illness and highlights how the origin of illness is complex and multifactorial. The model states that the experience of pain is determined by the interaction of biological, psychological and social factors. The psychological factors can be broken down into three parts, cognitive, affective and behavioural processes. The social factors include the social/cultural context that influences a person's perception and response to physical signs and symptoms. This model proposes a multidimensional understanding of pain compared to early theories. A number of different theories and models utilise a biopsychosocial model and are described below.

1.3.3.2.1. The gate control theory.

The Gate Control Theory (Melzack & Wall, 1965), when first introduced was heavily criticised for abandoning the notion of a hard-wired system that results in chronic pain. The authors suggested a revolutionary approach which incorporated both biological and psychological elements in the form of a dynamic system in trying to understand the sensations of pain. The theory has been the most influential model to understanding pain, it has highlighted the important role of psychological factors in pain and it has been argued that there is still not a more comprehensive overall theory of pain modulation (Hadjistavropoulos & Craig, 2004; Sufka & Price, 2002). The theory posits that signals from the injury site are sent to the brain via nerve fibres to the dorsal horn in the spinal cord. Here a gating mechanism is opened or closed depending on the type of nerve that is excited. Emotional reactions to pain are thought to influence the gating mechanism. It was proposed that high levels of expressed emotions would lead to the gate being opened wider leading to greater signals of, and therefore experience of, pain. The theory was able to explain how the sensation of pain is not directly linked to the extent of tissue damage or external stimulation. The

link between emotional and biological processes has been demonstrated and the theory has received support based on findings from neuro-imaging research (Gatchel et al., 2007; Main, 2013; Melzack, 2001). Despite this the theory does oversimplify and make architectural errors regarding the neuronal structure within the spinal cord (Nathan & Rudge, 1974). Furthermore there is evidence that suggests a critical role of the brain stem in sending modulating messages. It was previously thought that only emotional reactions emanating from the cortex modulated the gating mechanism. It can therefore be concluded that modulation of the experience of pain does occur outside of the neo cortex within the brain stem (Treede, 2006).

1.3.3.2.2. Behavioural model.

The key principle in the behavioural model is operant conditioning and how it is instrumental in maintaining '*pain behaviours*' (Fordyce et al., 1973). Pain behaviours can be described as any behaviour that is displayed in response to pain and can include verbal agitation, altered gait, avoidance of activities or requesting/taking medication. It was hypothesised that sympathetic responses from others to pain behaviours (e.g., providing comfort or reassurance) led to them being reinforced through operant conditioning. It was thought that patients would then demonstrate behaviours as signals to others that they were in pain. This was regardless of whether pain was experienced. A repeated cycle of this type of behaviour was hypothesised to exacerbate recovery. Research into the behavioural approach has found that when pain behaviours are not reinforced the frequency of these behaviours does decrease as a form of extinction. Furthermore positive verbal reinforcement for coping with activities (e.g., socialising, chores, walking, riding a bike) has been shown to increase their frequency and have been defined as '*well behaviours*' (Cairns & Pasino, 1977; Fordyce et al., 1973).

Turk and Rudy (1991) criticise the behavioural approach and highlights that learning new behaviours is the easy part but maintaining these is difficult especially if these new behaviours are not reinforced. Cairns and Pasino (1977) found that when verbal reinforcement was removed it would lead to an extinction of "well-behaviours" and a return to "pain behaviours" potentially leading to an exacerbation of symptoms. Therefore under this model the learning of new behaviours is relatively straightforward however it requires substantial effort from the patient and significant others for the benefits to be achieved and maintained.

1.3.3.2.3. Fear-avoidance model.

The Fear-Avoidance Model (Lethem, Slade, Troup, & Bentley, 1983) proposes that an individual may avoid tasks such as movement, leisure activities and social interactions based on fear that it will lead to increased levels of pain. The notion of fear is underpinned by the term '*catastrophic thinking*' whereby individuals make predictions about the nature of, consequences of and ability to, cope with pain. Catastrophic thoughts are hypothesised to lead to a fear of experiencing pain, hyper vigilance to pain sensations and avoidance behaviours in anticipation of experiencing pain. This can result in a vicious cycle leading to prolonged avoidance of certain movements which can lead to loss of physical conditioning, known as the deconditioning syndrome described earlier (Bortz II, 1984). In the long-term this can exacerbate a person's functional impairment through disuse as well as emotional distress resulting from the inability to engage in normal social roles. The model has received strong support regarding the connections between elements of the model (Vlaeyen & Linton, 2000). It has been found that pain-related fear is associated with impaired physical performance and increased self-reported disability (Heuts et al., 2004; Nederhand, Ijzerman, Hermens, Turk, & Zilvold, 2004; Vlaeyen, Kole-Snijders, Boeren, & Van Eek, 1995). Interventions aimed at reducing negative

attitudes and beliefs that mediate avoidance behaviour can reduce pain related absences from work (Buchbinder, Jolley, & Wyatt, 2001). The model includes previous ideas regarding how emotions can influence pain but also incorporates a cognitive element. The model includes cognitions made regarding pain and also the beliefs and expectations about what it means to experience pain.

It should be noted that the fear-avoidance model only accounts for the development and maintenance of chronic pain within the sub-group of chronic lower back pain (Leeuw et al., 2007). Furthermore there may well be different processes other than just fear that lead to the progression of lower back pain and therefore this model takes a reductionist approach. There is not a linear relationship between fear of pain and symptoms of chronic pain and therefore there could be other factors which are influential as lower back pain can be an erratic and recurrent problem. The population is diverse and other factors such as pain intensity, level of disability, occupational consequences and use of health care can vary considerably (Leeuw et al., 2007).

1.3.3.2.4. Third wave behavioural models.

Traditional western ideology regarding human suffering is based on a "healthy normality". This is the idea that if one is not healthy, happy, content, satisfied then one is abnormal and that something is wrong which needs to be fixed (S. C. Hayes, Strosahl, & Wilson, 1999). It is understandable that modern societies have come to this conclusion given the success of modern medicine whereby physical illnesses, to a large extent, are resolved through interventions which alleviate suffering and health is simply the absence of disease. Therefore abnormality is seen as a disease, symptom or illness which must be eradicated in order to return to a healthy normality. Traditional psychological understanding and treatment of human suffering has also utilised this same approach and has been championed by the most evidence based psychological

therapy Cognitive Behaviour Therapy. People are seen as dysfunctional beings with faulty cognitions and experiencing the wrong emotions and therefore must be challenged to think differently and try their best to feel something different.

It could be argued that the assumption of a healthy normality should be challenged and that not being healthy, happy, content, satisfied is natural and a normal part of human existence and one that does not make someone abnormal. This has led to a lot of interest in '*Third-wave*' behavioural approaches, in particular mindfulness-based models and Acceptance and Commitment Therapy known as 'ACT' (S. C. Hayes et al., 1999; Kabat-Zinn, 1982, 1990). These approaches share a similar philosophy that incorporates the idea that human existence includes a wide array of experiences which includes 'pain'. The notion that pain is ubiquitous to life implies that you can't eradicate it. Third-wave behavioural approaches do however state that that we can choose how we live with this pain. A core component of both approaches is '*mindfulness'*. Kabat-Zinn (2003, p. 145) describes mindfulness as "the awareness that emerges through paying attention on purpose, in the present moment, and non-judgementally to the unfolding of experience moment by moment". This ideology is incorporated into mindfulness-based stress reduction programmes which have evidenced reductions in psychological distress and improvements in QoL for people suffering with chronic pain (Grossman, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007; Kabat-Zinn, Lipworth, & Burney, 1985; Pradhan et al., 2007; Sephton et al., 2007). In section 1.4 the model of ACT, theoretical underpinning of ACT and evidence for this approach will be explored across different chronic conditions.

1.3.4. Treatment.

Patients suffering with chronic pain present at primary care services which predominately utilise a biomedical approach in an attempt to relieve pain. Patients that do not respond to this approach are then referred on to specialist pain management

services that incorporate interdisciplinary teams that utilise a biopsychosocial model. Services aim to reduce pain. In circumstances where this cannot be achieved the focus of treatment is on reducing disability, mental health difficulties associated with pain and improving QoL (Department of Health, 2012, 2015). Services can provide surgical interventions, medication, physiotherapy, and spinal stimulation-induced analgesia. The British Pain Society (2013) highlight the importance of education provided by services which cover topics such as scheduling activities, use of aids, self-management, and the role of emotions. Increasingly pain management services are offering psychological interventions provided by clinical psychologists utilising cognitive behavioural, mindfulness and acceptance-based approaches (The British Pain Society, 2013).

1.3.4.1. Behavioural therapy.

The popularity of the behavioural approach led to the development of behavioural treatment programmes utilising classical reinforcement techniques. As the model states the aim of the therapy is to reduce pain behaviours with the use of operant conditioning whilst attempting to increase well behaviours. Morley, Eccleston, and Williams (1999) reported a decrease in frequency and intensity of pain behaviours, reduced anxiety and increased social functioning in a review of behavioural therapy compared to a waiting list control (WLC) in a meta-analysis (M-A). Despite its popularity and promising findings the behavioural model has come under considerable criticism (Sharp, 2001; Turk, 1996). Relapse following treatment programmes is high suggesting that the target of treatment does not address the underlying factors that maintain pain. The concept of pain behaviours is ill-defined and the suggestion that they are dysfunctional is not substantiated. The aim to extinguish behaviours is not often shared by patients and can lead to the underreporting of symptoms resulting in medical mismanagement such as reductions

in medication and failure to investigate new symptoms by clinicians (Turk, 1996; Turk & Rudy, 1991).

1.3.4.2. Cognitive-behavioural therapy.

Cognitive Behavioural Therapy (CBT) has a substantial evidence base and has therefore been the primary therapy for chronic pain management for a number of years. The primary target for treatment in CBT is on '*cognitive restructuring*', changing thoughts/beliefs about pain, and changing behaviour. Treatment also includes a number of behavioural techniques which can include pacing, activity scheduling, and relaxation strategies (Morley, Williams, & Hussain, 2008). The Fear-Avoidance Model has been an integral part of the CBT approach and components of the model including changes in catastrophic thinking, pain beliefs, and self-efficacy have been shown to result in increases in physical functioning (Jensen, Turner, & Romano, 2007; J. A. Turner, Holtzman, & Mancl, 2007; Vowles, McCracken, & Eccleston, 2007).

There have been however mixed results regarding the efficacy of CBT. Glombiewski et al. (2010) conducted a M-A of the efficacy of CBT within a fibromyalgia population. They found a significant small effect for pain reduction in the short-term and small to medium effect for long-term pain reduction over an average of 7.4 months based on 23 eligible studies. The research noted that many of the included studies in the M-A were of poor quality and were uncontrolled. Furthermore, different psychological treatments were pooled together bringing into question the integrity of the CBT approach in the analysis. Bernardy, Fuber, Kollner, and Hauser (2010) conducted a M-A of the efficacy of CBT within a fibromyalgia population. They found a small effect in improving depression however CBT was grouped together with alternative treatments such as behavioural therapy and mindfulness-based stress reduction (MBSR). In seven out of the 13 studies CBT was

the main intervention however it is not possible to distinguish its effect from the other interventions in the analysis. Furthermore, there was considerable heterogeneity for multiple outcomes used in the research. Eccleston, Williams, and Morley (2009) reported a weak treatment effect for disability, pain, and psychological distress at follow-up when compared to active control groups in a review of studies. Researchers have questioned the treatment fidelity of many studies and that key parts of the CBT approach were missing which may have reduced the effectiveness of CBT (Eccleston et al., 2009; Morley, 2011). Morley et al. (2008) found in a large sample that 25% reported reduced levels of pain and 33% reported reduced depression and anxiety based on a four-week CBT-informed pain management programme. The gains received by the minority of this sample is important but it does highlight the need for further research into why CBT is effective for some and not others (Crombez, Eccleston, Van Damme, Vlaeyen, & Karoly, 2012; Vlaeyen & Morley, 2005).

It has been argued that it is unclear how the various ingredients of CBT are linked with modifications in functional disability and levels of pain, or if these are similar in all patients (Keefe, Rumble, Scipio, Giordano, & Perri, 2004; Morley & Keefe, 2007). Furthermore, improvement in psychological outcome can occur despite no cognitive restructuring (Longmore & Worrell, 2007) which questions if this is important for change. There has been a rise in the popularity of alternative psychological treatments that pay less, or no, emphasis on cognitive restructuring and instead focus on the relationships between cognitions, emotions and physical sensations and how together they can influence behaviour. This further confuses the picture regarding what the important mechanisms for change are.

1.3.4.3. Mindfulness-based stress reduction

Mindfulness-based stress reduction (MBSR) is a manualised group-based intervention which integrates Buddhist mindfulness meditation with Western clinical

and psychological practices (Kabat-Zinn, 2003; Kabat-Zinn et al., 1985). The approach was originally developed for patients with chronic pain during the 1970s (Kabat-Zinn, 1990). MBSR encourages participants to bring their focus towards the present moment and change their attitude to one of acceptance and openness without self-judgement. The intervention predominately comprises eight weekly group sessions and includes three different techniques; awareness of breathing, body scan (e.g., shifting attention across the entire body from head to toe) and '*hatha yoga'* which includes breathing, stretches and postural exercises.

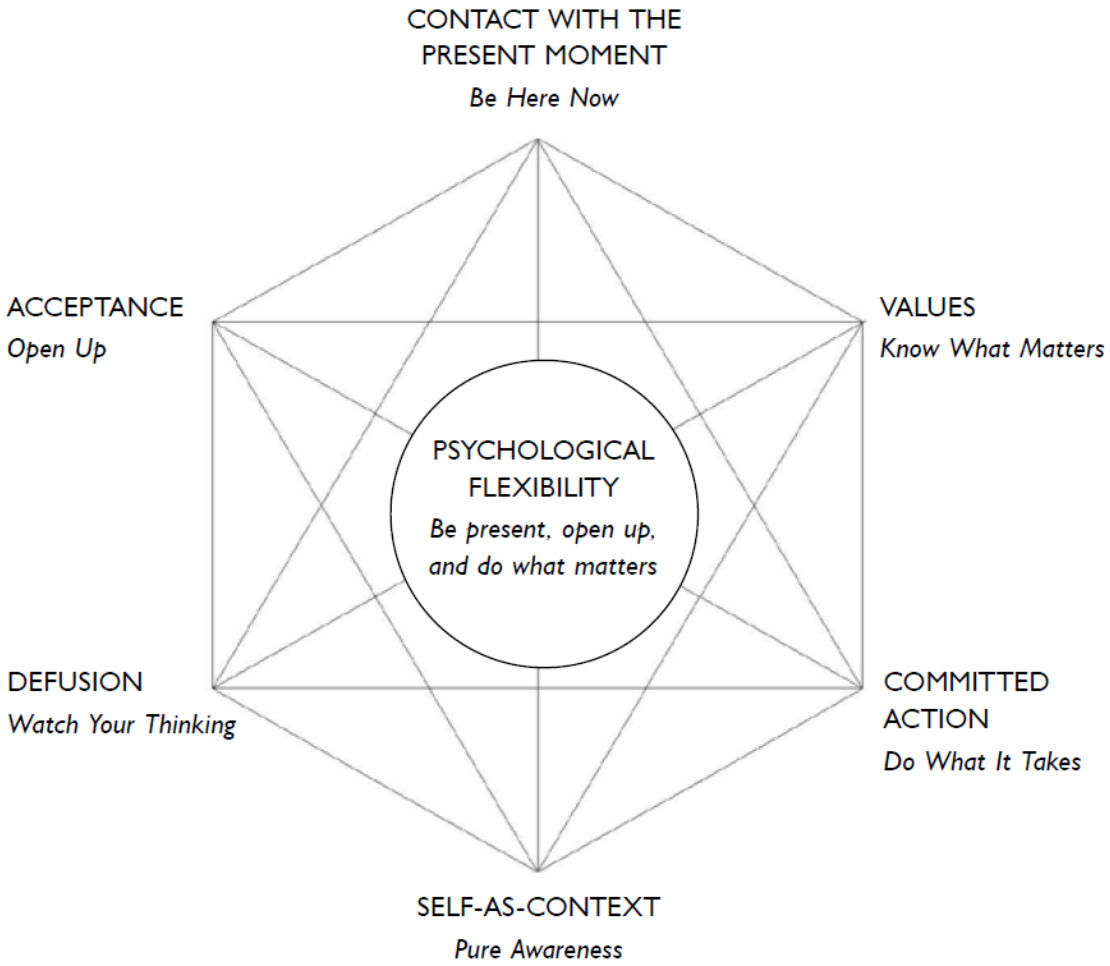
A number of studies have been conducted regarding the efficacy of the approach and have found promising results. Astin et al. (2003) found that patients suffering with fibromyalgia reported improvements in pain, disability and depression post-MBSR and that these improvements were maintained at six-months follow-up. Grossman et al. (2007) conducted a randomised controlled trial (RCT) and found that MBSR, compared to progressive muscle relaxation, resulted in significant improvements for QoL, coping with pain, anxiety, depression and somatic complaints in a chronic pain sample. Morone, Greco, and Weiner (2008) found that MBSR resulted in significant reductions in self-reported pain and improvement in chronic pain acceptance within a lower back pain population. The evidence base for MBSR is growing and guidelines in Scotland have added MBSR as a recommended treatment option for the management of pain (SIGN, 2013).

1.4. Acceptance and Commitment Therapy

ACT proposes a transdiagnostic approach of psychological well-being (S. C. Hayes et al., 1999; S. C. Hayes, Strosahl, & Wilson, 2011) and has therefore been considered across different populations where there is psychological suffering (Öst, 2008, 2014). ACT is a mindfulness and acceptance-based therapy that has been influenced by radical behaviourism and a theory of language and cognition known as

Relational Frame Theory which is explored in section 1.4.1. It was developed in the 1980s and formalised into a therapy in the 1990s (S. C. Hayes et al., 1999). ACT proposes that human suffering is a result of a dysfunctional relationship with '*private experiences*' (e.g., thoughts, emotions and bodily sensations) and neglecting values (e.g., not pursuing what is truly important in life) (S. C. Hayes et al., 2011). The overall aim of ACT is to improve a person's '*psychological flexibility*'; the ability to connect with the present moment fully and, based on the situation, to persist or change behaviour, in the service of living a valued life (Harris, 2006, 2009; S. C. Hayes et al., 1999). There are six components to the ACT model which are described in detail below and illustrated visually with the '*hexiflex*' in Figure 1.1.

Figure 1.1.The ACT Hexiflex (Harris, 2009).



'*Acceptance*' can be described as a willingness to experience physical sensations and emotions without the need to suppress, avoid or control them (Harris, 2006). The willingness to engage in these experiences highlights 'giving up on the struggling with pain' which allows for a natural level of physical and emotional discomfort (Harris, 2006). The opposite inflexible approach '*experiential avoidance*' occurs when attempts are made to avoid, suppress or control private experiences (S. C. Hayes et al., 1999, 2011). Experiential avoidance may provide short-term relief from symptoms (e.g., a socially anxious person avoiding crowds will not have to feel anxious) but this can prevent them from engaging in activities that are valued (e.g., losing contact with friends) which reduces psychological flexibility (Harris, 2006, 2009).

'*Defusion*' is the process of distancing from the content of thoughts which can therefore undermine their influence (S. C. Hayes et al., 1999). Thoughts are therefore interpreted in a different context and viewed as just thoughts and not facts or rules that must be followed. The inflexible approach '*cognitive fusion*' refers to the dominance that a particular thought can have which can then influence behaviour (S. C. Hayes et al., 1999). People can be described as fused when they have a strong belief in a cognition (e.g., "I am fat") and engage in accordance with it (e.g., over eating unhealthy food), even if this is inconsistent with their goals (e.g., weight loss) or values (e.g., being healthy) leading to psychological inflexibility.

'*Contact with the Present Moment*' emphasises the importance of focusing on the here and now; connecting with external senses and internal private experiences at the current moment in time (Harris, 2006, 2009). The inflexible approach involves the '*dominance of the conceptualised self*' based on self-judgements either about the past or future events. Poor contact with the present moment may lead people to 'live in their heads' fixated to the content of thoughts about the past/future which results in disconnection with the here and now resulting in reduced psychological flexibility.

'*Self-as-Context*' focuses on taking an observer stance, almost looking at yourself in the third person, making you aware of where your private experiences come from. It can be understood as '*pure awareness*' a space where one is free to just observe thoughts, emotions and physical sensations. When others are encouraged to see the self-as-context they distance themselves from their conceptualised self which may be filled with negative appraisals about themselves. This leads to a more de-centred self. The inflexible approach leads to '*attachment to the conceptualised self*' regarding the past and future. One can become consumed by the content of negative ruminations about the past (e.g., "I shouldn't have said that", "I am a horrible person") or negative predictions about the future (e.g., "Because I said that everyone will think I am a horrible person") which further reduces psychological flexibility (Harris, 2009).

'*Values*' represent the things that truly matter to someone in their life. They differ from goals in that they are never fully achieved and are more like a guide to living life i.e., being compassionate, being funny, and being helpful. They are a way of being which is in line with what is meaningful for that given person (Harris, 2009; S. C. Hayes et al., 1999, 2011). ACT proposes that when people have clear values they have a good appreciation about what is important to them in life. The inflexible approach results when people lack values, have unclear values, have lost contact with their values or have become fused with values. The lack of clear values results in behaviour being guided by fusion and experiential avoidance which takes people away from what is important in life (Harris, 2009; S. C. Hayes et al., 2011). Values should also be 'held lightly' as fusion with values turns them into ridged rules rather than a guide to living life which reduces psychological flexibility.

'*Committed Action*' is about taking effective action towards living life in line with values (S. C. Hayes et al., 1999). It is the application of values that brings about observable changes in behaviour. Whilst in the pursuit of value directed behaviour,

described as '*value congruence*', there is a possibility that it could give rise to pleasant and unpleasant private experiences. Committed action involves 'doing what it takes' to live a life based on values even if this brings up pain and discomfort. The inflexible approach includes '*unworkable actions*', these are behaviours that take you away from valued living, increase struggles and contradict actions required to live a valued life. This can include actions that are; impulsive, reactive, automatic, procrastinatory or motivated by experiential avoidance leading to further suffering and reduced psychological flexibility.

The six components of the ACT model are intimately linked and therefore changes in one part of the hexiflex may lead to improvements in others (Fletcher & Hayes, 2005; S. C. Hayes, Luoma, Bond, Masuda, & Lillis, 2006). An increase in defusion would lead to an increase in self-as-context and the present moment focus. This may allow the person to help clarify their values and make committed actions towards value congruent behaviours.

The process of change is achieved by learning mindfulness skills, using experiential learning (e.g., learning through experience) and employing techniques such as the use of metaphors and paradoxes which act as shortcuts in understanding (Harris, 2009). The theory that underpins ACT is explained in section 1.4.1 (S. C. Hayes et al., 1999, 2011). As stated previously ACTs primary goal is to improve psychological flexibility and to promote living a valued life. ACT is not directly targeted to reduce symptoms such as depression or anxiety but acknowledges that symptoms can reduce as a by-product of living a valued and meaningful life (Harris, 2006, 2009). What separates ACT from traditional CBT is the acceptance of negative thoughts and emotions without trying to avoid, control, or suppress them. ACT, rather than challenging thoughts and attempting to control feelings, teaches to embrace all thoughts and feelings. This change in attitude towards private experiences seems

highly relevant for chronic conditions where there is evidence of painful private experiences (Naylor et al., 2012).

To place the therapy in context it may be helpful to consider the elements of the hexiflex in relation to a chronic health condition such as chronic pain. From an ACT perspective it can be argued that patients suffering with chronic pain will experience physical sensations of pain, thoughts about pain and emotions related to pain. The model would suggest that individuals that are unwilling to experience this and are not accepting of it will try their best to experientially avoid it such as, taking lots of pain relief, avoiding activities and attempts at distracting from physical sensations and thoughts (i.e., "I can't live with this pain", "my life is over", "things will never change"). This may lead to additional suffering such as, side effects from medication (i.e., stomach ulcers, kidney damage, liver damage, cognitive impairments), neglecting activities that make their life meaningful (i.e., spending time with family, going to work, and leisure pursuits), amplifications of sensations and dwelling on thoughts which leads to additional suffering (i.e., sadness, anger, anxiety).

Unwillingness to experience pain and having thoughts regarding pain may lead to an increase in suffering. In order to reduce this additional suffering there is a need to separate the "self" from the content of the mind and increase willingness to experience painful sensations. This is achieved through the practice of mindfulness which aids connection with the present moment. Pain in all its forms should be accepted only when behavioural change is needed towards valued living.

With the development of these psychological skills it may allow for the clarification of values i.e., being courageous, being creative, being sociable etc. Furthermore, this would lead to the development of committed actions in line with values such as, climbing a mountain, drawing a self-portrait, going to a restaurant

with friends. Importantly, it would be the pursuit of such endeavours together with private experiences as living a valued life is the only form of life that is lived.

1.4.1. Theory of acceptance and commitment therapy.

ACT is grounded in functional contextualism (FC) and relational frame theory (RFT) (Fletcher & Hayes, 2005; S. C. Hayes et al., 1999). FC draws from radical behaviourism which states that behaviour includes not only what others can experience (e.g., walking, talking) but also mental processes (i.e., thinking) and sensory input (i.e., physical and emotional feelings) which are termed private experiences (Skinner, 1957, 1975). Private experiences are not inherently harmful, however they can function in a way that leads to suffering (e.g., an agoraphobic who is unable to leave their home due to thoughts of danger). ACT teaches people to become aware of their behaviour and notice how it functions in the context of their life known as '*workability*'.

RFT is a theory of language and cognition and focuses on how humans derive relationships, develop complex relational networks and transform functions leading to '*relational framing*' (Fletcher & Hayes, 2005; Harris, 2009). RFT purports that humans can learn without having direct experience which contradicts applied behavioural analysis (ABA) where antecedents, behaviour and consequences through direct experience result in learning (Skinner, 1975). When learning language however children are able to derive relationships without having direct experience (e.g., the sound of the word "dog" relates to a picture of a dog). When the same child sees a dog in real life they make the sound "dog" as they have derived the relationship even though it is not the same as the picture. If the child is bitten by a dog this may associate it with fear based on ABA. Fear would now be in a complex relational network of many relations regarding "dog" (e.g., the word dog, picture of a dog, sound of a dog, smell of a dog, the feel of a dog). The child may then respond in fear

when presented with the sound of a dog which is a derived relationship and has not been learned through direct experience. This can now be taken a step further by getting the child to say "perro" which may mean nothing to the child however once they are told "perro" means dog in Spanish its function has been transformed and is now a part of the complex network. In RFT, FC is applied as a means for extending radical behaviourism to account for complex cognitions and language and this is known as relational framing (S. C. Hayes et al., 1999, 2011).

The ability to use relational framing is very important as it allows you to talk, plan, imagine, compare, invent, solve problems and so on. Within ACT the use of FC and RFT, within a clinical setting, relates to how relational framing (e.g., thinking, cognition, human language, the mind) can also lead to human suffering based on the development of complex networks about the self (S. C. Hayes et al., 2011). Fletcher and Hayes (2005, p. 318) propose that "psychopathology evolves in part because derived relations dominate over other sources of behavioural regulation due to an inability to detect the ongoing process of thinking as distinct from the products of thinking". The aim of ACT is to distance the self from painful private experiences by increasing psychological flexibility. This is achieved by changing the context in which they occur and therefore reducing the function of these experiences without having to try to change the content of them (Harris, 2009).

1.4.2. Research evidence.

Corrigan (2001) argued that utilising ACT within a clinical setting was premature due to the lack of empirical evidence. Over the past 15 years there has been a surge of evidence in defining/measuring the concepts involved in ACT and its use in clinical trials (Öst, 2008, 2014). A measure of acceptance, the Acceptance and Action Questionnaire (AAQ) has been developed (S. C. Hayes et al., 2006) as an internally consistent measure of ACTs model of mental and behavioural effectiveness. AAQ

was designed to measure experiential avoidance; low scores on the scale would indicate a willingness to experience unwanted private experiences in the pursuit of valued living. It has been reported that the AAQ predicts a wide-range of QoL outcomes.

A M-A of 27 studies that used this measure found that it predicted depression, anxiety, general mental health, job satisfaction, future work absence and future job performance with an effect size (ES) of, r = .42 (Chawla & Ostafin, 2007; S. C. Hayes et al., 2006). Ruiz (2010) reported that from 20 studies a range of correlations have been reported between depression scores and the AAQ, r = .37 to r = .77. Furthermore, in 14 studies anxiety symptoms correlations for the AAQ ranged between, r = .16 and r = .76. Despite these findings the AAQ does have its shortcomings. Scale brevity, item wording and item selection procedures have resulted in low alpha levels (McCurry et al., 2004). As a result the AAQ-II was developed to address these issues and has a strong correlation, r = .97 with the AAQ (Bond et al., 2011). Initially the scale was defined by the word acceptance however as ACT has evolved and developed, the term psychological flexibility has become more prominent and a better overarching description for the ACT model. The AAQ-II is therefore a measure of psychological flexibility but can still be described by the construct of acceptance and experiential avoidance.

There have been a number of RCTs conducted with ACT across a number of different populations with a significant concentration within chronic pain (A-Tjak et al., 2015; DerSimonian & Laird, 1986; Öst, 2008, 2014). The following sections will provide evidence from RCTs investigating ACT within different populations including psychiatric and somatic disorders.

1.4.2.1. Evidence for ACT in psychological disorders.

Folke, Parling, and Melin (2012) found that participants on long-term sick leave, due to depression, when randomised to ACT improved regarding levels of depression, general health and QoL compared to controls. L. Hayes, Boyd, and Sewell (2011) reported improvements in depression and global functioning for a sample of adolescents. The findings seem promising however in both studies the control group received less therapeutic input which brings into question the validity of the conclusions.

Hayes-Skelton, Roemer, and Orsillo (2013) concluded that 'acceptance-based' treatment is a viable alternative for treating generalised anxiety disorder (GAD). Participants improved significantly and at the same rate as controls in an applied relaxation group on measures of GAD severity, anxiety, depression and QoL. The authors acknowledged that there could have been contamination between the two groups regarding the intervention. Twohig et al. (2010) reported on findings from an RCT investigating ACT compared to progressive relaxation training with patients suffering from obsessive compulsive disorder (OCD). They found greater improvements at post treatment and follow-up for OCD severity in the ACT group. Furthermore, depression reduced amongst patients reporting a mild level at pre-treatment and greater gains were observed in QoL for the ACT group. It should be noted that progressive relaxation training is not an established treatment for OCD and its appropriateness as a control condition is questioned.

A preliminary controlled effectiveness trial with trainee therapists found that participants with mixed presentations, predominantly depression, mood problems and anxiety, showed significantly greater improvements in an ACT condition compared to CBT. A total of 14 participants in each group received ten 60-minute sessions of either ACT or CBT. Treatment was delivered by trainees who were new to both CBT

and ACT and who were taught and supervised by the authors. Improvements were reported in general mental health, social functioning, life satisfaction and depression. The study did however have limitations; the sample was small and from a general outpatient population seeking support for undiagnosed self-reported problems. Supervisors taught the trainees both approaches but recognise that they could have been biased towards ACT. Furthermore, the CBT approach was not comprehensive and was missing some components such as cognitive restructuring.

ACT has been utilised within drug addiction population, Luoma, Kohlenberg, Hayes, and Fletcher (2012) found that residents at a drug treatment program showed smaller immediate gains in shame from three two-hour sessions of ACT compared to treatment as usual (TAU). Participants reported greater reductions after a four-month follow-up. Furthermore, those in the ACT group also had fewer days of substance use and higher treatment attendance at follow-up. The authors concluded that utilising ACT and focusing on shame produces better treatment attendance and reduced substance abuse. The study suffered from a significant amount of missing data at follow-up but did still utilise an intent-to-treat analysis. Also the measure of shame used in the study correlates with guilt and therefore it is unclear what ACT was targeting.

ACT has also shown some promising evidence within a borderline personality disorder (BPD) population with two RCTs reporting ACT as significantly better than TAU (Gratz & Gunderson, 2006; Morton, Snowdon, Gopold, & Guymer, 2012). Gratz and Gunderson (2006) conducted a RCT with women with BPD and self-harm utilising a 14 week ACT intervention. Results indicate that those that received the intervention showed significant positive improvements on emotional dysregulation, experiential avoidance, self-harm behaviours, BPD-specific symptoms and symptoms of depression, anxiety and stress. The intervention utilised in this RCT had elements of dialectical behavioural therapy and behaviour therapy and therefore it is difficult to

distinguish the sole effect of ACT. Morton et al. (2012) reported significant improvement from baseline in the ACT plus TAU group compared to TAU alone. The treatment consisted of 12 two-hour sessions. Participants showed significant improvements on self-reported BPD symptoms along with improvements on hopelessness, psychological flexibility, emotion regulation, mindfulness and fear of emotions. The results appear promising however the TAU condition received six hours of treatment compared to 24 hours in the active treatment condition. Furthermore, both studies had small samples and the control condition did not include an active treatment which is a better control than TAU.

1.4.2.2. Evidence for ACT in somatic conditions.

Chronic pain has by far the largest amount of research regarding ACT. Johnston, Foster, Shennan, Starkey, and Johnson (2010) utilised a self-help intervention within a chronic pain population comparing ACT to a WLC. A total of 14 participants, 11 in the ACT group and eight in the WLC were included in the study. The ACT group read a self-help book for a six-week period with weekly telephone support. Significant improvements were noted for acceptance, QoL, satisfaction with life, values and pain ratings. The study however had a small sample size and the control group was inappropriate as a comparison because it did not involve an active treatment.

Mo'tamedi, Rezaiemaram, and Tavallaie (2012) conducted a RCT with an all-female chronic pain population comparing ACT with TAU. Eleven participants in the ACT group received eight weekly sessions of therapy plus TAU (medical treatment) compared to 15 in the TAU only group. They found that the ACT group reported significant improvements regarding affective distress and disability. The study however did not use an appropriate control group such as an alternative therapy and had a small sample size.

Buhrman et al. (2013) conducted a RCT utilising an internet-delivered ACT for chronic pain. Thirty-eight participants were allocated to either receive a seven week internet ACT for chronic pain compared to a control group that took part in a moderated online discussion forum. The authors report that the ACT group showed significant increases regarding activity engagement and pain willingness based on the Chronic Pain Acceptance Questionnaire (CPAQ) which is a chronic pain version of the AAQ-II. Furthermore, reductions were also noted regarding pain-related distress, anxiety and depressive symptoms. The control group used in this study was not appropriate given that it was not an active therapy and it was only moderated and not monitored for activity. The authors also acknowledge that the large number of outcome measures used in the study may have inflated the risk of chance findings.

McCracken, Sato, and Taylor (2013) randomised 73 participants to either ACT for chronic pain (n=37) or TAU (n=36). The ACT condition included 4 four-hour group sessions over two weeks. Participants in the ACT group at post-treatment demonstrated lower depression and higher ratings of overall improvement. At three-month follow the ACT group reported lower disability, less depression and significantly higher pain acceptance. Intent-to-treat analysis revealed only significant effects in favour of ACT for depression and disability. The study had adequate power to detect effects however the control group was not suitable as it was TAU and not an active treatment control.

Hesser et al. (2012) applied a self-help internet-delivered ACT protocol with a tinnitus population compared to an internet-delivered CBT protocol. In this RCT 35 participants received ACT and 32 CBT with an additional 32 in a control group involving a monitored internet discussion forum. They reported significant improvement regarding tinnitus severity and distress in both the ACT and CBT group compared to the control at post-treatment. Furthermore, they reported no significant

difference between ACT and CBT highlighting that ACT may be a viable alternative to traditional CBT in the management of tinnitus. This study had a much larger sample size compared to the studies described above. The control condition was an internet discussion forum and therefore nonspecific effects cannot be ruled out (i.e., having a forum may provide attention and emotional/social support). The CBT and ACT protocols differed regarding their content in that the CBT protocol utilised written text with the ACT protocol relying more on pictorial information and experiential exercises. The evidence for internet-delivered or self-help ACT protocols is still in its infancy and therefore there is a need for more research in this area before this can be deemed a viable alternative approach.

Gregg, Callaghan, Hayes, and Glenn-Lawson (2007) conducted an RCT within a diabetic population. Eighty-one participants were randomised to an ACT plus education group (n=43) or education group alone (n=38). The education group received advice on how to manage their diabetes better during a seven-hour workshop. The ACT group received an abbreviated version of the education (four-hours) as well as mindfulness and acceptance training. The authors found that participants in the ACT group had significantly more control over their glucose levels compared to the controls. Furthermore, the ACT group scored better on self-management which included self-reported items regarding diet, exercise and glucose monitoring. Finally, the ACT group scored higher on a diabetic measure of psychological flexibility compared to controls. In this study the fidelity to the treatment manual was not assessed and the ACT intervention was delivered by a single therapist. Furthermore, the self-management index did not represent a comprehensive set of behaviours which are pertinent to this population such as medication adherence, smoking, alcohol use, foot and eye care.

Lillis, Hayes, Bunting, and Masuda (2009) undertook a RCT by randomly assigning 87 patients that had completed a six-month weight loss program.

Participants were randomised to a one-day ACT intervention (n=43) targeting obesity-related stigma and psychological distress or a WLC (n=44). The ACT condition consisted of a single six-hour workshop in a group based format with participants also receiving a workbook to take away. After a three-month follow up the ACT group had significant improvements on all measures which included; psychological distress, QoL, weight-related stigma, body mass index and percentage weight loss. The study did have its weaknesses particularly with the sample being relatively homogenous as they were predominately white, middle-class, women, from the USA. The control group was a WLC which is not an appropriate control group as there is no active treatment. Lastly the adherence to the ACT interventions was not formally assessed.

Weineland, Arvidsson, Kakoulidis, and Dahl (2012) investigated the utility of an ACT intervention with post-bariatric surgery patients suffering with morbid obesity. A total of 39 patients were randomised to either an ACT intervention (n=19) or TAU (n=20). The ACT group received two face to face sessions, a six-week treatment via the internet and a 30-min support session weekly over the telephone. The authors found that in the ACT group patients scored significantly lower on a measure of eating disorders behaviour which consists of four sub-scales; restraint, eating concerns, weight concerns and shape concerns. There was also a significant improvement in QoL and psychological flexibility as measured on the Acceptance and Action Questionnaire for Weight (AAQW) within the ACT group. The study did suffer with having a small sample size and short-term follow up of three-months considering the aim is long-term weight control. The study relied on self-reports when objective measures such as measuring weight or physical activity would have been more appropriate. The TAU group did not include an active treatment and therefore is not an appropriate control group.

1.4.2.3. Evidence from meta-analyses.

The findings from the RCTs above provide promising evidence regarding the utility of ACT within a number of different populations. ACT has been investigated in a wide range of populations including psychiatric and somatic conditions. Many of the studies outlined above however do have a number of methodological concerns. The control groups in many of the trials have relied on WLC/TAU rather than offering a suitable alternative therapy which has a proven evidence base. Furthermore, studies have suffered with small sample sizes. There have been a number of M-As which have investigated the utility of ACT and evidence is presented below chronologically (A-Tjak et al., 2015; Öst, 2008, 2014; Powers, Zum Vörde Sive Vörding, & Emmelkamp, 2009; Ruiz, 2012; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011). Statistics for ES are presented as Cohen's *d* and the interpretation of these statistics is based on the convention small, medium and large (.2, .5 and .8 respectively) as described by J. Cohen (1988).

Öst (2008) conducted a M-A investigating the efficacy of ACT across a range of clinical presentations. He found a significant medium to large mean ES of, $d = 0.68$, $Z = 5.11$, $p < .001$ based on primary outcomes reported in the RCTs. Primary measures included, anxiety, depression and pain. A test of heterogeneity, a measure of how far the observed ES differs from the true ES, was significant. Therefore further moderator analysis was conducted to interpret the reason for the observed range of ESs. Analysis of the control conditions revealed that ACT vs. WLC yielded a large ES whereas ACT vs. active therapy yielded a medium ES. Therefore studies that included a WLC rather than an active control would report larger ES. Öst (2008) does criticise the evidence base for ACT stating that methodologically it is inferior to evidence based approaches such as CBT.

Powers et al. (2009) analysed 18 RCTs totalling 917 participants utilising ACT across different presentations. They reported that compared to controls ACT was significantly superior with a reported small to medium ES, d = .42, on primary outcome measures. When analysed separately ACT was superior to WLCs and psychological placebos d = .68 and TAU d = .42. However, ACT was not significantly more effective than evidence-based treatments d = .18, p = 0.13. When investigating the utility of ACT across different populations the results were mixed. The authors reported that ACT was superior compared to controls across primary and secondary outcome measures. This conclusion was based on multiple M-As with only a few studies e.g., only two studies were used in the depression M-A. The researchers also state that a majority of studies utilise TAU which is not an appropriate control group due to the lack of an active treatment.

Veehof et al. (2011) investigated the effectiveness of ACT within a chronic pain population utilising an M-A. The authors included 22 studies, nine RCTs, five control studies without randomisation and eight uncontrolled studies totalling 1235 participants. The combination of both controlled and uncontrolled studies yielded a significant small to medium ES for ACT, d = .43, Z = 4.06, p < .01 for the primary outcome, pain. The combination of both controlled and uncontrolled studies yielded a significant medium to large ES for ACT, d = .63, Z = 3.58, p < .01 for the secondary outcome, QoL. The authors stated that only two studies met the criteria of high quality in their M-A again criticising the methodology used in these studies.

Ruiz (2012) compared the relative effectiveness of ACT against CBT using a M-A. Sixteen studies totalling 954 participants across different populations (e.g., depression, anxiety disorders, smoking, cancer, stress) were included. Ruiz (2012) reported that the small to medium mean ES significantly favoured ACT compared to CBT based on primary outcomes, d = .40, Z = 3.23, p = .001. ESs for depression (d = .27), anxiety (d = .14) and QoL (d = .25) favoured ACT but were not statistically

significant. The M-A also investigated how well ACT and CBT affected their respective putative processes of change. ACT affected more on its processes of change (e.g., psychological flexibility) compared to CBT (e.g., cognitive restructuring) leading to the conclusion that ACT produces better outcomes and works through different processes than traditional CBT. The studies used in the M-A suffer with small sample sizes and methodological problems such as subclinical psychological problems and non-randomised trials. The use of varied populations may also provide ranging ESs as each therapy may be more or less effective in different populations.

Öst (2014) conducted a large scale M-A including all the reported RCTs that have investigated the efficacy of ACT in any population (e.g., psychiatric disorders, somatic disorders and stress at work) since 1986 in order to update a previous M-A (Öst, 2008). 60 RCTs totalling 4234 participants were included. A small to medium ES was calculated across all comparisons, $d = .42$, $Z = 7.47$, $p < .001$ which was smaller than the previous M-A, $d = 0.68$, $Z = 5.11$, $p < .001$ (Öst, 2008). Öst (2014) concluded that ACT is not yet a well-established treatment for any disorder. Furthermore, that ACT is 'probably efficacious' for chronic pain and tinnitus whereas it is 'possibly efficacious' for depression, psychotic symptoms, OCD, mixed anxiety, drug abuse and stress at work; and that ACT is 'experimental' for nicotine dependence, borderline personality disorder, trichotillomania, epilepsy, overweight/obesity, diabetes, multiple sclerosis and ovarian cancer based on additional analyses. Öst (2014) argues that the current evidence base of ACT is lacking in methodological quality which has not improved since his previous M-A and therefore many of the claims of its effectiveness or superiority (Ruiz, 2012) are unfounded. The conclusions made by Öst regarding the efficacy within this M-A was based on an unrestricted inclusion criteria resulting in a range of studies investigating sub-clinical populations. Utilising sub-clinical populations may also make it more

difficult to effectively measure change as participants would already be scoring at the lower level on measures. The inclusion of studies not treating clinically relevant disorders such as stress at work may have had an effect on the overall ES. Investigating all possible M-As that have utilised ACT makes the interpretations of the results much more difficult. The interpretation of the overall ES is relevant to all sub-groups and therefore it is not possible to separate out each clinical group. Furthermore, the assessment of methodological quality was conducted by the author and not cross checked to allow for investigation of the inter-rater reliability which may have introduced bias.

A-Tjak et al. (2015) undertook an M-A of ACT for clinically relevant mental and physical health problems. 39 studies totalling 1,821 participants with mental disorders or somatic health problems were included. The authors concluded that ACT was superior to control conditions and reported a medium ES for primary outcome measures $d = .54$, $p < .001$. ACT was also superior to controls on secondary outcome measures ($d = .30$, $p < .001$), QoL ($d = .37$, $p < .001$) and process measures ($d = .56$, $p < .001$). As previously noted ACT was significantly better than WLC and TAU however ACT was not significantly better than established treatments such as CBT, $d = .32$, $p = .140$). A-Tjak et al. (2015) concluded that ACT outperformed control conditions for primary/secondary outcome measures, QoL and process measures. There was no significant difference between ACT and established treatments however the ES for ACT was slightly larger. The authors concluded that ACT therefore could be considered as an alternative to CBT within the populations under investigation. In contrast to Öst (2014), the authors reported a relative improvement in methodological quality over the years since the first Öst review (Öst, 2008) but did acknowledge that studies with greater quality reported smaller ESs.

Following the publication of A-Tjak et al. (2015), there has been correspondence between researchers (Hertenstein & Nissen, 2015; Morina, A-Tjak, &

Emmelkamp, 2015) regarding the contradictory findings between this M-A and Öst (2014). The correspondence highlighted the methodological issues pertaining to conducting a M-A and how selection of different procedures can result in different results. Morina et al. (2015) argued that the A-Tjak et al. M-A included stricter inclusion criteria invoving only clinically relevant populations (e.g., excluding studies investigating work stress). Secondly the statistics utilised intent-to-treat analysis and completer analysis separately where applicable, and a comparison of the differences. Thirdly, the rating of methodological quality was conducted by two of the authors to remove bias. Lastly, the criterion applied to examine the efficacy of ACT was based on the findings from the M-A and not the criteria for well-established treatments of the American Psychological Association (APA). The conclusions drawn by Öst actually contradict the assertions of the APA (Division of Society of Clinical Psychology) which state there is strong research support for using ACT in chronic pain and modest support in depression, mixed anxiety, OCD and psychosis (http://www.div12.org/psychological-treatments/treatments/).

1.4.2.4. Summary of evidence.

The evidence above highlights the growing research base for ACT and its potential utility across a number of varied populations. Research has predominately been conducted across psychiatric and somatic populations with promising findings. Furthermore, data from M-As conducted report ESs ranging from .40 to .68 which represent small to medium effects of ACT across a diverse population. It should be noted that despite these promising findings a number of concerns have been raised regarding the methodology of many studies. In summary these include the use of WLC and TAU as control groups instead of active treatments that have a recognised evidence base; and small sample sizes with unrepresentative participants some of whom do not have a formal diagnosis. There has been a debate about how issues such

as these have been addressed since they were first highlighted (A-Tjak et al., 2015; Hertenstein & Nissen, 2015; Morina et al., 2015; Öst, 2014). There will always be more room for well controlled high quality studies investigating the efficacy of any treatment program. This will go a long way to help make clearer the picture regarding the utility of ACT across a diverse population (S. C. Hayes et al., 2006).

1.5. Rationale

There is evidence to suggest that ACT may have potential in reducing psychological distress in a range of populations (A-Tjak et al., 2015; Öst, 2008, 2014; Powers et al., 2009; Ruiz, 2012; Veehof et al., 2011). However the sequelae of chronic health conditions can have a wide reaching effect on different areas such as QoL. The purpose of this current thesis is to investigate the efficacy of ACT on improving QoL in people who have chronic health conditions via a M-A. Based on the authors knowledge there does not appear to have been a previous review that has specifically investigated the efficacy of ACT in improving QoL in patients with chronic physical conditions.

Previous reviews of ACT have concentrated on how symptoms such as anxiety and depression are improved. Mental health has predominately been viewed as the absence of psychopathologies such as anxiety and depression (Westerhof & Keyes, 2010). The contemporary approach to understanding mental health has been more concerned with not just the absence of mental illness but also the presence of mental health (Friedli, 2009). Friedli (2009) further argues that people suffering with mental health difficulties should be taught psychological skills to help them cope with their suffering rather than focus on changing how they think which may or may not change their mood. This is especially pertinent within the ACT philosophy and the chronic health population which we know affects many aspects of functioning and well-being and not just mental health.

QoL was chosen as an outcome measure as it was considered to better reflect the effects of chronic health conditions compared to simply the presence of mental health difficulty. Chronic health conditions appear to be associated with reductions in physical, social and mental well-being and functioning. QoL is a multi-dimensional construct and possibly for this reason it has become an important clinical outcome measure within this population (Arnold et al., 2004). ACT proposes to improve psychological flexibility which is in the service of living a valued life. QoL has been shown to correlate with the AAQ and AAQ-II (Bond et al., 2011; S. C. Hayes et al., 2006). Given the shortcomings of the AAQ and the relatively recent development of the AAQ-II and that it has not always been routinely used, QoL was chosen as an all-encompassing outcome measure especially given its pertinence within this population.

ACT may provide an alternative therapeutic approach which could potentially be suited within the chronic health population. ACT does not aim to reduce psychological distress, but acknowledges that this can be a by-product; instead it tries to improve flexibility with the aim of living a valued life. This approach resonates with the aims of treatment within the chronic health population and therefore may be an efficacious approach to improving the QoL.

1.6. Research Questions

The aim of this thesis is to review the efficacy of ACT for improving QoL in individuals with a chronic health condition, via a M-A. Secondary questions relate to investigating sub-groups analysis.

Primary Research Question

1. Is ACT an effective treatment in improving QoL for people with chronic health conditions?

Secondary Research Questions

2. Does study quality mediate changes in QoL?

3. Does treatment intensity (time) correlate with effect size?
4. Does publication date correlate with effect size?
5. Does the control group (WLC/TAU vs. active control) mediate changes in QoL?

Chapter Two: Methodology

2.1. Overview

The following chapter outlines the methodology. It begins with a description of the inclusion and exclusion criteria which contains; participants, intervention, study design and outcomes. Next the search strategy is described followed by the procedure for data extraction, ES calculation and study quality assessment. Finally the process of the meta-analysis is described including how threats to internal and external validity will be investigated and addressed.

2.2. Inclusion and Exclusion Criteria

2.2.1. Participants.

Studies were included if the participants were 18 years or over. Studies with participants under the age of 18 were excluded unless the data could be separated in the analysis. Included participants must have been suffering from a chronic physical health condition. There is no universal agreed definition of 'chronic health condition' and therefore there was a need for a clear definition that would be used in this study. The definition below was utilised in this research (O'Halloran et al., 2004).

A chronic health condition was defined as a condition which has:

a) A duration that has lasted, or is expected to last, at least six months
b) A pattern of reoccurrence or deterioration
c) A poor prognosis
d) Consequences or sequelae that impact on the individual's quality of life

2.2.2. Intervention.

Studies were included that utilised ACT as described by Steven Hayes (S. C. Hayes et al., 1999, 2011). Some researchers have described 'acceptance-based' interventions which utilise the principles of ACT varyingly. Studies that have utilised an acceptance-based approach which have utilised only one or two components of ACT were excluded as has been the protocol in a recent M-A (Öst, 2014). This was to ensure the integrity of the intervention was maintained and that clear conclusions could be drawn about the efficacy of ACT per se rather than a derivative of the approach. ACT can be delivered 1:1 or as group therapy and should be administered by therapists with relevant experience. A number of protocols developed for different target populations are documented on the Association for Contextual Behavioural Science website (http://contextualscience.org/treatment_protocols), however ACT tends not to follow a strict manualised approach but adheres to the principles outlined by Steven Hayes (S. C. Hayes et al., 1999, 2011). There is however a great emphasis on the need to adhere to its core principles which have been outlined in the introduction in section 1.4 (S. C. Hayes et al., 1999, 2011). Treatments administered only via self-help or over the internet were excluded to ensure treatment fidelity.

2.2.3. Study design.

Quantitative studies that were written in English were included. This included controlled studies that utilised a control or comparison group e.g., active control, WLC or TAU with or without randomisation. Uncontrolled studies were not excluded from this M-A as research into ACT is still developing. Single case series, case studies, and qualitative studies were excluded. Previous systematic reviews, M-A, or studies reporting previously published data were also excluded to avoid duplication of data (Senn, 2009). Studies that did not provide relevant information to calculate ESs were also excluded unless it was possible to gain data from the authors.

2.2.4. Outcome.

The primary outcome measure was QoL. Within the literature there is a broad agreement that QoL is a multidimensional construct that encompasses the subjective experience of physical and psychosocial aspects of a person's life (Ali et al., 2010; McDowell, 2006; Speight et al., 2009). Studies were included if they utilised any self-report measure that measured QoL pre and post intervention. Studies that utilised more than one measure of QoL were subjected to a selection process with the measure that was theoretically and psychometrically superior being selected. Studies that utilised only a single item measure of QoL (e.g., visual analogue scales) were excluded as they do not adequately measure the multifaceted construct of QoL (Cella, 1994).

2.3. Systematic Search Strategy

2.3.1. Databases searched.

The following psychological, medical, and allied health professionals' databases (PsychINFO, MEDLINE and CINAHL Plus) plus Google Scholar were searched, as well as the Cochrane Library:

1. PsychINFO (1880s onwards) is an electronic abstracting and indexing database compiled by the American Psychological Association. It searches behavioural and mental health literatures and has more than 3.7 million records which are updated weekly. PsychINFO covers approximately 2,562 journals, books and dissertations from more than 50 countries.
2. MEDLINE (1946 onwards) is the leading electronic bibliographic database of articles in the life sciences, with a focus on biomedicine and health. It is compiled by the National Library of Medicine in America and has over 24.6 million records from over 5,600 worldwide journals, with weekly updates.

3. CINAHL Plus (1937 onwards) is an electronic indexing database provided by EBOSCO Publishing. It searches literature related to nursing, allied health professionals, biomedicine and healthcare. There are over 4.2 million records from approximately 5,015 journals.
4. Google Scholar is a freely accessible web search engine that indexes the full text or metadata of scholarly literature across disciplines and publishing formats. It includes most peer-reviewed online journals across Europe and America's largest scholarly publishers. It has been estimated that Google Scholars database includes 160 million documents.
5. The Cochrane Library is a collection of databases in medicine and other healthcare specialities provided by the Cochrane Collaboration. It hosts the collection of Cochrane Reviews, a database of systematic reviews and M-As which summarise and interpret the results of research. The library aims to make the results of well-conducted controlled trials available and is a key resource in evidence-based medicine.

2.3.2. Search terms.

Articles were sought by combining key words, as summarised in Table 2.1. Search terms included UK and USA terminology and truncation. Studies published/completed after 1980 were included; following the development of ACT into a formalised therapy in the 1990s (S. C. Hayes et al., 1999). An age filter was also applied to ensure that only studies with participants aged 18 and over were included.

Table 2.1.

Search Terms used for the Systematic Literature Search

Category	Search terms
1. Target population	Chronic OR Physical OR Medical OR Health OR Condition OR Disease
2. Intervention	Acceptance and commitment therapy OR Acceptance-Based OR ACT
3. Outcome data	Quality of life OR Life-satisfaction OR Well-being
4. Research	Random* OR Trial OR RCT OR Study
5. Search string	1 AND 2 AND 3 AND 4

2.3.3. Additional searches.

To ensure that the literature search was as comprehensive as possible a number of additional search strategies were used. The ancestry method was used to identify relevant articles from the reference lists of included studies based on the initial search; review articles references were also searched. Furthermore, key journals such as the Journal of Contextual Behavioural Science, the Journal of Psychosomatic Research, the British Journal of Health Psychology, Psychosomatic Medicine and Pain were searched with the term 'Acceptance and Commitment therapy'. The Association for Contextual Behavioural Science website (http://contextualscience.org/ACT_Randomized_Controlled_Trials) has a list of RCTs that have utilised an ACT protocol. The website was searched to identify if any studies were appropriate that had been missed by the initial search. Key researchers within the field were also contacted via email with a request to identify any relevant ongoing or unpublished research.

2.3.4. Initial study screening.

The titles and abstracts of the studies were read to determine whether they met the inclusion criteria. In instances where further information was required the full text of the article was read. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram (PRISMA; Liberati et al., 2009) has been included. The PRISMA diagram outlines; identification, screening, inclusion and exclusion of all articles throughout the process with clear justifications (see Section 3.2).

2.4. Data Extraction

Information was extracted from the research articles in a systematic format using a data extraction form (see Appendix A). Data that was difficult to interpret or missing was requested directly from the authors via email. Data extraction was completed by the primary researcher and checked for completeness and accuracy by the primary supervisor. Disagreements where they occurred were resolved following discussions.

2.4.1. Effect sizes

It was expected that researchers would use different measures of QoL (Speight et al., 2009). It was therefore important to have a standardised measure of ES to measure the effect of ACT on QoL across the studies. The decision was made to use the standardised mean difference (SMD) as a measure of ES. The SMD is a measure of the treatment effect in each study and is relative to the variability observed within that study (Borenstein, Hedges, Higgins, & Rothstein, 2011; Lipsey & Wilson, 2000). ESs (SMD) were calculated using Hedges' *g* which is a conservative measure of ES based on Cohen's *d* and corrects for possible positive bias in studies with small sample sizes (J. Cohen, 1988; Hedges, 1981). The standard error and variance of *g* was calculated and interpreted based on the convention small, medium and large (.2,

.5 and .8 respectively) as described by J. Cohen (1988). Studies that utilised multiple comparison groups were subjected to a selection process. Primarily, active treatment groups were selected over WLC/TAU as they represented a better quality control group. All ESs were calculated with the Cochrane Collaboration Review Manager Software (RevMan Version 5.3, 2014).

2.5. Study Quality Assessment

When conducting a M-A it is important that the included research is of good methodological quality to ensure the integrity of the M-A. Included studies were screened to assess the methodological quality of the research. It has been recommended by PRISMA that a checklist or component approach is used rather than scales due to problems with reliability (Liberati et al., 2009). The NICE Quality Appraisal Checklist for Quantitative Intervention Studies (NICE, 2012) was used to assess study quality (see Appendix B). The NICE checklist allows for the appraisal of internal and external validity of both randomised and non-randomised trials. The checklist was completed for each study included in the M-A by the primary researcher and primary supervisor independently in order to check for reliability. Each study received a score based on 27 ratings. Two ratings were excluded because they were summary scores, therefore a total of 25 coded ratings were utilised for each included study. The inter-rater reliability was assessed using the Kappa statistic (Altman, 1991).

2.6. Meta-analysis

2.6.1. Model.

There are two ways in which a M-A can be conceptualised: fixed-effect and random-effects models (Borenstein et al., 2011). The fixed-effect model assumes that the studies included in a M-A are sampled from a population that has a fixed but

unknown ES. Therefore, sample ESs are expected to be homogeneous because they have been derived from the same population which has a fixed average ES. Consequently, any variation in the distribution of ES is thought to be the result of purely sampling error (Cohn & Becker, 2003; Lipsey & Wilson, 2000).

The second method is the random-effects model, which assumes that population ESs vary randomly from study to study. In reality, and especially within psychological research, it can be argued that there is not always a common ES within a sample from the population (Field, 2003). The studies included in a M-A are thought to be each sampled from a distribution of population ESs that naturally vary in their average ES (Hedges & Vevea, 1998; Hunter & Schmidt, 2000), related to factors such as methods used and the context of the research (Cohn & Becker, 2003; Field, 2003; Hunter & Schmidt, 2000). Therefore, the studies included in a M-A can be thought of as being sampled from a 'superpopulation' of possible effects and the overall ES is an estimate of the mean of the superpopulation's ES distribution.

Depending on the choice of model used in the M-A there is a subtle variation regarding the statistical standpoint. The main difference is regarding the source of error that is accounted for. In fixed-effect models, there is within-study error which is the result of sampling studies from a population of studies. This error is present within random-effects models but, in addition, between-study error is also assumed as a result of sampling studies from individual sub-populations which make up the 'superpopulation'.

2.6.1.1. Rationale for using a random-effects model.

Following the recommendation by Borenstein et al. (2011) and Lipsey and Wilson (2000), a random-effects model was used here for two principal reasons. First, research within social sciences is inherently conducted by a range of researchers using a wide and varied array of methodologies which ultimately results in variability in

ESs as the norm (Borenstein et al., 2011; Field, 2003, 2005; Hunter & Schmidt, 2000). It was expected that studies would differ regarding the intervention, diagnosed condition and outcome measures used. Secondly, the inferences made from a random-effects model are relatively unconditional and may be applied to a population of studies larger than the sample. A fixed-effect model is appropriate for making inferences that extend to only the studies included in the analysis. Since social science researchers hope to extend their findings to subsequent research, including previous research, or research that may have not been included in the M-A a random-effects model is appropriate (Borenstein et al., 2011; Cohn & Becker, 2003; Hedges & Vevea, 1998; Hunter & Schmidt, 2000).

2.6.2. Sensitivity analysis.

The process of undertaking a M-A involves making various decisions about the choice of articles that are under review, and about the methods of analysis. It is important to ensure that findings are robust and not a result of the decisions made in the process of obtaining them (Deeks, Higgins, & Altman, 2011). Thus the M-A should be repeated under different assumptions and after different decisions to see how far the obtained findings are consistent.

2.6.3. Heterogeneity assessment.

As part of conducting a M-A there is an underlying aim to attempt to measure and control for heterogeneity. The two sources of variability, within-study and between-study, must be assessed for and their effect minimised to ensure the robustness of the M-A. Within-study variability is an ever present within a M-A as every study uses a different sample (Huedo-Medina, Sánchez-Meca, Marín-Martínez, & Botella, 2006). There are a number of factors which can affect between-study

variability such as participants, measures, treatment conditions, study designs and so on (Borenstein et al., 2011; Cohn & Becker, 2003; Field, 2003).

2.6.3.1. The I^2 statistic test.

The I^2 statistic was used to explore heterogeneity as it provides a measure of variability across studies that is due to heterogeneity rather than chance (Higgins & Thompson, 2002). The rational for using the I^2 statistic compared to the Cochran *Q* test is the ability to quantify heterogeneity. Furthermore it provides a measure of the degree of inconsistency in the study's results and there is no reliance on the number of studies used in the analysis (Higgins & Thompson, 2002; Higgins, Thompson, Deeks, & Altman, 2003; Huedo-Medina et al., 2006). The following classifications were used to assess the level of heterogeneity; High (75%), Medium (50%) and Low (25%) (Higgins et al., 2003).

2.6.4. Publication bias.

Publication bias, or the 'file drawer problem' (Rosenthal, 1979), describes the tendency for the dissemination of research to depend on results (Vevea & Woods, 2005). Bias could possibly manifest itself if only those studies with significant results are published and all other studies are left unpublished. This situation could arise because researchers are less likely to write up and submit these studies, or because journal editors and reviewers are unlikely to publish them (Vevea & Woods, 2005). This would result in M-As over estimating the population ES, potentially leading to inappropriate conclusions. The results from a M-A are often used to make practical recommendations for medical or psychological interventions and therefore there is a need to address this bias. A number of authors have suggested strategies for eliminating or preventing publication bias in the long-term, as well as statistical methods for detecting and correcting for it (Vevea & Woods, 2005).

Publication bias has traditionally been assessed using funnel plots whereby ESs are plotted against sample sizes (Light & Pillemer, 1984). A skewed and asymmetrical plot may indicate a bias and a potential 'file drawer problem' (Greenhouse & Iyengar, 2009; Rosenthal, 1979). In this scenario the fail-safe N (Rosenthal, 1991) has historically been the method used to assess the effect of bias. Funnel plots require a large number of studies ranging in sample size, suffer from low inter-rater reliability (Song, Hooper, & Loke, 2013) and bias is not the only source of asymmetry in plots (Egger, Smith, Schneider, & Minder, 1997). Different formulas for the fail-safe N can lead to varying estimations and they do not take into account heterogeneity and are more concerned with significance than ES (Becker, 2005). In light of the concerns, preliminary inspection of the forest plot was undertaken to see if there was a skew towards smaller studies having larger ESs.

2.6.4.1. Orwin's fail-safe N.

Orwin's fail-safe N (Orwin & Boruch, 1983) allows the researcher to specify how many studies it would take to bring the ES down to the smallest effect deemed of substantive importance (i.e., clinical significance). If the resulting N is relatively small it would indicate a reason for publication bias (Borenstein et al., 2011). This method was used to assess for the presence of publication bias (see Section 3.4.3).

2.6.5. Moderator variables.

The purpose of a M-A is to determine the effect of a given treatment on a certain sample from the population (Borenstein et al., 2011). In this research the effect of ACT on QoL within a chronic health sample was investigated. The nature of synthesising research inevitably involves analysing studies that have a wide range of methodologies (Öst, 2008, 2014). This introduces into the M-A a range of variables that can affect what the researcher is interested in, the ESs. These variables are known

as moderator variables and can affect the strength and the direction of the ESs. Potential moderator variables include; overall study quality, study type (randomised vs. non-randomised), treatment intensity etc. Essentially, a moderator variable can be anything that could affect the strength and direction of the ES. The effect of moderator variables is described in the results section and explored later in the discussion section (see Section 3.4.2.1 and 4.2).

Chapter Three: Results

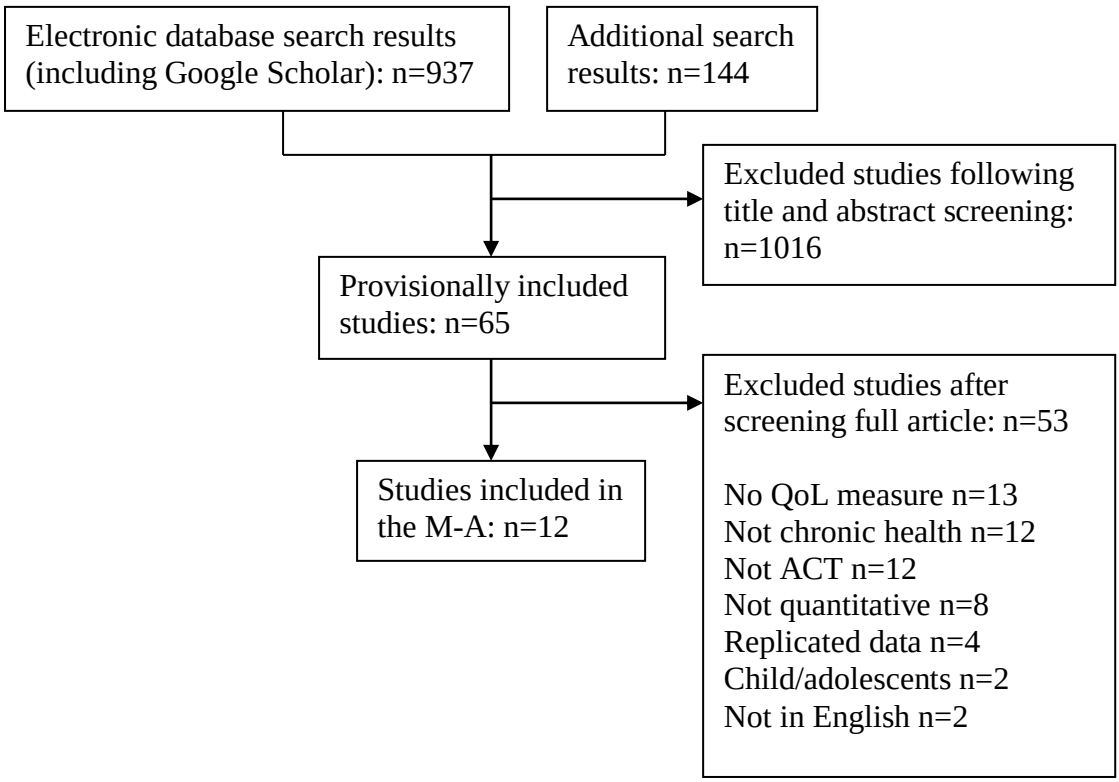
3.1. Overview

The chapter begins with a detailed account of the outcome from the literature search including a PRISMA diagram. A description of the included/excluded studies and study quality is also provided. The findings from the within and between-group M-A which includes further sub-group analyses and assessment of publication bias are reported. The results chapter presents the findings from the M-A with the aim of answering the primary research question regarding the efficacy of ACT in improving QoL within a chronic health population. The findings from moderator analysis are outlined as part of the secondary research questions.

3.2. Literature Search Outcome

The literature search was completed on 23rd April 2015 and yielded a preliminary database of 1081 articles from the electronic databases, Google Scholar and additional searches outlined in section 2.3 (see Figure 3.1). This initial pool of studies was reviewed (titles and abstracts) to determine eligibility. The full articles of potential studies were acquired and subjected to the inclusion and exclusion criteria (see Section 2.2) resulting in a final group of studies (see Figure 3.1 and Table 3.2).

Figure 3.1. PRISMA flow diagram.



3.2.1. Included studies.

Of the 1081 published studies 65 (6.01%) were identified for potential inclusion following the screening of the title and abstract. The majority of articles excluded during the initial screen included; books, book chapters, theses and review articles including M-As. A number of articles were not intervention studies and some studies utilised samples that did not include chronic health conditions. Following the full review 12 studies of the 1081 (1.11%) were included in the M-A based on meeting the inclusion and exclusion criteria. Studies included in the M-A are described in detail in Table 3.2.

The 12 studies included in the M-A collectively investigated ACT with 788 participants with a mean age of 46.7 years (SD = 11) with a range of 18 to 89. Studies were primarily controlled trials (83%) and used an active control group (n = 6) or

WLC/TAU (n = 5). One study did not utilise a control group (Feros, Lane, Ciarrochi, & Blackledge, 2013) and one study was not randomised (Dindo, Recober, Marchman, Turvey, & O'Hara, 2012). The most common disorder studied was chronic pain (n = 5) followed by cancer (n = 3). Eleven studies reported information on the hours of therapeutic contact (mean = 9.23, SD = 4.03) which ranged from 4 to 18. Eleven studies measured QoL after a follow-up period which ranged from 3 to 18 months post intervention (mean = 8, SD = 4.86). Eight different self-report measures were used to measure QoL and are reported in Table 3.1. All scales measuring QoL had either acceptable or good internal consistency (.7 to .9) as measured by Cronbach's alpha (Cronbach, 1951).

Table 3.1.

Description of Quality of Life Measures

Measure	Description	Internal Consistency (Cronbach's α)
FACT-C	A measure of physical, emotional, functional and social well-being across four domains with additional questions related to colorectal cancer	.84
FACT-G	A measure of physical, emotional, functional and social well-being across four domains	.87
LSQ	A measure of physical health and social functioning across six domains	.70 to .90
QOLI	A measure of general QoL, physical health and social well-being.	.79 to .89
SF-36	A measure of physical, emotional, psychological and social well-being	.79 to .93
SF-12	A measure of physical, emotional, psychological and social well-being with fewer items than the SF-36	.81 to .84
SWLS	A measure of global life satisfaction	.87
WHOQOL-BREF	A global measure of QoL across four domains, physical health, psychological, social relationships and environment	.81 to .90

Note. FACT-C: The Functional Assessment of Cancer Therapy-Colorectal is from Ward et al. (1999); FACT-G: The Functional Assessment of Cancer Therapy-General is from Cella et al. (1993); LSQ: Life Satisfaction Questionnaire is from Carlsson, Hamrin, and Lindqvist (1999); QOLI: Quality of Life Inventory is from Frisch, Cornell, Villanueva, and Retzlaff (1992); SF-36: The Short Form-36 Health Survey is from Ware and Sherbourne (1992); SF-12: The Short Form-12 Health Survey is from (Ware, Kosinski, and Keller (1996); Ware, Kosinski, Turner-Bowker, and Gandek (2002)); SWLS: The Satisfaction With Life Scale is from Diener, Emmons, Larsen, and Griffin (1985); WHOQOL-BREF: The World Health Organization Quality of Life, short version is from Herrman et al. (1998).

Table 3.2.

A Description of the Included Studies

Study ID	Diagnosis	Group	N[a]	Mean age (SD)	ACT intensity (minutes)[b]	QoL measure	Follow-up (months)	Between ES*	Within ES (pre to post)*	Within ES (post to follow-up)*
Dahl *et al.* (2009)	Chronic pain/Stress	ACT TAU	11 8	37.6 44.4	240	LSQ	6	.236	.122	-.163
Dindo *et al.* (2012)	Migraine	ACT WLC	31 14	32.5 (13.3) 33.5 (12.9)	240	SF-36	3	.661	.683	.427
Feros *et al.* (2013)	Cancer	ACT -	28	51.8 (18.3)	405	FACT-G	3	No Control group	.547	-.037
Hawkes *et al.* (2014)	Colorectal Cancer	ACT TAU	171 176	- -	-	FACT-C	6	.183	Unable to calculate	.183
Lundgren *et al.* (2006)	Epilepsy	ACT Attention placebo	14 13	38.9 42.5	540	WHOQ OL-BREF	12	.355	.604	.929
Lundgren *et al.* (2008)	Epilepsy	ACT Yoga	10 8	21.9 25.8	540	WHOQ OL-BREF	12	-.364	.748	.168
Rost *et al.* (2012)	Ovarian cancer	ACT CBT	15 16	- -	720	FACT-G	-	.960	.781	No follow-up

Study ID	Diagnosis	Group	N[a]	Mean age (SD)	ACT intensity (minutes)[b]	QoL measure	Follow-up (months)	Between ES*	Within ES (pre to post)*	Within ES (post to follow-up)*
Thorsell *et al.* (2011)	Chronic pain	ACT Relaxation	33 31	- -	390	SWLS	12	.741	.741	.540
Westin *et al.* (2011)	Tinnitus	ACT TRT	21 18	53.5 (12.9) 48.6 (14.5)	615	QOLI	18	.187	.242	.087
Wetherell *et al.* (2011)	Chronic pain	ACT CBT	49 50	- -	720	SF-12	6	-.268	.151	-.064
Wicksell *et al.* (2008)	Whiplash/Chronic pain	ACT WLC	11 9	48.2 (7.8) 55.1 (11.2)	600	SWLS	4	1.008	1.048	-.047
Wicksell *et al.* (2013)	Fibromyalgia /Chronic pain	ACT WLC	20 14	- -	1080	SF-36	3	.356	.330	.023

Note. FACT-C: The Functional Assessment of Cancer Therapy-Colorectal; FACT-G: The Functional Assessment of Cancer Therapy-General; LSQ: Life Satisfaction Questionnaire; QOLI: Quality of Life Inventory; SF-36: The Short Form-36 Health Survey; SF-12: The Short Form-12 Health Survey; SWLS: The Satisfaction With Life Scale; WHOQOL-BREF: The World Health Organization Quality of Life, short version

TRT = Tinnitus Retaining Therapy

*All ESs are presented as Hedge's *g*

[a] N is based on the participants that had complete data and entered into the final analysis which may vary from the number participants recruited.

[b] This is a measure of the total number of therapeutic time with participant's measured in minutes.

3.3. Study Quality

Study quality was assessed by the primary researcher and independently by the primary supervisor using The NICE Quality Appraisal Checklist for Quantitative Intervention Studies (NICE, 2012). This method utilises a checklist approach (see Appendix B) therefore each rating was given a numerical score in order to calculate the inter-rater reliability using the Kappa statistic (Altman, 1991). A total of 300 ratings were computed with each study scoring a potential maximum score of 50 based on 25 possible ratings. The mean score across 12 studies was 32 (SD 6.16). The kappa statistic was calculated as, $k = .73$ which based on benchmarks indicates a 'good' level of agreement between raters (Altman, 1991).

Overall the studies included in the M-A utilised reliable and valid measures of QoL. ACT interventions were described well but many studies did not utilise a treatment manual. A total of six studies utilised an active treatment as the control group (Lundgren, Dahl, Melin, & Kies, 2006; Lundgren, Dahl, Yardi, & Melin, 2008; Rost, Wilson, Buchanan, Hildebrandt, & Mutch, 2012; Thorsell et al., 2011; Westin, Schulin, Hesser, & Karlsson, 2011; Wetherell et al., 2011) and five studies utilised a WLC/TAU control group (Dahl, Wilson, & Nilsson, 2004; Dindo et al., 2012; Hawkes, Pakenham, Chambers, Patrao, & Courneya, 2014; Wicksell, Ahlqvist, Bring, Melin, & Olsson, 2008; Wicksell et al., 2013). There was limited data on therapist ratings and treatment adherence. Many studies were underpowered (Dahl et al., 2004; Lundgren et al., 2006; Lundgren et al., 2008; Rost et al., 2012; Thorsell et al., 2011; Wicksell et al., 2008; Wicksell et al., 2013). Of the studies included in the M-A, five studies (Dahl et al., 2004; Feros et al., 2013; Lundgren et al., 2006; Lundgren et al., 2008; Rost et al., 2012) scored below the median rating of 31.

3.4. Findings from the Meta-Analysis

The following section reports the results of the M-A. Prior to reporting these statistics it is important to clarify that some SMD calculations of Hedge's *g* required additional analysis before the SMDs could be calculated (Dindo et al., 2012; Hawkes et al., 2014; Rost et al., 2012; Wetherell et al., 2011; Wicksell et al., 2013).

Wetherell et al. (2011) and Wicksell et al. (2013) utilised the Short-Form Health Survey (SF-36 and SF-12) which produces two summary scores, the physical component summary (PCS) and the mental component summary (MCS) (Ware et al., 1996; Ware & Sherbourne, 1992). A decision was made to combine the PCS and MCS scores to create a new total score which would then provide a mean and SD to enable the calculation of the SMD. The rationale and justification for this is that the SF-36 and SF-12 both measure fundamental aspects of QoL such as psychological, emotional, social and physical well-being (Ware et al., 1996; Ware & Sherbourne, 1992). Furthermore, research has demonstrated that the underlying factor structure (PCS and MCS) within the SF-36 and SF-12 is correlated (r = .98 to .97) and therefore is measuring the same latent variable (Farivar, Cunningham, & Hays, 2007). Finally, a study already included in this review, has also combined the PCS and MCS scores as they report a SF-36 total score (Dindo et al., 2012). It was therefore deemed appropriate to combine these scores in order to compute the SMD. There was a need to compute a pooled SD and therefore a mean SD was computed which slightly underestimates the true SD. The result of this is a slightly inflated SMD as the SD is underestimated. The estimation of the SD in principle will only be slightly smaller than the true SD and therefore the practical effect on the size of the SMD would be minimal.

Secondly, Hawkes et al. (2014) did not report means and SD for QoL and instead only reported mean change scores and the standard error (SE). It was therefore

necessary to compute the SD and calculate the SMD based on mean change scores. A calculation of the SD was completed using the method described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008). Furthermore, a calculation of the SMD was based on the calculation provided by (Lipsey & Wilson, 2000). There was a need to include the test re-test reliability of the of the QoL measure from the study to calculate the SMD however this was not reported in the Hawkes article. Bausell and Li (2002) recommend that a conservative approach should be taken and that a reliability of .6 should be used which was included in the calculation.

Thirdly, two studies reported only the SE and not the SD for QoL (Dindo et al., 2012; Rost et al., 2012). Therefore a calculation of the SD was conducted as outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008).

Lastly, Feros et al. (2013) was not a RCT and a control group was not used in the design. Since this was the only study in the M-A that did not include a control condition it was decided to remove this study from the overall between-group M-A but to include the results in the within-group M-A.

3.4.1. Within-group M-A.

A total of 11 studies reported data to calculate within-group pre to post ESs and were investigated in order to answer the primary hypothesis. One study did not report any follow up data (Rost et al., 2012) and another did not report statistics to calculate a pre to post ES (Hawkes et al., 2014). ESs were calculated for participants that received the ACT intervention only. This involved isolating the pre, post and follow-up data for individuals that completed the active ACT treatment condition.

Data from 11 studies reporting the pre to post outcomes on QoL were included in a random-effects M-A, it was not possible to calculate the ES for one study

(Hawkes et al., 2014). A small to medium significant ES, $g = .49$, $Z = 5.59$, $p < .001$ (95% CI [0.32, 0.67]) was found for pre to post ES (see Figure 3.2). The test of heterogeneity was not significant, $I^2 = 0\%$, $p = .52$, indicating that there was no significant inconsistency across the studies. This result indicates that people who receive ACT improve on measures of QoL in this M-A.

Data from 11 studies reporting the post to follow-up outcomes on QoL were included in a random-effects M-A, one study did not conduct any follow-up assessments (Rost et al., 2012). A significant ES, $g = .17$, $Z = 2.32$, $p < .02$ (95% CI [0.03, 0.31]) was found for post to follow-up ES (see Figure 3.3). The test of heterogeneity was not significant, $I^2 = 0\%$, $p = .52$, indicating that there was no significant inconsistency across the studies. This result indicates that the treatment effects for ACT are enduring and that participants who undergo ACT will maintain improvements in QoL in the longer-term in this M-A.

Figure 3.2. Forest plot: M-A within-group pre vs. post treatment.

Study or Subgroup	Std. Mean Difference	SE	ACT-Pre Total	ACT-Post Total	Weight	Std. Mean Difference IV, Random, 95% CI
Dahl et al., 2004	0.1223	0.4269	11	11	4.3%	0.12 [-0.71, 0.96]
Wetherell et al., 2011	0.1513	0.1951	57	49	20.6%	0.15 [-0.23, 0.53]
Westin et al., 2011	0.2419	0.3098	21	21	8.2%	0.24 [-0.37, 0.85]
Wicksell et al., 2013	0.3303	0.3123	23	20	8.0%	0.33 [-0.28, 0.94]
Feros et al., 2013	0.5466	0.2452	45	28	13.0%	0.55 [0.07, 1.03]
Lundgren et al., 2006	0.6043	0.3879	14	14	5.2%	0.60 [-0.16, 1.36]
Dindo et al., 2012	0.6833	0.2618	31	31	11.4%	0.68 [0.17, 1.20]
Thorsell et al., 2011	0.7409	0.2266	52	33	15.2%	0.74 [0.30, 1.19]
Lundgren et al., 2008	0.7476	0.4663	10	10	3.6%	0.75 [-0.17, 1.66]
Rost et al., 2012	0.7812	0.3393	25	15	6.8%	0.78 [0.12, 1.45]
Wicksell et al., 2008	1.048	0.4607	11	11	3.7%	1.05 [0.15, 1.95]
Total (95% CI)			**300**	**243**	**100.0%**	**0.49 [0.32, 0.67]**

Heterogeneity: Tau² = 0.00; Chi² = 9.08, df = 10 (P = 0.52); I² = 0%

Test for overall effect: Z = 5.59 (P < 0.00001)

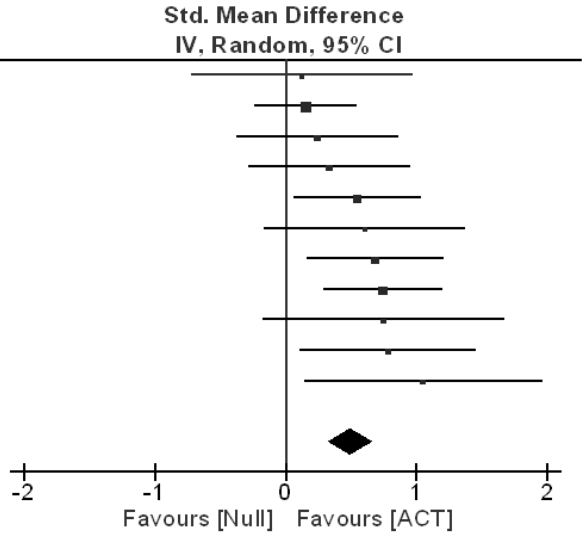
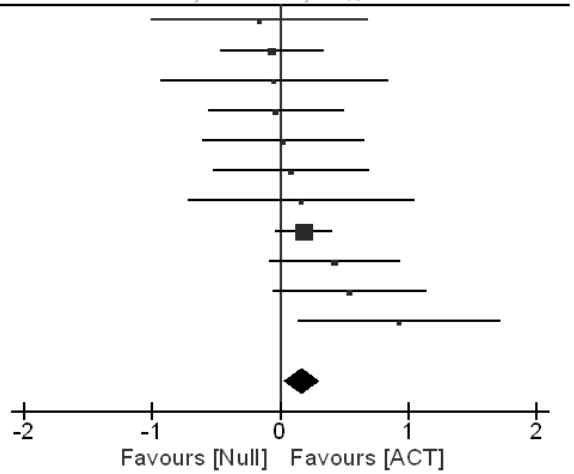


Figure 3.3. Forest plot: M-A within-group post vs. follow-up treatment.

Study or Subgroup	Std. Mean Difference	SE	ACT-Post Total	ACT-Follow Total	Weight	Std. Mean Difference IV, Random, 95% CI
Dahl et al., 2004	-0.1628	0.4273	11	11	2.9%	-0.16 [-1.00, 0.67]
Wetherell et al., 2011	-0.0642	0.2021	49	49	13.0%	-0.06 [-0.46, 0.33]
Wicksell et al., 2008	-0.0473	0.4495	11	9	2.6%	-0.05 [-0.93, 0.83]
Feros et al., 2013	-0.0367	0.2673	28	28	7.4%	-0.04 [-0.56, 0.49]
Wicksell et al., 2013	0.0227	0.3204	19	20	5.2%	0.02 [-0.61, 0.65]
Westin et al., 2011	0.0869	0.3088	21	21	5.6%	0.09 [-0.52, 0.69]
Lundgren et al., 2008	0.1676	0.4482	10	10	2.6%	0.17 [-0.71, 1.05]
Hawkes et al., 2014	0.1832	0.1104	171	159	43.6%	0.18 [-0.03, 0.40]
Dindo et al., 2012	0.427	0.2571	31	31	8.0%	0.43 [-0.08, 0.93]
Thorsell et al., 2011	0.54	0.3038	33	17	5.8%	0.54 [-0.06, 1.14]
Lundgren et al., 2006	0.9292	0.401	14	14	3.3%	0.93 [0.14, 1.72]
Total (95% CI)			**398**	**369**	**100.0%**	**0.17 [0.03, 0.31]**

Heterogeneity: Tau² = 0.00; Chi² = 9.15, df = 10 (P = 0.52); I² = 0%
Test for overall effect: Z = 2.32 (P = 0.02)

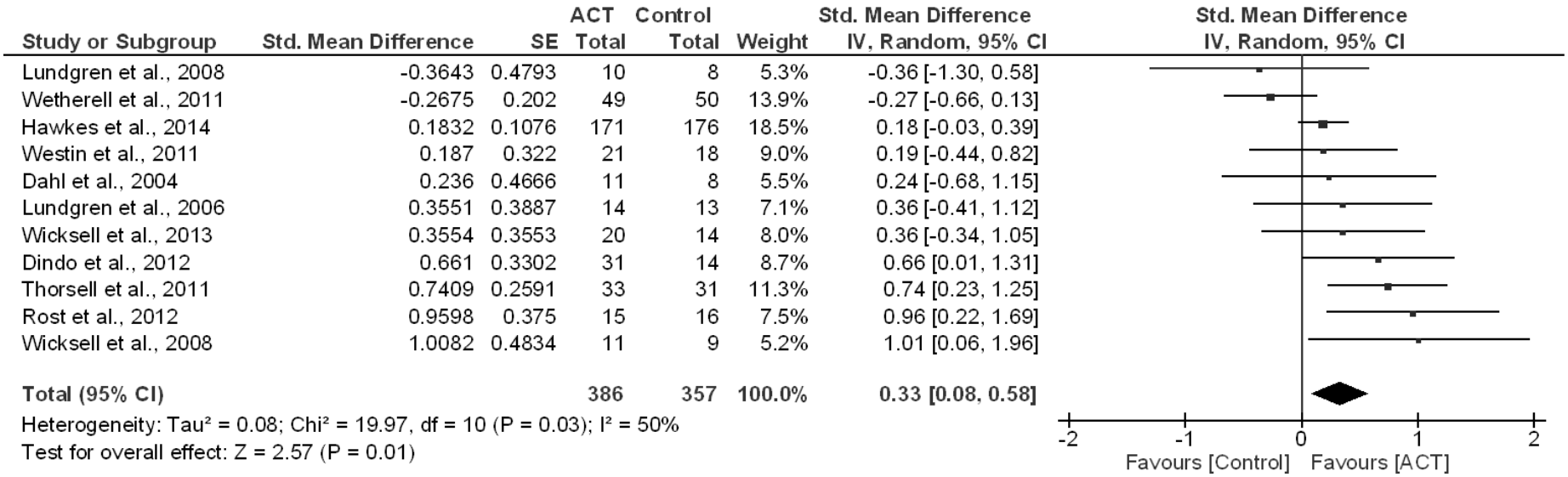


3.4.2. Between-group M-A.

A total of 11 studies compared ACT with a control group and were initially investigated together in order to answer the primary hypothesis. One study compared ACT to two different control groups, a WLC and an active control group (Westin et al., 2011). It was decided to include only the active control data (Tinnitus retraining therapy) from this study in the analysis as this is a better control condition. The WLC data from this one study was removed from the analysis to ensure that the study was not included twice in the M-A. Furthermore, as previously stated, one study did not have a control group and was not included in this analysis (Feros et al., 2013).

ACT led to greater improvements in QoL across all controlled studies. A small to medium significant ES of, $g = .33$, $Z = 2.57$, $p = .01$, (95% CI [0.08, 0.58]) was found (see Figure 3.4). A measure of between-study heterogeneity ($Tau^2 = 0.08$) was small indicating that between-study variance is low. The test of between-study heterogeneity was significant, $I^2 = 50\%$, $p = .03$. Further sub-group analysis were justified as the ESs were not consistent between studies with the I^2 statistic reporting a 'moderate level' of heterogeneity (see Figure 3.2) (Higgins & Thompson, 2002; Higgins et al., 2003).

Figure 3.4. Forest plot: M-A between-groups post treatment.



3.4.2.1. Sub-group analysis.

In order to investigate possible moderating variables, correlation and sub-group analysis was used to investigate the relationship between ES and study quality, treatment intensity (time), publication date, and type of control group (WLC/TAU vs., Active).

3.4.2.1.1. Study quality.

An analysis of the relationship between ES and study quality was conducted. Pearson's correlation coefficient *r* was used to test the relationship, $r(10) = -.13$, $p = .690$ (two-tailed). This finding indicates that there was no significant relationship between study quality and ES.

3.4.2.1.2. Treatment intensity.

An analysis of the relationship between the ES and the amount of therapy offered in the ACT group was conducted. Pearson's correlation coefficient *r* was used to test this relationship, $r(9) = .02$, $p = .953$ (two-tailed). This finding indicates that there was no significant relationship between the amount of therapy offered and the ES.

3.4.2.1.3. Publication date.

An analysis of the relationship between the ES and the publication date of the study was conducted as it has been suggested this can mediate the ES (Light & Pillemer, 1984). Pearson's correlation coefficient *r* was used to test this relationship, $r(10) = .32$, $p = .311$ (two-tailed). This finding indicates that there was no significant relationship between the publication date and the ES.

3.4.2.1.4. Type of control group.

Two further random-effects M-As were conducted to determine the effect of type of control group on the ES (see Figure 3.5 and 3.6). A decision was made to combine WLC and TAU based on the rationale that TAU is still offered to people (i.e., consultations, medication, advice etc.) when in a WLC and that there is substantial ambiguity and overlap in these two types of control groups in the literature (Freedland, Mohr, Davidson, & Schwartz, 2011). An active control was used as a control group in six studies whereas WLC/TAU was utilised in five studies.

A small to medium significant ES, g = .32, Z = 2.11, p = 0.04 (95% CI [0.02, 0.62]) was found when ACT was compared to studies that utilised a WLC/TAU control group (see Figure 3.5). The test of heterogeneity was not significant, I^2 = 27%, p = .24; thus there was no significant inconsistency across the studies.

A small non-significant ES, g = .27, Z = 1.19, p = 0.23 (95% CI [-0.17, 0.72]) was found when ACT was compared to studies that utilised an active control group (see Figure 3.6). The test of heterogeneity was significant, I^2 = 67%, p = .01, indicating a substantial level of heterogeneity.

Figure 3.5. Forest plot: M-A, ACT vs. WLC/TAU.

Study or Subgroup	Std. Mean Difference	SE	ACT Total	WLC/TAU Total	Weight	Std. Mean Difference IV, Random, 95% CI
Dahl et al., 2004	-0.236	0.4666	11	8	9.3%	-0.24 [-1.15, 0.68]
Hawkes et al., 2014	0.1882	0.1076	171	176	51.1%	0.19 [-0.02, 0.40]
Wicksell et al., 2013	0.3554	0.3553	20	14	14.6%	0.36 [-0.34, 1.05]
Dindo et al., 2012	0.661	0.3302	31	14	16.3%	0.66 [0.01, 1.31]
Wicksell et al., 2008	1.0082	0.4834	11	9	8.7%	1.01 [0.06, 1.96]
Total (95% CI)			**244**	**221**	**100.0%**	**0.32 [0.02, 0.62]**

Heterogeneity: Tau² = 0.03; Chi² = 5.51, df = 4 (P = 0.24); I² = 27%
Test for overall effect: Z = 2.11 (P = 0.04)

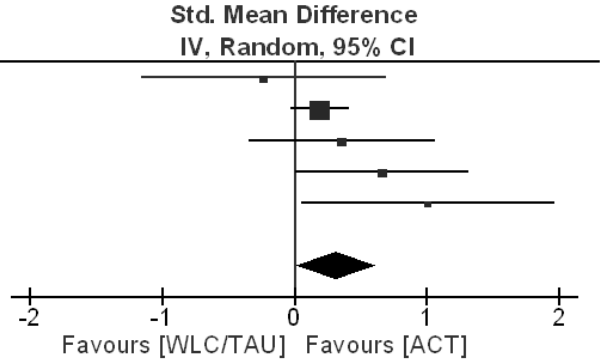
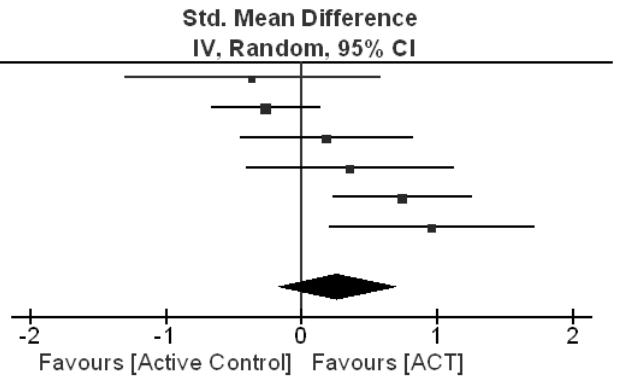


Figure 3.6. Forest plot: M-A, ACT vs. Active control.

Study or Subgroup	Std. Mean Difference	SE	ACT Total	Active Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Lundgren et al., 2008	-0.3643	0.4793	10	8	12.1%	-0.36 [-1.30, 0.58]
Wetherell et al., 2011	-0.2673	0.202	49	50	21.6%	-0.27 [-0.66, 0.13]
Westin et al., 2011	0.1874	0.322	21	18	17.1%	0.19 [-0.44, 0.82]
Lundgren et al., 2006	0.3551	0.3887	14	13	14.8%	0.36 [-0.41, 1.12]
Thorsell et al., 2011	0.7409	0.2591	33	31	19.5%	0.74 [0.23, 1.25]
Rost et al., 2012	0.9598	0.3823	15	16	15.0%	0.96 [0.21, 1.71]
Total (95% CI)			**142**	**136**	**100.0%**	**0.27 [-0.17, 0.72]**

Heterogeneity: Tau² = 0.20; Chi² = 15.21, df = 5 (P = 0.010); I² = 67%
Test for overall effect: Z = 1.19 (P = 0.23)



3.4.3. Publication bias.

In order to assess for publication bias a preliminary inspection of the forest plot was undertaken (see Figure 3.2). Two studies (Rost et al., 2012; Wicksell et al., 2008) reported large ESs and also had small sample sizes. Orwin's fail-safe N was calculated (Orwin & Boruch, 1983). Analysis revealed that seven studies, with an ES of g = .0, or a negative value, would be needed to overturn the obtained mean ES (g = .33) to a small ES of less than, g = .2. As this number (k = 7) is relatively small the results cannot be considered robust to the effects of publication bias. For further discussion of the implications of this finding see section 4.5.2.

Chapter Four: Discussion

4.1. Overview

The chapter begins with a summary of the findings from the M-A and sub-group analysis in relation to the research hypotheses. The theoretical and clinical implications of the research findings are considered. The methodological strengths and limitations of the study are reflected on with suggestions for future research and concluding remarks.

4.2. Summary of Main Findings

4.2.1. Research question 1: Is ACT an effective treatment in improving QoL for people with chronic health conditions?

The results from the within-group M-A revealed that participants suffering with a chronic health condition that received ACT significantly improved on measures of QoL with a small to medium ES (g = .49, p < .001). Next a between-groups M-A revealed that participants suffering with a chronic health condition that received ACT significantly improved on measures of QoL compared to controls with a small to medium ES (g = .33, p = .01). Furthermore, a within-group M-A revealed that improvements post treatment were maintained at follow-up in the ACT group (g = .17, p < .02). The results from these three M-As together indicate that ACT is an efficacious intervention at improving scores on measures of QoL within a chronic health population at post treatment compared to controls and that improvements are maintained longer-term. Orwin's fail-safe N was calculated to assess for publication bias. A score of seven indicates that the results from this M-A cannot be considered robust to the effects of publication bias. A test of between-study heterogeneity in the between-groups M-A was significant, I^2 = 50%, p = .03 and therefore further sub-

group analyses were conducted to explore for moderator variables which are discussed in sections 4.2.2 to 4.2.5.

4.2.2. Research question 2: Does study quality mediate changes in QoL?

The analysis of the relationship between ES and study quality revealed no significant relationship, $r(10) = -.13$, p = .690 (two-tailed). Therefore study quality is not a mediator of ES in this M-A. The moderate level of heterogeneity reported in the between-groups M-A cannot be explained by differences in study quality.

4.2.3. Research question 3: Does treatment intensity (time) correlate with effect size?

The analysis of the relationship between ES and amount of therapy offered revealed no significant relationship, $r(9) = .02$, $p = .953$. Therefore the intensity of treatment is not a mediator of the ES in this M-A. The moderate level of heterogeneity reported in the between-groups M-A cannot be explained by differences in treatment intensity.

4.2.4. Research question 4: Does publication date correlate with effect size?

The analysis of the relationship between ES and publication date revealed no significant relationship, $r(10) = .32$, $p = .311$. Therefore publication date is not a mediator of the ES in this M-A. The moderate level of heterogeneity reported in the between-groups M-A cannot be explained by when a study was published.

4.2.5. Research question 5: Does the control group (WLC/TAU vs. active control) mediate changes in QoL?

The results from comparing the type of control group (WLC/TAU or active control) revealed a significant ES for ACT vs. WLC/TAU group ($g = .32$, $p = .04$) but

not for ACT vs. active control group (g = .27, p = .23). This finding is congruent with results from previous M-As regarding the superiority of ACT compared to WLC/TAU (A-Tjak et al., 2015; Öst, 2008, 2014; Powers et al., 2009; Veehof et al., 2011). The small non-significant ES for ACT vs. active control underlines that within this sample of studies ACT was not significantly better at improving scores on QoL compared to an active control. Previous M-As (A-Tjak et al., 2015; Powers et al., 2009) have also reported similar findings regarding different outcomes. The moderate level of heterogeneity reported in the between-groups M-A to some extent could be explained by the type of control group. The implications of this finding are discussed below.

4.2.5.1. ACT compared to active treatment.

In the present M-A the finding that ACT was significantly better than WLC/TAU and not significantly better than an active treatment presents a confusing picture regarding the efficacy of ACT. Especially when taken in the context of a previous M-A which found ACT to be significantly better at improving outcomes compared to CBT (Ruiz, 2012).

The active control groups in the M-A include a range of treatments and some which were not appropriate comparison groups. In the current review six studies utilised an active treatment condition and three studies utilised an evidence based approach (Rost et al., 2012; Westin et al., 2011; Wetherell et al., 2011). Lundgren et al. (2006) utilised an attention placebo as the control group and Lundgren et al. (2008) utilised yoga in the treatment of epilepsy both of which are not evidenced based treatment options. Furthermore, Lundgren et al. (2008) accepted that there was crossover between their two groups regarding the themes of the intervention in the treatment of epilepsy. It should be noted that at pre-treatment the active control group had a higher mean score compared to the ACT group at baseline which remained high at post treatment. This is despite the rate of mean improvement being greater in the

ACT group (5.9 vs. 1.3). A Cochrane review has also reported inconclusive evidence for the efficacy of yoga in the treatment of epilepsy (Panebianco, Sridharan, & Ramaratnam, 2015). Thorsell et al. (2011) utilised applied relaxation as a treatment control for chronic pain, although relaxation has been used as a supplementary treatment in pain management programmes, previous research has found inconclusive evidence that it is an efficacious treatment in chronic pain (Henschke et al., 2010; Seers & Carroll, 1998; van Middelkoop et al., 2011). Of the three evidence based approaches only Wetherell et al. (2011) reported an ES (g = -.268) in favour for the control treatment (CBT). Interestingly, Rost et al. (2012) also utilised CBT for the control condition but reported a large ES in favour for ACT, g = .960.

Participants in the studies included in the M-A would not have been selected based on a pre-treatment score of QoL, this was not an explicit target for treatment and therefore it was not a criterion for inclusion in the study (i.e., a low cut-off score for QoL). There was one study which investigated QoL as a primary outcome (Wicksell et al., 2008) which reported the largest ES (g = 1.008). This may, to some extent, explain why larger ESs were not reported regarding QoL in some studies. Elsewhere ESs have been reported for both primary and secondary outcomes that range between small and large (A-Tjak et al., 2015; Öst, 2008, 2014; Powers et al., 2009; Ruiz, 2012; Veehof et al., 2011). With QoL not identified as a primary outcome in the studies, the magnitude of improvement in this outcome may not have been as large. Considering the importance of QoL in this population it may be appropriate to use QoL levels during recruitment as an inclusion/exclusion criterion and as a target for treatment. The results from this M-A may therefore suffer from a ceiling effect as lower scores of QoL would not have been one of the inclusion criteria in the studies. Therefore the magnitude of ESs may have been compromised resulting in the finding of much lower ESs.

In short, although the results indicate that ACT was not more effective when compared to an active control group, this finding should be treated with caution. A relatively small number of studies (k = 6) was used to calculate the effect of active control groups. Of the six studies included, four reported treatment effects in favour of ACT (Lundgren et al., 2006; Rost et al., 2012; Westin et al., 2011; Wetherell et al., 2011) and three utilised an evidence based approach. Additionally, QoL was a primary outcome measure in only one study (Wicksell et al., 2008). Therefore, the finding that ACT is not more effective compared to an active treatment condition needs further investigation before a definitive conclusion can be drawn.

4.3. Theoretical Implications

The findings from the present study lend support to the claim that treatment with ACT within a chronic health population does lead to increases in QoL when compared to controls. This finding provides support to the underlying theoretical understanding of ACT. ACT is based on RFT which is grounded in FC (see Section 1.4.1). RFT asserts that learning can occur without direct experience based on the inherent human ability of language through derived relationships, relational networks and transformation of functions. The aim of ACT has been to change the function of private experiences rather than their form/content (S. C. Hayes et al., 1999), which is the primary aim of CBT (Beck, 1979). There is a clear differentiation between traditional CBT and ACT in what is understood to lead to change. Both approaches rely heavily on behavioural techniques, as both approaches are derived from behaviourism, to implement change however the rationale is different. CBT asserts the use of cognitive restructuring and behavioural activation with the aim to challenge thoughts and change emotions. This is contrasted with ACT which aims to change the function and context in which private experiences occur rendering them less important. There is a growing evidence base for the underlying theoretical principles

of ACT. Levin, Hildebrandt, Lillis, and Hayes (2012) report the findings from a M-A which included 66 laboratory studies that have investigated the processes within the ACT model. The authors reported significant positive ESs for the individual components of the ACT model and supplementary analysis reported support for psychological flexibility. This is in contrast to the assertions made by CBT where improvements in outcome can occur despite no cognitive restructuring (Longmore & Worrell, 2007). CBT has a large evidence base however the notion that cognitive change is a necessary for clinical improvement is not well evidenced. Dobson and Khatri (2000, p. 913) have argued that there is "no additive benefit to providing cognitive interventions in cognitive therapy". Furthermore the initial response to CBT has been suggested to occur prior to the implementation of cognitive restructuring (Ilardi & Craighead, 1994). It would suggest that positive clinical improvements following CBT may not occur through the proposed methods of change outlined in the model and therefore there is a need for further investigation as to what the mechanisms of change are in CBT. ACT however has a clearer theoretical standpoint and one which is evidence based. Nevertheless when examining the relative effectiveness of CBT and ACT in this M-A, no consistent differences emerged.

With regards to the ACT model (S. C. Hayes et al., 1999) an increase in QoL can be explained as an increase in acceptance and a reduction in experiential avoidance, which can be ultimately described as an increase in psychological flexibility. The acceptance of private experiences which cannot be controlled allows the ability to focus and put energy into clarifying and pursuing meaningful values. This makes life more meaningful and worth living (Harris, 2006, 2009). As private experiences no longer hold a person back from engaging in life this can lead to an increase in QoL despite, in some circumstances, the persistence of physical symptoms. The treatment approach therefore relies on changing the function and context of private experiences. This is not to say that participants did not continue to

experience painful private experiences. The conclusion is that participants were able to, based on RFT, distance themselves from painful thoughts and accept emotions/physical pain when in the context of living a meaningful life in line with their values. In addition, ACT claims to be a transdiagnostic approach to human suffering (Harris, 2009). The current M-A reported on 12 studies within a diverse chronic health population and found that all studies reported improvements in QoL from pre to post-treatment following ACT. This provides further support for RFT regarding the function and context of private experiences rather than their form. Despite different chronic health conditions resulting in different forms of private experiences participants reported improvements in QoL following ACT. This underpins the notion that psychopathology from the RFT perspective is linked to human language and cognition (S. C. Hayes et al., 2006).

4.4. Clinical Implications

Within the chronic health population the primary approach traditionally has been to improve or manage medical symptoms including psychological distress (e.g., anxiety and depression). Progressively, improvements in QoL have become an important factor and now improving QoL is seen as an important outcome (Department of Health, 2012, 2015). Psychological interventions have increasingly become central in attempting to improve QoL. The findings from this M-A suggest that ACT can improve QoL within a chronic health population and that these improvements are maintained at follow-up. ACT may therefore be an alternative treatment option for clinicians when working within this population.

The effectiveness of psychological interventions have traditionally been based on how participants scores improve on measures of anxiety and depression (Öst, 2008). These outcome measures may not be as salient within this population compared to QoL. The rationale for this is that patients may continue to experience

distress as part of their condition but what bearing does this have on their QoL? Based on the treatment philosophy of ACT, participants learn to live with painful private experiences whilst in the pursuit of a meaningful life (S. C. Hayes et al., 1999). Furthermore, the absence of psychological distress does not equate to well-being or necessarily improved mental health (WHO, 1947). Improvements therefore in a multidimensional construct such as QoL highlight how ACT could help to improve a person's life despite suffering with a chronic health condition.

With the rise in popularity of third-wave behavioural approaches such as ACT there is a need to consider how outcomes are measured and what important outcomes are for patients. This is particularly pertinent within the chronic health population where learning to live a valued and meaningful life whilst suffering with a chronic health condition is of great importance (Dysvik, Sommerseth, & Jacobsen, 2011), especially when considering that, despite all other interventions, the primary condition will remain or even deteriorate. The implication for clinical practice is therefore to include measures of QoL to measure treatment outcome.

There continues to be pressure on the NHS to provide a quality service of healthcare whilst trying to keep costs down especially concerning long-term conditions (Department of Health, 2015; Naylor et al., 2012). Of the studies included in this M-A a range of different study designs and therapists were utilised when carrying out the ACT intervention. This included ACT groups, 1:1 therapy, telephone support, and intensive one day workshop groups. Furthermore, therapists from a range of backgrounds were included such as clinical psychologists, trainee clinical psychologists, CBT therapists, nurses, psychology interns and a physician. There have also been a number of internet and self-help protocols that have been evaluated (Buhrman et al., 2013; Gregg et al., 2007; Hesser et al., 2012; Johnston et al., 2010; Trompetter, Bohlmeijer, Veehof, & Schreurs, 2015). ACT has therefore been delivered in a number of different ways. The finding that there was no significant

relationship between treatment intensity and ES would suggest that ACT is just as effective in this population over long and short treatment protocols. ACT may therefore be a cost effective treatment within this population which would have a significant effect on clinical services. At present there is no formal certification required for therapists to practice ACT and there are a number of different ways that skills can be taught, via books, DVDs, peer consultation groups, special interest groups and conferences (https://contextualscience.org/act_certification). This would allow the rapid and widespread delivery of a treatment intervention which has been shown to have promising results regarding the improvement of a key outcome in chronic health. Despite this, there is also the reasonable counter argument that if services are already set up to offer treatments such as CBT, which have a strong evidence base, what benefit is there in changing to offer ACT? A greater understanding of what makes ACT and CBT effective, and if this differs, may help to clarify this debate and allow consideration of which approach would be most appropriate (S. C. Hayes et al., 2006; Levin et al., 2012; Longmore & Worrell, 2007).

The majority of studies included in the M-A investigated a chronic pain sample ($k = 5$) however the included studies used a diverse population including patients suffering from epilepsy, various cancers, tinnitus and migraine. There is therefore a clinical dilemma when considering the findings from this M-A in isolation in deciding whether a service should adopt ACT for their client group. The strongest evidence for ACT is within a chronic pain population (http://www.div12.org/psychological-treatments/treatments/) which is also the most researched population (https://contextualscience.org/state_of_the_act_evidence). There is also the problem that QoL scores at pre-treatment in this M-A were varied. Thus the relative effect ACT has on QoL regarding different condtions is unclear. The purpose of ACT is to improve psychological flexibility. ACT is concerned with changing the relationship someone has with their thoughts and feelings in the context

of living a meaningful life. QoL is a broad multidimensional construct that measures psycholoigcal, social and physical factors and it could be that ACT effects change more so on the psychological element of QoL. As such, those particpants whose difficulties are within this construct of QoL may have reported greater gains from ACT. The measures of QoL may also not have tapped into other psychological parts of QoL which have been deemed important such as existential/spiritual QoL (S. R. Cohen, Mount, Tomas, & Mount, 1996). There is also the potential for a ceiling effect as samples may not have been recruited based on 'clinical' scores of QoL which could affect the magnitude of ESs. Further investigation would be needed to consider how effective ACT is across sub-samples of this population.

4.5. Strengths and Limitations

4.5.1. Strengths.

The current M-A, to the authors knowledge, is the first M-A to examine the efficacy of ACT in improving the QoL in patients suffering from chronic health conditions. ACT has an ever growing evidence base and proposes to be a transdiagnostic treatment which has been utilised in a number of different populations (Öst, 2014). Researchers have reported contradictory findings regarding the efficacy of ACT within different populations and between different treatment controls (A-Tjak et al., 2015; Öst, 2008, 2014; Powers et al., 2009; Ruiz, 2012; Veehof et al., 2011). It was therefore important to try to understand this confusing picture by conducting a systematic appraisal of the literature and providing evidence in the form of an M-A. The research is still, relative to CBT, in its early stages however this M-A does provide some insight in the potential utility of ACT within the chronic health population.

In order to minimise bias during the literature search, and selection of publications, a clearly defined set of inclusion and exclusion criteria were utilised. It

is important to ensure that the initial search is comprehensive and therefore a number of electronic databases were utilised. Manual searching of key journals and reference lists of included studies were also conducted. Furthermore, a PRISMA diagram outlined the process involved in finalising the pool of included studies with clear reasons for the exclusion of studies. The studies were then scrutinised with a quality checklist which was rated by the primary researcher and independently by the primary supervisor to allow for assessment of the inter-rater reliability to minimise bias. An attempt was also made to gather present, ongoing and unpublished research by contacting prominent researchers in the field based on the literature search.

There is a need to ensure that a M-A has a clear set of criteria regarding the types of research that should be included in the analysis. The current M-A had clearly defined criteria regarding participants, intervention, study design and outcomes. A well-defined definition of chronic health conditions and QoL was also utilised to ensure that only studies that reported on this were included. The focus on studies that utilised ACT increases the validity of the findings as some allegedly ACT research incorporate 'mindfulness-based' approaches such as mindfulness-based stress reduction and mindfulness-based cognitive therapy. To ensure the fidelity of the treatment approach and increase the generalisability of the results a decision was made to exclude studies that only used self-help or internet based approaches.

4.5.2. Limitations.

The current M-A included a total of 12 studies in the analysis. This is a relatively small number of studies compared to previous analyses (Öst, 2014). A potential reason for the small number of studies could be explained in terms of the inclusion and exclusion criteria. The current M-A was investigating a narrow field of research into QoL in chronic health with ACT which, in relative terms when compared to established treatments such as CBT, is still very much in its infancy. A

number of publications had investigated ACT within chronic health; however many studies were excluded as there was no measure of QoL. As such, there may not yet be the volume of research available to conduct a large M-A with the criteria utilised in this study. This also constrains the approach that can be taken when considering the inclusion of studies as a number of studies had inadequate power. A Cochrane review recommended the removal of underpowered studies when a rapid analysis is required (e.g., when conducting time limited reviews in preparation for NICE guidelines) as they add little value to the overall M-A if several large RCTs have already been found (R. M. Turner, Bird, & Higgins, 2013). The current M-A included all studies which met the criteria and did not exclude smaller studies because, given the limited research base, it was important to include as many studies as possible especially when the aim is to resolve scientific uncertainty and investigate between-study heterogeneity (R. M. Turner et al., 2013). The result of having a small number of studies with small sample sizes is that it can affect the overall precision of the M-A. Nevertheless there are no definitive guidelines that specify a minimum number of studies or the particular number of participants that should be included in order to conduct a M-A (Borenstein et al., 2011; Valentine, Pigott, & Rothstein, 2010).

The current M-A included a relatively small number of studies which can lead to a reduction in statistical power. Furthermore, additional sub-analyses were carried out in this M-A. The ability to detect significant differences from the null hypothesis is compromised when power is low. This has the potential for an increase in the risk of type II errors whereby the null hypotheses is incorrectly accepted resulting in a false negative. This is especially pertinent regarding the results from the sub-group analyses. It is reasonable to assume that the methodological quality of a study will affect the magnitude of the ES that will be reported (Borenstein et al., 2011). Furthermore, research suggests that as time passes and further research is carried out within a particular field the magnitude of ES changes resulting in a relationship with

the ES and publication date (Light & Pillemer, 1984). The tests of significant relationships in the sub-group analysis may suffer from being underpowered and therefore the ability to detect a significant difference may have been compromised resulting in potentially false negative results. The reduced power of this M-A may well be an artefact of the limited research which fits the inclusion and exclusion criteria of this M-A.

The relative effects varied chronic health conditions have on QoL may have been different. Considering the multidimensional nature of QoL different conditions may have contributed to impairment on only selective domains. Chronic pain for example may have a major bearing on physical functioning (Flor & Turk, 2015) compared to epilepsy which may have a greater bearing on psychosocial functioning of QoL (Suurmeijer, Reuvekamp, & Aldenkamp, 2001). The ability to tease out these differences was beyond the scope of the data analysis in this M-A due to the small number of studies reporting on different conditions. This may explain to some extent why only a small to moderate ES was reported compared to much larger ESs found regarding different outcome measures (A-Tjak et al., 2015; Öst, 2008, 2014; Powers et al., 2009; Ruiz, 2012; Veehof et al., 2011). The aim of this M-A was to assess the efficacy of ACT across the chronic health population and therefore the subtle nuances within each condition regarding the relative effect on QoL were not assessed (Arnold et al., 2004) in part due to the small number of included studies.

The current M-A conducted a systematic search for published work; however the potential for publication bias (Rosenthal, 1979) is a significant obstacle in M-A. The potential for studies reporting small or null findings and not being published through either the reluctance from authors or journal editors dismissing them is a real problem. The results from this study may well suffer from the effects of publication bias however the burden of publication bias should not be shouldered by M-As alone. Borenstein et al. (2011) argued that publication bias is a problem for any researcher

within any field of research using any form of analysis. The spotlight is often placed on M-As as there is an attempt to provide an accurate statistical synthesis of research compared to systematic or narrative reviews. There is an emphasis on observing and controlling for potential bias. Thus publication bias is a problem for all research and not just for M-As.

4.6. Recommendations for Future Research

There are several concerns which need to be addressed when considering future research based on the findings from this M-A, especially poor methodological standards which should be rectified. Many of the included studies suffered from low sample sizes. There was lack of evidence to suggest that a priori power calculations had been conducted and that adjustments had been made for attrition. A number of studies utilised a WLC/TAU group instead of an active control group. Also only three of the six active controls included an evidence based treatment. It is imperative to ensure that when comparing the efficacy of a new treatment that it is compared to a gold standard which has a strong evidence base. This is to ensure that the new approach is properly scrutinised and that conclusions drawn are valid. It is also important to scrutinise the treatment itself to ensure that the intervention is carried out as intended, including the philosophy, principles and processes. Given these methodological concerns there is a need for researchers to conduct larger scale RCTs using a priori power calculations and taking into account attrition rates. ACT should be compared to control groups that receive gold standard evidence based treatments. Furthermore treatment fidelity should be measured either through supervision or video/audio tapes to ensure that the intervention is true to the model.

A number of studies in this M-A were excluded due to a lack of a QoL measure. There is now a much greater focus on the importance of QoL when measuring outcomes within a chronic health population (Naylor et al., 2012; The

Department of Health 2012, 2015). Psychological therapies are at the forefront of trying to improve the QoL for patients. It is therefore important that this construct is measured routinely when considering chronic health conditions. Treatments should consider targeting QoL as a primary outcome. The inclusion criteria should specify clear cut-off scores in order to target individuals that may benefit from an intervention and reduce the chance of celling effects. Based on the evidence from this M-A this could potentially result in larger ESs for QoL.

It has not been possible in this M-A to tease apart the effective ingredients of ACT and if they are differentially effective for different disorders. The main aim of ACT is to improve psychological flexibility whilst in pursuit of a meaningful life. It therefore would be informative to measure psychological flexibility to better understand which elements of ACT are important and particularly how this relates to QoL. Research may uncover that parts of the ACT model (i.e., the hexiflex) are critical with regards to QoL. Does clarifying values and taking committed action towards living these values promote QoL? Does increasing acceptance and distancing from negative thoughts promote QoL? Are improvements in QoL linked to being present in the moment and just observing the self non-judegemntally? It may transpire that certain parts of the model are more or less effective within different populations. This would allow for a customised approach which targeted key areas to ensure that the most benefit could be attained from treatment.

A decision was made in the current M-A to exclude studies that utilised a solely internet delivered or self-help intervention to ensure as far as possible that the treatments across studies were comparable. There is a growing evidence base regarding these approaches and specifically these treatment approaches (Buhrman et al., 2013; Gregg et al., 2007; Hesser et al., 2012; Johnston et al., 2010; Trompetter et al., 2015). Given that this M-A, to the authors knowledge, is the first to investigate the efficacy of ACT within the chronic health population it was decided to ensure that

interventions incorporated therapist/patient contact as experiential learning is a key process in the ACT approach (S. C. Hayes et al., 1999). Furthermore, there is a need to provide robust evidence for ACT as delivered in its conventional format prior to considering innovative delivery approaches. The use of internet and self-help approaches could make the interpretation of data difficult. Despite this, further investigation into this area does seem important. There are already internet-based (Ruwaard, Lange, Schrieken, & Emmelkamp, 2011) and self-help based (Coull & Morris, 2011) CBT protocols which have provided mixed results regarding their efficacy. The use of these approaches has been within the mild range of psychological disorders and therefore there is still the need for more evidence. Considering the large evidence base for CBT and inconclusive evidence for internet and self-help approaches there is clearly a need for more research within that field including in ACT. Potentially this would have major implications for clinical services and offer the prospect of delivering treatment to a large number of people.

4.7. Conclusion

The aim of this M-A was to investigate the efficacy of ACT on QoL in chronic health conditions. The findings from this M-A indicate that ACT is an efficacious treatment option within the chronic health population for improving QoL with a small to medium ES compared to controls. Improvements at post-intervention have been shown to be maintained at follow-up indicating that effects are enduring. Findings did however suggest that ACT was not significantly better at improving QoL when compared to an active control group.

There has been a greater focus within the chronic health population on trying to improve QoL as an important feature of treatment rather than just managing physical symptoms. This has led to a greater role for psychological interventions. Clinically, it is important to provide treatment options within a time limited and cost

effective manner that address important and relevant outcomes. Findings from this M-A indicate that ACT can improve QoL within the chronic health population. There is a need for further research that uses improved methodology which will clarify the picture regarding the efficacy of ACT when compared to active controls.

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Appendices

Appendix A: Data Extraction Form

Appendix B: The NICE Quality Appraisal Checklist for Quantitative Intervention Studies (NICE, 2012)

Appendix A: Data Extraction Form

Data Collector: _____

General

1. Study ID:

2. Reference:

3. Year of Publication:

4. Country of Origin:

5. Type of Report:
    - Journal Article
    - Book chapter
    - Thesis or doctoral dissertation
    - Conference paper
    - Other:

6. General Notes:

_____
_____
_____
_____
_____

Groups

7. ACT Format:
    - Individual
    - Group
    - Other_____

8. Number of Control Groups:

9. Format of Control Group/s:
    - Active therapy
    - Treatment as usual
    - Waiting list
    - Attention placebo

Control Group	1	2	3
Code			

10. Length of Each Treatment Session (minutes):

11. Number of Sessions Offered:

12. Mean Number of Sessions Attended:

13. Total Length of Treatment Offered (minutes):

14. Mean Total Length of Treatment Received (minutes):

15. Baseline Group Differences:
    - Not assessed
    - Assessed, Negligible Differences
    - Assessed, Some Differences, Judged Unimportant
    - Assessed, Some Differences, Judged Important (across several variables/major variable i.e. QoL)

Samples

16. Chronic Condition (description):

17. Total Sample Size (baseline):

18. Intervention Sample Size (baseline-completed):

19. Sample Size of Control Group/s (baseline-completed):

Control Group	1	2	3
Code			

20. Mean Age of Total Sample:

21. Age SD/Range of Total Sample:

22. Mean Age of Intervention Group:

23. Age SD/Range of Intervention Group

24. Mean Age of Control Group/s:

Control Group	1	2	3
Code			

25. Age SD/Range of Control Group/s:

Control Group	1	2	3
Code			

Design

26. Randomisation:
    - Randomised
    - Non-randomised

27. Additional Treatments Balanced Between Groups (e.g. medication):
    - Yes
    - No
    - State Treatment

28. ACT processes utilised
    - Acceptance
    - Cognitive defusion
    - Self-as-context
    - Observing self
    - Values
    - Committed action

TOTAL:

29. Outcome Measures:

30. Length of Follow up:

Effect Size/s – Record all effect sizes (M-A post and last follow-up only)

31. Effect Size type:
    - Immediately post intervention
    - Follow up

32. Intervention Group Mean (SD):

33. Control Group Mean (SD):

34. Direction of Effect:
    - Favours treatment
    - Favours control
    - Neither

Appendix B: The NICE Quality Appraisal Checklist for Quantitative Intervention Studies (NICE, 2012)

Checklist items are worded so that 1 of 5 responses is possible:

++	Indicates that for that particular aspect of study design, the study has been designed or conducted in such a way as to minimise the risk of bias.
+	Indicates that either the answer to the checklist question is not clear from the way the study is reported, or that the study may not have addressed all potential sources of bias for that particular aspect of study design.
–	Should be reserved for those aspects of the study design in which significant sources of bias may persist.
Not reported (NR)	Should be reserved for those aspects in which the study under review fails to report how they have (or might have) been considered.
Not applicable (NA)	Should be reserved for those study design aspects that are not applicable given the study design under review (for example, allocation concealment would not be applicable for case control studies).

In addition, the reviewer is requested to complete in detail the comments section of the quality appraisal form so that the grade awarded for each study aspect is as transparent as possible.

Each study is then awarded an overall study quality grading for internal validity (IV) and a separate one for external validity (EV):

++ All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter.
+ Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
− Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

Checklist

Study identification:		
Study design: Refer to the glossary of study designs and the algorithm for classifying experimental and observational study designs to best describe the paper's underpinning study design		
Guidance topic:		
Assessed by:		
Section 1: Population		
1.1 Is the source population or source area well described? Was the country (e.g. developed or non-developed, type of healthcare system), setting (primary schools, community centres etc.), location (urban, rural), population demographics etc. adequately described?	++ + – NR NA	Comments:
1.2 Is the eligible population or area representative of the source population or area? Was the recruitment of individuals, clusters or areas well defined (e.g. advertisement, birth register)? Was the eligible population representative of the source? Were important groups under-represented?	++ + – NR NA	Comments:
1.3 Do the selected participants or areas represent the eligible population or area? Was the method of selection of participants from the eligible population well described? What % of selected individuals or clusters agreed to participate? Were there any sources of bias? Were the inclusion or exclusion criteria explicit and appropriate?	++ + – NR NA	Comments:

Section 2: Method of allocation to intervention (or comparison)		
2.1 Allocation to intervention (or comparison). How was selection bias minimised? Was allocation to exposure and comparison randomised? Was it truly random ++ or pseudo-randomised + (e.g. consecutive admissions)? If not randomised, was significant confounding likely (−) or not (+)? If a cross-over, was order of intervention randomised?	++ + – NR NA	Comments:
2.2 Were interventions (and comparisons) well described and appropriate? Were interventions and comparisons described in sufficient detail (i.e. enough for study to be replicated)? Was comparisons appropriate (e.g. usual practice rather than no intervention)?	++ + -– NR NA	Comments:
2.3 Was the allocation concealed? Could the person(s) determining allocation of participants or clusters to intervention or comparison groups have influenced the allocation? Adequate allocation concealment (++) would include centralised allocation or computerised allocation systems.	++ + – NR NA	Comments:
2.4 Were participants or investigators blind to exposure and comparison? Were participants **and** investigators – those delivering or assessing the intervention kept blind to intervention allocation? (Triple or double blinding score ++) If lack of blinding is likely to cause important bias, score −.	++ + – NR NA	Comments:
2.5 Was the exposure to the intervention and comparison adequate? Is reduced exposure to intervention or control related to the intervention (e.g. adverse effects leading to reduced compliance) or	++ + –	Comments:

fidelity of implementation (e.g. reduced adherence to protocol)? Was lack of exposure sufficient to cause important bias?	NR NA	
2.6 Was contamination acceptably low? Did any in the comparison group receive the intervention or vice versa? If so, was it sufficient to cause important bias? If a cross-over trial, was there a sufficient wash-out period between interventions?	++ + – NR NA	Comments:
2.7 Were other interventions similar in both groups? Did either group receive additional interventions or have services provided in a different manner? Were the groups treated equally by researchers or other professionals? Was this sufficient to cause important bias?	++ + – NR NA	Comments:
2.8 Were all participants accounted for at study conclusion? Were those lost-to-follow-up (i.e. dropped or lost pre-,during or post-intervention) acceptably low (i.e. typically <20%)? Did the proportion dropped differ by group? For example, were drop-outs related to the adverse effects of the intervention?	++ + – NR NA	Comments:
2.9 Did the setting reflect usual UK practice? Did the setting in which the intervention or comparison was delivered differ significantly from usual practice in the UK? For example, did participants receive intervention (or comparison) condition in a hospital rather than a community-based setting?	++ + – NR NA	Comments:
2.10 Did the intervention or control comparison reflect usual UK practice? Did the intervention or comparison differ significantly from usual	++ +	Comments:

practice in the UK? For example, did participants receive intervention (or comparison) delivered by specialists rather than GPs? Were participants monitored more closely?	– NR NA	
Section 3: Outcomes (Only rate QoL measures)		
3.1 Were outcome measures reliable? Were outcome measures subjective or objective (e.g. biochemically validated nicotine levels ++ vs self-reported smoking –)? How reliable were outcome measures (e.g. inter- or intra-rater reliability scores)? Was there any indication that measures had been validated (e.g. validated against a gold standard measure or assessed for content validity)?	++ + – NR NA	Comments:
3.2 Were all outcome measurements complete? Were all or most study participants who met the defined study outcome definitions likely to have been identified?	++ + – NR NA	Comments:
3.3 Were all important outcomes assessed? Were all important benefits and harms assessed? Was it possible to determine the overall balance of benefits and harms of the intervention versus comparison?	++ + – NR NA	Comments:
3.4 Were outcomes relevant? Where surrogate outcome measures were used, did they measure what they set out to measure? (e.g. a study to assess impact on physical activity assesses gym membership – a potentially objective outcome measure – but is it a reliable predictor of physical activity?)	++ + NR NA	Comments:

3.5 Were there similar follow-up times in exposure and comparison groups? If groups are followed for different lengths of time, then more events are likely to occur in the group followed-up for longer distorting the comparison. Analyses can be adjusted to allow for differences in length of follow-up (e.g. using person-years).	++ + NR NA	Comments:
3.6 Was follow-up time meaningful? Was follow-up long enough to assess long-term benefits or harms? Was it too long, e.g. participants lost to follow-up?	++ + – NR NA	Comments:
Section 4: Analyses		
4.1 Were exposure and comparison groups similar at baseline? If not, were these adjusted? Were there any differences between groups in important confounders at baseline? If so, were these adjusted for in the analyses (e.g. multivariate analyses or stratification). Were there likely to be any residual differences of relevance?	++ + – NR NA	Comments:
4.2 Was intention to treat (ITT) analysis conducted? Were all participants (including those that dropped out or did not fully complete the intervention course) analysed in the groups (i.e. intervention or comparison) to which they were originally allocated?	++ + – NR NA	Comments:
4.3 Was the study sufficiently powered to detect an intervention effect (if one exists)? A power of 0.8 (that is, it is likely to see an effect of a given size if	++ +	Comments:

one exists, 80% of the time) is the conventionally accepted standard. Is a power calculation presented? If not, what is the expected effect size? Is the sample size adequate?	– NR NA	
4.4 Were the estimates of effect size given or calculable? Were effect estimates (e.g. relative risks, absolute risks) given or possible to calculate?	++ + – NR NA	Comments:
4.5 Were the analytical methods appropriate? Were important differences in follow-up time and likely confounders adjusted for? If a cluster design, were analyses of sample size (and power), and effect size performed on clusters (and not individuals)? Were subgroup analyses pre-specified?	++ + – NR NA	Comments:
4.6 Was the precision of intervention effects given or calculable? Were they meaningful? Were confidence intervals or p values for effect estimates given or possible to calculate? Were CI's wide or were they sufficiently precise to aid decision-making? If precision is lacking, is this because the study is under-powered?	++ + – NR NA	Comments:
Section 5: Summary		
5.1 Are the study results internally valid (i.e. unbiased)? How well did the study minimise sources of bias (i.e. adjusting for potential confounders)? Were there significant flaws in the study design?	++ + –	Comments:
5.2 Are the findings generalisable to the source population (i.e.	++	Comments:

externally valid)? Are there sufficient details given about the study to determine if the findings are generalisable to the source population? Consider: participants, interventions and comparisons, outcomes, resource and policy implications.	+ −	