How do we intervene to increase healthy adults' fruit and vegetable intake? A systematic review

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Master of Philosophy

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To my family and my beloved country Indonesia

“It is He who sends down water (rain) from the sky, with it We produce vegetation of all kind, from some We produce green (crops), out of which We produce grain, heaped up (at harvest) out of the date palm and its sheaths (or spathes) (come) clusters of dates hanging low and near and (then there are) gardens of grapes and olives and pomegranates. Each similar (in kind) yet different (in variety and taste) when they begin to bear fruit, feast your eyes with the fruit and the ripeness thereof. Behold! In these things there are signs for people who believe.” ***(the Holy Qur'an, Surah Al-An’am:99)***

Abstract

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Background
Increased fruit and vegetable intake is associated with reduced levels of chronic disease. However types of interventions that work best to increase healthy adults' fruit and vegetable intake had not been systematically examined.

Objectives
To assess which elements of interventions work best to encourage healthy adults to increase their fruit and vegetable intake.

Data sources
Electronic databases (The Cochrane Library, MEDLINE, EMBASE, LILACS, PsycInfo, ERIC) and library catalogues.

Study eligibility criteria
Randomised controlled trials (RCTs) aimed at increasing fruit and vegetable intake in healthy adults (16+) with at least three months of follow-up.

Study appraisal and synthesis methods
Selection of titles and abstracts for inclusion, data extraction and risk of bias assessment were conducted independently by at least two reviewers. Where differences occurred discussion was conducted until consensus was agreed. Random effects meta-analysis using direct comparisons, subgroup analyses and indirect comparisons were conducted.

Results
36 RCTs with 69,356 participants (mean age=49.6, sd=9.7) were included. Most of the studies were from the USA. All RCTs had unclear risk of bias. Fruit and vegetable intake was self reported by participants mostly using FFQ. Overall interventions increased fruit and vegetable intake by 0.64 portions per day (95% CI 0.40 to 0.87, I^2=97%). Individually tailored interventions, improving access, teaching practical skills, social support and motivational interviews statistically significantly increased fruit and vegetable intake by 0.29 to 0.55 portions per day more than interventions without these elements. Strong evidence (direct comparison and not heterogeneous) was found for individually tailored interventions.

Conclusions and implications of key findings
Individually tailored interventions increased fruit and vegetable intake more than non-tailored interventions. Improving access, practical skills, social support and using motivational interviews are also likely to be effective.

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Contents

Abbreviations

CHD	coronary heart disease
CI	confidence interval
CVD	cardiovascular disease
DASH	dietary approaches to stop hypertension
EMIS	Egton Medical Information System
EPIC	European prospective investigation into cancer and nutrition
FAO	Food and Agriculture Organization
FFQ	food frequency questionnaire
GP	general practitioner
IDRC	International Development Research Centre
MCSDS	Marlowe-Crowne social desirability scale
MI	myocardial infarction
NICE	National Institute for Health and Clinical Excellence
RCT	randomised controlled trial
RevMan	Cochrane's Review Manager
RR	relative risk
SDC	the Swiss Agency for Development Research Centre
SDR	socially desirable responding
TPB	theory of planned behaviour
TTM	transtheoretical model
WHO	World Health Organization

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Chapter 1 Introduction

1.1. Why systematic review?

The leading cause of mortality in the world according to World Health Organization report in 2005 is chronic diseases, namely heart disease, stroke, cancer and diabetes which represent 60% of all deaths (World Health Organization 2005). There is evidence that increased fruit and vegetable intake is associated with reduced levels of chronic diseases as well as other related co-morbidities. For example high blood pressure, dyslipidemia and obesity (Willett 1994; Ammerman, Lindquist C.H. et al. 2002; Byers T. 2002; US Department of Agriculture and Department of Health and Human Services 2005; American Institute for Cancer Research 2010).

Previous meta-analysis of cohort studies by Dauchet (Dauchet, Amouyel et al. 2006) assessed the strength of relationship between fruit and vegetable consumption with reduced rate of coronary heart disease (CHD). The meta-analysis included six cohorts with a total of 48,039 men and 127,316 women. At the end of the cohorts there were a total of 3561 events namely, fatal and nonfatal Myocardial Infarction (MI) in three studies, coronary deaths in two studies and CHD incidents in one. The Relative Risk (RR) of CHD for each increase of one portion of fruit and vegetables per day were 0.79 to 0.97. The pooled RR (using the random-effects model) was 0.96 (95% CI 0.93 to 0.99, P=0.0027). This indicated that fruit and vegetable consumption was inversely associated with CHD occurrences and that each additional portion of fruit and vegetables per day lowers the risk of CHD by 4%. There was significantly lower risk of CHD in the exposed (higher fruit and vegetables) groups compared to the non-exposed (lower fruit and vegetables) groups.

A systematic review conducted by Rashid (Rashid, Leonardi-Bee et al. 2003) included seven Randomised Controlled Trials (RCTs) to assess the effect of lowering blood pressure on recurrent vascular events in patients with prior ischemic or hemorrhagic stroke or transient ischemic attack. The findings suggested that lowering blood pressure may significantly lower the possibility of stroke (fatal and non-fatal) (OR=0.76, 95% CI 0.63 to 0.92, P=0.005), myocardial infarction (fatal and non-fatal) (OR=0.79, 95% CI 0.63 to 0.98, P=0.03) and vascular events (fatal and non-fatal) (OR=0.79, 95% CI

0.66 to 0.95, P=0.01). Moreover findings from prospective studies with at least two decades of follow-up data, including the Framingham Heart Study, the Manitoba Study and the Harvard School of Public Health Nurses Study all concluded that obesity is an independent predictor of clinical CHD (Rabkin, Mathewson et al. 1977; Hubert, Feinleib et al. 1983; Manson, Colditz et al. 1990; Wilson, D'Agostino et al. 2002). Therefore it would be useful to know what types of interventions work best to help people to increase their fruit and vegetable intake. It would also be useful to understand the effects of increasing fruit and vegetable intake on health indicators such as blood pressure and weight.

This thesis seeks to address research questions about which types of interventions work best in increasing fruit and vegetable intake and the effects of interventions to increase fruit and vegetable intake on health indicators (blood pressure and weight). Literature review would be a possible way to answer the research questions. However literature review is relatively less structured than some other methods like systematic review thus it is less likely that a wide range of robust evidence would be achieved as a basis for understanding behaviour changes to increase fruit and vegetable intake. According to Antman and Oxman (Antman, Lau et al. 1992; Oxman and Guyatt 1993) in contrast to basic literature review systematic reviews apply explicit and laterally organized methods to reduce bias so that findings are reliable and conclusions are conveyed to the readers. This systematic and rigorous process enables the best evidence to be used in decision making.

A systematic review design is appropriate to answer a clearly formulated question by applying systematic and explicit methods to identify, select, collect and analyse data that is included in the review (Higgins and Green 2008). A systematic review aims to identify relevant studies according to its objective and aims by searching databases or literature. The information from included studies is then statistically pooled and weighted according to the sample sizes so that smaller sample studies with limited statistical powers can be joined together with bigger sample size studies which had greater statistical power (Glass 1976; Higgins and Green 2008; Webb 2008).

Often but not always a meta-analysis is included in a systematic review. Meta-analysis is a statistical analysis of the results from separate studies. According to the Cochrane Handbook (Higgins and Green 2008) there are two main benefits of conducting a meta-analysis. Firstly meta-analysis may increase the power of a review because when several small studies are combined in meta-analysis there is a higher possibility of discovering the effect of an intervention or a specific type of drug. Secondly meta-analysis may improve precision because when more information is obtained from a study the estimation of effect could be more precise. Therefore it may be concluded that a systematic review which uses meta-analysis could provide significantly higher power and precise estimation of interventions effects.

Systematic reviews have several advantages suggested by the International Development Research Centre (IDRC) and the Swiss Agency for Development Research Centre (SDC) (International Development Research Centre (IDRC) and the Swiss Agency for Development and Cooperation (SDC) 2011) as follows:

1. Condensed: this provides compact results from a big amount of information.
2. Objective: by reducing the risk of bias and error.
3. Balanced: includes a broad range of studies which have been identified using a systematic search.
4. Verifiable: this incorporates transparent processes that allow the reader to understand how the conclusions were reached.
5. Replicable: by using a structured methodology.
6. Flexible: can be updated on a regular basis.
7. Dynamic: being able to identify areas that need more research.
8. Readable: it is set out to be easily understood.

According to Mulrow (Mulrow 1994) systematic review is needed by health care providers, researchers or policy makers who need efficient, compact and trustworthy additional data for policy making. In addition a systematic review is able to analyse whether scientific findings are consistent and may be generalized to a wider target based on specific characteristics (settings or treatment types).

Another possibility would have been to conduct a trial to answer the research questions due to constraints in time and budget this was not feasible. The advantages of systematic review mentioned above meant that to conduct a systematic review in order to answer these research questions was the best option to at least provide an evidence base for a future trial.

1.2. Gap in systematic review of dietary interventions

It has been shown that there are positive effects of fruit and vegetable intake on the reduction of CVD risks, a gap in evidence was identified about which types of interventions work more effectively in increasing fruit and vegetable intake. Since 2002 systematic reviews have examined interventions that might influence diet. A study by Ammerman (Ammerman, Lindquist C.H. et al. 2002) investigated types of interventions that might be effective in influencing dietary intake. This study collected RCTs and non-RCTs published in English during 1975 to 1999 that had been conducted in North America, Europe and Australia about the intake of total fat, saturated fat, fruit and vegetable intake in children, adolescents and adults. The included studies were analysed by creating dichotomous indicators as a summary of significant findings. Out of 22 studies on fruit and vegetable interventions, 17 studies (77%) found significant results of interventions in increasing intake of fruit and vegetables. The review developed a rating system and found that interventions with a theoretical basis have >20% differences in the median differences in change between the intervention groups and the control groups compared to interventions that did not. Interventions with goal setting and food-related activities had a 5-9% median difference between the intervention groups and the control groups. The review suggested a summary of significant results which is the number of studies which reported significant effects of interventions to increase fruit and vegetable intake. However further analysis on the number of fruit and vegetables in portions per day increased in each intervention was not done using meta-analysis which might be able to explain interventions to increase fruit and vegetable intake more rigorously. The review also examined studies which suggested significant effects of interventions to increase fruit and vegetable intake on all human with any health conditions. Therefore the true effects of the interventions in primary prevention of disease were not analysed.

A systematic review of barriers and facilitators of healthy eating in children by Thomas (Thomas, Sutcliffe et al. 2003) collected papers published in English from twelve countries. The searches were carried out for papers published in 1990 to 2003. The review focused on barriers and facilitators of healthy eating among children aged four to ten years of age. The analysis involved RCT interventions, controlled trials and other designs. The unique design of the study is the combination of statistical meta-analysis with thematic qualitative synthesis of studies focused on children's views of healthy eating. The findings concluded that the interventions were able to increase fruit and vegetable in children by 0.23 servings per day (95% CI 0.11 to 0.35). In addition multi-component interventions (for example aimed to increase physical activity as well as fruit and vegetable intake) were able to increase fruit and vegetable by one-fifth of portions per day while studies that focused on increasing fruit and vegetable intake only were able to increase by half a portion per day. Similarly the review found that studies with longer follow-up did not increase fruit and vegetable intake significantly compared to shorter follow-up. Branding fruits and vegetables as 'exciting', child-relevant product and tasty proved to be more effective and may have increased fruit and vegetable intake by half a portion per day compared to a one-fifth portion per day for other studies. However this review included all types of randomised and non-randomised studies and focused on children aged 4-10 years of age. Therefore which elements of interventions work best in increasing fruit and vegetable intake in adults were not yet examined, it could be that factors found to increase fruit and vegetable intake in children could also be applicable to adults.

A systematic review by Pomerleau (Pomerleau, Lock et al. 2005) analysed the effectiveness of intervention to increase fruit and vegetable intake in adults aged 16-69 years of age who are not acutely ill, with ≥3 months of follow-up. Searches were carried out on 14 publication databases for papers from earliest record to April 2004 and included studies from USA, UK, Japan, New Zealand, India and the Netherlands. In primary prevention interventions, fruit and vegetable intake increased by between 0.1 to 1.4 servings per day while a higher effect was found for interventions at individual with high-risk or pre-existing health disorder. The review also found positive effect of face to face education or counselling, telephone contact, computer-tailored and community based multi-component interventions (interventions using more than one method). A criticism about this study is that as it included adults with pre-existing health disorder and high-risk individuals, the effect of the intervention as a prevention means was not analysed. As previously suggested interventions aimed at high-risk individual or with pre-existing health disorder showed more effective results (Ebrahim and Davey Smith 1997; Pomerleau, Lock et al. 2005). Therefore Pomerleau suggested that trials targeted at high-risk individual should be considered separately from studies with participants from general population.

Two systematic reviews (Kroeze, Werkman et al. 2006; Eyles and Mhurchu 2009) have specifically analysed the effect of tailoring (an intervention catered specifically to individual needs) in increasing fruit and vegetable intake. A systematic review by Kroeze (Kroeze, Werkman et al. 2006) included interventions studies in English published from 1965 to September 2004 which were identified using three databases and included interventions aimed at healthy adults aged eighteen years of age and older. The review only included studies that have computer tailored interventions aimed at physical activities or nutritional behaviours. The interventions reviewed were mostly print computer tailored personal feedbacks, letters or newsletters. Included studies were then categorized into measurements periods namely, short-term (<3 months), medium-term (3-6 months) and long-term (>6 months) while effect sizes were divided into cut-off points of 0.2-0.5 for small effect size, 0.5-0.8 for moderate effect size and >0.8 for large effect size. Out of fourteen studies aimed at increasing fruit and vegetable intake, ten studies measured short-term interventions effects. Furthermore five studies compared computer tailored with no intervention and found significant effects while two studies compared computer tailored with generic information and found significant effects. Four studies that analysed medium-term effects found significant effects in favour of computer-tailored compared to no intervention. In addition two studies that reported long-term effects also found significant computer tailored effects. The limitation of this review were most of the included studies that found significant effects compared computer-tailored to no intervention, there were only two studies that compared computer tailored education with generic information (non-tailored) and the intervention effects (mean difference between the intervention and control groups were not presented, because the review only reported whether the interventions were significant or not).

Similarly a review by Eyles (Eyles and Mhurchu 2009) examined the effectiveness of tailoring on nutrition education both for total fat and fruit and vegetables outcomes. The review included studies published between January 1990 and December 2007 through a number of electronic databases namely, Medline, Psycinfo, Cinahl, Eric, Embase, DARE, CDSR, Digital Abstracts, Science Citation Index and PubMed. Interventions included had at least six months of follow-up and included adults (≥18 years of age) of any health status. The review included four trials that compared tailored with non-tailored nutrition education and found that tailored intervention may increase 0.35 servings per day (95%CI 0.19 to 0.52). A comparison of tailored nutrition education with no nutrition education concluded that tailored nutrition education may increase 0.59 servings per day (95% CI 0.21 to 0.98) which included six studies in the analysis. The review has several limitations. Firstly the studies that were included had a wide range of dietary outcomes and therefore it was difficult to differentiate which one is the main outcome which made it possible that positive effects were in fact the result of chance rather than true effect of tailored intervention. Secondly the 'tailoring' terms used in the included studies were diverse therefore difficult to be distinguished whether it is individual or group tailoring interventions and also which components of tailoring intervention work best compared to others were not assessed. Thirdly Eyles's review only included one study targeted at increasing fruit and vegetable intake in low income groups and was therefore not sufficient or representative.

Both studies by Kroeze (Kroeze, Werkman et al. 2006) and Eyles (Eyles and Mhurchu 2009) concluded that in order to analyse the effectiveness of an intervention (for example tailored intervention) compared to generic intervention (non-tailored intervention) a more in depth analysis need to be carried out by establishing an indirect comparison that enables us to compare tailored interventions with generic interventions (non-tailored) by indirectly comparing them with a common intervention (Bucher, Guyatt et al. 1997; Song, Altman et al. 2003; Song, Harvey et al. 2008).

A more recent systematic review by Shaikh (Shaikh, Yaroch et al. 2008) analysed papers published in English from 1994 to 2006 that described the relationship between psychosocial predictors and fruit and vegetable intake in adults. The review included 35 studies of which 21 were cross-sectional or descriptive studies and 14 were prospective studies. The study used systematic meta-evaluation method in which results for each psychosocial construct across groups of related studies were qualitatively summarized, leading to ratings of strong, sufficient or insufficient evidence of effectiveness. The study found strong evidence for self-efficacy, social support and knowledge as predictors of adults' fruit and vegetable intake and weaker evidence was found for variables including barriers, intentions, attitudes/beliefs, stages of changes and autonomous motivations. However the study has several limitations. Firstly there were no randomised controlled trials among 35 studies which were included and therefore the ideal condition in analyzing the true effect of the intervention may not be established. Secondly the review only included six studies that have mediation analysis which is a way to quantitatively assess how interventions induce changes in individual's behaviour by assessing the impact on intermediate psychosocial variables. The mediation analysis would have been the key to understand how interventions affected individual's behaviour.

The differences of findings from systematic reviews may arise due to the difficulties in combining interventions. According to Brown (Brown 2009) the results of systematic reviews may differ because of the following differences in the design:

- Differences in review protocols: studies specifically aimed at increasing fruit and vegetable intake were more effective in increasing fruit and vegetable intake compare to those that has several other aims, for example lowering fat intake, increasing physical activity or increasing cancer awareness through screenings.

- Differences in outcome measures: studies used different methods of dietary measurements (FFQs, 24-hour recalls or food records).

- Differences in assessment of participants: differences in results were because all participants were assessed according to the groups they were randomised into.

Studies in which intent to treat was carried out reported a more favourable effects of interventions.

The National Institute for Health and Clinical Excellence (NICE) Public Health Guidance 6: Behaviour change at population, community and individual levels (National Institute for Health and Clinical Excellence October 2007) identified several gaps in existing evidence based on the results of assessments which were as follows:

- Cost-effectiveness of behaviour change particularly in specific subgroups.
- Adequate outcome measures that may explain the link between interventions and health outcomes.
- Interventions based on psychological model that clearly described the relations of outcome measures to the model.
- In-depth separate descriptions of the links between knowledge, attitudes and behaviour.
- Definitive explanations of the effects of behaviour change interventions on health inequalities.
- Reliable data to expand the long-term health outcomes of interventions.

Based on the above findings, the NICE Public health guidance on behaviour change (National Institute for Health and Clinical Excellence October 2007) recommended several points for consideration when conducting a research which were as follows:

- Adequate descriptions and rationale used of research methods, including explanations of the forms of interpretation used. And also adequate descriptions of how reliable and valid the measurements of behaviour changes were.
- Clear descriptions of the interventions (the messages delivered, durations, target participants and settings).
- Data on the impact on health.
- Reports of differences found in access or recruitment, especially in different characteristics of participants (social class, education, gender, or income).
- Clear definition of outcomes measured in the study.

This NICE guidance (National Institute for Health and Clinical Excellence October 2007) also suggested factors to be addressed when planning an intervention to change a behaviour.

1. Individual factors such as target groups' age, socioeconomic status, ethnicity and gender. These characteristics will then help in setting up target populations, target of behaviours, analyse the barriers and facilitators and relevant theoretical links.
2. Social, environmental, economic and legislative factors that may help to change behaviours for example community interventions or mass media interventions set up by the government.

In order to be able to comprehensively answer the gap in evidence and address the recommendations given by NICE as well as provide high quality evidence, the study will need to be conducted using systematic review.

1.3. Theory based intervention models

Interventions aimed to increase fruit and vegetable intake can be presented in the forms of advice, discussion, teaching and counselling the intention being to increase knowledge of the benefits leading to changes in beliefs, attitude, values and behaviour of individuals, families and/or communities (Minnesota Department of Health Section of Public Health Nursing 2001; National Institute for Health and Clinical Excellence March 2006).

Cross-sectional study and literature review (Glanz, Basil et al. 1998; Story, Neumark-Sztainer et al. 2002) suggested the main factors that influences dietary choices were food taste, cost, availability and preferences. Similarly according to Cox and Anderson (Cox and Anderson 2004) food choices were patterned based on characteristics such as age, gender, social class, ethnicity, marital status and psychosocial factors. These factors must be considered when developing interventions to influence dietary intake.

Several psychological models have been developed to predict and explain health behaviour of individuals as the basis for health behavioural oriented interventions.

These are Social Cognitive/Social Learning Theory, Theory of Planned Behaviour (TPB) and the Transtheoretical Model of Change (TTM) or Stage of Change Model. All of these are social cognition models, based on theories that specify the adjacent cognitive determinants of behaviour.

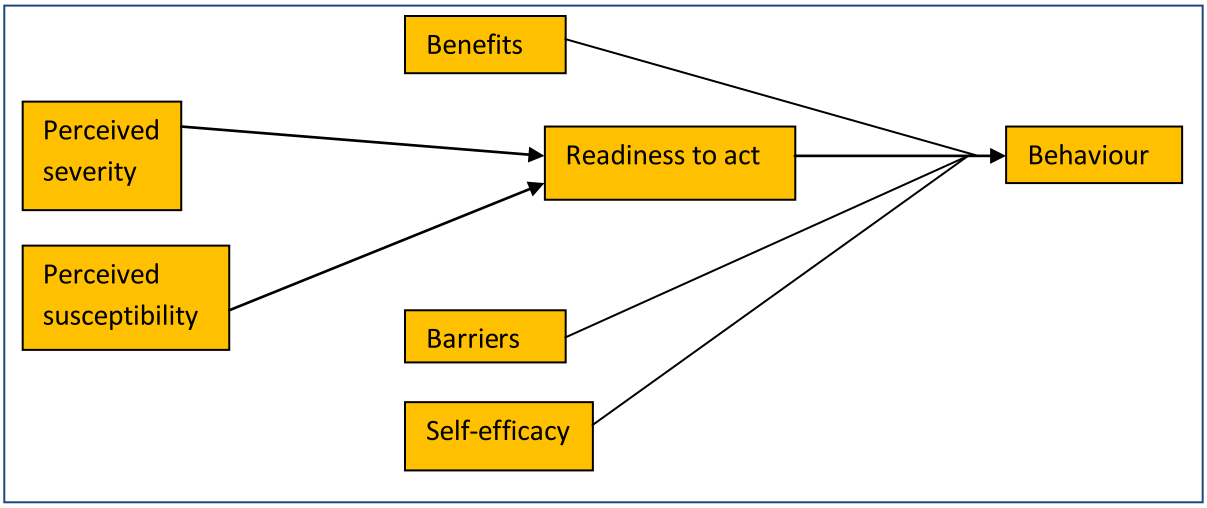
1.3.1. Social Cognitive/ Social Learning Theory

According to Social Cognitive/ Social Learning theory by Bandura (Bandura 1986) behaviour is affected by two norms namely social sanctions and self-sanctions. Certain behaviour that violates the social norms is punished while behaviour which conforms to the social norm is rewarded. People develop their own standards of behaviour and control their actions through self-evaluation of the consequences and then may behave in ways that do not violate the standards. However people's standards may change depending on the settings or environments that they are in (Bandura 1991; Bandura 1997).

1.3.2. The Health Belief Model

The Health Belief Model was first developed by Hochbaum and Rosenstock (Hochbaum 1958; Rosenstock 1966; Tilley, Glanz et al. 1999; Stevens, Glasgow et al. 2003) to explain why people have certain behaviours. The initial model has been modified by Baranowski (Sorensen, Stoddard et al. 2007) to conclude that different beliefs such as readiness to act, barriers, self-efficacy and benefits would motivate people to take preventive measures for their health. Two factors are seen to influence people's readiness to act which are perceived severity and perceived susceptibility. For example in relation to the benefit of increasing fruit and vegetable intake it is believed that increased consumption may reduce CVD risks, however there may be barriers to increase the intake such as cost or availability (Winett, Anderson et al. 2007). This model is presented in Figure 1.01.

Figure 1.01 a schematic representation of the Health Belief Model



Adapted from(Djousse, Arnett et al. 2004): 20

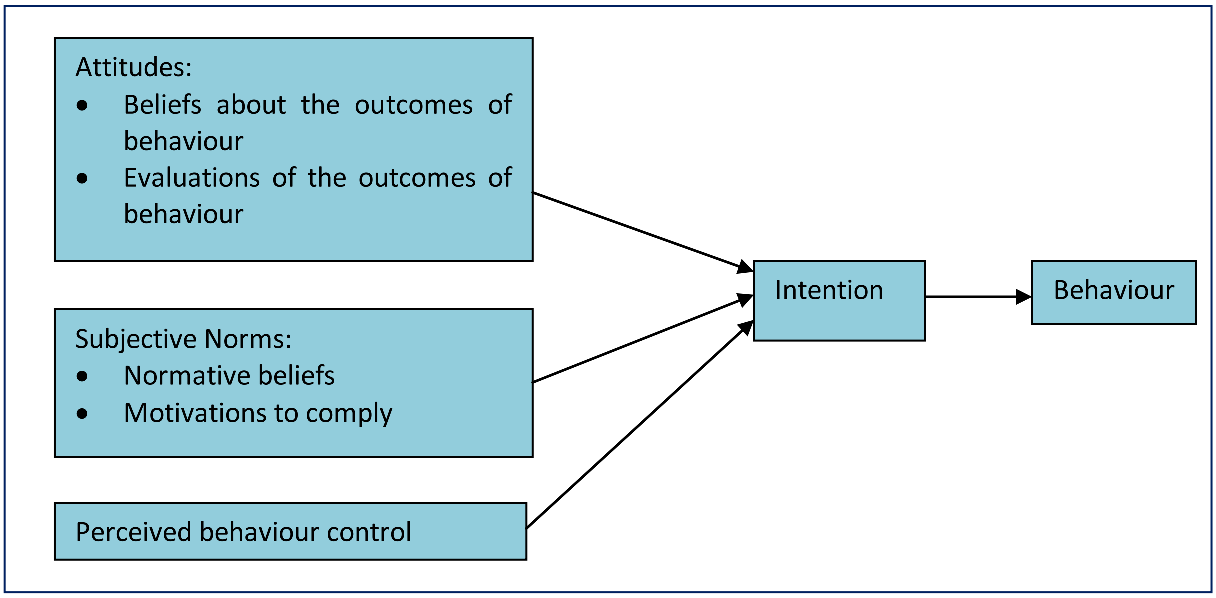
The Health Belief model does not include the people's perception that they are able to change their behaviour. In addition the model focus more on beliefs about risk rather than emotional responses to perceived risk (Peters, Slovic et al. 2006; Lawton, Conner et al. 2007). The main criticism of the theory is that the model focuses on people's decisions and does not address social and environmental factors (Edberg 2007).

1.3.3. Theory of Planned Behaviour (TPB)

The theory was developed by Ajzen (Ajzen and Madden 1986) to study the cognitive determinants of health behaviour by adding perceived behaviour control as determinant to the previous theory of reasoned action (Ajzen and Fishbein 1980).

Theory of Planned Behaviour has been used to predict health behaviours in various types of interventions. According to the theory people's behaviour is decided by the strength of intention to perform a specified behaviour which then determines the amount of effort people put in to change a behaviour (Ajzen 1991). The theory suggests that the strength of people's intention is determined by three factors which are their attitude toward the behaviour, a person believes others think they should do (subjective norms) and their perceived behaviour control. The model is represented schematically in Figure 1.02.

Figure 1.02 a schematic representation of the Theory of Planned Behaviour



Adapted from (National Institute for Health and Clinical Excellence 2007): 182

Taylor (Taylor 2009) concludes that TPB is useful because it provides a model that connects beliefs and behaviour. Thus it can give an idea of people's intentions in relation to a certain health habit. However Sutton states the potential difficulty in implementing TPB based interventions is "that it is not always easy to design messages that target a single component of the theory" (Sutton 2010). Furthermore the model does not consider people's characteristics such as gender, ethnicity or age that might influence their norms and beliefs (Edberg 2007).

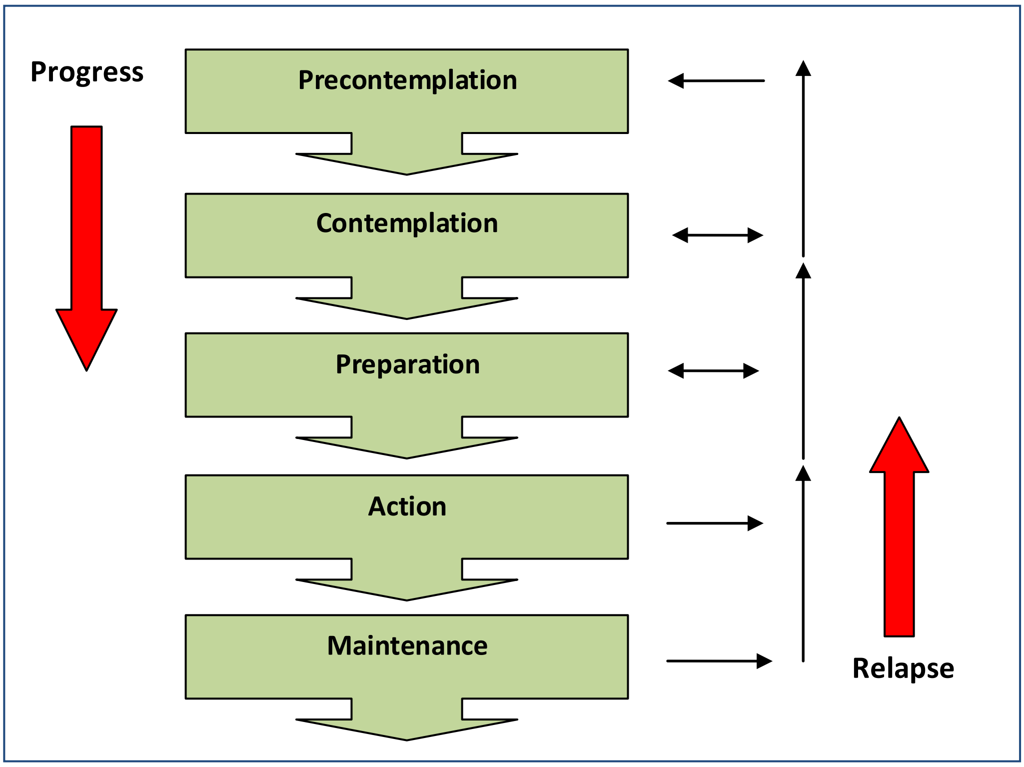
1.3.4. Transtheoretical Model of Change (TTM)/Stage of Change Model

Prochanska and associates (Prochaska, DiClemente et al. 1992; Prochaska 1994) developed the TTM which was based on the thinking that promoting beneficial habits or changing bad habits is not an instant process. People go through stages while they are trying to implement a good habit or stop a bad habit. The support they may require from therapist, family or friends and a formal behaviour changing program may vary depending on which stage they have reached (Prochaska 1994; Rothman 2000). The model suggested treatment goals and interventions for each stage. The model was originally developed to treat addictive disorders and has now been applied to other life habits. As Blalock and Weinstein suggested the TTM is useful in analyzing people's readiness to change by categorizing them into stages in order to address specific types of interventions (Weinstein 1988; Blalock, DeVellis et al. 1996). The stages are divided into the following:

1. Precontemplation: at this stage, people have no intention of changing their behaviour. Often people at this stage seek treatment or help if they are pressured by others or forced into changing their behaviour. Thus they often revert to their old behaviours.
2. Contemplation: People at this stage are aware of their problem and have started thinking about it but have not made any commitment to take action. These people are still weighing the pros and cons of changing their behaviour and continuing to find the positive aspects of the behaviour enjoyable.
3. Preparation: at this stage people have the intention to change their behaviour but may not have acted or have made slight changes to their behaviour but have not yet made the commitment to eliminate the behaviour completely. However they have intended to change their behaviour in the near term (within a month).
4. Action: people at this stage have already modified their behaviour. To succeed at this stage requires commitment of time and energy to making real behaviour change. This stage is marked at the first six months of abstinence or change in their behaviour.
5. Maintenance: This is the stage in which people have been continuously change their behaviour for more than six months and work to prevent relapse and to consolidate the gains made.

People are assumed to move through five stages according to the order in Figure 1.03. The first three stages involve motivational processes, while the later two stages are considered to be behavioural processes.

Figure 1.03 a schematic representation of Transtheoretical Model of Change (TTM)/Stage of Change Model



Adapted from (Health Promotion New Zealand 2011):
http://www.healthpromotion.co.nz/?page_id=566

The TTM intervention that was able to make people assess how they feel and think about the problem and changes that might occur after stopping it, move people from contemplation to preparation. To bridge the gap between preparation and action, researchers should design an intervention that would get people to commit about when and how they will change their behaviour. Interventions which aimed at delivering social support, stimulus control, coping skills and self-reinforcement should be most successful with people already moving through the action phase into long-term maintenance. According to Taylor "when success rates are recalculated to include only individuals who are ready to change their behaviour, namely those people in the action or preparation stage these programs look more successful" (Taylor 2009). Thus the implementation of the model has yielded mixed success. The model has been developed to examine different types of health behaviours for example modification of a high-fat diet, practice of safe sex, regular mammograms and smoking cessation (Prochaska, DiClemente et al. 1992). Intervention based on people's stages has been successful to stop smoking but the model did not show positive effects on other studies which aimed to reduce dietary fat (Lamb and Joshi 1996). In a study conducted by Prochanska it was concluded that stage-matched intervention directed to multiple health behaviour (smoking, diet and sun exposure) produced significant behaviour change even in people who were not prepared to change (Prochanska, Velicer et al. 2004).

The TTM has been criticize because there is little evidence that people will progress in steps according to the model (Littell and Girvin 2002). Also studies often use stage progress as dependent variables rather than actual behaviour change which assume the validity of the model rather than testing it (Sniehotta and Aunger 2010).

The theories mentioned above may help in building foundations in developing interventions to increase fruit and vegetable intake. For example in the following factors of the interventions:

1. Printed messages (newsletters, leaflets, emails) to increase knowledge of the importance of sufficient amount of fruit and vegetable intake.
2. Interventions specifically based on people's self efficacy, intentions, attitudes, beliefs or barriers and facilitators.
3. Motivational interview interventions to assess people's stage of change given by dietitians, other health care professionals (nurses, GPs, physicians) or non health care professionals (trained staffs).
4. Settings of interventions (work places, schools, communities or clinics)

1.4. Fruit and vegetable recommendations

The result of FAO/WHO joint consultation on diet, nutrition and prevention of chronic disease, recommended minimum intake of 400 grams of fruit and vegetable per day for the prevention of chronic diseases such as heart diseases, cancer, obesity and diabetes (World Health Organization 2003). Based on the Dietary Guidelines for Americans recommended two cups of fruit and 2½ cups of vegetables per day for a person with 2000-calorie intake with higher or lower amounts depending on the calorie level (U.S. Department of Health and Human Services 2005). Meanwhile in the UK the 5-a-day program recommended at least five portions of fruit and vegetable intake per day with one portion equal to 80 grams (Food Standards Agency 2010; National Health Service 2010).

However a recent survey in the US showed that 75.7% of adults consumed less than five or more servings of fruits and vegetables daily (US Centers for Disease Control & Prevention and National Center for Chronic Disease Prevention and Health Promotion 2007). In addition another survey from the UK revealed that on average adults in the UK only eat 4.4 portions a day. Among them 62.6% of men and 66.7% of women eat less than five portions a day (Food Standards Agency 2010).

Low intake of fruits and vegetables has been found to be a global problem. A recent study based on a World Health Organization survey in 2002-2003 revealed that 77.6% of men and 78.4% of women from the 52 mainly low and middle income countries consumed less than the minimum recommended five daily servings of fruits and vegetables (Hall, Moore S. et al. 2009).

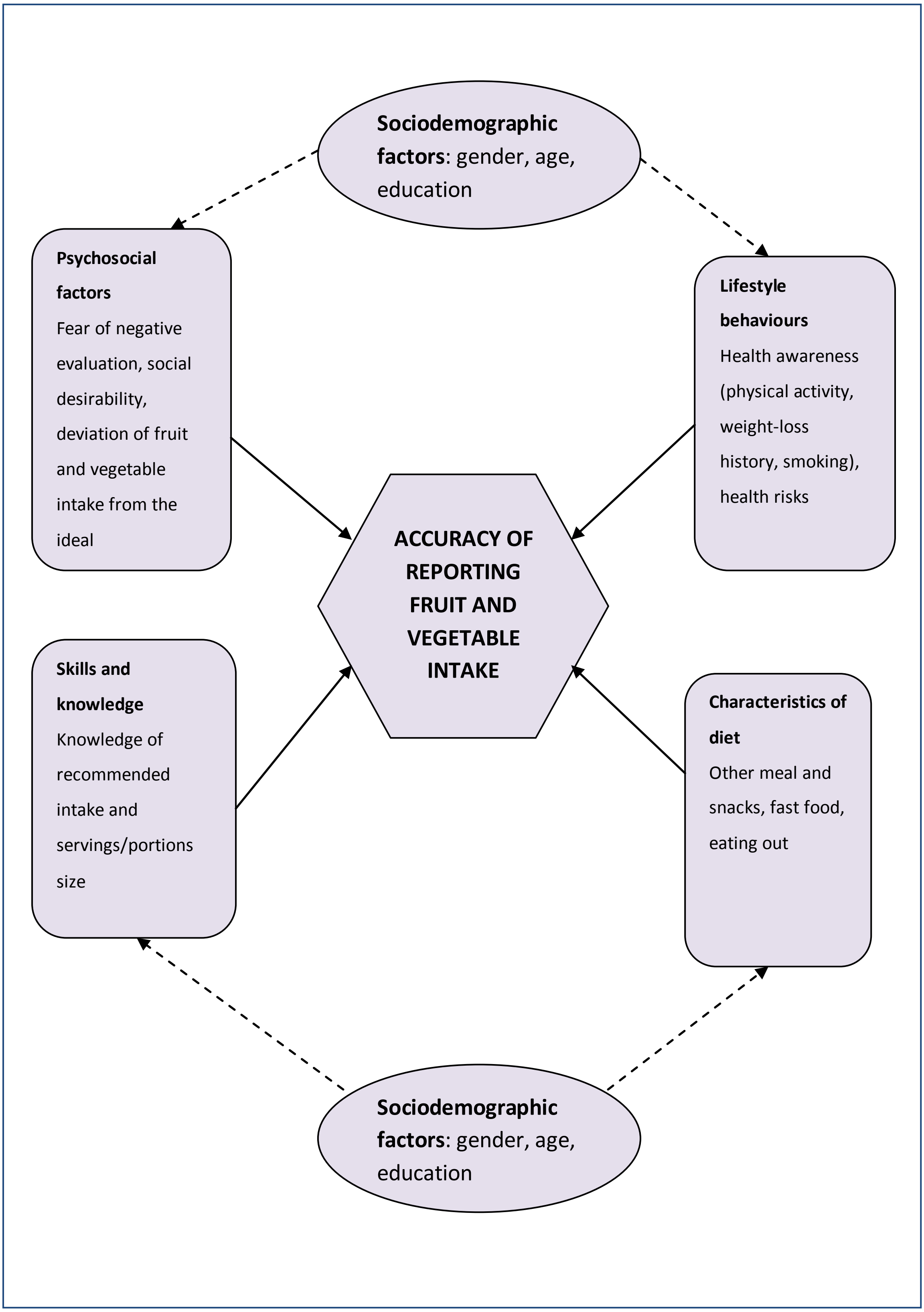
1.5. Fruit and vegetable intake measurements

Tooze (Tooze, Sabar et al. 2004) stated that there are four domains that affected the accuracy of reporting energy intake which were then modified for accuracy of reporting fruit and vegetable intake as follows:

1. Psychosocial factors which include the fear of negative evaluation, social desirability and deviation of fruit and vegetable intake from the recommended intake.
2. Lifestyle behaviours which include health awareness (physical activity, smoking, weight loss history) and health risk (hypertensive, overweight or obese).
3. Skills and knowledge which include knowledge of the recommendation of fruit and vegetable intake and size of one serving or portion of fruit and vegetables.
4. Characteristics of diet which include low-fat diet, fast-food, eating out habit and other meals and snacks.

These four domains may affect the accuracy of reporting fruit and vegetable intake of people. The domains are influenced by people's gender, age and education (Figure 1.04).

Figure 1.04. Analytical framework of factors that affected the accuracy of reporting fruit and vegetable intake



Adapted from Tooze (Tooze, Sabar et al. 2004): 798

According to Gibson (Gibson 2005) there are several tools to measure individual's food consumption as follows:

1. The food frequency questionnaire (FFQ) is a tool that consists of a list of specific foods (1 to more than 200 items) and frequency-of-use response categories (more than once per day, once per day, 3-6 times per week). The individual is then asked to tick the questionnaire for each of food and the suitable frequency the food was eaten over a reference period (one week, 1-3 months, 6 months or one year)
2. The 24-hour recall is a tool used to interview the individual about the exact food intake and the specific amounts eaten during the previous 24 hour period or preceding day. Repeated 24-hour recall is used when additional interview is conducted sometimes on different days of the week or in different seasons of the year in order to estimate the average food intake of individual over a longer time period (usual food intake). A skilful interviewer is needed for good accuracy.
3. The food record is a tool used by the individual to record all foods and beverages (including snacks) eaten over a specific time period (usually several days). Additional details may also be collected, including method of preparation and cooking, final weight of dish, the amount eaten by individual and brand names of food (if known). Food records may be equipped with details of food portion size (80 grams for a portion of fruit and vegetables, amount of food in cups and spoons, size of meat and cake (using ruler), counts for eggs and bread slices).
4. A weighted food record is a food record that also requires the individual to weigh all foods and beverages consumed by individual during a specific time. For mixed dishes like spaghetti Bolognese, the individual should record the final weigh of the finished dish, full descriptions of ingredients used in the meal, and brand of the ingredients used (if known). The weighed food record is frequently used in the UK and Europe. At the beginning, the participants are given instructions on how to keep their records and at the end of the record period the record is ideally reviewed for completeness by the researchers.
5. The dietary history is a tool used to estimate the usual intake of individual and meal pattern over a relatively longer period (up to a month). There are usually three components in dietary history namely interview about usual overall eating

pattern, using questionnaire or 24-hour recall to cross-check the intake and the individual is asked to record the food intake at home for three days using the same method as food record.

Studies with self reported measurement of intake using FFQs, 24-hour recalls, food records or food diary were included in this review. Agudo (Agudo 2005) adds that the most used instruments to estimate fruit and vegetable intake are food frequency questionnaires (FFQs) and 24-hour dietary recalls.

Larger-scale studies aimed at communities or populations prefer FFQs because FFQs can be delivered by mail and telephone call. FFQs can be completed in less time than diet history or recall. They can be processed electronically and repeated at regular intervals (Willett 1998) making them inexpensive and standardised ways of collecting information from large samples. FFQs can also quantify the frequency information by categorizing the respondent's usual portion size into three categories namely large, medium or small. In fruit and vegetable intake one portion is equal to 80 grams.

The problem with self reported measurements of intake using FFQs, 24-hour recalls or food records is that in using self assessment the respondents were asked to answer the questionnaires therefore there was no manner of assessing whether answers are honest or correct. Biases that may exist in self reported measures include the tendency to report what the examiner or people around the participants may desire (social desirability) and which details they remember of food intake which may cause participants to report false measurements or have difficulties remembering past intake.

According to Van de Mortel "the tendency for people to present a favourable image of themselves on questionnaires is called socially desirable responding (SDR)" (Van de Mortel 2008). In the study, Van de Mortel searched CINAHL database for questionnaire-based studies published in English between 2004 and 2005. The findings suggested that among 14,275 questionnaire-based studies found on CINAHL; only 31 studies (0.2%) used the Social Desirability Scale to examine the effects of SDR on the outcomes. Further investigation suggests that only 13 studies (43%) found that SDR influenced outcomes (participants' answers of questionnaires were influenced by social desirability bias). On the other hand 45% of studies that used the Social Desirability Scale were not influenced by SDR. The study also suggested that participants were more likely to be influenced by social desirability when reporting socially sensitive topics such as dietary intake or physical activity level, making social desirability highly relevant to fruit and vegetable research. Limitations to this study were the limited search duration (studies published in 2004 and 2005 only) and the fact that effects of SDR and Social Desirability Scales were presented in proportions therefore the true differences were not identified, if the review was conducted using systematic review then the mean differences of over reporting could be examined in greater detail.

Methods of assessing dietary exposure such as food records, FFQs and 24-hours recalls are subjective because they are prone to substantial errors from reporting, portion size estimations or inaccurate recalls. Furthermore studies showed that food frequency questionnaires have a tendency to overestimate fruit and vegetable consumption and a greater tendency to overestimate where more questions are asked to the respondents (Krebs-Smith, Heimendinger et al. 1995).

Inaccurate recall as explained by Smith (Smith 1991) happens because people have episodic memory about eating or drinking. The accuracy of episodic memory reduces over time and is only based on people's usual intake. This is the greatest problem for FFQs measurements as participants are often asked to recall their intake for the past 3-6 months, compared to 24-hour recalls or food records in which participants are asked to note their intake within the past 24-hours (24-hour recalls) or 3 to 7 days (food records) (Hebert, Clemow et al. 1995; Kristal, Andrilla et al. 1998).

A study by Bingham (Bingham, Gill et al. 1994) collected dietary data from 160 women aged 50-65 years of age around Cambridge area. The study checked the accuracy and feasibility of the European Prospective Investigation into Cancer and Nutrition (EPIC) study and compared seven dietary assessment methods to a 16 day weighed food record (seen as the gold standard for assessment of intake) which included the following:

1. A simple 24-hour recall.
2. A structured 24-hour recall with portion size assessments using photographs (unstructured 24-hour recall was collected once at the beginning of season 1, while structured 24-hour recall was given once to participants on day 0 of season 2 and collected on day 1).
3. Oxford FFQ.
4. Cambridge FFQ.
5. A 7 day estimated record or open-ended food diary.
6. A structured food-frequency (menu) record.
7. A structured food-frequency (menu) record with portion sizes assessed using photographs on each of four occasions (seasons) over one year period.

Findings of Bingham's study suggested that there were significant overestimations of vegetable intake measured by Oxford FFQ, Cambridge FFQ, 7-day checklist season 1 and 7-day checklist season 4 when compared to 16 days weighted records all four seasons (Table 1.01). The results of fruit and vegetables outcomes were available on the following measurements:

Table 1.01
Daily food consumption values (g/d) obtained using seven different dietary assessment methods completed by 160 women aged 50-65 years (Bingham, Gill et al. 1994)

Intake	16 days weighted records All four seasons (SD)	Oxford FFQ Season 3 (SD)	Cambridge FFQ Season 3 (SD)	24-hour recall (unstructured) Season 1 (SD)	24-hour recall (structured) Season 2 (SD)	7-day checklist Season 1 (SD)	7-day checklist Season 4 (SD)
Vegetables	272 (85)	406 (153)*	386 (161)*	273 (143)	294 (157)	246 (74)*	397 (164)*
Fruit	206 (130)	219 (145)	231 (167)	224 (194)	218 (211)	198 (125)	232 (157)

Note: *=mean values were significantly different from those obtained by 16 day weighted records

Bingham explained that overestimation of Oxford FFQ was because some of the portion weights used in the Oxford questionnaire were greater than those recorded by the 16-days weighted records (for example in carrots, 80 grams for questionnaire and 65 grams for weighted records). Cambridge FFQ used portion weights were very similar to those used in 16-days weighted records (for example carrots 59 grams for questionnaire and 65 grams for weighted records) which was why overestimation of vegetable intake measured by Cambridge FFQ was smaller than that measured by Oxford FFQ. Bingham also added that the discrepancy in average total vegetable consumption was because of the greater reported frequency of consumption reported by FFQs than measured by 16-days weighted records. In summary 24-hour recalls provided more accurate estimations of dietary intake than FFQs or 7–day checklists. This may be because the participants were asked to recall food eaten more recently (within 24-hours or 3 to 16 days ago).

1.6. Biomarkers of fruit and vegetable intake (α-carotene and β-carotene)

Most nutritional biomarkers components are body fluids or tissues that have strong direct relationships with dietary intakes of one or more nutrients or dietary components. Although biomarkers are objective and not prone to the biases of self reported recalls or records; many biomarkers have low sensitivity to intake. In other words, biomarkers are only able to distinguish between the extremes of the intake range (e.g. very low or very high intakes) (Gibson 2005). According to Blanck (Blanck, Bowman et al. 2003) lack of agreement between biomarkers and dietary intake does not necessarily indicate that the dietary measurements method has failed to assess the intake correctly. Lack of agreement may also occur because of biological confounders and laboratory measurement errors of the biomarkers.

Patterson and Pietinen (Patterson and Pietinen 2004) argue that although biomarkers are considered to be objective, biomarkers require biological samples which are not suitable for restricted budgets and may also be impractical because at least two measurements at different time points are needed for each participant (baseline and end of intervention data) which may subject the data to laboratory error. Biomarker levels may also be influenced by bioavailability, metabolic regulation and other non dietary factors such as inflammation.

In conclusion despite the limitations mentioned above, reliable biomarkers of fruit and vegetable intake would be useful in trials aiming to increase fruit and vegetable intake as they have the potential to offer a more objective measure of fruit and vegetable intake not subject to recall or social desirability biases, unlike self reported dietary assessments.

In order to find out which biomarkers of fruit and vegetable most appropriate for healthy adults, I conducted a separate analysis. The inclusion criteria for the analysis were RCTs, healthy participants, had outcomes on possible biomarkers of fruit and vegetable intake (α-tocopherol, α-carotene, β-carotene, lutein, zeaxanthin, lycopene, β-cryptoxanthin, ascorbic acid/vitamin C, glucose, folate, homocysteine, flavonoids, pH, and melatonin). The biomarkers were measured by either blood sample or urine sample. The analysis included the following studies: Brevik (Brevik, Andersen et al. 2004), Svendsen (Svendsen, Blomhoff et al. 2007), Flood (Flood, Mai et al. 2008), Oba (Oba, Nakamura et al. 2008), Bogers (Bogers, Dagnelie et al. 2007), Djuric (Djuric, Vanloon et al. 2008; Djuric, Ren et al. 2009), John (John, Ziebland et al. 2002), and Brevik (Brevik, Rasmussen et al. 2004) .

Findings from the studies are summarised in the table below:

Table 1.02 Descriptions and summary of findings of RCTs for the biomarker analysis

No.	Author	Description of Studies	Findings
1.	Brevik	RCT crossover design study set in Norway and conducted among 40 healthy participants. One group was given two portions (300 grams) of fruit and vegetables per day while the other group received five portions (750 grams) for two weeks.	There were significant increases found in the intervention group compared to control for α-carotene, lutein and total flavonoids. No significant changes were found for β-carotene, zeaxanthin, lycopene and β-cryptoxanthin.
2.	Svendsen	RCT conducted among 103 men and 35 women obese patients with sleep-related breathing disorder (SRBD) from Norway. The intervention group was	There were significant increase found in the intervention group for α-tocopherol, α-carotene, β-carotene and ascorbic acid. No

		given dietary advice or counselling during three months of intervention.	significant changes were found for lutein, zeaxanthin, lycopene, β-cryptoxanthin and folate.
3.	Flood	RCT conducted among 375 participants with and 375 participants without recurrent polp and without a history of diabetes, who were older than 35 years of age in the USA with four years of follow-up.	The study found no significant changes on glucose level of participants after the intervention.
4.	Oba	RCT conducted among 94 healthy women from Japan. In the intervention group, the participants were asked to consume high amounts of six selected vegetables (corn, gourd, sprout and mushroom). The vegetables are naturally high in melatonin and easily accessible in Japan, with a target of 350 grams per day for 65 days. In the control group, participants were asked to avoid those vegetables.	The study found significant increase in melatonin in the intervention group.
5.	Bogers	RCT set in the Netherlands among 71 healthy non-smoking women aimed to increase fruit and vegetable intake by receiving free weekly packages of fruit and vegetables for one month.	The study found no significant effects of intervention to plasma folate and homosysteine.
6.	Djuric	RCT set in the USA among 69 healthy and non-obese women. The intervention group was given Mediterranean diet for six months.	The study found significant results on α-carotene, β-carotene, zeaxanthin and β-cryptoxanthin. No significant change was found for lutein.

7.	John and Huxley	RCT conducted among 660 healthy participants in the UK. The intervention group was given brief negotiation method to encourage increase in fruit and vegetable consumption for six months.	The study found significant changes on α-carotene, β-carotene, lutein, β-cryptoxanthin and ascorbic acid. No significant changes were found for α-tocopherol, lycopene and flavonoids.
8.	Steptoe	RCT set in the USA which included 271 participants. The interventions were behavioural and nutritional counselling to increase fruit and vegetable intake.	The study found significant change on β-carotene. No significant changes were found for α-tocopherol, β-cryptoxanthin and homocysteine.

The criteria for judging a biomarker was useful were as follows:

1. The biomarker must be used in at least half of the included studies; this was to suggest that the biomarkers were used more frequent in population studies.
2. The biomarker must show significant results in almost all of the studies (for example, if the biomarker is included in five studies, at least four significant results must be obtained).

The findings from the analysis which were summarised above suggested that α-carotene and β-carotene may be possible biomarkers of fruit and vegetable intake in healthy adults. Ascorbic acid or plasma vitamin C may be potential biomarker of fruit and vegetable intake however there are only two studies out of eight studies that I examined which measured ascorbic acid or plasma vitamin C. Therefore the consistent significant results were not accomplished. Furthermore according to Institute of Medicine, the average intake of vitamin C is 30-180 mg per day while the efficiency of absorption is 70-90% (Institute of Medicine 2000). Ball states that if an individual consume a single 1 gram dose of vitamin C, 75% is absorbed, while if 12 grams dose of vitamin C is absorbed, only 16% is absorbed, "This fall-off in efficiency occurs because absorption of high luminal concentrations of vitamin C takes place mainly by simple diffusion and this passive movement proceeds at a very low rate"(Ball 2004). Ball also adds that vitamin C is mostly stored in liver and therefore measurement of the ascorbate present in leucocytes is most suitable. Thus, plasma ascorbate reflects recent intakes of vitamin C and not total stored in the body. Hay also states that excess of vitamin C in the body is release through urine (Hay 1998). Due to previous reasons, vitamin C is not considered to be potential biomarkers of fruit and vegetable intake.

Provitamin A carotenoids are mostly found in vegetables (Gregory, Foster et al. 1990; Chug-Ahuja, Holden et al. 1993). Webb suggested that carotene is mostly found in many dark green, red or yellow fruits and vegetables (Webb 2008). Unlike other vitamins, most intakes of vitamin A are stored in the liver (Ball 2004). Therefore plasma retinol reflects body stores of nutrients and not sensitive to short term fluctuations of intake, on the contrary, plasma vitamin C reflect recent intake. α-carotene and β-carotene are carotenoids with vitamin A activity which are dependent to vitamin A status and requirements. There are currently no established normal range for α-carotene and β-carotene (Department of Health 2011). In addition a tolerable Upper Intake Level (UL) in the U.S. has not been established for β-carotene or carotenoids. However according to Webb (Webb 2008), Reference Nutrient Intake (RNI) for vitamin A (retinol) in male and female is 700/600 μg/day (24.43/20.94 μmol/L) while the lower RNI (LRNI) is 300/250 μg/day (10.47/8.73 μmol/L). Similarly the U.S. recommended dietary allowance (RDA) for vitamin A (retinol) is 900/700 μg/day (31.41/24.43 μmol/L). Webb (Webb 2008) also states that the average intake of vitamin A (retinol) from food of UK adults is <80% of the RNI.

Gibson (Gibson 2005) states that "the serum or plasma contains only about 1% of the total body reserve of vitamin A and concentrations do not reflects body stores until they are severely depleted or excessively high." Furthermore the U.S. Food and Nutrition Board and the IVACG suggests that the absorption of provitamin A β-carotene from plant sources is only half of that previously assumed (IOM (Institute of Medicine) 2001; IVACG (International Vitamin A Consultative Group) 2002).

Although the absorption efficiency of retinol is high (70-90%) (Sivakumar and Reddy 1972) the amount available for utilisation is only 5-50% (Garrow, James et al. 2000), which is influenced by many factors such as, the type of carotenoids, the amount of consumption, the presence of fat, nutrient status, genetic factors, host-related factors and interactions between these variables (De Pee and West 1996). Webb (Webb 2008) suggested that 6 μg of carotene is equivalent to 1 μg of retinol, this is because the absorption of carotene is less efficient than retinol and also the absorption is varied from different types of food, for example, less than 10% of carotene is absorbed from raw carrots.

1.7. Health indicators (blood pressure and weight)

As previously mentioned in section 1.1, lowering blood pressure may significantly lower the chance of recurrent vascular events and obesity is an independent factor of clinical coronary heart disease. Therefore it is useful to examine the effects of increased fruit and vegetable intake to health indicators (blood pressure and weight) as primary prevention of chronic disease.

According to Egton Medical Information System (EMIS) blood pressure is the pressure in arteries or blood vessels which is measured in millimetres of mercury (mmHg). "Systolic blood pressure is the pressure in the arteries when the heart contracts while diastolic blood pressure is the pressure in the arteries when the heart rests between each heartbeat" (EMIS 2009). The Blood Pressure Association stated that "high blood pressure is the biggest known cause of disability and premature death in the UK through stroke, heart attack and heart disease. Furthermore one in three adults in the UK had high blood pressure and everyday 350 people have a preventable stroke or heart attack caused by the condition" (Blood Pressure Association 2008). According to Health Survey for England 2006, 31% of male and 28% of women had high blood pressure and mean blood pressure levels were 130.8/74.2 mmHg in men and 124.0/72.4 mmHg in women (Falaschetti, Chaudhury et al. 2009). Recent surveys suggested that the mean body mass index (kg/m^2) for all adults (aged 16 or over) are 27.2 in men, and 28.0 in women which is classified as overweight. According to surveys 24% of adults were obese (BMI ≥30 kg/m^2) which is an overall increase from only 15% in 1993 (The NHS Information Centre 2009; Food Standards Agency 2010). And 47% of male and 41% of women who are obese had high blood pressure (The NHS Information Centre 2009). Hypertension is a condition of having a higher than average measurement in either systolic blood pressure (≥140 mmHg) or diastolic blood pressure (≥90 mmHg) (Falaschetti, Chaudhury et al. 2009).

1.8. Gap in systematic review of the effects of fruit and vegetable intake on health indicators (systolic blood pressure, diastolic blood pressure and weight)

A number of studies examined the effects of various dietary trials on health indicators namely, systolic blood pressure, diastolic blood pressure and weight. However there is still a lack of evidence of the effects on mainly healthy participants.

The Dietary Approaches to Stop Hypertension (DASH) diet is a type of diet that is high in fruits, vegetables, low-fat dairy products and small amount of red meat, sweets, sugar-containing beverages and food that is high in cholesterol. There have been many published studies on intervention using DASH diet. The DASH diet contained smaller amounts of total and saturated fat and cholesterol and larger amounts of potassium, calcium, magnesium, dietary fibre and protein than typical diet (Appel, Moore et al. 1997; Karanja, Obarzanek et al. 1999). More importantly DASH studies provided data of changes in fruit and vegetable intake as well as sodium intake and calcium intake. The interventions were also large scaled and tightly controlled. One of the study was conducted by Appel (Appel, Moore et al. 1997) among 459 adults with and without hypertension. The study examined the change in participants' diet in relation to their blood pressure level. Participants were randomised to three groups namely, the control diet, a diet rich in fruits and vegetables or a 'combination' diet rich in fruit, vegetables and low-fat dairy products and reduced saturated and total fat. After eight weeks intervention the results for non-hypertensive (n=326) participants in the change in fruit and vegetables group minus the change in control group were non-significant reduce in both systolic and diastolic blood pressure. The results were (-0.8 mmHg, 97.5% CI -2.7 to 1.1, P=0.33) for systolic blood pressure and (-0.3 mmHg, 97.5% CI -1.9 to 1.3, P=0.71) for diastolic blood pressure. On the contrary the results for systolic blood pressure and diastolic blood pressure for hypertensive participants were both significant. The results were (-7.2 mmHg, 97.5% CI -11.4 to -3.0, P<0.001) and (-2.8 mmHg, 97.5% CI -5.4 to -0.3, P=0.01) for systolic blood pressure and diastolic blood pressure respectively.

A systematic review by Ebrahim (Ebrahim and Davey Smith 1997) examined the effectiveness of multiple risk factor intervention in reducing cardiovascular risk factors, total mortality and mortality from coronary heart disease among adults. The pooled net difference among 11 RCT studies (with at least six month of follow-up) that compared counselling interventions with control groups (placebo or usual care) results suggested that the intervention trials caused significant falls in systolic blood pressure (-4.2 mmHg, fixed 95% CI -3.8 to -4.6, Chi^2=178.1, df=13, P<0.0001) and diastolic blood pressure (-2.1 mmHg, random 95% CI -1.9 to -2.3, Chi^2=249.6, df=12, P<0.001). The significant interaction between intervention and degree of risk of coronary heart disease (event rate in control group or combined treatment and control group rate) suggested that trials that recruited participants at higher risk were more likely to show beneficial effects compared to participants with no high risk of CHD. The study included various interventions (diet, smoking, exercise, antihypertensive drug, cholesterol lowering drugs) which was evident in the significant heterogeneity test results, therefore the specific effect of fruit and vegetables on blood pressure in healthy participants was not analysed.

Meta-analysis by Brunner (Brunner, White et al. 1997) investigated whether dietary interventions were able to change diet and cardiovascular risk factors. Eight studies were included for the analysis of estimate effects of dietary advice on systolic and diastolic blood pressure for 3-6 months of follow-up while five studies were included for the outcomes at 9-18 months. The results suggested that there were significant falls in systolic blood pressure at 3-6 months (-1.3 mmHg, 95% CI -2.4 to -0.3) and at 9-18 months (-1.9 mmHg, 95% CI -3.0 to -0.8). On the other hand results for diastolic blood pressure were not significant. The results were (-0.7 mmHg, 95% CI -1.5 to 0.0) for 3-6 months and (-1.2 mmHg, 95% CI -2.6 to 0.2) for 9-18 months. The study included hypertensive patients therefore the effects of dietary interventions to healthy participants were not examined.

In a randomised crossover design by Nowson (Nowson, Worsley et al. 2004) which included hypertensive adults participants, three types of diet were compared namely, DASH-type diet (OD), Low-sodium high potassium diet (LNAHK) and high calcium diet (HC). The OD and LNAHK groups recommended 3-4 servings of fruit and at least 4-5 servings of vegetable daily in this four weeks trial. The results of comparisons between HC and OD groups (48 participants) suggested that the HC group had higher systolic blood pressure, diastolic blood pressure and weight compared to OD group. The results of (ΔHC-ΔOD) in (means ±SEM) were as follows (+3.1 ±0.9) for systolic blood pressure,

(+0.8±0.6) for diastolic blood pressure and (+0.7 ±0.2) for weight. The results were significant for systolic blood pressure and weight only. The study was aimed at hypertensive participants and compared high fruit and vegetable diet with high calcium diet and did not analyse the effects of high fruit and vegetable diet directly to blood pressure and weight.

A systematic review by Franz (Franz, Van Wormer et al. 2007) included RCT interventions on overweight and obese adults with at least one year of follow-up using eight types of interventions namely, exercise only, diet and exercise, diet only, meal replacements, very low energy diet, Orlistat, Sibutramine and advice only. The review included 80 studies with 26,455 participants. Average weight loss of 5 to 8.5 kg (5% to 9%) was observed after six months of follow-up for all intervention types except in the advice only and exercise only interventions. The biggest weight loss was apparent in the very low energy diet (nearly 18 kg). However there was also an increase of 6 kg after 12 months of follow-up. The diet only interventions in which participants were given reduced-energy diet and behavioural strategies were able to caused weight loss by 5 kg (at 6 months) to 3 kg (48 months). However the review did not focus on healthy participants and the effect of fruit and vegetables specifically on weight was not analysed.

Whelton (Whelton P.K., He et al. 1997) examined the effects of oral potassium on blood pressure. Fruit and vegetable contains potassium which is a mineral that can help counteract the negative effects of salt thus lowering the blood pressure (Appel, Moore et al. 1997; Van Duyn and Pivonka 2000; Bazzano, Serdula et al. 2003; Blood Pressure Association 2008). The review included 33 RCTs in adults (21 RCTs on hypertensive subjects and 12 in normotensive subjects). The findings from 12 RCTs on normotensive subjects advised that oral potassium supplement resulted in a significant fall on systolic blood pressure (-1.8 mmHg, 95%CI -0.6 to -2.9) but not on diastolic blood pressure (-1.0 mmHg, 95% CI 0.0 to -2.1). Statistically significant falls were found in RCTs with hypertensive subjects (-4.4 mmHg, 95% CI -2.2 to -6.6) on systolic blood pressure and (-2.5 mmHg, 95% CI -0.1 to -4.9) on diastolic blood pressure. The participants were given oral potassium supplements. Therefore a limitation here is that the natural effects of potassium in fruit and vegetables may not be identified. In summary the review suggested that dietary potassium may affect blood pressure as the biomarker of cardiovascular diseases.

Another meta-analysis by Whelton (Whelton, Hyre et al. 2005) was conducted among 25 RCTs with adult participants. The duration of RCTs ranged from 2 weeks to 26 weeks. The RCTs were either crossover or parallel. Types of fibre included were fibre pill, fruit or vegetables, cereal, guar gum, pectin or a combination of cereal, vegetables or fruit. The included RCTs either had no hypertensive participants, mixed participants, or all hypertensive participants. The results suggested that statistically significant falls in systolic blood pressure and diastolic blood pressure were only found on hypertensive participants but not on normal participants. The results were a fall of 5.95 mmHg (95% CI -9.50 to -2.40) and 4.20 mmHg (95% CI -6.55 to -1.85) for systolic blood pressure and diastolic blood pressure consecutively in hypertensive participants. Subgroup analysis on the types of fibre among the four studies did not suggest statistically significant effects of fruit or vegetables on systolic blood pressure (-1.15 mmHg, 95% CI -9.08 to 6.77) and diastolic blood pressure (-4.17 mmHg, 95% CI -8.46 to 0.13).

Several studies have examined the effects of reduced blood pressure and weight on CVD risks. Firstly a review by Cook (Cook, Cohen et al. 1995) which examined the impact of population-wide strategy using findings from Framingham Heart Study which is a longitudinal cohort study with two decades of follow-up. The findings reported that a reduction of diastolic blood pressure by 2 mmHg in population average of white US resident aged 35-64 years of age may affected to 17% decrease in the prevalence of hypertension, 14% reduction in the risk of stroke and transient ischemic attacks and 6% reduction in the risk of coronary heart disease. However participants of Framingham Heart Study were mostly middle class white people. Therefore the generalisability of the findings was questionable to a wider population.

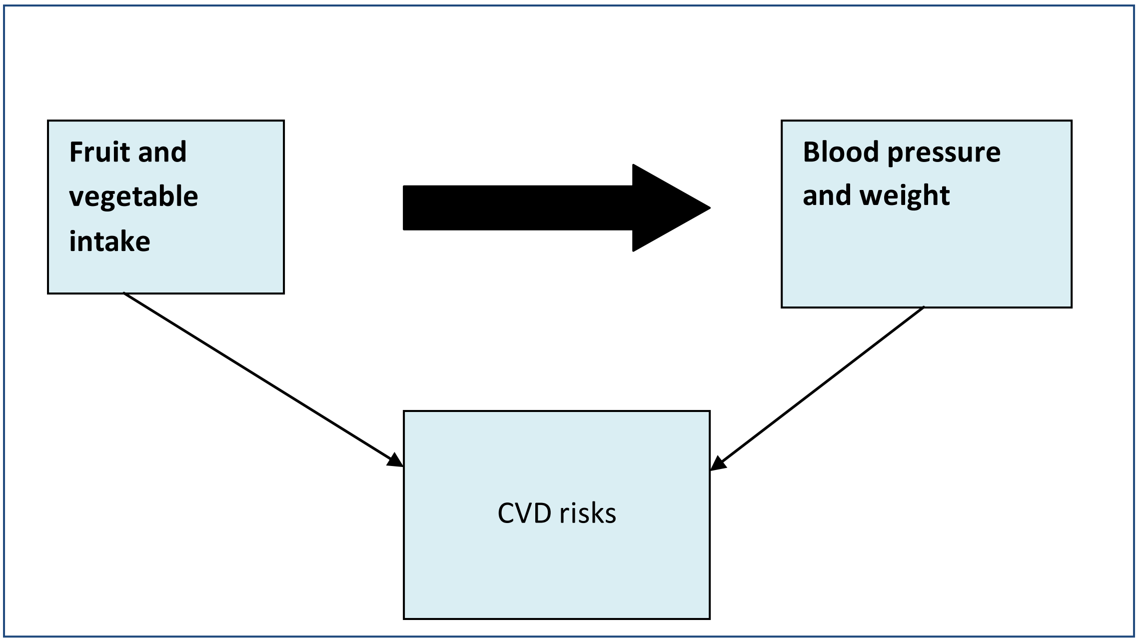
Secondly Lawes (Lawes, Bennett et al. 2004) included seventeen RCTs with 2-27 years of follow-up (>73,500 participants and 29,000 stroke events recorded) in the meta-analysis that compared the effects of β-blocker and/or diuretic with a placebo or no treatment. The results for non-hypertensive participants (mean baseline sBP <140 mmHg) and net difference in sBP/dBP (3/1) was a relative risk reduction of stroke by 30% (95% CI 15-42%). The main findings of this study is the meta-regression of seven trials which indicated that 10 mmHg reduction of sBP was associated with reduction in the risk of stroke by 31% (R^2=0.71). However the main finding included all types of participants, with or without hypertension, with mean age of 63 years of age and mean duration of RCTs of 4.5 years. Furthermore the meta-analysis was conducted to examine the effects of drug to lower blood pressure and not the effects of fruit and vegetable intake to blood pressure.

Thirdly according to a prospective cohort study among 21,414 male physicians in the Physicians' Health Study with 12.5 years of follow-up by Kurth (Kurth, Gaziano et al. 2002) an increase of BMI by one unit, may increase the risk of ischemic stroke by 4% and hemorrhagic stroke by 6% but the severity of stroke for ischemic stroke was not associated with BMI. This study used Cox proportional hazard models to analyse the association between BMI and stroke. Person-time was calculated from return of the baseline questionnaire until the date of stroke, death or the period of study end. The limitations to this study were the self-reported BMI which may lead to misclassification and the fact that the participants of this study were all white male physicians and somewhat leaner than the average US population and may not represented the whole populations.

Fourthly the relationship of age to blood pressure in relation to coronary heart disease was investigated by Franklin (Franklin, Larson et al. 2001) from the Framingham Heart Study with 20 years of follow-up. Findings showed consistent significant results relations between age, systolic blood pressure and the risk of CHD. Meanwhile the results for diastolic blood pressure were only significant for age group of < 50 years of age. The results of proportional-hazard regression coefficients were (1.14, 95% CI 1.06 to 1.24, P<0.01) (sBP) and (1.34, 95% CI 1.18 to 1.51, P<0.001) (dBP) for age <50 years, (1.08, 95% CI 1.02 to 1.15, P<0.05) (sBP) and (1.11, 95% CI 0.99 to 1.24, P=not significant) (dBP) for age 50-59, and (1.17, 95% CI 1.11 to 1.24, P<0.001) (sBP) and (1.12, 95% CI 0.99 to 1.27, P=not significant) (dBP) for age ≥60 years. Findings suggested that systolic blood pressure significantly correlated to incidence of CHD. Furthermore a comparison of group age 50-59 years of age with ≥60 years of age suggested that as participants get older, the hazard ratio also increased by 0.09. The same as previous findings from the Framingham Study, the limitations of this study is the generalisability since most of the participants were white and from middle class. However this study did not include participants who were taking antihypertensive drug therapy and included participants who were free or had no history of CHD at baseline.

Studies mentioned above outlined the effects of reduced blood pressure and weight on CVD risks. Therefore it may be concluded that the three factors (fruit and vegetable intake, blood pressure and weight, and CVD risk factors) are correlated and may influence each other. The relationship between fruit and vegetable, blood pressure and weight and CVD risk could be described as schematic below:

Figure 1.05 Analytic frameworks of the relationship between fruit and vegetable intake, blood pressure and weight, and CVD/CHD risks. Predictor variables were grouped into three domains (fruit and vegetable intake, blood pressure and weight, and CVD risks) that affected each other. The relationship highlighted by bold black arrow was investigated in the study



The review analysed the relationship between fruit and vegetable intake with blood pressure and weight which is indicated by the big arrow in Figure 1.5. As mentioned previously in this section, there is lack of evidence about the effect of RCT interventions to increase fruit and vegetable intake on systolic blood pressure, diastolic blood pressure and weight which specifically targeted healthy participants.

1.9. Thesis Aims

Previous systematic reviews mentioned in Section 1.8 have analysed the effects of the interventions to increase fruit and vegetable intake and effects of altering blood pressure and weight on CVD risks. However there is lack in evidence of RCT interventions to increase healthy adults' fruit and vegetable intake and the effects on blood pressure and weight.

Therefore the aim of this study was to systematically evaluate interventions aimed at increasing fruit and vegetable intake in healthy adults as well as comprehensively assessed which elements of the interventions work best to increase fruit and vegetable intake in healthy adults and analysed the effect of interventions to increase fruit and vegetable in healthy adults on systolic blood pressure, diastolic blood pressure and weight.

1.10. Structure of this thesis

This study aimed to understand interventions to increase healthy adults' fruit and vegetable intake and the effects on blood pressure and weight using systematic review. The thesis included two systematic reviews. The first systematic review aimed to identify which types of interventions that work best to increase fruit and vegetable intake. The results of the analyses were presented based on the level of evidence as follows:

1. Direct comparisons.
2. Subgroup analyses.
3. Indirect comparisons.

Comparisons were conducted based on the following characteristics or types of interventions:

1. Characteristics of interventions (settings, gender target, trial duration, target of fruit and vegetable intake, aim of interventions and dietary measurements).
2. Motivational interview.
3. Social support.
4. Practical skills.
5. Access.
6. Message deliveries (printed message, computer message, video or any combination).
7. Theory based (Social Cognitive/Social Learning, Transtheoretical Model/Stage of Change, Theory of Planned Behaviour or Health Behaviour Change).
8. Psychosocial factors (1-3, 4-6 or more than seven psychosocial factors).
9. Counselling methods (face to face, telephone or email).
10. Counsellors (dietitians, other health care professionals or non health care professionals).
11. Tailored interventions (individually tailored, group tailored or combined)

Mean differences in the intervention groups compared to the control groups after the interventions were analysed using random effects subgroup analysis of interventions characteristics and specific interventions types. Due to the absence of direct comparisons between interventions, adjusted indirect comparisons of interventions were conducted. In addition mean differences of level of biomarkers (α-carotene and β-carotene) were also examined using random effects subgroup analysis.

The second systematic review aimed to analyse the effects of interventions to increase fruit and vegetable intake on systolic blood pressure, diastolic blood pressure and weight. Studies included in the intervention review that contained outcomes of changes in systolic blood pressure, diastolic blood pressure or weight were included in the second review. Random effects subgroup analyses were conducted on data of mean differences in systolic blood pressure, diastolic blood pressure and weight in the intervention groups compared to the control groups after the interventions.

Chapter 2 Methods

2.1. Systematic review of interventions to increase fruit and vegetable intake in healthy adults

2.1.1. Objectives

This study aimed to find out which types of interventions may work best to increase fruit and vegetable intake in adults in relation to the following interventions:

- Whether interventions tailored to specific groups (gender, ethnic, socioeconomic) is more effective than those that are not.
- Whether individual tailored interventions are more effective than those that are not.
- Whether theory based interventions (Social Cognitive/Social Learning, Theory of Planned Behaviour, Transtheoretical Model/Stage of Change) are more effective than those that are not based on theories and analysis of which types of theories are more effective than others.
- Whether interventions with psychosocial factors such as intentions, attitudes, beliefs, self efficacy, knowledge or motivations are more effective than those that are not and analyse which type of psychosocial factors are more effective.
- Whether interventions delivered through computers, telephones, printed messages or email are more effective than other methods and to analyse which types of deliveries are more effective.
- Whether interventions involving practical skills/cooking demonstrations, shopping and preparation are more effective than those without.
- Whether interventions involving role models are more effective than those without.
- Whether media based interventions (delivered through television, radio, newspapers) is more effective than others.
- Whether interventions aimed at pricing and accessibility are more effective than others.

- Whether interventions that involve counselling sessions led by nutritionists/nurses/community workers/other professional workers are more effective than those that are not.
- Whether interventions that build on action plans are more effective than those that are not.
- Whether longer term interventions (more than one year) are more effective than shorter term ones(less than one year).
- Whether interventions that deliver a message that fruit and vegetables are 'fun and tasty' are more effective than those that deliver the message that they are 'healthy'.
- Whether interventions with higher targets of consumption (more than six portions/day) are more effective than those with general targets (≥5 portions/day) or with no specific targets (only to increase fruit and vegetable intake).
- Whether single component interventions aimed at increasing fruit and vegetable intake are more effective than multi-component interventions which address other dietary behaviour (low fat intake), lifestyle (physical activity) or other (screening).

The review also included biomarker analysis of α-carotene and β-carotene from studies that provide such data for analysis. This was done in order to assess the effects of interventions in changing the level of biomarkers in fruit and vegetable intake. The results from biomarker analysis of α-carotene and β-carotene were compared to the interventions effects assessed by self reported dietary intake reported using FFQs, 24-hour recalls or food records.

2.1.2. Development of protocol

Before the start of this study a review protocol was developed to be used as a guideline for conducting this study (for full details, see Appendix 1). The review protocol was formulated using the structure recommended in the Cochrane Handbook for the systematic review of interventions (Higgins and Green 2008), which gives guidelines on conducting high quality reviews. The protocol explicitly refers to the following:

- The objectives of the review.
- The types of studies, participants, and interventions required for studies to be included.
- The types of outcome measures considered important.
- The search strategies to be used for identifying studies.
- The methods of assessing risk of bias.
- The methods of data extraction.

2.1.3. Types of studies

All randomised controlled trials (RCTs) that describe 'random' or 'randomisation' of participants, including cluster randomisation of at least six groups or communities, with follow-up of three months or more were included. This was done in order to include good quality RCTs with long enough duration to assess the intervention effects.

2.1.4. Types of participants

Participants were healthy adults aged 16 years or older. Interventions that were aimed at participants with high-risk of cardiovascular disease (obese, hypertensive, smokers) or pregnant women were excluded, examples of which were studies that specifically only included obese participants (all the participants were obese). This was done to analyse primary care prevention interventions effects in healthy adults.

2.1.5. Types of outcomes measures

The primary outcome of this study was the estimated mean differences in fruit and vegetable intake (portions per day) between the intervention groups and the control groups, collected either from total fruit and vegetable intake (portions per day) at the end of the interventions or the changes in fruit and vegetable intake (portions per day) in the intervention groups and the control groups after the interventions.

The secondary outcomes were the mean differences in biomarker outcomes (serum plasma of α-carotene and β-carotene) between the intervention groups and the control groups compiled either from total serum plasma of α-carotene and β-carotene (μmol/L) at the end of the interventions or changes in total serum plasma of α-carotene and β-carotene (μmol/L) in the intervention groups and the control groups after the interventions.

2.1.6. Search Methods

2.1.6.1. Electronic searches

Six electronic databases were searched namely, The Cochrane Library; MEDLINE; EMBASE; LILACS; PsycInfo and ERIC, for the period of January 2004 to August 2009 with an updated search in March 2010. The review built upon a systematic review by Pomerleau (Pomerleau, Lock et al. 2005) and included all the studies from Pomerleau's review which fit the inclusion criteria; these are randomised controlled trials which were aimed at increasing fruit and vegetable intake in healthy adults (without any cardiovascular disease risk, such as, diabetes, obesity or hypertension and other diseases such as cancer). However an updated new search from 2004 onwards was carried out because Pomerleau's review was published in 2005.

2.1.6.2. Other sources

Theses were searched using the university library catalogue. In addition reference checking from all studies which were included was conducted to find additional or related studies.

2.1.6.3. Search strategies for identification of studies

Search strategies for each of the databases were based on the filtering strategies for randomised controlled trials in the Cochrane Library Handbook (Higgins and Green 2008).

Terms used in the database searches were randomised controlled trials, controlled clinical trial, randomised, placebo, drug therapy, randomly, trial, groups, animals not humans and animals, fruit, vegetable, adult children or adult. Studies satisfying the inclusion criteria were selected.

2.1.6.4. Search strategies

Full details of the search strategies, including the period searched, are given in Appendix 2.

2.1.7. Data collection and analysis

2.1.7.1. Selection of studies

Firstly the titles and then the abstracts of potentially relevant studies were read independently by two reviewers. Full text of relevant studies were obtained and assessed independently by two reviewers for suitability of inclusion in the review. Each of the studies were judged using the inclusion/exclusion form which consists of seven questions as follows: whether the study was randomised, had a control group, was aimed at increasing fruit and vegetable intake, was individual or population based, involved healthy adult participants, had three months of follow-up and if data outcomes were available (see Appendix 3).

2.1.7.2. Data extraction

For all outcome measures, intervention effects was estimated using mean differences of fruit and vegetable intake (portions per day) between the intervention groups and the control groups collected either from total fruit and vegetable intake (portions per day) at the end of the interventions or a change in data in relation to fruit and vegetable intake (portions per day) in the intervention groups and the control groups after the interventions. Data on total fruit or vegetable intake at the end of the interventions or the mean changes of fruit or vegetable intake after the interventions was also collected if provided separately but mean change data was more preferable to end of follow-up data. If the outcomes were given separately for fruit and vegetables then the combined values were calculated using the combined group formula from the Cochrane Handbook (Higgins and Green 2008). The intake of each participant was measured using self-reported food frequency questionnaires or 24-hour recall. If standard deviations were not given I calculated it from standard error, confidence interval or P-value of a t-test according to the formula given in the Cochrane Handbook (Higgins and Green 2008).

In addition the mean differences of biomarker outcomes (serum plasma of α-carotene and β-carotene) between the intervention groups and the control groups were included which were compiled either from total serum plasma of α-carotene and β-carotene (μmol/L) at the end of the interventions or the changes in total serum plasma of α-carotene and β-carotene (μmol/L) in the intervention groups and the control groups after the interventions. If the outcomes were given in other unit, then values were converted to μmol/L according to SI units for clinical data (Rowlett 2001).

Each study was independently extracted by two reviewers and then discussed. Any disagreements were resolved by further discussion, with reference to a third researcher if no agreement could be reached.

Information extracted on the data extraction form was as follows:

- General study population – published or unpublished, author, title, year of publication, journal, year research was conducted and country of origin.
- Study characteristics and descriptive data – sample size, randomised controlled trial (RCT) criteria, number of participants recruited in each group, number of participants at follow-up.
- Participants' characteristics – gender, mean age, marital status, parental status, educational level, income, ethnicity, location (rural or urban), smoking status, alcohol consumed per week, physical activity level, vitamin intake and Body Mass Index. Mean age of participants was calculated from baseline values at the beginning of the interventions or if given separately for each group, the combined value was calculated using the combined group formula from the Cochrane Handbook (Higgins and Green 2008). All participants' characteristics were collected, however the characteristics that have the most outcomes available in the included studies were analysed and presented in the results chapter. Intervention characteristics – psychological and behavioural models used for the intervention designs, follow-up periods, number of sessions in each intervention group, length of sessions, types of interventions (tailored to specific groups or individual, based on barriers and facilitators, based on theories, developed and worked on self efficacy, social support, knowledge, motivation, using personal computers/telephones/printed messages/email, involved role model or practical skills, media based, intervened with access and pricing, involved group-led, or developed and worked on action plans), information given, strategies used, additional treatments given to either group (the intervention group or the control group), locations of interventions. If a study has more than one outcome in the duration of studies (for example have

outcomes for 6 months and 12 months) then both outcomes from that study were included in both trial duration subgroups (3-11 and 12-36 months). On the other hand if two outcomes of duration in the same range were available (for example 3 and 6 months) then only the outcomes at 6 months were included in the subgroup analysis.

- Outcome measure characteristics – assessment methods (food records, FFQs, or 24-hour recalls), results of each measurement, baseline and follow-up results, outcome measures and reported outcome measures. The outcomes were the estimated mean differences of fruit and vegetable intake (portions per day) between the intervention groups and the control groups which were collected either from total fruit and vegetable intake (portions per day) at the end of the interventions or the changes in fruit and vegetable intake (portions per day) in the intervention groups and the control groups after the interventions. If the fruit and vegetable outcomes were given separately then combined values were calculated according to the combined groups formula from the Cochrane Handbook (Higgins and Green 2008). Similarly if there were more than one intervention groups, the combined values were calculated using the combined groups formula from the Cochrane Handbook (Higgins and Green 2008). All fruit and vegetable intake outcomes were collected (for example from 1 item or 26 items FFQs). The FFQ that was closest to 20-item was chosen, if available. Mean differences in biomarker outcomes (serum plasma of α-carotene and β-carotene) were also collected between the intervention groups and the control groups compiled either from total serum plasma of α-carotene and β-carotene (μmol/L) at the end of the interventions or the changes in total serum plasma of α-carotene and β-carotene (μmol/L) in the intervention groups and the control groups after the interventions. Unadjusted outcomes were chosen. Outcomes that were presented in log-transformed, adjusted to baseline, sex, age, BMI or given in servings/1000kcal were excluded from the analysis.

For consistency the main researcher conducted data extraction for all included studies. Each study was extracted by at least two reviewers. The results from each reviewer were discussed with the main researcher and differences were resolved through discussion. More details on the data extraction form are given in Appendix 4.

2.1.7.3. Risk of bias

The risk of bias for each included study were analysed according to the Cochrane Handbook (Higgins and Green 2008) by considering the following risk criteria:

2.1.7.3.1. Sequence generation; was the allocation sequence adequately generated? (Question 2.3 in data extraction form).

2.1.7.3.1.1. Criteria for the judgment of 'YES' (low risk of bias) if the investigators describe a random component in the sequence generation process such as:

- Referring to a random number table.
- Using a computer random number generator.
- Coin tossing.
- Shuffling cards or envelopes.
- Throwing dice.
- Drawing of lots.
- Minimisation (may be implemented without a random element, and this is considered to be equivalent to being random).

2.1.7.3.1.2. Criteria for the judgement of 'NO' (high risk of bias) if the investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach for example:

- Sequence generated by odd or even date of birth.
- Sequence generated by some rule based on date (or day) of admission.
- Sequence generated by some rule based on hospital or clinic record number.

Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgment or some method of non-random categorization of participants for example:

- Allocation by judgement of the clinician.

- Allocation by preference of the participant.
- Allocation based on the results of a laboratory test or a series of tests, allocation by availability of the intervention.

2.1.7.3.1.3. Criteria for the judgement of 'UNCLEAR' (unclear risk of bias) if there was insufficient information about the sequence generation process to permit judgement of 'YES' or 'NO'.

2.1.7.3.2. Allocation concealment; was allocation concealed? (Question 2.4 in data extraction form).

2.1.7.3.2.1. Criteria for the judgment of 'YES' (low risk of bias) if participants and investigators enrolling participants could not foresee assignment because one of the following or an equivalent method was used to conceal allocation:

- Central allocation (including telephone, web-based, and pharmacy-controlled randomization).
- Sequentially numbered drug containers of identical appearance.
- Sequentially numbered, opaque, sealed envelopes.

2.1.7.3.2.2. Criteria for the judgement of 'NO' (high risk of bias) if participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias such as allocation based on:

- Using an open random allocation schedule (list of random numbers).
- Assignment envelopes were used without appropriate safeguards (if envelopes were unsealed or non-opaque or not sequentially numbered).
- Alternation or rotation.
- Date of birth, case record number.
- Any other explicitly unconcealed procedure.

2.1.7.3.2.3. Criteria for the judgement of 'UNCLEAR' (unclear risk of bias) if there was insufficient information to permit judgment of 'YES' or 'NO'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgment for example if the use of assignment envelopes is described but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

2.1.7.3.3. Blinding of participants, personnel, and outcome assessors; was knowledge of the allocated interventions adequately prevented during the study? (Question 2.5 and 2.6 in data extraction form).

2.1.7.3.3.1. Criteria for the judgment of 'YES' (low risk of bias) if any one of the following was fulfilled:

- No blinding but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

2.1.7.3.3.2. Criteria for the judgment of 'NO' (high risk of bias) if any one of the following was fulfilled:

- No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded and the non-blinding of others likely to introduce bias.

2.1.7.3.3.3. Criteria for the judgment of 'UNCLEAR' (unclear risk of bias) if any one of the following was fulfilled: there was insufficient information to permit judgment of 'YES' or 'NO' or the study did not address this outcome.

2.1.7.3.4. Incomplete outcome data; were incomplete outcome data adequately addressed? (Question 2.9a, 2.9b, 3.1.-3.6b in data extraction form).

2.1.7.3.4.1. Criteria for the judgment of 'YES' (low risk of bias) if any one of the following was fulfilled:

- No missing outcome data (all participants who were randomised or had the interventions included in the outcomes).
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups with similar reasons for missing data across groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size
- Missing data have been imputed using appropriate methods.
- The descriptions of participants in each arm were done in all of the following: number of participants who were randomised, number of female/male randomised, number of dropouts, reasons for dropouts, number analysed, reasons for non-analysis, number analysed and description of dropouts.

2.1.7.3.4.2. Criteria for the judgment of 'NO' (high risk of bias) if any one of the following was fulfilled:

- Reason for missing outcome data likely to be related to the true outcome with either imbalance in numbers or reasons for missing data across intervention groups (not all participants who were randomised or had the interventions included in the outcomes).
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size.

- ‘As-treated’ analysis done with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.
- The descriptions of participants in each arm were not done or only partially done on the following: number of participants who were randomised, number of female/male randomised, number of dropouts, reasons for dropouts, number analysed, reasons for non-analysis, number analysed and description of dropouts.

2.1.7.3.4.3. Criteria for the judgment of ‘UNCLEAR’ (unclear risk of bias) if any of the following was fulfilled: there was insufficient reporting of attrition/exclusions to permit judgment of ‘YES’ or ‘NO’, for example number randomised not stated, no reasons for missing data provided or the the study did not address this outcome.

2.1.7.3.5. Selective outcome reporting; were reports of the study free of suggestions of selective outcome reporting? (Question 2.11 in data extraction form).

2.1.7.3.5.1. Criteria for the judgment of ‘YES’ (low risk of bias) if any of the following was fulfilled:

- The study protocol is available and all of the study’s pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
- The study protocol is not available but it is clear that the published report include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

2.1.7.3.5.2. Criteria for the judgment of ‘NO’ (high risk of bias) if any of the following was fulfilled:

- Not all of the study’s pre-specified primary outcomes have been reported
- One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (for example subscales) that were not pre-specified

- One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided such as, an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

2.1.7.3.5.3. Criteria for the judgment of 'UNCLEAR' if there was insufficient information to permit judgment of 'YES' or 'NO'. It is likely that the majority of the studies will fall into this category.

2.1.7.3.6. Industry funding: was the study free of industry funding? (Question 2.10a in data extraction form).

2.1.7.3.6.1. Criteria for the judgment of 'YES' (low risk of bias) if there was a specific statement that the study was funded by the government (for example Department of Health), non-profit organization (for example Cancer Research) or universities.

2.1.7.3.6.2. Criteria for the judgment of 'NO' (high risk of bias) if there was a specific statement that the study was funded by private industry or private bodies.

2.1.7.3.6.3. Criteria for the judgment of 'UNCLEAR' (unclear risk of bias) if there was insufficient information to permit judgment of 'YES' or 'NO'.

Each study were categorised according to the points stated above as either 'YES', 'NO' or 'UNCLEAR' and based on this categorisation, the study was then categorised as having low, medium or unclear risk of bias. According to the following criteria:

- A study was categorised as 'low risk of bias' if allocation sequence was adequately generated, allocation was concealed, knowledge of the allocated interventions was adequately prevented, incomplete outcome data was adequately addressed, reports of the study was free of suggestions of selective outcome reporting and the study was free of private funding.

- A study was categorised as ‘high risk of bias’ if at least two of the following categories were fulfilled: allocation sequence was inadequately generated, allocation was not concealed, knowledge of the allocated interventions was inadequately prevented, incomplete outcome data was inadequately addressed, reports of the study was not free of suggestions of selective outcome reporting, or the study was funded by private industry.
- A study that did not fall under ‘low risk of bias’ or ‘high risk of bias’ was automatically categorised as being ‘unclear risk of bias’.

2.1.7.4. Data analysis

2.1.7.4.1. Type of interventions

Interventions aimed at increasing fruit and vegetable intake which had to be stated as one of the aims of the study were included. However interventions could also include additional aims such as lowering fat intake, increasing physical activity, increasing cancer awareness through screenings or smoking cessation.

Various types of intervention that were used to intervene with adults’ fruit and vegetable intake were identified as follows:

1. Interventions tailored for specific groups are interventions aimed at increasing fruit and vegetable intake in specific groups which could be grouped according to ethnicity, income status, gender and age group. The intervention is therefore tailored (modified) according to specific characteristics and needs of the targeted groups.

2. Interventions tailored to individuals are aimed at increasing individual fruit and vegetable intake and the intervention is therefore tailored (modified) accordingly. For example an intervention based on a stage of change model, the specific recommendation is therefore based on the individual stage of change (pre-contemplation, contemplation, preparation and action) and the advice is given accordingly.

3. Intervention tailored based on barriers and facilitators are based on individual/group barriers and facilitators. The intervention is therefore modified in relation to barriers and facilitators that were given. For example from a pilot study this used focus groups or questionnaires on barriers and facilitators to increase fruit and vegetable intake.

4. Theory based interventions are based on a specific theory for example Social Cognitive/Social Learning, Transtheoretical Model/Stage of Change, Health Belief or Health Behaviour Change which are aimed to increase fruit and vegetable intake.

5. Interventions aimed to improve the participants' self efficacy are based on a specific theory which is then developed to modify a person's self efficacy in changing their behaviour towards increasing fruit and vegetable intake.

6. Interventions aimed to improve the participants' social support are based on the theory of planned behaviour theory or developed specifically to build social support in changing the behaviour towards increasing fruit and vegetable intake.

7. Interventions aimed to improve the participants' knowledge are aimed at increasing a person's knowledge of the importance of fruit and vegetable intake by giving counselling sessions, brochures, leaflets or any other means.

8. Interventions aimed to improve the participants' motivation are based on motivational theory or decision making theory or developed specifically to increase motivation in changing the behaviour towards increasing fruit and vegetable intake.

9. Interventions that use personal computers/telephones/printed messages/email are interventions that use various means of personal communications namely, computers/telephones/printed messages/email to convey the interventions to participants using general and sometimes tailored messages.

10. Interventions that involved practical skills use cooking demonstrations or hands-on-experiences involving participants trying to cook food to increase the participants' cooking and preparation skills, it might also involve shopping skills,

for example an intervention that gives guidance and tips on shopping for healthier and low cost food.

11. Interventions that involve role models present a person who serves as an example, whose behaviour is emulated by others in increasing fruit and vegetable intake. The role model can be a famous person (actor, singer or model) or a community/religious/ organization leader or even a community worker.

12. Interventions which are media based employing television/radio/newspapers or other means of mass media to convey the message of increasing fruit and vegetable intake for any period of time to a mass audience using a general message.

13. Accessibility interventions aim to make fruit and vegetables more accessible for example by giving vouchers or establishing local fruit and vegetables shops.

14. Group-led interventions are conducted in groups and led by a nutritionist or community health workers who will give counselling to group members.

15. Interventions developed and worked on action plans are based on the Transtheoretical Model theory or developed in making specific action plans or goals to increase fruit and vegetable intake.

16. The following criteria in the interventions were also identified:

    - Whether the interventions convey a message of fruit and vegetables as being fun and tasty or healthy.

    - The specific plan target of each intervention for example the number of portions of fruit and vegetables per day that is targeted to the specific intervention in the study.

    - The means of collecting data on fruit and vegetable intake; what kind of dietary measurement is used in the study, for example using food frequency questionnaires, 24-hour recalls or food records.

From the information collected in the data extraction forms (see Appendix 4 for details), the findings were summarized in a table of description, which tabulated a description of the participants, study quality and types of interventions.

The mean differences in reported fruit and vegetable intake (portions per day) were analysed in each study using Cochrane's Review Manager (RevMan version 5.1) (The Nordic Cochrane Centre 2011) to report mean differences and 95% random effects confidence intervals for continuous outcome measures because the presence of heterogeneity was assumed. Standard deviations were calculated from standard error, confidence intervals or P-value where appropriate.

The main analysis was conducted to analyse the overall effects of interventions on fruit, vegetable, total fruit and vegetables and on the level of biomarkers in fruit and vegetables (α-carotene and β-carotene). Studies which reported either changes of fruit or vegetable intake only were reported in separate subgroups.

Evidence of heterogeneity across studies was explored using the I-square test of heterogeneity. According to Higgins (Higgins 2003; Higgins and Green 2008), heterogeneity can be detected by both the value of I^2 and the result of heterogeneity test (P-value). If $I^2>50\%$ and P-value≤ 0.05 then the heterogeneity present in the studies is substantial. To anticipate heterogeneity, random effects model was selected. In addition subgroup analysis was conducted for each intervention. Furthermore a funnel plot was used to assess the presence of publication bias. In the absence of bias the funnel plot would resemble a symmetrical inverted funnel (Higgins and Green 2008).

2.1.7.4.2. Level of evidence

This review consisted of three levels of evidence in terms of comparisons namely, direct comparison, subgroup analysis and indirect comparison. According to Glenny and Bandolier (Glenny, Altman et al. 2005; Bandolier 2011) direct comparison of two interventions within an RCT is the highest level of evidence followed by indirect comparison of each of the two interventions versus a common comparator within RCTs. Due to the lack of direct comparisons between interventions in this review, adjusted indirect comparisons among interventions were conducted. This was because most of the elements of interventions were combined with other elements of interventions for example, individually tailored interventions using computer and printed messages to increase fruit and vegetable intake compared to colon cancer awareness intervention (placebo) or stage based computer intervention with motivational interviewing compared to any interventions not aimed at increasing fruit and vegetable intake or no intervention or delayed intervention. The quality of indirect comparison relies heavily on the studies' similarity assumption (participants, comparisons, setting), homogeneity and consistency (Donegan, Williamson et al. 2010) which may be examined by subgroup analysis, sensitivity analysis or meta-regression. This study conducted subgroup analyses and sensitivity analysis to examine the similarity assumption. If a direct comparison between interventions did not exist I conducted subgroup analysis (random effects 95% CI) followed by indirect comparisons of interventions using a common comparator.

In general there were three levels of comparison that existed within the review namely:

1. Direct comparison

   Direct comparisons were available for the following comparisons:

   1.1. All interventions versus control.
   1.2. Interventions using printed message versus telephone.
   1.3. Interventions using printed message and video (combined) versus social support interventions.
   1.4. Tailored versus non-tailored interventions.
   1.5. Motivational interview interventions versus control.
   1.6. Social support interventions versus control.
   1.7. Practical skills interventions versus control.
   1.8. Access interventions versus control.

2. Subgroup analyses

   Subgroup analyses were conducted for the studies' characteristics below:

   2.1. Interventions settings: workplace, university or community.
   2.2. Gender targets: women, men or both.
   2.3. Trial durations: short follow-up or long follow-up.

2.4. Target of interventions: basic target (5 portions per day), non-specific target (increase fruit and vegetable intake) or higher target (6-9 portions per day).

2.5. Aims of interventions: single aim (only aimed at increasing fruit and vegetable intake) or multiple aim (aimed also at lowering fat intake, increasing physical activity, increasing cancer awareness by screenings or smoking cessation).

2.6. Dietary measurements: Food Frequency Questionnaires (FFQs), 24-hour recalls or food records.

2.7. Message deliveries: printed message, computer message, video message or any combination.

2.8. Theory based interventions: Social Cognitive/Social Learning, Transtheoretical Model/Stage of Change, Health Behaviour Change or any combination.

2.9. Psychosocial factors: interventions with 1-3, 4-6, and at least 7 psychosocial factors.

2.10. Counselling methods: interventions using counselling were given face to face or using the telephone versus no counselling or no intervention/delayed interventions.

2.11. Counsellors: interventions using counselling sessions were given by dietitians or nutritionists, other health care professionals (GPs, nurses, physicians) or non health care professionals (trained staff, community workers) versus no counselling or no intervention or delayed interventions.

2.12. Tailored: individual tailored or group tailored versus no intervention or delayed interventions.

2.13. 24-hour recalls versus FFQs.

3. Indirect comparison

Adjusted indirect comparison was a method suggested by Bucher (Bucher, Guyatt et al. 1997; Song, Altman et al. 2003; Song, Harvey et al. 2008). Song stated that 'adjusted indirect comparison was an indirect comparison of competing interventions adjusted according to the results of their direct comparison with a common control so that the strength of the randomised trials is preserved' (Song 2009). The method of analysis was to compute the mean difference of the indirect comparison using the Indirect Treatment Comparison computer software (Wells, Sultan et al. 2009). For example to assess the effectiveness of printed message versus computer message interventions, I entered the mean difference result from the direct comparisons of printed message interventions versus control and then entered each of the data of mean, standard deviations and number of participants to weight the studies accordingly. Similarly I entered the mean difference result from direct comparison of computer message versus control and then entered the mean, standard deviations and number of participants of each studies using computer message. The software then calculates the summary of mean difference for indirect comparison of printed message versus computer message interventions. In the analysis I used derived weight and random effects. When comparing printed message versus computer message, the common comparators were interventions on fall prevention, sleep disorder, health awareness program (colon cancer, HIV/AIDS, elderly health, adolescent health), delayed interventions or no intervention.

Because direct comparisons were not present for the following intervention types, indirect comparisons and test for subgroup differences were conducted for the following comparisons:

3.1. Printed message versus computer message.
3.2. Face to face counselling versus telephone counselling.
3.3. Face to face versus telephone counselling.
3.4. Telephone versus email counselling.
3.5. Dietitians versus other health care professionals.
3.6. Dietitians versus non health care professionals.
3.7. Other health care professionals versus non health care professionals.
3.8. Individual tailored versus group tailored.
3.9. 1-3 versus 4-6 psychological factors.
3.10. 1-3 versus at least 7 factors.
3.11. 4-6 versus at least 7 factors.
3.12. Transtheoretical Model/Stage of Change Model versus Social Cognitive/Social Learning Theory.

3.13. Transtheoretical Model/Stage of Change Model versus Health Behaviour Change Model.

In order for strong evidence to be present in this study it had to fulfill all five criteria:

1. Direct comparisons which include at least three studies.
2. Not heterogenous (I^2>50%).
3. Heterogeneity can be explained by subgrouping.
4. The comparisons are stable to sensitivity analysis
5. The study included study validity.

Subgroup analysis was conducted on mean differences in α-carotene and β-carotene in the intervention groups and the control groups after the interventions for the biomarkers data. This was done in order to test whether the interventions to increase fruit and vegetable intake demonstrated significant effects on the biomarker outcomes.

2.2. The effects of increased fruit and vegetable intake on blood pressure and weight: A systematic review

2.2.1. Objectives

This study aimed to analyse the effects of interventions to increase fruit and vegetable intake on health indicators (systolic blood pressure, diastolic blood pressure and weight) in healthy adults. An assessment was conducted on whether an increase in fruit and vegetable intake (portions per day) has significant effects on systolic blood pressure (mmHg), diastolic blood pressure (mmHg) and weight (kg) in the intervention groups and the control groups after the interventions.

2.2.2. Development of protocol

For guideline purposes a protocol was developed at the start of this study (for full details, please see Appendix 5). The review protocol was formulated using the structure recommended in the Cochrane Handbook (Higgins and Green 2008). The protocol explicitly described:

- The objective of the review.
- The type of studies, participants and interventions required for studies to be included.
- The type of outcome measures considered important.
- The search strategy to be used for identification of studies.
- The methods of risk of bias assessment.
- The methods of data extraction.

2.2.3. Types of studies

All randomised controlled trials (RCTs) that describe ‘random’ or ‘randomisation’ of participants including cluster randomisation of at least six groups or communities with follow-up of three months or more were included.

2.2.4. Types of participants

Participants were healthy adults aged 16 years of age or older. Interventions that were aimed at participants with high-risk of cardiovascular disease (obese, hypertensive, smokers) or pregnant women were excluded examples of which were studies that specifically only included obese participants (all participants were obese). This was done to analyse primary care prevention interventions effects in healthy adults.

2.2.5. Types of outcome measures

The main outcomes were estimated mean differences in systolic blood pressure (mmHg), diastolic blood pressure (mmHg) and mean change in weight (kg) in the intervention groups and the control groups after the interventions as well as standard deviations for each outcome at the end of interventions. In addition the estimated mean differences of fruit and vegetable intake (portions per day) between the intervention groups and the control groups, collected either from total fruit and vegetable intake (portions per day) at the end of interventions or change data of fruit and vegetable intake (portions per day) in the intervention groups and the control groups after the interventions, were also collected.

2.2.6. Search Methods

The search method namely, electronic searches, other sources and search strategy for identification of studies were carried out similar to the review of interventions to increase fruit and vegetable intake. For full details of the search strategies including the period searched, please refer to Appendix 2.

2.2.7. Data collection and analysis

2.2.7.1. Selection of studies

Studies included in the intervention to increase fruit and vegetable intake review were screened by the main researcher of whether the study has data outcomes available on either one of systolic blood pressure, diastolic blood pressure or weight. Selected studies were independently duplicated by two reviewers for inclusion in the review (for details please refer to Appendix 6).

2.2.7.2. Data extraction

The methods in data extraction were the same as for the study of interventions to increase fruit and vegetable intake except that for this review, additional information that need to be extracted were the estimated mean difference of systolic blood pressure (mmHg), diastolic blood pressure (mmHg) and weight (kg) between the intervention groups and the control groups. These were collected either from mean systolic blood pressure (mmHg), mean diastolic blood pressure (mmHg) and mean weight (kg) at the end of interventions or change data of mean systolic blood pressure (mmHg), mean diastolic blood pressure (mmHg) and mean weight (kg) in the intervention groups and the control groups after the interventions. If the fruit and vegetable outcomes were given separately then combined values were calculated according to the combined groups formula from the Cochrane Handbook (Higgins and Green 2008). Similarly if there were more than one intervention groups the combined values were calculated using the combined groups formula from the Cochrane Handbook (Higgins and Green 2008). For more details on data extraction form, please refer to Appendix 4.

2.2.7.3. Risk of bias

The risk of bias of included studies were analysed according to the Cochrane Handbook (Higgins and Green 2008) and similar to the risk of bias analysis conducted for the systematic review of interventions to increase fruit and vegetable intake mentioned in section 2.1.7.3.

2.2.7.4. Data analysis

From each study the information collected in the data extraction form was tabulated (Please refer to Appendix 4 for details) which consist of participants' descriptions, study quality, the estimated mean difference of fruit and vegetable intake (portions per day) and the estimated mean differences of systolic blood pressure (mmHg), diastolic blood pressure (mmHg) and weight (kg). The data were converted to mmHg for blood pressure and kg for weight where necessary.

Then a meta-analysis was conducted on the end of follow-up or mean change data and standard deviation using Cochrane Review Manager (RevMan version 5.1) (The Nordic Cochrane Centre 2011). Mean change data was used if both end and mean change data were available. Weighted mean differences and 95% confidence intervals were reported for continuous outcomes. Standard deviations were calculated from standard error, confidence intervals or P-value where necessary.

Evidence of heterogeneity across studies was explored using the I-square test of heterogeneity. According to Higgins (Higgins 2003; Higgins and Green 2008), heterogeneity can be detected by both the value of I^2 and the result of heterogeneity test (P-value). If $I^2>50\%$ and P-value≤ 0.05 then the heterogeneity present in the studies is substantial.

The main analyses was conducted to assess the effects of interventions to increase fruit and vegetable intake on health indicators namely, systolic blood pressure (mmHg), diastolic blood pressure (mmHg) and weight (kg) on healthy adults. An assessment of whether an increase in fruit and vegetable intake (portions per day) has significant effects on systolic blood pressure (mmHg), diastolic blood pressure (mmHg) and weight (kg) in the intervention groups and the control groups was also conducted. Direct comparisons of interventions versus control were present on the changes in systolic blood pressure, diastolic blood pressure and weight. Therefore subgroup analyses and indirect comparisons were not conducted.

Chapter 3 Results

3.1. Systematic reviews of interventions to increase fruit and vegetable intake in healthy adults

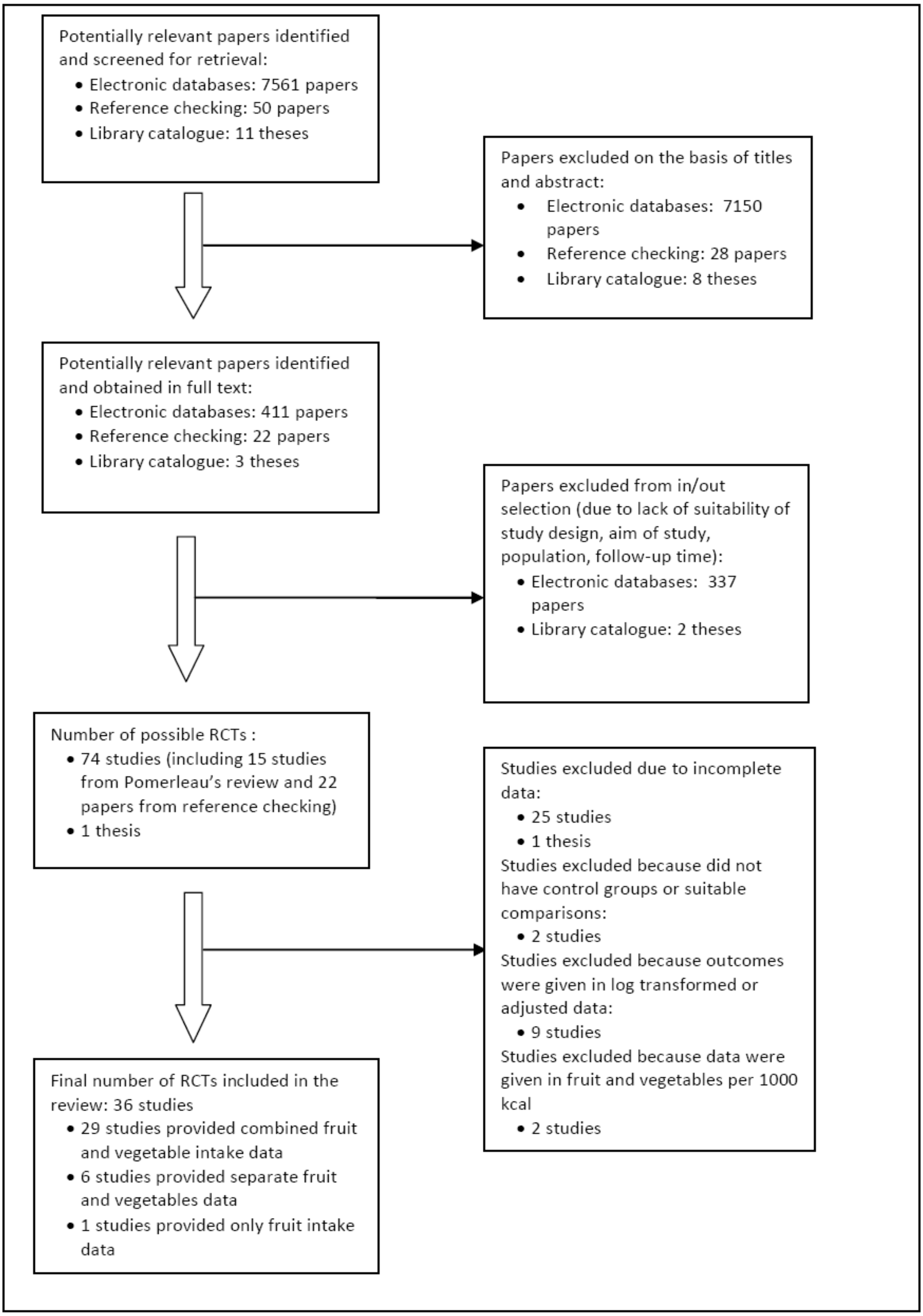
3.1.1. Results of searches

The electronic databases searches on Cochrane Library, MEDLINE, EMBASE, LILACS, PsycInfo and ERIC generated 7561 hits. A total of 50 papers were collected from the reference checking process. Eleven theses were retrieved from the library catalogue. Screenings of titles and abstracts identified 411 papers from electronic databases, 22 papers from reference checking and three theses obtained in full text and entered for formal inclusion or exclusion process. Among 74 studies that met the inclusion criteria, 15 studies were also included in the previous review by Pomerleau (Pomerleau, Lock et al. 2005) and 22 papers were part of the included study and retrieved from reference checking. There was also one thesis that was identified as possible RCTs to be included in the review (Figure 3.01).

However there were a total of 25 studies and one thesis which had incomplete data, for the following reasons namely, did not provide baseline or follow-up fruit and vegetable intake data, fruit and vegetable intake portions were given in percentage of participants eating ≤ 5 portions per day or ≥5 portions per day, the number of participants in each group at baseline and follow-up were not clearly stated, portions of fruit and vegetable intake data were given according to certain categories (ethnicity or age) but not in total of participants in each group, or essential data were not given (standard deviation, standard error or P-value) (Figure 3.01). Authors of studies with incomplete data were contacted and yielded thirteen author responses however only three studies among them provided complete data and were able to be included in the review. Further selection excluded another two studies which did not have control groups or suitable comparison. These were studies by Williams-Piehota 2004 which compared telephone-delivered message which emphasised personal responsibility with social responsibility. Another study which was excluded was by Williams-Piehota 2009 which compared lengthy tailored message with shorter tailored message. Another nine studies had to be excluded because the outcomes were given in log transformed or adjusted data while another two studies provided fruit and vegetable servings/1000 kcal and therefore had to be excluded from the analysis (Figure 3.01).

Finally 38 studies and one thesis had to be excluded from the review. The resulting total of 36 studies included 29 studies providing combined fruit and vegetable intake data, six studies providing fruit and vegetable intake data separately and one study providing only fruit intake data (Figure 3.01).

Figure 3.01 Flow diagrams for locating RCTs for systematic review



3.1.2. Included studies

36 RCTs with 69,356 participants were included in the review (Figure 3.01). Twenty nine of 36 included studies were conducted in the USA, four from the UK (Oxford Trial, South London Study, Bradbury, Macdonald), two from The Netherlands (De Vries and Steenhuis) and one from Japan (Hiraka Study) (Appendix 7, Table 1).

3.1.2.1. Participants and intervention settings

In general the mean age of participants was 49.59 (SD=9.65) years of age. Mean age was taken from baseline values at the beginning of the interventions for overall participants or if given separately for each group, the combined value was calculated using the combined group formula from the Cochrane Handbook (Higgins and Green 2008). Three studies did not provide mean age of participants while seven studies provided age of participants in percentages for each age range.

The intervention settings can be classified into three categories namely workplace, university and community settings based on where the study took place, where the participants were recruited or target age of participants. Most of the studies had community setting (22 studies), the rest had workplace setting (three studies) and university setting (one studies) (Table 3.02). The other nine studies (Alexander, Buller, Resnicow, Wise Woman Arizona, Well Works, De Vries, Heimendinger, South London and Premier) provided no control but were included in the direct comparisons as follows: 24-hour recalls versus FFQs (Figure 3.04), individually tailored versus non-tailored (Figure 3.08), face to face versus printed message and video (Figure 3.06), individually tailored versus group tailored (Figure 3.09) or motivational interview, social support, practical skills and access versus control (Figure 3.10 to 3.13).

3.1.2.2. Trials durations

All studies with at least three months of follow-up were included which were then categorized as short duration (3-11 months), medium duration (12-36 months) and long duration (at least 37 months) (Table 3.02). There were a total of sixteen studies with short durations, twelve studies with medium durations and one study with long duration. There were three studies namely, Health Works for Women, Women Health

Trial and Puget Sound that provided outcomes at two follow-up (3-11 months and 12-36 months); both outcomes were included in the trial duration analysis.

3.1.2.3. Outcomes measures

Most of the outcomes were measured using self-reported dietary measurements such as food frequency questionnaires (FFQs) with a total of 23 studies (Table 3.02). One study used 24-hour recalls (unweighted) which were measured twice (at the beginning and end of interventions) by participants while two other studies used food records to measure fruit and vegetable intake (7 days food record and food diary three months onward, unweighted). Studies by Buller (Buller, Morrill et al. 1999) and Marcus 2001 (Marcus, Heimendinger et al. 2001) provided data using FFQs and 24-hour recalls which were presented in the comparison of 24-hour recalls versus FFQs (Figure 3.04).

In addition I collected the plasma biomarkers of fruit and vegetable intake of α-carotene from three studies and β-carotene from four studies.

Details of methods, participants, interventions and outcome measures are presented in the included studies table (see Appendix 7, Table 1 for details).

3.1.3. Risk of bias

Risk of bias assessments were done independently by at least two reviewers for each study. If any differences occurred discussion between reviewers was conducted until consensus was agreed. The assessments were conducted for six categories as follows, whether the sequence generation adequately generated, whether allocation adequately concealed, whether participants, personnel or outcome assessors adequately blinded, whether incomplete outcome data adequately addressed, whether the study was free from selective outcome reporting and whether the study was free from industry funding. The complete risk criteria were stated in section 2.1.7.3.

Findings suggested that there were five studies with adequate sequence generation (Oxford Trial, PREMIER, Rio Grande, South London and Women's Health Initiative), while the rest were unclear. Oxford Trial, PREMIER, Rio Grande and Women's Health Initiative used computer random number generator while South London used minimisation method to generate allocation sequence. All studies provide insufficient information to permit judgment of whether allocation was adequately concealed. Four studies (NC Strides Study, Oxford Trial, PREMIER, and Rio Grande) adequately prevented knowledge of the allocated intervention (provided blinding of participants, personnel, or outcome assessors) while the rest of the study were unclear. Nineteen studies addressed incomplete outcome data adequately (Alexander, Buller, De Vries, Good Grubbin, Greene, The Hiraka Dietary Intervention Study, Lutz, Mediterranean Eating Study, The Next Step Trial, NC Strides Study, Oxford Trial, PREMIER, Rio Grande, Sorensen, South London, Steenhuis, Watch Project, Women's Health Initiative and Wolf) by providing adequate descriptions of participants in each arm, descriptions of dropouts or had imputed the missing data using appropriate methods while the rest did not. All studies provided insufficient information to judge whether studies were free from selective outcome reporting (study protocol was available and all expected outcomes were reported). Only one study was funded by private industry (Lutz) while the rest were funded by non-private industry.

In summary all of the RCTs included in this study had unclear risk of bias. This was because all of the RCTs provide insufficient information on particularly the following criteria sequence generation process, method of concealment, blinding of participants, personnel or outcome assessors and selective outcome reporting. Detailed descriptions of risk of bias for each included RCT are available in Appendix 8.

3.1.4. Analysis of results

3.1.4.1. Direct Comparisons

3.1.4.1.1. Interventions to increase fruit and vegetable intake versus control

Analysis was conducted to examine the overall effect of interventions on fruit and vegetables (combined) and fruit only data. The combined values for fruit and vegetable intake (if provided separately) were calculated using the combined group formula from the Cochrane Handbook (Higgins and Green 2008). A total of 26 studies with 54,985 participants were included in the analysis of effects on fruit and vegetables (combined) compared to control (no intervention, delayed intervention or intervention not aimed to increase fruit and vegetable intake) (Figure 3.02). The results suggested a strong evidence (P<0.00001) of overall interventions effects to increase fruit and vegetable intake (combined) by 0.64 portions per day (95% CI 0.40 to 0.87) in the intervention groups compared to the control groups after the interventions. However substantial heterogeneity (I^2=97%) (Figure 3.02) was identified in the studies. Although heterogeneity was detected almost every study showed greater fruit and vegetable intake in the intervention groups compared to the control groups. The subgroup analysis which included one study with 38 participants for fruit only suggested that the intervention was able to increase fruit by 0.05 portions per day (95% CI -1.22 to 1.32) (Figure 3.02) in the intervention groups compared to the control groups after the interventions. However the increase was not significant (P=0.94). Due to heterogeneity present in the overall analysis of intervention effects it was important to examine it in further using subgroup analyses.

In the analysis of overall intervention effects I included the outcomes of fruit and vegetable intake at the end of the follow-up. For example in Marcus 2001 study the outcomes were reported after 4 weeks, 4 months and 12 months follow-up. Therefore I included the outcomes at 12 months in the overall analysis of intervention effects (Figure 3.02).

Findings from funnel plot analysis on overall effects on fruit and vegetables (combined), fruit, and vegetables indicated that the funnel-plot was asymmetrical (Figure 3.03). There are many possible causes of asymmetrical funnel plots, namely, selection bias or publication bias (language, citation, or multiple publication), bigger effects found in smaller studies compared to bigger studies (heterogeneity in results), low quality of study design, analysis and effect measure or pure chance (Egger, Smith et al. 1997; Sterne and Harbord 2004).

Funnel plot revealed that most of the studies clustered at mean difference of around 0.2 to 0.3, slightly lower than the result of pooled mean difference estimate (0.64 portions per day, 95% CI 0.40 to 0.87) (Figure 3.03). The funnel plot tells us that there was an over positive results reported among the studies. This may be because studies that showed significant effect of the intervention were more likely to be published compared to studies with non-significant findings. The ideal funnel plot would be symmetrical and inverted shape. This implies that larger studies with bigger precision would spread narrowing towards the top while smaller studies would scatter more widely at the bottom of the graph (Sterne and Egger 2001). Therefore the true effects of the intervention should lie around the value of biggest sample study in this case is the WHI study with 36,203 participants. WHI study was able to increase 1.10 portions per day (95% CI 1.05 to 1.15) (Figure 3.02) in the intervention groups compared to the control groups after the interventions which was not the case showed in the review. While studies with less participants such as Bradbury and Mediterranean Eating showed the highest increase of fruit and vegetable intake in the intervention groups compared to the control groups after the interventions. Cochrane Handbook pointed out that asymmetry shape of funnel plot may also be due to clinical heterogeneity (because of different control event rates) or methodological heterogeneity (because of failure in allocation concealment) (Higgins and Green 2008).

Sensitivity analysis was conducted to assess the strength of results by exclusion of studies with inadequate allocation concealments or studies with small samples (less than 100 participants in each group). The results of random effects (95% CI) sensitivity analysis indicated that substantial heterogeneity was present in the studies. The result for analysis without small sample studies was a significant increase by 0.51 portions per day (95% CI 0.26 to 0.75) (Table 3.01). This analysis excluded four studies namely Bradbury, Good Grubbin, Macdonald and Mediterranean Eating.

Figure 3.02

Comparison: Direct comparison of the intervention on fruit and/or vegetables versus control (no interventions or delayed interventions)

Outcome: Mean differences of fruit and vegetables consumed (portions per day)

Study or Subgroup	Intervention Mean	Intervention SD	Intervention Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
1.1.1 Fruit and vegetables								
Bradbury 2006	5.9	3.2	30	3.5	1.88	28	1.8%	2.40 [1.06, 3.74]
Cookin' Up Health 2007	3.74	2.11	131	3.55	2.24	131	3.7%	0.19 [-0.34, 0.72]
Eat Healthy Life 2009	0.29	1.32	990	0.16	1.32	955	4.5%	0.13 [0.01, 0.25]
EFNEP 1988	3.7	2.4	355	2.6	2	328	4.2%	1.10 [0.77, 1.43]
Good Grubbin' 2009	2.75	2.24	30	2.81	2.19	30	2.2%	-0.06 [-1.18, 1.06]
Greene 2008	5.16	0.82	410	5.04	1.04	424	4.5%	0.12 [-0.01, 0.25]
Health Works Women 2002	3.6	3.1	282	3.4	2.9	256	3.8%	0.20 [-0.31, 0.71]
High 5 2008	4.84	2.82	406	4.52	2.7	325	4.0%	0.32 [-0.08, 0.72]
Hiraka Study 2003	0.23	4.87	231	0.02	4.87	239	2.8%	0.21 [-0.67, 1.09]
Kristal 1997	3.54	1.79	369	3.44	1.83	371	4.3%	0.10 [-0.16, 0.36]
Lutz 1999	4.2	2.41	422	3.6	1.97	151	4.1%	0.60 [0.21, 0.99]
Macdonald 2009	4.9	2.5	63	2.6	1.89	56	3.0%	2.30 [1.51, 3.09]
Marcus 1998	4.83	2.15	615	4.5	2.15	671	4.4%	0.33 [0.09, 0.57]
Marcus 2001	5.04	2.31	507	4.59	2.31	509	4.3%	0.45 [0.17, 0.73]
Mediterranean Eating 2009	4.3	1.38	27	2.1	1.36	33	3.3%	2.20 [1.50, 2.90]
NC Strides 2009	5.6	1.9	341	5.3	2	120	4.0%	0.30 [-0.11, 0.71]
Next Step Trial 1999	3.62	1.59	1578	3.52	2.18	1899	4.5%	0.10 [-0.03, 0.23]
Oxford Trial 2004	1.4	1.7	329	0.1	1.3	326	4.4%	1.30 [1.07, 1.53]
Puget Sound 2000	0.47	1.83	601	0.14	1.8	604	4.4%	0.33 [0.13, 0.53]
Rio Grande 2008	7.6	5.62	242	6.8	3.75	231	2.8%	0.80 [-0.06, 1.66]
Sorensen 2007	1.52	3.89	298	-0.09	3.31	280	3.6%	1.61 [1.02, 2.20]
Steenhuis 2004	2.03	1.35	798	1.89	1.35	215	4.4%	0.14 [-0.06, 0.34]
Watch Project 2004	3.72	2	458	3.4	2.04	129	4.1%	0.32 [-0.08, 0.72]
WHI 2007	5	2.4	14183	3.9	2	22020	4.6%	1.10 [1.05, 1.15]
Wolf 2009	4.6	3.8	240	3.4	2.2	239	3.6%	1.20 [0.64, 1.76]
Women's Health Trial 1999	0.44	1.09	285	0.05	1.09	194	4.4%	0.39 [0.19, 0.59]
Subtotal (95% CI)			**24221**			**30764**	**100.0%**	**0.64 [0.40, 0.87]**
Heterogeneity: Tau² = 0.31; Chi² = 716.12, df = 25 (P < 0.00001); I² = 97%								
Test for overall effect: Z = 5.33 (P < 0.00001)								
1.1.2 Fruit								
Heneman 2005	0.25	2.08	33	0.2	1.2	5	100.0%	0.05 [-1.22, 1.32]
Subtotal (95% CI)			**33**			**5**	**100.0%**	**0.05 [-1.22, 1.32]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.08 (P = 0.94)								

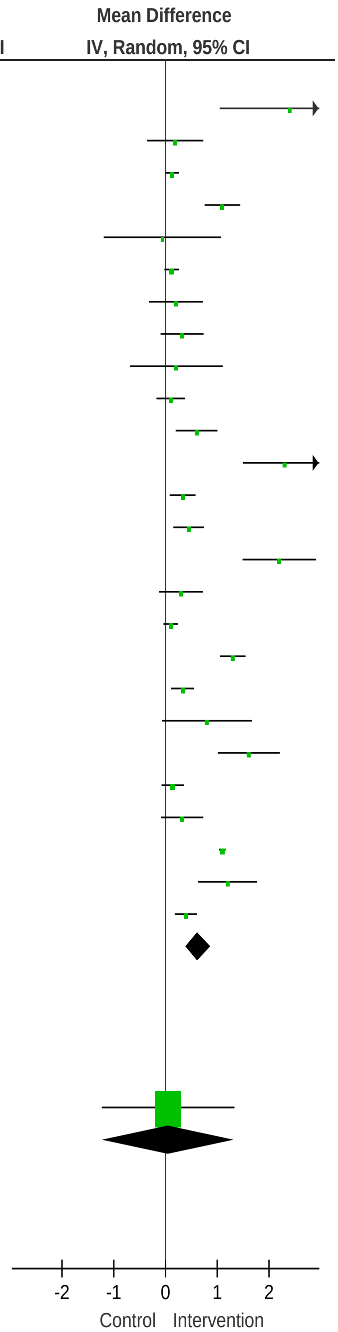


Figure 3.03: Funnel plot of overall effects of interventions to fruit and vegetables (combined) and fruit intake

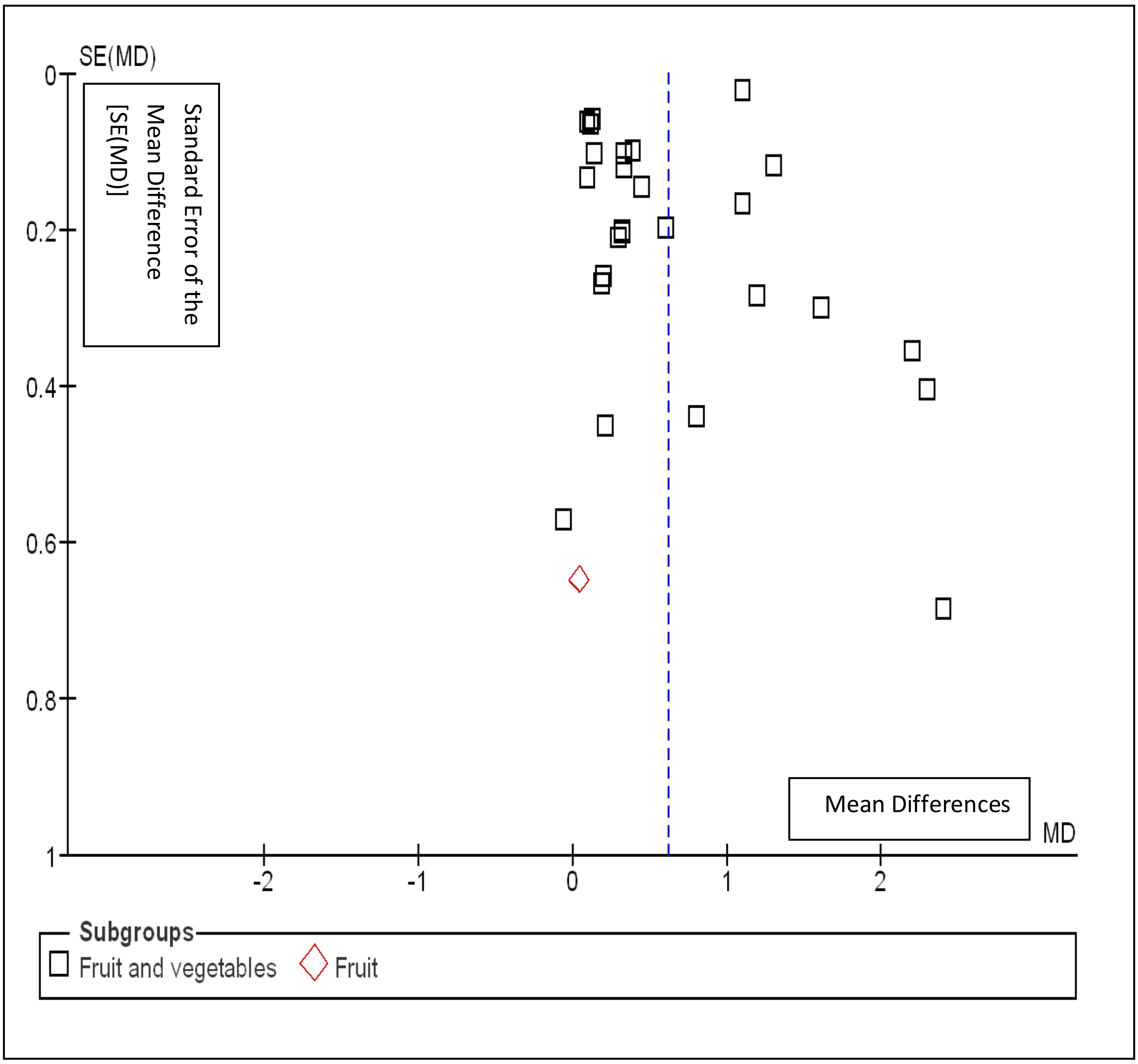


Table 3.01
Comparison: Analysis of all studies and studies without small sample (less than 100 participants in each arm/group)
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

Type of analysis	**No. of studies**	**Mean differences (Random effects 95% CI)**	**P-value for heterogeneity**
Overall analysis	26	0.64 (0.40, 0.87)	P<0.00001
Sensitivity analyses:			
• Without small sample (less than 100 participants in each arm or group)	22	0.51 (0.26, 0.75)	P<0.00001

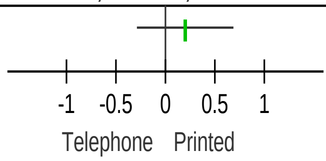
3.1.4.1.2. Printed message versus telephone

There was one study which provided direct comparison of intervention using printed message versus telephone message (Figure 3.04). The results suggested that there was a non-significant difference of 0.20 portions per day (95% CI -0.28 to 0.68, I^2=not applicable) higher in intervention with printed message compared to telephone message (Figure 3.04).

Figure 3.04
Comparison: Direct comparison of intervention using tailored printed message versus tailored telephone message
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Printed			Telephone				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
NC Strides 2009	5.5	1.6	110	5.3	2	109		0.20 [-0.28, 0.68]

Mean Difference
IV, Random, 95% CI



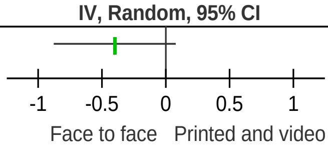
3.1.4.1.3. Face to face versus printed message and video

The result of direct comparison between face to face group session versus tailored print video intervention suggested that face to face group session intervention reported lower but not significant intake of fruit and vegetables (-0.40 portions per day, 95% CI -0.87 to 0.07, I^2=not applicable) (Figure 3.05).

Figure 3.05
Comparison: Direct comparison of intervention using face to face group sessions versus tailored printed message and video
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Face to face			Printed video				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Watch Project 2004	3.5	2	123	3.9	2.01	159		-0.40 [-0.87, 0.07]

Mean Difference
IV, Random, 95% CI



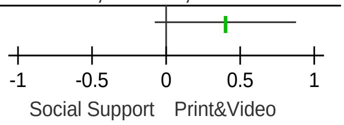
3.1.4.1.4. Printed message and video interventions versus social support and role model interventions

The result of direct comparison between combined printed message and video intervention versus social support and role model intervention suggested that there was a non-significant difference of 0.40 portions per day (95% CI -0.07 to 0.87, I^2=not applicable) between tailored printed message and video intervention with social support intervention (Figure 3.06).

Figure 3.06
Comparison: Direct comparison of intervention using tailored printed message and video versus social support
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Print&Video			Social Support				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Watch Project 2004	3.9	2.01	159	3.5	2	123		0.40 [-0.07, 0.87]

Mean Difference
IV, Random, 95% CI



3.1.4.1.5. Individually tailored versus non-tailored interventions

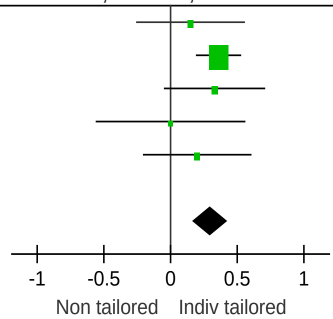
Five studies with 4202 participants compared individually tailored interventions versus non-tailored interventions (Figure 3.07). The results suggested that individually tailored interventions may significantly increase fruit and vegetable intake by 0.30 portions per day (95% CI 0.17 to 0.43, I^2=0%) higher compared to non-tailored interventions (interventions aimed to increase fruit and vegetable intake with general/non-tailored message but not placebo) (Figure 3.07).

Figure 3.07
Comparison: Direct comparison of individually tailored interventions versus non-tailored interventions
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Indiv tailored			Non tailored				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Alexander 2010	6.98	3.7	613	6.83	3.5	619	10.3%	0.15 [-0.25, 0.55]
de Vries 2008	0.11	1.48	608	-0.25	1.56	723	62.1%	0.36 [0.20, 0.52]
Heimendinger 2005	5.4	2.94	442	5.07	2.9	498	11.9%	0.33 [-0.04, 0.70]
Lutz 1999	4.1	2.45	136	4.1	2.25	140	5.4%	0.00 [-0.56, 0.56]
Resnicow 2008	4.5	2.2	208	4.3	2	215	10.3%	0.20 [-0.20, 0.60]
Total (95% CI)			**2007**			**2195**	**100.0%**	**0.30 [0.17, 0.43]**

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.43$, df = 4 (P = 0.66); $I^2 = 0\%$
Test for overall effect: Z = 4.54 (P < 0.00001)

Mean Difference
IV, Random, 95% CI

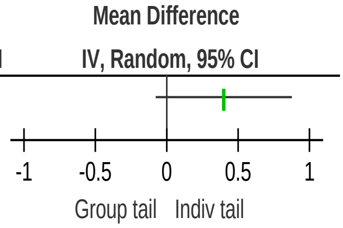


3.1.4.1.6. Individually tailored versus group tailored

The result of direct comparison between individually tailored versus group tailored suggested that individually tailored intervention may increase fruit and vegetable intake higher than group tailored intervention. However the difference was not significant (0.40 portions per day, 95% CI -0.07 to 0.87, I^2=not applicable) (Figure 3.08).

Figure 3.08
Comparison: Direct comparison of individually tailored interventions versus group tailored interventions
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Indiv tail			Group tail				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Watch Project 2004	3.9	2.01	159	3.5	2	123		0.40 [-0.07, 0.87]



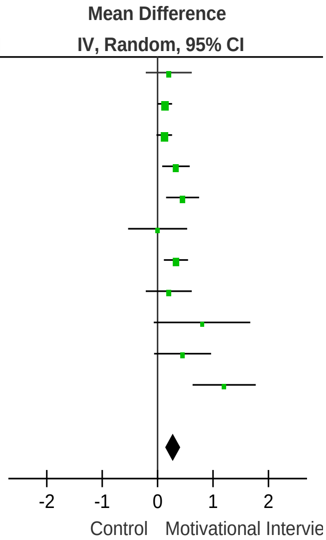
3.1.4.1.7. Motivational interview interventions versus control

There were eleven studies with 9506 participants that provided direct comparisons of motivational interview interventions versus control (Figure 3.09). Three studies (Alexander, NC Strides, and Resnicow) compared tailored interventions with additional motivational interview versus the same interventions but without motivational interview. Two other studies (Greene and Wolf) compared motivational interview with other health awareness programs (fall prevention and prostate cancer awareness), while the rest compared motivational interview with no intervention or delayed interventions. Result of the analysis suggested that motivational interview interventions were significant in increasing fruit and vegetable intake by 0.29 portions per day (95% CI 0.16 to 0.42, I^2=59%) higher compared to the control groups (Figure 3.09).

Figure 3.09
Comparison: Direct comparison of motivational interview interventions versus control (tailored interventions, fall prevention, prostate cancer awareness and no interventions or delayed interventions)
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Motivational Interview			Control				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Alexander 2010	7.18	3.4	588	6.98	3.7	613	6.9%	0.20 [-0.20, 0.60]
Eat Healthy Life 2009	0.29	1.32	990	0.16	1.32	955	17.2%	0.13 [0.01, 0.25]
Greene 2008	5.16	0.82	410	5.04	1.04	424	16.8%	0.12 [-0.01, 0.25]
Marcus 1998	4.83	2.15	615	4.5	2.15	671	12.1%	0.33 [0.09, 0.57]
Marcus 2001	5.04	2.31	507	4.59	2.31	509	10.3%	0.45 [0.17, 0.73]
NC Strides 2009	5.3	2	109	5.3	2	120	4.8%	0.00 [-0.52, 0.52]
Puget Sound 2000	0.47	1.83	601	0.14	1.8	604	13.4%	0.33 [0.13, 0.53]
Resnicow 2008	4.5	2.2	208	4.3	2	215	7.0%	0.20 [-0.20, 0.60]
Rio Grande 2008	7.6	5.62	242	6.8	3.75	231	2.1%	0.80 [-0.06, 1.66]
South London 2004	1.44	2.11	136	0.99	2.1	135	5.1%	0.45 [-0.05, 0.95]
Wolf 2009	4.6	3.8	240	3.4	2.2	239	4.3%	1.20 [0.64, 1.76]
Total (95% CI)			**4646**			**4716**	**100.0%**	**0.29 [0.16, 0.42]**

Heterogeneity: Tau² = 0.02; Chi² = 24.29, df = 10 (P = 0.007); I² = 59%
Test for overall effect: Z = 4.37 (P < 0.0001)



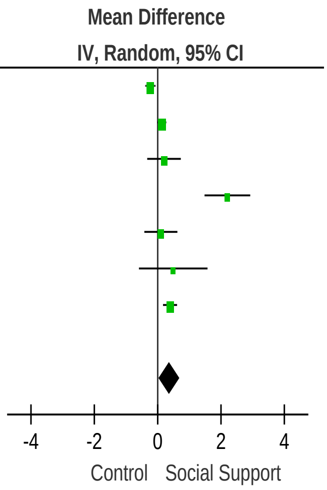
3.1.4.1.8. Social support interventions versus control

Seven studies with 4109 participants were included in the meta-analysis (Figure 3.10). These were studies which provided direct comparison of social support interventions versus control. The Wise Woman Arizona study compared provider counselling and health education versus the same intervention but with additional community health workers support. Buller compared social support and printed message versus printed message while other studies compared social support interventions versus no intervention or delayed interventions. The results suggested that there was strong evidence that social support interventions may increase fruit and vegetable intake by 0.35 portions per day (95% CI 0.02 to 0.68, I^2=91%) higher compared to the control groups (Figure 3.10).

Figure 3.10
Comparison: Direct comparison of social support interventions versus control (printed message, provider counselling, no interventions and delayed interventions)
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Social Support			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Buller 1999	3.24	0.64	363	3.47	1.16	332	18.9%	-0.23 [-0.37, -0.09]
Eat Healthy Life 2009	0.29	1.32	990	0.16	1.32	955	19.1%	0.13 [0.01, 0.25]
Health Works Women 2002	3.6	3.1	282	3.4	2.9	256	13.4%	0.20 [-0.31, 0.71]
Mediterranean Eating 2009	4.3	1.38	27	2.1	1.36	33	10.4%	2.20 [1.50, 2.90]
Watch Project 2004	3.5	2	123	3.4	2.04	129	13.5%	0.10 [-0.40, 0.60]
WiseWoman Arizona 2004	0.26	3.13	67	-0.23	3.26	73	6.5%	0.49 [-0.57, 1.55]
Women's Health Trial 1999	0.44	1.09	285	0.05	1.09	194	18.3%	0.39 [0.19, 0.59]
Total (95% CI)			**2137**			**1972**	**100.0%**	**0.35 [0.02, 0.68]**

Heterogeneity: $Tau^2 = 0.14$; $Chi^2 = 64.85$, df = 6 ($P < 0.00001$); $I^2 = 91\%$
Test for overall effect: $Z = 2.10$ ($P = 0.04$)



3.1.4.1.9. Practical skills interventions versus control

Fifteen studies and 52,888 participants were included in the analysis that involved demonstrations, cooking skills, shopping skills and preparation skills, instructions on buying, storing and preparing fruit and vegetables in the intervention groups versus control groups namely, tailored print, other types of interventions (aimed at other factors: prevent sleep disorder, HIV/AIDS awareness) or placebo (no intervention or delayed intervention) (Figure 3.11). For example in the Watch Project the intervention groups were given recipes while the control group was given health education on topics related to HIV/AIDS, adolescent health, prostate cancer awareness, elderly health). In other studies the comparisons were as follows, cook book versus no intervention, shopping tips and information on how to read nutrition label versus no intervention, cooking demonstration versus no intervention. The results suggested that interventions which implemented practical skills were significant in increasing fruit and vegetable intake by 0.41 portions per day (95% CI 0.10 to 0.72, I^2=96%) higher compared to the control groups (Figure 3.11).

Figure 3.11

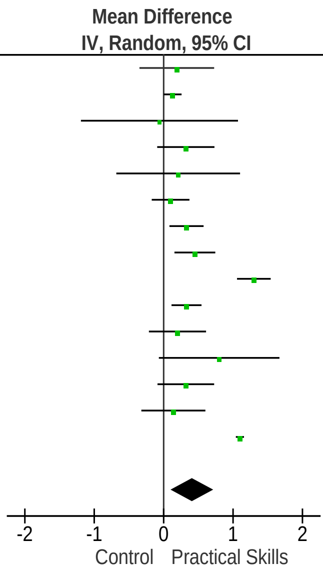
Comparison: Direct comparison of practical skills interventions versus control [health education (HIV/AIDS, elderly or adolescent health, cancer awareness), fall prevention, no interventions or delayed interventions)]

Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Practical Skills			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Cookin' Up Health 2007	3.74	2.11	131	3.55	2.24	131	6.4%	0.19 [-0.34, 0.72]
Eat Healthy Life 2009	0.29	1.32	990	0.16	1.32	955	7.7%	0.13 [0.01, 0.25]
Good Grubbin' 2009	2.75	2.24	30	2.81	2.19	30	3.8%	-0.06 [-1.18, 1.06]
High 5 2008	4.84	2.82	406	4.52	2.7	325	6.9%	0.32 [-0.08, 0.72]
Hiraka Study 2003	0.23	4.87	231	0.02	4.87	239	4.8%	0.21 [-0.67, 1.09]
Kristal 1997	3.54	1.79	369	3.44	1.83	371	7.4%	0.10 [-0.16, 0.36]
Marcus 1998	4.83	2.15	615	4.5	2.15	671	7.5%	0.33 [0.09, 0.57]
Marcus 2001	5.04	2.31	507	4.59	2.31	509	7.3%	0.45 [0.17, 0.73]
Oxford Trial 2004	1.4	1.7	329	0.1	1.3	326	7.5%	1.30 [1.07, 1.53]
Puget Sound 2000	0.47	1.83	601	0.14	1.8	604	7.6%	0.33 [0.13, 0.53]
Resnicow 2008	4.5	2.2	208	4.3	2	215	6.9%	0.20 [-0.20, 0.60]
Rio Grande 2008	7.6	5.62	242	6.8	3.75	231	4.9%	0.80 [-0.06, 1.66]
Watch Project 2004	3.72	2	458	3.4	2.04	129	6.9%	0.32 [-0.08, 0.72]
WellWorks 2002	3.56	9.5	3423	3.42	9.5	3409	6.7%	0.14 [-0.31, 0.59]
WHI 2007	5	2.4	14183	3.9	2	22020	7.8%	1.10 [1.05, 1.15]
Total (95% CI)			**22723**			**30165**	**100.0%**	**0.41 [0.10, 0.72]**

Heterogeneity: $Tau^2 = 0.31$; $Chi^2 = 391.38$, $df = 14$ ($P < 0.00001$); $I^2 = 96\%$

Test for overall effect: $Z = 2.61$ ($P = 0.009$)



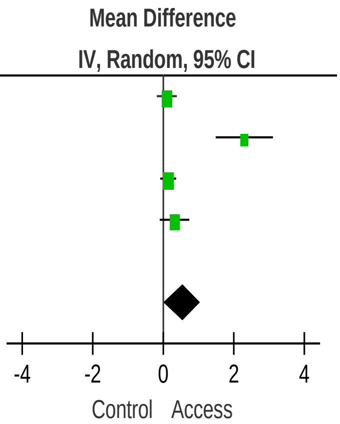
3.1.4.1.10. Access interventions versus control

The meta-analysis included four studies with 2459 participants that intervene with access to fruit and vegetable by providing fruit and vegetables labelling or signs in the supermarkets, supplied varieties of fruit and vegetables in workplaces or taste testing in church activities and compared them with other health awareness education topics (HIV/AIDS, elderly health, adolescent health, prostate cancer) or placebo (no intervention or delayed intervention) (Figure 3.12). For example changes in workplace cafeteria namely, point of purchase displays, signs, menus and giving incentives to participants versus no intervention. The results suggested that interventions that aimed at increasing access to fruit and vegetable was quite significant in increasing the intake of fruit and vegetables by 0.55 portions per day (95% CI 0.04 to 1.07, I^2=89%) higher than control groups (Figure 3.12).

Figure 3.12
Comparison: Direct comparison of access interventions versus control [health education (HIV/AIDS, elderly or adolescent health, cancer awareness), no interventions or delayed interventions)]
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Access			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kristal 1997	3.54	1.79	369	3.44	1.83	371	28.0%	0.10 [-0.16, 0.36]
Macdonald 2009	4.9	2.5	63	2.6	1.89	56	17.6%	2.30 [1.51, 3.09]
Steenhuis 2004	2.03	1.35	798	1.89	1.35	215	28.8%	0.14 [-0.06, 0.34]
Watch Project 2004	3.72	2	458	3.4	2.04	129	25.6%	0.32 [-0.08, 0.72]
Total (95% CI)			**1688**			**771**	**100.0%**	**0.55 [0.04, 1.07]**

Heterogeneity: $Tau^2 = 0.23$; $Chi^2 = 28.19$, df = 3 (P < 0.00001); $I^2 = 89\%$
Test for overall effect: Z = 2.12 (P = 0.03)



3.1.4.2. Subgroup analysis and indirect comparisons on intervention characteristics and biomarkers (α-carotene and β-carotene)

In order to examine substantial heterogeneity found in the overall analysis, subgroup analyses were conducted on several characteristics of the studies namely, settings, gender target, trial duration, target of interventions, aim of interventions and dietary measurements methods. The analysis was conducted among 26 studies with 54,985 participants that provided combined fruit and vegetable intake data. Ten studies were not included in the analysis because they did not provide control or delayed groups but gave other comparison. The examples were motivational interview (Alexander, Resnicow and South London Study), social support (Wise Woman Arizona and Premier), practical skills (Well Works), comparison of 24-hour recall with FFQ (Buller), only gave fruit intake outcomes (Heneman) or tailored versus non-tailored interventions (DeVries and Heimendinger). Detailed descriptions of intervention types in each arm are available in Appendix 9, Table 3. If direct comparison of interventions were not found I conducted indirect comparison by comparing the interventions using common comparators. The common comparator was any intervention that is not aimed to increase fruit and vegetable intake or no intervention or delayed intervention.

3.1.4.2.1. Intervention settings

Most of the studies had community settings (22 studies with 50,044 participants) (Table 3.02) which were able to provide strong evidence in increasing fruit and vegetable intake by 0.65 portions per day (95% CI 0.38 to 0.92, I^2=99%) in the intervention groups compared to the control groups after the interventions (Table 3.02). These were studies either randomised by or conducted in an area, community or city. Interventions set in university were not significant to increase fruit and vegetable intake (-0.06 portions per day, 95% CI -1.18 to 1.06). While interventions in workplace had significantly increase fruit and vegetable intake by 0.11 portions per day (95% CI 0.01 to 0.22, I^2=0%). Subgroup differences test (random effect 95% CI) results indicated that the three types of settings were significantly different (Chi^2=13.57, df=2, P=0.001, I^2=85.3%) (Table 3.02).

3.1.4.2.2. Gender targets

Most of the studies were targeted at both men and women (19 studies with 16,921 participants) which were able to increase fruit and vegetable intake by 0.45 portions per day (95% CI 0.30 to 0.61, I^2=90%) in the intervention groups compared to the control groups after the interventions (Table 3.02). Thus random effects subgroup analysis implied that intervention targeted at men were able to increase fruit and vegetable intake by 1.20 portions per day (95% CI 0.64 to 1.76, I^2=not applicable) (Table 3.02). Significant result was also found for interventions targeted at women (0.66 portions per day, 95% CI 0.20 to 1.12, I^2=90%). Random effect subgroup differences test (95% CI) suggested that the interventions targeted at women, men or both men and women were all significantly different (Chi^2=6.85, df=2, P=0.03, I^2=70.8%) (Table 3.02).

3.1.4.2.3. Trials durations

There were more short durations RCTs included in the review (16 studies with 11,100 participants) (Table 3.02) which were able to significantly increase fruit and vegetable intake by 0.55 portions per day (95% CI 0.32 to 0.79, I^2=88%) while medium duration trials (12-36 months) were able to increase by 0.26 portions per day (95% CI 0.16 to 0.37, I^2=68%) in the intervention groups compared to the control groups after the interventions. Longer duration trial (37+ months) was able to significantly increase fruit and vegetable intake by 1.10 portions per day (95% CI 1.05 to 1.15, I^2=not applicable) (Table 3.02). Three studies (Guide to Health, Health Works for Women and Women Health Trial) provided outcomes for both durations (short and medium durations). Results from random effect subgroup differences test (95% CI) indicated significant differences in the subgroups (Chi^2=213.96, df=2, P<0.00001, I^2=99.1%) (Table 3.02). The trial duration was taken from follow-up data of the RCTs.

3.1.4.2.4. Targets of interventions

Most of the studies had basic target of ≥5 portions per day (13 studies with 47,303 participants) which were able to significantly increase fruit and vegetable intake by 0.53 portions per day (95% CI 0.20 to 0.85, I^2=97%) (Table 3.02). Similarly interventions with non-specific target (only to increase fruit and vegetable intake) were also able to significantly increase fruit and vegetable by 0.40 portions per day (95% CI 0.20 to 0.59, I^2=77%) in the intervention groups compared to the control groups after the interventions. Significant result was also found for interventions with higher target (6-9 portions per day) which was able to increase fruit and vegetable intake by 1.32 portions per day (95% CI 0.68 to 1.96, I^2=8%). Random effect subgroup differences test (95% CI) showed that the subgroups were significantly different (Chi^2=7.47, df=2, P=0.02, I^2=73.2%) (Table 3.02).

3.1.4.2.5. Aims of interventions

Most of the studies were multiple aimed interventions (aimed at other healthy behaviour for example, lowering fat intake, increasing physical activity or cancer screenings) (14 studies with 46,726 participants) which were able to increase fruit and vegetable intake by 0.44 portions per day (95% CI 0.11 to 0.78, I^2=99%) in the intervention groups compared to the control groups after the interventions (Table 3.02). On the other hand single aimed studies were able to increase fruit and vegetable intake by 0.69 portions per day (95% CI 0.40 to 0.97, I^2=89%) in the intervention groups compared to the control groups after the interventions (Table 3.02). Random effect subgroup differences test (95% CI) indicated that the two subgroups were significantly different (Chi^2=1.17, df=1, P=0.28, I^2=14.6%) (Table 3.02).

3.1.4.2.6. Dietary measurements

Most of the studies used self reported FFQs to collect the dietary measurements data (23 studies with 54,199 participants) (Table 3.02). The FFQs used were varied from 1-item to 127-items. Eight studies provided more than one FFQs types; in this case if an average or composite results was not given then I chose FFQs items which was closer to 20-items FFQs or not a log transformed FFQ result. Two studies provided direct comparison of 24-hour recalls with FFQs. One study with 683 participants found that 24-hour recalls reported significant intervention effects of an increase by 1.10 portions per day (95% CI 0.77 to 1.43, I^2=not applicable) compared to 0.50 portions per day (95% CI 0.26 to 0.75, I^2=99%) in the intervention groups compared to the control groups after the interventions for FFQs (Table 3.02). Studies with food records found significantly higher increase by 1.26 portions per day (95% CI 0.13 to 2.40, I^2=45%). Random effect subgroup differences test (95% CI) indicated that the dietary measurements methods were significantly different (Chi^2=8.91, df=2, P=0.01, I^2=77.6%) (Table 3.02).

Table 3.02 Subgroup analyses

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Mean difference	I^2 (%)
Overall effects	26	54,985	Mean difference (IV, Random, 95% CI)	0.64 (0.40, 0.87)*+	97
1. Settings Subgroup differences test (Chi^2)= 13.57, df=2, P=0.001, I^2=85.3%					
1.1. Workplace	3	5028	Mean difference (IV, Random, 95% CI)	0.11 (0.01, 0.22)*	0
1.2. University	1	101	Mean difference (IV, Random, 95% CI)	-0.06 (-1.18, 1.06)	not applicable
1.3. Community	22	50,044	Mean difference (IV, Random, 95% CI)	0.65 (0.38, 0.92)*+	99
2. Gender targets Subgroup differences test (Chi^2)=6.85, df=2, P=0.03, I^2=70.8%).					
2.1. Women targeted	6	37,773	Mean difference (IV, Random, 95% CI)	0.66 (0.20, 1.12)*+	90
2.2. Men targeted	1	479	Mean difference (IV, Random, 95% CI)	1.20 (0.64, 1.76)*	not applicable
2.3. Mix targeted	19	16,921	Mean difference (IV, Random, 95% CI)	0.45 (0.30, 0.61)*+	90
3. Trial durations Subgroup differences test (Chi^2=213.96, df=2, P<0.00001, I^2=99.1%)					
3.1. Short (3-11 months)	16	11,100	Mean difference (IV, Random, 95% CI)	0.55 (0.32, 0.79)*+	88
3.2. Medium (12-36 months)	12	11,445	Mean difference (IV, Random, 95% CI)	0.26 (0.16, 0.37)*+	68
3.3. Long (37+ months)	1	36,203	Mean difference (IV, Random, 95% CI)	1.10 (1.05, 1.15)*	not applicable
4. Target of interventions Subgroup differences test (Chi^2=7.47, df=2, P=0.02, I^2=73.2%)					
4.1. Basic target (≥5 portions)	13	47,303	Mean difference (IV, Random, 95% CI)	0.53 (0.20, 0.85)*+	97
4.2. Non-specific target (increase	11	7331	Mean difference (IV, Random, 95% CI)	0.40 (0.20, 0.59)*+	77

4.3. Higher target (6-9 portions)	2	539	Mean difference (IV, Random, 95% CI)	1.32 (0.68, 1.96)*	8
5. Aim of interventions Subgroup differences test (Chi^2=1.17, df=1, P=0.28, I^2=14.6%)					
5.1. Single aim	12	8447	Mean difference (IV, Random, 95% CI)	0.69 (0.40, 0.97)*+	89
5.2. Multiple aim	14	46,726	Mean difference (IV, Random, 95% CI)	0.44 (0.11, 0.78)*+	99
6. Dietary measurements Subgroup differences test (Chi^2=8.91, df=2, P=0.01, I^2=77.6%)					
6.1. FFQs	23	54,199	Mean difference (IV, Random, 95% CI)	0.50 (0.26, 0.75)*+	99
6.2. 24-hour recalls	1	683	Mean difference (IV, Random, 95% CI)	1.10 (0.77, 1.43)*	not applicable
6.3. Records	2	291	Mean difference (IV, Random, 95% CI)	1.26 (0.13, 2.40)*	45

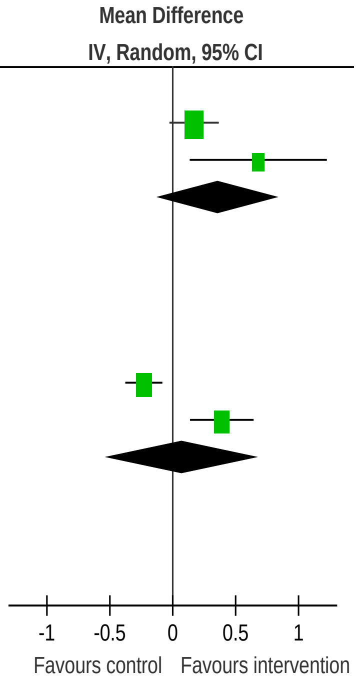
Note:
*=Significant at P<0.05
+=Substantial heterogeneity at I^2>50%

3.1.4.2.7. 24-hour recalls versus FFQs

Two studies with 1875 participants provided comparison of two types of dietary measurements (24-hour recalls versus FFQs) in the intervention groups compared to the control groups after the interventions. Subgroup analysis was conducted among these two studies which provided both outcomes (FFQs and 24-hour recall) only in order to present comparison of intervention versus control by each outcome. The results from Marcus 2001 study differs than previously stated in the overall comparison because data for the intervention and control groups for 24-hour recall was given for four months follow-up only and not for the twelve month follow-up duration (the results for FFQs after 12 months of follow-up in the intervention and control groups were given in the overall analysis) (Figure 3.13). Therefore the comparison of 24-hour recall and FFQs for Marcus 2001 below was for the four months of follow-up. The results suggested that fruit and vegetable intake measured by 24-hour recalls reported slightly bigger increase than if reported by FFQs. However the results were not significant. The results were 0.36 portions per day (95% CI -0.12 to 0.84) for 24-hour recalls and 0.07 portions per day (95% CI -0.54 to 0.68) for FFQs. Both studies used 7-item FFQs (Figure 3.13).

Figure 3.13
Comparison: Subgroup analysis of interventions using 24-hour recalls versus FFQs
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Intervention			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
1.42.1 24-hour recalls								
Buller 1999	3.81	1.01	363	3.64	1.48	332	62.7%	0.17 [-0.02, 0.36]
Marcus 2001	6.75	4.72	573	6.07	4.72	607	37.3%	0.68 [0.14, 1.22]
Subtotal (95% CI)			**936**			**939**	**100.0%**	**0.36 [-0.12, 0.84]**
Heterogeneity: Tau² = 0.09; Chi² = 3.06, df = 1 (P = 0.08); I² = 67%								
Test for overall effect: Z = 1.46 (P = 0.14)								
1.42.2 FFQ								
Buller 1999	3.24	0.64	363	3.47	1.16	332	51.4%	-0.23 [-0.37, -0.09]
Marcus 2001	4.68	2.16	573	4.29	2.16	607	48.6%	0.39 [0.14, 0.64]
Subtotal (95% CI)			**936**			**939**	**100.0%**	**0.07 [-0.54, 0.68]**
Heterogeneity: Tau² = 0.18; Chi² = 18.30, df = 1 (P < 0.0001); I² = 95%								
Test for overall effect: Z = 0.23 (P = 0.82)								



3.1.4.2.8. Messages deliveries

Direct comparison between the types of message deliveries (printed messages, computers, videos, any combination of printed messages, computers or videos) versus control included twenty studies with 17,041 participants (Figure 3.14). Four types of message deliveries included in the review were printed messages (booklets, newsletters, leaflets) from nine studies with 9236 participants, computer messages (emails or websites) from two studies with 1011 participants, video tapes from one study with 60 participants or any combination (printed messages, computer messages or videos) from 8 studies with 6734 participants (Figure 3.14).

Subgroup analysis compared interventions with different types of message deliveries namely, printed messages, computer messages, videos or any combination versus control namely, fall prevention, sleep disorder, colon cancer awareness, HIV/AIDS awareness, elderly health, adolescent health or placebo (no intervention or delayed interventions). For example tailored booklets or newsletters versus no intervention or cooking videos versus sleep disorder focused messages. The results suggested significant effects for interventions using printed messages and any combination (printed messages, computer messages or videos) but not on computers and videos interventions (Figure 3.14). The results were significant increase by 0.46 portions per day (95% CI 0.21 to 0.71, I^2=87%) and 0.60 portions per day (95% CI 0.27 to 0.93, I^2=93%) in the intervention groups compared to the control groups after the interventions for printed message and any combination respectively (Figure 3.14). While the results for computer message and video intervention were 0.40 portions per day (95% CI -0.16 to 0.95) and -0.06 portions per day (95% CI -1.18 to 1.06, I^2=not applicable) (Figure 3.14).

Results from random effect (95% CI) subgroup differences analysis indicated that the subgroups were not significantly different (Chi^2=1.52, df=3, P=0.68, I^2=0%) (Figure 3.14). Subgroup differences test between printed message and computer message suggested that both interventions were not significantly different (Chi^2=0.50, df=1, P=0.48, I^2=0%), printed message and video were not significantly different (Chi^2=0.78, df=1, P=0.38, I^2=0%), computer and video were also not significantly different (Chi^2=0.51, df=1, P=0.47, I^2=0%) (Table 3.03).

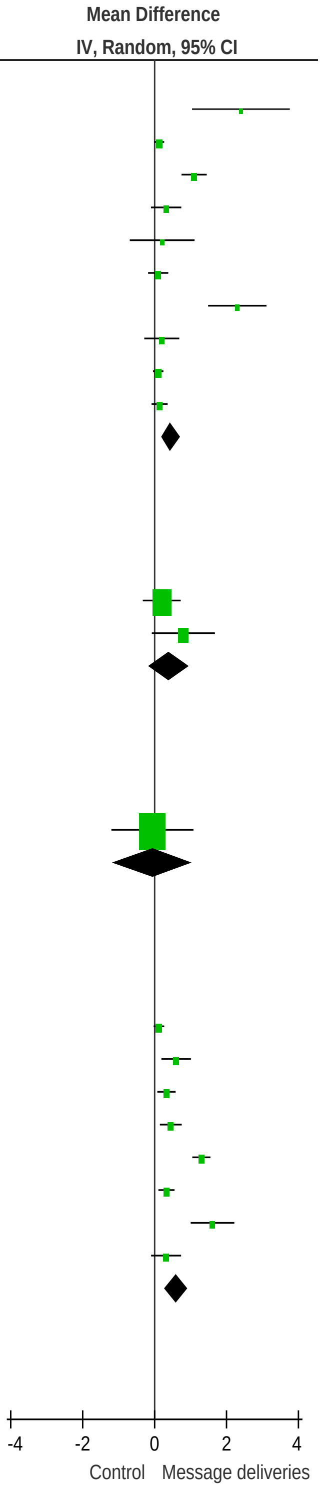
Due to lack of direct comparison among the message delivery types, adjusted indirect comparisons were conducted between printed messages versus computers (0.09 portions per day, 95% CI -0.53 to 0.7), printed messages versus videos (0.52 portions per day, 95% CI -0.63 to 1.67), computer messages versus videos (0.46 portions per day, 95% CI -0.79 to 1.71) (Table 3.03) which suggested that none of the comparisons were significantly different.

Figure 3.14

Comparison: Subgroup analysis of interventions using printed message, computer message, video and any combination versus control [(sleep disorder prevention, fall prevention, health education (HIV/AIDS, elderly or adolescent health, cancer awareness), no interventions or delayed interventions)]

Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Message deliveries			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
1.10.1 Printed message								
Bradbury 2006	5.9	3.2	30	3.5	1.88	28	2.8%	2.40 [1.06, 3.74]
Eat Healthy Life 2009	0.29	1.32	990	0.16	1.32	955	14.2%	0.13 [0.01, 0.25]
EFNEP 1988	3.7	2.4	355	2.6	2	328	11.6%	1.10 [0.77, 1.43]
High 5 2008	4.84	2.82	406	4.52	2.7	325	10.6%	0.32 [-0.08, 0.72]
Hiraka Study 2003	0.23	4.87	231	0.02	4.87	239	5.2%	0.21 [-0.67, 1.09]
Kristal 1997	3.54	1.79	369	3.44	1.83	371	12.6%	0.10 [-0.16, 0.36]
Macdonald 2009	4.9	2.5	63	2.6	1.89	56	5.9%	2.30 [1.51, 3.09]
NC Strides 2009	5.5	1.6	110	5.3	2	120	9.7%	0.20 [-0.27, 0.67]
Next Step Trial 1999	3.62	1.59	1578	3.52	2.18	1899	14.1%	0.10 [-0.03, 0.23]
Steenhuis 2004	2.03	1.35	798	1.89	1.35	215	13.3%	0.14 [-0.06, 0.34]
Subtotal (95% CI)			**4930**			**4536**	**100.0%**	**0.46 [0.21, 0.71]**
Heterogeneity: Tau² = 0.11; Chi² = 70.94, df = 9 (P < 0.00001); I² = 87%								
Test for overall effect: Z = 3.61 (P = 0.0003)								
1.10.2 Computer message								
Health Works Women 2002	3.6	3.1	282	3.4	2.9	256	67.3%	0.20 [-0.31, 0.71]
Rio Grande 2008	7.6	5.62	242	6.8	3.75	231	32.7%	0.80 [-0.06, 1.66]
Subtotal (95% CI)			**524**			**487**	**100.0%**	**0.40 [-0.16, 0.95]**
Heterogeneity: Tau² = 0.05; Chi² = 1.39, df = 1 (P = 0.24); I² = 28%								
Test for overall effect: Z = 1.41 (P = 0.16)								
1.10.3 Video								
Good Grubbin' 2009	2.75	2.24	30	2.81	2.19	30	100.0%	-0.06 [-1.18, 1.06]
Subtotal (95% CI)			**30**			**30**	**100.0%**	**-0.06 [-1.18, 1.06]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.10 (P = 0.92)								
1.10.4 Any combination								
Greene 2008	5.16	0.82	410	5.04	1.04	424	13.9%	0.12 [-0.01, 0.25]
Lutz 1999	4.2	2.41	422	3.6	1.97	151	11.8%	0.60 [0.21, 0.99]
Marcus 1998	4.83	2.15	615	4.5	2.15	671	13.2%	0.33 [0.09, 0.57]
Marcus 2001	5.04	2.31	507	4.59	2.31	509	12.8%	0.45 [0.17, 0.73]
Oxford Trial 2004	1.4	1.7	329	0.1	1.3	326	13.3%	1.30 [1.07, 1.53]
Puget Sound 2000	0.47	1.83	601	0.14	1.8	604	13.4%	0.33 [0.13, 0.53]
Sorensen 2007	1.52	3.89	298	-0.09	3.31	280	9.8%	1.61 [1.02, 2.20]
Watch Project 2004	3.72	2	458	3.4	2.04	129	11.8%	0.32 [-0.08, 0.72]
Subtotal (95% CI)			**3640**			**3094**	**100.0%**	**0.60 [0.27, 0.93]**
Heterogeneity: Tau² = 0.20; Chi² = 95.01, df = 7 (P < 0.00001); I² = 93%								
Test for overall effect: Z = 3.58 (P = 0.0003)								



Test for subgroup differences: Chi² = 1.52, df = 3 (P = 0.68), I² = 0%

3.1.4.2.9. Theory based interventions (Transtheoretical Model/Stage of Change, Social Cognitive/Social Learning, and/or Theory of Planned Behaviour)

In general there were several theories underlining the included studies namely, Transtheoretical Model/Stage of Change, Social Cognitive/Social Learning Theory and Health Behaviour Change. Subgroup analysis was conducted on studies that have Transtheoretical Model/Stage of Change, Social Cognitive/Social Learning, Health Behaviour Change or combined (Transtheoretical Model/Stage of Change, Social Cognitive/Social Learning, and Health Behaviour Change theories) incorporated in the intervention versus control (no intervention or delayed intervention or studies without clear definition of underlining theory) (Figure 3.15). For example tailored mailed material based on participants' current stage (based on stage of change theory) versus manual on fall prevention or cooking show based on Social Cognitive theory versus sleep disorder awareness. Significant results were found for all types of theories except Health Behaviour Change. The results were 0.41 portions per day (95% CI 0.15 to 0.67, I^2=79%) for Transtheoretical Model/Stage of Change, 0.36 portions per day (95% CI 0.02 to 0.71, I^2=0%) for Social Cognitive/Social Learning, 0.20 portions per day (95% CI -0.31 to 0.64, I^2=not applicable) for Health Behaviour Change, and 0.42 portions per day (95% CI 0.24 to 0.60, I^2=79%) for combined theories groups (Figure 3.15). Meanwhile subgroup difference test suggested that the groups were not significantly different (Chi^2=0.69, df=3, P=0.88, I^2=0%) (Figure 3.15).

Findings from random effect (95% CI) also suggested that all types of theories were not significantly different (Chi^2=0.69, df=3, P=0.88, I^2=0%) (Figure 3.15). Subgroup differences test between Transtheoretical Model/Stage of Change and Social Cognitive/Social Learning theory were not significantly different (Chi^2=0.52, df=1, P=0.47, I^2=0%), Transtheoretical Model/Stage of Change and Health Behaviour Change Theory were not significantly different (Chi^2=0.01, df=1, P=0.91, I^2=0%), Social Cognitive and Health Behaviour Change theories were also not significantly different (Chi^2=0.27, df=1, P=0.61, I^2=0%) (Table 3.03).

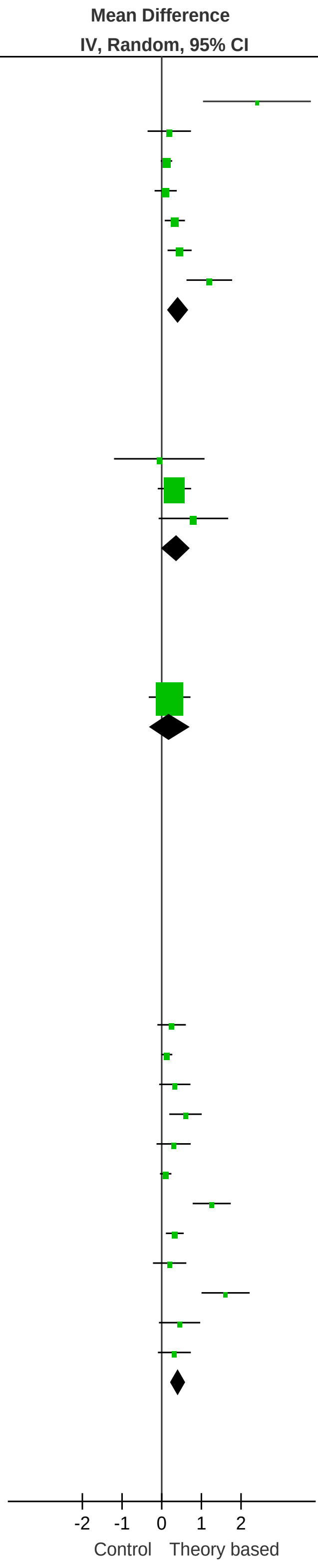
Indirect comparison between Transtheoretical Model/Stage of Change versus Social Cognitive/Social Learning suggested that both types of theories were not significantly different (0.05 portions per day, 95 CI -0.34 to 0.48) while comparisons of Transtheoretical Model/Stage of Change versus Health Behaviour Change theory suggested that both types of theories were not significantly different (0.21 portions per day, 95% CI -0.36 to 0.78), Social Cognitive/Social Learning theory versus Health Behaviour Change were also not significantly different (0.16 portions per day, 95% CI -0.46 to 0.77) (Table 3.03).

Figure 3.15

Comparison: Subgroup analysis of interventions based on Transtheoretical Model/Stage of Change, Social Cognitive/Social Learning, and Health Behaviour Change versus control (no interventions or delayed interventions or studies without clear definition of underlining theory)

Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Theory based			Control				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
1.14.1 TTM								
Bradbury 2006	5.9	3.2	30	3.5	1.88	28	3.2%	2.40 [1.06, 3.74]
Cookin' Up Health 2007	3.74	2.11	131	3.55	2.24	131	11.4%	0.19 [-0.34, 0.72]
Greene 2008	5.16	0.82	410	5.04	1.04	424	20.8%	0.12 [-0.01, 0.25]
Kristal 1997	3.54	1.79	369	3.44	1.83	371	17.9%	0.10 [-0.16, 0.36]
Marcus 1998	4.83	2.15	615	4.5	2.15	671	18.5%	0.33 [0.09, 0.57]
Marcus 2001	5.04	2.31	507	4.59	2.31	509	17.3%	0.45 [0.17, 0.73]
Wolf 2009	4.6	3.8	240	3.4	2.2	239	10.9%	1.20 [0.64, 1.76]
Subtotal (95% CI)			**2302**			**2373**	**100.0%**	**0.41 [0.15, 0.67]**
Heterogeneity: Tau² = 0.08; Chi² = 28.63, df = 6 (P < 0.0001); I² = 79%								
Test for overall effect: Z = 3.12 (P = 0.002)								
1.14.2 Social Cognitive/Social Learning								
Good Grubbin' 2009	2.75	2.24	30	2.81	2.19	30	9.5%	-0.06 [-1.18, 1.06]
High 5 2008	4.84	2.82	406	4.52	2.7	325	74.2%	0.32 [-0.08, 0.72]
Rio Grande 2008	7.6	5.62	242	6.8	3.75	231	16.3%	0.80 [-0.06, 1.66]
Subtotal (95% CI)			**678**			**586**	**100.0%**	**0.36 [0.02, 0.71]**
Heterogeneity: Tau² = 0.00; Chi² = 1.59, df = 2 (P = 0.45); I² = 0%								
Test for overall effect: Z = 2.05 (P = 0.04)								
1.14.3 Health Behaviour Change								
Health Works Women 2002	3.6	3.1	282	3.4	2.9	256	100.0%	0.20 [-0.31, 0.71]
Subtotal (95% CI)			**282**			**256**	**100.0%**	**0.20 [-0.31, 0.71]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.77 (P = 0.44)								
1.14.4 Theory of Planned Behaviour								
Subtotal (95% CI)			**0**			**0**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								
1.14.5 Combined								
Alexander 2010	7.08	3.55	1201	6.83	3.5	619	8.6%	0.25 [-0.09, 0.59]
Eat Healthy Life 2009	0.29	1.32	990	0.16	1.32	955	11.8%	0.13 [0.01, 0.25]
Heimendinger 2005	5.4	2.94	442	5.07	2.9	498	8.1%	0.33 [-0.04, 0.70]
Lutz 1999	4.2	2.41	422	3.6	1.97	151	7.8%	0.60 [0.21, 0.99]
NC Strides 2009	5.6	1.9	341	5.3	2	120	7.5%	0.30 [-0.11, 0.71]
Next Step Trial 1999	3.62	1.59	1578	3.52	2.18	1899	11.7%	0.10 [-0.03, 0.23]
Premier 2007	1.76	3.14	457	0.5	2.8	232	6.8%	1.26 [0.80, 1.72]
Puget Sound 2000	0.47	1.83	601	0.14	1.8	604	10.7%	0.33 [0.13, 0.53]
Resnicow 2008	4.5	2.2	208	4.3	2	215	7.7%	0.20 [-0.20, 0.60]
Sorensen 2007	1.52	3.89	298	-0.09	3.31	280	5.3%	1.61 [1.02, 2.20]
South London 2004	1.44	2.11	136	0.99	2.1	135	6.3%	0.45 [-0.05, 0.95]
Watch Project 2004	3.72	2	458	3.4	2.04	129	7.7%	0.32 [-0.08, 0.72]
Subtotal (95% CI)			**7132**			**5837**	**100.0%**	**0.42 [0.24, 0.60]**
Heterogeneity: Tau² = 0.07; Chi² = 52.98, df = 11 (P < 0.00001); I² = 79%								
Test for overall effect: Z = 4.60 (P < 0.00001)								



Test for subgroup differences: Chi² = 0.69, df = 3 (P = 0.88), I² = 0%

3.1.4.2.10. Psychosocial factors

The subgroup analysis included all interventions with psychosocial factors as follows:

1. Intention, attitude, belief.
2. Self efficacy.
3. Social support.
4. Knowledge.
5. Motivation.
6. Barriers and facilitators.
7. Action plans.
8. Role model.

These studies were then classified based on the numbers of psychosocial factors incorporated in the interventions which were divided into three categories:

- 1-3 factors.
- 4-6 factors.
- At least 7 factors.

The next step was to conduct a subgroup analysis comparing interventions with psychosocial factors (intention, attitude, belief, self efficacy, social support, knowledge, motivation, barriers and facilitators, action plans or role model) versus control (aimed at other factors: sleep disorder awareness, fall prevention, colon cancer awareness, prostate cancer awareness) or placebo (no intervention or delayed intervention). The psychosocial factors were incorporated in the interventions in the form of tailored interventions, printed messages or computer messages. Examples of the interventions were individual tailored intervention versus no intervention or individual counselling session versus no intervention. The results found that all of the studies which were included had at least one psychosocial factor in the intervention. However studies were included in the meta-analysis if they provided a direct comparison with a control group (studies which incorporated psychosocial factors in both intervention arms were not included).

Findings suggested that interventions with 1-3 psychosocial factors (ten studies with 4413 participants), 4-6 psychosocial factors (twelve studies with 13,059 participants) and at least 7 psychosocial factors (one study with 587 participants) were all significant in increasing fruit and vegetable intake (Figure 3.16). The results were 0.80 portions per day (95% CI 0.41 to 1.19, I^2=89%) for 1-3 psychosocial factors, 0.54 portions per day (95% CI 0.31 to 0.77, I^2=92%) for 4-6 psychosocial factors, and 0.32 portions per day (95% CI -0.08 to 0.72) for at least 7 psychosocial factors in the intervention groups compared to the control groups after the interventions consecutively (Figure 3.16).

Findings from random effect (95% CI) subgroup differences test suggested that the three subgroups were not significantly different (Chi^2=2.83, df=2, P=0.24, I^2=29.3%) (Figure 3.16). Subgroup difference tests for 1-3 and 4-6 factors suggested that the subgroups were not significantly different (Chi^2=1.26, df=1, P=0.26, I^2=20.9%), 1-3 and at least 7 factors were not significantly different (Chi^2=2.81, df=1, P=0.09, I^2=64.4%), 4-6 and at least 7 factors were also not significantly different (Chi^2=0.85, df=1, P=0.36, I^2=0%) (Table 3.03).

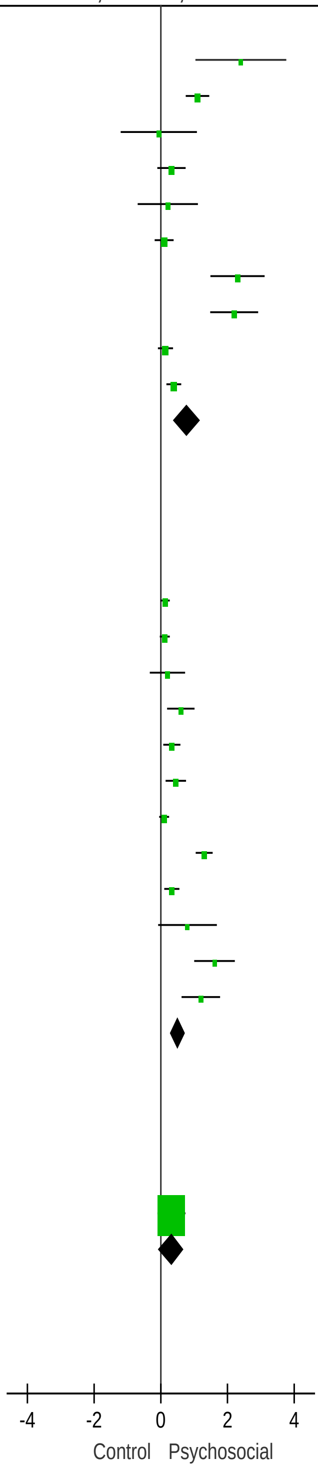
Meanwhile due to lack of direct comparison among the two types of psychosocial factors, indirect comparisons were conducted. The results suggested that interventions with 1-3 versus 4-6 psychosocial factors were not significantly different (0.28 portions per day, 95% CI -0.17 to 0.73), 1-3 versus at least 7 were not significantly different (0.48 portions per day, 95% CI -0.08 to 1.04) and 4-6 versus at least 7 were also not significantly different (0.22 portions per day, 95% CI -0.24 to 0.68) (Table 3.03).

Figure 3.16

Comparison: Subgroup analysis of interventions with 1-3 and 4-6 psychosocial factors versus control [(sleep disorder awareness, manual on fall prevention, health education (HIV/AIDS, elderly/adolescent health, and cancer awareness), no interventions or delayed interventions)]
Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Psychosocial			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
1.13.1 1-3 factors								
Bradbury 2006	5.9	3.2	30	3.5	1.88	28	5.2%	2.40 [1.06, 3.74]
EFNEP 1988	3.7	2.4	355	2.6	2	328	12.2%	1.10 [0.77, 1.43]
Good Grubbin' 2009	2.75	2.24	30	2.81	2.19	30	6.4%	-0.06 [-1.18, 1.06]
High 5 2008	4.84	2.82	406	4.52	2.7	325	11.7%	0.32 [-0.08, 0.72]
Hiraka Study 2003	0.23	4.87	231	0.02	4.87	239	8.0%	0.21 [-0.67, 1.09]
Kristal 1997	3.54	1.79	369	3.44	1.83	371	12.6%	0.10 [-0.16, 0.36]
Macdonald 2009	4.9	2.5	63	2.6	1.89	56	8.6%	2.30 [1.51, 3.09]
Mediterranean Eating 2009	4.3	1.38	27	2.1	1.36	33	9.4%	2.20 [1.50, 2.90]
Steenhuis 2004	2.03	1.35	798	1.89	1.35	215	12.9%	0.14 [-0.06, 0.34]
Women's Health Trial 1999	0.44	1.09	285	0.05	1.09	194	12.9%	0.39 [0.19, 0.59]
Subtotal (95% CI)			**2594**			**1819**	**100.0%**	**0.80 [0.41, 1.19]**
Heterogeneity: Tau² = 0.30; Chi² = 85.67, df = 9 (P < 0.00001); I² = 89%								
Test for overall effect: Z = 4.00 (P < 0.0001)								
1.13.4 4-6 factors								
Eat Healthy Life 2009	0.29	1.32	990	0.16	1.32	955	10.2%	0.13 [0.01, 0.25]
Greene 2008	5.16	0.82	410	5.04	1.04	424	10.1%	0.12 [-0.01, 0.25]
Health Works Women 2002	3.6	3.1	282	3.4	2.9	256	6.9%	0.20 [-0.31, 0.71]
Lutz 1999	4.2	2.41	422	3.6	1.97	151	8.0%	0.60 [0.21, 0.99]
Marcus 1998	4.83	2.15	615	4.5	2.15	671	9.4%	0.33 [0.09, 0.57]
Marcus 2001	5.04	2.31	507	4.59	2.31	509	9.0%	0.45 [0.17, 0.73]
Next Step Trial 1999	3.62	1.59	1578	3.52	2.18	1899	10.2%	0.10 [-0.03, 0.23]
Oxford Trial 2004	1.4	1.7	329	0.1	1.3	326	9.5%	1.30 [1.07, 1.53]
Puget Sound 2000	0.47	1.83	601	0.14	1.8	604	9.7%	0.33 [0.13, 0.53]
Rio Grande 2008	7.6	5.62	242	6.8	3.75	231	4.3%	0.80 [-0.06, 1.66]
Sorensen 2007	1.52	3.89	298	-0.09	3.31	280	6.2%	1.61 [1.02, 2.20]
Wolf 2009	4.6	3.8	240	3.4	2.2	239	6.5%	1.20 [0.64, 1.76]
Subtotal (95% CI)			**6514**			**6545**	**100.0%**	**0.54 [0.31, 0.77]**
Heterogeneity: Tau² = 0.13; Chi² = 130.84, df = 11 (P < 0.00001); I² = 92%								
Test for overall effect: Z = 4.58 (P < 0.00001)								
1.13.5 at least 7 factors								
Watch Project 2004	3.72	2	458	3.4	2.04	129	100.0%	0.32 [-0.08, 0.72]
Subtotal (95% CI)			**458**			**129**	**100.0%**	**0.32 [-0.08, 0.72]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.58 (P = 0.11)								

Mean Difference
IV, Random, 95% CI



Test for subgroup differences: Chi² = 2.83, df = 2 (P = 0.24), I² = 29.3%

3.1.4.2.11. Counselling methods

Subgroup analysis on the counselling methods were conducted which can be separated into face to face (6 studies with 38,000 participants), using telephones (8 studies with 5056 participants) methods and using email counselling (1 study with 1201 participants) (Figure 3.17). The types of counselling method were then compared to control (participants were given a copy of recommended guidelines, aimed at other factors namely, non-tailored intervention, manual on fall prevention, colon cancer awareness, HIV/AIDS awareness, prostate cancer awareness) or placebo (no intervention or delayed intervention) (Figure 3.17). Examples of the methods were face to face counselling versus delayed interventions or telephone calls by counsellors versus no intervention.

The results suggested that telephone counselling may increase fruit and vegetable intake by 0.85 portions per day (95% CI 0.41 to 1.29, I^2=95%), face to face counselling was able to significantly increase fruit and vegetable intake by 0.60 portions per day (95% CI 0.11 to 1.10, I^2=94%), meanwhile, email counselling caused a non-significant increase in fruit and vegetable intake by 0.20 portions per day (95% CI -0.20 to 0.60) in the intervention groups compared to the control groups after the interventions (Figure 3.17).

Random effect test (95% CI) of subgroup differences inferred that the three subgroups were not significantly different (Chi^2=4.75, df=2, P=0.09, I^2=57.9%) (Figure 3.17). Each counselling method was then compared to each other. The results were (Chi^2=0.53, df=1, P=0.21, I^2=35.6%) for face to face versus telephone counselling, (Chi^2=1.55, df=1, P<0.0001, I^2=94.0%%) for face to face versus email counselling (Table 3.03). On the contrary significant difference was found for telephone versus email counselling (Chi^2=5.86, df=1, P=0.02, I^2=82.9%) (Table 3.03).

Direct comparisons of face to face and telephone methods were not available therefore adjusted indirect comparison analysis was conducted by comparing face to face counselling versus telephone counselling. The results suggested that the two types of counselling were not significantly different; -0.25 portions per day (95% CI -0.91 to 0.41) (Table 3.03). Meanwhile a comparison of face to face versus email counselling was

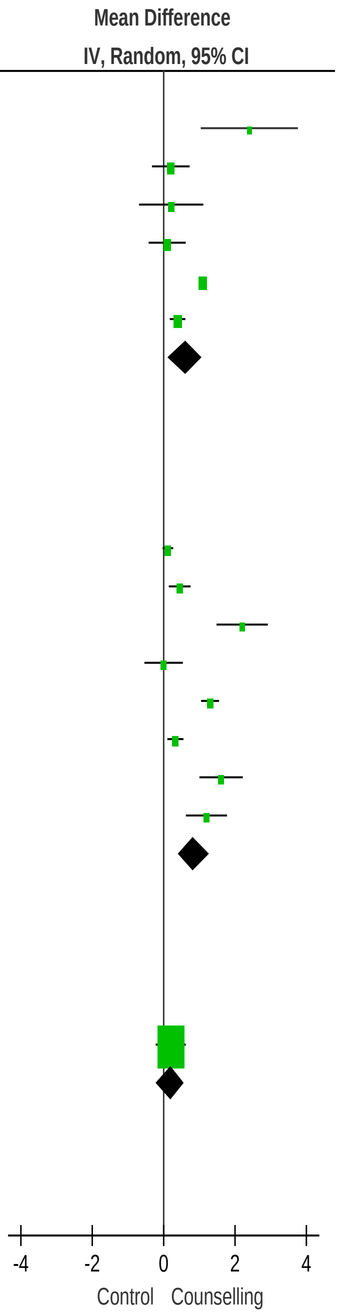
0.40 (95% CI -0.24, 1.04) and a comparison of telephone versus email counselling was 0.77 (95% CI 0.15 to 1.4) (Table 3.03). The result suggested that telephone counselling may significantly increase fruit and vegetable intake by 0.77 portions higher than counselling by email (Table 3.03).

Figure 3.17

Comparison: Subgroup analysis of face to face or telephone counselling methods versus control [(advice on blood pressure, increasing physical activity, fall prevention, health education (HIV/AIDS, elderly/adolescent health, cancer awareness) or placebo (no interventions or delayed interventions)]

Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Counselling			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
1.18.1 Face to face								
Bradbury 2006	5.9	3.2	30	3.5	1.88	28	8.4%	2.40 [1.06, 3.74]
Health Works Women 2002	3.6	3.1	282	3.4	2.9	256	17.8%	0.20 [-0.31, 0.71]
Hiraka Study 2003	0.23	4.87	231	0.02	4.87	239	12.9%	0.21 [-0.67, 1.09]
Watch Project 2004	3.5	2	123	3.4	2.04	129	17.9%	0.10 [-0.40, 0.60]
WHI 2007	5	2.4	14183	3.9	2	22020	21.9%	1.10 [1.05, 1.15]
Women's Health Trial 1999	0.44	1.09	285	0.05	1.09	194	21.2%	0.39 [0.19, 0.59]
Subtotal (95% CI)			**15134**			**22866**	**100.0%**	**0.60 [0.11, 1.10]**
Heterogeneity: Tau² = 0.29; Chi² = 78.66, df = 5 (P < 0.00001); I² = 94%								
Test for overall effect: Z = 2.40 (P = 0.02)								
1.18.2 Telephone								
Greene 2008	5.16	0.82	410	5.04	1.04	424	14.0%	0.12 [-0.01, 0.25]
Marcus 2001	5.04	2.31	507	4.59	2.31	509	13.4%	0.45 [0.17, 0.73]
Mediterranean Eating 2009	4.3	1.38	27	2.1	1.36	33	10.4%	2.20 [1.50, 2.90]
NC Strides 2009	5.3	2	109	5.3	2	120	11.8%	0.00 [-0.52, 0.52]
Oxford Trial 2004	1.4	1.7	329	0.1	1.3	326	13.7%	1.30 [1.07, 1.53]
Puget Sound 2000	0.47	1.83	601	0.14	1.8	604	13.8%	0.33 [0.13, 0.53]
Sorensen 2007	1.52	3.89	298	-0.09	3.31	280	11.3%	1.61 [1.02, 2.20]
Wolf 2009	4.6	3.8	240	3.4	2.2	239	11.5%	1.20 [0.64, 1.76]
Subtotal (95% CI)			**2521**			**2535**	**100.0%**	**0.85 [0.41, 1.29]**
Heterogeneity: Tau² = 0.35; Chi² = 128.07, df = 7 (P < 0.00001); I² = 95%								
Test for overall effect: Z = 3.82 (P = 0.0001)								
1.18.4 Email								
Alexander 2010	7.18	3.4	588	6.98	3.7	613	100.0%	0.20 [-0.20, 0.60]
Subtotal (95% CI)			**588**			**613**	**100.0%**	**0.20 [-0.20, 0.60]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.98 (P = 0.33)								



Test for subgroup differences: Chi² = 4.75, df = 2 (P = 0.09), I² = 57.9%

3.1.4.2.12. Counsellors

The following subgroup analysis categorized studies by counsellors namely, dietitians/nutritionists (five studies with 37,270 participants), other health care professionals (GP, physicians, nurse) from one study with 655 participants and non health care professionals (trained staffs or community workers) from nine studies with 6332 participants and compared them with control (non-tailored intervention, aimed at other factors namely, manual on fall prevention, colon cancer awareness, prostate cancer awareness and HIV/AIDS awareness) or placebo (no intervention or delayed intervention) (Figure 3.18). Counselling was given through websites, group meetings, telephone calls, individual meetings or lectures for example, tailored telephone interviews by trained staffs versus no intervention.

The results found significant effects of counselling by all types of counsellors such as, dietitians (1.11 portions per day, 95% CI 0.56 to 1.66, I^2=94%), other health professionals (1.30 portions per day, 95% CI 1.07 to 1.53, I^2=not applicable) and non health care professionals (0.42 portions per day, 95% CI 0.17 to 0.66, I^2=80%) in the intervention groups compared to the control groups after the interventions (Figure 3.18).

Results from random effect (95% CI) test for subgroup differences indicated that the three types of counsellors were significantly different (Chi^2=26.86, df=2, P<0.00001, I^2=92.6%) (Figure 3.18). Comparisons between subgroups reported non-significant difference for dietitians versus other health care professionals (Chi^2=0.38, df=1, P=0.54, I^2=0%) and significant differences on dietitians versus non health care professionals (Chi^2=5.15, df=1, P=0.02, I^2=80.6%) and other health care professionals versus non health care professionals (Chi^2=26.25, df=1, P<0.00001, I^2=96.2%) (Table 3.03).

Because direct comparisons among different types of counsellors were not present, adjusted indirect comparisons were conducted among three types of counsellors. The results from adjusted indirect comparison were significant for dietitians versus non health care professionals, 0.69 portions per day (95% CI 0.08 to 1.30) and other health care professionals versus non health care professionals, 0.88 portions per day (95% CI

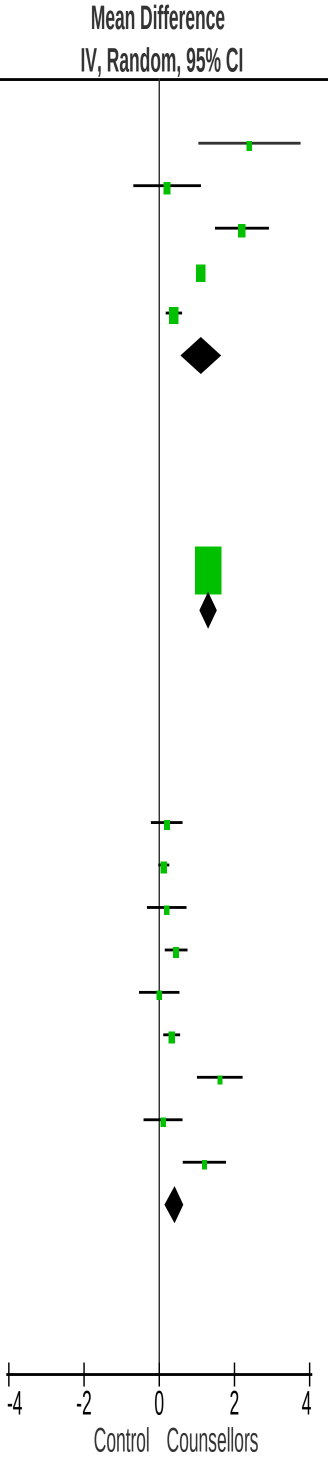
0.54 to 1.22) (Table 3.03). Meanwhile result was not significant for counselling led by dietitians compared to other health care professionals, -0.19 portions per day (95% CI -0.79 to 0.40) (Table 3.03). The results suggested that counselling by other health care professionals may significantly increase fruit and vegetable intake by 0.69 portions per day higher than counselling by non health care professionals. Similarly counselling by other health care professionals may also increase fruit and vegetable intake by 0.88 portions per day higher than counselling by non health care professionals.

Figure 3.18

Comparison: Subgroup analysis of counsellors' types (dietitians/nutritionists, other health care professionals and non health care professionals) versus studies without counsellors [(non-tailored intervention, aimed at other factors: fall prevention, health education (HIV/AIDS, elderly/adolescent health, cancer awareness) or placebo (no interventions or delayed interventions)]

Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Counsellors			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
1.17.1 Dietitians								
Bradbury 2006	5.9	3.2	30	3.5	1.88	28	10.4%	2.40 [1.06, 3.74]
Hiraka Study 2003	0.23	4.87	231	0.02	4.87	239	16.1%	0.21 [-0.67, 1.09]
Mediterranean Eating 2009	4.3	1.38	27	2.1	1.36	33	19.1%	2.20 [1.50, 2.90]
WHI 2007	5	2.4	14183	3.9	2	22020	27.6%	1.10 [1.05, 1.15]
Women's Health Trial 1999	0.44	1.09	285	0.05	1.09	194	26.7%	0.39 [0.19, 0.59]
Subtotal (95% CI)			**14756**			**22514**	**100.0%**	**1.11 [0.56, 1.66]**
Heterogeneity: $Tau^2 = 0.28$; $Chi^2 = 63.96$, df = 4 ($P < 0.00001$); $I^2 = 94\%$								
Test for overall effect: Z = 3.98 ($P < 0.0001$)								
1.17.2 Other health care professionals								
Oxford Trial 2004	1.4	1.7	329	0.1	1.3	326	100.0%	1.30 [1.07, 1.53]
Subtotal (95% CI)			**329**			**326**	**100.0%**	**1.30 [1.07, 1.53]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 11.00 ($P < 0.00001$)								
1.17.3 Non health care professionals								
Alexander 2010	7.18	3.4	588	6.98	3.7	613	11.2%	0.20 [-0.20, 0.60]
Greene 2008	5.16	0.82	410	5.04	1.04	424	15.4%	0.12 [-0.01, 0.25]
Health Works Women 2002	3.6	3.1	282	3.4	2.9	256	9.5%	0.20 [-0.31, 0.71]
Marcus 2001	5.04	2.31	507	4.59	2.31	509	13.2%	0.45 [0.17, 0.73]
NC Strides 2009	5.3	2	109	5.3	2	120	9.4%	0.00 [-0.52, 0.52]
Puget Sound 2000	0.47	1.83	601	0.14	1.8	604	14.4%	0.33 [0.13, 0.53]
Sorensen 2007	1.52	3.89	298	-0.09	3.31	280	8.4%	1.61 [1.02, 2.20]
Watch Project 2004	3.5	2	123	3.4	2.04	129	9.7%	0.10 [-0.40, 0.60]
Wolf 2009	4.6	3.8	240	3.4	2.2	239	8.8%	1.20 [0.64, 1.76]
Subtotal (95% CI)			**3158**			**3174**	**100.0%**	**0.42 [0.17, 0.66]**
Heterogeneity: $Tau^2 = 0.10$; $Chi^2 = 39.60$, df = 8 ($P < 0.00001$); $I^2 = 80\%$								
Test for overall effect: Z = 3.33 ($P = 0.0009$)								



Test for subgroup differences: $Chi^2 = 26.86$, df = 2 ($P < 0.00001$), $I^2 = 92.6\%$

3.1.4.2.13. Tailored

Subgroup analysis was conducted on studies that were individually tailored (19 studies with 53,074 participants), group tailored (three studies with 2928 participants) or combined individually tailored and group tailored (two studies with 940 participants) and compared them with control (aimed at other factors: sleep disorder prevention, fall prevention, prostate cancer awareness, colon cancer awareness and HIV/AIDS awareness) or placebo (no intervention or delayed intervention) (Figure 3.19). Tailored interventions were given through computer feedbacks, face to face or telephone counselling, group sessions, mailed materials (newsletter, magazine, booklet, tips) or motivational interviews based on stage of change.

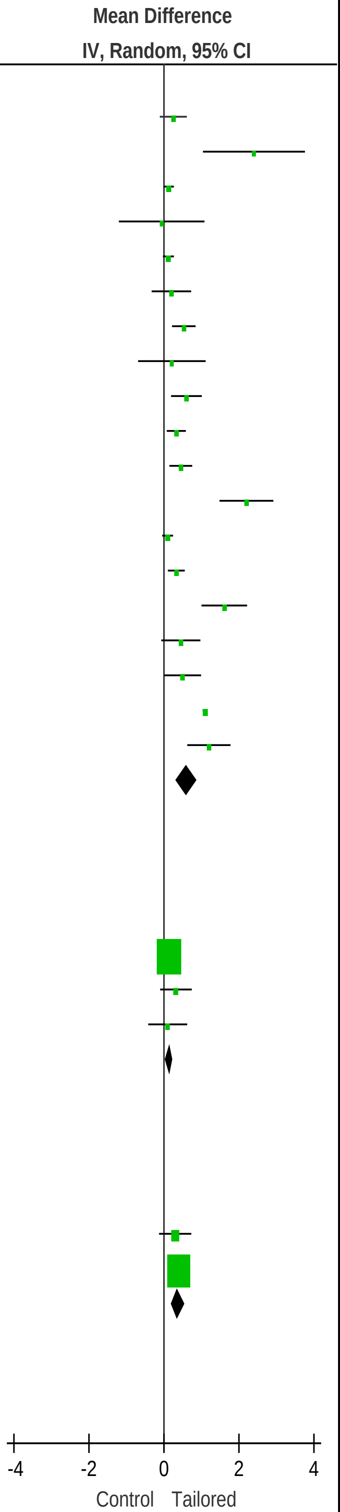
The results suggested significant effects of individually tailored, group tailored and combined interventions. Individually tailored interventions were able to significantly increase fruit and vegetable intake by 0.60 portions per day (95% CI 0.32 to 0.89, I^2=97%) (Figure 3.19) while group tailored interventions and combined tailored interventions were able to significantly increase fruit and vegetable intake by 0.14 portions per day (95% CI 0.03 to 0.26, I^2=0%) (Figure 3.19) and 0.37 portions per day (95% CI 0.19 to 0.55, I^2=0%) respectively in the intervention groups compared to the control groups after the interventions (Figure 3.19).

Figure 3.19

Comparison: Subgroup analysis of tailored interventions (individual tailored, group tailored or combined) versus control [(sleep disorder prevention, fall prevention, health education (HIV/AIDS, elderly/adolescent health, cancer awareness) or placebo (no interventions or delayed interventions)]

Outcome: Mean differences of fruit and vegetables consumed (portions per day)

	Tailored			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
1.21.1 Individually tailored								
Alexander 2010	7.08	3.55	1201	6.83	3.5	619	5.7%	0.25 [-0.09, 0.59]
Bradbury 2006	5.9	3.2	30	3.5	1.88	28	2.6%	2.40 [1.06, 3.74]
Eat Healthy Life 2009	0.29	1.32	990	0.16	1.32	955	6.2%	0.13 [0.01, 0.25]
Good Grubbin' 2009	2.75	2.24	30	2.81	2.19	30	3.1%	-0.06 [-1.18, 1.06]
Greene 2008	5.16	0.82	410	5.04	1.04	424	6.2%	0.12 [-0.01, 0.25]
Health Works Women 2002	3.6	3.1	282	3.4	2.9	256	5.2%	0.20 [-0.31, 0.71]
Heimendinger 2005	5.6	2.89	1415	5.07	2.9	498	5.9%	0.53 [0.23, 0.83]
Hiraka Study 2003	0.23	4.87	231	0.02	4.87	239	3.9%	0.21 [-0.67, 1.09]
Lutz 1999	4.2	2.41	422	3.6	1.97	151	5.6%	0.60 [0.21, 0.99]
Marcus 1998	4.83	2.15	615	4.5	2.15	671	6.0%	0.33 [0.09, 0.57]
Marcus 2001	5.04	2.31	507	4.59	2.31	509	5.9%	0.45 [0.17, 0.73]
Mediterranean Eating 2009	4.3	1.38	27	2.1	1.36	33	4.5%	2.20 [1.50, 2.90]
Next Step Trial 1999	3.62	1.59	1578	3.52	2.18	1899	6.2%	0.10 [-0.03, 0.23]
Puget Sound 2000	0.47	1.83	601	0.14	1.8	604	6.1%	0.33 [0.13, 0.53]
Sorensen 2007	1.52	3.89	298	-0.09	3.31	280	4.9%	1.61 [1.02, 2.20]
South London 2004	1.44	2.11	136	0.99	2.1	135	5.2%	0.45 [-0.05, 0.95]
Watch Project 2004	3.9	2.01	159	3.4	2.04	129	5.3%	0.50 [0.03, 0.97]
WHI 2007	5	2.4	14183	3.9	2	22020	6.3%	1.10 [1.05, 1.15]
Wolf 2009	4.6	3.8	240	3.4	2.2	239	5.0%	1.20 [0.64, 1.76]
Subtotal (95% CI)			**23355**			**29719**	**100.0%**	**0.60 [0.32, 0.89]**
Heterogeneity: Tau² = 0.33; Chi² = 600.47, df = 18 (P < 0.00001); I² = 97%								
Test for overall effect: Z = 4.22 (P < 0.0001)								
1.21.2 Group tailored								
Eat Healthy Life 2009	0.29	1.32	990	0.16	1.32	955	87.7%	0.13 [0.01, 0.25]
High 5 2008	4.84	2.82	406	4.52	2.7	325	7.5%	0.32 [-0.08, 0.72]
Watch Project 2004	3.5	2	123	3.4	2.04	129	4.9%	0.10 [-0.40, 0.60]
Subtotal (95% CI)			**1519**			**1409**	**100.0%**	**0.14 [0.03, 0.25]**
Heterogeneity: Tau² = 0.00; Chi² = 0.82, df = 2 (P = 0.66); I² = 0%								
Test for overall effect: Z = 2.55 (P = 0.01)								
1.21.3 Individual and Group tailored								
NC Strides 2009	5.6	1.9	341	5.3	2	120	19.0%	0.30 [-0.11, 0.71]
Women's Health Trial 1999	0.44	1.09	285	0.05	1.09	194	81.0%	0.39 [0.19, 0.59]
Subtotal (95% CI)			**626**			**314**	**100.0%**	**0.37 [0.19, 0.55]**
Heterogeneity: Tau² = 0.00; Chi² = 0.15, df = 1 (P = 0.70); I² = 0%								
Test for overall effect: Z = 4.08 (P < 0.0001)								



Test for subgroup differences: Chi² = 11.58, df = 2 (P = 0.003), I² = 82.7%

Table 3.03 Summary of findings

No.	Comparison	Direct Mean difference (Random 95% CI)	Indirect Mean difference (Random 95% CI)	Test for subgroup difference (Random 95% CI)	Meaning/Interpretation
1.	All interventions versus control	**0.64 (0.40, 0.87)**	-	-	Interventions aimed to increase fruit and vegetable intake were able to significantly increase fruit and vegetable by 0.64 portions per day compared to control groups.
2.	24-hour recalls versus FFQs	1.31 (-0.16, 2.77)	-	-	24-hour recalls reported fruit and vegetable intake by 1.31 portions per day higher than FFQs. However this was not significant.
3.	Printed messages versus telephones	0.20 (-0.28, 0.68)	-	-	Printed messages may increase fruit and vegetable intake by 0.20 portions per day higher compared to telephone messages. However the result was not significant.
4.	Face to face versus printed messages and videos	-0.40 (-0.87, 0.07)	-	-	Printed message and video interventions were able to increase fruit and vegetable intake by 0.40 portions per day higher than face to face interventions. However the result was not significant.
5.	Printed messages and videos (combined)	0.40 (-0.07, 0.87)	-	-	Printed message and video interventions (combined) may increase fruit and vegetable intake by 0.40 portions per day higher than social support and role model interventions. However the result

No.	Comparison	Direct Mean difference (Random 95% CI)	Indirect Mean difference (Random 95% CI)	Test for subgroup difference (Random 95% CI)	Meaning/Interpretation
	versus social support and role model				was not significant.
4.	Individually tailored versus non-tailored	**0.30 (0.17, 0.43)**	-	-	Individually tailored interventions may significantly increase by 0.30 portions per day higher compared to non-tailored interventions (intervention also aimed to increase fruit and vegetables/not placebo or control interventions).
5.	Individually tailored versus group tailored	0.40 (-0.07, 0.87)	-	-	Individually tailored interventions may increase fruit and vegetable intake by 0.40 portions per day higher than group tailored interventions. However the result was not significant.
6.	Motivational interview versus control	**0.29 (0.16, 0.42)**	-	-	Motivational interview interventions may significantly increase fruit and vegetable intake by 0.29 portions per day higher than the control groups.
7.	Social support versus control	**0.35 (0.02, 0.68)**	-	-	Social support interventions may significantly increase fruit and vegetable intake by 0.35 portions per day higher than the control groups.

No.	Comparison	Direct Mean difference (Random 95% CI)	Indirect Mean difference (Random 95% CI)	Test for subgroup difference (Random 95% CI)	Meaning/Interpretation
8.	Practical skills versus control	**0.41 (0.10, 0.72)**	-	-	Practical skills interventions may significantly increase fruit and vegetable intake by 0.41 portions per day higher than the control groups.
9.	Access versus control	**0.55 (0.04, 1.07)**	-	-	Acess interventions may significantly increase fruit and vegetable intake by 0.55 portions per day higher than the control groups.
10.	Printed messages versus computer messages	Not available	0.09 (-0.53, 0.7)	Chi^2=0.50, df=1, P=0.48, I^2=0%	Printed messages and computer messages were not significantly different.
11.	Printed messages versus video messages	Not available	0.52 (-0.63, 1.67)	Chi^2=0.78, df=1, P=0.38, I^2=0%	Printed messages and video messages were not significantly different.
12.	Computer messages versus video messages	Not available	0.46 (-0.79, 1.71)	Chi^2=0.51, df=1, P=0.47, I^2=0%	Computer messages and video messages were not significantly different.
13.	TTM versus Social Cognitive/Social Learning	Not available	0.05 (-0.34, 0.48)	Chi^2=0.52, df=1 (P=0.47), I^2=0%	Intervention based on Transtheoretical Model and Social Cognitive theory were not significantly different.

No.	Comparison	Direct Mean difference (Random 95% CI)	Indirect Mean difference (Random 95% CI)	Test for subgroup difference (Random 95% CI)	Meaning/Interpretation
14.	TTM versus Health Behaviour Change Theory	Not available	0.21 (-0.36, 0.78)	Chi^2=0.01, df=1 (P=0.91), I^2=0%	Intervention based on Transtheoretical Model and Health Behaviour Change Theory were not significantly different.
15.	Social Cognitive/ Social Learning Theory versus Health Behaviour Change Theory	Not available	0.16 (-0.46, 0.77)	Chi^2=0.27, df=1 (P=0.61), I^2=0%	Intervention based on Social Cognitive Theory and Health Behaviour Change Theory were not significantly different.
16.	1-3 vs. 4-6 psychosocial factors	Not available	0.28 (-0.17, 0.73)	Chi^2=1.26, df=1 (P=0.26), I^2=20.9%*	Interventions with 1-3 and 4-6 psychosocial factors were not significantly different.
17.	1-3 versus at least 7 psychosocial factors	Not available	0.48 (-0.08, 1.04)	Chi^2=2.81, df=1 (P=0.09), I^2=64.4%*	Interventions with 1-3 and at least 7 psychosocial factors were not significantly different.
18.	4-6 versus at least 7 psychosocial factors	Not available	0.22 (-0.24, 0.68)	Chi^2=0.85, df=1 (P=0.36), I^2=0%	Interventions with 4-6 and at least 7 psychosocial factors were not significantly different.

No.	Comparison	Direct Mean difference (Random 95% CI)	Indirect Mean difference (Random 95% CI)	Test for subgroup difference (Random 95% CI)	Meaning/Interpretation
19.	Face to face versus Telephone counselling	Not available	-0.25 (-0.91, 0.41)	Chi^2=0.53, df=1 (P=0.21), I^2=35.6%	Face to face and telephone counseling were not significantly different.
20.	Face to face versus Email counselling	Not available	0.40 (-0.24, 1.04)	Chi^2=1.55, df=1 (P<0.0001), I^2=94.0%	Face to face and email counseling were not significanlty different.
21.	Telephone versus Email counselling	Not available	**0.77 (0.15, 1.4)**	**Chi^2=5.86, df=1 (P=0.02), I^2=82.9%**	Telephone counseling may significantly increase fruit and vegetable intake higher than email counseling by 0.77 portions per day.
22.	Dietitians versus other health care professionals	Not available	-0.19 (-0.79, 0.40)	Chi^2=0.38, df=1 (P=0.54), I^2=0%	Counseling conducted by dietitians and other health care professionals were not significantly different.
23.	Dietitians versus non health care professionals	Not available	**0.69 (0.08, 1.30)**	**Chi^2=5.15, df=1 (P=0.02), I^2=80.6%**	Counseling conducted by dietitians may increase more fruit and vegetable intake (0.67 portions per day) compared to counseling by non health care professionals.

No.	Comparison	Direct **Mean difference (Random 95% CI)**	Indirect **Mean difference (Random 95% CI)**	Test for subgroup difference (Random 95% CI)	Meaning/Interpretation
24.	Other health care professionals versus non health care professionals	Not available	**0.88 (0.54, 1.22)**	**Chi^2=26.25, df=1 (P<0.00001), I^2=96.2%**	Counseling conducted by other health care professionals may increase more fruit and vegetable intake (0.86 portions per day) compared to counseling by non health care professionals.

Note: bold fonts=Significant at P<0.05

In summary the results can be categorized into two categories as follows:

Results from direct comparisons

All of the direct comparisons provided more than three studies and had unclear risk of bias. Of all direct comparisons only individually tailored versus non tailored interventions did not have substantial heterogeneity (I^2>50%). The detailed results were as follows:

1. Overall interventions effects may increase fruit and vegetable intake by 0.64 portions per day (95% CI 0.40, 0.87) higher than the control groups (Figure 3.02).
2. Individually tailored interventions worked more effectively and may increase fruit and vegetable intake by 0.30 portions per day (95% CI 0.17, 0.43) higher than non-tailored interventions (Figure 3.08).
3. Motivational interview interventions worked more effectively and may increase fruit and vegetable intake by 0.29 portions per day (95% CI 0.16, 0.42) higher than the control groups (Figure 3.10).
4. Social support interventions worked more effectively and may increase fruit and vegetable intake by 0.35 portions per day (95% CI 0.02, 0.68) higher than the control groups (Figure 3.11).
5. Practical skills interventions worked more effectively and may increase fruit and vegetable intake by 0.41 portions per day (95% CI 0.10, 0.72) higher than the control groups (Figure 3.12).
6. Access interventions worked more effectively and may increase fruit and vegetable intake by 0.55 portions per day (95% CI 0.04, 1.07) higher than the control groups (Figure 3.13).

Results from indirect comparisons and test for subgroup differences tests

Subgroup differences tests were conducted to explain the heterogeneity. While indirect comparisons were conducted if direct comparisons was not present. Most of the subgroup analysis and indirect comparisons included at least three studies with unclear risk of bias. Substantial heterogeneity (I^2>50%) were found in most of the analysis. The detailed results were as follows:

1. Telephone counselling worked more effectively and may increase fruit and vegetable intake by 0.77 portions per day (95% CI 0.15, 1.4) higher than email counseling (Table 3.03).
2. Counseling by dietitians worked more effectively and may increase fruit and vegetable intake by 0.69 portions per day (95% CI 0.08, 1.30) higher than non health care professionals (Table 3.03).
3. Counseling by other health care professionals worked more effectively and may increase fruit and vegetable intake by 0.88 portions per day (95% CI 0.54, 1.22) higher than non health care professionals (Table 3.03).

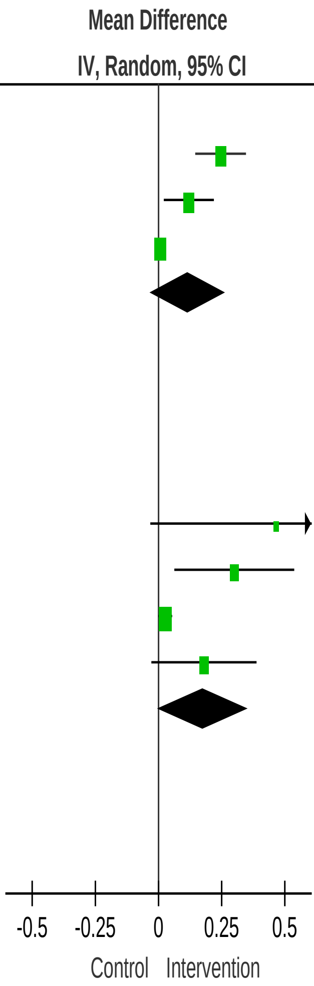
Based on the requirements needed for stronger evidence previously mentioned in section 2.1.7.4.2. there was only one comparison that provides strong evidence which was the individually tailored versus non tailored interventions. Therefore, this study suggested strong evidence of individually tailored interventions over non tailored interventions to increase fruit and vegetable intake in healthy adults.

3.1.4.2.14. Intervention effects on biomarkers

The changes in plasma biomarkers (α-carotene and β-carotene) in the intervention groups and the control groups after the interventions were analysed in order to examine the effects of interventions to increase fruit and vegetable intake on participants' plasma biomarkers (α-carotene and β-carotene). There were three studies with 1184 participants included in the subgroup analysis of the effect of interventions to increase fruit and vegetable intake on α-carotene (Figure 3.20). The results suggested a non-significant increase of 0.12 μmol/L (95% CI -0.03 to 0.27)(Figure 3.20). Substantial heterogeneity was detected in the analysis (I^2=93%) (Figure 3.20). Similarly findings from four studies with 1462 participants also suggested that the interventions were able to increase β-carotene by 0.18μmol/L (95% CI -0.00 to 0.35)(Figure 3.20). However the increase was not significant and substantial heterogeneity was detected in the analysis (I^2=70%) (Figure 3.20). The results of the analysis suggested that there is no strong evidence that the overall significant effects of interventions in increasing fruit and vegetable intake measured by self reported dietary intake had any positive effects on plasma biomarkers (α-carotene and β-carotene) (Figure 3.20).

Figure 3.20
Comparison: Subgroup analysis of plasma biomarkers (α-carotene and β-carotene) in the intervention and control groups
Outcome: Level of α-carotene and β-carotene (μmol/L)

	Intervention			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
3.1.1 α-Carotene (μmol/L)								
Hiraka Study 2003	0.186	0.62	231	-0.06	0.44	239	31.7%	0.25 [0.15, 0.34]
Mediterranean Eating 2009	0.32	0.21	27	0.2	0.16	33	31.8%	0.12 [0.02, 0.22]
Oxford Trial 2004	0.002	0.06	325	-0.005	0.06	329	36.5%	0.01 [-0.00, 0.02]
Subtotal (95% CI)			**583**			**601**	**100.0%**	**0.12 [-0.03, 0.27]**
Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 27.94$, df = 2 ($P < 0.00001$); $I^2 = 93\%$								
Test for overall effect: Z = 1.55 (P = 0.12)								
3.1.2 β-Carotene (μmol/L)								
Hiraka Study 2003	0.056	3.14	231	-0.41	2.25	239	9.8%	0.47 [-0.03, 0.96]
Mediterranean Eating 2009	0.81	0.55	27	0.51	0.32	33	23.8%	0.30 [0.07, 0.53]
Oxford Trial 2004	0.001	0.17	331	-0.026	0.15	333	40.1%	0.03 [0.00, 0.05]
South London 2004	1.22	0.92	134	1.04	0.79	134	26.3%	0.18 [-0.03, 0.39]
Subtotal (95% CI)			**723**			**739**	**100.0%**	**0.18 [-0.00, 0.35]**
Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 10.12$, df = 3 ($P = 0.02$); $I^2 = 70\%$								
Test for overall effect: Z = 1.93 (P = 0.05)								



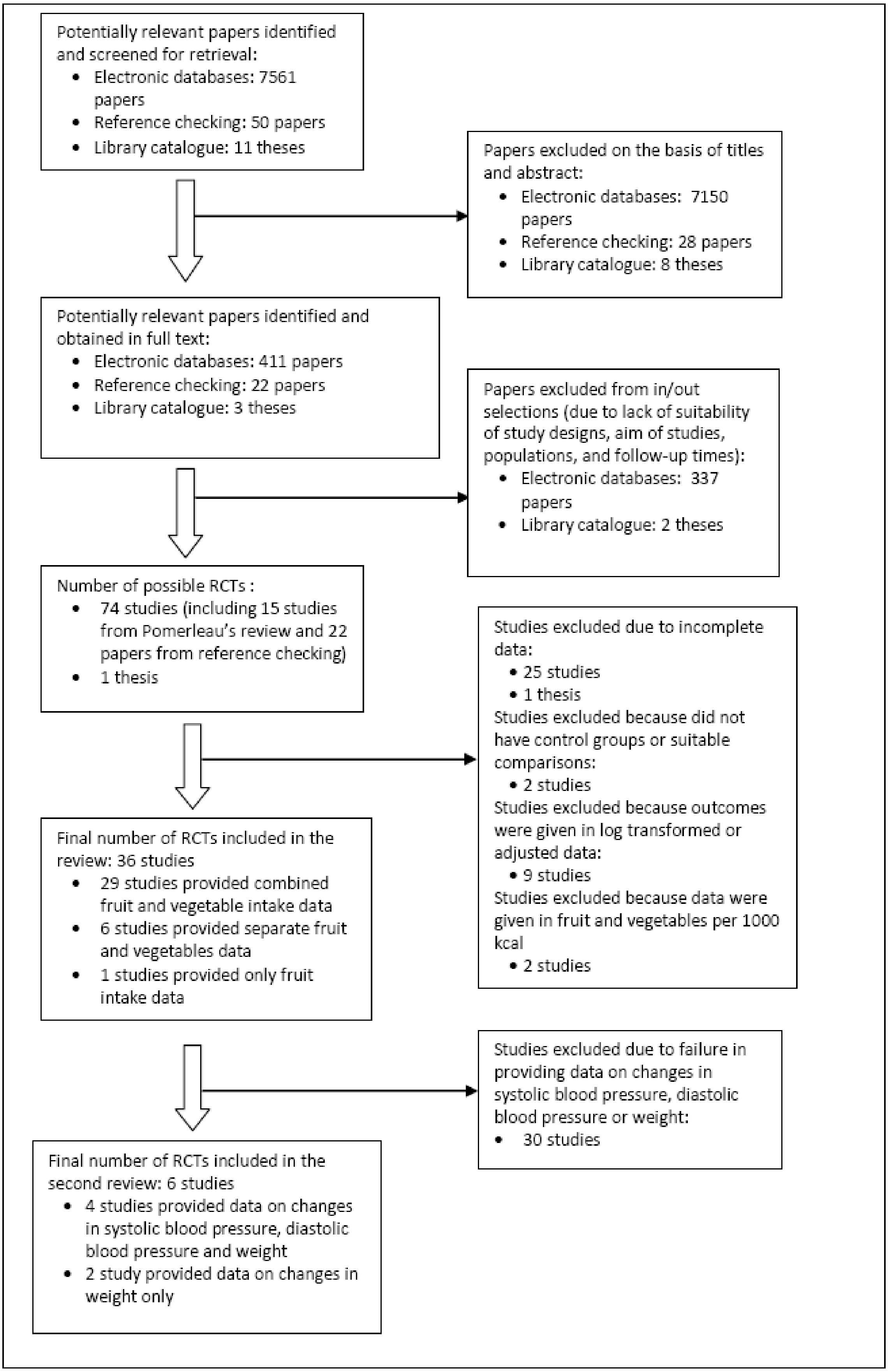
3.2. The effects of increased fruit and vegetable intake on blood pressure and weight: A systematic review

3.2.1. Results of searches

Two reviewers independently assessed the searches and screened the studies that were included in the review of interventions to increase fruit and vegetable intake in healthy adults which provided data on the changes in systolic blood pressure (mmHg), diastolic blood pressure (mmHg) or weight (kg). The process excluded thirty studies from the interventions on healthy adults' review which did not fit the criteria of providing the changes in systolic blood pressure (mmHg), diastolic blood pressure (mmHg) or weight (kg) (Figure 3.21).

Six studies were finally included in the review namely, the Oxford Trial (John, Ziebland et al. 2002; Huxley, Lean et al. 2004), the Premier trial (Writing group of the PREMIER collaborative research group 2003; Brevik, Andersen et al. 2004; Campbell, Resnicow et al. 2007), the South London trial (Steptoe 2003; Steptoe, Perkins Porras et al. 2004; Perkins-Porras, Cappuccio et al. 2005), The Wise Woman Arizona trial (Staten, Gregory Mercado et al. 2004), the Women's Health Initiative trial (Langer, White et al. 2003; Beresford, Johnson et al. 2006; Howard, Manson et al. 2006; Prentice, Schoenmakers et al. 2006; Prentice, Caan et al. 2006; Prentice, Thomson et al. 2007) and the Women's Health Trial (White, Shattuck et al. 1992; Ascherio, Hennekens et al. 1996; Bowen, Clifford et al. 1996; Coates, Bowen et al. 1999; Kristal, Shattuck et al. 1999). Three of six studies provided complete data on changes in systolic blood pressure, diastolic blood pressure and weight (Oxford Trial, South London, and Wise Woman Arizona) while three other studies provided data on changes in weight only (Premier, Women's Health Initiative, and Women's Health Trial) (Figure 3.21).

Figure 3.21 Flow diagrams for locating RCTs for systematic review



3.2.2. Included studies

Six RCTs were included in the review. Four were conducted in the USA (Premier, Wise Woman Arizona, Women's Health Initiatives and Women's Health Trial) while the other two were conducted in the UK (Oxford Trial and South London Study) (Figure 3.22). The duration of RCTs ranges from 6 months (Oxford Trial and Premier) to 8.1 years (Women's Health Initiative).

All of the studies were conducted in community settings. Three of five studies were targeted only at female participants (Women's Health Initiative, Wise Woman Arizona and Women's Health Trial) and the rest were targeted at both gender. In general the mean age of participants was 53.13 (SD=8.52) years of age. Mean age was taken from baseline values at the beginning of the interventions for overall participants or if given separately for each group, the combined value was calculated using the combined group formula from the Cochrane Handbook (Higgins and Green 2008).

There was one study which specifically aimed at lowering blood pressure (Premier) using the DASH diet. However the study provided mean change after adjusted for baseline value or other group value and therefore was not included in the subgroup analysis for blood pressure. Details of included studies are given in Appendix 7, Table 1.

3.2.3. Risk of bias

Risk of bias assessments were done independently by at least two reviewers for each study. If any differences occurred discussion between reviewers was conducted until consensus was agreed. The assessments were conducted for six categories as follows, whether the sequence generation adequately generated, whether allocation adequately concealed, whether participants, personnel or outcome assessors adequately blinded, whether incomplete outcome data adequately addressed, whether the study was free from selective outcome reporting and whether the study was free from industry funding. The complete risk criteria were stated in section 2.1.7.3.

Among the included studies there were three studies which clearly described the process of randomisation (Oxford Trial, Premier and South London) while the rest partially described the process of randomisation. All of the included studies were unclear of whether the randomisation was adequately concealed. Two studies masked the researchers and participants (Oxford Trial and Premier) while the rest were unclear. Three studies included all participants randomised in the outcomes and included all participants with interventions in the outcomes (Oxford Trial, Premier and South London) while the rest did not. None of the studies were funded by industry. Only one study described participants in each arms adequately (Oxford Trial) while the rest did not. Lastly all studies have unclear description of selective outcome reporting. In summary all the included RCTs had high risk of bias. Please refer to Appendix 8 for details.

3.2.4. Analysis of results

3.2.4.1. The effects of increased fruit and vegetable intake on blood pressure

Three studies with 1096 healthy participants were included for assessment of systolic blood pressure and 1097 healthy participants for assessment of diastolic blood pressure in the meta-analysis to examine whether increased fruit and vegetable intake had any effect on systolic blood pressure and diastolic blood pressure of participants (Figure 3.22).

The studies included in the meta-analysis were all had similar types of interventions aimed to increase fruit and vegetable intake by giving counselling advice. All interventions in the blood pressure meta-analysis gave advice through other health care professionals (nurses, GPs or physicians) and compared them with interventions to increase physical activity or placebo (no intervention or delayed interventions) (Figure 3.22).

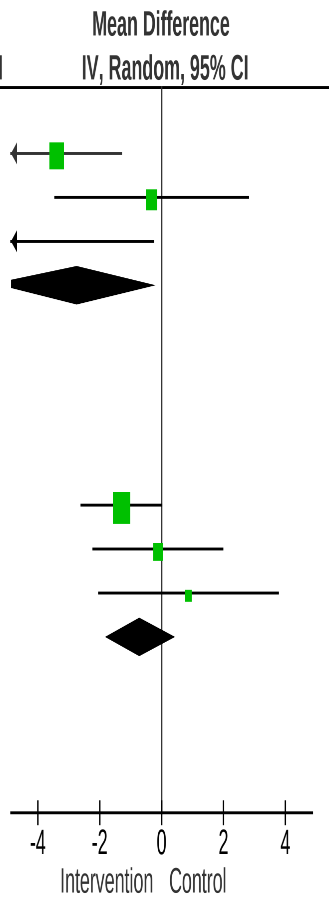
Random effects meta-analysis suggested that an increase of 0.82 portions of fruit and vegetables per day (95% CI 0.13 to 1.51, I^2=81%) affected a significant fall on systolic blood pressure (-2.72 mmHg, 95% CI -5.26 to -0.17, I^2=47%) of participants in the intervention groups compared to the control groups after the interventions (Figure 3.22). However increased fruit and vegetable intake caused a non-significant fall in diastolic blood pressure (-0.68 mmHg, 95% CI -1.81 to 0.46, I^2=11%) (Figure 3.22).

Figure 3.22

Comparison: Overall effects of increased fruit and vegetables on systolic blood pressure and diastolic blood pressure in the intervention (dietary counselling) and control (intervention aimed to increase physical activity, no intervention or delayed intervention) groups

Outcome: Mean differences of systolic blood pressure and diastolic blood pressure (mmHg)

Study or Subgroup	Intervention Mean	Intervention SD	Intervention Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
1.1.1 Systolic blood pressure (mmHg)								
Oxford Trial 2004	-2	13.5	344	1.4	14.6	346	48.0%	-3.40 [-5.50, -1.30]
South London 2004	-0.86	13.09	136	-0.54	13.06	133	34.3%	-0.32 [-3.45, 2.81]
Wisewoman Arizona 2004	-5.1	16.07	67	0.4	15.15	70	17.7%	-5.50 [-10.73, -0.27]
Subtotal (95% CI)			**547**			**549**	**100.0%**	**-2.72 [-5.26, -0.17]**
Heterogeneity: $Tau^2 = 2.36$; $Chi^2 = 3.75$, df = 2 (P = 0.15); $I^2 = 47\%$								
Test for overall effect: Z = 2.09 (P = 0.04)								
1.1.2 Diastolic blood pressure (mmHg)								
Oxford Trial 2004	-1.6	8.7	344	-0.3	8.7	346	59.2%	-1.30 [-2.60, -0.00]
South London 2004	-0.07	8.77	136	0.05	8.77	134	26.4%	-0.12 [-2.21, 1.97]
Wisewoman Arizona 2004	1.3	8.56	67	0.43	8.75	70	14.4%	0.87 [-2.03, 3.77]
Subtotal (95% CI)			**547**			**550**	**100.0%**	**-0.68 [-1.81, 0.46]**
Heterogeneity: $Tau^2 = 0.12$; $Chi^2 = 2.24$, df = 2 (P = 0.33); $I^2 = 11\%$								
Test for overall effect: Z = 1.17 (P = 0.24)								



3.2.4.2. The effects of increased fruit and vegetable intake on weight

Six studies with 43,581 healthy participants were included in the meta-analysis to assess the effects of increased fruit and vegetable intake on weight of participants (Figure 3.23).

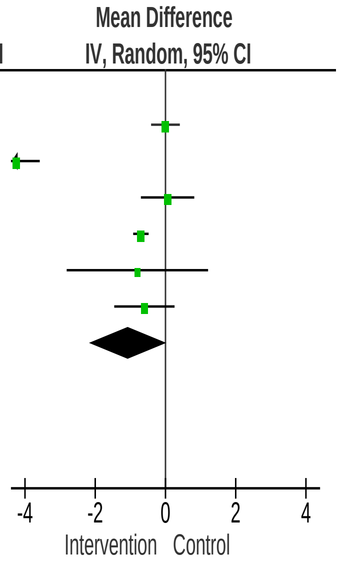
The studies included in the analysis provided interventions for participants through dietary advice given by dietitians/nutritionists (Premier, Women's Health Initiative and Women's Health Trial) while in other studies (Oxford trial, South London and Wise Woman Arizona) the advice were given by other health care professionals (nurses, GPs or physicians) and the interventions were compared to advice on blood pressure, physical activity or placebo (no intervention or delayed interventions) (Figure 3.23).

Random effects meta-analysis suggested that increased of fruit and vegetable intake by 0.88 portions per day (95% CI 0.43 to 1.33, I^2=91%) failed to cause a statistically significant fall in weight (-1.06 kg, 95% CI -2.16 to 0.04, I^2=96%) of participants in the intervention groups compared to the control groups after the interventions (Figure 3.23).

Figure 3.23
Comparison: Overall effects of increased fruit and vegetables on weight in the intervention (dietary counselling) and control (intervention aimed to increase physical activity, lower blood pressure, no intervention or delayed intervention) groups
Outcome: Mean differences of weight (kg)

	Intervention			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
1.2.1 Weight (kg)								
Oxford Trial 2004	0.6	2.6	344	0.6	2.6	346	18.3%	0.00 [-0.39, 0.39]
Premier 2003	-5.35	5.65	471	-1.1	3.2	242	17.5%	-4.25 [-4.90, -3.60]
South London 2004	-0.11	3.09	136	-0.17	3.11	135	17.2%	0.06 [-0.68, 0.80]
WHI 2007	-0.8	10.1	16297	-0.1	10.1	25056	18.6%	-0.70 [-0.90, -0.50]
Wisewoman Arizona 2004	0.1	3.96	67	0.9	7.53	71	11.6%	-0.80 [-2.79, 1.19]
Women's Health Trial 1999	-1.3	4.5	202	-0.7	4.2	214	16.8%	-0.60 [-1.44, 0.24]
Subtotal (95% CI)			**17517**			**26064**	**100.0%**	**-1.06 [-2.16, 0.04]**

Heterogeneity: Tau² = 1.68; Chi² = 130.61, df = 5 (P < 0.00001); I² = 96%
Test for overall effect: Z = 1.89 (P = 0.06)



Chapter 4 Discussion

4.1. Summary of key findings

The review of interventions included 36 RCTs with 69,356 participants. The results suggested that the interventions were able to increase fruit and vegetable intake by 0.64 portions per day (95% CI 0.40 to 0.87, I^2=97%) in healthy adults (Figure 3.02). Findings are summarized in Chapter 3, Table 3.03.

The reviews' aim was to find out which types of interventions work best to increase fruit and vegetable intake in healthy adults and the effects of increased fruit and vegetable intake on biomarkers (α-carotene and β-carotene). The review suggested several types of interventions that worked more effectively than others as follows:

4.1.1. Results from direct comparisons

All of the direct comparisons provided more than three studies and they had unclear risk of bias. Amongst all direct comparisons only individually tailored versus non tailored interventions did not have substantial heterogeneity (I^2>50%). The detailed results were as follows:

1. Overall intervention effects may increase fruit and vegetable intake by 0.64 portions per day (95% CI 0.40, 0.87) which is higher than the control groups (Figure 3.02).
2. Individually tailored interventions worked more effectively, this may increase fruit and vegetable intake by 0.30 portions per day (95% CI 0.17, 0.43) than non-tailored interventions (Figure 3.08).
3. Motivational interview interventions worked more effectively, this may increase fruit and vegetable intake by 0.29 portions per day (95% CI 0.16, 0.42) than the control groups (Figure 3.10).
4. Social support interventions worked more effectively, this may increase fruit and vegetable intake by 0.35 portions per day (95% CI 0.02, 0.68) than the control groups (Figure 3.11).

5. Practical skills interventions worked more effectively, this may increase fruit and vegetable intake by 0.41 portions per day (95% CI 0.10, 0.72) than the control groups (Figure 3.12).
6. Access interventions worked more effectively, this may increase fruit and vegetable intake by 0.55 portions per day (95% CI 0.04, 1.07) than the control groups (Figure 3.13).

4.1.2. Results from subgroup differences and indirect comparisons tests

Subgroup differences tests were conducted to explain the heterogeneity and indirect comparisons were conducted if direct comparisons was not present. Most of the subgroup analysis and indirect comparisons included at least three studies with unclear risk of bias. Substantial heterogeneity (I^2>50%) were found in most of the analysis. The detailed results were as follows:

1. Telephone counselling worked more effectively, this may increase fruit and vegetable intake by 0.77 portions per day (95% CI 0.15, 1.4) than email counseling (Table 3.03).
2. Counseling by dietitians worked more effectively, this may increase fruit and vegetable intake by 0.69 portions per day (95% CI 0.08, 1.30) than non health care professionals (Table 3.03).
3. Counseling by other health care professionals worked more effectively, this may increase fruit and vegetable intake by 0.88 portions per day (95% CI 0.54, 1.22) than non health care professionals (Table 3.03).

In order for strong evidence to be present in this study it had to fulfill all five criteria:

1. Direct comparisons which include at least three studies.
2. Not heterogenous (I^2>50%).
3. Heterogeneity can be explained by subgrouping.
4. The comparisons are stable to sensitivity analysis
5. The study included study validity.

Based on the criteria there was only one comparison that provided strong evidence which was the individually tailored versus non tailored interventions. The individually tailored intervention showed a significantly greater increased intake in healthy adults.

This study was able to address most of the aims and objectives. However media based interventions and interventions that deliver messages about fruits and vegetables being fun and tasty were not found. Therefore the effects of media based and fun and tasty messages were not analysed. Furthermore due to lack of availability of participants' characteristics data (gender, marital status, parental status, educational level, income, ethnicity, rural or urban location, smoking status, alcohol consumed per week, physical activity level, vitamin intake and BMI) this study was only able to assess gender target and mean age of participants. Mean age of participants was 49.59 (SD=9.65) years of age for the review of interventions and 53.13 (8.52) years of age for the review of effects of interventions on blood pressure and weight.

A funnel plot was developed to examine the presence of bias in the studies this was asymmetrical and not an inverted shape which suggested that there was bias present among the studies. The funnel plot also suggested that the studies may over-report the positive results of intervention effects because most of the studies were clustered around the mean difference of 0.2 to 0.3 (Figure 3.03) which was lower than the results of pooled mean difference estimation (0.64 portions per day, 95% CI 0.40 to 0.87) (Figure 3.02). This may be because studies with significant effects were more likely to be published compared to studies with non-significant findings. Bigger effects were also reported from small sample studies which were likely to be of lower quality and did not have adequate allocation concealments. For example Bradbury's study with 58 participants which reported the biggest intervention effects of increased fruit and vegetable intake by 2.40 portions per day (95% CI 1.06 to 3.74) in the intervention groups compared to the control groups after the interventions (Figure 3.02).

A way to incorporate heterogeneity present in the studies was by using random effects meta-analysis and subgroup analysis (Higgins and Green 2008). Sensitivity analysis which excluded small studies with less than 100 participants in each arm or group resulted in a slightly lower increase of fruit and vegetable intake (0.51 portions per day, 95% CI 0.26 to 0.75) (Table 3.01). The heterogeneity was still significant in the sensitivity analysis (Table 3.01).

Meta-analysis on studies which provided outcomes on α-carotene and β-carotene suggested that intervention did not affect significant changes in α-carotene and β-carotene level. The α-carotene increased but non-significantly by 0.12 μmol/L (95% CI -0.03 to 0.27, I^2=93%) from a baseline of 0.12μmol/L[1] (SD 0.09 μmol/L) in the intervention compared to control groups (Figure 3.20). For β-carotene the change was again a non-significant rise of 0.18 μmol/L (95% CI -0.00 to 0.35, I^2=70%) from a baseline of 0.43 μmol/L (SD 0.27 μmol/L) in the intervention compared to the control participants (Figure 3.20). As well as being non-statistically significant the changes were small as a percentage of baseline carotene status in contrast to the effects seen with dietary intake data.

The review of the effects of interventions on blood pressure and weight included six studies. Three RCTs with nearly 1100 participants were included in the analysis about blood pressure. The results suggested that increased fruit of vegetable intake by 0.82 portions per day (95% CI 0.13 to 1.51, I^2=81%) caused a significant fall in systolic blood pressure (-2.72 mmHg, 95% CI -5.26 to -0.17, I^2=47%) but not on diastolic blood pressure (-0.68 mmHg, 95% CI -1.81 to 0.46, I^2=11%) shown in figure 3.22. The meta-analysis on weight included six studies with 43,581 participants. Findings suggested that increased fruit and vegetable intake by 0.88 portions per day (95% CI 0.43 to 1.33, I^2=91%) did not cause significant fall in weight (-1.06 kg, 95% CI -2.16 to 0.04, I^2=96%) shown in figure 3.23.

4.2. Interpretation of results

The results suggested the characteristics and types of interventions that may work more effectively to increase fruit and vegetable intake in healthy adults as summarized in Section 4.1.

[1] The baseline levels given here are from the largest single study in this analysis, the Oxford Trial, while the changes are from the meta-analyses.

As stated in section 3.1.3 all of the RCTs that were included in this study had unclear risk of bias. This is because most of the RCTs provided insufficient information particularly in the following risk criteria sequence generation process, allocation concealment, blinding of participants, personnel or outcome assessors and selective outcome reporting.

Further examination using a funnel plot stated in figure 3.03 suggested that there was a possibility of publication bias present because of the overestimation of intervention effects reported in this study. Therefore findings from this study should be approached with awareness of the unclear risk of bias of the RCTs included.

The adjusted indirect comparisons conducted in this study used any intervention not aimed to increase fruit and vegetable intake or no intervention or delayed intervention as common comparators. Due to the differences in participants' characteristics, interventions and other trial characteristics, findings from indirect comparisons should act as supplementary information, discrepancy between the direct and adjusted indirect estimate may be present.

All of the included studies measured the change in intake using self reported measurements.

According to Krebs-Smith, Calver and Agudo (Krebs-Smith, Heimendinger et al. 1995; Calvert, Cade et al. 1997; Agudo 2005) self reported dietary measurements using FFQs, 24-hour recalls or food records had disadvantages including:

1. Strong reliance on respondents' memory or inaccurate recalls.
2. Multiple days needed in order to estimate usual intake.
3. Person-specific biases such as gender, age, obesity.
4. Food checklist may not be appropriate for all participants.
5. Under reporting or over reporting of intake and error in portion size estimation

Furthermore most of the studies I included were assessed by FFQs (23 of 36 studies) as mentioned in section 1.5 FFQs measured the participants' intake over a reference period (one week, 1-3 months, 6 months or one year) this may introduce several limitations. Firstly FFQs tends to overestimate fruit and vegetable consumption and have an even greater tendency to overestimate intake when more questions were asked to the respondents. Secondly FFQs also tend to measure habit in fruit and vegetable consumption but not the participants' actual intake because participants may not remember past intake or have inaccurate recall of fruit and vegetable intake. Thirdly the participants may not have accurate knowledge or estimation of fruit and vegetable portion size which may lead to inaccurate reported intake.

As discussed in Section 1.5 individuals' socio-demographic factors such as gender, age and education may affect the accuracy of reporting. Findings suggested that women may alter their intake more than men (Patterson and Pietinen 2004). Psychosocial factors such as fear of negative evaluation, social desirability and deviation of ideal intake from the recommendation, knowledge of recommended intake, lifestyle and characteristics of other meals may also have affected the accuracy of intake (Tooze, Sabar et al. 2004). In addition interviewers' skills in probing and interviewing about the intake also determined the inaccuracy.

Subgroup analysis on trial duration conducted for this study was based on the studies' follow-up duration and not duration of interventions. The intention was to analyze the intervention effects even after the intervention has ended. As mentioned in section 3.1.4.2 all durations of follow-up suggest significant results. The highest intervention effect was found in one study with the longest follow-up duration (more than 37 months). Nevertheless short duration studies (3-11 months of follow-up) had higher changes in fruit and vegetables intake compared to medium duration studies (12-36 months of follow-up). In this subgroup analysis a study may be included in two subgroups (for example, if a study provides data at 3 and 12 months) because of that and the heterogeneity found in the analysis careful consideration should be implemented when interpreting the results.

As mentioned in Section 1.6 biomarkers were also used as outcome measures of fruit and vegetable intake as they can be seen as a more objective means to assess nutritional intake compared to self reported dietary measurements. However they are not perfect measurements because physiological processes might affect the accuracy of their reflection of fruit and vegetable intake. The results of the analysis on RCTs interventions aimed at healthy adults mentioned in section 1.6 suggested that changes in α-carotene and β-carotene can confirm whether an intervention to increase fruit and vegetable intake was effective. This is due to consistent results shown for α-carotene and β-carotene in the studies.

According to Iverson (Iverson, Christiansen et al. 2007) the reference range for β-carotene is 0.2 to 1.6 μmol/L. The Reference Nutrient Intake (RNI) for vitamin A is 700 μg/day (24.43 μmol/L) (Webb 2008). The analysis included four studies with outcomes on α-carotene and β-carotene. The baseline levels of α-carotene and β-carotene were as follows:

Table 4.01 Baseline level of α-carotene and β-carotene in the intervention and control groups

	Intervention			Control		
	Mean	**SD**	**Total**	**Mean**	**SD**	**Total**
α-carotene (μmol/L)						
Hiraka Study	0.15	1.33	231	0.15	1.16	239
Mediterranean Eating	0.13	0.08	35	0.16	0.14	34
Oxford Trial	0.12	0.09	325	0.12	0.09	329
β-carotene (μmol/L)						
Hiraka Study	0.88	9.26	231	0.86	8.52	239
Mediterranean Eating	0.46	0.34	35	0.49	0.28	34
Oxford Trial	0.43	0.27	331	0.43	2.80	333
South London	0.90	0.62	134	0.92	0.68	134

The baseline levels of α-carotene in both groups were (0.12 to 0.15 μmol/L) in the intervention group and (0.12 to 0.16 μmol/L) in the control group (Table 4.01). The baseline level of β-carotene (0.43 to 0.90 μmol/L) in the intervention group and (0.43 to 0.92 μmol/L) in the control group was within the reference range according to Iverson (Iverson, Christiansen et al. 2007). The baseline β-carotene level in the Oxford Trial (a study with the biggest sample size) in the intervention groups was within the reference range 0.43 μmol/L (SD 0.27 μmol/L) while the baseline level of α-carotene was slightly below the reference range.

Findings from this study suggested that positive effects in interventions to increase fruit and vegetable intake caused an increase in α-carotene by 0.12 μmol/L (95% CI -0.03 to 0.27) and β-carotene by 0.18 μmol/L (95% CI -0.00 to 0.35). The total increase of 0.30 μmol/L in carotene contributes around 0.05 μmol/L when converted into vitamin A (retinol) (6 μg of carotene = 1 μg of retinol) (Webb 2008). The increases were not statistically significant and small as a percentage of baseline carotene status, in contrast to the effect sizes found with self reported dietary measurements.

A cohort study by Pollard (Pollard 2002) assessed the association between antioxidant vitamin intake from all food sources or supplements. The study collected two blood samples at two points in time among 54 women (mean age 55 years of age). Prior to the first blood sample 4-day food diaries were collected and 24-hour recalls were collected at the time of the second blood collection. The results were as follows:

Table 4.02. Unadjusted results from the linear regression model describing the impact of micronutrient and fruit and vegetable intake, assessed by 24-hour recall at 2nd time point on plasma micronutrient levels (N=54)

Percentage increase in blood nutrient concentrations of β-carotene and ascorbic acid (95% CI) and P-value associated with a doubling of dietary intake unadjusted for other factors		
	β-carotene % (95% CI), P-value	**Ascorbic acid Mean (95% CI), P-value**
Vegetable intake	3.5 (-1.4 to 8.5), P=0.16	1.7 (-0.2 to 3.6), P=0.08
Fruit intake	4.9 (1.3 to 8.7), P<0.01*	1.8 (0.4 to 3.2), P=0.01*
Fruit juice	2.5 (-0.1 to 5.3), P=0.06	0.9 (-0.1 to 2.0), P=0.07

Note: * significant at P<0.05

Unadjusted regression analysis suggested the doubling of fruit intake (unadjusted for other factors) affected significant increases of 4.9% (95% CI 1.3 to 8.7) for β-carotene and 1.8% (95% CI 0.4 to 3.2) for ascorbic acid when measured at the second time point. Vegetable intake and fruit juice also caused increases in β-carotene and ascorbic acid; however the increases were not significant (Table 4.02). The limitations of this study was that it is not representative of healthy adults in general because the participants were all female, middle aged and from one region in England.

Further findings from this study also suggested that participants of studies that examined plasma biomarkers (α-carotene and β-carotene) namely the Oxford Trial and the Mediterranean Eating study tended to report a higher increase in fruit and vegetable intake compared to overall intervention effects and other studies that provided the same outcome (Hiraka Study and South London). The results were 1.30 portions per day (95% CI 1.07 to 1.53) for the Oxford Trial and 2.20 portions per day (95% CI 1.50 to 2.90) for the Mediterranean Eating study respectively. These were higher than the average increase in fruit and vegetable intake in other studies as well as overall average increase. However these were not fully supported by the results of mean changes in α-carotene and β-carotene. The results for α-carotene were increases of levels by 0.12 μmol/L (95% CI 0.02 to 0.22) for the Mediterranean Eating and 0.01 μmol/L (95% CI -0.00 to 0.02) for the Oxford Trial. A significant increase was only found in the Mediterranean Eating study and not in the Oxford trial. The results for β-carotene were 0.30 μmol/L (95% CI 0.07 to 0.53) for the Mediterranean Eating and 0.03 μmol/L (95% CI 0.00 to 0.05) for the Oxford Trial therefore both studies suggested significant increases of β-carotene. The Oxford Trial and the Mediterranean Eating study intervened with counselling sessions given by dietitians (the Mediterranean Eating) and other health care professionals (the Oxford Trial) using telephone and measured the intake using food records (the Mediterranean Eating) and FFQs (the Oxford Trial).

As discussed in section 1.5 counselling conducted by dietitians and other health care professionals may be confounded by social desirability bias. This might possibly explain why some of the participants reported higher fruit and vegetable intake.

This study addressed a gap in evidence by providing systematic review that examined the effects of increased fruit and vegetable intake on blood pressure in healthy adults. The findings suggested that increased fruit and vegetable intake had a significant effect on the fall of systolic blood pressure (-2.72 mmHg, 95% CI -5.26 to -0.17, I^2=47%) but not on diastolic blood pressure and weight.

Additional findings from Bingham's study (Bingham, Gill et al. 1994) mentioned in section 1.5 suggested the positive correlations between carotene and fibre (0.47), carotene and potassium (0.42) and carotene and protein (0.24). Carotene was not significantly correlated with energy (-0.02), fat (-0.12) or carbohydrate (0.02). The study also suggested positive correlations between vitamin C and fibre (0.58), vitamin C and potassium (0.68) and vitamin C and protein (0.32). Vitamin C was not significantly correlated with energy (0.17), fat (0.02) and carbohydrate (0.18). The findings were collected from the 16 days weighted records over one year these were collected four times each for four days. The data collected involved 146 women who completed all four data collections. This study was conducted in the Cambridge area, this means that it is a limited representation of the dietary habits of a general population. This study suggested that carotene and vitamin C, mostly found in fruits and vegetables, were significantly correlated with fibre, potassium and protein.

Furthermore dietary fibre and potassium increase may influence systolic and diastolic blood pressure but the relationship of fruit and vegetable intake and weight remains unclear. Blood pressure was also affected by age and the condition of the participants. The mean age of participants in this study was 53.13 (SD=8.52) who have lower risk compared to individuals over the age of 60 years according to findings from the study (Franklin, Larson et al. 2001) mentioned in section 1.8. In the study with significant sBP findings (the Oxford Trial and the Wise Woman Arizona) the measurements of blood pressure and weight were carried out at baseline and follow-up. The measurements were conducted by nurses at the Oxford Trial and clinical technicians at the Wise Woman Arizona. Measurements of blood pressure were taken twice and then the mean of two readings was used as the final blood pressure data. A third reading was conducted if the two initial measurements disagree by more than a specified amount (>1 lbs for weight and >5 mmHg for sBP and dBP) however there was still a possibility of error in the measurements process. For example, it was unclear whether the sphygmomanometers and scales have been validated, calibrated or standardized in order to be certain that they were valid and reliable.

Findings from the review suggested a significant reduction in systolic blood pressure but not in diastolic blood pressure and weight. As mentioned in section 1.2 a result of Pomerleau's study (Pomerleau, Lock et al. 2005) showed that a higher increase in fruit and vegetable intake was found in high-risk participants. This may be because most of these participants were more conscious of their dietary intake due to their conditions. Studies that detected significant effects on systolic blood pressure were the Oxford Trial and the Wise Woman Arizona study. Both of the studies used counselling by other health care professionals and aimed to increase fruit and vegetables intake. However the Wise Woman Arizona study was also targeted to increase physical activity among women by establishing walking groups for participants lead by community health workers who provided social support. The social support walking group intervention resulted in a significant reduction of systolic blood pressure but not of diastolic blood pressure and weight.

4.3. Strengths and limitations

As argued in section 1.2 previous systematic reviews had examined interventions to increase fruit and vegetable intake in adult populations (Ammerman, Lindquist C.H. et al. 2002; Pomerleau, Lock et al. 2005; Kroeze, Werkman et al. 2006; Shaikh, Yaroch et al. 2008; Eyles and Mhurchu 2009). This study took it further by exploring which components of interventions to increase fruit and vegetable intake made them more successful and analysed the effects on blood pressure and weight.

This study focused on healthy, non-pregnant adults over 16 years of age and without pre-existing chronic conditions. Several systematic reviews had examined interventions to increase fruit and vegetable intake in adults; however those reviews included high risk and healthy participants. In summary there had not been any systematic reviews on fruit and vegetable intake that focused solely on healthy adults. The purpose of focusing on healthy adults in this study was aimed at providing information towards the potential for preventative care using increased fruit and vegetable intake.

This study only included randomised controlled trials with at least three months of follow-up which differed to previous reviews that included all types of interventions and a variety of durations. The criteria were created in order to select only high quality RCTs with enough duration to assess the actual effect of interventions. Two meta-analyses indicated that non RCT studies may have more potential for bias and tend to show greater treatment effects and heterogeneity (DerSimonian and Laird 1986; Jones 1992). A point of estimate (P<0.05) and a confidence interval (95%) were established to analyse the effectiveness of interventions.

By choosing to conduct systematic reviews to answer the research questions this study addressed several points from NICE recommendations mentioned in section 1.8. Firstly this study provided clear explanations of the rationale for choosing to conduct the systematic reviews. Secondly clear explanations of the interventions namely type, duration, target participants and settings were written throughout the analysis. Thirdly this study assessed the effects of increased fruit and vegetable intake on health indicators such as blood pressure and weight. Fourthly this study included subgroup analysis of specific participants characteristics based on gender. Other subgroup analyses were mainly focused on intervention types. Subgroup analysis on other characteristics of participants, for example, education or socioeconomic status were not carried out because there were very few studies that provided this data and among them there were no specific data standards about differences in educational level and income level data. Fifthly the methods chapter clearly described the outcomes selected for this study which were mean differences in fruit and vegetable intake (portions per day) and mean differences in level of blood pressure (mmHg) and weight (kg) in the intervention groups compared to the control groups after the interventions.

This study has several limitations. Firstly most of the included studies were conducted in the USA with the exception of studies from other countries for instance the UK, the Netherlands and Japan. Therefore the findings were not applicable to the developing world.

Secondly although extensive search strategies have been carried out and a large number of authors have been contacted for further data. Some authors did not reply so these

RCTs were excluded from the review. Furthermore an extensive grey literature search was not carried out so there is still a possibility that some relevant literature is missing.

Thirdly this study explored strategies to counter the substantial heterogeneity present in some of the analyses by conducting random-effects meta-analysis, subgroup analyses and subgroup differences tests. However due to a wide variance of the studies included, substantial heterogeneity was still detected in some subgroup analyses conducted.

Fourthly all of the RCTs included in this study had unclear risk of bias. This is because most of the included studies provided insufficient information particularly on risk criteria; sequence generation process, method of concealment, blinding of participants, personnel or outcome assessors and selective outcome reporting.

Fifthly there is some possibility of publication bias. According to Thornton and Webb (Thornton and Lee 2000; Webb 2008) studies with positive significant findings have a higher chance of being published and studies with bigger samples are likely to demonstrate significant effects. Most of the included studies were published in journals therefore there is a possibility of missing important unpublished results. Likewise the same study can be published many times due to its significant findings causing a covert duplicate publication. This is possible by the study being masked using a change of named author, language or added extra data which makes it difficult to identify that these were from the same RCT and suggests the need for trial identifiers (Sterne and Harbord 2004). Publication bias and selective outcome reporting were investigated in a systematic review by Dwan (Dwan, Altman et al. 2008), this review included inception cohort of RCTs with study protocols being registered before the start of the study. The review examined eleven studies for publication bias and five studies for outcome reporting bias. Three of eleven studies found that statistically significant results had higher odds of being fully reported compared to non-significant results (OR=2.2 to 4.7). The result of five studies comparing trial publications to protocols suggested that 40-62% of included studies had at least one primary outcome that was changed, findings being introduced or omitted. Limitations to this study were the question of whether the

inception cohort chosen could represent general population and the fact that meta-analysis was not conducted due to the differences between studies.
Sixthly the indirect comparisons in this study were conducted by comparing interventions using common comparators, these are any interventions not aimed at increasing fruit and vegetable intake or no intervention or delayed intervention. Due to a wide range of common comparators which are differences in participants, interventions and other trials characteristics, discrepancies between the direct and adjusted indirect estimate may be present. Therefore the results from indirect comparisons should act as supplementary information and the results should be interpreted with caution.

Seventhly most of the studies included in the review used FFQs to measure fruit and vegetable intake. As discussed in section 1.5, the validity of dietary assessments using FFQs, 24-hour recalls or food records were questionable due to the form of reporting which is prone to substantial errors of portion size estimation or inaccurate recall (Krebs-Smith, Heimendinger et al. 1995).

Eighthly this study addressed the suggestions from NICE public health guidance on behaviour change mentioned in section 1.8. Due to the available data this study was only able to analyse individual factors based on participants' age and gender. The majority of RCTs included in this study were community interventions set up by independent institutions. This is due to the non-availability of studies including social, environmental, economic and legislative factors that were set up by the government therefore these factors cannot be analysed.

Despite the limitations mentioned this study used explicit and comprehensive methods in order to minimized bias and provides reliable findings. This was done in order to suggest the types of interventions that work best to increase fruit and vegetable intake and to assess the effects on blood pressure and weight using meta-analysis. It can be concluded that bearing in mind the limitations, answering the research questions using systematic reviews was a good choice.

4.4. Implications of the systematic reviews

The results of the meta-analysis suggested that interventions with healthy adults enabled an increase of fruit and vegetable intake by 0.64 portions per day (95% CI 0.40 to 0.87). In addition increased fruit and vegetable intake caused a significant fall in systolic blood pressure (-2.72 mmHg, 95% CI -5.26 to -0.17, I^2=47%). There remains a question of whether implementing these types of interventions would be worthwhile for all healthy adults due to the limitations stated in section 4.3.

Results of a study from the USA suggested that the average daily serving of fruit and vegetables (mean ±SD) was 3.2±1.7 for men and 3.5±1.8 for women (Djousse, Arnett et al. 2004). Results from the National Health and Nutrition Examination Survey (NHANES 1999-2002) (Casagrande, Wang et al. 2007) suggested that the mean (SE) of total fruit and vegetable servings eaten by American adults was 3.04 (0.06). A survey from the UK suggested that on average adults eat 4.4 portions per day (Food Standards Agency 2010). In Scotland the mean consumption was 3.3 portions of fruit and vegetables per day, 3.4 for women and 3.1 for men (The Scottish Government 2009). A recent WHO survey from 52 mainly low-and middle income countries suggested that 77,6% of men and 78,4% of women consumed less than the minimum recommended five daily servings of fruits and vegetables (Hall, Moore S. et al. 2009).

The findings of my study suggested that an increase of 0.64 portions of fruit and vegetables per day may not be sufficient to fulfil the recommendations for general populations. The reasoning behind this was that findings from a previous review by Pomerleau (Pomerleau, Lock et al. 2005) suggested that participants with high risk or pre-existing health conditions were more likely to instigate a higher increase in fruit and vegetable intake compared to healthy participants. Similarly a small but statistically significant fall in diastolic blood pressure and non-significant findings on systolic blood pressure in this study supported previous systematic review findings. Statistically significant falls in systolic blood pressure and diastolic blood pressure were found on hypertensive participants but not on non-hypertensive participants (Whelton, Hyre et al. 2005).

This study indicates several types of interventions that worked more effectively if compared to control groups namely motivational interview, social support, practical skills and access interventions. Tailored interventions rather than non-tailored interventions provided stronger evidence because it is a direct comparison and not heterogeneous. This is because individually tailored interventions were specifically catered to individuals' needs and characteristics, for example, based on the individuals' readiness to change or stage of change. Motivational interviews are based on initial information of participants' stage of change; this determines the type of interview given by counsellors using the telephone, meeting in person or by email. A multiple component intervention is the combination of stage of change, motivational interview and individual tailoring; these were more likely to yield significant results. This type of intervention was found in several studies by Alexander, Greene, Marcus 2001, Puget Sound and Wolf.

The implications of this study suggest that individually tailored interventions may increase fruit and vegetable intake by 0.30 portions per day (95% CI 0.17 to 0.43, I^2=0%) compared to non-tailored interventions. This finding concurred with a a previous finding from a systematic review by Eyles (Eyles and Mhurchu 2009) which suggested that tailored interventions may increase fruit and vegetable intake by 0.35 portions per day (95% CI 0.19 to 0.52, I^2=7%). This study also included two out of five studies that were used by Eyles including studies by Heimendinger and Lutz. The difference was that Eyles's study conducted the analysis using weighted mean difference and fixed effects analysis (95% CI) and this study conducted mean difference and random effects analysis (95% CI).

In this study telephone counselling is shown to work more effectively than email counselling by 0.77 portions per day (95% CI 0.15 to 1.4). Counselling usually requires instant interactive communication therefore email counselling is not as effective because it cannot provide this. Further findings also suggested that counselling done by dietitians and other health care professionals (nurses, GP, or physicians) worked more effectively than counselling by non health care professionals (trained staff). Telephone counselling carried out by dietitians and other health care professionals are prone to social desirability bias. As mentioned in section 1.5 individuals are more likely to document positive increase of intake. Self reported dietary measurements for instance FFQs, 24-hour recalls or food records were prone to the under or over reporting of intake. Two studies had interventions carried out by health care professionals on the telephone and were reported using food records (the Mediterranean Eating) and FFQs (the Oxford Trial). Both of the studies reported a higher mean difference of fruit and vegetable intake compared to other studies. The results were 2.20 portions per day (95% CI 1.50 to 2.90) in the Mediterranean Study and 1.30 portions per day (95% CI 1.07 to 1.53) in the Oxford Study for intervention groups compared to the control groups after the interventions.

This study attempted to cross-check the interventions effects measured by self reported dietary measurements for example FFQs, 24-hour recalls, food records with results from plasma biomarker measurements of α-carotene and β-carotene. The result suggested that significant intervention effects found in self reported dietary measurements were not supported by plasma biomarkers measurements results. There are several possible explanations for this. Firstly most of the fruit and vegetable intake in the included studies were measured by FFQs which were prone to overestimation or over reporting of intake. Secondly the possibility of error in the biomarker results may be caused by biological confounders, lab measurement errors, physiological processes effects or the fact that biomarkers in general have low sensitivity to intake.

The analysis in this study illustrated the effects of increased fruit and vegetable intake on α-carotene and β-carotene. There are some limitations to α-carotene and β-carotene as biomarkers: non-nutritional factors namely age, sex, alcohol intake, physiological state, body mass index, smoking status and season may have influenced the concentrations (Jarvinen, Knekt et al. 1993; Brady, Mares-Perlman et al. 1996; Neuhouser, Rock et al. 2001). As stated in section 1.6 carotenoids are mostly found in vegetables and fruits with red-yellow and dark green pigments therefore the measurements of α-carotene and β-carotene could represent tomato, broccoli, carrots, banana and melon (Webb 2008).

A significant fall in systolic blood pressure (-2.72 mmHg, 95% CI -5.26 to -0.17, I^2=47%) was shown to be caused by increased fruit and vegetable intake. Non-significant falls in diastolic blood pressure and weight were detected.

Despite the limitations mentioned in section 4.5 systematic review methods used in this study were able to answer the gap in evidence. In addition the findings suggested the need for future studies to include biomarkers measurements in the interventions in order to cross-check results from self reported dietary measurements. Future research needs to incorporate biomarker assessments to complement self reported dietary results.

This review found strong evidence of individually tailored intervention compared to non-tailored interventions to increase fruit and vegetable intake. The increase of intake caused a significant fall in systolic blood pressure. This study also emphasises the need to cross-check the results of self reported dietary reports with biomarker measurements.

Results of this study indicated the characteristics and types of interventions that worked more effectively to increase fruit and vegetable intake in healthy adults. In addition increased fruit and vegetable intake caused a significant fall in participants' systolic blood pressure but not on their diastolic blood pressure and weight. This study also suggested future interventions should include α-carotene and β-carotene measurements to cross-check the results of self reported dietary intake.

Chapter 5 Conclusions and recommendations

5.1. Conclusions

This study is believed to be the first to comprehensively analyse interventions aimed to increase fruit and vegetable intake in healthy adults using systematic reviews. The aims of this study were to analyse the most effective types of interventions to increase fruit and vegetable intake in healthy adults and the effects of increased fruit and vegetable intake on blood pressure and weight. Random effects (95% CI) meta-analyses were performed on characteristics of studies and subgroups of interventions. In addition random effect (95% CI) meta-analyses were conducted to analyse differences between subgroups. These were performed in order to examine the heterogeneity present in the review.

The major conclusions were that firstly most of the included studies originated from the USA with others from the UK, the Netherlands and Japan therefore the findings of this study are only applicable to similar countries.

Secondly all RCTs included in this study had unclear risk of bias. This was because the studies provided insufficient information on sequence generation process, method of concealment, blinded of participants, personnel or outcome assessors and selective outcome reporting. Further funnel plot analysis also revealed that there is a possibility of publication bias and overestimation of intervention effects reported in the RCTs.

Thirdly this study found strong evidence for individually tailored compared to non-tailored interventions. Motivational interviews, social support, practical skills and access interventions provided less certain evidence because the comparisons were heterogeneous (I^2>50%). Indirect comparisons found preferences for telephone counselling compared to email counselling, counselling by dietitians or other health care professionals (nurse, GP, physicians) compared to non health care professionals to increase fruit and vegetable intake in healthy adults.

Fourthly results of the analysis suggested that intervention effects were not supported by significant increase in plasma biomarkers of α-carotene and β-carotene. This may be because of possible bias in self reported dietary measurements (FFQs, 24-hour recalls, and food records) caused by the following: social desirability, memory bias, inaccurate recalls, participants' characteristics (age, gender, education, knowledge, lifestyle, characteristics of diet), interviewer's error (probing was not done properly or general skills in asking the intake by phone or face to face), or error in biomarkers measurements (biological confounders, lab measurement errors and generally because biomarkers has low sensitivity to intake).

Fifthly results from this study suggested that increased fruit and vegetable intake caused a significant fall in systolic blood pressure but caused non-significant falls in diastolic blood pressure and weight. Previous studies mentioned in section 1.8 reported various effects of dietary interventions on systolic or diastolic blood pressure and weight. Given the results of this study systolic blood pressure may be a good biomarker of CVD or CHD.

This study suggested the types of interventions that may worked more effectively to increase fruit and vegetable intake in healthy adults. Several studies in the review provided biomarkers of fruit and vegetable intake measurements (α-carotene and β-carotene) that had unclear risk of bias. Therefore the validity of their outcomes was questionable to some extent. Findings from the review emphasised the importance for future research to include biomarkers of intake measurements of α-carotene and β-carotene to cross check findings from self reported measurements using FFQs, 24-hour recalls and food records in order to avoid bias and obtain accurate measurements of fruit and vegetable intake.

5.2. Recommendations

This study suggested that interventions may increase fruit and vegetable intake but with the following limitations:

1. The increase of fruit and vegetable intake were collected using participants' self reported measurements; FFQs, 24-hour recalls, and food records. This may caused overestimation of intake.
2. All studies had unclear risk of bias.
3. There was substantial heterogeneity detected in the analysis.
4. There was a possibility of publication bias due to the inequality of criteria used to decide which studies are published.
5. Variations in the control groups which include any interventions not aimed at increasing fruit and vegetable intake or no intervention or delayed intervention.

Given the limitations this study had strong evidence, provided from direct comparison which is not heterogeneous, to recommend individually tailored over non-tailored interventions. The results of this study would indicate a recommendation for access, practical skills, social support and motivational interview interventions over control but with less certainty due to heterogeneity found in the comparisons.

This study suggested that future research should add plasma biomarkers measurements of intake (α-carotene and β-carotene) as a compliment to traditional self-reported dietary measurements using FFQs, 24 hour recalls or food records. At the very least when using FFQs a study should have one other self-reported dietary measurement, either 24-hour recalls or food records to cross-check the results from FFQs.

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Appendices

Appendix 1

PROTOCOL

Systematic review of interventions to increase healthy adults' fruit and vegetable intake

1. Background

The leading cause of mortality in the world according to World Health Organization report in 2005 is chronic diseases namely, heart disease, stroke, cancer, and diabetes, which represent 60% of all deaths (World Health Organization 2005). There is good evidence that increased fruit and vegetable intake is associated with reduced levels of chronic disease as well as other related co-morbidities, such as: high blood pressure, dyslipidemia and obesity (Willett 1994; Ammerman, Lindquist C.H. et al. 2002; Byers T. 2002; US Department of Agriculture and Department of Health and Human Services 2005; American Institute for Cancer Research 2010)

According to United States Department of Agriculture report (US Department of Agriculture and Department of Health and Human Services 2005) 5-13 servings or 2 ½-6 ½ cups per day (depending on calorie needs) was associated with a reduced risk of cardiovascular disease, cancer (oral cavity and pharynx, larynx, lung, oesophagus, stomach, and colon-rectum) also type 2 diabetes. The finding was also supported by World Health Organization (World Health Organization 2003) which recommend daily intake of five servings or equal as 400gr of fruit and vegetables.

However previous survey in the US showed that 75.7% of adults consumed less than five or more servings daily (US Centers for Disease Control & Prevention and National Center for Chronic Disease Prevention and Health Promotion 2007). A recent survey from the UK revealed that adults in the UK on average eat 4.4 portions of fruit and vegetable a day. Among them 62.6% of men and 66.7% of women eat less than five portions a day (Food Standards Agency 2010).

Low intake of fruit and vegetable has become a global problem. A recent study based on World Health Organization survey in 2002-2003 revealed that 77,6% of men and 78,4% of women from the 52 mainly low-and middle income countries consumed less than the minimum recommended five daily servings of fruits and vegetables (Hall, Moore S. et al. 2009).

Previous systematic reviews have examined interventions that might influence diet. A study by Ammerman (Ammerman, Lindquist C.H. et al. 2002) investigated types of intervention that might be effective in influencing dietary intake. The study collected randomised controlled trials and other study designs published in English during 1975-1999 that had been conducted in North America, Europe and Australia on intake of total fat, saturated fat and fruit and vegetable intake in children, adolescents and adults. The studies were analysed by creating dichotomous indicators of whether the study reported significant effects (summary of significant findings). Out of 22 studies on fruit and vegetable intervention, 17 studies (77%) found significant results of intervention in increasing intake of fruit and vegetables. The review developed a rating system and found that intervention with theoretical basis has >20% difference in the median difference in change between intervention and control groups compared to interventions that did not while interventions involving goal setting and food-related activities has a 5-9% difference in the median difference in change between intervention and control groups. In addition analysis on age, family components and social supports as intervention characteristics failed to generate at least a 5% difference in favour of the characteristics. However the review failed to give multiple analytic strategies on fruit and vegetable outcomes because it could not conduct meta-analysis to change in fruit and vegetable intake. One of the reasons for this is because the number and comparability of studies was much lower compared to studies on total fat and saturated fat.

A further systematic review by Shaikh (Shaikh, Yaroch et al. 2008) analysed papers published in English from 1994 to 2006 that described the relationship between psychosocial predictors and fruit and vegetable intake in adults. The review included 35 studies of which 21 were cross-sectional or descriptive study and 14 were prospective study. The study used a systematic meta-evaluation method in which results for each psychosocial construct across groups of related studies were qualitatively summarized, leading to ratings of strong, sufficient or insufficient evidence of effectiveness. The study found strong evidence for self-efficacy, social support and knowledge as predictors of adult fruit and vegetable intake and weaker evidence was found for variables including barriers, intentions, attitudes/beliefs, stages of change and autonomous motivation. However the study has several limitations, among 35 studies included there are no randomised controlled trials included and therefore the ideal condition in analyzing the true effect of intervention may not have been established. The review only included six studies that have mediation analysis which is a way to quantitatively assess how interventions induce changes in individual's behaviour by assessing the impact on intermediate psychosocial variables. The mediation analysis would have been the key to understanding how the intervention affected individual's behaviour.

A systematic review by Thomas (Thomas, Sutcliffe et al. 2003) collected papers published in English from 12 countries. The searches were carried out for papers published in 1990 to 2003. The review focused on barriers and facilitators of healthy eating among children aged four to ten years of age. The analysis involved RCT interventions, controlled trials and other designs. The study found that on average, interventions are able to increase children's fruit intake by one fifth of a portion a day and their vegetable intake by a little less than one fifth of a portion a day. In addition further analysis revealed the effects of interventions which focused more specifically on healthy eating were nearly three times higher than those which tried to target healthy eating alongside physical activity and/or smoking. It also appeared to be easier to increase children's consumption of fruit than vegetables. The unique design of the study is the combination of statistical meta-analysis with thematic qualitative synthesis of studies focused on children's views of healthy eating.

The findings concluded that the interventions were able to increase fruit and vegetable in children by 0.23 portions per day (95%CI 0.11 to 0.35). In addition intervention that has multi-component element in the intervention (for example aimed also at increasing physical activity) could only increase fruit and vegetable by one-fifth portion while studies that focus on increasing fruit and vegetable intake could increase half portion. Similarly the review found that studies with longer follow-up time do not increase fruit and vegetable intake significantly compared to shorter follow-up. Branding fruit and vegetables as 'exciting', child-relevant product and tasty proved to be more effective and may increase fruit and vegetable intake by half portion compared to one-fifth portion for other studies. However the review included all kinds of study: randomised and non-randomised and focused on children aged 4-10 years of age. It is therefore important to find out which elements of interventions works best in increasing fruit and vegetable intake in adults.

A systematic review by Pomerleau (Pomerleau, Lock et al. 2005) analysed the effectiveness of intervention to increase fruit and vegetable intake in adults aged 16-69 years of age who are not acutely ill with ≥3 months of follow-up. Searches were carried out on 14 publication databases for papers from earliest record to April 2004 and included papers published in English, French, Spanish, Portuguese, Russian, Danish, Norwegian and Swedish. In primary prevention interventions fruit and vegetable intake can be increased by 0.1 to 1.4 servings per day while higher effect was found on interventions at individual with high-risk or pre-existing health disorder. The review also found positive effect on face-to-face education or counselling, telephone contact, computer-tailored and community based multi-component interventions (interventions with more than one method). The studies have several limitations. Firstly is the issue of publication bias which was caused by translation because the study included studies published in many different languages, the study also included adults with pre-existing health disorder and high-risk individuals and therefore the effect of intervention as a primary prevention means could not be analysed. Interventions aimed at high-risk individual or with pre-existing health disorder showed more effective results (Ebrahim and Davey Smith 1997; Pomerleau, Lock et al. 2005). Therefore Pomerleau concluded that trials targeted at high-risk individual should be considered separately from studies with participants from general population. A systematic review which analyses which elements of interventions works best in healthy adults is therefore needed.

Previously two systematic reviews (Kroeze, Werkman et al. 2006; Eyles and Mhurchu 2009) have analysed the effect of tailoring in increasing fruit and vegetable intake. A systematic review by Kroeze (Kroeze, Werkman et al. 2006) included intervention studies in English published from 1965 to September 2004 which was identified through three databases. It included interventions aimed at healthy adult aged eighteen years and older. The review only included studies that have computer-tailored intervention aimed at physical activity or nutritional behaviour. The intervention reviewed is mostly print computer-tailored personal feedback, letters or newsletters. Included studies were then categorized into measurement periods: short-term (<3 months), medium-term (3-6 months) and long-term (>6 months) while effect sizes were divided into cut-off points of 0.2-0.5 for small effect size, 0.5-0.8 for moderate effect size, and >0.8 for large effect size. Out of fourteen studies aimed at increasing fruit and vegetable, ten studies measured short-term intervention-effects, five compared computer-tailored with no intervention and found significant effects while another two studies compared computer-tailored with generic information and found significant effect. Four studies that analysed medium-term effect found significant effect in favour of computer-tailored compared to no intervention. In addition two studies that reported long-term effects also found significant computer tailored effects. However there are several limitations to the review, most of the included studies that found significant effects compared computer tailored to no intervention, therefore I may not conclude that computer tailored is more effective than non-tailored intervention. The review also did not include theoretical framework or theories which underline a computer tailored intervention, while this theory basis is essential in understanding why and when computer tailoring will initiate changes in diet or physical activity.

Similarly a review by Eyles (Eyles and Mhurchu 2009) examined the effectiveness of tailoring on nutrition education both for total fat and fruit and vegetables outcome. The review included studies published between January 1990 and December 2007 through electronic databases namely, Medline, Psycinfo, Cinahl, Eric, Embase, DARE, CDSR, Digital Abstracts, Science Citation Index and PubMed. Intervention included has at least six months of follow-up and included adults (≥18 years of age) of any health status. The review included four trials that compared tailored with non-tailored nutrition education and found that tailored intervention may increase 0.35 portions per day (95%CI 0.19 to 0.52). A comparison of tailored nutrition education with no nutrition education concluded that tailored nutrition education may increase 0.59 portions per day (95% CI 0.21 to 0.98) which included six studies in the analysis. The review has several limitations as follows, the studies that were included had a wide range of dietary outcomes and therefore it was difficult to differentiate which one is the main outcome, which made it possible that positive effects were in fact the result of chance, rather than true effect of tailored intervention. Furthermore the 'tailoring' terms used in the included studies were diverse therefore it cannot be distinguished whether it is individual or group tailoring intervention, and also we cannot tell which components of tailoring intervention works best compared to others. Eyles's review included analysis on fruit and vegetable intervention with low income groups but this only included one study and was therefore not sufficient or representative.

Both of the studies by Kroeze (Kroeze, Werkman et al. 2006) and Eyles (Eyles and Mhurchu 2009) concluded that in order to analyse the effectiveness of an intervention (for example tailored intervention) compared to generic intervention (non-tailored intervention) I need to establish a more in depth analysis by establishing an indirect comparison that enables us to compare tailored interventions with generic interventions (non-tailored) by indirectly comparing them with a common intervention (placebo)(Bucher, Guyatt et al. 1997; Song, Altman et al. 2003; Song, Harvey et al. 2008).

From the description above I conclude that there is a gap in knowledge of elements of interventions that works best in healthy adults. By focusing the systematic review to healthy adults, I may identify interventions that might work as primary prevention means in adults.

1.1. Fruit and vegetable intake measurement

According to Gibson (Gibson 2005), The methods used for measuring food consumption of individuals are as follows:

1. 24-hour recalls.
2. Repeated 24-hour recalls.

3. Estimated food records.
4. Weighted food records.
5. Dietary history.
6. Food frequency questionnaires.

Rutishauser (Rutishauser 2005) grouped the methods into the following:

1. Records;
    - Menu record.
    - Estimated record.
    - Weighed record.
2. Recalls;
    - 24-hour recalls
    - Diet history.
    - Food frequency questionnaires.

In general there are two methods in collecting dietary data, which are: prospective and retrospective methods. Prospective method is not ideal to measure dietary intake because it allow subject to adjust their dietary intake during the intervention (Bingham S.A., Nelson et al. 1988) therefore retrospective method is commonly used.

As mentioned above in the systematic review I will include population and individual based intervention, which explains why we will include record, recall and questionnaire methods. According to Agudo (Agudo 2005), the most used instruments to estimate fruit and vegetable intake are food frequency questionnaires (FFQs) and 24-hour dietary recalls.

In order to capture dietary habit of a certain individual, at least a one week diet history is needed (Rutishauser 2005) but this method requires skilled interviewers and respondents who can easily describe their intake from memory, therefore it is not a method that is easily applied in interventions with a large randomly selected sample.

Bigger scale studies aiming at community or population could use food-frequency questionnaires (FFQs) because they can be delivered by mail and telephone call. FFQs can be completed in less time than diet history or recalls. It can be processed electronically and repeated at regular times (Willett 1998). Therefore it is inexpensive and a standardised way of collecting information from a large number of individuals. FFQs can also quantify the frequency information by determining respondent's usual portion size into 3 categories: large, medium, or small. In fruit and vegetable intake this means number of portion per day, where one portion equal to 80 grams.
The problem with FFQ is that it is a self assessment means of collecting data where the respondents fill or answers the questionnaire themselves therefore there are no means of assessing whether their answer is honest or correct. Other biases that may be introduced by self reported outcome measures is the possibility of reporting what the examiner or people around the participants desires (social desirability) or memory bias which may cause participants to report dietary changes they have made when in fact they have not made them yet.

I will also include 24-hour recalls which is usually conducted by face-to-face, telephone or computer assisted interview in which the respondents are asked to mention all food eaten over the previous 24-hours. Although it provides detailed information on food intake, this method cannot provide information on habitual intake, unless it is repeated a number of times. The same as FFQs this method also is self assessed, therefore there's no way of knowing whether the answer given is honest or correct. This method also requires a skilful interviewer to probe the data needed chronologically.

Other than FFQs and 24-hour recalls I will also include other forms of dietary assessment such as: food diary, questionnaires (short, dietary), self reported dietary intake, 4 day food records (4DFR) which are conducted the same way as 24-hour recall or FFQs.

1.2. Moderators

This study will focus on improving fruit and vegetable intake among healthy adults aged 16 years and above. I will focus on primary prevention intervention meaning I will only include interventions that are aimed at healthy and non-risk person which means I will exclude intervention at hypertensive, overweight/obese, or chronically ill individuals. In order to benefit from an intervention I must consider different factors that influences or mediates the intervention.

A three years multiethnic cohort study by Park (Park, Murphy et al. 2005) has 195,298 participants from the USA. The results concluded that age, gender and ethnicity has significant effect on vegetable consumption. Participants who are at age criteria of 65-75 has odds ratio of 1.31 (95%CI 1.28 to 1.35) which was the highest odds ratio (being in the upper half of the dietary pattern score) among age criteria 45-54 and 55-64. Being male has lower odds ratio of being in the upper half of dietary score; OR=0.71 (95%CI 0.70 to 0.73). Being Hawaiians and Japanese American has the highest odds (OR=2.27 to 2.71) of being in the upper half of dietary score compared to Whites, African Americans and Latinos. The study only analysed vegetable intake therefore can only be compared partially with others.

A cross-sectional survey among 658 African American adults aged 18-70 years was conducted by Watters (Watters, Satia et al. 2007) in North Carolina, USA. The survey examined psychosocial factors (predisposing, reinforcing, enabling) of fruit and vegetable intake. Predisposing factors relate to knowledge of the benefit of fruit and vegetable also attitude, taste preference and self-efficacy. Reinforcing factors include social support of the people close to them about how to prepare food, encourage them, and eat with them meanwhile enabling factors relate to perceived barrier to healthy eating and whether they feel they would be able to prepare food, afford the food and time availability. The results concluded that gender has a significant effect ($P<0.001$) on predisposing, reinforcing but not on enabling factors. Age only has significant effect on enabling factors while education only has significant effect on predisposing factors, BMI on enabling factors and marital status on reinforcing factors only. The study has several limitations such as, the study was homogenous, in that it only includes African-

Americans, and 76% of them were overweight or obese with mean age of 43.9 years and it is a cross-sectional survey.

Blanchard (Blanchard, Kupperman et al. 2009) examined 413 university students in Canada using theory of planned behaviour to understand fruit and vegetable consumption among Black/White and female/male students. They used ANCOVA analysis as well as path analysis to examine it. The results from ANCOVA was as follows, Whites had higher attitudes $F(1,409)=19.67$, $P<0.001$, PBC $F(1,409)=4.09$, $P<0.05$, and intentions $F(1,409)=18.53$, $P<0.01$ compared to Blacks, while Female had higher attitude $F(1,409)=14.23$, $P<0.001$, subjective norm $F(1,409)=3.95$, $P<0.05$ and intentions $F(1,409)=10.05$, $P<0.01$ compared to males. Meanwhile path analysis showed that intentions is a significant predictors to 5-a-day ($R^2=0.17$ to 0.22) also attitude and perceived behaviour control are significant predictors for all categories ($R^2=0.32$ to 0.40) while subjective norms only significant predictors among blacks, males and females only. This study has several limitations; the study only include Blacks and Whites ethnicity, the study participants were only students who attended fitness and health classes, the findings were therefore cannot be easily generalized.

Campbell (Campbell, McLerran et al. 2008) analysed five different projects aiming at 5-a-day goal, among a total of 9089 participants. All projects are from the Northeast, Southeast, Pacific Northwest, Southwest and East part of the USA. Cross-sectional associations between self-efficacy, knowledge and autonomy (shopping, planning, preparing meals) and mean fruit and vegetable intake at baseline and follow-up analysis showed significant effects of self-efficacy and knowledge ($P<0.001$) but not for autonomy for both baseline and follow-up. The same findings can also be concluded for the intervention effect on mediator analysis. At follow-up all five sites showed significant high knowledge in the intervention groups compared to control ($P<0.01$). The same pattern was also found for self-efficacy at four sites that collect this measure ($P<0.01$). They did not find significantly difference value for autonomy. The review tried to pick up uniformity by including only 3 mediation factors. Aside from that self measured questionnaire using FFQs was rather than a more ‘gold standard’ food records.

A study by Fuemmeler (Fuemmeler, Mâsse et al. 2006) examined psychosocial variables as mediators for fruit and vegetable intake in a clustered, randomised effectiveness trial conducted in 14 African American churches (8 interventions and 6 controls) with 470 participants from intervention groups and 285 participants from control groups. The effects of intervention was analysed before and after the intervention. The result showed significant value ($P<0.05$) for autonomous motivation (motivation that comes from self believe), self-efficacy and social support ($R=0.10$, 0.42, and 0.18 respectively). The results are on borderline significant $P<0.05$, and therefore was not be a sufficient evidence.

A survey among 1024 adults (mean age=60 years) by Baker (Baker and Wardle 2003), revealed that men consume fewer fruit and vegetable than women (2.52 versus 3.47; $P<0.01$). Linear regression analysis concluded that gender significantly associated with fruit and vegetable intake ($R=0.26$, $P<0.001$). From the model of gender and knowledge they concluded that there was a significant difference between gender on knowledge of recommended servings ($R=0.36$, $P<0.001$). From the model of gender and preference between fruit and vegetable they concluded significant findings on attitudes ($R=0.15$, $P<0.001$) and from the most complete model of gender, diet, knowledge, preferences, and attitude they found significant findings for recommended servings ($R=0.33$, $P<0.001$). Several other factors found significant result but P-values are <0.01 and above. The limitations to this study are that fruit and vegetable intake were assessed only with a very simple, single-item scale, therefore, cross-sectional data and causal relationship cannot be assumed.

NICE public health guidance on behaviour change at population, community and individual level (National Institute for Health and Clinical Excellence 2007) recommended that an intervention should consider factors such as, the role of support networks and neighbourhood, time scale, targeting on specific population group and primary or secondary prevention intervention.

From previous studies mentioned above I may conclude that more research is required to examine which elements of intervention work best to increase fruit and vegetable intake in healthy adult, in order to analyse the effectiveness of specific components of interventions (tailoring to individual or group, theory based: stage of change, theory of planned behaviour, psychosocial factors: self efficacy, knowledge, social support, motivation, practical skills, media based, computer/telephone/printed messages/emails, role model, accessibility, counselling/group session by nutritionist/community workers) in different population sub-groups based on ethnicity, gender, age and education or income level.

2. Objectives

The review is aimed at finding out what kind of intervention works best as primary prevention means by increasing fruit and vegetable intake in the hope that it will reduce the risk of developing chronic diseases, as well as assessing which elements of intervention work best to increase fruit and vegetable intake in healthy adults and specifically to analyse whether:

- Interventions tailored to specific groups (gender, ethnic, socioeconomic) are more effective than those that are not.
- Individually tailored interventions are more effective than those that are not.
- Theory based interventions (theory of planned behaviour, stage of change, decisional balance, trans-theoretical) are more effective than those that are not based on theories and analyse which types of theories are more effective than others.
- Interventions with psychosocial factors: intention, attitude, belief, self efficacy, knowledge or motivations are more effective than those that are not and analyse which type of psychosocial factors are more effective.
- Interventions delivered through computer, telephone, printed messages or email are more effective than other methods and analyse which types of delivery are more effective.
- Interventions involving practical skills/demonstration in cooking, shopping and preparation are more effective than those without.
- Interventions involving role models are more effective than those without.
- Media based interventions (delivered through television, radio, newspaper) are more effective than others.

- Interventions aimed at pricing and accessibility are more effective than others.
- Interventions that involving counselling sessions led by nutritionist/nurse/community workers are more effective than those that are not.
- Interventions that develop on action plans are more effective than those that are not.
- Longer term duration of interventions (more than one year) are more effective than shorter term (less than one year).
- Interventions that deliver a message of fruit and vegetable as fun and tasty are more effective that those that deliver it as healthy.
- Interventions with higher targets of consumption (more than 6 servings/day) are more effective than those with general targets (≥5 servings/day).
- Single component interventions aiming at increasing fruit and vegetable intake are more effective than multi-component interventions which address other dietary behaviour also such as, lifestyle (physical activity) or other (screening).

3. Methods

Criteria for considering studies for this review

3.1. Type of studies

All randomised controlled trial (RCTs) that describe 'random' or 'randomisation' to participants including cluster randomisation of at least six groups/communities with follow-up of 3 months or more.

3.2. Type of participants

Studies will include free-living not acutely ill (without any disease) adult participants (age 16 and above). I will exclude intervention that was aimed at participants with high-risk of cardiovascular disease (obese, hypertensive, smokers). I will also exclude intervention that was aimed at pregnant women.

3.3. Type of interventions

I will identify interventions which aimed at increasing fruit and vegetable intake and fulfil our inclusion criteria. Interventions must provide outcome measures data of fruit and vegetable intake of the intervention and control groups in portions/day or servings/day.

I will identify a number of interventions that were used to intervene with adults' fruit and vegetable intake including different types of interventions:

1. 'Tailored for specific groups interventions' are an intervention aimed at increasing fruit and vegetable intake in a specific groups which could be grouped according to ethnicity, income status, gender or age group and the intervention is therefore tailored (modified) according to specific characteristics and needs of the targeted groups.

2. 'Individually tailored interventions' are aimed at increasing individual fruit and vegetable intake and the intervention is therefore tailored (modified) accordingly. For example an intervention based on a stage of change model, a specific recommendation is based on the individual stage of change (pre-contemplation, contemplation, preparation, and action) and the advice is given accordingly.

3. 'Intervention tailored based on barriers and facilitators' are based on individual/group barriers and facilitators, the intervention is therefore modified in relation to barriers and facilitators that were given. For example from a pilot study used focus groups or questionnaires on barriers and facilitators to increase fruit and vegetable intake.

4. 'Theory based interventions' are based on a specific theory (theory of planned behaviour, stage of change, social cognitive/social learning theory) with the aim to increase fruit and vegetable intake.

5. 'Interventions developed and works on self efficacy' are based on a specific theory and then developed to modify a person's self efficacy in changing their behaviour towards increasing fruit and vegetable intake.

6. ‘Interventions developed and works on social support’ are based on the theory of planned behaviour or developed specifically to build social support in changing the behaviour towards increasing fruit and vegetable intake.

7. ‘Interventions developed and works on knowledge’ are aimed at increasing a person’s knowledge of the importance of fruit and vegetable intake by giving counselling sessions, brochures, leaflets, or any other means.

8. ‘Interventions developed and works on motivation’ are based on motivational theory or decision making theory or developed specifically to increase motivation in changing the behaviour towards increasing fruit and vegetable intake.

9. ‘Interventions that use personal computer/telephone/printed messages/email are intervention that uses various means of communications namely, personal computer/telephone/printed messages/email to convey the intervention to participants.

10. ‘Interventions that involves practical skills uses cooking demonstrations or hands-on-experiences involving participants to try cooking food to increase participants’ cooking and preparation skills, it might also involve shopping skill, for example an intervention that gives guidance and tips on shopping for healthier food with low cost.

11. ‘Interventions that involve role models’ present a person who serves as an example, whose behaviour is emulated by others in increasing fruit and vegetable intake. The role model can be a famous person (actor, singer, and model) or a community/religious/organization leader or even a community worker.

12. ‘Interventions which are media based’ use television/radio/newspaper or other means of media to convey the message of increasing fruit and vegetable intake for any period of time.

13. ‘Accessibility interventions’ aim to make fruit and vegetable more accessible, for example by giving vouchers or establishing a local fruit and vegetables shops.

14. ‘Group-led interventions’ are conducted in groups, led by a nutritionist or community health workers who will give counselling to group members.

15. ‘Interventions developed and worked on action plans’ are based on the theory of reasoned action or developed in making specific action plans or goals to increase fruit and vegetable intake.

16. I will also identify the following:

    - Whether the interventions convey a message of fruit and vegetable as fun and tasty or healthy.
    - The specific plan target of each intervention: how many portions of fruit and vegetable per day that is targeted for the specific intervention in the study.
    - The means of collecting data on fruit and vegetable intake: What kind of dietary measurement is used in the study, for example using food frequency questionnaires or 24-hours recalls.

3.4. Type of outcome measures

The main outcome is the total fruit or vegetable intake at the end of intervention in both groups and change of fruit and vegetable intake in each group after the intervention. The intake of each participant is measured by self reported food frequency questionnaires or 24-hour recalls. I will also include studies that reported biomarkers (α-carotene and β-carotene) measurement results.

3.5. Search Methods

I will search the following databases from beginning of 2004 to May 2010:

- Cochrane Library
- MEDLINE (1950 to present)
- EMBASE
- LILACS
- PsycINFO (BIDS)
- ERIC

This review builds upon a systematic review by Pomerleau (Pomerleau, Lock et al. 2005). However I conducted an updated new search from 2004 onwards because Pomerleau's review was published in 2005 and I will include all studies from Pomerleau's review which fit the inclusion criteria which are randomised controlled trials which aimed at increasing fruit and vegetable intake in healthy adults (without any cardiovascular disease risk such as, diabetes, obese, or hypertension and other disease such as cancer).

3.5.1. Search strategy for identification of studies

Search strategies for each of the databases will be based on the filtering strategies for randomised controlled trial on the Cochrane Library Handbook (Higgins and Green 2008).

The keywords used in the database search will be as follows, randomised controlled trial, controlled clinical trial, randomised, placebo, drug therapy, randomly, trial, groups, animals not (humans and animals), fruit, vegetable, adult children or adult. Trials satisfying the inclusion criteria will then be selected. I will also include theses search. I include all studies published in different languages and will contact authors for further details if necessary.

In addition I will also conducted grey literature searches by searching theses from libraries, online theses, reports and reference checking from included studies.

3.5.2. Search strategy

Search strategy for each database is available Appendix 2.

4. Data collection and analysis

4.1. Study selection

The titles and abstracts identified in the searches will be independently screened by two review authors to select potentially relevant studies. These studies will be obtained in full text and assessed independently by two reviewers for suitability of inclusion to the review. Each study will be judged using our inclusion/exclusion form which consists of seven questions as follows, whether the study is randomised, have control group, aimed at increasing fruit and vegetable intake, individual/population based, involving healthy adult participants, have 3 months of follow-up, and have data outcomes available (see Appendix 3).

4.2. Data extraction

Six reviewers will independently extract data on participants, interventions, outcomes and trial quality from the included studies. Any disagreement will be resolved by discussion. Information will be extracted on the data extraction form which consists of the following: general study population – published/unpublished, author, title, year of publication, journal, year the research was conducted and country of origin (see Appendix 4 for detail).

- Study characteristics and descriptive data – sample size, randomised controlled trial (RCT) criteria, number of participants recruited in each group, number of participants at follow-up.
- Participants' characteristics – gender, mean age, marital status, parental status, educational level, income, ethnicity, location (rural/urban), smoking status, alcohol consumed per week, physical activity level, vitamin intake and Body Mass Index.
- Intervention characteristics – psychological and behavioural model used for the intervention design, follow-up period, number of sessions in each intervention group, length of sessions, type of intervention (tailored to specific groups or individual, based on barriers and facilitators, based on theory of planned behaviour or stage of change, developed and worked on self efficacy, social support, knowledge, motivation, using personal computer/telephone/printed message/email, involve role model or practical skills, media based, intervene with access and pricing, involve group-led, or developed and worked on action plans), information given, strategies used, additional treatments given to either group (intervention or control group), location of intervention.
- Outcome measure characteristics – type of measurements, results of each measurements, baseline and follow-up results, outcome measures and reported

outcome measures. The outcomes are total fruit and vegetable (portions per day) and also fruit only (portions per day) and vegetable only (portions per day) where available at baseline, end of intervention and the changes after intervention as continuous data and standard deviation of each value.

4.2.1. For consistency the main researcher will data extract every study. The result from each reviewer will be discussed with the main researcher and any differences will be resolved. Result of the discussion will be transferred into a single form which will be the final version of data extraction for the next stage of analysis.

4.3. Risk of bias

The risk of bias for each included study were analysed according to the Cochrane Handbook (Higgins and Green 2008) by considering the following risk criteria:

4.3.1. Sequence generation; was the allocation sequence adequately generated? (question 2.3 in data extraction form).

4.3.1.1. Criteria for the judgment of 'YES' (low risk of bias) if the investigators describe a random component in the sequence generation process such as:

- Referring to a random number table.
- Using a computer random number generator.
- Coin tossing.
- Shuffling cards or envelopes.
- Throwing dice.
- Drawing of lots.
- Minimisation (may be implemented without a random element, and this is considered to be equivalent to being random).

4.3.1.2. Criteria for the judgement of 'NO' (high risk of bias) if the investigators describe a non-random component in the sequence generation process.

Usually the description would involve some systematic, non-random approach for example:

- Sequence generated by odd or even date of birth.
- Sequence generated by some rule based on date (or day) of admission.
- Sequence generated by some rule based on hospital or clinic record number.

Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgment or some method of non-random categorization of participants for example:

- Allocation by judgement of the clinician.
- Allocation by preference of the participant.
- Allocation based on the results of a laboratory test or a series of tests, allocation by availability of the intervention.

4.3.1.3. Criteria for the judgement of 'UNCLEAR' (unclear risk of bias) if there was insufficient information about the sequence generation process to permit judgement of 'YES' or 'NO'.

4.3.2. Allocation concealment; was allocation concealed? (question 2.4 in data extraction form).

4.3.2.1. Criteria for the judgment of 'YES' (low risk of bias) if participants and investigators enrolling participants could not foresee assignment because one of the following or an equivalent method was used to conceal allocation:

- Central allocation (including telephone, web-based, and pharmacy-controlled randomization).
- Sequentially numbered drug containers of identical appearance.
- Sequentially numbered, opaque, sealed envelopes.

4.3.2.2. Criteria for the judgement of 'NO' (high risk of bias) if participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:

- Using an open random allocation schedule (list of random numbers).

- Assignment envelopes were used without appropriate safeguards (if envelopes were unsealed or non-opaque or not sequentially numbered).
- Alternation or rotation.
- Date of birth, case record number.
- Any other explicitly unconcealed procedure.

4.3.2.3. Criteria for the judgement of 'UNCLEAR' (unclear risk of bias) if there was insufficient information to permit judgment of 'YES' or 'NO'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgment, for example if the use of assignment envelopes is described but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

4.3.3. Blinding of participants, personnel, and outcome assessors; was knowledge of the allocated interventions adequately prevented during the study? (question 2.5 and 2.6 in data extraction form).

4.3.3.1. Criteria for the judgment of 'YES' (low risk of bias) if any one of the following was fulfilled:

- No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

4.3.3.2. Criteria for the judgment of 'NO' (high risk of bias) if any one of the following was fulfilled:

- No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted but likely that the blinding could have been broken.

- Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

4.3.3.3. Criteria for the judgment of 'UNCLEAR' (unclear risk of bias) if any one of the following was fulfilled: there was insufficient information to permit judgment of 'YES' or 'NO' or the study did not address this outcome.

4.3.4. Incomplete outcome data; were incomplete outcome data adequately addressed? (question 2.9a, 2.9b, 3.1.-3.6b in data extraction form).

4.3.4.1. Criteria for the judgment of 'YES' (low risk of bias) if any one of the following was fulfilled:

- No missing outcome data (all participants who were randomised or had the interventions included in the outcomes).
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size
- Missing data have been imputed using appropriate methods.
- The descriptions of participants in each arm were done in all of the following: number of participants who were randomised, number of female/male randomised, number of dropouts, reasons for dropouts, number analysed, reasons for non-analysis, number analysed, and description of dropouts.

4.3.4.2. Criteria for the judgment of 'NO' (high risk of bias)if any one of the following was fulfilled:

- Reason for missing outcome data likely to be related to the true outcome, with either imbalance in numbers or reasons for missing data across intervention groups (not all participants who were randomised or had the interventions included in the outcomes).
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size.
- 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.
- The descriptions of participants in each arm were not done or only partially done in the following: number of participants who were randomised, number of female/male randomised, number of dropouts, reasons for dropouts, number analysed, reasons for non-analysis, number analysed, and description of dropouts.

4.3.4.3. Criteria for the judgment of 'UNCLEAR' (unclear risk of bias) if any of the following was fulfilled: there was insufficient reporting of attrition/exclusions to permit judgment of 'YES' or 'NO', for example number randomised not stated, no reasons for missing data provided or the study did not address this outcome.

4.3.5. Selective outcome reporting; were reports of the study free of suggestions of selective outcome reporting? (question 2.11 in data extraction form).

4.3.5.1. Criteria for the judgment of 'YES' (low risk of bias) if any of the following was fulfilled:

- The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.

- The study protocol is not available but it is clear that the published report include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

4.3.5.2. Criteria for the judgment of 'NO' (high risk of bias) if any of the following was fulfilled:

- Not all of the study's pre-specified primary outcomes have been reported
- One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (for example subscales) that were not pre-specified
- One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

4.3.5.3. Criteria for the judgment of 'UNCLEAR' if there was insufficient information to permit judgment of 'YES' or 'NO'. It is likely that the majority of the studies will fall into this category.

4.3.6. Industry funding: was the study free of industry funding? (question 2.10a in data extraction form).

4.3.6.1. Criteria for the judgment of 'YES' (low risk of bias) if there was a specific statement that the study was funded by the government (for example Department of Health), non-profit organization (for example Cancer Research) or universities.

4.3.6.2. Criteria for the judgment of 'NO' (high risk of bias) if there was a specific statement that the study was funded by private industry or private bodies.

4.3.6.3. Criteria for the judgment of 'UNCLEAR' (unclear risk of bias) if there was insufficient information to permit judgment of 'YES' or 'NO'.

Each study will be categorised according to the points stated above as either 'YES', 'NO' or 'UNCLEAR' and based on this categorisation, the study will then categorised as having low, medium, or unclear risk of bias. According to the following criteria:

- A study will be categorised as 'low risk of bias' if allocation sequence was adequately generated, allocation was concealed, knowledge of the allocated interventions was adequately prevented, incomplete outcome data was adequately addressed, reports of the study was free of suggestions of selective outcome reporting and the study was free of private funding.
- A study will be categorised as 'high risk of bias' if at least two of the following categories were fulfilled: allocation sequence was inadequately generated, allocation was not concealed, knowledge of the allocated interventions was inadequately prevented, incomplete outcome data was inadequately addressed, reports of the study was not free of suggestions of selective outcome reporting or the study was funded by private industry.
- A study that did not fall under 'low risk of bias' or 'high risk of bias' will automatically categorised as being 'unclear risk of bias'.

4.4. Analysis

From the information in the data extraction forms I will tabulate our findings into a table of description which consists of participants' description, study quality and types of intervention.

From the studies included I will extract total fruit and vegetable (portions per day) data at the end of follow-up with standard deviation for each intervention and control groups. I will then analyse the mean difference of fruit and vegetable (portions per day) in each study using Cochrane Review Manager (RevMan) (The Nordic Cochrane Centre 2011) with weighted mean differences and 95% confidence intervals will be reported for continuous outcomes. Standard deviations will be calculated from standard error where necessary. To decide whether heterogeneity (genuine variation in effect sizes) was present, I will conduct a test of heterogeneity, "I^2 is an estimate of the proportion of total observed variability that is due to genuine variation rather than random error within studies, when I^2>50% it is considered to be substantial"(Higgins 2003; Higgins and Green 2008). Statistical heterogeneity will be tested using the chi-square method and heterogeneity will be assumed with P-values<10%. To anticipate heterogeneity I will perform random effects model, also I will conduct sub-group analysis for each intervention. In addition, funnel plots will be use to assess the evidence of publication bias (Egger, Smith et al. 1997) and sensitivity analysis will be performed to assess the vigorousness of results.

This review will consist of three levels of evidence in terms of comparisons namely, direct comparison, subgroup analysis and indirect comparison. According to Glenny and Bandolier (Glenny, Altman et al. 2005; Bandolier 2011) direct comparison of RCT is the highest level of evidence followed by indirect comparison with common comparator from RCTs. If direct comparisons were not available adjusted indirect comparisons will be conducted. However the quality of indirect comparison relies heavily on similarity assumption, homogeneity and consistency (Donegan, Williamson et al. 2010) which may be examined by subgroup analysis, sensitivity analysis or meta-regression. In addition subgroup analyses and sensitivity analysis will be conducted to examine the similarity assumption. If a direct comparison between interventions did not exist I conducted subgroup analysis (random effects 95% CI) followed by indirect comparisons of interventions using a common comparator.

In general there were three level of comparison existed in the study namely:

1. Direct comparison

Direct comparisons will be conducted on the following comparisons:

- 1.1. All interventions versus control.
- 1.2. 24-hour recalls versus FFQs.
- 1.3. Interventions using printed message versus telephone.
- 1.4. Interventions using printed message and video (combined) versus social support interventions.
- 1.5. Tailored versus non-tailored interventions.
- 1.6. Motivational interview interventions versus control.
- 1.7. Social support interventions versus control.
- 1.8. Practical skills interventions versus control.
- 1.9. Access interventions versus control.

2. Subgroup analyses

Subgroup analyses will be conducted for the studies' characteristics below:

2.1. Interventions settings: workplace, university or community.

2.2. Gender targets: women, men or both.

2.3. Trial durations: short follow-up or long follow-up.

2.4. Target of interventions: basic target (5 portions per day), non-specific target (increase fruit and vegetable intake) or higher target (6-9 portions per day).

2.5. Aims of interventions: single aim (only aimed at increasing fruit and vegetable intake) or multiple aim (aimed also at lowering fat intake, increasing physical activity, increasing cancer awareness by screenings or smoking cessation).

2.6. Dietary measurements: Food Frequency Questionnaires (FFQs), 24-hour recalls or food records.

2.7. Message deliveries: printed message, computer message, video message or any combination.

2.8. Theory based interventions: Social Cognitive/Social Learning, Transtheoretical Model/Stage of Change, Health Behaviour Change or any combination.

2.9. Psychosocial factors: interventions with 1-3, 4-6, and at least 7 psychosocial factors.

2.10. Counselling methods: interventions using counselling were given face to face or using the telephone versus no counselling or no intervention/delayed interventions.

2.11. Counsellors: interventions using counselling sessions were given by dietitians or nutritionists, other health care professionals (GPs, nurses, physicians) or non health care professionals (trained staff, community workers) versus no counselling or no intervention or delayed interventions.

2.12. Tailored: individual tailored or group tailored versus no intervention or delayed interventions.

3. Indirect comparison

Adjusted indirect comparison was a method suggested by Bucher (Bucher, Guyatt et al. 1997; Song, Altman et al. 2003; Song, Harvey et al. 2008). Song states that "adjusted indirect comparison was an indirect comparison of competing interventions adjusted according to the results of their direct comparison with a common control so that the strength of the randomised trials is preserved" (Song 2009). The method of analysis was to compute the mean difference of the indirect comparison using the Indirect Treatment Comparison computer software (Wells, Sultan et al. 2009). For example to assess the effectiveness of printed message versus computer message interventions I will enter the mean difference result from the direct comparisons of printed message interventions versus control and then the mean, standard deviations and number of participants to weight the studies accordingly. Similarly I will enter the mean difference result from direct comparison of computer message versus control and then the mean, standard deviations and number of participants of each studies using computer message. The software then calculates the summary of mean difference for indirect comparison of printed message versus computer message interventions. In the analysis, derived weight and random effects will be used. For example when comparing printed message versus computer message, the common comparators are interventions on fall prevention, sleep disorder, health awareness program (colon cancer, HIV/AIDS, elderly health, adolescent health), delayed interventions or no intervention. Adjusted indirect comparisons will be conducted on comparison that do not have direct comparison so post-hoc decisions will be made on adjusted indirect comparisons which are necessary to be conducted.

In order for strong evidence to be present in this study it had to fulfill all five criteria:

1. Direct comparisons which include at least three studies.
2. Not heterogenous (I^2>50%).
3. Heterogeneity can be explained by subgrouping.
4. The comparisons are stable to sensitivity analysis
5. The study included study validity.

For the biomarker data, direct comparisons of the changes in α-carotene and β-carotene in the intervention groups and the control groups after the interventions were available and therefore subgroup analysis was conducted on mean differences in α-carotene and β-carotene in the intervention groups and the control groups after the interventions in order to test whether the interventions to increase fruit and vegetable intake demonstrated significant effects on the biomarker outcomes.

Appendix 2

Search strategies

Database: Ovid MEDLINE(R) <1950 to March Week 2 2010>

----

1 randomised controlled trial.pt. (282770)

2 controlled clinical trial.pt. (80250)

3 randomised.ab. (192262)

4 placebo.ab. (115950)

5 drug therapy.fs. (1357455)

6 randomly.ab. (139664)

7 trial.ab. (198905)

8 groups.ab. (946636)

9 1 or 6 or 2 or 4 or 7 or 3 or 5 or 8 (2490591)

10 (animals not (humans and animals)).sh. (3359807)

11 9 not 10 (2110631)

12 fruit*.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier] (42404)

13 vegetable*.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier] (28269)

14 Fruit/ (17548)

15 exp Vegetables/ (64554)

16 15 or 12 or 14 or 13 (106466)

17 11 and 16 (10394)

18 adult children/ or exp adult/ (4534198)

19 18 and 17 (4557)

20 limit 19 to yr="2004 -Current" (2023)

Database: EMBASE <1980 to 2010 Week 10>

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1 fruit*.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (33288)

2 vegetable*.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (26338)

3 adult children/ or exp adult/ (2365754)

4 exp fruit/ or exp vegetable/ (68663)

5 exp fruit juice/ (3983)

6 5 or 2 or 1 or 4 (96164)

7 Adult/ (2365741)

8 exp senescence/ or exp aging/ (96488)

9 8 or 3 or 7 (2438205)

10 random$.ti,ab. (429702)

11 factorial$.ti,ab. (9131)

12 placebo$.ti,ab. (117031)

13 (doubl$ adj blind$).ti,ab. (89245)

14 (singl$ adj blind$).ti,ab. (7988)

15 assign$.ti,ab. (117735)

16 allocat$.ti,ab. (37499)

17 volunteer$.ti,ab. (104718)

18 double-blind procedure.sh. (76644)

19 randomised controlled trial.sh. (183269)

20 single blind procedure.sh. (9153)

21 11 or 17 or 12 or 20 or 15 or 14 or 18 or 19 or 10 or 13 or 16 (702561)

22 animal/ or nonhuman/ or animal experiment/ (3628851)

23 human/ (6889847)

24 22 and 23 (595195)

25 22 not 24 (3033656)

26 21 not 25 (613068)

27 6 and 26 and 9 (2953)

28 limit 27 to yr="2004 -Current" (1526)

COCHRANE

MODIFIED FROM: fruitvegfinal160609limit: last update

ID	Search	Hits	Edit	Delete
#1	fruit*	1667	edit	delete
#2	vegetable*	1586	edit	delete
#3	MeSH descriptor **Fruit**, this term only	591	edit	delete
#4	MeSH descriptor **Vegetables** explode all trees	1647	edit	delete
#5	(#1 OR #2 OR #3 OR #4)	3285	edit	delete

Save Search Strategy Clear History

LILACS

("RANDOM" or "RANDOMISADOS" or "RANDOMISATION" or "RANDOMISED" or "RANDOMISACAO" or "RANDOMISACION" or "RANDOMISADA" or "RANDOMISADAMENTE" or "RANDOMISADAS" or "RANDOMISADE" or "RANDOMISADO" or "RANDOMISADOS" or "RANDOMISAMOS" or "RANDOMISANDO" or "RANDOMISANTEMENTE" or "RANDOMISAR" or "RANDOMISARON" or "RANDOMISATION" or "RANDOMISATO" or "RANDOMISDO" or "RANDOMISE" or "RANDOMISED" or "RANDOMISEDCONTROLLED" or "RANDOMISEDSDESIGN" or "RANDOMLY" or "RANDOMLYASSIGNED" or "RANDOMLYDIVIDED" or "RANDOMLYDRAWN" or "RANDOMOZADA" or "RANDOMOZADO" or "RANDOMSAMPLE" or "ALEATORIO" or "ALEATORIOS" or "ALEATORIZAR" or "ALEATORIAMENTE" or "SELECIONADOSALEATORIAMENTE" or random$)

("FRUTA" or "FRUTAS" or "FRUIT" or "FRUITS" or fruit$ or "VEGETAL" or "VEGETAIS" or "VERDURA" or "VERDURAS" or "LEGUMBRE" or "LEGUMBRES" or "LEGUME" or "LEGUMES" or "VEGETABLE" or "VEGETABLES" or vegetable$)

0 Results

ERIC

Search history:

No.	Database	Search term	Info added since	Results
0		[Clipboard]		0
1	ERIC - 1966 to date	INTERVENTION.W..DE.	unrestricted	20404
2	ERIC - 1966 to date	RANDOM OR RANDOMLY OR RANDOMISE OR RANDOMISED OR RANDOMISE OR RANDOMISED	unrestricted	18508
3	ERIC - 1966 to date	1 OR 2	unrestricted	37862
4	ERIC - 1966 to date	FRUIT OR FRUITS OR VEGETABLE OR VEGETABLES	unrestricted	1099
5	ERIC - 1966 to date	3 AND 4	unrestricted	58
6	ERIC - 1966 to date	limit set 5 YEAR > 2004	unrestricted	38

Database: PsycINFO <1806 to February Week 3 2010>

Search Strategy:

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1 random*.mp. [mp=title, abstract, heading word, table of contents, key concepts] (87151)

2 (control* adj3 (trial* or group*)).mp. [mp=title, abstract, heading word, table of contents, key concepts] (61319)

3 randomised.ab. (20962)

4 placebo.ab. (22482)

5 drug therapy.mp. [mp=title, abstract, heading word, table of contents, key concepts] (81766)

6 randomly.ab. (36396)

7 trial.ab. (41323)

8 groups.ab. (271534)

9 1 or 6 or 2 or 4 or 7 or 3 or 5 or 8 (449095)

10 (animals not (humans and animals)).sh. (5014)

11 9 not 10 (448660)

12 fruit*.mp. [mp=title, abstract, heading word, table of contents, key concepts] (8262)

13 vegetable*.mp. [mp=title, abstract, heading word, table of contents, key concepts] (1774)

14 12 or 13 (8795)

15 11 and 14 (1385)

16 limit 15 to yr="2004 -Current" (689)

****

Appendix 3
Inclusion/exclusion form

Fruit and Vegetable Review Update, 2009

Inclusion/exclusion form

Trial: author year

journal ref unique identifier

in/outed by: Silvia Devina, Lee Hooper

1. randomised? (randomised controlled trial)	**y / n / ?**
2. control group? (no dietary advice, other advice)	**y / n / ?**
3. increase fruit and vegetable intake?	**y / n / ?**
4. individual or population based intervention?	**y / n / ?**
5. healthy adult human (no acute illness, not pregnant)?	**y / n / ?**
6. follow-up time of at least 3 months?	**y / n / ?**
7. data available on diet outcomes?	**y / n / ?**

Studies are 'in' if all questions have yes answers, 'out' if any question has a 'no' answer and 'pending' if any answer is unclear.

in **out** **pending**

Full text papers: Data extract included studies and note reason for exclusion of excluded studies.

action:

number randomised:

intervention and dose:

reason for exclusion:

Additional detail for in/out form:

Question 1: The study included must be randomised controlled trial. A clear random allocation procedure should be described, mentioning 'random' or 'randomisation'. We will include matched pairs or cluster randomisation. Alternation or allocation based on family name, date of birth etc is not random and so should be excluded.

Question 2: The control group must receive no treatment (placebo) or other type of intervention to increase fruit and vegetable intake, or treatment aiming other than increasing fruit and vegetable intake (physical activity, smoking cessation, breast self examination). Studies with control group which did not fit to the criteria above will be excluded.

Question 3: The intervention group must be advised to increase consumption of fruit and vegetable. We will include pricing initiative on fruit and vegetable. Studies without intervention to increase fruit and vegetable intake will be excluded.

Question 4: We include all individual and population based studies aiming at increasing fruit and vegetable intake which stated clearly in the methods that in the intervention arm it advised to increase fruit and vegetable, while it was not provided in the control arm. We include studies with one intervention (i.e. aiming at increasing fruit and vegetable intake or healthy eating) or multi-component intervention (i.e. targeting fruit and vegetable intake with physical activity, smoking cessation or breast self examination program). Interventions include dietary counselling sessions, group lectures, workshops, computer-generated tailored nutrition newsletters or any combination of these. Studies not aiming at increasing fruit and vegetable intake will be excluded.

Question 5: We include study involving healthy adults above 16 years of age that are not acutely ill and living independently (pregnant women and people with chronic diseases such as, CVD, diabetes, cancer will be excluded).

Question 6: We include studies with at least 3 months follow-up time. Studies with less than 3 months follow-up time will be excluded.

Question 7: Studies will be 'included' if they report any of our stated outcomes. If they do not state any of these outcomes in published papers they will be classified as 'pending', and not included at this stage (we are not writing to authors this time). Ongoing studies (which have not published any outcomes) will be excluded.

Outcomes for assessment of inclusion:

- food frequency questionnaire
- food diary
- 24-hour recall
- short questionnaire
- dietary questionnaire
- self reported dietary intake
- 4 day food records (4DFR)
- serum vitamin C
- blood pressure measurement

Appendix 4
Data extraction form

Fruit and Vegetable Intake Systematic Review

Data extraction form

1.1 Study ID	
1.2 Authors	
1.3 Year publication	
1.4 Journal reference	
1.5 Reviewer	Lee Hooper, Silvia Devina, Mohannad Kafri, Steph Howard, Atef Bakhoum, Girmaye Dinsa

Other papers extracted as part of this study:

Extract any papers from one study all onto 1 form (we are interested in whole studies, not papers)

Do the publications extracted suggest that other papers have been published as part of this study which should also be collected? If so, please give details:

- **Country of origin?**

Trial details and quality

2.1 Trial duration (duration of <u>intervention</u> period(s)	months
Setting (circle or write in)	e.g. ward, outpatient clinic, community, worksite, etc.
2.2 <u>Study type</u> (tick which applies)	☐ RCT

2.3 Was the allocation sequence adequately generated? Give details e.g. opaque envelopes, random numbers, computer system, 'randomisation' stated only	Yes / No / Unclear Any description of process:
2.4 Was randomisation adequately concealed? (Yes if central computer system, sealed opaque envelope or any system where person allocating treatment clearly cannot influence it) – give details	Yes / No / Unclear
2.5 Was the researcher masked[2] to intervention?	Yes / No / Unclear
Was the outcome assessor masked to intervention?	Yes / No / Unclear
Were other health care professions masked?	Yes / No / Unclear
2.6 Were participants masked to intervention?	Yes / No / Unclear
2.7 Were statistical analysis staff masked?	Yes / No / Unclear
2.8 Were laboratory staff masked to intervention	Yes / No / Unclear
2.9a Were all those randomised included in outcomes?	Yes / No / Unclear
2.9b Were all those who had any of the intervention included in the outcomes?	Yes / No / Unclear
2.10a Was the study free of any industry funding? If no, what industry?	Yes / No / Unclear
2.10b Was any of the authors working for private bodies?	Yes / No / Unclear
2.10c Were any products supplied free by industry?	Yes / No / Unclear
2.10d Any other industry involvement?	Yes / No / Unclear
2.11.Was the study free of selective outcome reporting (study protocol available and all the study's pre-specified primary or secondary outcomes of interest have been reported)?	Yes / No / Unclear
2.12 Was intake measured by questionnaire?	Yes / No / Unclear
2.13 Was intake measured by 24-hour recall (food diary)?	Yes / No / Unclear
2.14 Were blood sample/urine sample taken? (carotenoid, serum vitamin C, flavonoid)	Yes / No / Unclear

[2] **Where study reports 'double blind' the participant is assumed masked, but not any staff or health professionals.**

2.15 Were blood pressure measurement taken?	Yes / No / Unclear

Participants

Numbers - for crossover studies need only fill in one column

No.	Participants detail	Intervention 1:	Intervention 2:	Intervention 3:	Control
3.1	Number randomised				
3.2	No. of females / males randomised				
3.3	Number of dropouts				
3.4	Reasons for dropouts				
3.5	Number not analysed (other than above)				
3.6	Reason for non-analysis				
3.6a	Numbers analysed				
3.6b	Description of dropouts	Done	partial	not done	
3.7	Details of study inclusion criteria				

Risk of Bias

Overall risk of bias: based on result on Section 2 and 3, does the study has low/high/unclear risk of bias? Consider questions: 2.3 Was the allocation sequence adequately generated? 2.4 Was randomisation adequately concealed? 2.5 Was the researcher masked to intervention? 2.6 Were participants masked to intervention? 2.9a Were all those randomised included in outcomes? 2.9b Were all those who had any of the intervention included in the outcomes? 2.9a and 2.9b (was intention to treat done?) 2.10a Was the study free of any industry funding? 2.11 Was the study free of selective outcome reporting? 3.1-3.6b: Was description of participants in each arm adequately described? (circle where appropriate)	**Low risk of bias if 'YES' to 2.3, 2.4, 2.5, 2.6, 2.9a, 2.9b, 2.10a, 2.11, and 3.1-3.7.** **High risk of bias if the answers were 'NO' to at least two of the following: 2.4, 2.9a-2.9b, 2.10a, 2.11, and 3.1-3.6b.** **Unclear risk of bias for all other studies.**

For detail see Cochrane Handbook 2008, Chapter 8

Characteristics

No.	Define the intervention	Intervention 1:	Intervention 2:	Intervention 3:	Control
4.1	Mean age, sd				
4.2	Age range: 16-25 26-50				

	51+				
4.3	Gender: Female Male Both				
4.4	Educational Level: <high school High school grad Some college College grad Post grad				
4.5	Income (Socioeconomic Status) <$20,000 $20-39,000 $40-59,000 $60-79,000 $80,000+				
4.6	Ethnicity White Black Hispanic Asian Other				
4.7	Marital Status Married				

	Single Living together				
4.8	Parental status (have children) Yes No				
4.9	Location Rural Urban				
4.10	Smoking Yes No				
4.11	Alcohol (drinks/week) 0 1-7 8-14 14-21 21+				
4.12	Physical Activity Mainly sedentary Moderate activity Regular/heavy exercise				
4.13	Vitamin intake Yes No				

4.14	Body Mass Index Normal Overweight Obese				

Intervention

Planned content of intervention

No.	**Define the interventi on**	Intervention 1:	Intervention 2:	Intervention 3:	Control
5.1	Type of fruit and veg interventio n (describe)				
5.2	Other dietary int.				

5.3	Other lifestyle int.				
5.4	Other int. eg screening				

No.	**Is the intervention:**	Int 1	Int 2	Int 3	Control
6.1	Tailored for specific group (gender, ethnic, socioeconomic)				
6.2	Individually tailored				
6.3	Tailored based on barriers and facilitators				
6.4	Theory based (theory of planned behaviour, stage of change, etc)				
6.5	Developed and worked on intention, attitude, and belief				
6.6	Developed and worked on self efficacy				
6.7	Developed and worked on social support				
6.8	Developed and worked on knowledge				
6.9	Developed and worked on motivation				
6.10	Using personal computer/ telephone/ printed messages/ emails				
6.11	Involve practical skills: demonstration, cooking skills, shopping skills, preparation skills, etc				
6.12	Involve role model				
6.13	Media based (television, radio, newspaper,etc)				
6.14	Accessibility intervention (pricing, access)				
6.15	Intensity of intervention (duration)				

6.16	Involve counselling or group session led by nutritionist/nurse/community workers				
6.17	Developed and worked on action plans				
6.18	Message as healthy or fun and tasty				
6.19	Planned target of intervention (servings/day)				
6.20	Dietary measurement (FFQ, 24-hour recall)				

Outcomes

Analysed content of <u>fruit and vegetable</u>

No.	**Mean daily intake (please give sds):**	Intervention 1:	Intervention 2:	Intervention 3:	Control
7.1	Total fruit and vegetable (servings/gram) at baseline (sd)				
7.2	Total fruit and vegetable (servings/gram) at end (sd)				
7.3	Change in total fruit and vegetable (servings/gram) (sd)				
7.4	Total fruit (servings/gram) at baseline (sd)				
7.5	Total fruit (servings/gram) at end (sd)				
7.6	Change in total fruit (servings/gram) (sd)				

7.7	Total vegetable (servings/gram) at baseline (sd)				
7.8	Total vegetable (servings/gram) at end (sd)				
7.9	Change in total vegetable (servings/gram) (sd)				

Biomarkers

No.	**Biomarkers**	Intervention 1:	Intervention 2:	Intervention 3:	Control
8.1	Time of data extraction (weeks)				
8.2	Numbers included in results				
8.3	α-carotene at baseline (sd)				
8.4	α-carotene at end (sd)				
8.5	Change in α-carotene (sd)				
8.6	β-carotene at baseline (sd)				
8.7	β-carotene at end (sd)				
8.8	Change in β-carotene (sd)				

Health Outcomes

No.	**Health Outcomes**	Intervention 1:	Intervention 2:	Intervention 3:	Control
9.1	Systolic blood pressure at baseline (mmHg) (sd)				
9.2	Systolic blood pressure at end (mmHg) (sd)				
9.3	Change in systolic blood pressure (mmHg) (sd)				
9.4	Diastolic blood pressure at baseline (mmHg) (sd)				
9.5	Diastolic blood pressure at end (mmHg) (sd)				
9.6	Change in diastolic blood pressure (mmHg) (sd)				
9.7	Mean BMI at baseline (sd)				
9.8	Mean BMI at end (sd)				
9.9	Change in BMI (sd)				
9.10	Mean weight at baseline (kg/lb/stones) (sd)				
9.11	Mean weight at end (kg/lb/stones) (sd)				
9.12	Change in weight (kg/lb/stones) (sd)				
9.13	Mean total cholesterol at baseline (mmol/L or mg/dL) (sd)				
9.14	Mean total cholesterol at end (mmol/L or mg/dL) (sd)				
9.15	Change in total cholesterol (mmol/L or mg/dL) (sd)				

9.16	Mean total LDL at baseline (mmol/L or mg/dL) (sd)				
9.17	Mean total LDL at end (mmol/L or mg/dL) (sd)				
9.18	Change in total LDL (mmol/L or mg/dL) (sd)				
9.19	Mean total HDL at baseline (mmol/L or mg/dL) (sd)				
9.20	Mean total HDL at end (mmol/L or mg/dL) (sd)				
9.21	Change in total HDL (mmol/L or mg/dL) (sd)				
9.22	Mean total triglycerides at baseline (mmol/L or mg/dL) (sd)				
9.23	Mean total triglycerides at end (mmol/L or mg/dL) (sd)				
9.24	Change in total triglycerides (mmol/L or mg/dL) (sd)				

Data to be collected:

- ***For all outcomes collect baseline data and change data where available, end data are only needed if change data are not available.***
- **Where studies present data at several time points we need to collect data on ALL time points presented. Note which was the primary outcome point.**
- **Collect data on men, pre-menopausal women, and postmenopausal women separately, but also extract any data presented on combined groups - on additional sheets where necessary.**

Adverse effects 1 – collect for ALL studies.

	Intervention 1:	Intervention 2:	Intervention 3:	Control
14.1 Numbers of people experiencing side effects (what?)				
14.2 Numbers of people dropping out due to adverse events (what?)				
14.2a Numbers excluded from analysis				Number: unclear
14.3 Please provide any available data on costs here (and overpage)				

Conclusions

15.1 List any data that it would be valuable to obtain from author(s) if possible (circle and add as necessary)

details of randomisation allocation concealment blinding

change data sds of the change from baseline

within patient differences between intervention and placebo sds of these differences

adverse effects reasons for dropouts

other:

15.2 Any other reviewer comments

15.3 Are data provided grouped specifically by: baseline risk of cardiovascular disease, baseline total and LDL cholesterol levels, use of lipid-lowering medication; carbohydrate level, calorific level or vitamin status? If yes, please circle which.
Yes No

Space for additional data or calculations:

Appendix 5

Protocol

The effects of increased fruit and vegetable intake on blood pressure and weight: A systematic review

1. Background

Chronic diseases such as coronary heart disease, stroke, cancer and diabetes are major causes of illness and mortality in the world (McAlister, Lawson et al. 2001; Chobanian, Bakris et al. 2003; World Health Organization 2005). Studies have concluded that high blood pressure and obesity are risk factors of coronary heart disease, stroke and other vascular diseases (Martin, Browner et al. 1986; Rashid, Leonardi-Bee et al. 2003; Avenell, Brown et al. 2004). Thus findings from prospective study with at least two decades of follow-up data namely Framingham Heart Study, the Manitoba Study and the Harvard School of Public Health Nurses Study concluded obesity as independent predictor of clinical coronary heart disease (Rabkin, Mathewson et al. 1977; Hubert, Feinleib et al. 1983; Manson, Colditz et al. 1990; Wilson, D'Agostino et al. 2002).

According to Egton Medical Information System (EMIS) blood pressure is the pressure in arteries or blood vessels which is measured in millimetres of mercury (mmHg). 'Systolic blood pressure is the pressure in the arteries when the heart contracts, while diastolic blood pressure is the pressure in the arteries when the heart rests between each heartbeat' (EMIS 2009). The Blood Pressure Association stated that 'high blood pressure is the biggest known cause of disability and premature death in the UK through stroke, heart attack and heart disease. Furthermore one in three adults in the UK had high blood pressure and everyday 350 people have a preventable stroke or heart attack caused by the condition' (Blood Pressure Association 2008). According to Health Survey for England 2006, 31% of male and 28% of women had high blood pressure and mean blood pressure levels were 130.8/74.2 mmHg in men and 124.0/72.4 mmHg in women (Falaschetti, Chaudhury et al. 2009). Recent surveys suggested that the mean body mass index (kg/m^2) for all adults (aged 16 or over) are

27.2 in men, and 28.0 in women which is classified as overweight. According to surveys 24% of adults were obese (BMI ≥30 kg/m^2) which is an overall increase from only 15% in 1993 (The NHS Information Centre 2009; Food Standards Agency 2010). And 47% of male and 41% of women who are obese had high blood pressure (The NHS Information Centre 2009). Hypertension is a condition of having a higher than average measurement in either systolic blood pressure (≥140 mmHg) or diastolic blood pressure (≥90 mmHg) (Falaschetti, Chaudhury et al. 2009).

Evidence from a study concluded that an increase in diastolic blood pressure of 10 mmHg may increase the risk of first stroke by one half (MacMahon, Peto et al. 1990). Thus a reduction of 6 mmHg in diastolic blood pressure may reduce one third risk of stroke and one fifth risk of coronary heart disease (Falaschetti, Chaudhury et al. 2009). Previous studies also stated that an increase in dietary fiber can lower blood pressure level (Sacks and Kass 1988; Ascherio, Hennekens et al. 1996). Previous recommendation stated that a modest reduce in weight loss has positive effects such as lowering blood pressure level, amend lipid profile and lower the risk of diabetes. A 5-7% weight loss is associated with clinical improvement which affirms the importance of modest weight loss for health benefits (Klein, Burke et al. 2004; Katz, O'Connell et al. 2005) Meanwhile according to a prospective cohort study among 21,414 male physicians in the Physicians' Health Study with 12.5 years of follow-up by Kurth (Kurth, Gaziano et al. 2002) an increase of BMI by one unit, may increase the risk of ischemic stroke by 4% and hemorrhagic stroke by 6% but the severity of stroke for ischemic stroke was not associated with BMI.

Result from previous studies concluded that modification to a person's lifestyle such as, weight loss, increase in potassium intake or adoption of the Dietary Approaches to Stop Hypertension (DASH diet) is crucial in the prevention of high blood pressure (Kesteloot 1984; Kromhout 1988; Appel, Moore et al. 1997; Whelton, He et al. 2002). The DASH diet is a program developed by the National Institutes of Health in the United States which aimed to lower blood pressure for people with hypertension or pre-hypertension in just 14 days (Amidon Press 2010). It is a diet low in saturated fat but high in potassium, calcium and magnesium. The diet also requires daily servings of 4-6 portions of fruit and vegetables. Fruit and vegetable are full of vitamins, minerals and fibre which are good for the body. Fruit and vegetable also contains potassium which can counteract the negative effects of salt and keep blood pressure down (Blood Pressure Association 2008).

Despite positive effects of fruit and vegetables recent surveys from the United States and UK concluded that fruit and vegetable consumption in both countries were still below the recommended intake. In the US 75.7% of adults consumed less than five or more servings per day (US Centers for Disease Control & Prevention and National Center for Chronic Disease Prevention and Health Promotion 2007). Similarly according to a recent survey in the UK on average UK adults eat 4.4 portions of fruit and vegetable a day. Among them 62.6% of men and 66.7% of women eat less than five portions a day (Food Standards Agency 2010).

The positive effect of dietary factors in lowering coronary heart disease was recently evaluated by Mente (Mente 2009). The review included 507 cohorts and 94 randomised controlled trials. Pooled estimates from cohort studies found that an increased consumption of fruit and vegetables, were significantly associated with lower risk of coronary heart disease, the relative risk for fruit was 0.80 (95%CI 0.66 to 0.93) and vegetables 0.77 (95%CI 0.68 to 0.87) respectively. On the other hand pooled estimates from randomised controlled trial did not find significant effects in relative risk 1.01 (95%CI 0.74 to 1.27). The review emphasised on checking whether the evidence from RCT was concordant with that of cohort studies using Bradford Hill guidelines for scoring based on four criteria namely, strength, consistency, temporality and coherence. However the study did not include data on mean changes in health indicators such as blood pressure and weight to support self report dietary data from food frequency questionnaires.

A meta-analysis conducted by Whelton (Whelton, Hyre et al. 2005) assessed the effect of dietary fibre intake on blood pressure. The analysis included 25 randomised controlled trials either parallel or crossover design with any duration and published in English before February 2004. The study included all randomised controlled trials in adults, with or without hypertension. They included all types of fibre in the analysis which includes fruit or vegetables, cereal and fibre pills. The study also included intervention with or without weight reduction. Results concluded significant effect of dietary fiber on hypertensive participants: 5.95 mmHg (95%CI -9.50 to -2.40) decrease in systolic blood pressure and 4.20 mmHg (95%CI -6.55 to-1.85) decrease in diastolic blood pressure. Significant effect was also found in studies with ≥8 weeks of duration: 3.12 mmHg (95%CI -5.68 to -0.56) decrease in systolic blood pressure and 2.57 mmHg (95%CI -4.01 to -1.14) decrease in diastolic blood pressure. Due to the broad inclusion criteria mentioned above, it is not possible to analyse the effect of fruit and vegetable in particular to blood pressure.

Two other systematic reviews investigated the effects of diet to blood pressure (Hooper, Kroon et al. 2008; Ried, Frank et al. 2008). Hooper (Hooper, Kroon et al. 2008) investigated the effects of interventions aimed to increase flavonoids intake on cardiovascular risk factors: systolic and diastolic blood pressure, LDL and HDL. A total of 133 randomised controlled trials with healthy adult participants (not critically ill or pregnant) were included. The result of comparison between treatment and control groups concluded that chocolate reduced systolic blood pressure by 5.88 mmHg (95%CI -9.55 to -2.21) and diastolic blood pressure by 3.30 mmHg (95%CI [-5.77, -0.83]), while soy protein isolate (but not other soy product or components) was also able to reduce diastolic blood pressure by 1.99 mmHg (95%CI -2.86 to -1.12). There was insufficient evidence to draw conclusions about efficacy in other types of flavonoids. On the other hand, Ried (Ried, Frank et al. 2008) examined the effect of garlic on blood pressure. A total of 11 studies (randomised controlled trial and non-placebo controlled trials) were included in the meta-analysis. A subgroup meta-analysis on normal or hypertensive systolic and diastolic blood pressure participants before and after the intervention concluded that the effects of garlic was more significant in hypertensive participants: systolic blood pressure was able to decrease by 8.38 mmHg (95%CI -11.13 to -5.62) in hypertensive participants as compare to a decrease of 2.28 mmHg (95%CI -4.61 to 0.05) in normal participants. Similarly a more significant effect was also found in diastolic blood pressure in hypertensive participants: a decrease of 7.27 mmHg (95%CI -8.77 to -5.76) while in normal participants there was a decrease of 0.06 mmHg (95%CI -1.37 to 1.25). Ried's review included published papers in English and German which raises the issue of publication bias, in translating the papers from German to English. Both of the reviews revealed that there is evidence on the effects on garlic and flavonoids in relation to blood pressure level, but none specifically on fruit and vegetables.

A recent systematic review assessed interventions on weight loss (Franz, Van Wormer et al. 2007). The review investigated eight types of interventions: diet only, diet and exercise, exercise only, meal replacements, very-low-energy diets, weight-loss medications (orlistat and sibutramine) and advice only. The review included randomised controlled trials with at least 1 year of follow-up. 47 of 80 studies from the systematic review were included in the meta-analysis. Findings from meta-analysis comparing diet only and exercise advice only concluded that there were 3.7±4.3 kg (6 months), 4.5±4.1 kg (12 months), 3.3±5.9 kg (24 months) and 2.2±6.2 kg (36 months) more weight loss in the diet only group compared to advice only groups. The homogeneity test showed that effect sizes were significantly heterogeneous across studies at six months, ($Q_{6mo}(6)=22.05$, $P<0.001$ and 12, $Q_{12mo}(9)=364.27$, $P<0.001$). There were several limitations to the study. Firstly the study included overweight and obese participants therefore we could not analyse the true preventive effects weight loss in the same matter as if we only included healthy and non-risk adults. Secondly the intervention on diet includes high protein diets and reduced-energy diet, but none on fruit and vegetables. It may be concluded that there is lack of evidence on the effects of fruit and vegetable interventions to weight loss.

Despite positive effects of fruit and vegetables in lowering health factors risks leading to chronic diseases there is a gap in systematic review analyzing the effects of interventions to increase fruit and vegetable intake on health indicators (systolic blood pressure, diastolic blood pressure and weight) in healthy adults in relation to primary prevention of chronic diseases. In order to analyse such effect a systematic review which include all interventions aimed at increasing fruit and vegetable intake on healthy adults (aged 16 or over) who are not pregnant or ill and without high-risk of health (overweight or obese, diabetes, or hypertension) with follow-up of three months or more and have outcomes on blood pressure, and/or weight should be conducted. This systematic review is the second study which is part of a systematic review on fruit and vegetable intervention on healthy adults. The first study analysed elements of interventions that works best to increase fruit and vegetable intake which was a follow-up to Pomerleau's review (Pomerleau, Lock et al. 2005) published in 2005. For the first study I collected outcomes data on fruit and vegetable intake, α-carotene and β-carotene, systolic blood pressure, diastolic blood pressure, weight, body mass index, total cholesterol, LDL, HDL and triglycerides. However, for this particular study, I will focus on systolic blood pressure, diastolic blood pressure and weight outcomes only.

2. Objectives

The review aimed at analyzing the effects of intervention to increase fruit and vegetable intake on health indicators (systolic blood pressure, diastolic blood pressure and weight) in healthy adults and more specifically whether an increase in fruit and vegetable intake (portions per day) has significant effects on systolic blood pressure (mmHg), diastolic blood pressure (mmHg) and weight (kg) in the intervention and control groups.

3. Methods

3.1. Type of studies

I will include all randomised controlled trial (RCTs) that describe 'random' or 'randomisation' to participants including cluster randomisation of at least six groups or communities with follow-up of three months or more, and aimed at increasing fruit and vegetable intake.

3.2. Type of participants

I will include all studies with adults participants (age 16 and above). The review only includes healthy adults therefore I will exclude intervention that aimed at participants with high-risk of cardiovascular disease (obese, hypertensive, smokers) and pregnant women.

3.3. Type of outcome measures

The main outcome are estimated mean differences in systolic blood pressure (mmHg), diastolic blood pressure (mmHg) and mean change in weight (kg) for each intervention and control group as well as standard deviation for each outcome. In addition the estimated mean difference of fruit and vegetable intake (portions per day) between the intervention and control group collected either from total fruit and vegetable intake (portions per day) at the end of intervention or change data of fruit and vegetable intake (portions per day) in intervention and control group after the intervention.

3.4. Search methods

This is the second study which follows previous systematic review on interventions to increase fruit and vegetable intake in healthy adults. The first study was build upon previous systematic review by Pomerleau (Pomerleau, Lock et al. 2005). Therefore I will search for studies from beginning of 2004 to May 2010 from six databases, based on previous search conducted for the first study:

- Cochrane library.
- MEDLINE.
- EMBASE.
- LILACS.
- PsycINFO.
- ERIC.

3.4.1. Search strategy for identification of studies

Search strategies for each of the databases will be based on the filtering strategies for randomised controlled trial on the Cochrane Library Handbook (Higgins and Green 2008).

3.4.2. Search strategy

Search strategy for each database is available in the Appendix 2.

4. Data collection and analysis

4.1. Study selection

The titles and abstract from our first review will be independently screened by two review authors to select for inclusion in the study. Each study will be selected based on the following inclusion criteria: whether the study is randomised, have control group, aimed at increasing fruit and vegetable intake, individual/population based, involving healthy adult participants, have three months of follow-up and have data outcomes available on systolic and diastolic blood pressure or weight (see Appendix 6).

4.2. Data extraction

Six reviewers will independently extract data on participants, interventions, outcomes, and trial quality of included studies. For consistency, the main researcher will data extract every study. The result from each reviewer will be discussed with the main researcher and any differences will be resolved by discussion until a consensus has been reached.

4.3. Risk of bias

I will analyse the risk of bias of included studies according to Cochrane Handbook (Higgins and Green 2008) in concordance with risk of bias criteria appended in our first study the points considered are:

- Whether the process of randomisation was described.
- Whether randomisation was adequately concealed.
- Whether the researchers were blinded to interventions.
- Whether participants were blinded to interventions.
- Whether industry funding was reported.
- Whether the description of participants in each arm was adequately described (loss of follow-up description in each arm).
- Whether selective outcome reporting was present (compare the methods in the protocol to data in the publication).

Each study will be categorized according to the points stated above as either 'yes', 'no', or 'unclear' and based on this categorization, the study was then considered as being at low, high or unclear risk of bias according to the following criteria:

- A study will be categorized as 'low risk of bias' if the process of randomisation was adequate (using opaque envelope, random numbers, or a computer system). Randomisation was adequately concealed (using a sealed opaque envelope or if there was a specific person appointed to do the randomisation), the researchers were masked to interventions, participants were masked to interventions, all the participants who were being randomised and had any of the intervention were included in the outcome (intention to treat was done), descriptions of participants in each arm were adequately described and no industry funding involved.

- A study will be categorized as 'high risk of bias' if the process of randomisation was inadequate (using opaque envelope, random numbers or a computer system). Randomisation was inadequately concealed (using a sealed opaque envelope or if there was a specific person appointed to do the randomisation), the researchers were not masked to interventions, participants were not masked to interventions, all the participants who were being randomised and had any of the intervention were not included in the outcome (intention to treat was done) and descriptions of participants in each arm were inadequately described.
- A study that do not fall under 'low risk of bias' or 'high risk of bias' will be automatically categorized as having 'unclear risk of bias'.

4.4. Analysis

I will extract the outcomes data on systolic blood pressure (mmHg), diastolic blood pressure (mmHg), and weight (kg). I will convert the data into mmHg for blood pressure and kg for weight where necessary then I will conduct meta-analysis on the end of follow-up or mean change data and standard deviation using Cochrane Review Manager (RevMan) (The Nordic Cochrane Centre 2011). I will use mean change data if both end and mean change data were available. Weighted mean differences and 95% confidence intervals will be reported for continuous outcomes. Standard deviations will be calculated from standard error where necessary.

To decide whether heterogeneity (genuine variation in effect sizes) was present I will conduct a test of heterogeneity. According to Higgins (Higgins 2003; Higgins and Green 2008), heterogeneity can be detected by both the value of I^2 and the result of heterogeneity test (P-value). If $I^2>50\%$ and P-value≤ 0.05 then the heterogeneity present in the studies is substantial. To anticipate with heterogeneity I will perform random effects model. In addition funnel plots will be use to assess the evidence of publication bias or small study effects (Egger, Smith et al. 1997).

Appendix 6

Inclusion/exclusion form

Health indicators review, 2009

Inclusion/exclusion form

Trial: author year

journal ref unique identifier

in/outed by: Silvia Devina, Lee Hooper

1.	**randomised? (randomised controlled trial)**	**y / n / ?**
2.	**control group? (no dietary advice, other advice)**	**y / n / ?**
3.	**increase fruit and vegetable intake?**	**y / n / ?**
4.	**individual or population based intervention?**	**y / n / ?**
5.	**healthy adult human (no acute illness, not pregnant)?**	**y / n / ?**
6.	**follow-up time of at least 3 months?**	**y / n / ?**
7.	**data available on diet outcomes?**	**y / n / ?**
8.	**data available on blood pressure or weight?**	**y / n / ?**

Studies are 'in' if all questions have yes answers, 'out' if any question has a 'no' answer and 'pending' if any answer is unclear.

in **out** **pending**

Full text papers: Data extract included studies and note reason for exclusion of excluded studies.

action:

number randomised:

intervention and dose:

reason for exclusion:

Additional detail for in/out form:

Question 1: The study included must be randomised controlled trial. A clear random allocation procedure should be described, mentioning ‘random’ or ‘randomisation’. We will include matched pairs or cluster randomisation. Alternation or allocation based on family name, date of birth etc is not random and so should be excluded.

Question 2: The control group must receive no treatment (placebo) or other type of intervention to increase fruit and vegetable intake, or treatment aiming other than increasing fruit and vegetable intake (i.e. physical activity, smoking cessation, breast self examination). Studies with control group which did not fit to the criteria above will be excluded.

Question 3: The intervention group must be advised to increase consumption of fruit and vegetable. We will include pricing initiative on fruit and vegetable. Studies without intervention to increase fruit and vegetable intake will be excluded.

Question 4: We include all individual and population based studies aiming at increasing fruit and vegetable intake which stated clearly in the methods that in the intervention arm it advised to increase fruit and vegetable, while it was not provided in the control arm. We include studies with one intervention (i.e. aiming at increasing fruit and vegetable intake or healthy eating) or multi-component intervention (i.e. targeting fruit and vegetable intake with physical activity, smoking cessation or breast self examination program). Interventions include dietary counselling sessions, group lectures, workshops, computer-generated tailored nutrition newsletters or any combination of these. Studies not aiming at increasing fruit and vegetable intake will be excluded.

Question 5: We include study involving healthy adults above 16 years of age that are not acutely ill and living independently (pregnant women and people with chronic diseases such as, CVD, diabetes, cancer will be excluded).

Question 6: We include studies with at least 3 months follow-up time. Studies with less than 3 months follow-up time will be excluded.

Question 7: Studies will be ‘included’ if they report any of our stated outcomes. If they do not state any of these outcomes in published papers they will be classified as ‘pending’, and not included at this stage (we are not writing to authors this time). Ongoing studies (which have not published any outcomes) will be excluded.

Outcomes for assessment of inclusion:

- food frequency questionnaire
- food diary
- 24-hour recall
- short questionnaire
- dietary questionnaire
- self reported dietary intake

– 4 day food records (4DFR)
– serum vitamin C
– blood pressure measurement

Question 8: Studies will be 'included' if they report data on systolic and diastolic blood pressure or weight. Studies without systolic and diastolic blood pressure or weight data of participants will be excluded.

Appendix 7

Table 1 Details of included studies

No.	Study	Participants	Interventions	Outcomes
1.	Alexander(Alexander, McClure et al. 2010) USA	2540 participants from five health plans (community intervention). Gender: I1: 69%f I2: 69%f C: 69%f Mean age: I1: 46.5(10.8) I2: 46.4(10.9) C: 46.1(10.6)	Intervention 1: • Tailored behavioural intervention using website (basic level). Website was tailored to participants' needs, dietary preferences and interests. Four sessions: 4-5 pages core content, illustrations, optional links, special features (serving sizes, nutritional similarities of frozen and canned food, 300 recipes). Intervention 2: • Tailored behavioural intervention plus motivational interviewing based counselling via email: same as above but plus four added email counselling sessions based on motivational interviewing. Control: • Online untailored program: general fruit and vegetable nutrition information.	• Follow-up at 12 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
2.	Bradbury(Bradbury, Thomason et al. 2006) UK	58 edentulous patients at dental hospital (community intervention). Gender: I: 67%f C: 47%f Mean age: I: 65.4 C: 66.6	Intervention: • Two individual dietary counselling with nutritionist. • Individual tailored nutrition messages based on answer to questions (knowledge of diet-disease relationship, barriers, diet requirements, gender, BMI). Control: standard care.	• Follow-up at 18 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
3.	Buller(Buller, Morrill et al. 1999) USA	2,091 employees from 10 public employers (workplace intervention).	Intervention: • General 5 a day: mail, posters, cafeteria promotion, guest speakers.	• Follow-up at 24 months. • Outcomes of fruit and vegetable intake.

No.	Study	Participants	Interventions	Outcomes
		Gender: 26%f (unclear between groups). Mean age: 43.13(10.07) (unclear between groups).	• 5 a day peer education: group leader was selected at each workplace to influence and discuss with other co-workers (given printed 5 a day once a month, materials/guidebook: nine themed booklets, newsletters and recipes in Anglo and Mexican diet). Control: • General 5 a day: mail, posters, cafeteria promotion, guest speakers.	• Dietary intake was measured by FFQs and 24-hour recalls.
4.	Cookin' Up Health(Tessaro, Rye et al. 2006; Tessaro, Rye et al. 2007) USA	262 women in rural clinics (community intervention) Gender: 100%f Mean age: I: 49.95 C: 50.56	Intervention: Computer based interactive nutrition intervention about 'oven-fried chicken' recipe, nutritional message, and labels. Each woman also received a refrigerator magnet about correct portion sizes and recipe booklet. Control: none <u>Aimed also at lowering fat intake</u>	• Follow-up at 3 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
5.	De Vries(De Vries, Kremers et al. 2008) The Netherlands	2827 participants from random address in the Netherlands (community intervention). Gender: 50%m, 50%f (unclear between groups). Mean age: 49.0(10.6) (unclear between groups).	Intervention: • Three tailored health education letters. Control: • Three generic health education letters. <u>Aimed also at lowering fat intake, smoking cessation and increasing physical activity</u>	• Follow-up at 9 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.

No.	Study	Participants	Interventions	Outcomes
6.	Eating for a Healthy Life(Bowen, Beresford et al. 2004; Bowen, Beresford et al. 2009) USA	2175 members of religious organizations (community intervention). Gender: I: 84.2% C: 86.8% Mean age: unknown	Intervention: • Volunteer advisory board. • Dietary change mailings: pamphlets and brochure based on stage of change. • Motivational messages printed on posters and flyers. • Social activities. • Healthy eating sessions: choosing and preparing healthy food. • Health policies. Control: none	• Follow-up at 12 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
7.	Expanded Food and Nutrition Education Program(Del Tredici, Joy et al. 1988) USA	683 individual from 15 counties (low-income, majority from ethnic minorities) (community intervention). Gender: unknown Mean age: I: 28.7(8.3) C: 29.9(9.0)	Intervention: Teaching and nutrition education from nutrition assistants. Control: none	• Follow-up at 6 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
8.	Good Grubbin(Clifford, Anderson et al. 2009) USA	101 students from upper-level non-health courses who were living off-campus (university intervention). Gender: 63%f (unclear between groups). Mean age: unknown	Intervention: Four weekly episodes of the cooking show ‘Good Grubbin’ which students explain struggles and successes with a particular meal-planning or nutritional issue, registered dieticians took the student to the grocery store, cooking demonstration, interview on how students overcome barriers through strategies learned on the show.	• Follow-up at 4 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.

No.	Study	Participants	Interventions	Outcomes
			Control: four weekly episodes on sleep disorders. Aimed also at sleep disorder and weight loss	
9.	Greene(Greene, Fey Yensan et al. 2008) USA	1277 participants aged 60 years or older from physician practices in rural Virginia (community intervention). Gender: 27.1%m, 72.9%f (unclear between groups). Mean age: 74.73(6.44) (unclear between groups).	Intervention: • Monthly contact by mails or phone calls. • Manuals (recipe tips to increase fruit and vegetables). • Monthly newsletters (stage based) –expert report-computer based-stories, tips, suggested activities, interactive section, recipes. • Coaching calls 3x15min 4-6 weeks after expert reports. Control: Manual on exercise or fall-preventions.	• Follow-up at 12 months and 24 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by NCI fruit and vegetable screeners, five a day screeners, and single item screeners.
10.	Health Works for Women(Campbell , Tessaro et al. 2002) USA	859 workers from nine small to mid-size workplaces (workplace intervention). Gender: 100%f Mean age: unknown	Intervention: • Computer tailored messages: two individualized computer tailored messages in the format of women magazines consist of name, workplace, age, shift, health concerns, and current health behaviours (fat, fruit and vegetable, physical activity, smoking, cancer screening) and choice of behavioural priority for change. The magazine consist of testimonial story, advice column, behavioural feedback section, stage-specific action plan, community resources, social support 'buddy' message, recipes or exercises. • Social support activities used workplace natural helpers recruited from each workplace to share information, organized activities such as walking groups, promote healthy vending machine choices, held interactive activities (games, role plays, group discussions and skill	• Follow-up at 6 months and 18 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.

No.	Study	Participants	Interventions	Outcomes
			training). Control: delayed Aimed also at lowering fat intake, increasing exercise, smoking cessation, and cancer screening.	
11.	Heimendinger(Heimendinger, O'Neill et al. 2005) USA	3,402 callers to Cancer Information Service (CIS) (community intervention). Gender: 82%f (unclear between groups). Mean age: unclear between groups.	Intervention 1: Single tailored (ST) • Twelve pages tailored booklets (participant's name, number of servings, cost comparison). • Four pages pamphlets with feedback on consumption, skill building. Intervention 2: Multiple tailored/Brief Educational Message+Single Tailored (MT) (idem to above) plus: • Three more mailings (twice 4 pages newsletters and 2 pages letters). Intervention 3: Multiple Retailored /Brief Educational Message+Multiple Retailored Print Communications (MRT) • Idem to MT but retailored based on 5 months follow-up information. Intervention 4: Single Untailored (SU): Booklet pamphlet (12 page)	• Follow-up at 5 months and 12 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
12.	Heneman(Heneman, Block Joy et al. 2005) USA	38 low income women (community intervention). Gender: 100%f Mean age: unknown	Intervention 1: Education Group • Expanded Food and Nutrition Education/Food Stamp Nutrition Education "Food Guide Pyramid" lesson (1 hour classes for 4 weeks): healthful approaches to eating and in-depth discussions of the components of the USDA Food Guide Pyramid.	• Follow-up at 9 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.

No.	Study	Participants	Interventions	Outcomes
			Intervention 2: Contract Group Same as above plus contract for change: dietary goals for target populations. Control: life-skills lessons: money management.	
13.	High 5(Reynolds, Franklin et al. 2000; Haire-Joshu, Brownson et al. 2003; Haire Joshu, Elliott et al. 2008) USA	1306 parents and their children (community intervention). Gender: I: 98.5%f C: 98.4%f Mean age: I: 29.1(8) C: 29.4(8)	Intervention: 1. Five personal visits: • Assess current intake • Read nutrition label • Shopping tips • Food tips while eating out • Recipe modification 2. Ten bimonthly newsletters 3. Group meetings Control: none <u>Aimed also at lowering fat intake</u>	• Follow-up at 5 years. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs
14.	The Hiraka Dietary Intervention Study(Takashashi, Sasaki et al. 2003) Japan	550 volunteer (community intervention). Gender: I: 67.4%f C: 66.1%f Mean age: I: 56.3(7.7) C: 56.6(8.0)	Intervention: • Two counselling (15 minutes each) • One group lecture • Two newsletters • Forty page leaflets: info, tips on cooking • 4-5 leaflets computer tailored • Two motivation newsletter Control: none <u>Aimed also at lowering sodium/salt</u>	• Follow-up at 24 months. • Outcomes of fruit and vegetable intake, α-carotene, and β-carotene. • Dietary intake was measured by FFQs.
15.	Kristal (Kristal 1997) USA	740 shoppers from 8 supermarkets (community intervention). Gender: 84%f (unclear between	Intervention: • Weekly flyers f&v on sale, recipe, menu idea, voucher on f&v	• Follow-up at 8 months. • Outcomes of fruit and vegetable intake.

No.	Study	Participants	Interventions	Outcomes
		groups) Mean age: unknown	• Label/sign in store • Food demo two times a month Control: None	• Dietary intake was measured by FFQs.
16.	Lutz(Lutz 1999) USA	710 health maintenance organization clients (community intervention). Gender I1: 63.1%f, 36.9%m I2: 63.3%f, 36.7%m I3: 67.8%f, 32.2%m C: 63.3%f, 36.7%m Mean age I1: 39.2(0.78) I2: 38.4(0.73) I3: 38.6(0.73) C: 38.9(0.73)	Intervention 1: • Tailored based on baseline survey result • Computer newsletter • Printed tips Intervention 2: • Tailored +3 sub-goals Intervention 3: • Non-tailored newsletter Control: None	• Follow-up at 6 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQ.
17.	Macdonald(Macdonald, Black et al. 2008; Macdonald, Hardcastle et al. 2009) UK	276 postmenopausal women (community intervention). Gender: 100%f Mean age: I1: 59.6 I2: 59.7 I3: 59.2	Intervention 1: High-dose potassium citrate group (given two dose=55.5 mEq/d potassium citrate). Intervention 2: Low-dose potassium citrate group (given one dose=18.5 mEq/d potassium citrate). Intervention 3: Diet group (given additional 300gr fruit and vegetables per day) and also additional interventions as	• Follow-up at 24 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by Food diary (3 days dietary checklist).

No.	Study	Participants	Interventions	Outcomes
		C: 59.7	follows: • Nutritionist calculated the portions of fruit and vegetables to be eaten (daily intake from food diary plus 300gr). • Research nurse used a range of photograph to explain a portion size. • Financial contribution $2 per day to purchase fruit and vegetables. Control: none	
18.	Marcus 1998(Marcus 1998) USA	2109 callers to the Cancer Information Service (CIS) (community intervention). Gender: 80% f (unclear between groups) Mean age: unclear between groups	Intervention: Individual tailored telephone education + two follow-up mail outs (targeted message) consisted messages as follows: • At breakfast have a glass of juice. • At lunch eat cut up fruit and vegetable as snack. • At dinner add raw vegetable to salad. • For snack keep a bowl of fruit on the kitchen counter. • When eating out, choose a restaurant with salad bar. Control: none	• Follow-up at 4 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs and 24-hours recalls.
19.	Marcus 2001(Marcus, Heimendinger et al. 2001) USA	861 callers to Cancer Information Service (community intervention). Gender: 78.7%f (unclear between groups) Mean age: unclear between groups	Intervention: • Tailored telephone interview consisted of short series of educational and motivational messages tailored to readiness to change. • Two packets materials consisted of booklet of suggestions, worksheets, recipes, bookmark, and refrigerator magnets. Control: none	• Follow-up at 4 months and 12 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs and 24-hour recalls.

No.	Study	Participants	Interventions	Outcomes
20.	Mediterranean Eating Study(Djuric, Vanloon et al. 2008; Djuric, Ren et al. 2009) USA	69 women 25-59 years of age, (community intervention). Gender: 100%f Mean age: 44 (unclear between groups)	Intervention: Telephone counselling at baseline and 3 months by a dietitians. Exchange list of fats and fruit and vegetables recommendation, seven days example of menus. Control: no telephone counselling, if vitamin/mineral <67% of recommended, then list of food from National Cancer Institute action guide was sent. <u>Aimed also at reducing fat by ½ replace by olive oil, increasing by 1 serving of herbs</u>	• Follow-up at 3 months and 6 months. • Outcomes of fruit and vegetable intake, α-carotene, β-carotene. • Dietary intake was measured by 7 days food records.
21.	The Next Step Trial(Tilley, Glanz et al. 1999) USA	5,042 employees from 28 countries (workplace intervention). Gender: I: 3%f C: 2%f Mean age: I: 55 C: 58	Intervention: • Five nutrition classes • Mailed self-help materials • Posters • Personalized feedback: graphic comparison to USDA food guide pyramid and motivational messages based on stage of dietary change and results from FFQs. • Quarterly newsletter consisted of information on screening and nutrition. Control: none <u>Aimed also at lowering fat and increasing fiber intake</u>	• Follow-up at 24 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
22.	NC Strides Study (NCCCS)(Campbell, Carr et al. 2009) USA	735 participants from 33 county areas (community intervention). Gender: I1: 13.3%f I2: 10.9%f C: 12.7%f	Intervention 1 (TPC): Four individually tailored newsletters. Intervention 2 (TMI): Four individually tailored telephone motivational calls (20 minutes each).	• Follow-up at 12 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.

No.	Study	Participants	Interventions	Outcomes
		Mean age: I1: 66.2(10.5) I2: 67.1(9.5) C: 66.6(10.1)	Intervention 3 (TPC+TMI): Four individual newsletters and Four motivational telephone calls. Control: colon cancer awareness <u>Aimed also to increase physical activity and colon screening</u>	
23.	Oxford Trial(John, Ziebland et al. 2002; Huxley, Lean et al. 2004) UK	690 healthy participants from Primary-Care Health Centres (community intervention). Gender I: 53%m, 47%f C: 45%m, 55%f Mean age I: 45.7(10.1) C: 46.0(10.1)	Intervention: Brief negotiation method using leaflets, telephone from nurses, letters+booklets of recipes and strategy checklists. Control: delayed	• Follow-up at 6 months. • Outcomes of fruit and vegetable intake, α-carotene, β-carotene, systolic and diastolic blood pressure, and weight. • Dietary intake was measured by FFQs.
24.	PREMIER(Svetkey, Harsha et al. 2003; Writing group of the PREMIER collaborative research group 2003; Campbell, Resnicow et al. 2007) USA	810 adults participants with above optimal blood pressure (community intervention). Gender: 62%f (unclear between groups). Mean age: 50.0(8.9) (unclear between groups).	Intervention 1: Eighteen face to face (14 group meeting) and 4 individual counselling sessions, no goals on fruit and vegetables, instead goals to lower dairy saturated fat by 10% less and fat goal by 30% less. Intervention 2: Established + DASH: instructions plus counselling on DASH diet. Intervention 3: Advice only: one 30 minutes individual session on non-pharmacological factors that affect blood pressure. <u>Aimed also at increasing physical activity, lowering total energy intake, substituting high fat and calorie food</u>	• Follow-up at 6 months. • Outcomes of fruit and vegetable intake, systolic and blood pressure, weight. • Dietary intake was measured by FFQs.

No.	Study	Participants	Interventions	Outcomes
25.	The Puget Sound Eating Patterns Study(Kristal, Curry et al. 2000) USA	1,459 adults selected randomly from computerized lists (community intervention). Gender: 50.9%m (unclear between groups). Mean age: 44.9(14.9) (unclear between groups).	Intervention: Individually tailored self-help, which consisted of the following: • Help-yourself manual: short and long-term benefit, suggestions, skills (label reading and grocery shopping). • Dietary change materials: tip sheets, refrigerator magnet, recipe cards, shopping list, evaluations. • Behavioural feedback: analysis of nutrient intake, positive feedback of food choice, quantitative goals, recommendations. • Motivational telephone calls: encouragements to use materials, acknowledge motives based on stage of change. • Newsletters: seasonal info on purchase and preparation, enhance motivation. Control: none	• Follow-up at 3 months and 12 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
26.	Resnicow(Resnicow, Davis et al. 2008) USA	512 African American (community intervention). Gender: I: 73.1%f C: 70.2%f Mean age: I: 48.3 C: 48.0	Intervention: • Three tailored newsletter (8 pages each once a month). • Two recipe cards. • Small bag of spices. • Refrigerator notepad or magnet with fruit and vegetables information. Control: • Same as above but not motivational interview.	• Follow-up at 3 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
27.	Rio Grande(Woodall, Buller et al. 2007; Buller, Woodall et al. 2008) USA	762 adults from Upper Rio Grande Valey (community intervention).	Intervention: 5 a day rio grande website consisted of:	• Follow-up at 4 months. • Outcomes of fruit and

No.	Study	Participants	Interventions	Outcomes
		Gender I: 12%male, 88%female. C: 12%male, 88%female. Mean age: unknown	• Information of healthy benefit of fruit and vegetables. • Instructions on buying, storing, preparing family diet (children), gardening, recipes, directory of sellers, garden supply, and health resource listing. Participants were asked to log in once a month for 4 months, every 2 months participants received a small gift reminder to visit web. The community outreach trainers instructed participants to visit website. Control: none	• vegetable intake, α-carotene, β-carotene, and weight. • Dietary intake was measured by all day screeners.
28.	Sorensen(Sorensen 2007) USA	582 construction workers members of Labourers' International Union of North America (LIUNA) (community intervention). Gender: I: 6%f C: 5%f Mean age: I: 40.3 C: 40.8	Intervention: • Tailored: telephone counselling, feedback report, and targeted education materials. • One-to-one motivational interviewing counselling sessions by telephone with a health advisor. • A mailed tailored feedback report. • Mailed written educational materials targeted to the specific needs and work experiences of construction labourers. Control: none <u>Aimed also at smoking cessation</u>	• Follow-up at 6 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
29.	South London(Steptoe 2003; Steptoe, Perkins Porras et al. 2004; Perkins-Porras, Cappuccio et al. 2005) UK	271 patients from one primary health centre (community intervention). Gender: unknown Mean age: I: 43.3(13.8) C: 43.2(14.0)	Intervention: • Two 15 minutes individual counselling by nurse to increase fruit and vegetables benefit nutrition content, 5-a-day message, varieties of fruit and vegetables. • Change in behaviour tailored to individuals namely, specific advice, setting short and long-term goals to incorporate fruit and vegetables in diet dealing with obstacles.	• Follow-up at 12 months. • Outcomes of fruit and vegetable intake, β-carotene, systolic and blood pressure, total cholesterol, weight. • Dietary intake was measured by FFQs.

No.	Study	Participants	Interventions	Outcomes
			Control: General individual counselling by nurse (not personal advice)	
30.	Steenhuis(Steenhuis, Van Assema et al. 2004) The Netherlands	17 workplace cafeterias (workplace intervention). Gender: 38%f (unclear between groups). Mean age: 38 (unclear between groups).	Intervention 1: Food supply Program (FSP) + Educational Program (EP): • FSP: Increased availability of low-fat products, fruits and vegetable, butter/margarine, milk, cheese, meat products, desserts and snacks. • EP: posters, brochures, table tents, and self-help manual, newsletters, badges for personnel, and contests. Intervention 2: Labelling Program (LP) + Educational Program (EP) • LP: Six food in the FSP were labelled with signs in front of the products: logo, name of item, indication that it is low-fat, fruit and vegetables. • EP: posters, brochures, table tents, and self-help manuals, newsletters, badges for personnel, and contests. Intervention 3: Educational Program (EP) • EP: posters, brochures, table tents, and self-help manual, newsletters, badges for personnel, and contests. Control: no program	• Follow-up at 6 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
31.	WATCH Project(Campbell, James et al. 2004) USA	587 African American members of 12 rural area (community intervention). Gender: I1: 72.4%f I2: 73.6%f	Intervention 1: Lay Health Advisor (LHA) appointed by members of each church which assisted in the following: • Provided information/knowledge. • Organized and conducted at least three church-wide	• Follow-up at 9 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.

No.	Study	Participants	Interventions	Outcomes
		I3: 74.0%f C: 77.3%f Mean age: 52 (unclear between groups)	• activities: spread info, enhance supports on healthy eating, physical activity and colorectal cancer screenings, walking/exercise groups, taste tests, provided healthy food choices at church-wide events, invite local physicians to speak at Sunday services. Intervention 2: Tailored Print and Video (individually and group tailored to African American) which intervened participants as follows: • Four personalized computer-tailored newsletters which were tailored to group and consisted of graphic design, photographs, stories, and recipes. And also tailored to individual, consisted of the following: name of participant, pastor, church, and tailored elements, feedback of fruit and vegetables consumptions. • Four group targeted videotapes mailed bimonthly: featuring community members and pastor consisted of how to prepare fruit and vegetables, serving size, five-a-day goal, testimonials, and pastor giving sermons. Intervention 3: LHA+TPV (combined) Control: health education sessions on HIV/AIDS, adolescent health child care and health, prostate cancer awareness, elderly health and also consisted of LHA training manuals and sessions, tailored newsletters, and targeted videos. <u>Aimed also at increasing physical activity and awareness of colorectal cancer screening</u>	
32.	WellWorks(Sorensen, Stoddard et al. 1998; Sorensen, Stoddard et al. 2002)	Fifteen workplaces which employed 400-2000 workers, used chemical hazard, had turnover of less than 20% (workplace	Intervention: 1. Food catering-cafeteria policies 2. Nutrition target setting	• Follow-up at 2 years. • Outcomes of fruit and vegetable intake.

No.	Study	Participants	Interventions	Outcomes
	USA	intervention). Gender: I: 33.6%f C: 43.1%f Mean age: unknown	3. Self assessment with feedback 4. Activities 5. Contests 6. Demos 7. Displays Control: 1. Food catering-cafeteria policies 2. Nutrition target setting 3. Self assessment with feedback <u>Aimed also at tobacco practices and hazardous substances</u>	• Dietary intake was measured by FFQs.
33.	Women's Health Initiative(Langer, White et al. 2003; Beresford, Johnson et al. 2006; Prentice, Thomson et al. 2007) USA	48,835 women aged 50-79 years of age (community intervention). Gender: 100%f Mean age: I: 62.3(6.9) C: 62.3(6.9)	Intervention: Behavioural modification which consisted of 18 group sessions (1st year) then quarterly session led by nutritionists. Each participants was given fat-gram goal according to height-self monitoring motivational interviewing. Control: Participants were given a copy of diet guideline for Americans and other materials (but not asked to change diet). <u>Aimed also at lowering fat intake to less than 20% from energy, increasing grain intake by ≥6 servings</u>	• Follow-up at 8.1 years. • Outcomes of fruit and vegetable intake, α-carotene, β-carotene, and weight. • Dietary intake was measured by FFQs.
34.	WiseWoman Arizona(Staten, Gregory Mercado et al. 2004) USA	217 women from 2 clinics (community intervention). Gender: 100%f Mean age: I1: 56.7(4.9) I2: 58.0(4.7)	Intervention 1: Provider counselling group (PC) which consisted of health education from nurses; brochures, benefits and barriers discussion, which were tailored to behaviour change. Intervention 2: Provider counselling + Health education (PC+HE) group	• Follow-up at 12 months. • Outcomes of fruit and vegetable intake, systolic and blood pressure, total cholesterol, weight. • Dietary intake was measured by 24-hour recalls.

No.	Study	Participants	Interventions	Outcomes
		I3: 57.0(4.8)	which consisted of elements as above but included one health education each on nutrition and physical activity, monthly newsletter for 12 months, and also call reminder for those who did not attend. Intervention 3: Provider counselling+Health education+Community health workers (PC+HE+CHW) group which consisted of elements as above but plus community health workers intervention, information and support, bimonthly walks, 1 CHW for 20 participants, walking partners for friendship and supporters.	
35.	Wolf(Wolf, Lepore et al. 2008; Wolf, Lepore et al. 2009) USA	490 urban primarily immigrant Black men (community intervention). Gender: I: 47.1%f C: 51.5%f Mean age: unknown	Intervention: Tailored telephone education (20 minutes each) and mailed brochures. Control: prostate cancer awareness	• Follow-up at 8 months. • Outcomes of fruit and vegetable intake. • Dietary intake was measured by FFQs.
36.	Women's Health Trial (White, Shattuck et al. 1992; Bowen, Clifford et al. 1996; Coates, Bowen et al. 1999; Kristal, Shattuck et al. 1999) USA	2208 women aged 50-79 years of age (community intervention). Gender : 100% f Mean age: 60.2(6.6) (unclear between groups)	Intervention: Group sessions with nutritionist on the following time: • Weekly for 6 weeks • Biweekly for 6 weeks • Monthly for 9 months • Then, quarterly Group sessions were conducted by shared experiences, role play, support (family members are invited to join), and problem solving. Sessions were translated to Spanish for participants who were not familiar with English.	• Follow-up at 6 months and 18 months. • Outcomes of fruit and vegetable intake and weight. • Dietary intake was measured by FFQs and 4 days food records on alternate days.

No.	Study	Participants	Interventions	Outcomes
			Control: none Aimed also at lowering fat intake, saturated fat and cholesterol, and increasing grain intake	

Note:

1. Gender:
    - f: female
    - m: male
2. Groups:
    - I: Intervention
    - I1: Intervention 1
    - I2: Intervention 2
    - I3: Intervention 3
    - C: control

Appendix 8
Table 2 Risk of bias summary

No.	Study	Sequence generation adequately generated	Allocation adequately concealed	Knowledge of the allocated interventions adequately prevented	Incomplete outcome data adequately addressed	Free from selective outcome reporting	Free from Industry funding	Summary
1.	Alexander	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
2.	Bradbury	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
3.	Buller	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
4.	Cookin' Up Health	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
5.	De Vries	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
6.	Eating for a Healthy Life	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
7.	Expanded Food and Nutrition Education Program	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
8.	Good Grubbin	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
9.	Greene	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
10.	Health Works for Women	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**

No.	Study	Sequence generation adequately generated	Allocation adequately concealed	Knowledge of the allocated interventions adequately prevented	Incomplete outcome data adequately addressed	Free from selective outcome reporting	Free from Industry funding	Summary
11.	Heimendinger	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
12.	Heneman	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
13.	High 5	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
14.	The Hiraka Dietary Intervention Study	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
15.	Kristal	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
16.	Lutz	Unclear	Unclear	Unclear	Yes	Unclear	No	**Unclear**
17.	Macdonald	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
18.	Marcus 1998	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
19.	Marcus 2001	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
20.	Mediterranean Eating Study	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
21.	The Next Step Trial	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**

No.	Study	Sequence generation adequately generated	Allocation adequately concealed	Knowledge of the allocated interventions adequately prevented	Incomplete outcome data adequately addressed	Free from selective outcome reporting	Free from Industry funding	Summary
22.	NC Strides Study (NCCCS)	Unclear	Unclear	Yes	Yes	Unclear	Yes	**Unclear**
23.	Oxford Trial	Yes	Unclear	Yes	Yes	Unclear	Yes	**Unclear**
24.	PREMIER	Yes	Unclear	Yes	Yes	Unclear	Yes	**Unclear**
25.	The Puget Sound Eating Patterns Study	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
26.	Resnicow	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
27.	Rio Grande	Yes	Unclear	Yes	Yes	Unclear	Yes	**Unclear**
28.	Sorensen	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
29.	South London	Yes	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
30.	Steenhuis	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
31.	WATCH Project	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
32.	WellWorks	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**

No.	Study	Sequence generation adequately generated	Allocation adequately concealed	Knowledge of the allocated interventions adequately prevented	Incomplete outcome data adequately addressed	Free from selective outcome reporting	Free from Industry funding	Summary
33.	Women's Health Initiative	Yes	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
34.	WiseWoman Arizona	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**
35.	Wolf	Unclear	Unclear	Unclear	Yes	Unclear	Yes	**Unclear**
36.	Women's Health Trial	Unclear	Unclear	Unclear	No	Unclear	Yes	**Unclear**

Appendix 9

Table 3 Type of interventions

No.	Studies	Groups	Group tailored	Individually tailored	Barriers & facilitators	Theory based (stage of change/TTM)	Intention, attitude, belief	Self efficacy	Social support	Knowledge	Motivation	Using computer/telephone/printed message/emails	Practical skills	Role model	Media based	Access	Duration (month)	Counselling	Action plans	Message as fun&healthy	Target
1.	Alexander	I1		√	√	√		√		√		√ C					12		√	h	≥5
		I2		√	√	√		√		√	√	√ C					12	√ NP (email)	√	h	≥5
		C								√		√ C					12			h	≥5
5.	Bradbury	I		√	√	√				√		√ P					18	√ D (F)	√	h	NS
		C																			
3.	Buller	I			√	√	√		√	√		√ P					18	√ NP		h	≥5
		C								√		√ P					18	√ NP		h	≥5
4.	Cookin' Up Health	I			√	√	√			√		√ C	√				3			h	≥5
		C								√		√ C					18			h	≥5
5.	De Vries	I		√		√	√	√			√	√ P					9		√	h	NS
		C				√	√	√			√	√ P					9		√		
6.	Eating for a Healthy Life	I		√		√	√	√	√	√	√	√ P	√	√			12			h	NS
		C																			

No.	Studies	Groups	Group tailored	Individually tailored	Barriers & facilitators	Theory based (stage of change/TTM)	Intention, attitude, belief	Self efficacy	Social support	Knowledge	Motivation	Using computer/telephone/printed message/emails	Practical skills	Role model	Media based	Access	Duration (month)	Counselling	Action plans	Message as fun&healthy	Target
7.	Expanded Food and Nutrition Education Program	I				√	√	√		√							6			h	≥5
		C																			
8.	Good Grubbin	I			√	√	√	√			√	√ v	√				1			h	NS
		C																			NS
9.	Greene	I		√		√		√		√	√	√ combine					12	√ NP (T)	√	h	≥5
		C																			
10.	Health Works for Women	I		√	√	√			√	√		√ C					18	√ NP (F)	√	h	NS
		C																			
11.	Heimendinger	I1		√	√	√	√	√	√	√	√	√ P					12			h	NS
		I2		√	√		√	√	√	√	√	√ P					12			h	NS
		I3		√	√	√	√	√	√	√	√	√ P					12			h	NS
		I4								√		√ P					12			h	NS
12.	Heneman	I1				√				√							9	√ NP		h	≥5

No.	Studies	Groups	Group tailored	Individually tailored	Barriers & facilitators	Theory based (stage of change/TTM)	Intention, attitude, belief	Self efficacy	Social support	Knowledge	Motivation	Using computer/telephone/printed message/emails	Practical skills	Role model	Media based	Access	Duration (month)	Counselling	Action plans	Message as fun&healthy	Target
		I2				√				√							9	√ NP	√		≥5
		C																			
13.	High 5	I	√							√		√ P	√				60			h	NS
		C																			
14.	The Hiraka Dietary Intervention Study	I		√						√	√	√ P	√				10	√ D (F)		h	NS
		C																			
15.	Kristal	I				√	√	√		√		√ P	√			√	8			h	≥5
		C																			
16.	Lutz	I1		√	√	√	√	√		√	√	√ combine					4			h	≥5
		I2		√	√	√	√	√		√	√	√ combine							√		
		I3				√				√		√ combine									
		C																			
17.	Macdonald	I1																			
		I2																			

No.	Studies	Groups	Group tailored	Individually tailored	Barriers & facilitators	Theory based (stage of change/TTM)	Intention, attitude, belief	Self efficacy	Social support	Knowledge	Motivation	Using computer/telephone/printed message/emails	Practical skills	Role model	Media based	Access	Duration (month)	Counselling	Action plans	Message as fun&healthy	Target
		I3									√	√ P				√	24			h	NS
		C																			
18.	Marcus 1998	I		√	√	√	√	√		√	√	√ combine	√				4			h	≥5
		C																			
19.	Marcus 2001	I		√		√	√	√	√		√	√ combine	√				12	√ NP (T)		h	≥5
		C																			
20.	Mediterranean Eating Study	I		√	√				√	√							6	√ D (T)	√	h	HT
		C																			
21.	The Next Step Trial	I		√		√	√	√	√	√	√	√ P					24			h	≥5
		C																			
22.	NC Strides Study	I1	√	√	√	√		√	√	√		√ combine					12			h	NS
		I2		√	√	√		√	√	√	√	√ combine						√ NP (T)			NS
		I3	√	√	√	√		√	√	√	√	√ combine						√ NP (T)		h	N

No.	Studies	Groups	Group tailored	Individually tailored	Barriers & facilitators	Theory based (stage of change/TTM)	Intention, attitude, belief	Self efficacy	Social support	Knowledge	Motivation	Using computer/telephone/printed message/emails	Practical skills	Role model	Media based	Access	Duration (month)	Counselling	Action plans	Message as fun&healthy	Target
		C								√		√ combine									
23.	Oxford Trial	I			√		√			√		√ combine	√				6	√ HP (T)	√	h	≥5
		C																			
24.	PREMIER	I1								√							6	√ D (F)		h	HT
		I2								√							6	√ D (F)		h	HT
		I3								√							6	√ D (F)		h	HT
25.	The Puget Sound Eating Patterns Study	I		√		√		√		√	√	√ combine	√				12	√ NP (T)	√	h	NS
		C																			
26.	Resnicow	I		√	√		√	√	√	√	√	√ P					3		√	h	NS
		C		√	√		√	√	√	√		√ P					3			h	NS
27.	Rio Grande	I				√	√	√	√	√	√	√ C	√				4		√	h	≥5
		C																			

No.	Studies	Groups	Group tailored	Individually tailored	Barriers & facilitators	Theory based (stage of change/TTM)	Intention, attitude, belief	Self efficacy	Social support	Knowledge	Motivation	Using computer/telephone/printed message/emails	Practical skills	Role model	Media based	Access	Duration (month)	Counselling	Action plans	Message as fun&healthy	Target
28.	Sorensen	I		√		√	√	√	√	√	√	√ combine					3	√ NP (T)	√	h	NS
		C																			
29.	South London	I		√	√	√		√		√							12	HP (F)	√	h	≥5
		C								√							12	√ HP (F)		h	≥5
30.	Steenhuis	I1					√	√		√		√ P				√	6			h	NS
		I2					√	√		√		√ P				√	6			h	NS
		I3					√	√		√		√ P					6			h	NS
		C																			
31.	WATCH Project	I1			√	√			√	√			√	√		√	9	√ NP (F)		h	≥5
		I2	√	√	√	√	√	√	√	√	√	√ combine	√			√	9			h	≥5
		I3	√	√	√	√	√	√	√	√	√	√ combine	√			√	9			h	≥5
		C																			
32.	WellWorks	I							√	√			√				24			h	≥5
		C								√										h	≥5

No.	Studies	Groups	Group tailored	Individually tailored	Barriers & facilitators	Theory based (stage of change/TTM)	Intention, attitude, belief	Self efficacy	Social support	Knowledge	Motivation	Using computer/telephone/printed message/emails	Practical skills	Role model	Media based	Access	Duration (month)	Counselling	Action plans	Message as fun&healthy	Target
33.	Women's Health Initiative	I		√				√	√	√	√		√				36	√ D (F)		h	≥5
		C								√											
34.	WiseWoman Arizona	I1	√	√	√		√			√		√ P					12	√ HP (F)		h	≥5
		I2	√	√	√		√			√		√ P					12	√ HP (F)		h	≥5
		I3	√	√	√		√		√	√		√ P					12	√ HP (F)		h	≥5
35.	Wolf	I		√	√	√	√			√	√						1	√ NP (T)	√	h	HT
		C																			
36.	Women's Health Trial	I	√	√					√		√						18	√ D (F)	√	h	≥5
		C																			

Note:

1. Groups:
   - I1: Intervention 1
   - I2: Intervention 2
   - I3: Intervention 3
   - C: control
2. Using printed message/computer/video
   - P= printed message
   - C= computer
   - V= video
   - Combine= any combination

3. Counselling methods
    - F=face to face
    - T=telephone
    - email
4. Counselling:
    - D=dieticians/nutritionists
    - HP=other health care professionals
    - NP=non health care professionals
5. Message as fun and health:
    - h = healthy
    - f = fun
6. Target:
    - B = basic target to increase fruit and vegetables ≥5 portions per day
    - NS= non specific target, only increase fruit and vegetables
    - HT= higher target to increase fruit and vegetable intake to 6-9 portions per day