

JYU DISSERTATIONS 30

Hanna Kuninkaanniemi

Brief Interventions in Counselling for Nutrition and the Prevalence of Metabolic Syndrome in Primary Care Adult Patients



UNIVERSITY OF JYVÄSKYLÄ
FACULTY OF SPORT AND
HEALTH SCIENCES

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ABSTRACT

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(Finnish summary)

Diss.

This research i) examined the influence of a brief nutrition-based intervention among primary care patients in changing nutrition and clinical values related to metabolic syndrome (study 1), and ii) assessed nutrition and the prevalence of metabolic syndrome and its clinical determinants among primary care patients in different sociodemographic groups (study 2). In study 1, a systematic literature review was conducted on eight databases during Sept.-Oct. 2016 with a final update in Nov. 2017. In study 2, data (n=557 for RO II-III, n=251 for RO IV-V) collected in primary care practices in Central Finland in 2006-2008 for the EVI study were analysed using Chi-Square test, GLM and Logistic Regression.

Study 1: The systematic search produced 983 articles, five of which met the inclusion criteria. The studies found only a weak effect of a brief intervention in modifying nutrition behaviour. The brief interventions had no influence on clinical outcomes. Study 2: Sociodemographic status influenced both the prevalence of metabolic syndrome and incidence of the single clinical determinants of metabolic syndrome. Both were most commonly found in men, the lower educated, retirees, and students and the unemployed. In total, 40 % of men and 27 % of women had metabolic syndrome. The association between obesity and metabolic syndrome was strong: only 4 % of the patients without metabolic syndrome were obese. No influence on the prevalence of metabolic syndrome was found for nutrition or nutrition-related health behaviours.

To conclude, high quality trials are needed to appraise the effectiveness of brief interventions in modifying nutrition. The prevalence of metabolic syndrome differed between the sociodemographic groups; hence health promotion and disease prevention should be targeted accordingly. Owing to data limitations, no influence on the prevalence of metabolic syndrome was observed for nutrition or other health-related behaviours; however a clear association was found between the prevalence of metabolic syndrome and obesity. Thus, metabolic syndrome should be addressed in primary care patients when obesity, alone or with abnormal blood pressure, another easy-to-address indicator, is present.

Keywords: brief intervention, counselling, primary care, nutrition, metabolic syndrome

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It was in mid-June last year when my attention was caught by a phrase: “Don’t always postpone your plans. Sometimes it’s better just to realise them. “

Immediately two things seeped into my mind. The first was running a marathon in Hämeenlinna, the city of my birth. The other was the present project, completing my doctoral thesis. The first appeared to be the easy one of the two and was realised only a month later, in mid-July 2017, on the eve of my grandfather’s birthday. The other has been a journey where the steps taken have included learning, engagement and persistence. During this later marathon, debts of gratitude to many people have accrued.

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My greatest thanks I dedicate to you, my mother, Sirpa and my father, Auvo. You gave me the best childhood to grow to meet the challenges yet to come. I hope I have somehow managed to express my gratitude for your constant support. I cannot imagine a better gift than to have you as my parents.

I dedicate this work to my beloved grandparents - with good *sisu*.
Omistan tämän työn rakkaille isovanhemmilleni - hyvällä sisulla.

Looking forward to new paths,

Niinisaari, 30th of September 2018

Hanna

Footnote: And as I obviously did run out of words, I decided to use pictures and flowers instead.

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ABBREVIATIONS

A=Abstract

ATP III=National Cholesterol Education Program Adult Treatment Panel III

BI=Brief intervention

BMI=Body Mass Index

CI=Confidence Interval

CHD=Coronary Heart Disease

CT=Search category

DPB=Diastolic Blood Pressure

DRVs=Dietary Reference Values

ETENE= The National Advisory Board on Social Welfare and Health Care Ethics

EVI=The Early Recognition of Lifestyle Diseases (Elämäntapasairauksien varhainen tunnistaminen ja interventio)

EVIRA=Finnish Food Safety Authority

F=Full text

FACET= Five-a-day Community Evaluation Tool

FGluc=Fasting Glucose

FIN-D2D=Finnish national prevention programme of diabetes

GP=General practitioner

GRADE=Grading of Recommendations, Assessment, Development and Evaluation

GLM=General Linear Model

HDL=High Density Lipoprotein Cholesterol

HTA= Health Technology Assessment

II=Intensive intervention

IPAQ=Physical Activity Questionnaire

KTL= National Public Health Institute of Finland

LDL=Low Density Lipoprotein Cholesterol

MANOVA=Multivariate Analysis of Variance

MetS=Metabolic syndrome

MI=Motivational Interviewing

N/A=Not applicable

Nov=November

Oct=October

OR=Odds Ratio

PA=Physical Activity

Phys. work=Physical work

RCT=Randomised Controlled Trial

RO=Research objectives

SBP=Systolic Blood Pressure

SDS=Sociodemographic status

Sept=September

Stud=Student

T=Title

THL=National Institute for Health and Welfare

Total chol=Total Cholesterol

Trigly=Triglycerides

TTA=Transtheoretical Approach

TTM=Transtheoretical Model

Unemp=Unemployed

Veg=Vegetables

WHO=World Health Organization

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1 INTRODUCTION

Health promotion is high on the global and national development agenda (WHO 2016, European Commission 2017b, Oikeusministeriö 2017, WHO 2017). In the primary care context, this principally means preventing diseases and promoting good health through different interventions. In Finland, the incidence of health behaviour-related diseases has been growing. Already a half of the Finnish adult population is overweight and a fifth is obese (Murto et al. 2017, THL 2017). Together, obesity and health behaviour-related diseases constitute a major human and economic burden (THL 2016, WHO 2016, European Commission 2017b, WHO 2017).

In addition to overweight and obesity, other risk indicators for health behaviour-related diseases have been identified. These include a high level of triglycerides, a low level of high-density lipoprotein cholesterol, elevated blood pressure and abnormal blood sugar metabolism. As a group, these metabolic abnormalities are termed metabolic syndrome (MetS) (Alberti, Zimmet & Shaw 2006, Alberti, Zimmet & Shaw 2007, Alberti et al. 2009).

The role of health behaviour in metabolic syndrome is widely acknowledged. On the one hand nutrition is associated with risk for developing health behaviour-related diseases and on the other intensive interventions have been shown to influence nutrition, decrease body weight and decrease the incidence of developing these diseases for people at risk (Patja et al. 2005, Lindstrom et al. 2006, Lindström et al. 2013, Ley et al. 2014, Lehtisalo et al. 2016). A crucial part of health promotion therefore comprises interventions targeting reasonable behaviour change on the population level.

However, lack of time and resources, and even unclear roles in primary care are often barriers that prevent health care professionals from routinely advising patients about obesity-related matters (Douglas et al. 2006, McAlpine & Wilson 2007, Blane et al. 2017). There are indications that rates of obesity counselling have actually declined (Smith et al. 2011, Kraschnewski et al. 2013). Furthermore, there is a need to further develop methods to support the implementation of obesity and overweight assessment practices in primary care (Goodfellow et al. 2016) and the accurate documentation of patients' body mass index (BMI) (Barnes,

Theeke & Mallow 2015). Hence, new simple yet effective methods to prevent diseases based on health behaviour are called for.

In addition to intensive interventions, brief interventions have been used in patient counselling in primary care. They have been successful in terms of harmful alcohol consumption and in smoking cessation. Findings on the influence of nutrition counselling, however, are few and conflicting (see e.g. Lewis et al. 2013, McKnight-Eily et al. 2017, Wong et al. 2017). Studying the evidence related to brief interventions conducted on physical activity and nutrition called for more thorough research on the effectiveness of the method (Kuninkaanniemi & Poskiparta 2016).

Primary care interventions are often based on the Transtheoretical Approach and its practical applications (Prochaska & DiClemente 2005, Salmela et al. 2009, Vallis et al. 2013, Lee, Park & Min 2015, Carvalho de Menezes et al. 2016, DiClemente et al. 2017, Torti et al. 2017). Werch et al. (2006) define a brief intervention as any intervention between a health professional and individual or individuals that is purposely limited in the number and length of contacts and provides personalised information to increase motivation to improve health-related behaviours. Brief interventions last up to 15 minutes, and they may include either one or a series of contacts. Whitlock et al. (2004) have classified brief interventions into three groups according to their intensity.

Brief interventions can be conducted during a routine visit to a primary care centre, and because they are limited in duration they can be cost-effective (Fleming 2004, Werch et al. 2006). However, criticism has been levelled at the brief intervention approach for its lack of generalisability to different settings and its lack of efficacy as a treatment. Furthermore, the success of counselling is related not only to the participants individual motivation and willingness to change their behaviour but also to the study context and the person conducting the counselling (Kaner et al. 2001, Glasgow et al. 2004b, Werch et al. 2006, Salmela et al. 2012b, Apovian, Garvey & Ryan 2015).

Metabolic syndrome is both a public health and clinical problem. On the public health level, it is necessary to influence sedentary health behaviour and decrease obesity. From the clinical point of view, the greatest concern is to be able to identify people with metabolic syndrome and thus address and reduce their multiple risk factors (Alberti et al. 2009).

It is estimated that the incidence of health behaviour-related diseases will markedly increase in the near future. To enhance the development of effective methods to prevent health behaviour-related diseases requires a systematic evaluation of the efficacy of nutrition counselling in the form of a brief intervention. In addition, it is important to identify patients who are at risk for health behaviour-related diseases and target offer health promotion to them. Consequently, the aim of this doctoral thesis was i) to examine the influence of a brief nutrition-based intervention among primary care patients in changing nutrition behaviour and clinical values related to metabolic syndrome (study 1), and ii) to assess nutrition behaviour and the prevalence of metabolic syndrome

and its single clinical determinants among primary care patients in different sociodemographic groups (study 2).

The research objectives of study 1 were addressed through a systematic literature review. Study 2, in turn, focused on nutrition behaviour and the prevalence of metabolic syndrome. The empirical data used in study 2 concerned patients, i.e. *persons using health care services* (as defined in the Finnish Act on patient status and rights, Finnish Ministry of Social Affairs and Health 1992), and hence the term patient rather than client is used throughout the study. Both studies were conducted within the context of primary healthcare.

Chapters 2 to 4, drawing on the two studies, describe the theoretical background of the research conducted following the principles of a literature review. Chapter 5 presents the aim of the study and the specific research objectives. Chapters 6 and 7 describe the methods and present the results of each study in detail. Chapter 8 discusses the results together with their practical implications and makes suggestions for further research. The chapter also discusses the limitations and representativeness of the research along with the relevant ethical considerations. Chapter 9 concludes the findings.

2 HEALTH PROMOTION INTERVENTIONS IN COUNSELLING FOR HEALTH BEHAVIOUR CHANGE

2.1 The role of primary health care in health promotion

According to the World Health Organization (http://www.who.int/topics/health_promotion/en/) (WHO 2017), health promotion is “the process of enabling people to increase control over, and to improve, their health.” Health promotion actions address, e.g., the leading risk factors for health, and place health issues on the broader national and global development agenda. The focus of health promotion interventions thus extends from individual behaviours to a wider perspective where social and environmental factors are considered.

Primary health care, which concerns public health services, is a central context for health promotion. It has a crucial role in preventing both communicable and chronic non-communicable diseases, of which the latter account for 80 percent of health care costs in the EU. It is estimated that the great majority of health behaviour-related diseases could be prevented by promoting health behaviour in such areas as nutrition, physical activity, alcohol consumption and use of tobacco products. However, only three percent of national health budgets in the EU are spent on prevention (European Commission 2017a, WHO 2017).

In Finland, the Health Care Act (=Terveydenhuoltolaki, 30.12.2010/1326) (Oikeusministeriö 2017) emphasises the importance of the above issues by setting five major objectives: “1. Promote and maintain the population’s health and welfare, work ability and functional capacity, and social security; 2. Reduce health inequalities between different population groups; 3. Ensure universal access to the services required by the population and improve quality and patient safety; 4. Promote client orientation in the provision of health care services; 5. Improve the operating conditions of primary health care and strengthen

cooperation between health care providers, between local authority departments, and with other parties in health and welfare promotion and the provision of social services and health care.” According to the Act, health promotion includes actions aimed at individuals and populations, and at living environments with a view of maintaining and improving health and ability to function (Oikeusministeriö 2017).

The organisation of the Finnish social and welfare services is currently in flux as a part of a wider reform of the system of delivering public services. At the beginning of 2020, the responsibility for arranging public health and social services will shift from municipalities to regions (Valtioneuvosto 2017). Many regions have for years addressed the issue of health promotion via regional programmes and co-operation between different sectors, such as in the regions of Central Finland (Puustinen 2008) and South Savo (Kuninkaanniemi 2011). However, in the future, municipalities will also have a role in conducting health promotion actions. One of the aims of the reform is to reduce differences between citizens in health and wellbeing across the country (Valtioneuvosto 2017).

2.2 Counselling interventions and their effectiveness in changing nutrition and related health behaviours

2.2.1 Interventions in primary health care

Interventions in primary health care have a central role in health promotion. One major aim of counselling interventions in public health promotion is to prevent the emergence of health behaviour-related diseases. Counselling, which refers to different practices of professional guidance in seeking to resolve an individuals’ problems (Oxford Dictionaries 2018), is built on interaction between patient and counsellor aiming to create a desired change and personal growth (Bordin 1968). In addition to the clinical ward, usual care can include patient counselling and support in health behaviour-related issues aimed at promoting behaviour change. In the context of nutrition behaviour, change can be defined as a desired modification in an individual’s consumption of different nutrition items and improvement in overall nutrition behaviour. Counselling interventions can be strengthened by a variety of methods (Goldstein et al. 2004, Cofta-Woerpel, Wright & Wetter 2007, Apovian, Garvey & Ryan 2015, Oikeusministeriö 2017).

In primary health care practice, patient counselling interventions aimed at preventing health behaviour-related diseases can be intensive (referred to in this thesis by the abbreviation II) or brief (BI). In Finland, a major project targeting health behaviour change on a population level was the North Karelia Project launched in 1971. The main aim of the project was to decrease the risk for cardiovascular disease and events and related communicable diseases by affecting individuals’ nutrition behaviour, especially towards avoidance of saturated fats, such as butter, and decreasing smoking (Pohjois-Karjalan Kansanterveyden Keskus 2016, Puska et al. 2016, Puska 2016). The project

resulted in significantly improved health on the population level, and lowered the risk for succumbing to these health behaviour-related diseases. It was concluded that seeking to influencing health behaviour through health promotion and other health-related policies is a cost-effective way to improve public health (Puska et al. 2016).

A few decades later, during 2000-2010, the Finnish National Diabetes Prevention programme (FIN-D2D) was the first attempt in Finland to implement methods of preventing type 2 diabetes in the primary health care setting (Saaristo et al. 2007, Saaristo et al. 2010, Wikström et al. 2015). It combined three strategies at both the population and high-risk individual level along with methods for early diagnosis of the disease (Saaristo et al. 2007). The project was successful in increasing awareness of diabetes on the population level (Wikström et al. 2015). Currently, among others, the StopDia project 2016 -2019 is continuing the preventive work against type 2 diabetes on two interventional levels: the individual, including digital and face-to-face methods, and the environmental, aimed at affecting health behaviour choices and choice strategies (Leväsluoto, Kohl & Poutanen 2017).

Interventions can be conducted by health care professionals such as nurses and physicians. Elements of health behaviour counselling are often, to some extent, theory-grounded, drawing on, for example, the Transtheoretical Model (TTM) (Salmela et al. 2009, Lee, Park & Min 2015, Ma et al. 2015, Mostafavi et al. 2015, Carvalho de Menezes et al. 2016). The methods, advice-giving practices and counselling content used should support the patient's individual situation and needs (Goldstein et al. 2004, Kiuru et al. 2004, Kettunen et al. 2006, Poskiparta, Kasila & Kiuru 2006, Miller & Rose 2009, Apovian, Garvey & Ryan 2015). The patient's perceived need for behaviour change is an important part of change (Salmela et al. 2012a). Furthermore, to obtain sustainable changes in patient's health behaviour, it is necessary to find good quality structures for counselling interventions (Salmela et al. 2012b).

2.2.1.1 Intensive intervention

Intensive interventions are a traditional type of intervention in primary health care settings. Typically, such interventions consist of a minimum of four counselling session lasting at least ten minutes each. The patient is encouraged to maintain the motivation for health behaviour change throughout the change process. In the case of relapse, support is also given (Cofa-Woerpel, Wright & Wetter 2007).

Intensive interventions are assumed to be required for change in complex behaviours such as nutrition (Baer et al. 2015). The intensity of the intervention is also expected to decrease the dropout (Cofa-Woerpel, Wright & Wetter 2007). Despite the partially conflicting results of some interventions, others have been successful in reducing body weight in overweight and obese patients (Goldstein et al. 2004, Volger et al. 2013, De Vos, Runhaar & Bierma-Zeinstra 2014, Tol et al. 2014, Armenta Guirado et al. 2015, Aveyard et al. 2016, Eaton et al. 2016, Alghamdi 2017, Coppell et al. 2017). In addition, patients with an already

diagnosed behaviour-related disease or who are highly sedentary have benefitted from an intensive behavioural intervention (Rodríguez Cristóbal et al. 2012, Dutton et al. 2015, Eaton et al. 2016, Illamola Martin et al. 2017).

Supportive elements in addition to counselling have produced changes in the participants' health behaviour. Internet-based behavioural programmes on healthier food choices have been found to produce weight loss for obese and sedentary patients with no increase in health care costs (Little et al. 2016). Web-based individualised counselling and the use of behavioural tools also have potential in offering a cost-effective method of combatting obesity (Smith et al. 2016). Web-based interventions combined with support from a primary care nurse have been proposed as a promising means for weight management in the primary care context (Yardley et al. 2014).

In addition to web-based solutions, telephone support has been suggested as a feasible way of delivering nutrition and physical activity counselling for patients with a chronic disease (Eakin et al. 2009). Furthermore, telemonitoring, comprising telephone coaching and telephone calls, have been found to improve weight loss and metabolic syndrome definers in patients with metabolic syndrome (Luley et al. 2014). In addition, the results of a pilot study by Dutton et al. (2015) indicated that peer coaching (peer-delivered telephone contacts) was successful in achieving weight loss in sedentary primary care patients with weight-related comorbidities.

However, in their the systematic review and meta-analysis, Booth et al. (2014) concluded that behavioural weight loss interventions in primary care have only produced small reductions in patients' body weight. Moreover, the intervention effect tends to decrease over time (De Vos et al. 2016) and weight loss is poorly maintained (De Vos, Runhaar & Bierma-Zeinstra 2014, Holzapfel et al. 2014). An intensive intervention including in-person visits and telephone calls in between these visits was found to be more successful in maintaining a patient's weight loss than the mailing of reminder materials (Tsai et al. 2015).

Furthermore, a systematic review by Ball et al. (2015) found that while interventions involving nutrition in primary care have the potential to modify a patient's nutrition behaviour, their outcomes remain unclear. To manage obesity, intensive interventions are recommended with ongoing support and taking both physiological and behavioural challenges into account (Apovian, Garvey & Ryan 2015). To conclude, while some intensive interventions have been successful in treating nutrition- and obesity-related issues, the results remain conflicting (e.g. Volger et al. 2013, Booth et al. 2014, De Vos, Runhaar & Bierma-Zeinstra 2014, Tol et al. 2014, Armenta Guirado et al. 2015, Baer et al. 2015, Ball et al. 2015, Aveyard et al. 2016, Eaton et al. 2016, Alghamdi 2017, Coppell et al. 2017).

2.2.1.2 Brief intervention

Brief interventions are brief counselling situations where a healthcare professional broaches a specific health behaviour issue with a patient, supports the patient's willingness to change the behaviour, and gives advice on how to

implement the behaviour change. Brief interventions can be conducted during a routine visit to primary care, are limited in time, and can be cost-effective. When needed, the counselling can be renewed during the patient's next visit (Fleming & Manwell 1999, Whitlock et al. 2002, Fleming 2004, Werch et al. 2006, Cofta-Woerpel, Wright & Wetter 2007).

According to Werch et al. (2006), a brief intervention is any counselling situation between a health care professional and an individual patient (or a group) where the length and frequency of the counselling is purposely determined. The aim is giving the patient personalised advice to support his/her health behaviour. In primary care, the main target is, with as few counselling contacts as possible, to decrease the individual risk for a health behaviour-related disease by motivating the patient to behaviour change.

Brief interventions last up to 15 minutes and may include either one or a series of contacts. Whitlock et al. (2004) divided brief interventions into three categories based on the length of a single counselling situation and on total number of counselling situations: a *very brief intervention*, which lasts up to five minutes and is conducted in one a single primary care visit; a *brief intervention*, which lasts from five to fifteen minutes and is also conducted during one meeting with the patient; and a *brief intervention with follow-up*, which consists of multiple visits, according to need, lasting up to fifteen minutes each.

The brief intervention has a long history, especially in the context of harmful alcohol use. Quick electronic screening instruments have been found to be successful in identifying patients with risky levels of alcohol consumption. Furthermore, brief interventions have also been effective in reducing excessive alcohol use for people at risk in the severe population groups, and in reducing alcohol-related problems with modest costs (Babor et al. 2005, Babor et al. 2006, Gebara, Carla Ferreira de Paula et al. 2013, Donoghue et al. 2014, McDevitt-Murphy et al. 2014, Tansil et al. 2016, McKnight-Eily et al. 2017, Pringle et al. 2017).

In addition, a brief intervention and screening have been found effective in unhealthy substance use for patients with a chronic medical condition (Timko et al. 2016). A recent observational cohort study suggests that patients with hypertension may also benefit from a brief intervention conducted on unhealthy alcohol consumption (Chi et al. 2017).

Smoking cessation is another theme where brief interventions have long been widely and effectively used in the primary care context (Goldstein et al. 2004, Stead, Bergson & Lancaster 2008, Christiansen et al. 2015, Wong et al. 2017). However, recent studies have also found the efficacy of smoking-related brief interventions to be unclear (Li et al. 2017a, Poblete et al. 2017).

Furthermore, brief interventions have been suggested as a promising method for promoting physical activity among adults (Peterson 2007), working mothers (Mailey & McAuley 2014) and sedentary groups (Leijon et al. 2011, Olson & McAuley 2015). The evidence seems nevertheless to be limited, and the earlier conclusion that the data are not sufficient to recommend brief physical activity counselling in primary care most likely still holds (Berg & US Preventive

Services Task Force 2003). Furthermore, the positive influence was found only in the short term, i.e. the change and improvement in the participants' physical activity was only momentary (Leijon et al. 2011, Olson & McAuley 2015).

Brief interventions have also been used for screening and recognizing obesity. Recent research suggests that a brief intervention can be successful in counselling for body weight reduction in obese patients (Lewis et al. 2013, Aveyard et al. 2016). However, the evidence adduced in different settings, mainly hospitals, for improved patient outcomes (e.g. BMI) following nutritional screening remains insufficient (Omidvari et al. 2013). Furthermore, nutrition-based brief interventions in the primary care context are rare (Steptoe et al. 2003, Sacerdote et al. 2006, Hardcastle et al. 2008, Kuninkaanniemi et al. 2011, Ackermann et al. 2015).

In sum, brief interventions have widely been used in health behaviour change counselling. They have been shown to be effective or cost-effective in decreasing excessive alcohol consumption and smoking cessation (Maciosek et al. 2006, McDevitt-Murphy et al. 2014, Tansil et al. 2016, McKnight-Eily et al. 2017). The evidence on modifying nutrition remains inadequate. Moreover, the results of very brief interventions (less than five minutes) are conflicting (Whitlock et al. 2002, Whitlock et al. 2004). In this study, a brief intervention was defined as from one to three time-limited (up to fifteen minutes) counselling sessions between a healthcare professional and an individual in the primary health care context.

2.3 A brief intervention: theoretical approaches and methods

2.3.1 The Transtheoretical Approach

2.3.1.1 Core elements of the Transtheoretical Approach

Interventions in primary care are often conducted using theoretical frameworks. In the health behaviour change interventions, elements from the Transtheoretical Approach (TTA) – widely known in its practical application as the Transtheoretical Model or Stages of Change Model –, such as individuals' readiness to change and self-efficacy are important factors in their success (Prochaska & DiClemente 1983, Prochaska & DiClemente 1992, Miller 1996, Prochaska & Velicer 1997, Vasilaki, Hosier & Cox 2006, Werch et al. 2006, Prochaska 2008, Miller & Rose 2009).

The Transtheoretical Approach, initiated in the 1980s, draws on theories of psychotherapy to address addictive behaviours. Its starting point was consideration of how to approach the process of change. This process is reflected not only in the individual's behaviour but also in the individual's affect and thinking related to the problem in question. The creators of the theory, James Prochaska and Carlo DiClemente have since proposed ten distinct Processes of Change: 1) consciousness-raising, 2) self-liberation, 3) social liberation, 4)

counterconditioning, 5) stimulus control, 6) self-re-evaluation, 7) environmental re-evaluation, 8) contingency management, 9) helping relationships, and 10) dramatic relief. They suggest that people naturally follow these processes to modify problem behaviour (Prochaska & DiClemente 1986, Prochaska & DiClemente 2005).

Another core element of the Transtheoretical Approach comprises the Stages of Change, which refers to an intentional and sequential feature of the process of behaviour change. Change is more a gradual movement than a simple decision or a state (Prochaska & DiClemente 2005). The Stages of Change is widely used in health promotion interventions. The five stages are: 1) precontemplation, 2) contemplation, 3) preparation, 4) action, and 5) maintenance. A stage of change contains the tasks needed to be done before moving to the next stage and the time this requires (Prochaska & DiClemente 2005). The Processes of Change are connected to specific Stages of Change as presented in figure 1.

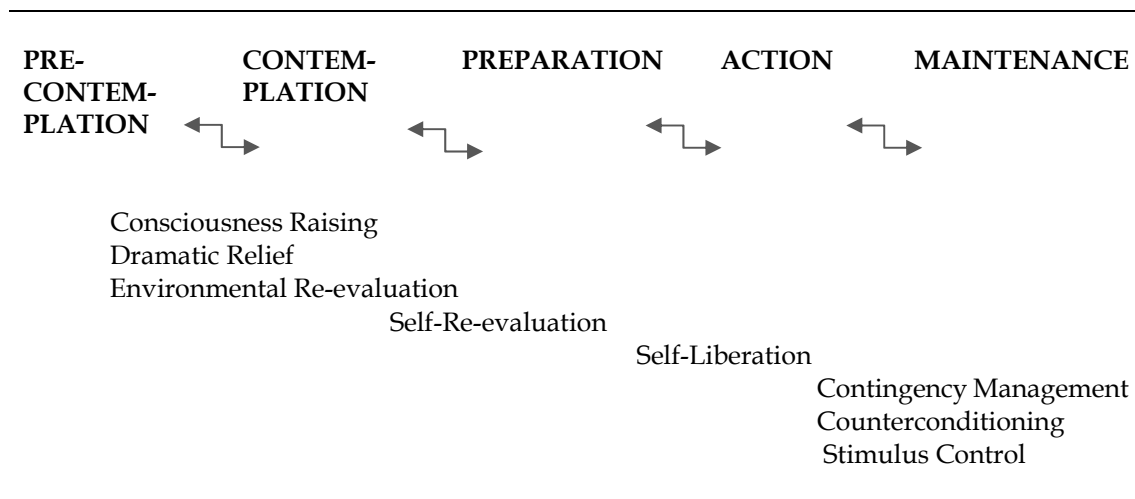


FIGURE 1 Process of Change emphasized at particular Stages of Change (modified from Prochaska & DiClemente 2005).

According to Prochaska and DiClemente (2005), during the pre-contemplation stage patients do not use many change processes, as they are not actively thinking about their problem or its influences. At this point, to help the patient move on from pre-contemplation to contemplation, consciousness raising interventions can awake the patient's awareness of the causes and consequences of the risk behaviour. To reach the contemplation stage, the patient must to some extent become aware of the negative consequences of the behaviour.

The contemplation stage involves more cognitive and evaluative processes, and the patient needs to be prepared for action. In the preparation stage the individual is ready for a behavioural change in the near future. A health care professional may have ideas about how to get the patient to evaluate and recognise the problem behaviour and subsequently help the patient prepare an action plan and set realistic goals for change (Prochaska & DiClemente 2005).

In the action stage, it is crucial that the patient has a sense of self-efficacy, that is a belief in one's own capacity to initiate the behavioural change and handle difficult situations. For self-liberation, effectiveness in implementing the change process, including stimulus control and counterconditioning, is also needed in addition to the relevant affective and cognitive factors. At this stage, a health care professional can enhance the change process by providing the patient with training and support (Prochaska & DiClemente 2005).

Success in the maintenance stage is built on the progress made in the previous stages and it also requires a pre-assessment of the possible situation should a relapse occur. Of central importance is one's own evaluation of the end-point situation, i.e. whether one has become or is becoming more a like the person one wants to be (Prochaska & DiClemente 2005).

The third essential element of the Transtheoretical Approach comprises the Pros and Cons of change. These refer to the motivational and decisional features of the target behaviour change. Originally, pros and cons were divided into four categories in relation to one self and to others. Pros, in other words benefits, were divided into instrumental pros benefitting the self and others, and approval from the self and others. Cons, in turn, were presented as the opposite, i.e. instrumental costs to the self or others, and disapproval from self or others. Later the division into pros and cons was reduced to these two components, as it was found that people do not divide pros into pros for the self and pros for others, or clearly divide instrumental from affective benefits (Prochaska & DiClemente 2005).

In addition to these three well-known core parts of the Transtheoretical Approach proposed by Prochaska and DiClemente, namely The Processes of Change, The Stages of Change and Pros and Cons of Change, a fourth part of the approach is the most clearly driven by psychotherapy and a psychological view of the problems in question. Here, the Transtheoretical Approach recognises the complexity of health behaviour and health behaviour change. Consequently, the fourth element, the Levels of Change, refers to five interrelated yet separate levels of the problem that need to be addressed: 1) symptom/situational problems, 2) maladaptive cognitions, 3) current interpersonal conflicts, 4) family/system conflicts, and 5) intrapersonal conflicts. While these five levels are interdependent, the Transtheoretical Approach prefers to initiate the intervention on the first level, i.e. on the symptom and situational level, as it is at that point that change happens more quickly (Prochaska & DiClemente 2005).

2.3.1.2 Application of The Transtheoretical Approach and its effectiveness in nutrition-related interventions

In the context of patient support for behaviour change, the Transtheoretical Approach applies the different processes of change at specific stages of change according to the pre-determined level of change (i.e. identified problem) (Prochaska & DiClemente 2005). Thus, the Transtheoretical Approach, or an approach based on it, is widely used in different health promotion and health behaviour change interventions (Prochaska & DiClemente 1983, Prochaska &

DiClemente 1992, Miller 1996, Prochaska & Velicer 1997, Vasilaki, Hosier & Cox 2006, Werch et al. 2006, Prochaska 2008, Miller & Rose 2009). For wider use, the Transtheoretical Approach was extended from being an assessment-based professional-driven tool to include treatment at the population level (Prochaska & DiClemente 2005). Widely used and a common term for that is the Transtheoretical model.

According to the model, accurate assessment of the patient's stage of change, processes of change as well as the level of change is important in successful communication between the patient and the health care professional. The intensity and length of the intervention would ideally be set in accordance with the previously mentioned elements (Prochaska & DiClemente 2005). For example, a patient with a health behaviour-related problem at the pre-contemplation stage of change, i.e. not yet on a symptom level, is likely to require more intensive and long-lasting support to achieve and maintain a desired change than a patient who already is on the preparation stage of the change process with symptom-level problems along with family conflicts.

However, for nutrition interventions evidence to support the use of the Transtheoretical model is weak and conflicting. In their review, Salmela et al. (2009) concluded that the evidence obtained thus far is insufficient to evaluate the benefits of the transtheoretical model in nutrition interventions for diabetic patients or patients at elevated risk for diabetes. Similarly, the more recent systematic review by Tuah et al. (2011), with an update in Mastellos et al. (2014), also concluded that the evidence for using the Transtheoretical model-based approach in weight loss interventions was of low quality and the results biased. Furthermore, a review by Carvalho de Menezes et al. (2016) concluded that studies using the Transtheoretical model for multi-behavioural interventions including nutrition and physical activity components also had methodological weaknesses.

Some studies, however, have since reported that Transtheoretical model-based methods were effective in nutrition interventions (Ma et al. 2015, Karintrakul & Angkatavanich 2017, Lee et al. 2017). Furthermore, an educational physical activity intervention based on the Transtheoretical model has increased physical activity and improved metabolic syndrome definers in women (Mostafavi et al. 2015). In addition, a review has found a positive impact of a Transtheoretical model-based intervention on type 2 diabetic patients' self-management practices, including healthier nutrition and an increase in physical activity (Mohamed Ibrahim, Arafat & Awaisu 2015).

2.3.2 Other practical methods to delivering a brief intervention

2.3.2.1 Motivational interviewing

Driven also by the Transtheoretical Approach, brief counselling methods are often founded on motivational interviewing (MI), which is a client-centred therapeutic method to promote a patient's readiness to change a certain health behaviour. Motivational interviewing is based on two central mechanisms,

relational and technical, the former focusing on empathy and the latter on reinforcement of the patient's change talk (Miller 1996, Vasilaki, Hosier & Cox 2006, Miller & Rose 2009). A recent meta-analysis by Magill et al. (2017) found that a higher proportion of change talk was associated with a reduction in risky health behaviour. Furthermore, as suggested in the review by Soderlund (2017), the motivational interviewing session should focus on a minimum number of self-management behaviours.

Motivational interviewing is also widely used in the context of primary care to treat various health behaviour-related matters (Purath, Keck & Fitzgerald 2014, VanBuskirk & Wetherell 2014, Barnes & Ivezaj 2015, Morton et al. 2015, DiClemente et al. 2017, Magill et al. 2017, Soderlund 2017). A systematic review and meta-analysis by VanBurskirk and Wetherell (2014) supported the effectiveness of the motivational interviewing style in enhancing patients' readiness to change a certain behaviour and achieve the targets set for the behaviour change. Barnes and Ivezaj (2015) concluded in their systematic review that motivational interviewing could serve as an effective tool in helping primary care patients to lose weight. However, the systematic review of Morton et al. (2015) concluded that the efficacy of the motivational interviewing style in health behaviour change interventions in the primary care context is unclear due to inconsistencies in reporting the use of the method in interventions.

2.3.2.2 Elements used in counselling

In addition to motivational interviewing, other practical methods for conducting interventions in primary care are also based on or have borrowed elements of the Transtheoretical Approach. Brief interventions commonly include six elements summarised by the acronym FRAMES. The six elements are: 1. assessment and Feedback; 2. individual's personal Responsibility for change; 3. Advice on making a change; 4. Menu of different options to complete the change; 5. Empathy as a counselling style; and 6. strengthening of individual's Self-efficacy (Miller & Sanchez 1994, Crawford et al. 2014). First, the patient is given feedback based on an assessment of the problem and situation. The patient's personal responsibility and autonomy to effect the behaviour change is fostered and a clear recommendation on the necessary change is given. The menu lists the alternative actions that can be taken to achieve the desired behaviour change. For the health care professional, an understanding attitude in the counselling process is recommended. Finally, the patient's self-efficacy need to be fostered to increase confidence in and commitment to change process (Marques & Furtado 2004, Cornuz & Bize 2006).

The 5As framework for behaviour change counselling, originally developed for smoking cessation, is also used in primary care (brief) interventions to deliver patient-centred counselling (Goldstein et al. 2004, Glasgow, Emont & Miller 2006, Carroll, Antognoli & Flocke 2011, Vallis et al. 2013, Campbell-Scherer et al. 2014, Rueda-Clausen et al. 2014, Osunlana et al. 2015). Elements of the 5As draw in part on the FRAMES. The aim is to guide health care professionals in patient counselling.

The 5As originally referred to five actions: Assess, Advise, Agree, Assist and Arrange. First, the patient's level of behaviour, motivation and beliefs are defined (Assess). She/he is then given clear advice on the situation based on the individual risks associated with the behaviour and the possible pros and cons of changing the behaviour (Advise). Realistic goals and methods to reach the goals are then determined together with the patient (Agree). In addition, the health care professional supports the patient in the process of health behaviour change and in developing a concrete action plan (Assist), and, when needed, offers the possibility of follow-up visits (Arrange) (Goldstein et al. 2004, Glasgow, Emont & Miller 2006). The terms have since been changed slightly to Ask, Assess, Advise, Agree, Assist/Arrange, i.e. the intervention starts with asking the patient about the latter's health behaviour-related concern and exploring the patient's readiness for change (see the Stages of Change in the Transtheoretical Approach). The final step is referred to as either Assist or Arrange, i.e. it includes both (Vallis et al. 2013, Nápoles et al. 2016, Asselin et al. 2017, Vijayaraghavan et al. 2017).

It has been suggested that 5As-based interventions for obesity management could be successful in, e.g., enhancing the communication between patient and health care professional and the planning of follow-up care (Rueda-Clausen et al. 2014). The review by Vallis et al. (2013) concluded that as an intervention strategy the 5As can potentially improve the success of weight management in primary care.

A recent application of the 5As framework is the 5As Team trial where clinic-based multidisciplinary teams worked together to develop obesity management in the primary care context (Campbell-Scherer et al. 2014, Ogunleye et al. 2015, Osunlana et al. 2015, Asselin et al. 2017). As part of the trial, a 5As tool kit, shared decision-making tools, was developed. The tool kit contained four kinds of tools: 1) provider tools, e.g. physical activity prescriptions, 2) patient tools to foster the counselling effect after the practice visit(s), including information handouts and fact sheets, 3) patient-provider communication tools, such as goal sheets and patient decision-making-tools to facilitate meaningful interaction between the patient and health care professional, and 4) evaluation tools for providers to rate and assess the usefulness of the tools in practice. All the tools were appraised as useful in trials on obesity management (Osunlana et al. 2015). Furthermore, patients reported expectations regarding obesity management in primary care, and they wish that care personnel would thoroughly assess their cases (Torti et al. 2017).

3 METABOLIC SYNDROME AND NUTRITION BEHAVIOUR

3.1 Metabolic syndrome

3.1.1 Metabolic syndrome and health behaviour-related diseases

The incidence of health behaviour-related diseases, such as type 2 diabetes and cardiovascular disease, has been increasing globally. Diabetes is a metabolic, chronic disease with elevated blood glucose levels. The most common type of diabetes is type 2 diabetes that occurs when the body is not able to use insulin effectively, i.e. becomes resistant to or does not produce enough insulin. According to the World Health Organization (WHO) 422 million adults currently have diabetes. The global prevalence has nearly doubled since 1980, reflecting the growth in associated risk factors such as overweight or obesity (WHO 2016). Such diseases impose a large economic burden worldwide both in the form of direct costs (e.g. medical costs) and indirect costs (e.g. productivity loss) (Seuring, Archangelidi & Suhrcke 2015, WHO 2016). Shared risk factors for health behaviour diseases include metabolic syndrome determinants.

Metabolic syndrome is a condition comprising multiple metabolic risk factors. People with metabolic syndrome are at twice the risk for developing cardiovascular disease during the five to ten years following diagnosis compared to people without the syndrome. In addition, metabolic syndrome is reported to increase the risk for type 2 diabetes by five-fold (International Diabetes Federation 2006, Alberti, Zimmet & Shaw 2006, Alberti, Zimmet & Shaw 2007, Alberti et al. 2009, Prasad et al. 2012). Furthermore, compared to people without metabolic syndrome, the people with this cluster of risk factors are twice as likely to die from stroke or heart attack according to the International Diabetes Federation (International Diabetes Federation 2006). Recently, metabolic syndrome has also been associated with colon, liver, breast and pancreatic cancer (O'Neill & O'Driscoll 2015).

3.1.2 Diverse definitions of metabolic syndrome

Obesity is a crucial indicator of risk for developing health behaviour-related diseases, and central obesity, in particular, has been highlighted as an independent risk factor. A high level of triglycerides, a low level of high-density lipoprotein (HDL) cholesterol, elevated blood pressure and abnormal blood sugar metabolism (elevated fasting plasma glucose or previously diagnosed diabetes) are also risk factors for metabolic syndrome. The diagnostic criteria for metabolic syndrome according to the global definition (Alberti et al. 2009) and the Finnish Medical Society Duodecim (Duodecim 2017) are as follows: 1. obesity (especially central obesity): waist circumference >100 cm for males and >90 cm for females; 2. a high level of triglycerides: >1.7 mmol/L; 3. a low level of high-density lipoprotein cholesterol: HDL <1.0 mmol/L for males and <1.3 mmol/L for females; 4. elevated blood pressure: systolic blood pressure (SBP) ≥ 130 mmHg and/or diastolic blood pressure (DBP) ≥ 85 mmHg; 5. abnormal blood sugar metabolism: fasting glucose >5.7 mmol/L. Three abnormal values out of these five would classify a person as having metabolic syndrome (Alberti et al. 2009, Cameron et al. 2009, Eckel et al. 2010, Prasad et al. 2012, Duodecim 2017). This definition was followed in this doctoral thesis.

However, numerous diagnostic criteria for metabolic syndrome have been presented. The most widely known have been issued by, among others, the World Health Organization, National Cholesterol Education Program Adult Treatment Panel III (ATP III), American Heart Association/National Heart, Lung and Blood Institute, and International Diabetes Federation. A central difference of opinion concerns the role of obesity (Alberti et al. 2009). The first formal definition, presented in 1998 by the World Health Organization, stressed insulin resistance as a major risk determinant. Obesity was included as an additional indicator among six other determinants (Alberti & Zimmet 1998). ATP III dropped the requirement of insulin resistance and made an opening attempt at a three-out-of-five definition, the five being abdominal obesity, elevated fasting glucose, reduced high-density lipoprotein cholesterol, elevated triglyceride, and elevated blood pressure (National Cholesterol Education Program, National Heart, Lung, and Blood Institute & National Institutes of Health 2002). The American Heart Association followed the ATP III definition, with slight modifications, and also did not require any mandatory risk criterion (Grundy et al. 2005). Later, the definition of the International Diabetes Federation was proposed as a new worldwide definition of metabolic syndrome. It was built on the presence of obesity. To be defined as having metabolic syndrome, a person had always to present with central obesity (with ethnicity-specific values) along with two of the above-mentioned abnormalities (Alberti, Zimmet & Shaw 2006, International Diabetes Federation 2006).

Although the definition of metabolic syndrome and its determinants have been controversial, agreement has been maintained on its core components: obesity, dyslipidaemia, hypertension and insulin resistance (International Diabetes Federation 2006). It is also claimed that these risk factors more frequently co-occur than exist as random single factors (Alberti et al. 2009). A

further attempt to unify the criteria brought several major global organisations together in 2009. The result of this meeting was an agreement that there should be no mandatory component. However, waist measurement was regarded as a suitable tool for preliminary screening (Alberti et al. 2009).

The Finnish diagnostic criteria accord with this recent definition, i.e. a person with three out of five abnormal values is deemed to have metabolic syndrome. In other words, it does not assume central obesity as an obligatory risk indicator (Duodecim 2017). However, it is widely agreed that obesity, together with all its clinical complications, including metabolic syndrome, requires more attention. At the same time, it is acknowledged that defining risk thresholds, especially for abdominal obesity, is also complicated (Alberti et al. 2009), including deciding on the most reliable waist-circumference measurement (Zimmet & Alberti 2008).

3.1.3 Prevalence and treatment of metabolic syndrome

Regardless of its complex and multidimensional assessment, it is estimated that up to a fourth of the population has metabolic syndrome (Alberti, Zimmet & Shaw 2006, International Diabetes Federation 2006, Prasad et al. 2012). In Finland, the estimates are higher: over a third of men and over a fourth of women (Duodecim 2017). Two decades ago, in a Finnish middle-aged population, Vanhala et al. (Vanhala 1996, Vanhala et al. 1997) found prevalences of eight percent for women and 17 percent for men. More recent studies conducted as a part of the Finnish National Diabetes Programme (FIN-D2D) estimated a total prevalence of metabolic syndrome of 53 percent (Korniloff et al. 2010), comprising 51 percent for women and 56 percent for men (Saltevo et al. 2011), in a middle-aged adult population. The increasing prevalence of metabolic syndrome is related to the increase in the number of obese people and sedentary health behaviour. This again makes metabolic syndrome both a public health and a medical issue (Alberti et al. 2009). At the same time, the incidence of type 2 diabetes has been growing rapidly. It is estimated that already half a million Finns have type 2 diabetes. Furthermore, for many people the disease can remain at first unnoticed as the symptoms are unclear and often undetectable at disease onset (Duodecim 2016, THL 2016).

Adequate physical activity and fitness have been found to influence the risk for metabolic syndrome (Shuval et al. 2012, Kim & Choi 2016, Lee, Kim & Jeon 2016, Li et al. 2017b, Zhang et al. 2017). A meta-analysis by He et al. (2014) suggested that a higher level of leisure time physical activity is associated with decreased risk for metabolic syndrome. In addition, physical activity combined with sufficient consumption of fruits and vegetables have found to reduce the risk for metabolic syndrome (Li et al. 2017b). Furthermore, the nutrition of study populations with metabolic syndrome or at risk for metabolic syndrome has been found to include a high intake of saturated fat and sodium, and low intake of polyunsaturated fat and dietary fibre (Jonsdottir et al. 2013).

In addition to obesity and related sedentary health behaviour, excess consumption of alcohol and smoking is linked to the prevalence of metabolic

syndrome. A review and meta-analysis by Vancampfort et al. (2016) found that more than one-fifth of the patients with alcohol use disorder have metabolic syndrome. Furthermore, a high intake of alcohol was significantly associated with increased prevalence of metabolic syndrome in men in the large population-based studies by Hirakawa et al. (2015), Kim et al. (2012) and Jin et al. (2011). The same conclusion was presented by Kim et al. (2011).

Kahl et al. (2010) found that alcohol dependency nearly doubled the prevalence of metabolic syndrome for both women and men compared to control subjects. In addition, the meta-analysis by Sun et al. (2014) found that heavy drinking is likely to be associated with increased prevalence of metabolic syndrome. In contrast, their results suggest that very light alcohol consumption seemed to decrease the prevalence of metabolic syndrome compared to non-drinkers.

Smoking is similarly associated with higher prevalence of metabolic syndrome in men (Nakashita et al. 2010, Zuo et al. 2011, Hwang et al. 2014, Yu et al. 2014, Huang et al. 2015). A large population-based study by Slagter et al. (2013) found the association for both genders. Li et al. (2013) found that current smokers compared to non-smokers were also at increased risk for developing metabolic syndrome. Furthermore, the meta-analysis by Sun et al. (2012) showed that smoking cessation reduces the risk for metabolic syndrome.

Treatment of metabolic syndrome aims at modifying abnormal clinical values. Primary management is inducing a change towards healthy lifestyle including behaviour modifications in nutrition and physical activity (International Diabetes Federation 2006). Of the nutrition components, an increase in the consumption of vegetables, fruits, whole grain products and monounsaturated fats are among those that seem to benefit people with metabolic syndrome (Prasad et al. 2012, Paniagua 2016, James et al. 2017). However, the results are partly controversial. For example, a Finnish longitudinal cohort study found an inverse association between the incidence of metabolic syndrome and the relative proportion of serum omega-6 polyunsaturated fatty acids (Vanhala et al. 2012). Furthermore, the review by Chen et al. (2017) found insufficient data to verify the association between metabolic syndrome and intake of dietary fibre.

Increase in physical activity is another crucial component in treatment of metabolic syndrome (International Diabetes Federation 2006, Samson & Garber 2014, Greer et al. 2015) and more widely in health promotion (Korniloff et al. 2010). Combined dietary and physical activity interventions have decreased the incidence of metabolic syndrome (Chang, Chien & Yu 2017). Frugé et al. (2015) found that an increase in physical activity may be even more protective against metabolic syndrome than reduced intake of calories. Drug therapy is considered as a secondary intervention only, i.e. for possible use if the changes in health behaviour are insufficient (International Diabetes Federation 2006).

For improving patient health in the long term, early recognition of metabolic syndrome is central (Hoffman, VonWald & Hansen 2015). A sensitive (96 % sensitivity) screening test for detection of metabolic syndrome was

developed in Finland by Vanhala (Vanhala 1996) already over two decades ago. The test was based on four risk indicators: obesity assessed by both body mass index and waist-hip ratio, hypertension or medication for blood pressure, and a first-degree relative with type 2 diabetes, all of which are easy to evaluate in primary care.

3.2 Nutrition behaviour

3.2.1 Finnish recommendations for healthy nutrition

As described in the previous sections, obesity and overweight are among the major causes of the global burden of diabetes and other health behaviour-related diseases related to metabolic syndrome. Many aspects of nutrition behaviour are associated with elevated body weight and obesity, e.g. a high intake of saturated fat, excess consumption of sugar, especially sugar-sweetened beverages, and a low intake of dietary fibre (Ley et al. 2014, WHO 2015, WHO 2016).

The Finnish recommendations for healthy nutrition in adults (Elintarviketurvallisuusvirasto, Evira 2016) address the importance of regular eating to control and balance blood glucose levels and avoidance of snacking. The current recommendations were published in 2014. Healthy nutrition includes at least the following: 1) half a kilogram of vegetables, root vegetables, mushrooms, fruits and berries a day to obtain enough dietary fibre and necessary vitamins and minerals; 2) different species of fish at least two to three times a week, as fish is a good source of vitamin D and polyunsaturated fats and proteins; 3) 30 g a day of various nuts and seeds as a daily source of beneficial unsaturated fats; 4) whole-grain products daily, six portions for women and nine portions for men, as whole grain is a good source of both dietary fibre and minerals; 5) restricting consumption of red meat and processed meat products of not more than 500 g per week. Poultry is considered a better choice of meat in addition to fish. Red meat and processed meat products should be as low-fat and low-salt as possible. 6) Sweetened drinks and beverages should be avoided. Instead, water or low-fat dairy products, i.e. milk or sour milk products, are recommended with meals (Elintarviketurvallisuusvirasto Evira 2016).

The Finnish recommendations for healthy nutrition have remained largely unchanged over the last ten years. In the previous recommendations, published in 2005 (Kansanterveyslaitos 2005), the core aims were 1) balancing energy intake and energy consumption to avoid weight gain, 2) increasing the intake of dietary fibre-rich carbohydrates, 3) avoiding refined sugars, 4) decreasing the consumption of saturated fats and partially replacing them with unsaturated fats, 5) reducing salt intake, and 6) decreasing the consumption of alcohol to safe amounts. Daily nutritional intake was guided by the “plate model” and “food pyramid”, which included, e.g. plenty of whole-grain products, vegetables, fruits and berries of different colours, potatoes prepared in diverse ways, reasonable amounts of dairy products, fish often, and meat in the form of low-fat products;

small amounts of fats; and sparing consumption of sugars (Kansanterveyslaitos 2005).

The main differences in nutrient intake in the new compared to previous recommendations were in the Dietary Reference Values (DRVs) for carbohydrates (a decrease in the bottom line values) and fats (an increase in the upper limit values). In addition, the quality of both these nutrient groups was more heavily emphasised (Kansanterveyslaitos 2005, Valtion ravitsemusneuvottelukunta 2014, Elintarviketurvallisuusvirasto Evira 2016).

The nutritional intake recommendations aim not only at benefitting and promoting the health of the Finnish adult population but also that of the natural environment (Elintarviketurvallisuusvirasto Evira 2016). With recommended, healthy nutrition known risk factors for obesity and health behaviour diseases are possibly detected (WHO 2015, WHO 2016, Ley et al. 2014).

3.2.2 Nutrition behaviour, obesity and associated sociodemographic factors

Overall, Finnish adults have shown a positive tendency in their nutrition behaviour, i.e. in this study nutrition items consumed, since 1978 (Helldán & Helakorpi 2015). Ten years ago, during 2006-2008, the consumption of vegetables, fruits and berries, along with low-fat milk increased, and the consumption of bread decreased. Margarines and low-fat spreads became the fats of choice on bread. However, there was a growing sociodemographic gap in nutrition behaviour (Kansanterveyslaitos, KTL 2005) in favour of those with a higher education (Helakorpi et al. 2007, Helakorpi, Prättälä & Uutela 2008, Helakorpi et al. 2009).

Over the past four years, the nutrition behaviour of the Finnish adult population has improved in many areas: for example, the consumption of fruits and vegetables has increased and the proportion of people consuming pastry (cookies, coffee bread etc.), chocolates and sweets every day has decreased. However, from 2015 to 2016 a slight shift away from the national recommendations was perceived (Elintarviketurvallisuusvirasto Evira 2016), namely an increase in the proportion of people not consuming fruits or berries, rye bread, vegetable oils, or fish at least once a week. In addition, the consumption of soft drinks and other sugar-sweetened liquids and beverages had increased (Murto et al. 2016, Murto et al. 2017).

At the same time, the proportion of overweight or obese people has been growing. In 2017 a fifth (19.7 %) of Finnish adults were estimated to be obese (BMI \geq 30). In 2013, the corresponding proportion was 18.5 percent and in 2006 16.4 percent (Murto et al. 2016, Murto et al. 2017, THL 2017). Of the working-age population (25-64 years), more than half (55 %) were estimated to be at least overweight (BMI \geq 25) in 2017 (THL 2017). In 2006, the corresponding proportion was 53.2 percent. The proportion of obese adults was also smaller in 2006 (16.4 %) than currently (THL 2017).

Both nutrition behaviour and body mass index vary in adults according to sociodemographic factors. In 2017, a clear difference, especially in the consumption of vegetables and fish, and in the consumption of fresh fruits and

berries, was evident in favour of the higher compared to lower educated. Also, those with the lowest educational level also showed the highest rate of obesity (22.8 %). The percentage of the obese population with a high level of education was 18.7 % and the corresponding rate for those with a medium level of education was 14.9 % (Murto et al. 2016, Murto et al. 2017).

4 SUMMARY OF THE THEORETICAL BACKGROUND

Theoretically, this research is based on health promotion in the primary healthcare context where brief counselling interventions serve as a means of disease prevention and a way of enhancing health equally across all population groups. The methods used to deliver a brief intervention are often founded on the Transtheoretical Approach. In study 1, a systematic literature review, evaluating brief interventions on nutrition, was conducted, while in study 2 empirical data were used to evaluate the prevalence of metabolic syndrome and its clinical determinants in different sociodemographic groups. Metabolic syndrome was chosen for assessment as it is a cluster of risk factors for many health behaviour-related diseases and is influenced by nutrition behaviour. Figure 2 summarises the theoretical framework and presents the central terms used in the study.

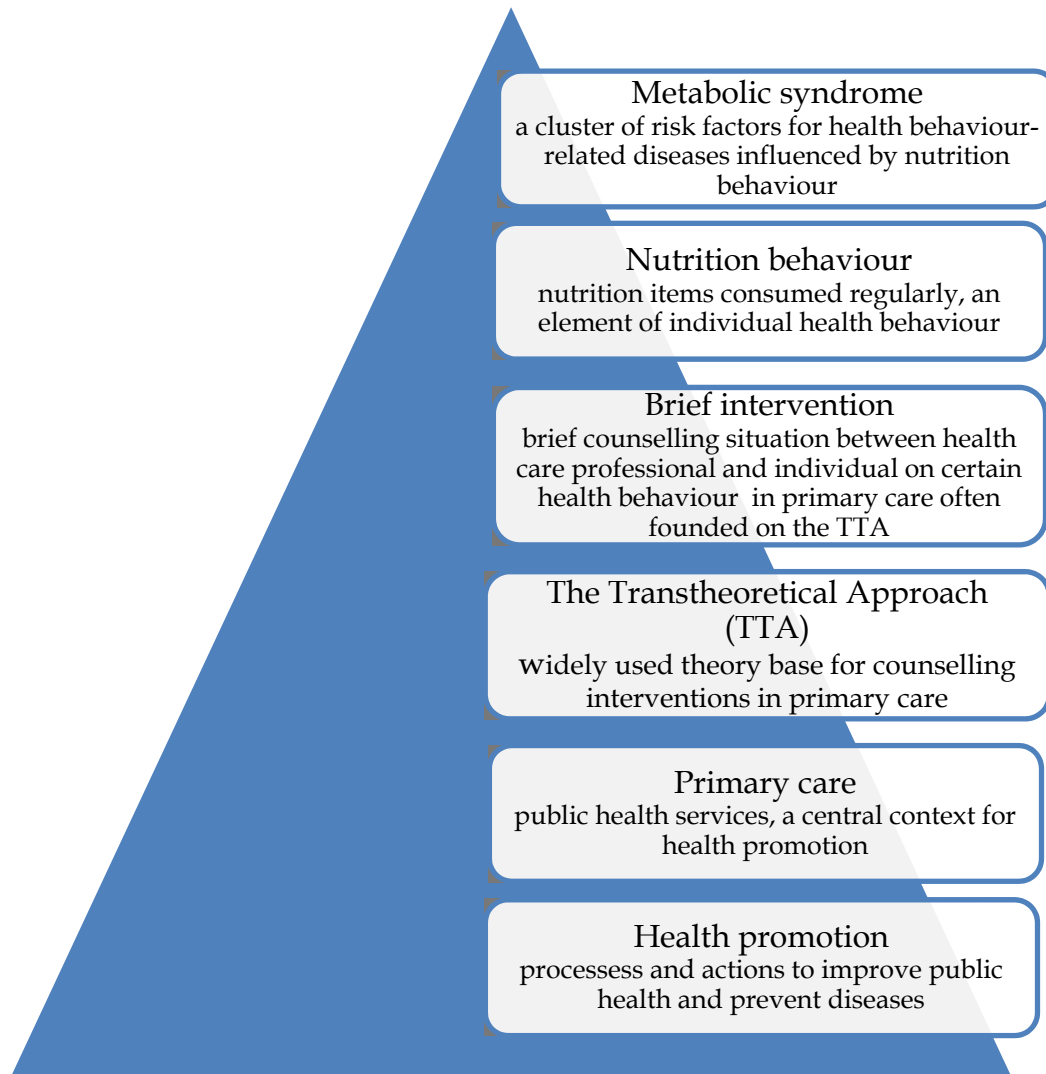


FIGURE 2 Summary of the theoretical framework of the study.

5 THE AIM OF THE STUDY

The aim of this doctoral thesis was

- i) to examine the influence of a brief nutrition-based intervention among primary care patients in changing nutrition behaviour and clinical values related to metabolic syndrome (study 1), and
- ii) to assess nutrition behaviour and the prevalence of metabolic syndrome and its single clinical determinants among primary care patients in different sociodemographic groups (study 2).

The overall aim of the study was to evaluate and increase awareness of methods in primary care that can be effective in preventing the spread of health behaviour-related diseases. To achieve this aim, in-depth information on the influence of brief interventions on nutrition behaviour was collected. Knowledge on the prevalence of metabolic syndrome and the influence of sociodemographic background on the definers of metabolic syndrome and on patients' nutrition behaviour and their willingness to change their nutrition habits can assist in the effective targeting of interventions.

The specific research objectives (RO) of the study were to evaluate:

- I the influence of a brief intervention on nutrition in modifying 1) nutrition behaviour and 2) metabolic syndrome determinants among adult patients in primary care;
- II nutrition behaviour and willingness to change nutrition behaviour among different sociodemographic groups of adult patients in primary care in Central Finland;
- III clinical determinants of metabolic syndrome among different sociodemographic groups of adult patients in primary care in Central Finland;
- IV the prevalence of metabolic syndrome among different sociodemographic groups of adult patients in primary care in Central Finland, and association of obesity and blood pressure with the prevalence of metabolic syndrome;
- V the association of nutrition and other related health behaviours with the prevalence of metabolic syndrome.

6 DATA AND METHODS

6.1 Summary of the data and analysis

This doctoral thesis comprises two studies that were designed to address five research objectives (RO) and eight outcome measures. Table 1 summarises the specific objectives, data, outcome measures and analyses conducted. The answer to research objective I is provided by the two outcome measures of the systematic review. The answers to research objectives II-V, are provided by the six outcome measures of the EVI data analysis. Sections 6.2. and 6.3. present the analytical methods in detail.

TABLE 1 Methods and data of the doctoral thesis.

RESEARCH OBJECTIVES	OUTCOME MEASURES	DATA	METHODS AND ANALYSIS
STUDY 1: SYSTEMATIC REVIEW			
<p>I: The influence of a brief intervention on nutrition in modifying nutrition behaviour and metabolic syndrome determinants among adult patients in primary care.</p>	<ol style="list-style-type: none"> 1. Change in patients' nutrition behaviour 2. Change in patients' clinical determinants of the metabolic syndrome 	<p>Systematic search in eight databases + supplementary searches</p> <p>Total number of articles found: 983</p> <p>Total number of articles excluding duplicates: 872</p> <p>Number of articles selected for review: 5</p>	<p>Synthesis of the included studies</p> <p>Quality assessment of the included studies</p> <p>Assessment of overall quality of the evidence</p>
STUDY 2: EVI STUDY, COHORT DESIGN			
<p>II: Nutrition behaviour and willingness to change nutrition behaviour among different sociodemographic groups of adult patients in primary care in Central Finland.</p>	<ol style="list-style-type: none"> 1. Nutrition behaviour and willingness to change nutrition behaviour in different sociodemographic groups in 2006 and 2007. 	<p>Data set I</p> <p>First questionnaire in 2006 + follow-up questionnaire in 2007</p> <p>n=557, representing the EVI study patients who had completed both the 2006 and 2007 questionnaires</p>	<p>Chi-Square test</p>

(continues)

TABLE 1 (continues)

<p>III: Clinical determinants of metabolic syndrome among different sociodemographic groups of adult patients in primary care in Central Finland.</p>	<p>2. Single clinical risk factors for metabolic syndrome in different sociodemographic groups in 2006 and 2008.</p> <p>3. Categorized clinical risk factors for metabolic syndrome in different sociodemographic groups in 2006 and 2008.</p>	<p>Data set II:</p> <p>Patients' medical history records, including clinical values for metabolic syndrome + self-reported body mass index and waist circumference from 2006 and 2008</p> <p>n=557: study patients for whom at least one metabolic syndrome-related clinical value was available</p>	<p>General Linear Model (Outcomes 2 and 3)</p> <p>Chi-Square test (Outcome 3)</p>
<p>IV: The prevalence of metabolic syndrome among different sociodemographic groups of adult patients in primary care in Central Finland, and association of obesity and blood pressure with the prevalence of metabolic syndrome.</p>	<p>4. Prevalence of metabolic syndrome in different sociodemographic groups in 2006.</p> <p>5. Association between i) metabolic syndrome and obesity, and ii) metabolic syndrome and obesity + blood pressure.</p>	<p>Data set III:</p> <p>Patients' medical history records including clinical values for metabolic syndrome + self-reported body mass index and waist circumference from 2006</p> <p>n=251: study patients for whom all five metabolic syndrome-related values were available</p>	<p>Chi-Square test (Outcomes 4-5)</p> <p>Logistic Regression (Outcome 4)</p>
<p>V: The association of nutrition and other related health behaviours with the prevalence of metabolic syndrome</p>	<p>6. Influence of nutrition and related health behaviours (physical activity, alcohol consumption and tobacco use) on the prevalence of metabolic syndrome in 2006.</p>	<p>Data set IV</p> <p>Combination of data set I from 2006 and data set III</p> <p>n=251</p>	<p>Logistic Regression</p>

6.2 Study 1: Systematic review

6.2.1 Formulation of the review question

The review question specifies the types of population, types of interventions, and the types of outcomes that are of interest. The acronym PICO serves as a reminder of the factors that must be considered in conducting a systematic review. P stands for the participants, I for the intervention to be evaluated, C for comparisons, and O for the outcomes that are of interest (Higgins & Green 2011). For this systematic review, PICO was defined as follows: P (patients and problem): adult patients in the primary health care without a diagnosed chronic or severe disease; I (intervention): brief intervention on nutrition or on a nutrition-related issue (brief intervention, brief counselling, nutrition screening); C (comparisons): no intervention, usual care, intensive intervention, other brief intervention; O (outcomes): primary outcome is a change in the patient's nutrition behaviour, and secondary outcomes, when applicable, are a change in the clinical determinants of metabolic syndrome. In addition, the following were defined: S (study design): randomised controlled trials (RCT) supplemented with other study designs, i.e. controlled trials and cohort studies; T (time): minimum follow-up duration of six months.

Because the review sought to evaluate the studies that have been conducted on brief interventions involving nutrition counselling in the primary care context, and because nutrition-based interventions also often include clinical values as outcome measures, determinants of metabolic syndrome were also considered as possible outcomes in the review. Consequently, the review objective (i.e. review question) was formulated as following aim: *to evaluate the influence of a brief nutrition-based intervention in primary health care on 1) adult patients' nutrition, and 2) determinants of metabolic syndrome*. The literature search was conducted between September and October 2016 with a final update in November 2017. The search covered all the publications available until that date. The Cochrane Handbook for systematic reviews (Higgins & Green 2011) was used as a guideline for conducting the systematic review.

6.2.2 Sources of information

The search for studies was divided into three categories by the relative weighting of the comprehensiveness and precision of the search. Together, these three search categories aim at a search result that is as wide as possible to ensure that the great majority of relevant studies are included, while at the same time maintaining a balance between the comprehensiveness and relevance of the studies responding to a search strategy.

The first category (CT 1) of the search stressed precision with quality-controlled publication hits. CT 1 formed the principal search category. The

following seven central health-related databases were used and included all the publications available up to the search date: 1. Cochrane Central Register of Controlled Trials (up to 09/2016); 2. Cochrane Database of Systematic Reviews (2005 - 10/2016); 3. Database of Abstracts of Reviews (DARE) (- 2015); 4. Medline (1946 - 10/2016); 5. ACP Journal Club (1991 - 10/2016); 6. Health Technology Assessment (HTA) (9 / 2016); 7. Medline Epub Ahead of Print (up to 27/10/2016). (See also figure 3.)

The Cochrane Central Register of Controlled Trials is considered the best single source for identifying the research to be considered for a systematic review (Higgins & Green 2011). The other six databases were used to obtain studies with high quality trials that were as relevant as possible. The above-described bibliographic search produced 121 hits of which 113 were different (i.e. there were eight duplicates).

The other systematic search category (CT 2) was supplementary to the first search category. Instead of precision, the weight was on comprehensiveness, the assumption being that the number of the hits would be greater. The PubMed (Medline) bibliographic database was used with this systematic, yet wider search strategy. The result was 611 studies to be considered for the review.

All eight databases were searched between September 2016 and October 2016. After that date, new relevant research was scanned weekly with the last update conducted on 10.11.2017. In total, 58 new hits were identified after the original search. Duplicates were removed manually from the two search categories (CT 1 and CT 2).

In addition to the systematic bibliographic search described above, relevant studies were located from the Cumulative Index to Nursing and Allied Sciences (CINAHL) database (164 hits), and by handsearching the other review articles and related studies and their references (11 hits). Furthermore, potential research was searched in non-published and non-indexed sources (Ovid MEDLINE In-Process & Other Non-Indexed Citations, until 10/2016, 18 hits). These served as the third and complementary search category (CT 3), the aim being to locate research that could have remained outside the systematic bibliographic search (such as conference papers). In total, 193 studies were found in this third category.

6.2.3 Search strategy

The terms used to search for a review are typically divided into three sets (Higgins & Green 2011): 1. terms related to the health condition of interest; 2. terms related to the evaluated intervention(s); 3. terms related to the study design. To ensure as wide a reach as possible and include all the relevant studies, a different search approach and strategy suited to the information source was developed for each of the search categories (1-3). Defining the search strategy and deciding on the right terms was a process which aimed on the one hand at comprehensiveness and on the other at maintaining an appropriate level of relevance, i.e. finding a balance between the sensitivity and precision.

Database-controlled and database-specific standardised subject terms were used for the search. In addition, to identify suitable search terms, subject-specific

vocabulary terms were identified by retrieving articles addressing the target topic. Both synonyms, related terms and variant spellings (British/USA) were used in the database search to ensure comprehensiveness. The search was targeted at abstracts and headlines. From the acronym PICO only the letters P and I, that is “population” and “intervention”, were used to narrow the systematic search in the databases, i.e. the search strategy was not restricted e.g. by a comparison group, outcome measures or follow-up time. Population referred to the words *adult in primary care or a primary ward or health center or health centre or clinical practice* and intervention to a variety of terms related to the intervention, i.e. *brief intervention or intervention or counseling or counselling or screening* combined with a nutrition-related term e.g. *nutrition or dietary*, and additionally with term *overweight* as such interventions often include counselling on nutrition behaviour (see figure 3).

The search was not limited exclusively to articles published in English. However, the systematic search only produced articles where at least the abstract was published in English. Furthermore, no date restrictions were applied in the search strategy, i.e. the search covered all the articles produced by the database. In addition, ahead prints and prepublications were eligible. Also, in order not to leave out suitable studies, automatic search filters were not used in any database. Instead a wide range of search terms was used, and the search results were then combined using the OR operator. Due to the nature of the review question, the literature search was not restricted to randomised controlled trials.

The first systematic search in the databases was based on the terms “brief intervention” and “brief counselling”. However, this strategy turned out to be over-precise and resulted in a small number of reports, as can be seen in figure 3. Therefore, the search strategy was reformulated, and the terms “intervention” and “counselling” were considered as a search terms with no a restriction to “brief”. In addition, the term “screening” was used to increase comprehensiveness. Another central search term was “nutrition” and related terms. These were combined with the term designating the intervention, i.e. they were not considered as outcomes, as shown in figure 3.

The final search strategy and the terms used as well as the number of hits obtained from the primary search (category 1) is presented in detail in figure 3. For the supplementary search (category 2), the search strategy is presented in Appendix 1.

DATABASES (search conducted in September – October 2016):

EBM Reviews - ACP Journal Club <1991 to October 2016>,
 EBM Reviews - Cochrane Central Register of Controlled Trials <September 2016>,
 EBM Reviews - Cochrane Database of Systematic Reviews <2005 to October 19, 2016>,
 EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2015>,
 EBM Reviews - Health Technology Assessment <3rd Quarter 2016>,
 Ovid MEDLINE(R) Epub Ahead of Print <October 21, 2016>,
 Ovid MEDLINE(R) <1946 to October Week 2 2016>

SEARCH STRATEGY:

- 1 **brief intervention and nutrition** ab. (18)
- 2 **brief intervention and dietary** ab. (18)
- 3 **brief intervention and overweight** ab. (17)
- 4 1 or 2 or 3 (47)

- 5 **intervention and nutrition** ab. (9667)
- 6 **intervention and dietary** ab. (18443)
- 7 **intervention and overweight** ab. (8436)
- 8 5 or 6 or 7 (31227)

- 9 **counseling and nutrition** ab. (1729)
- 10 **counseling and dietary** ab. (2382)
- 11 **counseling and overweight** ab. (973)
- 12 9 or 10 or 11 (4147)

- 13 **counselling and nutrition** ab. (516)
- 14 **counselling and dietary** ab. (917)
- 15 **counselling and overweight** ab. (310)
- 16 13 or 14 or 15 (1436)

- 17 **screening and nutrition** ab. (2564)
- 18 **screening and dietary** ab. (3231)
- 19 **screening and overweight** ab. (1717)
- 20 17 or 18 or 19 (6878)

- 21 4 or 8 or 12 or 16 or 20 (39925)

- 22 **primary care or primary ward or health center or health centre or clinical practice** ab. (189430)

- 23 21 and 22 (1741)

- 24 **adult** ab. (536809)

- 25 23 and 24 (121)

FIGURE 3 Search strategy for the primary search, combination of the search terms (in bold) and number of hits (in brackets).

6.2.4 Selecting studies and inclusion and exclusion criteria

The process of selecting the studies followed the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green 2011). The publications produced by the search process (described in the previous sections; see also 6.2.1 for a description of the PICO setting) was reviewed and the decision to exclude or include was made in three phases. Most of the publications were excluded based on the information presented in the title and brief descriptive publication details of the article (phase 1) or based on the abstract (phase 2). The full text version of the article and possible additional method articles were examined in phase three when the second phase did not produce enough information for the inclusion/exclusion decision. In unclear situations, the corresponding author of the study was contacted to ensure a correct inclusion/exclusion decision.

The following exclusion criteria A-F were used to evaluate the appropriateness of the study: A) Study theme was not appropriate, i.e. the study was not related to nutrition behaviour, e.g. studies conducted on tobacco use; B) Setting or intervention trial was not appropriate, i.e. setting was other than primary care or trial was other than brief intervention, e.g. studies with intensive interventions; C) Target group was not appropriate, i.e. target group was other than adults not affected with a severe disease, e.g. children, cancer patients; D) Publication did not describe an intervention trial, e.g. the publication was a guideline; E) Publication was a review article or a comment on an article; F) Follow-up of the study was less than six months.

Trials where a brief intervention was used in the counselling of adult patients on nutrition in the primary care context were included. A brief intervention was defined as time-limited (≤ 15 minutes) advice given by a health care professional (e.g. general practitioner, nurse). Interventions supplemented by written material or tests were included, but those with other additional elements (e.g. telephone reminder calls) or multi-contact counselling (> 3 sessions, as this indicates an intensive intervention) were excluded as the aim was to evaluate counselling that is brief and easily conducted during any visit to a primary health care professional. To evaluate more persistent change in behaviour studies with a follow-up of less than six months were also excluded. When a comparison intervention of an intensive intervention referred to standard care but nevertheless included the elements of a brief intervention, it was included in the review.

6.2.5 Quality assessment of the studies

To be able to draw conclusions on the efficacy of interventions, evaluation of their quality, i.e. external and internal validity, is a crucial part of the review process (Higgins & Green 2011). External validity is an assessment of the appropriateness of the research question addressed by the study. Internal validity, in turn, appraises whether the study answers the research question free from bias (Higgins & Green 2011).

Many tools for assessing risk for bias are available. The most suitable tool will depend on the nature of the studies to be reviewed. In this dissertation, the Quality Assessment Tool for Quantitative Studies (the Effective Public Health Practice Project 2008a, 2008b) was used to assess the internal and external validity of trials according to eight criteria relevant to public health studies: selection bias, allocation bias, confounding, detection bias, data collection methods, attrition bias, statistical analysis and intervention integrity (i.e. the consistency of the intervention, the percentage of the allocated intervention received by the participants and contamination or co-intervention). The tool is designed especially for use in public health research. The content and construct validity of this tool have been established and it has been proposed as suitable for reviewing RCTs, non-randomized controlled studies and uncontrolled studies (Thomas et al. 2004, the Effective Public Health Practice Project 2008a, Higgins & Green 2011).

For the evaluation of the reviewed studies, the Quality Assessment Tool for Quantitative Studies Dictionary was used. Each of the eight components of the quality assessment tools was evaluated independently. The final, summarising rating, so called global rating, for each study was then formulated based on the individual component ratings. The global rating of strong, moderate or weak is a result of the ratings of the following six components: selection bias, study design, confounders, blinding, data collection methods, and withdrawals and dropouts. Two or more weak ratings mean a weak global rating; fewer than four strong ratings and one weak rating mean a moderate global rating; and a strong global rating requires four strong ratings and no weak ratings (The Effective Public Health Practice Project 2008a).

Before the final ratings of the included studies, it was established that the minimum confounders that had to be controlled for in the trials were gender and age. In addition to the global rating, the mean score of the single ratings was calculated. The mean score is not part of the Quality Assessment Tool (the Effective Public Health Practice Project 2008b), but it was formulated to provide a more refined perspective on study quality and the differences between studies. The mean score could vary from 1 to 3, where the value 1 represents the highest quality and 3 the lowest quality.

6.2.6 Quality of the evidence

After the quality assessment of the included studies, the quality of the evidence and the strength of the recommendations were then assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system (Guyatt et al. 2008a, Guyatt et al. 2008b, Schunemann et al. 2008, Andrews et al. 2013). The quality of the evidence can be considered the summarising result of the review process. GRADE is recommended by the Cochrane Collaboration for evaluating evidence quality. It provides an explicit system for quality evaluation; this is important for avoiding overestimation of the intervention effects or making misguided recommendations. In addition, it enables a clear distinction to be drawn between the quality of the evidence and the strength of

recommendations that is useful, for example, when conducting systematic reviews (Guyatt et al. 2008a, Guyatt et al. 2008b, Schunemann et al. 2008).

The quality of evidence is crucial in forming accurate recommendations, as failure to distinguish high quality evidence from low quality evidence can lead to misleading recommendations. When an intervention's desirable effects clearly outweigh its undesirable effects (or vice versa) a strong recommendation becomes possible (Guyatt et al. 2008b).

GRADE classifies evidence quality on four levels: high, moderate, low, and very low. High evidence quality indicates that further research is very unlikely to change confidence in the estimate of effect. Low quality evidence, in turn calls for further research, which is also assumed to be very likely to change the estimate of effect. Assessment of randomised controlled trials begins with a rating of high evidence quality. Study limitations (e.g. lack of allocation concealment, lack of blinding, large losses to follow-up) inconsistency in the results, indirectness of evidence, imprecision and publication bias each decrease the quality of the evidence by one level. Quality can also be increased by a large effect size, reasonable confounding, and a dose-response gradient (Guyatt et al. 2008a, 2008b, Schunemann et al. 2008).

On the strength of recommendations, GRADE offers two levels: strong and weak. For systematic reviews, this reflects the amount of confidence that an estimated effect is correct rather than support for making recommendations. In addition to the quality of evidence assessed as described above, other factors influence estimation of the strength of recommendations, namely, uncertainty about the balance between desirable and undesirable effects, uncertainty or variability in values and preferences, and uncertainty about whether the intervention represents a wise use of resources (Guyatt et al. 2008a, Guyatt et al. 2008b).

6.2.7 Data extraction and synthesis of the included studies

The data obtained are presented in detail in Chapter 7 and discussed as a descriptive synthesis in Chapter 8. The limited number of publications identified as relevant to the review question rendered statistical analysis of the data inappropriate. Other reasons for not conducting a meta-analysis were the differences in the interventions and their outcome measures, and limitations in the quality of the trials. Clinical diversity and methodological diversity were also present. The synthesis of the trials is based on results reported on an intention-to-treat basis.

6.3 Study 2: The Early Recognition of Lifestyle Diseases (EVI) study

6.3.1 Study setting

The “Early Recognition of Lifestyle Diseases” study (later the EVI study) was designed to recognise risky health behaviour among primary care patients. The aim of the study was to promote the systematic use of a brief intervention as a routine part of primary care, and to address primary health care patients’ nutrition, physical activity, smoking and alcohol consumption. The study protocol is also described in Kuninkaanniemi et al. (2011).

The EVI study was conducted from November 2006 to May 2008 in nine municipalities in Central Finland. A questionnaire with questions on nutrition, physical activity, alcohol consumption, and smoking was given to all patients attending one of the participating nine health care centres (for any reason except an emergency) in November 2006. Patients able to complete the questionnaire individually and aged at least 15 were deemed eligible. In addition to the questions on health behaviour and sociodemographic data, the questionnaire contained items on the readiness to change health behaviour, based on the Stages of Change model (Prochaska et al. 1994). Patients’ body weight and height, for the calculation of body mass index, and waist circumference were also recorded. Information on healthy habits with suggestions for further reading was added at the end of the questionnaire. The parts of the questionnaire used in this thesis are presented in Appendix 2.

Primary care personnel (nurses, physicians and social workers) in the health centres were requested to conduct a brief intervention with their patients during the study period. The content of the intervention was based on national recommendations and on the patient’s individual situation. It included a conversation about the patient’s problem behaviour (either nutrition, physical activity, alcohol consumption or tobacco use), and recommendations and instructions on how to change the behaviour. No supplementary elements (e.g. telephone contacts, mailings or reminders) were included.

During 2006, 1 211 volunteer patients completed the questionnaire, and the 12-month follow-up questionnaire was mailed in November 2007 to the 1 020 patients who had given permission to be contacted for the follow-up. A written informed consent form allowing the researchers to obtain data from the patients’ medical history records was enclosed with the follow-up questionnaire. The follow-up questionnaire was returned by 599 patients. Table 2 presents the characteristic of these patients (Kontinen, Villberg & Poskiparta 2008). The flowchart for the whole EVI study, and this doctoral thesis, is presented in figure 4.

TABLE 2 Baseline characteristics obtained for the EVI study in 2006 and 2007 (Kontinen, Villberg & Poskiparta 2008).

	2006		2007	
	FEMALE	MALE	FEMALE	MALE
N	829	375	431	168
%	69	31	72	28
Age (mean, years)	51	52	52	53
Waist (cm)	89	101	88	97
BMI	27	27	27	28
Working, %	45	39	40	33
Retired, %	40	48	48	56

The results based on the questionnaires 2006 and 2007 are reported in Kontinen, Villberg & Poskiparta (2008), and a summary of the research questions, outcome measures and analysis presented in Appendix 3. Changes in behaviours were evaluated in a repeated measure setting. Overall nutrition behaviour, physical activity, alcohol consumption and use of tobacco products did not change much between 2006 and 2007. In nutrition behaviour, men had increased their consumption of vegetable oil and margarine in cooking and baking and use of low-fat cold cuts on bread. Both genders had changed the consumption of vegetables, fruits and berries. Women had reduced the addition of salt, ketchup and soya sauce to meals. Both women and men had increased their amount of light and moderate physical activity between 2006 and 2007, while among women vigorous physical activity had decreased in 2007. Between 2006 and 2007 no marked changes in alcohol use were reported. Men, but not women, reported an increase in the number of units consumed in 2007 compared to 2006. Use of tobacco products was overall rather rare and showed no changes in responses between the years 2006 and 2007 (Kontinen, Villberg & Poskiparta 2008).

6.3.2 Description of the data

The quantitative data to be analysed consisted of four different data sets drawn from those collected for the EVI study on a cohort basis. For the analysis of the patients' nutrition behaviour, the questionnaire data from 2006 and 2007 (n=557) were used (for the questionnaire items, see Appendix 2). This formed data set I. In addition to the questionnaire data, medical data were collected, with patients' consent, from the patients' electronic medical history records. The medical data included clinical values related to metabolic syndrome: these were: Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), High Density Lipoprotein (HDL), triglyceride, and fasting plasma glucose. In addition, total cholesterol and patients' medications were extracted. The pre-intervention values dated from 2006 (in a few cases from 2004-2005 in the absence of a value for 2006) and the post-intervention values from 2008. Consequently, data set II consisted of the patients who had completed the questionnaire in 2006 and 2007 and for whom at

least one of the diagnostic values for metabolic syndrome was available from both observation points, i.e. from 2006 and 2008 (n=557).

Assessment of the prevalence of metabolic syndrome only included patients for whom measurements of all five metabolic syndrome determinants were available (n=251). This information formed data set III. Data set IV combined the five clinical values (data set III) and questionnaire data (data set I) from 2006 (n=251). Figure 4 shows the flowchart and data formation.

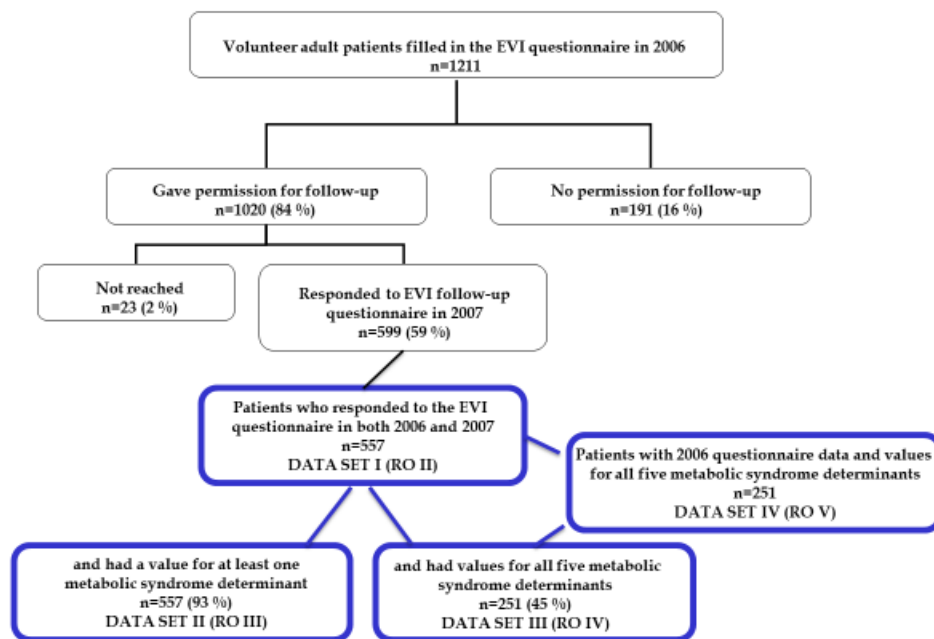


FIGURE 4 Flowchart of the patients and (framed in blue) the four data sets analysed in the doctoral thesis. RO=Research objective.

6.3.3 Outcome measures

Outcome measures, six in total, of the EVI data pertained to patients' nutrition behaviour and to metabolic syndrome and its single clinical determinants as follows: 1. Nutrition behaviour and willingness to change nutrition behaviour in different sociodemographic groups in 2006 and 2007; 2. Single clinical risk factors for metabolic syndrome in different sociodemographic groups in 2006 and 2008; 3. Categorised clinical risk factors for metabolic syndrome in different sociodemographic groups in 2006 and 2008; 4. Prevalence of metabolic syndrome in different sociodemographic groups in 2006; 5. Association between i) metabolic syndrome and obesity, and ii) metabolic syndrome and obesity + blood pressure; and 6. Influence of nutrition and related health behaviours (physical activity, alcohol consumption and tobacco use) on the prevalence of metabolic syndrome in 2006. Table 3 summarises the outcomes, indicators and sources.

Patients' nutrition behaviour was analysed for the following four items included in the questionnaire (Appendix 2): 1) consumption of fish at least two times a week, 2) consumption of whole grain products daily, 3) consumption of vegetables, fruits and berries daily, 4) and having snacks (e.g. sweets, cookies,

crisps) at least once daily. Willingness to change nutrition was evaluated in the questionnaire by the simple question "Are you willing to change your nutrition behaviour?" with response options yes or no. (Outcome 1, data set I.)

Associations of a cross-section of the single clinical mean values related to metabolic syndrome with sociodemographic background variables were measured at two time points, the year 2006 and the year 2008. Besides the clinical indicators of metabolic syndrome, total cholesterol was also controlled for to obtain information that was as representative as possible. The categorised values of the single metabolic syndrome determinants for 2006 and 2008 were analysed likewise. (Outcomes 2 and 3, data set II.) Flowchart and changes in the single values of the patients who received the intervention on nutrition are reported in detail in Kuninkaanniemi et al. (2011) and summarised in Appendices 4 and 5.

Metabolic syndrome and its diagnostic criteria were assessed according to the global definition (Alberti et al. 2009) presented in chapter 3, and according to the Finnish Medical Society Duodecim (Duodecim 2017) as follows: 1. obesity (especially central obesity): waist circumference >100 cm for males and >90 cm for females, and BMI ≥ 30 kg/m²; 2. a high level of triglycerides: >1.7 mmol/L; 3. a low level of high-density lipoprotein cholesterol: HDL <1.0 mmol/L for males and <1.3 mmol/L for females; 4. elevated blood pressure: SBP ≥ 130 mmHg and/or DBP ≥ 85 mmHg; 5. abnormal blood sugar metabolism: fgluc >5.7 mmol/L. When three out of these five are present, the condition is considered as a metabolic syndrome. Direct medication for a condition, i.e. for elevated blood pressure, for elevated cholesterol and for elevated blood glucose, was considered as an indicator of an abnormal value, as suggested in the global definition of metabolic syndrome (Alberti et al. 2009).

The clinical values for the prevalence of metabolic syndrome were drawn from the patient's medical records for the observation year 2006. The values for body mass index and waist circumference were self-reported (Outcome 4, data set III.) In addition to the prevalence of metabolic syndrome, its association with obesity was tested. Analysis included the effect of blood pressure. (Outcome 5, data set III.) The effects of nutrition and related health behaviours, namely physical activity, alcohol consumption and tobacco use, on the prevalence of metabolic syndrome was the sixth outcome (data set IV).

The sociodemographic determinants were educational level and job status. Education was classified into three categories: 1) low: comprehensive school or similar, 2) medium: upper secondary school or vocational school, and 3) high: lower academic degree or higher. Occupational status was categorised as 1) physical work, 2) office work, 3) retired, and 4) student or unemployed. The background variables of gender and age were controlled for. Patients were divided into three age groups: 1) 15-40 years, 2) 41-64 years, and 3) 65 years or over (up to 90 years).

TABLE 3 Summary of outcomes, indicators and data sources.

OUTCOME	INDICATORS	SOURCE
1. Nutrition behaviour and willingness to change nutrition behaviour in different sociodemographic groups in 2006 and 2007	<ul style="list-style-type: none"> - Fish \geq two times a week - Whole grain products daily - Vegetables, fruits, berries daily - Snacks at least once daily - Willing to change nutrition 	EVI questionnaires in 2006 and in 2007 (Data set I)
2. Single clinical risk factors for metabolic syndrome in different sociodemographic groups in 2006 and 2008	Continuous values: <ul style="list-style-type: none"> - SBP, mmHg - DBP, mmHg - Total chol., mmol/L - HDL, mmol/L - Trigly, mmol/l - Fgluc, mmol/L - BMI, kg/m² 	Patients' medical history records + self-reported body mass index and waist circumference from 2006 and 2008 (Data set II)
3. Categorized clinical risk factors for metabolic syndrome in different sociodemographic groups in 2006 and 2008	Categorized values: <ul style="list-style-type: none"> - SBP\geq130 and/or DBP\geq85 mmHg - HDL <1 / <1,3 mmol/L - Trigly >1,7 mmol/L - Fgluc, >5,7 mmol/L - BMI\geq30+waist>90/100 kg/m²+cm 	Patients' medical history records + self-reported body mass index and waist circumference from 2006 and 2008 (Data set II)
4. Prevalence of metabolic syndrome in different sociodemographic groups in 2006	Three out of the five categorised values: <ul style="list-style-type: none"> - SBP\geq130 and/or DBP\geq85 mmHg - HDL <1 / <1,3 mmol/L - Trigly >1,7 mmol/L - Fgluc, >5,7 mmol/L - BMI\geq30+waist>90/100 kg/m²+cm 	Patients' medical history records + self-reported body mass index and waist circumference from 2006 and 2008 (Data set III)
5. Association between i) metabolic syndrome and obesity, and ii) metabolic syndrome and obesity + blood pressure	Three out of the five above-mentioned categorised values comprising metabolic syndrome in relation to the categorised values of obesity and blood pressure	Patients' medical history records + self-reported body mass index and waist circumference from 2006 and 2008 (Data set III)
6. Influence of nutrition and related health behaviours (physical activity, alcohol consumption and tobacco use) on the prevalence of metabolic syndrome in 2006	Three out of the five above-mentioned categorised values comprising metabolic syndrome in relation to nutrition indicators (see outcome 1) and <ul style="list-style-type: none"> - Vigorous PA 0-1 times a week 2-4 times a week 5-7 times a week - Alcohol cons. \geq 2-3 times a week no consumption \leq once a month 2-4 times a month - Tobacco use No Yes 	EVI questionnaires in 2006 and in 2007 and patients' medical history records + self-reported body mass index and waist circumference from 2006 and 2008 (Data set IV)

6.3.4 Statistical analysis

The statistical analysis was performed using SPSS 24 with consultation with a specialist statistician. For significant difference between groups, a threshold of $\alpha \leq .05$ was set for all the analyses including Chi-Square tests, logistic regression analyses and General Linear Model (GLM) analyses.

Baseline characteristics were analysed using the Chi-Square test. Data on patients' nutrition behaviour and willingness to change this were drawn from the responses to the questionnaires administered in 2006 and 2007 (data set I). To evaluate the statistically significant difference between the sociodemographic groups in these variables the Pearson Chi-Square test was used.

All the clinical values gathered in 2006 and 2008 were analysed as continuous variables ($n=557$, data set II). To evaluate the influence of the sociodemographic factors, i.e. educational level and occupational status, on these clinical continuous outcomes the General Linear Model was used. In addition, categorised values for the five determinants of metabolic syndrome were used to assess the incidence of the single determinants of metabolic syndrome among the patients in 2006 and 2008 ($n=557$, data set II). The Chi-Square test was used for these analyses. The values for the recommended values, and for the abnormal values were categorised according to the definition of metabolic syndrome by the Finnish Medical Society Duodecim (Duodecim 2017) presented in the previous section. Direct medication for elevated blood pressure, for elevated cholesterol and for elevated blood glucose was considered an indicator of an abnormal value (Alberti et al. 2009).

In addressing the prevalence of metabolic syndrome, patients' clinical values from 2006 were used as categorised variables. The number of clinical values available for an individual patient was controlled for in these analyses. This meant that only patients for whom all five metabolic syndrome determinants were available, i.e. clinical measures in addition to self-reported body mass index and waist circumference, were included ($n=251$, data set III). To ensure that the selection of this patient sample was based on the relevant background characteristics of gender and age, as well as the sociodemographic background variables, these variables were compared to those of the patients for whom all five values were not available.

The analysis of the prevalence of metabolic syndrome was first conducted with the Chi-Square test. The Logistic Regression model was used to further model the prevalence of metabolic syndrome and associations in its appearance with sociodemographic background and patients' health behaviour. Logistic Regression does not assume a linear relationship between the dependent and independent variable and is widely used to model binary response data (Hilbe 2014). The Logistic Regression model was adjusted for all the background variables, and for medications that had been omitted from those used as determinants of metabolic syndrome (i.e. other relevant medication excluding medication for blood pressure, cholesterol and blood glucose).

The association between obesity and metabolic syndrome, and between metabolic syndrome and obesity accompanied with blood pressure, was tested

from two distinct perspectives: from that of metabolic syndrome and from that of obesity, i.e. from the perspective of the patient as healthy and the patient as obese. The analysis was conducted using the Chi-Square test.

In addition, Logistic Regression analysis was used to model the influence of nutrition behaviour and other metabolic syndrome-related health behaviours, i.e. the amount of vigorous physical activity, excessive alcohol consumption and tobacco use, on the prevalence of metabolic syndrome (n=251, data set IV). These three components of health behaviour were modelled in a Logistic Regression analysis, and as in the former Logistic Regression model, the analysis was adjusted for patients' medication, gender and age.

The effect of the intervention and changes over the study period from 2006 to -2008 are presented in Kuninkaanniemi et al. (2011) (included in the review), and in a table in Appendix 5. Logistic Regression and Multivariate Analysis of Variance (MANOVA) for repeated measures were used for these analyses. A summary of the research questions, outcome measures and analysis of the article is presented in Appendix 3.

7 RESULTS

7.1 Study 1

7.1.1 Results of the search process

A total of 983 articles was retrieved. The systematic search in the eight databases produced 790 hits (CT 1 + CT 2). Of these, 111 articles were duplicates (manually controlled), leaving 679 different articles to be examined for suitability in answering the review question. This ratio indicates that the search strategy was reliable, as nearly all the studies identified by the primary and precise systematic search (CT 1) were also identified by the more comprehensive search (CT 2). In addition, the supplementary search (CT 3) produced 193 hits. Figure 5 summarises the selection of the studies included in the review.

Article selection was performed in three phases. Most of the publications, 549 articles, were excluded from the review based on their title and the information gained from the brief description of the article (phase 1). The exclusion criterion was primarily A: "Study theme not appropriate", i.e. the study was not an intervention trial conducted on nutrition. After perusing the abstract (phase 2), 290 articles were excluded, mostly because the study theme was not appropriate (exclusion criterion A) or the setting or intervention trial was not appropriate (exclusion criterion B), i.e. the intervention was not conducted in a primary care setting or the intervention did not meet the inclusion criteria for a brief intervention.

The full-text version of the article and possible additional method articles were examined in phase three when the second phase did not yield enough information for the inclusion or exclusion decision. In unclear situations, the corresponding author of the study was contacted to ensure a correct inclusion or exclusion decision. For example, the study by Garies et al. (2015) was excluded from the review after receiving clarifying answers to questions related to the conduct of the intervention from the corresponding author and the research doctor who conducted the intervention. The content of the intervention study by

Tol et al. (2014), was also clarified by email with the authors. It turned out that both these interventions had been more intensive than specified by the inclusion criteria.

A further 28 articles were excluded in the third phase based on the exclusion criteria presented in figure 5. The comprehensive search process resulted in five articles reporting five different studies relevant to the research question. Appendix 6 presents brief information on all the results obtained from the primary search, including their exclusion phase and exclusion criteria.

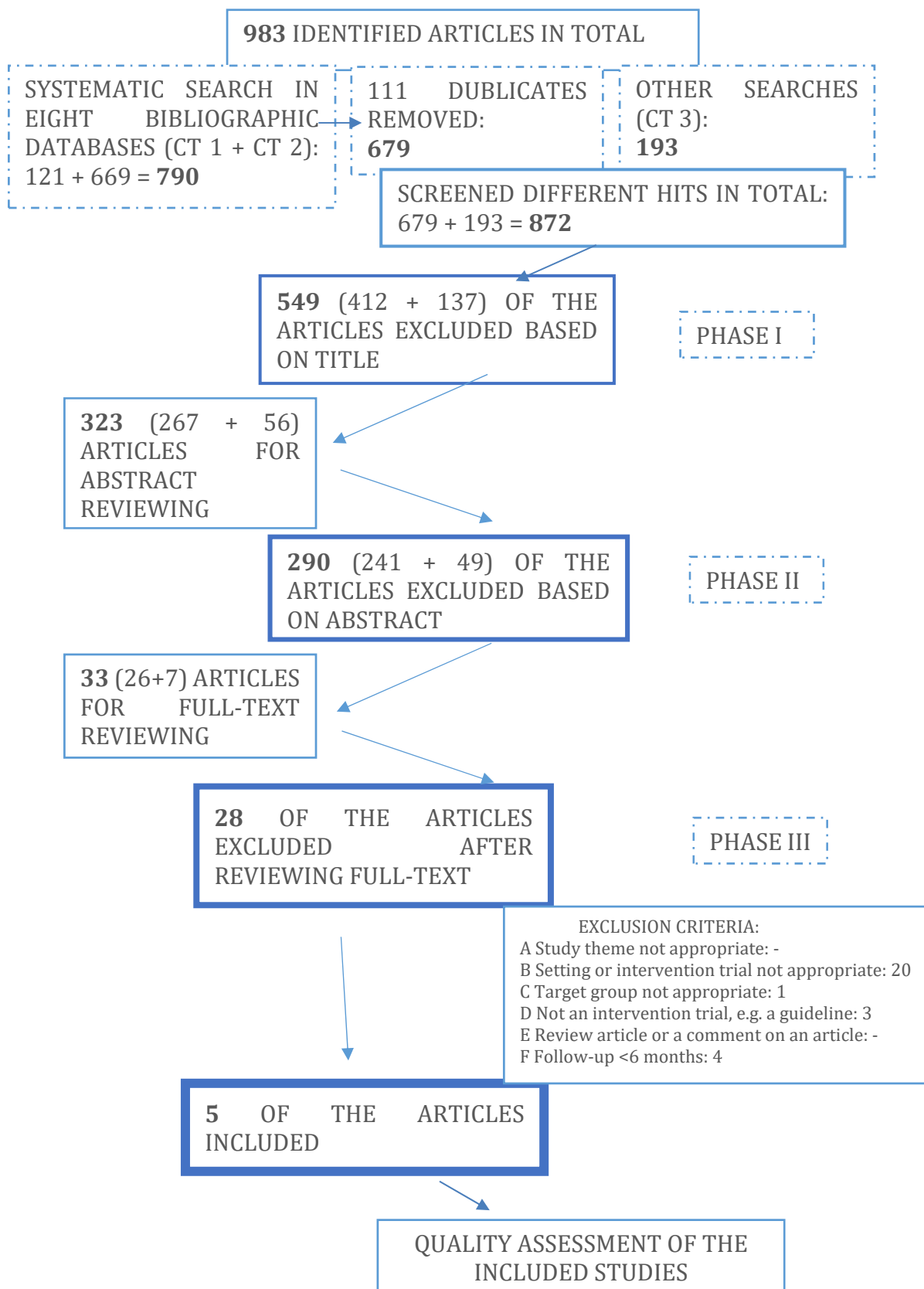


FIGURE 5 Flowchart on the selection of studies.

7.1.2 Description of the included studies

The study design, participants, study setting, intervention details, primary and secondary outcome measures and results of the five included trials are presented in table 4. Three of the studies Ackermann et al. (2015), Hardcastle et al. (2008) and Kuninkaanniemi et al. (2011) compared brief intervention to a more intensive intervention, and two of the studies, Sacerdote et al. (2006) and Steptoe et al. (2003) compared two brief interventions that varied in the content and intensity of the counselling. The setting of the interventions was one or more primary health care wards. One study was conducted in USA (Ackermann et al. 2015) and the others in Europe (Hardcastle et al. 2008, Kuninkaanniemi et al. 2011, Sacerdote et al. 2006, Steptoe et al. 2003).

The number of participants in these five different data sets totalled 4 511, ranging from 218 (Kuninkaanniemi et al. 2011) to 3 179 (Sacerdote et al. 2006). Following the inclusion criteria, a brief intervention was conducted with 4 012 individuals.

The mean age of the study participants ranged from 43 years to 51 years. Women were clearly over-represented in all the data sets, except Sacerdote et al. (2006), where both intervention groups contained 50% of each gender. Most participants were to some extent sedentary. The studies showed no marked differences in the inclusion criteria. Study follow-up times was 12 months, except for Hardcastle et al. (2008), where it was 6 months.

The interventions varied markedly in the content and intensity of the counselling offered to the participants. Written material(s) alone or supported by a brief questionnaire was common to all the brief interventions. The focus of the interventions was inducing change in nutrition and / or in the clinical values. All five studies included measures related to risk factors for metabolic syndrome, most often blood pressure. Ackermann et al. (2015) was the only study with no nutrition behaviour measures. Changes in nutrition behaviour were focused on increasing the consumption of fruits and vegetables, fish, olive oil, and whole grain products, and decreasing the consumption of red meat. Assessment of the consumption of fruits and vegetables was controlled for nutrition in all four studies. Hardcastle et al. (2008) also included measures of physical activity.

Two studies reported using a theoretical framework: in Steptoe et al. 2003), the counselling was based on the Transtheoretical Model and the Social Cognitive theory; and in Hardcastle et al. (2008) motivational interviewing was used.

TABLE 4 Description of the included studies and summary of the findings.

SOURCE	Ackermann et al. 2015, USA	Hardcastle et al. 2008, UK	Kuninkaanniemi et al. 2011, Finland	Sacerdote et al. 2006, Italy	Stephoe et al. 2003, UK
METHODS, SETTING AND PARTICIPANTS	<p><i>Study design:</i> RCT</p> <p><i>Study duration:</i> July 2008 - November 2010</p> <p><i>Setting:</i> 9 urban primary care clinics</p> <p><i>Participants:</i> n=509 Brief intervention (BI) n=252 Intensive intervention (II) n=257</p>	<p><i>Study design:</i> RCT</p> <p><i>Study duration:</i> N/A</p> <p><i>Setting:</i> Local health centre</p> <p><i>Participants:</i> n=334 Brief intervention (BI) n=131 Intensive intervention (II) n=203</p>	<p><i>Study design:</i> Cohort study</p> <p><i>Study duration:</i> November 2006 - May 2008</p> <p><i>Setting:</i> 9 health centres</p> <p><i>Participants:</i> n=218 Brief intervention (BI) n=179 Intensive intervention (II) n=39</p>	<p><i>Study design:</i> RCT</p> <p><i>Study duration:</i> N/A</p> <p><i>Setting:</i> 33 general practitioners' wards</p> <p><i>Participants:</i> n=3 179 Brief intervention 1 (BI 1) n=1 587 Brief intervention 2 (BI 2) n=1 592</p>	<p><i>Study design:</i> RCT</p> <p><i>Study duration:</i> June 1999 - November 2001</p> <p><i>Setting:</i> Primary health centre</p> <p><i>Participants:</i> n=271 Brief intervention 1 (BI 1) n=135 Brief intervention 2 (BI 2) n=136</p>

(continues)

TABLE 4 (continues)

	<p>Age (mean years): 51.2 in BI 50.8 in II</p> <p>Gender: BI: 68.7% women II: 72.8% women</p> <p>Inclusion: Participants ≥18 years of age and a BMI ≥24, no prior diagnosis of diabetes, and at least one blood test indicating high risk for developing type 2 diabetes</p>	<p>Age (mean years): 50.4 in BI 50.1 in II</p> <p>Gender: 67 % women</p> <p>Inclusion: Patients aged 18-65 drawn from an electronic patient database, and having at least one of the following CHD risk factors: BMI >28, hypertension or hypercholesterolemia</p>	<p>Age (<54): 56.9% in BI 51.4% in II</p> <p>Gender: BI: 71.5% women II: 64.1% women</p> <p>Inclusion: Volunteer patients ≥15 years entering a health centre for a primary health-care visit (for reasons except emergency visits) and responded to the 12 months follow-up enquiry</p>	<p>Age (mean years): 44.2 in BI 1 44.7 in BI 2</p> <p>Gender: 50% women in both intervention groups</p> <p>Inclusion: All patients aged 18-65 years attending the wards for reasons unrelated to gastrointestinal problems, without dietary restrictions, not obese (BMI>30) and not affected by severe chronic disease</p>	<p>Age (mean years): 43.2 in BI 1 43.3 in BI 2</p> <p>Gender: BI 1: 62% women BI 2: 60% women</p> <p>Inclusion: Patients aged 18-70 without serious illness or pregnancy drawn from register of one health centre and recruited by letter</p>
BRIEF INTERVENTIONS AND COMPARISONS	<p>Two interventions: Brief intervention (BI) vs. Intensive intervention (II)</p> <p>BI: Usual care supplemented with brief counselling and information about community resources for lifestyle modification, self-help written materials</p>	<p>Two interventions: Brief intervention (BI) vs. Intensive intervention (II)</p> <p>BI: Baseline assessments (questionnaires and tests) with a practice nurse and a standard information on exercise and nutrition</p>	<p>Two interventions: Brief intervention (BI) vs. Intensive intervention (II)</p> <p>BI: Total of 1-3 nutrition-related counselling sessions (i.e. the first visit with the questionnaire on health behaviour, plus at most two other counselling visits) each lasting up to 15 min</p>	<p>Two brief interventions (BI 1 vs. BI 2) of differing intensity in a conversation with a general practitioner (GP)</p> <p>Both intervention groups: three visits to a GP including the following elements: food frequency questionnaire (FFQ), brief lifestyle questionnaire,</p>	<p>Two brief interventions (BI 1 vs. BI 2) with different counselling content</p> <p>Both intervention groups: two 15-min individual consultations by practice nurse supported by written information (the difference in the content of the counselling between groups explained below)</p>

(continues)

TABLE 4 (continues)

	<p>II: Same as in the BI group + very intensive intervention, including 16 face-to-face group sessions (each 60-90min) followed by monthly support meetings; tools such as step counter, calorie tracking tools and food scales</p>	<p>II: Same as in the BI group + consultation with Physical Activity Specialist or Registered Dietician, and an opportunity to meet on up to four occasions, for 20-30 min</p>	<p>II: In total at least four nutrition-related counselling sessions (i.e. the first visit with the questionnaire, plus at least three other counselling visits) lasting more than 15 min</p>	<p>anthropometric measures (weight and blood pressure) conversation with GP (difference explained below)</p> <p>BI 1: Simple and non-personalised conversation without the use of the brochure</p> <p>BI 2: 15-min personalised nutritional intervention, based on brochure on diet and health summarising the Italian Guidelines for Correct Nutrition explained by the GP</p>	<p>BI 1: Nutritional counselling: education on the importance of increasing consumption of fruits and vegetables and the way these act biologically to maintain health (five-a-day message)</p> <p>BI 2: Behavioural counselling: tailored intervention with personalized advice, and goal-setting based on the Social learning theory and Stage of change model</p>
FOLLOW-UP	<p>12 months: n=215 in BI n=211 in II</p>	<p>6 months: n=93 in BI n=125 in II</p>	<p>12 months: n=179 in BI n=39 in II, See inclusion</p>	<p>6 months: n=1578 in BI 1 n=1584 in BI 2 12 months: n=1489 in BI 1 n=1488 in BI 2 (Results from the 12 months follow-up)</p>	<p>12 months: n=108 in BI 1 n=110 in BI 2</p>

(continues)

TABLE 4 (continues)

<p>OUTCOME MEASURES</p>	<p><i>Primary:</i></p> <ol style="list-style-type: none"> 1. Change in body weight over 12 months <p><i>Secondary:</i></p> <ol style="list-style-type: none"> 2. Percentage of participants who achieved weight-loss goals of 5% or greater 3. Changes in blood pressure, total and high-density lipoprotein (HDL)-cholesterol, and glycated haemoglobin (A1c) 	<p><i>Primary:</i></p> <ol style="list-style-type: none"> 1. SBP/DBP, fasting cholesterol, weight and height 2. Self-reported physical activity (PA), Met-min/week: total PA, vigorous PA, moderate PA and walking (International Physical Activity Questionnaire, IPAQ) 3. Fat intake, %/day (Dietary Instrument for Nutrition Education, DINE) 4. Consumption of fruit and vegetables, portions/day (five-a-day Community Evaluation Tool questionnaire, FACET) 	<p><i>Primary:</i></p> <ol style="list-style-type: none"> 1. Change in the consumption of fish, whole grain products and fruits and vegetables 2. Change in overall nutrition: nutrition index (fish at least two times a week; whole grain products daily; vegetables, fruits or berries daily) <p><i>Secondary:</i></p> <ol style="list-style-type: none"> 3. Changes in metabolic syndrome definers (SBP, DBP, total cholesterol, HDL, triglyceride, fasting plasma glucose, self-reported BMI and waist circumference) 	<p><i>Primary:</i></p> <ol style="list-style-type: none"> 1. Consumption of: >5 servings a day of fruits and vegetables, >1 serving of fish per week, <3 servings of red meat a week, olive oil in place of other fats 2. Attainment of BMI between 19 and 25 (normal weight) 3. Attainment of normal blood pressure (SBP ≤140 mmHg and DBP ≤90mmHg) <p><i>Secondary:</i></p> <ol style="list-style-type: none"> 4. Healthy diet score ranked from -3 (low-quality diet) to 5 (high-quality diet) based on consumption of fruits and vegetables, fish, red meats and olive oil 	<p><i>Primary:</i></p> <ol style="list-style-type: none"> 1. Changes in self-reported intake of fruit and vegetables: portions a day; proportion of individuals who increased consumption to five a day 2. Changes in biomarkers: plasma β carotene, α tocopherol, ascorbic acid concentrations, potassium excretion, potassium/creatinine ratio <p><i>Secondary:</i></p> <ol style="list-style-type: none"> 3. Changes in body weight, BMI, blood pressure, total cholesterol, and DINE measures (Dietary Instrument for Nutrition Education) measures
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(continues)

TABLE 4 (continues)

<p>RESULTS</p>	<p><i>Primary:</i></p> <p>1. Participants in II had a 2.3-kilogram (95% CI = 1.1, 3.4 kg; P < .001) greater weight loss at 12 months than those in BI</p> <p><i>Secondary:</i></p> <p>2. 13,4% in BI 32,4% in II (p<.001)</p> <p>3. No significant differences in clinical outcomes</p>	<p><i>Primary:</i></p> <p>1. SBP (mmHg): -0.60 in BI vs. -2.90 in II (ns p>.05)</p> <p>DBP (mmHg): 0.49 in BI vs. -1.98 in II (p<.001)</p> <p>Cholesterol (mmol/L): 0.00 in BI vs. -0.14 in II (ns p>.05)</p> <p>HDL (mmol/L): -0.07 in BI vs. -0.05 in II (ns p>.05)</p> <p>LDL (mmol/L): 0.25 in BI vs. 0.09 in II (ns p>.05)</p> <p>Triglycerides (mmol/L): -0.15 in BI vs. -0.17 in II (ns p>.05)</p>	<p><i>Primary:</i></p> <p>1. No significant change in dietary habits</p> <p>2. Positive change in the nutrition index: 12,5% in BI, 30 % in II (p=0.036)</p> <p><i>Secondary:</i></p> <p>3. No significant change in metabolic syndrome definers except for the increase in the self-reported BMI in II (p=0.008)</p>	<p><i>Primary:</i></p> <p>1. Effect of intervention was statistically significant for consumption of fish (p=.01).</p> <p>BI 2 had significantly increased Odds Ratios (OR) for reaching appropriate consumption of: fish (OR=1.84, CI 1.50-2.26), red meat (OR=1.19, CI 1.01-1.50) olive oil (OR=2.59, CI 1.92-3.09)</p> <p>Crude changes in the outcome variables from baseline to 12 months follow-up:</p> <p>servings of fruits and vegetables/ week: 1.58 in BI 1 vs. 2.89 in BI 2</p>	<p><i>Primary:</i></p> <p>1. Portions a day: 0.87 in BI 1 vs. 1.49 in BI 2, difference 0.62 (CI 0.09-1.13, p=.021)</p> <p>Five a day: 26.8% in BI 1 vs. 42.2% in BI 2 difference 15.4% (CI 2.52-28.3, p=.019)</p> <p>2. Plasma β carotene: 1.04 in BI 1 vs. 1.20 in BI 2, difference 0.16 (CI 0.001-1.34, p=.05)</p> <p>Other biomarkers: No significant difference between groups</p> <p>Adjusted change over 12 months: α tocopherol: 7.30 in BI 1 vs. 8.81 in BI 2</p>
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TABLE 4 (continues)

		<p>BMI (kg/m²): 0.15 in BI vs. -0.21 in II (p<.01)</p> <p>Bodyweight (kg): 0.12 in BI vs. -0.70 in II (p<.05)</p> <p>2. Total PA (Met-min/week): -122 in BI vs. 245 in II (p<.05)</p> <p>Moderate PA (Met-min/week): -29 in BI vs. 89 in II (ns p>.05)</p> <p>Vigorous PA (Met-min/week): 50 in BI vs. 149 in II (ns p>.05)</p> <p>Walking: -145 in BI vs. 198 in II (p<.01)</p> <p>3. -2.92 in BI vs. -0.92 in II (p<.01)</p> <p>4. 0.73 in BI vs. 1.05 in II (ns p>.05)</p>		<p>servings of fish/week: 0.16 in BI 1 vs. 0.40 in BI 2</p> <p>servings of red meat/week: -0.24 in BI 1 vs. -0.47 in BI 2</p> <p>consumption of olive oil (yes/no): 0.22 in BI 1 vs. 0.37 in BI 2</p> <p>2. No significant changes within time. Effect of intervention (p=.02). Crude change from baseline to 12 months follow-up: 0.00 in BI 1 vs. -0.41 in BI 2</p> <p>3. No significant changes over time and no significant difference between groups</p> <p>Crude change from baseline to 12 months follow-up:</p>	<p>ascorbic acid: 0.51 in BI 1 vs. -4.06 in BI 2</p> <p>potassium excretion: -0.27 in BI 1 vs. 0.19 in BI 2</p> <p>potassium/creatinine ratio: -0.20 in BI 1 vs. -0.07 in BI 2</p> <p><i>Secondary:</i></p> <p>3. No significant difference between groups</p> <p>Adjusted change over 12 months:</p> <p>body weight: -0.27 in BI 1 vs. -0.03 in BI 2</p> <p>BMI: -0.04 in BI 1 vs. 0.01 in BI 2</p> <p>SBP: -0.56 in BI 1 vs. -0.80 in BI 2</p>
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(continues)

TABLE 4 (continues)

				<p>SBP (mmHg): -0.20 in BI 1 vs. 0.15 in BI 2</p> <p>DBP (mmHg): 0.61 in BI 1 vs. 0.44 in BI 2</p> <p><i>Secondary:</i></p> <p>4. Crude score change: no difference in BI 1: -0.04; (CI -0.22-0.02) increase in the BI 2: 0.29; (CI 0.19-0.48) (difference between groups $p < .001$)</p>	<p>DBP: 0.03 in BI 1 vs. -0.13 in BI 2</p> <p>total cholesterol: -0.07 in BI 1 vs. -0.09 in BI 2</p> <p>DINE fibre intake: 0.07 in BI 1 vs. 0.11 in BI 2</p> <p>DINE fat intake: -2.09 in BI 1 vs. -4.10 in BI 2</p>
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7.1.3 Quality assessment and risk for bias in the included studies

The quality of the studies was assessed using the Quality Assessment Tool for Quantitative Studies (The Effective Public Health Practice Project 2008a, The Effective Public Health Practice Project 2008b), as described in the Methods section. This detailed evaluation revealed that overall quality of the studies in terms of risk for bias was weak in three studies, viz. Ackermann et al. (2015); Kuninkaanniemi et al. (2011); and Steptoe et al. (2003), and moderate in two studies, viz. Hardcastle et al. (2008) and Sacerdote et al. (2006).

Appendix 7 presents the quality assessment of the studies for the eight components of the Quality Assessment Tool (the Effective Public Health Practice Project 2008b). The results are colour-coded: red indicates weak, yellow moderate and green strong. The risk for bias results follows the same logic: red indicates high risk, green low risk and yellow moderate or unclear risk.

In addition to the evaluation of each of the eight components, a summarising rating for the studies was performed using the Quality Assessment Tool (the Effective Public Health Practice Project 2008b). The weak ratings for the selection bias component were mostly due to low agreement (less than 60%) of the selected individuals to participate in the study. However, the ratings for the study design component were mainly strong as the studies were, with one exception, randomised controlled trials.

Confounders (at least gender and age) were adequately controlled for in each study, resulting in strong ratings on that component. In turn, blinding of the outcome assessor(s) and study participants was often partial, i.e. one was blinded, and the other was not, leading to moderate ratings on this component.

The validity and reliability of the methods used were conflicting: some tools were shown to be valid or reliable while others were not, and validity and reliability were often not reported. Withdrawals and dropouts were not always reported with numbers and reasons per group, and the proportion of participants completing the study varied between the studies. Hence the ratings for this component ranged from weak to strong.

The consistency of the intervention was reported in only one study. Contamination or co-intervention was mostly unlikely to have occurred. In all the included studies, the statistical methods used were rated as appropriate.

Table 5 summarises the quality assessment of the five reviewed studies along with the mean scores. This reveals that overall the study by Sacerdote et al. (2006) showed the least risk for bias (lowest mean score and no weak ratings).

TABLE 5 Quality assessment of the included studies according to the Quality Assessment Tool of Quantitative Studies. The colours indicate the ratings given: red = weak, yellow = moderate and green = strong.

	Ackermann et al. 2015	Hardcastle et al. 2008	Kuninkaanniemi et al. 2011	Sacerdote et al. 2006	Steptoe et al. 2003
A) Selection bias	Weak	Weak	Weak	Moderate	Weak
B) Study design	Strong	Strong	Moderate	Strong	Strong
C) Confounders	Strong	Strong	Strong	Strong	Strong
D) Blinding	Moderate	Moderate	Strong	Moderate	Weak
E) Data collection methods	Weak	Moderate	Weak	Moderate	Moderate
F) Withdrawals and dropouts	Weak	Moderate	Weak	Strong	Strong
Mean score	2,17	1,83	2,17	1,5	1,83
Global rating	Weak	Moderate	Weak	Moderate	Weak

7.1.4 Influence of interventions

The outcomes of the included studies are presented in detail in table 4. Ackermann et al. (2015) compared a very intensive intervention to a brief intervention and found no significant differences in the clinical outcome (i.e., changes in blood pressure, total and high-density lipoprotein cholesterol, and glycated haemoglobin). However, the percentage of participants who achieved a weight loss of five percent or greater was 32.4 % in the intensive intervention group and 13.4 % in the brief intervention group.

Similarly, Hardcastle et al. (2008) reported no significant difference between the intensive and brief intervention groups in clinical outcomes (SPB, total cholesterol, HDL, LDL, Triglycerides) except for diastolic blood pressure. In addition, the intensive intervention group showed a greater decrease in body weight. Consumption of fruits and vegetables increased in both groups, and no significant differences were observed between the interventions. A significant difference between the two groups was found in fat intake: while in both groups fat intake decreased, the reduction was greater in the brief intervention group.

No change in the clinical outcomes related to metabolic syndrome was also observed in Kuninkaanniemi et al. (2011), who compared a brief with an intensive intervention. A significant change was found in the patients' overall nutrition (i.e., nutrition index, comprising consumption of fish at least two times a week, consumption of whole grain products daily; consumption of fruits, vegetables or berries daily) in favour of the intensive intervention group.

Sacerdote et al. (2006) compared two different brief interventions, the first of which was simple and non-personalised (brief intervention 1 = BI 1) while the other was personalised (brief intervention 2 = BI 2). The latter group showed significantly increased Odds Ratios for achieving appropriate levels of fish, red meat and olive oil consumption. The ranking of the healthy diet score (based on consumption of fruits and vegetables, fish, red meats and olive oil) was also increased in the intervention group receiving personalised counselling (BI 2). This trial also found no changes in clinical outcomes (SBP, DBP) or body mass index.

Steptoe et al. (2003), in turn, compared two brief interventions differing in counselling content: the first intervention group received nutritional counselling (BI 1) and the other behavioural counselling with personalised goal setting (BI 2). While both groups increased their intake of fruits and vegetables (portions a day and the proportions of individuals who increased their consumption to five a day), the behavioural counselling group increased their intake significantly more in both quantity and frequency. In addition, fat intake decreased in both intervention groups. As in the other reviewed trials, this study found no significant change in clinical outcomes (SBP, DBP, total cholesterol) or in body mass index.

7.1.5 Quality of the evidence

Evidence quality was assessed according to the GRADE system (Guyatt et al. 2008a, Guyatt et al. 2008b, Schunemann et al. 2008), as described in the Methods section. The GRADE system starts with the study design, which, for the included studies was strong. However, certain limitations lowered the quality of the evidence, namely study limitations and the indirectness of the evidence adduced. An example of the first was lack of blinding. The indirectness of evidence occurred when there were marked differences in the study populations, interventions and comparisons. Both types of limitations lowered the classification of the quality of the evidence by one grade, i.e. from high to moderate and from moderate to low. Following the GRADE criteria, no factors that would have increased the quality of evidence were present in the studies. Consequently, the quality of the evidence was classified as low.

Strength of recommendation, which in this context is a measure of the confidence that the estimate of the effect is correct (Guyatt et al. 2008b, Schunemann et al. 2008, Andrews et al. 2013), is weighted by the quality of the evidence as, for example, no undesirable effects or costs were reported in the included studies. Therefore, the strength of recommendation can only be rated as weak.

7.2 Study 2

7.2.1 Baseline characteristics of the patients

The EVI study reached 1 211 patients in the first phase during 2006, of whom 59% responded to the follow-up enquiry in 2007. Out the patients who completed both the 2006 and 2007 questionnaires, 93 % had at minimum one value representing metabolic syndrome available either self-reported (body mass index and waist circumference) or from their medical history records (blood pressure, cholesterol and glucose). Consequently, these patients formed the first two data sets for this study (data set I with the questionnaire data and data set II with clinical values, n=557). (See also table 1 and figure 4.)

The baseline characteristics of the patients are presented in table 6. Over 60 percent had a medium level education and almost half were retired. Also, almost half were aged between 41 to 64 years. Women were over represented. Mean value of body mass index for both men and women was 27, i.e. overweight when compared with the recommended values for body mass index.

TABLE 6 Baseline characteristics of patients in 2006 and 2007.

Baseline characteristic		2006			2007		
		FEMALE 70 % n= 391	MALE 30 % n= 166	Total n=557	FEMALE 70 % n= 391	MALE 30 % n= 166	Total n=557
Age	15-40 years	27	15	24	24	11	20
	41-64 years	45	52	46	44	48	45
	over 64 years	28	34	30	32	41	35
Education	high	16	8	14	16	8	14
	medium	64	64	64	64	64	64
	low	20	28	22	20	28	22
Occupation	phys. work	8	15	10	8	15	10
	office work	39	21	34	39	21	34
	retired	43	54	46	43	54	46
	unemp./stud.	10	10	10	10	10	10
BMI	mean kg/m ²	27	27	27	27	28	27

7.2.2 Nutrition behaviour and willingness to change the behaviour

Nutrition behaviour and willingness to change nutrition was assessed based on the responses to the questionnaires administered in 2006 and 2007 (data set I). Almost 90 percent ate whole grain products daily, and nearly the same proportions vegetables, fruits and berries. Snacking was rather rare: less than one-fourth had snacks daily or almost daily. The consumption of fish was low. Only 40 percent had fish at least two times a week.

Table 7 summarises the nutrition outcomes by gender. Women consumed vegetables, fruits and berries, but also snacks, significantly more often than men in 2006. In 2007, no significant gender differences remained in the nutrition. However, women were significantly more often willing to change their nutrition behaviour than men.

TABLE 7 Nutrition behaviour and willingness to change nutrition by gender in 2006 and 2007 (data set I).

Nutrition item	2006				2007			
	FEMALE	MALE	Total mean	P*	FEMALE	MALE	Total mean	P*
Fish at least two times a week	38,4 % n=141	41,9 % n=67	39,5 % n=208	.456	39,7 % n=141	41,0 % n=64	40,1 % n=205	.781
Whole grain products daily	88,8 % n=341	90,1 % n=146	89,2 % n=487	.650	90,5 % n=343	87,5 % n=140	89,6 % n=483	.297
Veg., fruits, berries daily	89,1 % n=345	80,4 % n=131	86,5 % n=476	.006	87,9 % n=340	81,8 % n=130	86,1 % n=470	.062
Snacks at least once daily	27,6 % n=102	16,9 % n=26	24,5 % n=128	.009	24,4 % n=91	24,5 % n=38	24,4 % n=129	.977
Willing to change nutrition	54,8 % n=198	46,0 % n=74	52,1 % n=272	.061	59,1 % n=215	42,9 % n=66	54,2 % n=281	.001

*P-value for significance between groups (Pearson Chi-Square). Significant difference between groups marked in bold.

Of the sociodemographic background variables, education had no influence on either the patients' nutrition behaviour or willingness to change the behaviour. Instead, occupational group had a significant influence on the consumption of fish ($p < 0.001$) in both 2006 and 2007. Retirees clearly ate fish most often. In 2006, 54 percent of retirees ate fish at least two times a week, compared to 25 percent of physical workers, 28 percent of office workers and 29 percent of students/unemployed. In 2007, the amounts had increased in all groups except for students/unemployed, whose consumption of fish had decreased.

In 2007, snacking also differed significantly by occupational group ($p < 0.001$). Snacking was the most common among manual and office workers. One-third in both groups reported snacking at least once daily. The corresponding proportions for retirees and students/unemployed were 17 and 18 percent.

Willingness to change nutrition behaviour was also influenced by occupational group. In 2006, physical workers were the most often willing to change their nutrition habits ($p = .008$): two-thirds reported willingness to change. In 2007, willingness to change nutrition behaviour had increased in all groups, but especially among office workers: over 70 percent reported a desire to change their nutrition habits. Tables 8 and 9 show the outcomes by these sociodemographic factors in detail.

TABLE 8 Nutrition behaviour and willingness to change nutrition by educational level in 2006 and 2007 (data set I).

Nutrition item	2006					2007				
	LOW	MEDIUM	HIGH	Total mean	<i>P</i> *	LOW	MEDIUM	HIGH	Total mean	<i>P</i> *
Fish at least two times a week	43,0 % n=43	35,3 % n=98	36,7 % n=22	37,2 % n=163	.387	43,2 % n=41	35,4 % n=95	41,9 % n=26	38,1 % n=162	.330
Whole grain products daily	93,0 % n=93	87,9 % n=255	82,3 % n=51	88,3 % n=399	.113	94,8 % n=92	88,4 % n=252	90,5 % n=57	90,1 % n=401	.186
Veg., fruits, berries daily	83,2 % n=84	85,5 % n=247	90,5 % n=57	85,7 % n=388	.426	90,0 % n=90	82,6 % n=238	89,1 % n=57	85,2 % n=385	.130
Snacks at least once daily	22,2 % n=22	26,4 % n=72	27,9 % n=17	25,6 % n=111	.656	18,2 % n=18	27,6 % n=77	30,6 % n=19	25,9 % n=114	.121
Willing to change nutrition	52,1 % n=49	51,1 % n=144	60,3 % n=38	52,6 % n=231	.411	48,4 % n=46	58,6 % n=163	61,9 % n=39	56,9 % n=248	.152

**P*-value for significance between groups (Pearson Chi-Square).

TABLE 9 Nutrition behaviour and willingness to change nutrition by occupational group in 2006 and 2007 (data set I).

Nutrition item	2006					P*	2007					P*
	PHYS. WORK	OFFICE WORK	RETIRED	UNEMP. /STUD.	Total mean		PHYS. WORK	OFFICE WORK	RETIRED	UNEMP. /STUD.	Total mean	
Fish ≥ two times a week	25,0 % n=13	27,7 % n=48	53,7 % n=131	29,1 % n=16	39,7 % n=208	<0.001	26,9 % n=14	30,1 % n=53	54,8 % n=126	22,0 % n=11	40,2 % n=204	<0.001
Whole grain products daily	89,1 % n=49	88,0 % n=161	89,6 % n=224	90,7 % n=49	89,1 % n=483	.926	92,7 % n=51	88,5 % n=162	91,4 % n=223	84,9 % n=45	89,9 % n=481	.404
Veg., fruits, berries daily	81,8 % n=45	89,0 % n=161	87,0 % n=221	81,8 % n=45	86,6 % n=472	.381	83,3 % n=45	83,2 % n=154	90,0 % n=224	79,6 % n=43	86,0 % n=466	.088
Snacks at least once daily	18,5 % n=10	30,5 % n=53	21,3 % n=51	25,5 % n=13	24,5 % n=127	.127	32,7 % n=17	33,3 % n=61	16,7 % n=40	18,0 % n=9	24,2 % n=127	<0.001
Willing to change nutr.	65,5 % n=36	57,8 % n=104	44,3 % n=102	52,8 % n=28	52,1 % n=270	.008	63,6 % n=35	71,1 % n=128	37,6 % n=85	57,7 % n=30	54,2 % n=278	<0.001

*P-value for significance between groups (Pearson Chi-Square). Significant difference between groups marked in bold.

7.2.3 Mean clinical values

Clinical outcomes were analysed as continuous mean values using General Linear Model (n=557, data set II). In table 10, the clinical outcomes are presented by gender. There was a significant gender difference in the following mean values: systolic blood pressure, high density lipoprotein cholesterol, triglycerides and fasting glucose in either both the 2006 and 2008 measurements or only the 2006 measurements.

TABLE 10 Mean clinical values in 2006 and 2008 by gender (data set II).

Clinical value	2006				2008			
	FEMALE	MALE	Total mean	P*	FEMALE	MALE	Total mean	P*
SBP, mmHg	137 n=261	142 n=106	139 n=367	.032	138 n=199	145 n=79	140 n=278	.003
DBP, mmHg	83 n=261	84 n=106	83 n=367	.288	83 n=200	85 n=79	84 n=279	.312
Total chol., mmol/L	4,6 n=238	4,4 n=105	4,5 n=343	.559	4,4 n=175	4,2 n=82	4,3 n=257	.440
HDL, mmol/L	1,6 n=235	1,3 n=100	1,5 n=335	<0.001	1,6 n=173	1,2 n=76	1,5 n=249	<0.001
Trigly, mmol/l	1,1 n=236	1,4 n=100	1,2 n=336	.007	1,3 n=166	1,4 n=72	1,3 n=238	.243
Fgluc, mmol/L	5,1 n=265	5,8 n=101	5,3 n=366	.004	5,1 n=172	5,7 n=72	5,3 n=244	.072
BMI, kg/m2	27 n=374	27 n=161	27 n=535	.395	27 n=390	28 n=166	27 n=556	.931

* General Linear Model. *P*-value for significance between groups. Significant difference between groups marked in bold.

Age had a significant effect on both systolic ($p < 0.001$) and diastolic blood pressure ($p = .002$ in 2006 and $p = .003$ in 2008). For systolic blood pressure, the highest mean values in 2006 and 2008 were found in the oldest age group, and for diastolic blood pressure the highest mean values were recorded among those aged between 41 and 64 years. In addition, body mass index differed significantly by age in both 2006 and 2008, although the differences remained small. Table 11 shows all the clinical mean values by the three age groups.

TABLE 11 Mean clinical values in 2006 and 2008 by age (data set II)

Clinical value	2006					2008				
	15-40	41-64	>64	Total mean	<i>P</i> *	15-40	41-64	>64	Total mean	<i>P</i> *
SBP, mmHg	126 n=66	138 n=173	147 n=119	139 n=358	<0.001	126 n=28	140 n=95	143 n=85	139 n=208	<0.001
DBP, mmHg	80 n=66	85 n=173	82 n=119	83 n=358	.002	81 n=28	86 n=96	80 n=85	83 n=209	.003
Total chol., mmol/L	4,6 n=33	4,7 n=173	4,3 n=130	4,5 n=336	.241	4,4 n=12	4,3 n=91	4,4 n=92	4,4 n=195	.911
HDL, mmol/L	1,5 n=33	1,6 n=169	1,6 n=126	1,6 n=328	.939	1,4 n=11	1,5 n=89	1,5 n=90	1,5 n=190	.939
Trigly, mmol/l	1,3 n=31	1,3 n=172	1,1 n=126	1,2 n=329	.173	0,9 n=10	1,5 n=85	1,2 n=85	1,3 n=180	.053
Fgluc, mmol/L	4,6 n=57	5,4 n=173	5,4 n=129	5,3 n=359	.052	4,8 n=13	5,4 n=89	5,5 n=83	5,4 n=185	.655
BMI, kg/m2	26 n=120	27 n=247	27 n=155	27 n=522	.016	26 n=86	28 n=191	26 n=146	27 n=423	.018

*General Linear Model. *P*-value for significance between groups. Significant difference between groups marked in bold.

General linear modelling was also used to analyse the influence of the sociodemographic background variables on the clinical mean values (data set II). Education showed a significant influence on systolic blood pressure ($p=.009$) and on the self-reported body mass index ($p=.007$) in 2006. Those in the group with the lowest educational level showed the highest systolic blood pressure value: 143mmHg compared to 135mmHg and 137mmHg for the patients with a medium-level and high-level education respectively. Body mass index was also the highest in the group with the lowest education; mean body mass index of 28 compared to 26 in the other two groups. In 2008, these differences between educational levels were smaller but remained statistically significant ($p=.043$ for SBP and $p=.026$ for BMI). Table 12 presents the outcomes by educational group in detail.

Occupational group had a significant influence on systolic blood pressure ($p<0.001$ in 2006 and $p=.012$ in 2008). In 2006, retirees had the highest systolic blood pressure: 145 mmHg, compared to 136mmHg, 131mmHg and 134mmHg manual workers, office workers and students/unemployed, respectively. In 2008, the group of students/unemployed showed the highest systolic blood pressure (147mmHg), while the retirees' values had decreased. In 2008, diastolic blood pressure also differed by occupational group ($p=.001$). The values followed those for systolic blood pressure, i.e. the highest value (92mmHg) was recorded for students/unemployed.

The values for fasting glucose also differed significantly ($p=.003$) by occupational status, but only in 2006. The highest value (6.3mmol/L) was found for the students/unemployed group. For the other groups, the values were from 4.4mmol/L to 5.4mmol/L. No significant influence of occupational group on body mass index or on the other clinical outcomes were observed. Table 13 presents the mean clinical values by occupational group.

TABLE 12 Mean clinical values in 2006 and 2008 by educational level (data set II).

Clinical value	2006					2008				
	LOW	MEDIUM	HIGH	Total mean	P*	LOW	MEDIUM	HIGH	Total mean	P*
SBP, mmHg	143 n=72	135 n=190	137 n=38	137 n=300	.009	143 n=67	137 n=139	142 n=18	139 n=224	.043
DBP, mmHg	83 n=72	83 n=190	84 n=38	83 n=300	.687	84 n=67	83 n=139	89 n=19	84 n=225	.162
Total chol., mmol/L	4,4 n=81	4,6 n=164	4,2 n=30	4,5 n=275	.474	4,6 n=62	4,3 n=120	4,9 n=21	4,5 n=203	.271
HDL, mmol/L	1,5 n=80	1,6 n=161	1,7 n=30	1,6 n=271	.167	1,4 n=60	1,5 n=118	1,5 n=21	1,5 n=199	.412
Trigly, mmol/l	1,2 n=80	1,2 n=161	1,1 n=30	1,2 n=271	.797	1,4 n=58	1,3 n=110	1,3 n=21	1,3 n=189	.658
Fgluc, mmol/L	5,8 n=80	5,2 n=181	5,1 n=35	5,3 n=296	.115	5,1 n=56	5,2 n=119	5,1 n=23	5,2 n=198	.965
BMI, kg/m2	28 n=98	26 n=284	26 n=62	27 n=444	.007	28 n=102	27 n=294	26 n=64	27 n=460	.026

* General Linear Model. *P*-value for significance between groups. Significant difference between groups marked in bold.

TABLE 13 Mean clinical values in 2006 and 2008 by occupational group (data set II).

Clinical value	2006					P*	2008					P*
	PHYS. WORK	OFFICE WORK	RETIRED	UNEMP./STUD.	Total mean		PHYS. WORK	OFFICE WORK	RETIRED	UNEMP./STUD.	Total mean	
SBP, mmHg	136 n=32	131 n=115	144 n=188	134 n=33	139 n=368	<0.001	134 n=23	136 n=80	141 n=154	147 n=20	139 n=277	.012
DBP, mmHg	85 n=32	82 n=115	83 n=188	82 n=33	83 n=368	.427	81 n=23	86 n=81	82 n=154	92 n=20	84 n=278	.001
Total chol., mmol/L	4,6 n=27	4,5 n=86	4,5 n=203	5,1 n=26	4,5 n=342	.417	3,6 n=19	4,6 n=61	4,4 n=161	4,1 n=16	4,3 n=257	.266
HDL, mmol/L	1,4 n=28	1,6 n=83	1,6 n=197	1,5 n=26	1,6 n=334	.486	1,4 n=18	1,5 n=58	1,5 n=158	1,4 n=15	1,5 n=249	.821
Trigly, mmol/l	1,1 n=26	1,2 n=83	1,2 n=199	1,5 n=27	1,2 n=335	.373	1,3 n=15	1,4 n=58	1,3 n=150	1,3 n=15	1,3 n=238	.969
Fgluc, mmol/L	4,4 n=35	4,9 n=96	5,4 n=203	6,3 n=31	5,3 n=365	.003	4,9 n=19	5,1 n=62	5,4 n=146	5,1 n=17	5,3 n=244	.683
BMI, kg/m2	27 n=53	26 n=180	27 n=244	27 n=54	27 n=531	.574	28 n=56	27 n=185	27 n=256	27 n=55	27 n=552	.773

*General Linear Model. P-value for significance between groups. Significant difference between groups marked in bold.

7.2.4 Categorical clinical values representing metabolic syndrome

In addition to mean values, the single clinical determinants of metabolic syndrome were also evaluated as categorised values for all the patients (data set II). The categorisation of the values for both the recommended and abnormal values, is described in the Methods section. Direct medication for a condition (for elevated blood pressure, elevated cholesterol or elevated blood glucose) was considered as indicative of an abnormal value.

Different associations with background variables and sociodemographic groups were found for all the other determinants, excepting high density lipoprotein cholesterol and obesity. In 2006, gender had a significant influence on blood pressure ($p=.004$) and fasting glucose ($p<0.001$), both of which were at a non-recommended level more often in men than in women. In 2008, there were no significant gender differences were observed. Table 14 shows the categorised values by gender.

TABLE 14 Categorical clinical metabolic syndrome determinants in 2006 and 2008 by gender (data set II).

Categorised clinical value	2006				2008			
	FEMALE	MALE	Total	<i>P</i> *	FEMALE	MALE	Total	<i>P</i> *
SBP\geq130 and/or DBP\geq85 mmHg	75,8 % n=207	89,1 % n=98	79,6 % n=305	.004	85,1 % n=194	91,0 % n=81	86,8 % n=275	.162
HDL <1/ <1,3 mmol/L	20,9 % n=49	13,0 % n=13	18,5 % n=62	.090	26,0 % n=45	19,7 % n=15	24,1 % n=60	.286
Trigly >1,7 mmol/L	37,3 % n=91	48,1 % n=51	40,6 % n=142	.058	54,8 % n=103	63,2 % n=55	57,5 % n=158	.188
Fgluc, >5,7 mmol/L	24,5 % n=65	46,5 % n=47	30,6 % n=112	<0.001	31,4 % n=54	44,4 % n=32	35,2 % n=86	.052
BMI\geq30+waist>90 /100 kg/m²+cm	10,1 % n=38	9,8 % n=16	10,0 % n=54	.918	20,0 % n=78	16,3 % n=27	18,9 % n=105	.303

**P*-value for significance between groups (Pearson Chi-Square). Significant difference between groups marked in bold.

Age was associated with elevated blood pressure levels in both 2006 and 2008 ($p<0.001$). Among the oldest patients, the values were mostly above the metabolic syndrome threshold (or, alternatively, medication was prescribed for the condition; see 6.2.3). The same applies for triglycerides and fasting glucose. The values and differences between age groups are presented in detail in table 15.

With respect to occupational group, retirees showed the most frequent increase in blood pressure values ($p<0.001$). Being unemployed or a student ($p=.006$) and having a low educational level ($p=.001$) were also associated with elevated fasting glucose levels. An abnormal level of triglycerides was more commonly found among retirees and the lower educated than among the other sociodemographic groups. The percentages of those with values above the

criterion levels for metabolic syndrome are presented in tables 16-17 by education and occupational group.

TABLE 15 Categorical clinical metabolic syndrome determinants in 2006 and 2008 by age (data set II).

Categorised clinical value	2006					2008				
	15-40	41-64	>64	Total	P*	15-40	41-64	>64	Total	P*
SBP≥130 and/or DBP≥85 mmHg	47,8 % n=32	80,2 % n=146	94,4 % n=117	79,1 % n=295	<0.001	55,2 % n=16	88,7 % n=94	92,2 % n=94	86,1 % n=204	<0.001
HDL <1 / <1,3 mmol/L	24,2 % n=8	16,7 % n=28	16,0 % n=20	17,2 % n=56	.519	36,4 % n=4	27,0 % n=24	18,9 % n=17	23,7 % n=45	.259**
Trigly >1,7 mmol/L	19,4 % n=6	36,3 % n=65	51,9 % n=69	40,8 % n=140	.001	10,0 % n=1	55,6 % n=55	71,6 % n=73	61,1 % n=129	<0.001**
Fgluc, >5,7 mmol/L	15,8 % n=9	33,5 % n=58	34,1 % n=44	30,9 % n=111	.026	15,4 % n=2	29,2 % n=26	42,2 % n=35	34,1 % n=63	.071**
BMI≥30+waist>90/100 kg/m ² +cm	6,6 % n=8	10,9 % n=27	10,1 % n=16	9,7 % n=51	.411	15,1 % n=13	23,0 % n=44	14,4 % n=21	18,4 % n=78	.303

*P-value for significance between groups (Pearson Chi-Square). Significant difference between groups marked in bold.

**P-value for significance between groups (Fisher's Exact Test). Expected count in one or more cells is below the minimum threshold: to be interpreted with caution.

TABLE 16 Categorical clinical metabolic syndrome determinants in 2006 and 2008 by educational level (data set II).

Categorised clinical value	2006					2008				
	LOW	MEDIUM	HIGH	Total	P*	LOW	MEDIUM	HIGH	Total	P*
SBP≥130 and/or DBP≥85 mmHg	85,3 % n=64	75,4 % n=150	71,8% n=28	77,3 % n=242	.146	91,4 % n=64	82,1 % n=133	86,4% n=19	85,0 % n=216	.185
HDL <1 / <1,3 mmol/L	20,3 % n=16	18,6 % n=30	6,7% n=2	17,8 % n=48	.229	27,1 % n=16	22,0 % n=26	28,6% n=6	24,2 % n=48	.673
Trigly >1,7 mmol/L	46,4 % n=39	38,7 % n=65	20,0% n=6	39,0 % n=110	.039	66,7 % n=44	54,0 % n=68	39,1% n=9	56,3 % n=121	.052
Fgluc, >5,7 mmol/L	46,3 % n=37	27,6 % n=50	14,3% n=5	31,1 % n=92	.001	47,3 % n=26	30,3 % n=36	13,0% n=3	33,0 % n=65	.008
BMI≥30+waist>90/100 kg/m2+cm	14,3 % n=14	9,1 % n=26	6,5% n=4	9,9 % n=44	.208	24,8 % n=25	16,7 % n=49	17,2% n=11	18,5 % n=85	.188

*P-value for significance between groups (Pearson Chi-Square). Significant difference between groups marked in bold.

TABLE 17

Categorised clinical metabolic syndrome determinants in 2006 and 2008 by occupational group (data set II).

Categorised clinical value	2006					P*	2008					P*
	PHYS. WORK	OFFICE WORK	RETIRED	UNEMP./STUD.	Total mean		PHYS. WORK	OFFICE WORK	RETIRED	UNEMP./STUD.	Total mean	
SBP≥130 and/or DBP≥85 mmHg	73,5 % n=25	64,4 % n=76	91,4 % n=180	71,4 % n=25	79,7% n=306	<0.001	72,0 % n=18	81,3 % n=74	92,1% n=164	85,0 % n=17	86,9% n=273	.008
HDL <1 / <1,3 mmol/L	17,9 % n=5	16,9 % n=14	17,5 % n=34	34,6 % n=9	18,7% n=62	.195	16,7 % n=3	32,8 % n=19	19,2% n=30	53,3 % n=8	24,3% n=60	.010**
Trigly >1,7 mmol/L	29,6 % n=8	20,7 % n=18	51,0 % n=106	40,7 % n=11	41,0% n=143	<0.001	43,8 % n=7	32,8 % n=21	68,2% n=120	47,1 % n=8	57,1% n=156	<0.001
Fgluc, >5,7 mmol/L	22,9 % n=8	19,8 % n=19	34,5 % n=70	48,4 % n=15	30,7% n=112	.006	36,8 % n=7	21,0 % n=13	41,7% n=60	35,3 % n=6	35,5% n=86	.044
BMI≥30+waist>90/100 kg/m2+cm	3,7 % n=2	7,8 % n=14	12,1 % n=30	13,0 % n=7	9,9% n=53	.158	21,4 % n=12	17,8 % n=33	18,5% n=47	21,8 % n=12	18,9% n=104	.873

*P-value for significance between groups (Pearson Chi-Square). Significant difference between groups marked in bold.

**P-value for significance between groups (Fisher's Exact Test). Expected count in one or more cells is below the minimum threshold: to be interpreted with caution. Significant difference between groups marked in bold.

7.2.5 Prevalence of metabolic syndrome

The prevalence of metabolic syndrome was assessed for the patients who had values for all five metabolic syndrome determinants (n=251, data set III) in 2006. Of the total number (n=557) of patients, all five metabolic syndrome values were available for 45 percent. These patients differed by age from those for whom not all the five values were available: the proportion in the two older age groups was higher. Also, a low educational level was more common among those patients with values for all five determinants. The same association was observed for retirees in the occupational groups. No association was found for gender. The results for these analysis are presented in table 18.

TABLE 18 Comparison of baseline characteristics of patients for whom all five metabolic syndrome values were available (data set III) and those for whom less than five values were available (data set II).

Baseline characteristics		5 VALUES	< 5 VALUES	P*
Gender	female	71,5 %	69,2 %	.550
	male	28,5 %	30,8 %	
Age	15-40 years	8,1 %	36,4 %	<0.001
	41-64 years	52,0, %	42,2%	
	over 64 years	39,8 %	21,4 %	
Education	high	11,9 %	15,8 %	.017
	medium	58,9 %	65,7 %	
	low	29,2 %	18,5 %	
Occupation	physical work	8,0 %	10,6 %	<0.001
	office work	22,8 %	40,4 %	
	retired	60,8 %	38,1 %	
	unemp./stud.	8,4 %	10,9 %	
% of the total n=557		45 %	55 %	

*P-value for significance between groups (Pearson Chi-Square). Significant difference between groups marked in bold.

The prevalence of metabolic syndrome was in total 30.7 percent. It was significantly higher in men (40.3 %) than women (26.8 %). Table 19 shows the prevalence of metabolic syndrome according to gender, age, education and occupation. Of the patients with a low educational level, 43.1 percent had metabolic syndrome compared to only 4.2 percent of those with a higher education. The occupational groups also differed significantly from each other. Metabolic syndrome was clearly more common among the retirees and the unemployed and student group than the other two occupational groups.

TABLE 19 Prevalence of metabolic syndrome in 2006 by gender, age, educational level and occupational group (data set III).

Background variable		%	Total	P*
Gender	female	26,8 %	30,7 % (n=77)	.036
	male	40,3 %		
Age	15-40 years	15,0 %	30,5 % (n=75)	.255
	41-64 years	30,5 %		
	over 64 years	33,7 %		
Education	high	4,2 %	29,6 % (n=60)	.002
	medium	28,1 %		
	low	43,1 %		
Occupation	physical work	23,8 %	30,8 % (n=77)	.010
	office work	14,0 %		
	retired	37,1 %		
	unemp./stud.	38,1 %		

*P-value for significance between groups (Pearson Chi-Square). Significant difference between groups marked in bold.

Logistic Regression modelling of the associations of the prevalence of metabolic syndrome and the factors influencing it, further revealed that those with a higher level of education were at a lower risk for metabolic syndrome compared to those with lower level of education (OR .077, 95 % C.I. for OR .009-.637, p=.017). The analysis was adjusted for other background variables and medication. Table 20 shows the result of the Logistic Regression analysis.

TABLE 20 Logistic Regression analysis for the prevalence of metabolic syndrome* (data set III).

Variables in the Equation		OR	95 % C.I. for OR	P**		
Gender	female	1	.676 - 2.792	.380		
	male	1.374				
Age	15-40 years	1	.376 - 6.364	.546		
	41-64 years	1.546				
	over 64 years	.826			.163 - 4.180	.818
Education	low	1	.329 - 1.342	.254		
	medium	.665				
	high	.077			.009 - .637	.017
Occupation	physical work	1	.197 - 3.067	.719		
	office work	.777				
	unemp./stud.	1.943			.457 - 8.256	.368
	retired	2.100			.611 - 7.216	.239

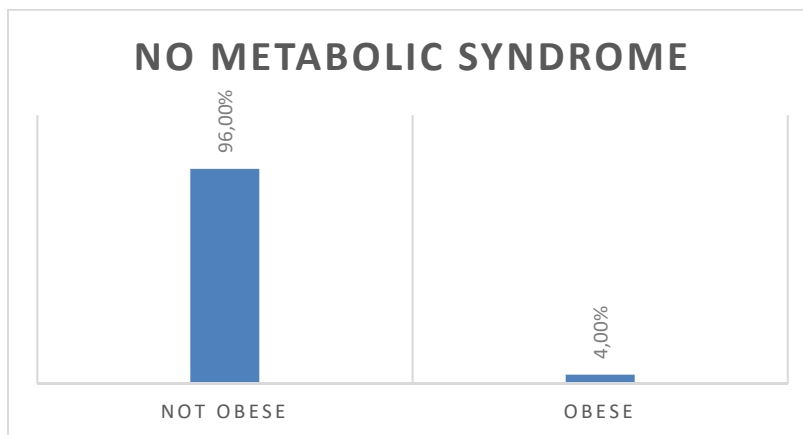
* Adjusted for medication.

** Statistically significant marked in bold.

7.2.6 Association of metabolic syndrome with obesity and blood pressure

The relationship between obesity and the incidence of metabolic syndrome, and between obesity and blood pressure and the incidence of the metabolic syndrome (data set III) was studied using a two-dimension approach, as described in the Methods section. The aim was to investigate the possible association from two different perspectives of practical value in primary care: The first approach looked at the connection from the metabolic syndrome perspective, and the other from the obesity perspective.

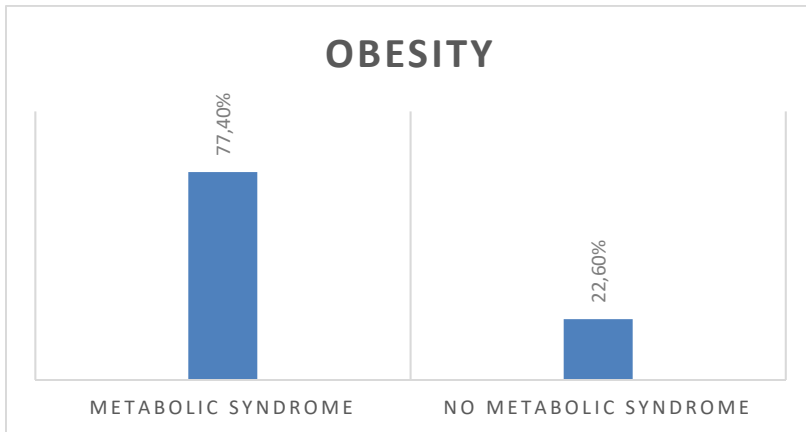
A clear association was found in both approaches. Of the patients who did not have metabolic syndrome, only 4 percent were obese, i.e. had both a waist circumference above the recommended dimensions (>100 cm for males and >90 cm for females) and a body mass index of 30 or over. In other words, 96 percent of the non-obese patients did not have metabolic syndrome, as shown in figure 6.



*Total n in the analysis 251.

FIGURE 6 Prevalence of obesity in patients not having metabolic syndrome in 2006 * (data set III).

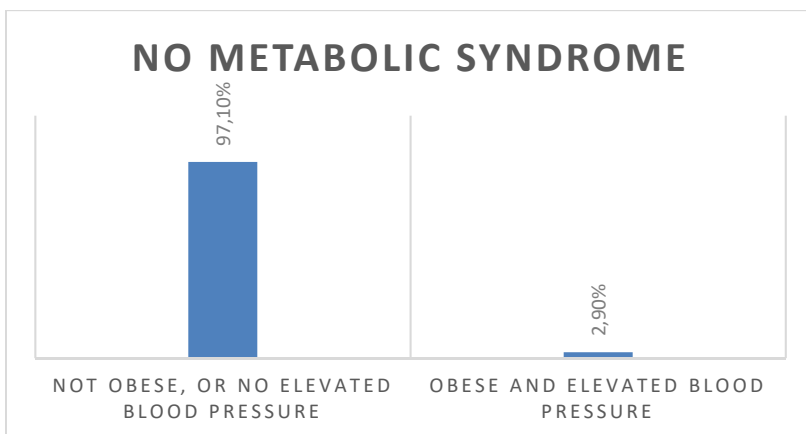
The other approach revealed that 77.4 percent of the obese patients had metabolic syndrome. Figure 7 illustrates this finding.



*Total n in the analysis 251.

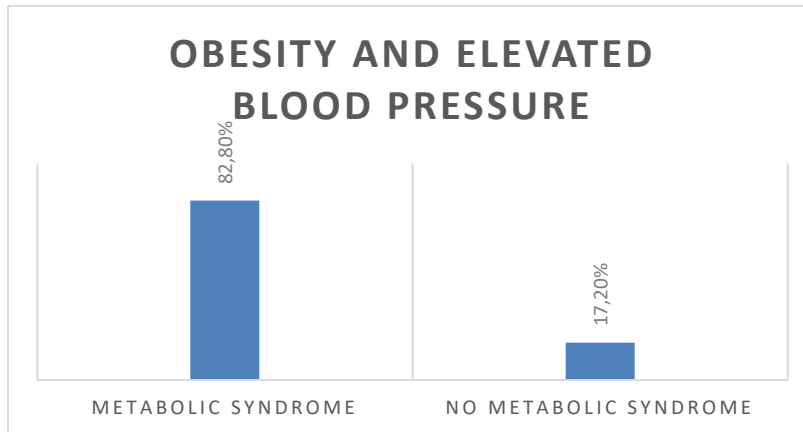
FIGURE 7 Prevalence of metabolic syndrome in obese patients in 2006 * (data set III).

When adding another clear indicator of metabolic syndrome, namely blood pressure, into the analysis, the association was even clearer, as illustrated in figures 8 and 9.



*Total n in the analysis 251.

FIGURE 8 Prevalence of obesity and elevated blood pressure in patients not having metabolic syndrome in 2006 * (data set III).



*Total n in the analysis 251.

FIGURE 9 Prevalence of metabolic syndrome in patients with obesity and elevated blood pressure in 2006 * (data set III).

7.2.7 Association of nutrition and other health behaviours with the prevalence of metabolic syndrome

For the Logistic Regression analysis on the association of nutrition and other related health behaviours with the prevalence of metabolic syndrome, data set IV combining the clinical values (data set III) and questionnaire data from 2006 (data set I) was used. The analyses was adjusted for patients' medication as in the analysis presented in table 20.

Nutrition behaviour, i.e. 1) consumption of fish at least two times a week, 2) consumption of whole grain products daily, 3) consumption of vegetables, fruits and berries daily, and 4) having snacks (e.g. sweets, cookies, crisps) at least once daily showed no significant differences in relation to the prevalence of metabolic syndrome. Table 21 presents the detailed results for each nutrition component.

TABLE 21 Logistic Regression analysis of the association of four nutrition items with the prevalence of metabolic syndrome* (data set IV).

Variables in the Equation		OR	95 % C.I. for OR	P
Fish \geq 2/week	No	1		
	Yes	1.348	.757 - 2.400	.311
Whole grain prod. daily	No	1		
	Yes	.619	.261 - 1.471	.277
Veg., fruits, berries daily	No	1		
	Yes	1.042	.482 - 2.251	.916
Having snacks at least once daily	No	1		
	Yes	1.507	.748 - 3.038	.251

* Adjusted for medication, age and gender.

As with the nutrition behaviours, no significant differences in influence on the prevalence of metabolic syndrome were observed in the other related health behaviour indicators, namely vigorous physical activity, excessive alcohol consumption and tobacco use. The results of these Logistic Regression analyses are presented in detail in tables 22-24.

TABLE 22 Logistic Regression analysis of the association of vigorous physical activity with the prevalence of metabolic syndrome* (data set IV).

Variable in the Equation		OR	95 % C.I. for OR	P
Gender		.666	.160 - 2.768	.576
Age		.769	.332 - 1.781	.540
Vigorous PA	0-1 times a week	1		
	2-4 times a week	.812	.253 - 2.602	.726
	5-7 times a week	.000	.000	1.000

* Adjusted for medication.

TABLE 23 Logistic Regression analysis of the association of alcohol consumption with the prevalence of metabolic syndrome* (data set IV).

Variable in the Equation		OR	95 % C.I. for OR	P
Gender		1.857	.984 - 3.502	.056
Age		1.423	.865 - 2.343	.165
Alcohol cons.	≥ 2-3 times a week	1		
	no consumption	.559	.213 - 1.468	.237
	≤ once a month	1.281	.535 - 3.068	.578
	2-4 times a month	.560	.224 - 1.402	.215

* Adjusted for medication.

TABLE 24 Logistic Regression analysis of the association of tobacco use with the prevalence of metabolic syndrome* (data set IV).

Variable in the Equation		OR	95 % C.I. for OR	P
Gender		1.841	1.004 - 3.374	.048
Age		1.196	.724 - 1.974	.485
Tobacco use	No	1		
	Yes	.935	.411 - 2.123	.872

* Adjusted for medication.

7.3 Summary of the findings

The two studies of this doctoral thesis sought answers to five research objectives through a systematic literature review (research objective I) and the use of quantitative data on EVI study in the primary care context in Central Finland (research objectives II-V). (See table 1.) For the review, five out of the 983

identified studies met the inclusion criteria and thus were included in the review. The quality of the studies was overall weak or moderate when evaluated with the Quality Assessment Tool for Quantitative Studies, indicating risk for bias.

An intervention influence on nutrition behaviour was found in all the four studies assessing nutrition. In three studies, the consumption of fruits and vegetables had increased, and in two studies overall nutrition, i.e. the sum of the nutrition elements, including the intake of fruits and vegetables, had improved. In addition, one study found a decrease in fat intake, even in favour of the brief compared to intensive intervention. Nevertheless, based on the results of all five studies, a brief intervention had no influence on the determinants of metabolic syndrome during the 12-month follow-up. However, as the quality of the evidence was low, confidence in the results is weak. The search for studies was comprehensive, which makes it unlikely that relevant research would have remained unlocated. Nevertheless, it is possible that some trials with no significant findings remain unpublished. Consequently, if publication bias existed, the brief intervention influence would likely have been even weaker.

EVI data were used in four different data sets, one of which was based on patients' responses to the EVI questionnaires (data set I, n=557), two on the patients' clinical values (medical history data; data sets II, n=557 and III, n=251), and one on both clinical values and questionnaire data (data set IV, n=251). The outcome measures were related to the patients' nutrition behaviour and prevalence of metabolic syndrome and its single determinants among different sociodemographic groups. In addition, the association of nutrition behaviour and three other related health behaviours, i.e. physical activity, smoking and alcohol consumption, with the prevalence of metabolic syndrome was analysed.

Patient nutrition closely followed the Finnish national recommendations (Elintarviketurvallisuusvirasto Evira 2016) in both 2006 and 2007 on the consumption of whole grain products and vegetables, fruits and berries. Nutrition behaviour did not differ significantly by educational level. Occupational group had a significant influence on the consumption of fish, retirees most often eating fish at least two times a week. In addition, snacking behaviour and willingness to change nutrition behaviour differed according to occupational group. Physical and office workers most frequently reported snacking and physical workers were the most often willing to change their nutrition behaviour. (Data set I.)

Sociodemographic background also had a significant influence on the single clinical determinants of metabolic syndrome, namely systolic blood pressure, triglycerides, fasting glucose and body mass index. The lower educated, retired and the occupational group comprising unemployed persons and students most often presented with risk values. (Data set II.) However, the single clinical values of the patients accorded overall with the recommended healthy levels, except for mean systolic blood pressure (data set II).

In all, the prevalence of metabolic syndrome among the patients was 30.7 percent. The prevalence was highest in men (40.3 %), and in those with a lower educational level (43.1 %). Compared to the more highly educated, patients with

a lower education had significantly increased odds ratios for metabolic syndrome. Prevalence of metabolic syndrome was clearly associated with obesity. This link was supported when blood pressure was incorporated into the analysis. (Data set III.) No influence on the prevalence of metabolic syndrome was found for nutrition or other related health behaviours, i.e. physical activity, alcohol consumption or tobacco use. (Data set IV.)

8 DISCUSSION

8.1 Systematic review

8.1.1 Brief intervention influenced nutrition behaviour

The systematic review revealed that the evidence for an influence of brief counselling interventions on nutrition in primary health care remains inadequate. The present focus was on interventions that can be conducted easily during a usual-care visit, without notable costs or expenditure of time, given that lack of time and resources are the reasons most often given for not counselling patients on nutrition in primary care. Brief interventions were conducted in multiple, non-comparable ways. An effect of a brief intervention on nutrition was found in all four studies (Steptoe et al. 2003, Sacerdote et al. 2006, Hardcastle et al. 2008, Kuninkaanniemi et al. 2011) that had outcomes related to patient nutrition. The consumption of fruits and vegetables was the variable most often assessed in all four studies. Three of these (Steptoe et al. 2003, Sacerdote et al. 2006, Hardcastle et al. 2008) found an increase in the consumption of fruits and vegetables in the brief intervention groups, and two (Sacerdote et al. 2006, Kuninkaanniemi et al. 2011) a corresponding increase as a part of overall improvement in patient nutrition. This result held for the total of 3 760 patients who received a brief intervention on nutrition.

A common procedure in these studies was the use of a questionnaire or questionnaires supplemented with some sort of written information. Otherwise, the brief interventions differed markedly in intensity and content. With respect to the intensity of the interventions, greater intensity did not produce clearly better outcomes. In turn, in two studies (Steptoe et al. 2003, Sacerdote et al. 2006), personalised advice seemed to result in more favourable changes in nutrition outcomes. This outcome is supported by the success claimed for the motivational interviewing style (Miller 1996) and for elements of the Transtheoretical Model (Prochaska & DiClemente 1983) in brief interventions for such factors as individuals' readiness to change and self-efficacy (Werch et al. 2006). Two studies

(Steptoe et al. 2003, Hardcastle et al. 2008) reported using a theoretical framework. The application of the theories was not, however, reported in detail. This raises the question of the systematicity of the use of these frameworks. In addition, the context in which the intervention is conducted and the counsellor delivering the intervention may have an influence on the outcome (Glasgow et al. 2004a, Werch et al. 2006). This aspect was not clearly discussed in the reviewed studies.

In addition to changes in the consumption of fruits and vegetables, a decrease in fat intake was found in Hardcastle et al. (2008). The difference between the groups in favour of the brief compared to intensive intervention was significant. Furthermore, Sacerdote et al. (2006) reported increased odds ratios in the consumption of recommended levels of fish, red meat and olive oil. Nevertheless, these results are based on only one study and cannot therefore be generalised any further. However, the findings of the review support Pignone et al. (2003), who concluded that brief counselling produces small changes in dietary behaviour, although they found no effect on health outcomes. Changes in nutrition are not easily adopted, as research has repeatedly shown. Interventions where physical activity is combined with dietary advice and higher intensity trials with additional elements, or interventions targeted at patients with chronic disease, may influence nutrition in the short term (Kriska et al. 2003, Pignone et al. 2003, Nield et al. 2007, Lindström et al. 2013, Booth et al. 2014, Ball et al. 2015) but not necessarily in the long term. Persistent long-term changes have not always been obtained even with intensive interventions. A systematic review by Booth et al. (2014) concluded that behavioural weight loss interventions in primary care produced very small changes in body weight. The fifteen randomised controlled trials that were included in their review were all intensive interventions.

8.1.2 Brief intervention had no influence on clinical values

All the five studies measured clinical values that are known determinants of metabolic syndrome. Blood pressure was an outcome in all five studies, cholesterol in four, body mass index in three and fasting glucose in one. During the 12-month follow-up, contrary to the results for nutrition behaviour, the participants in the brief intervention groups did not achieve positive changes in these clinical values. The same was often also the case for those receiving an intensive intervention. In Hardcastle et al. (2008), a significant difference between the brief and intensive intervention was found only for diastolic blood pressure and in body mass index, both of which decreased more in the intensive intervention. In Ackermann et al. (2015) even a very intensive intervention with 16 counselling sessions did not produce significant changes in the target clinical outcomes, despite a greater decrease in body weight in the intensive intervention group compared to the brief intervention group. In Kuninkaanniemi et al. (2011), in turn, the patients receiving the intensive intervention even showed an increase in body mass index at follow-up. These results make it plain that one cannot expect changes in clinical outcomes before there is a change in the target behaviour.

It can be concluded from the present review study that a brief intervention was not enough to induce changes in clinical outcomes, a finding that is in line with previous research (Whitlock et al. 2002, Werch et al. 2006, Booth et al. 2014, Baer et al. 2015). However, as the aim of the review was to ascertain the influence of brief interventions on change in nutrition behaviours, the outcomes for the metabolic syndrome definers were mostly secondary. Furthermore, as already stated, a pre-requisite for a change in clinical outcomes is a change in behaviour. This would require longer trials with longer follow-up times.

8.1.3 Inadequate quality of trials leads to low quality of evidence

As the quality assessment conducted using the Quality Assessment Tool for Quantitative Studies (the Effective Public Health Practice Project 2008b) revealed, the quality of the reviewed trials was overall only weak or moderate. This indicates a high risk for bias in the studies. The weaknesses were due to e.g. inadequate descriptions of the intervention processes, participant blinding, the validity and reliability of the tools and measures used, and the consistency of the intervention. A newly published systematic review of randomised controlled trials in nutrition intervention studies (Ball et al. 2017) also concludes that the quality and development of such trials should be improved to enhance the quality of the evidence in primary care interventions.

It should be noted, however, that blinding from the patients' perspective is often only partially possible in public health interventions of these kinds. For this reason, assessment regarding blinding in the Quality Assessment Tool for Quantitative Studies is not entirely adequate, despite the tool being explicitly designed for use in public health research. Blinding in studies like the ones reviewed here cannot be compared in blinding demands to medical double-blind experiments.

Consequently, the quality of the included studies was not necessarily wholly weak; rather, the reporting was deficient. It is claimed that the reporting of randomised controlled trials is often less than optimal (Pandis et al. 2017), and hence it is important that the assessment tools are unambiguous and that the study is reported with due care (Salmela et al. 2009). For scientific articles, limitations on length imposed by the publisher can be problematic. To improve reporting quality, the CONSORT Statement for Reporting Randomized Trials (Altman et al. 2001, Pandis et al. 2017) or, for a nonrandomized design, the TREND Statement (Des Jarlais et al. 2004, Armstrong et al. 2008) can be used. These statements provide guidelines for transparent reporting. Yet, neither of these tools was clearly followed, except in Sacerdote et al. (2006), which also seemed overall to be the highest quality trial, as shown in table 5.

Nevertheless, the evidence on the effectiveness of brief interventions in modifying nutrition or the clinical determinants of metabolic syndrome in primary care was, according to the GRADE system (Guyatt ym. 2008a, Guyatt ym. 2008b, Falck-Ytter 2012, Andrews ym. 2013), of low-quality due to the limited number of trials measuring the same outcome, and weaknesses in the trials that were included. Consequently, confidence in the results is weak. The systematic

review by Ball et al. (Ball et al. 2015) investigated the effect of nutrition interventions of different intensity in primary care and also concluded that the consistency and the significance of the results remained unclear even where the included studies described rather intensive interventions or interventions conducted on severely ill groups of patients.

8.2 EVI study

8.2.1 Nutrition behaviour followed the national recommendations

The nutrition behaviour of the EVI study patients was in general well in line with the national recommendations (Elintarviketurvallisuusvirasto Evira 2016), including the recommendations current during the data collection period (Kansanterveyslaitos, KTL 2005), and was thus good in both observation years. The consumption of fish was the only outcome that seemed to be below the recommended level. The result roughly follows the general trend in Finland (Murto et al. 2016, Murto et al. 2017). However, as the questions and study setting differed from those of the population-level studies conducted in Finland, the results are not strictly comparable. The study results show a tendency in line with the notion that the nutrition habits of people living in rural areas are, in part, healthier than those of people living in city centres. Positive indications in patient nutrition behaviours may also have had an influence on the clinical values in the EVI study.

The study patients' educational level showed no influence on their nutrition behaviour, unlike the national trends reported in Finland (Murto et al. 2016, Murto et al. 2017). Instead, differences in nutritional habits were observed between the occupational groups. Retirees ate fish the most often, while snacking was most commonly observed among the physical and office worker groups. This finding seems reasonable considering the course of the day for working people compare to those outside the labour market.

Given that the nutrition behaviour of the patients was already sufficiently in accordance with the current recommendations, their willingness to change their behaviour was rather high. More than half of the patients were willing to change their nutrition, women more often than men, with retirees clearly the most seldom. From the standpoint of the Transtheoretical Model (Prochaska & DiClemente 1983, Prochaska & DiClemente 2005), patient willingness to change the target behaviour is a good and even necessary starting point for the process of behaviour change towards a desired goal. Nevertheless, the findings for applications of the model to nutrition interventions remain conflicting (Salmela et al. 2009, Tuah et al. 2011, Mastellos et al. 2014, Carvalho de Menezes et al. 2016). However, it can be concluded from this result that a need exists for patient counselling on nutrition from a health care professional. In fact, over a third of the primary EVI follow-up patients (n=599) had received an intervention on nutrition during the years 2006-2007. The results of the intervention i.e. change

in the nutritional and clinical outcomes between pre- and post-intervention, for that patient sample are presented in Kuninkaanniemi et al. (2011), which is also included in the review and has been discussed in the previous sections (see also Appendices 3, 4 and 5). It must be borne in mind, however, that, even if nutrition-related interventions in primary care have a potential to modify patient's nutrition behaviour, the significance of such changes remains unclear (Ball et al. 2015). For example, behavioural weight loss interventions in primary care have generally achieved only small reductions in patients' body weight (Booth et al. 2014).

8.2.2 Sociodemographic background had an influence on the prevalence of metabolic syndrome and its single clinical values

The mean values of the determinants of metabolic syndrome, i.e. obesity (especially central obesity), a high level of triglycerides, a low level of high-density lipoprotein cholesterol, elevated blood pressure, and abnormal blood sugar metabolism, were, except for systolic blood pressure, adequate. Blood pressure was the most often recorded clinical indicator. However, when the values were categorised and analysed according to the clinical diagnostic criteria for metabolic syndrome presented by Alberti et al. and the Finnish Medical Society Duodecim (Alberti et al. 2009, Duodecim 2017), the prevalence of abnormal values was found to be rather high. 80 percent of the patients had elevated blood pressure or were on medication for that condition. When controlling for the use of medications, medication to reduce blood pressure was the commonest medication used by the study patients. Almost 30 percent were on medication on elevated blood pressure.

Furthermore, over 40 percent of the patients had triglyceride values above the recommendations, almost a third elevated fasting glucose levels and a fifth elevated high density lipoprotein cholesterol levels when compared against the diagnostic criteria for metabolic syndrome (Alberti et al. 2009, Duodecim 2017). One-fifth of the patients were on medication for elevated cholesterol levels. These findings are in line with the overall situation in Finland, where medication for cardiovascular diseases is common (Lääkealan turvallisuus- ja kehittämiskeskus Fimea & Kansaneläkelaitos 2017).

Obesity was the least prevalent indicator of metabolic syndrome among the patients. It should be noted that the obesity criteria applied in the analysis were strict, i.e. the patient had to have both waist circumference and body mass index over the critical level. The reason for using two criteria was to avoid misinterpretation of the results, as these values were self-reported and thereby vulnerable to measuring errors. It is, therefore, likely that the incidence of obesity in this study sample under- rather than overestimates the true situation. Furthermore, the metabolic syndrome criterion values (Alberti et al. 2009, Duodecim 2017) used are rather strict and based on target values, which is obviously reasonable. However, for example blood pressure, and especially systolic blood pressure, tends to be above 130mmHg in an aging population (Duodecim 2014) such as that used in in this study.

Nevertheless, the prevalence of metabolic syndrome among the patients was nearly one-third. As a reference value, the global prevalence is one-fourth (Prasad et al. 2012). In men, the prevalence was 40 percent compared to 27 percent in women. That again is in line with general estimates (Prasad et al. 2012), and also applies in Finland. It is estimated that the prevalence of metabolic syndrome in the Finnish adult population is over one-third among men and over one-fourth among women (Duodecim 2017). However, population-level research data on the prevalence is lacking. While the present sample of primary care patients was selected, an increase in the prevalence of metabolic syndrome can be assumed to have occurred in recent decades. For example, before the millennium the incidence of metabolic syndrome among Finnish middle-aged women was eight percent and among men 17 percent (Vanhala 1996, Vanhala et al. 1997). The global increase in the prevalence of the syndrome is claimed to be due to the increase in obesity and also, to some extent, in sedentary behaviours (Alberti et al. 2009).

The prevalence of metabolic syndrome and its clinical determinants differed by sociodemographic background. The lower educated, unemployed and students, and retired groups presented with metabolic syndrome significantly more often (43 %, 38 % and 37 % respectively) than the other sociodemographic groups. Surprisingly, in light of the assumption that the prevalence of metabolic syndrome increases with age (Prasad et al. 2012), no significant effect of age was observed in this study. As the prevalence for the retirees was high, it can be assumed that this group also included rather young people.

When further evaluating the associations between the prevalence of the metabolic syndrome and the sociodemographic factors, a clear effect was found for educational level: the patients with the highest education showed a lower risk for metabolic syndrome than those with the lowest educational level. The results of the Logistic Regression analysis were adjusted for the background variables and the use of medication except for the medication that was already included in the definition of an abnormal value. Although the odds ratios remained small, which is most likely due to the small number of patients in the analysis blocks, the difference remained significant. While little is known about the influence of sociodemographic background on the prevalence of metabolic syndrome, a recent study in China found an association between high education and a higher prevalence of metabolic syndrome in men (Song et al. 2015). This is the reverse of the present finding. In the same study, the overall prevalence was 27 percent and nearly the same for both men and women. The latter finding also contradicts the present results. However, Chinese society and its structures as well as its sociodemographic hierarchy differ from those in Europe, including Finland. Therefore, these results are not directly comparable.

The differences between the sociodemographic groups were also marked for nearly all the categorised metabolic syndrome determinants. No statistically significant differences between groups were found only for high density lipoprotein cholesterol and obesity. Furthermore, the groups with higher values

for the single determinants tended to be the same as those with a higher prevalence of metabolic syndrome, i.e. men, the lower educated, retirees and the small group comprising the unemployed and students. None of the groups, except the retired group, were representative of an average patient in the study. That suggests that if the study sample had more closely resembled the Finnish population, that is, contained more men and the same distribution of educational levels (Tilastokeskus 2017), the incidence of both metabolic syndrome and elevated single determinants of metabolic syndrome would have probably been even higher. That is an issue of special concern and needs to be considered when developing promotive and preventive actions. It is also among the aims at the EU level, which explicitly state the need to tackle the health-related differences between sociodemographic groups (European Commission 2017b).

In general, the single clinical mean values were mostly around the recommended levels in both 2006 and 2008. (The intervention effect and changes between the observational years are reported in Kuninkaanniemi et al. (2011), which was included in the systematic review.) The patients did not differ markedly in their mean values between sociodemographic groups. Systolic blood pressure and body mass index were highest among the patients with the lowest education. This finding is clearly in line with the results of population-level studies in Finland (Murto et al. 2016, Murto et al. 2017), and supports the findings that are discussed in the previous chapters. The retired group showed the most abnormal mean values among the occupational groups, as might be expected in view of the differences between the age groups. Abnormal values were more prevalent in the middle-aged and older patients. Another sociodemographic group that differed significantly in mean values was that comprising the unemployed and students. In 2006, the fasting glucose level in this group was abnormal at the first measurement, and in 2008 blood pressure was far higher in the same group than in the other occupational groups. The number of the students and unemployed in the study was small, a factor that increases the significance of each measurements. However, in total the results of the EVI study indicate that this patient group should also be of concern in health promotion and preventive interventions.

8.2.3 Associations between metabolic syndrome and health behaviour and obesity

Patients' nutrition or other metabolic syndrome-related health behaviours, i.e. physical activity, excessive alcohol consumption and smoking, had no influence on the prevalence of metabolic syndrome in this study, contrary to the findings of some trials e.g. (Kim, Kim & Kang 2012, Hwang et al. 2014, Hirakawa et al. 2015, Huang et al. 2015, Kim & Choi 2016, Lee, Kim & Jeon 2016, Zhang et al. 2017, Li et al. 2017b). However, most of the above-cited studies investigated Asian populations, which means that differences in population characteristics should be taken into account when comparing results. Furthermore, the health behaviour of the EVI study patients was generally adequate, and even good, especially in nutrition behaviour, alcohol consumption and the use of tobacco

products. This fact may also have influenced the association between the prevalence of metabolic syndrome and these health behaviours.

The physical activity level of the EVI study patients, in turn, was rather low. Many other trials have found a connection between physical activity and the incidence of metabolic syndrome (Shuval et al. 2012, Kim & Choi 2016, Lee, Kim & Jeon 2016, Li et al. 2017b, Zhang et al. 2017). For example, the meta-analysis by He et al. (2014) found that a higher level of leisure time physical activity was associated with a smaller risk for metabolic syndrome. Song et al. (2015) found that increased physical activity was associated with a decrease in the prevalence of metabolic syndrome in men, and another study by El Bilbeisi, Hosseini & Djafarian (2017) found a positive influence of physical activity for both genders. That is important to consider when planning promotive and preventive actions, especially in view of the systematic review by Booth et al. (2014), which called for more effective strategies for the management of obesity. In addition, a recent review found that exercise training improves the metabolic values of patients who already have metabolic syndrome (Ostman et al. 2017).

Overall, patient overweight should be noted. Besides being an independent risk factor for behaviour-related diseases, the importance of obesity prevention, particularly in older adults, who constituted a large proportion of the present study patients, has been highlighted in primary care, not only to reduce mortality and morbidity but also to improve quality of life (Batsis & Zagaria 2018). Furthermore, it has recently been reported that weight status is associated with higher comorbidity among overweight women than overweight men (Khan et al. 2017). Both of the above obesity-related findings for older adults and women are of particular interest for the present study, whose subjects were predominantly from those population groups.

The strength of the hypothesised association between obesity and the prevalence of metabolic syndrome was tested using a two-sided approach, the aim being to investigate the possible link from two perspectives that would have practical value in primary care, i.e. from the metabolic syndrome perspective, with particular reference healthy patients (i.e. patients who do not have metabolic syndrome), and from the perspective of obesity, with reference to obese patients. Of the patients who did not have metabolic syndrome, i.e. who in that sense were healthy, only four percent were obese. Thus, when referring obese patient for clinical tests, only four percent will be unnecessarily tested for the presence of metabolic syndrome. When investigated from the obese patient perspective, in almost 80 percent of the cases where obesity existed metabolic syndrome was also present. While this finding was partly a result of the smaller number of patients for the analysis compared to the former (i.e. the number of obese patients was smaller than the number of patients who did not have metabolic syndrome), it was reliable enough to be statistically analysed.

Obesity alone was, based on these findings, already a clear indicator of metabolic syndrome. When this hypothesis of the connection between metabolic syndrome and obesity was further evaluated with another easy and quick indicator, namely blood pressure, the association with the presence of metabolic

syndrome was even stronger. Reliable, wider population-level research data from this perspective is rare. The American National Health and Nutrition Examination Survey concluded that the prevalence of metabolic syndrome increases along with body mass index (Nguyen et al. 2008). A study among Sudanese young adults found that metabolic syndrome was diagnosed only among the obese individuals (Yasir et al. 2016). A Chinese study, in turn, concluded that waist-height ratio may be the best anthropometric test to identify metabolic syndrome (Huang et al. 2009). The association is also pertinent to the widely discussed question of whether obesity should always be considered as an obligatory indicator of metabolic syndrome (Alberti, Zimmet & Shaw 2006a, Zimmet & Alberti 2008, Alberti et al. 2009, Cameron et al. 2009). EVI study results suggest that obesity is a central and clear indicator of metabolic syndrome.

8.3 Implications for future research and practice

To prevent the overwhelming growth of health behaviour-related diseases, effective actions are needed. This study emphasises the need for high quality data in the use of brief interventions for nutrition counselling in primary care. An extensive literature search in eight central health-related databases and an additional subsequent hand search resulted in five different articles where the trials met the inclusion criteria, i.e. a brief (less than 15 minutes) intervention on nutrition easily conducted for adult patients in the primary care context. Brief interventions are widely used in counselling patients on alcohol consumption and tobacco use and have been shown to be efficacious and to some extent cost-effective in these areas (Higgins-Biddle et al. 1997, Zarkin et al. 2003, Babor et al. 2005, Babor et al. 2006, Gebara et al. 2013, Donoghue et al. 2014, McDevitt-Murphy et al. 2014, Tansil et al. 2016, McKnight-Eily et al. 2017). Both target behaviours are possibly addictive behaviours. It might, therefore, be expected that a similar brief intervention would also have a positive impact on non-addictive behaviours such as nutrition. However, the evidence is scarce, as shown by the total number of hits for this review. At the same time, the result is a strong indication that in the primary health care context no adequate research data related to brief interventions in nutrition counselling conducted on people not (yet) affected by a chronic, behaviour-related disease currently exists. Therefore, new high-quality research trials are required on the brief intervention method on nutrition.

Health promotion and disease prevention as part of an efficient health system have been emphasised by the European Commission in its State of Health in the EU report (European Commission 2017b). Tackling social inequalities is one priority that is clearly supported by the present study findings. Obesity also needs to be addressed in primary care practice. Given the human and the economic burden of obesity, together with the findings of this study, it would be important to refer obese patients encountered in primary care for further examinations and assessments of clinical values to determine the presence of

metabolic syndrome and their risk for health behaviour-related diseases. However, some studies have even reported a decline in the rates of obesity counselling (Smith et al. 2011, Kraschnewski et al. 2013).

The major aims of the Finnish National Obesity Programme 2012-2018 include encouraging loss of weight in people at high risk for developing diseases related to obesity and reducing differences between population groups in the prevalence of obesity. A further target is to decrease the number of children and young adults who are at risk for obesity in adulthood, and the number of people who gain weight in adulthood (Terveyden ja hyvinvoinnin laitos & Kansallisen lihavuusohjelman ohjausryhmä 2016). Hence, obesity management should be an integral part of practice in the primary ward (Duodecim 2013).

Furthermore, as found in the study, the two easy-to-administer measures, obesity and blood pressure, serve as a strong indication of the presence of metabolic syndrome. Result strongly supports the screening test for metabolic syndrome developed by Vanhala (1996). This finding seems valuable in terms of both disease prevention and reducing health care costs. Both measures are easy to administer during any primary care visit. Obesity can be recognised visually and measuring blood pressure does not require much time. Thus, this is also a possibility for the further development of the brief nutrition-based intervention method in primary care. In this connection, another approach reflecting health promotion is self-efficacy (Prochaska & DiClemente 1983, Miller 1996, Prochaska & DiClemente 2005), i.e., actions everyone can do on their own to reduce the risk for developing a health behaviour-related disease. This is an issue of the greatest importance at the general population level, as both obesity and blood pressure are indicators that many people can self-measure.

In addition, recent research suggests that personalised nutrition, that is, the development of unique, individual nutrition guidelines, may be useful in obesity management and the prevention of metabolic disturbances (Betts & Gonzalez 2016, Juan de Toro-Martín et al. 2017). Technological applications, including web-based methods, mobile methods and sensor technologies, have been used in giving such advice to patients. The Social Cognitive Theory is suggested to provide a possible framework for the development of personalised nutrition approaches, as e.g. self-efficacy and feedback have been shown to be important factors in contributing to change in a nutrition behaviour (Rankin et al. 2017). However, evidence on the effectiveness of such methods and, in general, on the rationale of the personalised nutrition approach, remains insufficient (Stewart-Knox et al. 2015, Betts & Gonzalez 2016, Forster et al. 2016).

Nevertheless, the potential of digitalisation to strengthen the health care system should be noted. Currently, 18 million health care professionals work in the EU member states. This number is forecast to increase by a further 1.8 million by 2025 (European Commission 2017b). Therefore, the education of existing and future professionals in interaction skills as well as digital applications could also contribute to the development and efficacy of brief intervention methods aimed at preventing health-behaviour related diseases.

The study also revealed that the use of the term 'brief intervention' is very heterogeneous. There is clearly no general meaning of the term; moreover, the terms brief intervention, brief counselling, and brief advice are used in contradictory ways. This makes it even more difficult to evaluate the effectiveness of a brief intervention. Therefore, the following classification of brief interventions is suggested: an intervention that lasts five minutes at most would be classed as 'brief advice', whereas an intervention with five to fifteen minutes of counselling would be classed as a 'brief intervention'. A brief intervention with follow-up visits would then be a 'multi-contact brief intervention, as previously suggested by Whitlock et al. (Whitlock et al. 2004). The same results cannot be expected from a few minutes advice on behaviour change compared to three fifteen-minute counselling sessions with personalised support and conversation. Something in between these extremes might be possible in a routine primary care visit, even as part of a visit with a different main function. An example of this would be a visibly obese patient who attends primary care for a reason other than a health behaviour-related issue, e.g. an ankle sprain. During inspection of the ankle, obesity could be brought up by the health care professional, and further support or clinical measures suggested if deemed appropriate. In sum, this is probably one of the ultimate aims, and possible strengths, of the brief intervention method.

The findings of the two studies are combined in the following summary of their implications for research and practice. Obese patients attending primary care for any reason should be advised on the (obesity) issue and referred for further clinical tests, measuring blood pressure at the minimum. In addition, brief information on the risks for metabolic syndrome and on healthy behaviours (at least in nutrition and physical activity) should be given to the patient (=brief advice). This can be done using written material or digital applications. The amount of time these actions require is minimal, yet it is likely to result in diagnosing whether the patient has metabolic syndrome. To evaluate the influence of this practice, research data should be collected for at least 24 months. Figure 10 sums up the main findings and implications.

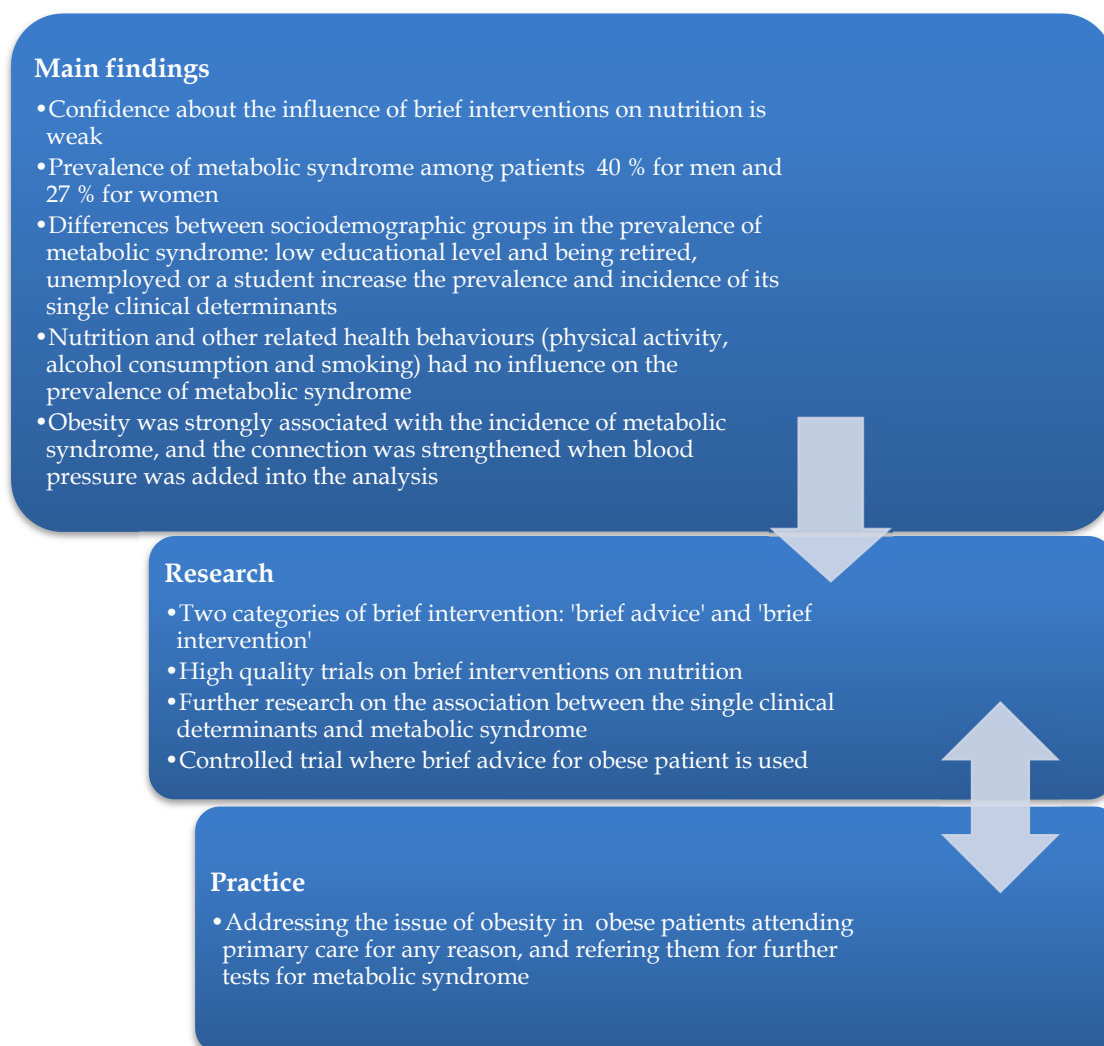


FIGURE 10 Main findings and implications for future research and practice.

8.4 Reliability and representativeness of the results

8.4.1 Comprehensiveness and reliability of the systematic review

The major limitations of the systematic review on trials where a brief intervention was used as a method of counselling patients nutrition in primary care were due to the small number and the weak quality of the studies. The latter is discussed in depth in the previous section. The inclusion criteria were formulated to capture studies on health promotion and disease prevention according to the specific aim of the review. Therefore, studies with additional resource-consuming elements beyond those needed for a brief counselling session were excluded. Trials focusing on patients with a chronic disease or serious illness, e.g. cancer, were not included because motivation and subjects' personal evaluations of the pros and cons of change influence the process of behaviour change

(Prochaska 2008). They are likely to be different for ill people than for healthy people.

Follow-up time was set at twelve months to evaluate the persistence of change in the target behaviour. Also, to effect change in the clinical values of the determinants of metabolic syndrome, a shorter follow-up time would have been unreasonable. Moreover, to reduce the risk for behaviour-related diseases requires long-term changes (Eden et al. 2002). It can, of course, be questioned whether it is even possible via a brief intervention to achieve long-term changes in nutrition- and obesity-related factors, as even intensive interventions have not always been successful in inducing such changes (Booth et al. 2014, Baer et al. 2015, Ball et al. 2015).

However, the volume of evidence was surprisingly small. It is nevertheless likely that brief interventions have been conducted in primary care, either intentionally or unintentionally, i.e. health care professionals do not necessarily recognize that giving a patient advice on 'health behaviour change' is tantamount to conducting a brief intervention. Furthermore, as brief interventions aiming at nutrition behaviour change have had low visibility, it might be that some trials remain unpublished or even unreported. Small-scale trials yielding non-significant results can also remain unpublished – and even when published, be cited less often (Eakin, Glasgow & Riley 2000). This could indicate the existence of publication bias. If so, that, in turn, would indicate that the effects of brief interventions might be even more uncertain and weaker than found in this study.

Despite the comprehensive yet appropriately precise systematic search in the databases, it is possible that some studies were ignored during the search process due, for example, to a deceptive study title or description. However, the search process was formulated to avoid such failures as far as possible. The aim of the three different search categories and search strategies was to ensure that relevant studies were identified, despite the loss in precision caused by raising the comprehensiveness of the search and consequent retrieval of even more non-relevant articles (Higgins & Green 2011). The high number of duplicates yielded by both the precise primary search (category 1) and comprehensive supplementary search (category 2) indicates that the search strategy was reliable. Of the 113 different articles found by the primary search, almost 90 percent were also found in the wider search (category 2). Additional handsearching was done to locate harder-to-reach studies, and authors were contacted by email if the inclusion or exclusion decision could not be made based on the published material. The wider search was even repeated during fall 2017 after the original search in fall 2016.

Another way to ensure the coverage of the review was the use of the diverse search terms. For example, if the term 'brief intervention' alone had been used to refer to the target intervention type, the number of hits would have remained extremely small. This can be seen in figure 3, which shows the primary search strategy flow. Use of the search term 'brief intervention' alone would have yielded only 47 articles, even in the absence of publication language limitations.

It was, therefore, necessary to add related terms, and even use the term 'intervention' unqualified by the term 'brief'.

Had the literature search been restricted to randomised controlled trials, it would have introduced the risk of omitting relevant research. On the other hand, limiting the search to randomised controlled trials alone would have enhanced the judgement of the effectiveness of the method. However, the study design is not considered the sole criterion of the quality of the evidence in public health intervention studies (Rychetnik et al. 2002). It has also been noted that well-conducted RCTs are rare in the field of public health, and that designs other than RCTs are needed in evidence-based public health research (Rychetnik et al. 2002, Victora, Habicht & Bryce 2004). The limited number of 'brief intervention' hits, as described above, supported this decision.

The five trials included in the review each compared two different interventions. Two of them, Sacerdote et al. (2006) and Steptoe et al. (2003) compared two different brief interventions. The effect of a brief intervention can thus be assessed based on seven different brief interventions. Furthermore, when the comparison intervention for an intensive intervention was named as standard care, but nevertheless fulfilled the criteria for a brief intervention, i.e. it went beyond the usual ward, it was included in the review. This was the case in the studies by Ackermann et al. (2015) and Hardcastle et al. (2008). Due to the already limited number of brief intervention studies, it was not possible to restrict inclusion to trials that compared similar interventions. The baseline characteristics of the participants were in any case alike between the studies. Most of the participants were middle-aged women, except in the study of Sacerdote et al. (2006), where half of the participants were men. In addition to different search categories and diverse use of the search terms as discussed previously, this, i.e. no restrictions on the study design, was a third way to guarantee the representativeness of the identification of studies included in the systematic review.

8.4.2 Generalisability and limitations of the EVI study

The study patients were mostly women with a medium-level education aged between 41 and 64 years. They represent a typical study population for trials conducted in primary care, as can be seen, for example, in the studies included in the review (Steptoe et al. 2003, Hardcastle et al. 2008, Ackermann et al. 2015). Such trials are based on volunteer study populations and therefore unavoidably represent somewhat selected and active patients. However, as this is common to trials addressing behaviour change in the primary health care context, the results are comparable to those of similar studies.

The main limitations are related to the characteristics and age of the rather small data set. Nutrition behaviour was assessed by questionnaire in 2006 and 2007 with simple questions answered as only yes or no. Misunderstandings are therefore unlikely. However, in questionnaire studies addressing health behaviour it is possible that patients tend to show positive bias. Although almost ten years have passed since the data were collected, the analysis and measures

can be considered valid today. The questions on nutrition behaviour included in the statistical analysis were in line with the current recommendations. However, even with valid questions, the results represent a situation that dates back several years and cannot be directly compared with that prevailing today.

Clinical values were obtained from the patients' medical history records, i.e. they were not measured primarily for the present research purpose. This meant that not all the values were available for all the patients for both observation years, i.e. 2006 and 2008. That again meant that the number of the patients included in the analysis varied for different outcomes. In addition, the number of patients in the different sociodemographic groups varied: in the educational level groups, those with the highest education were the fewest and in the occupation-based groups the smallest group was the one containing unemployed people and students. These differences are mentioned in the methods and results section and discussed further in the previous discussion sections. In the interests of comprehensiveness four different data sets were used. Moreover, the reliability and representativeness of the results was increased by analysing the clinical determinants of metabolic syndrome both as continuous and as categorised values. The use of medication was controlled for throughout the analysis. Direct medication was taken as an alternative indicator for an elevated value, as suggested in the global diagnostic criteria for metabolic syndrome (Alberti et al. 2009). In addition, the use of other related medication (medication for obesity or for coronary artery disease) was controlled for in the statistical analysis.

Waist circumference and the information needed to calculate body mass index were self-reported. There is a possibility that self-reported data are incorrect, e.g. if the waist circumference is not measured at the right place. As obesity, and especially central obesity, is a crucial determinant in metabolic syndrome (Alberti, Zimmet & Shaw 2006, Zimmet & Alberti 2008, Alberti et al. 2009, Cameron et al. 2009), and to avoid misinterpretations of the prevalence of the metabolic syndrome, both body mass index and waist circumference were used as an indicator of obesity, i.e. both had to be abnormal.

2006 was the only observation year for the prevalence of metabolic syndrome. It was likely that had especially those with abnormal values in 2006 been measured again in 2008 the prevalence would have been higher. This turned out to be the case when this assumption was tested. Furthermore, it was possible to determine the presence of metabolic syndrome in the patients for whom all five metabolic syndrome determinants were available, i.e. 1) triglycerides, 2) high-density lipoprotein cholesterol, 3) blood pressure including both systolic and diastolic blood pressure, 4) fasting glucose and 5) obesity determined by both waist circumference and body mass index. This meant that the number of the patients included in the latter analysis was lower. Consequently, analysis of the prevalence of metabolic syndrome in 2008 would not only have represented a highly selected part of the patients but the data would also have remained too small for a comprehensive and comparative analysis.

Compared to the rather good levels in the single clinical mean values, the incidence of metabolic syndrome was quite common. Consequently, there seems

to be a distinction between the study patients, i.e. those whose values were over the recommended levels, and others whose values were below the critical borderline levels (Alberti et al. 2009, Duodecim 2017). The reason for this is that the analysis evaluating the single clinical values (both as categorised and continuous) included all the study patients for whom a particular value was available. For the metabolic syndrome analysis, it was only possible to include the patients for whom all five determinants were available. Thus, it must be noted that when measuring the clinical values in primary care it is likely that some symptoms of metabolic syndrome exist. In other words, one can assume that some clinical values may be at an abnormal level.

The baseline comparison was made to see if this five measured values group of patients differed from the other patients in the study. The comparison revealed that the patients with five measured values were more often elderly, low educated and retired. This supports the findings discussed previously, i.e. that overall these groups differed from the others in the number of abnormal findings, and it is likely that they would more often have been referred for clinical investigation. Therefore, the analysis on the prevalence of metabolic syndrome represents a somewhat selected group of patients and cannot be generalised across the primary care level. Rather it represents a subgroup of primary health care patients who were referred for specialist examination for one reason or another. However, it is reasonable to conclude that the right patients were referred for these measures.

8.5 Ethics of the study

Respect for the patient and the patient's best interests are the guiding principles laid down by the Finnish National Advisory Board on Social Welfare and Health Care Ethics (ETENE) (2011) for Finnish social and health care and related research. This research was conducted following these principles. Figure 11 presents the ethical framework of the whole research.

The ethical framework adhered to in this research is driven by health promotion or, more specifically, from producing value in health care, thus applies not only to the context of the individual patient but also to the wider context of primary care, including the personnel working in the field of health promotion, as stipulated in the Finnish Act on the status and rights of patients (785/1992, 658/2009) (Finnish Ministry of Social Affairs and Health 1992) and the Finnish National Advisory Board on Social Welfare and Health Care Ethics (ETENE) (2011).

Following Niiniluoto (2015), a wider ethical perspective refers to the philosophical premises of a good life, and particularly concerns such questions as the values on which a good life is based and who determines these. One of the basic values, especially in welfare states, is that of health rather than merely the absence of disease. Equity in health is a primary aim tempered, however, by the recognition that equity as such is not truly possible as people differ in their health

by nature. Thus, instead of health per se, equity refers to the health care system and equality for all citizens in the opportunities for health care (Niiniluoto 2015). In the EVI study, patients were recruited on the principle of being offered a similar opportunity to participate. Theoretically, in randomised controlled trials, as mostly discussed in connection with study 1, equity does not apply as the participants have to receive different treatments for the effect of an intervention over usual treatment to be evaluated.

Another ethical consideration with respect to the study context reflects the valuing of health over healthy behaviour. Thus, to avoid health behaviour-based discrimination, the starting point of primary care practices should be the health and welfare of the patient rather than healthy behaviour per se. Furthermore, given the high value that many people place on health, as mentioned earlier, improvement in health rather than a change in behaviour would, as an intervention aim, be more likely to influence a patient's motivation. In counselling practice, in turn, it is easier to target a change in health-related behaviour and offer patients concrete options, thus also improving their self-efficacy.

Moreover, individual needs and cultural background must be considered in every encounter between a health care professional and an individual patient (Finnish Ministry of Social Affairs and Health 2009), as must also the influence of individual perceptions and self-efficacy on the success of health care practices, especially that of counselling. This might be one reason for the failure, as found in study 1, to of brief interventions to achieve their goals. It may be questioned whether it is even possible in such a brief encounter to recognise a patient's needs, including with respect to the stages of change posited by the Transtheoretical Model (see also Chapter 2).

The EVI study was granted ethical approval by the ethical committee of the Central Finland Health Care District in 2006. Patient participation in the study was voluntary. The term patient (instead of client) has been used throughout this report as the participants were all users of health care services (ref. the definition in the Finnish Act on the status and rights of patients, Finnish Ministry of Social Affairs and Health 1992). Appropriate ethical research principles were followed, and the anonymity of the patients ensured throughout the study, i.e. during the data collection, during the intervention, and in the analysing and reporting of the results.

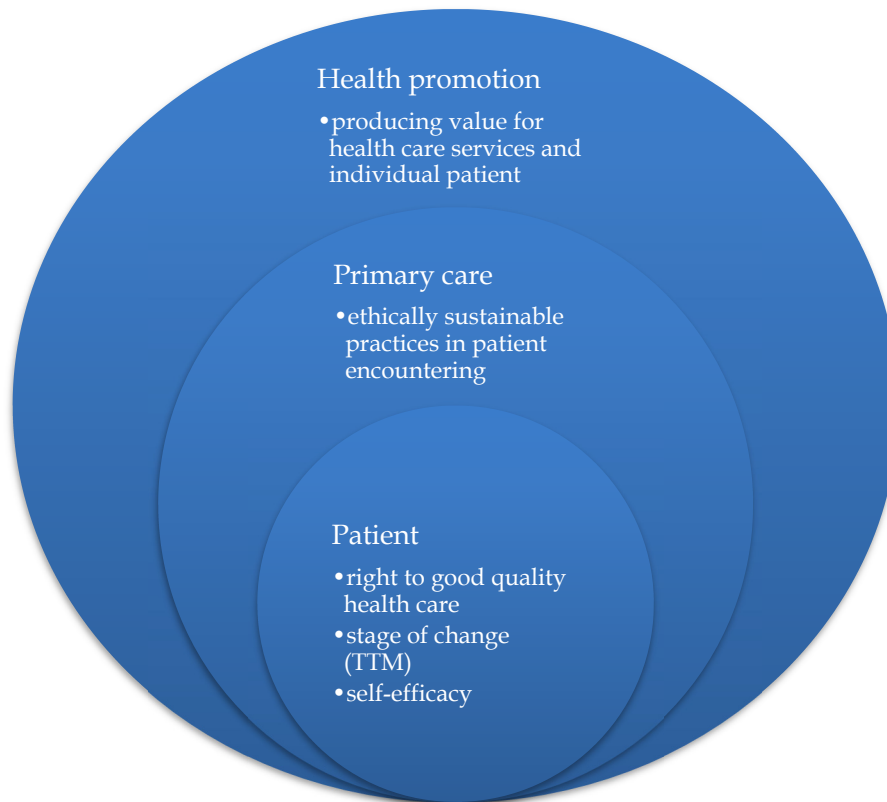


FIGURE 11 Ethical framework of the study.

9 CONCLUSIONS

This study produced new information on the use and influence of a brief nutrition-based intervention in the primary care context (study 1) and on the prevalence of metabolic syndrome among primary care patients (study 2). The following conclusions and recommendations for future research can be drawn from the results.

First, the data available for evaluating the influence of brief interventions for nutrition behaviour in primary care is insufficient. High quality trials with longer follow-up times are needed to appraise the effectiveness of the method in modifying patients' nutrition behaviour and hence the values of metabolic syndrome determinants.

Second, both the prevalence of metabolic syndrome and the single clinical determinants of metabolic syndrome differed significantly between the various sociodemographic groups studied, and hence health promotion and disease prevention should be targeted accordingly.

Third, owing to limitations in the data, nutrition and other health-related behaviours had no influence on the prevalence of metabolic syndrome, although a clear association between obesity and the prevalence of metabolic syndrome was found. Accordingly, metabolic syndrome should be addressed when obesity, alone or together with abnormal blood pressure, is present in patients in the primary care context. The two easy-to-address indicators may serve in assessing whether a patient has metabolic syndrome and should be referred for further health promotion, treatment or tests.

TIIVISTELMÄ (FINNISH SUMMARY)

Tässä väitöskirjassa tutkittiin perusterveydenhuollossa toteutetun lyhytneuvonnan (mini-interventio) vaikutusta ravitsemuskäyttäytymiseen (tutkimus 1), sekä metabolisen oireyhtymän ja sen indikaattorien yleisyyttä perusterveydenhuollon potilasasiakkailta (tutkimus 2). Lyhytneuvonta on lyhyt neuvontatilanne, jossa terveydenhuollon ammattilainen ottaa elintavan puheeksi ja tukee elintapamuutoksen toteutuksessa. Neuvonta voidaan toteuttaa perusterveydenhuollossa tavanomaisen vastaanottokäynnin yhteydessä. Metabolinen oireyhtymä tarkoittaa aineenvaihdunnallista häiriötilaa, jossa henkilöllä esiintyy samanaikaisesti vähintään kolme seuraavista viidestä riskitekijästä: kohonnut systolinen tai diastolinen verenpaine, alhainen veren HDL-pitoisuus, korkea veren triglyseridipitoisuus, kohonnut plasman paastoglukoosipitoisuus sekä vyötärölihavuus.

Väitöskirjan kaksi tutkimusta vastaa viiteen tutkimusongelmaan. Tutkimuksessa 1 toteutettiin kahdeksan keskeisintä terveystietokantaa kattava systemaattinen kirjallisuuskatsaus syys-lokakuussa 2016. Viimeinen päivitys tiedonhakuun tehtiin marraskuussa 2017. Artikkelit analysoitiin yksitellen ja niille toteutettiin laaja laadunarviointi. Tutkimuksessa 2 käytetty aineisto kerättiin Keski-Suomessa perusterveydenhuollon Elämäntapasairauksien varhaistunnistaminen ja intervention (EVI) -hankkeessa vuosina 2006-2008 (n=557 tutkimusongelmissa II-III ja n=251 tutkimusongelmissa IV-V). Aineisto koostui kyselylomakeaineistoista ja metaboliseen oireyhtymään liittyvistä kliinistä arvoista. Tilastolliset analyysimenetelmät olivat chi-square -testi, GLM ja logistinen regressio.

Tutkimus 1: Systemaattisen kirjallisuushaun tuloksena läpikäytiin 983 artikkelia, joista viisi vastasi tutkimuskysymykseen. Tutkimukset poikkesivat toisistaan ja olivat laadullisesti puutteellisia. Lyhytneuvonnan vaikuttavuus ravitsemuskäyttäytymisen muutokseen oli heikko. Metabolisen oireyhtymän indikaattoreissa ei tutkimuksissa saavutettu muutoksia. Tutkimus 2: Täysjyväviljatuotteiden sekä kasvien, marjojen ja hedelmien käyttö noudatti yleisesti kansallisia suosituksia. Koulutuksella ei ollut vaikutusta ravitsemuskäyttäytymiseen. Eläkeläiset söivät useimmin kalaa ja fyysistä tai toimistotyötä tekevät napostelivat useimmin. Fyysistä työtä tekevät myös olivat useimmin halukkaita muuttamaan ravintotottumuksiaan. Metabolisen oireyhtymän indikaattorit olivat keskimäärin normaalirajoissa verenpainetta lukuun ottamatta. Sosioekonominen status vaikutti merkittävästi sekä metabolisen oireyhtymän yksittäisten arvojen että metabolisen oireyhtymän esiintyvyyteen. Matalasti koulutetuilla, eläkeläisillä ja ryhmällä työttömiä ja opiskelijoita oli kohonneet arvot useimmin. Metabolisen oireyhtymän yleisyys oli miehillä 40 % ja naisilla 27 %. Sosioekonomisista ryhmistä esiintyvyyks oli yleisintä matalasti koulutetuilla (43 %). Metabolinen oireyhtymä oli selkeästi yhteydessä lihavuuteen. Henkilöistä, joilla ei ollut metabolista oireyhtymää, vain neljä prosenttia oli lihavia. Yhteys oli vielä selkeämpi, kun

henkilöllä oli lihavuuden lisäksi korkea verenpaine. Tutkittujen terveystietojen yhteydessä ei ollut yhteyttä metabolisen oireyhtymän ilmaantuvuuteen.

Tutkimustieto lyhytneuvonnan vaikuttavuudesta ravitsemuksen muuttamisessa on riittämätöntä ja uusia kontrolloituja tutkimusastelema tarviataan. Metabolisen oireyhtymän esiintyvyydessä on eroja sosiodemografisten ryhmien välillä ja terveyden edistämässä erityisesti näiden ryhmien tavoittamiseen tulee kiinnittää huomiota. Perusterveydenhuollon kontekstissa kerätty aineisto rajoittaa tulosten yleistettävyyden väestötasolle. Helposti arvioitavat indikaattorit, lihavuus ja verenpaine, kuitenkin toimivat metabolisen oireyhtymän seulonnassa.

Avainsanat: lyhytneuvonta, mini-interventio, perusterveydenhuolto, ravitsemus, metabolinen oireyhtymä

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APPENDIX 1: Search strategy for supplementary systematic search

Database: PubMed with no date restrictions, i.e. from the beginning. The last update of the search conducted on November 10, 2017. Total amount of search results 669.

Search strategy:

(brief intervention[Title/ Abstract] AND
nutrition[Title/ Abstract]) OR dietary[Title/ Abstract]) OR diet[Title/ Abstract]) OR
overweight[Title/ Abstract]) OR obesity[Title/ Abstract])

OR

intervention[Title/ Abstract] AND
nutrition[Title/ Abstract]) OR dietary[Title/ Abstract]) OR diet[Title/ Abstract]) OR
overweight[Title/ Abstract]) OR obesity[Title/ Abstract]))

OR

counseling[Title/ Abstract] AND
nutrition[Title/ Abstract]) OR dietary[Title/ Abstract]) OR diet[Title/ Abstract]) OR
overweight[Title/ Abstract]) OR obesity[Title/ Abstract]))

OR

counselling[Title/ Abstract] AND
nutrition[Title/ Abstract]) OR dietary[Title/ Abstract]) OR diet[Title/ Abstract]) OR
overweight[Title/ Abstract]) OR obesity[Title/ Abstract]))

OR

screening[Title/ Abstract] AND
nutrition[Title/ Abstract]) OR dietary[Title/ Abstract]) OR diet[Title/ Abstract]) OR
overweight[Title/ Abstract]) OR obesity[Title/ Abstract]))

AND

primary care[Title/ Abstract] OR primary ward[Title/ Abstract]) OR health
center[Title/ Abstract]) OR health centre[Title/ Abstract]) OR clinical
practice[Title/ Abstract]

AND

adult[Title/ Abstract]

APPENDIX 2: Items drawn from the EVI study questionnaire

NUTRITION

Do you mainly use vegetable oil or margarine in cooking?

Do you eat fish at least two times a week?

Do you use whole grain products daily?

Do you use vegetables, berries or fruits daily?

Do you have snacks or goodies at least once daily?

Are you willing to change your nutrition behaviour?

PHYSICAL ACTIVITY

How many days a week (from 0 to 7) you have vigorous physical activity at least 30 minutes a day?

ALCOHOL

How often do you consume beer, cider, wine or other alcohol drinks?

SMOKING

Do you use tobacco products?

BACKGROUND INFORMATION INCLUDING:

Gender

Working status

Identity number

Occupation

Education

Height

Weight

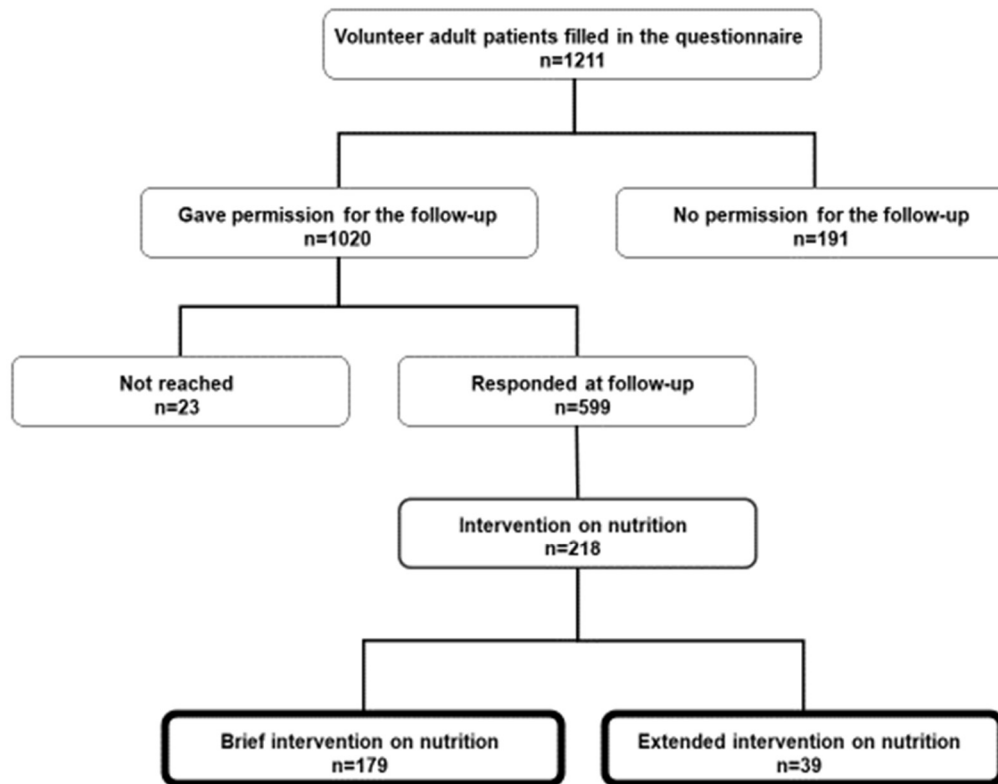
Waist circumference

APPENDIX 3: Research objectives, data and methods of the previously reported results of the EVI study by the author

SOURCE	RESEARCH OBJECTIVE	OUTCOME MEASURES	DATA	METHODS AND ANALYSIS
EVI-STUDY (Kontinen, Villberg & Poskiparta 2008)	Health behaviour and willingness to change health behaviour among the EVI study patients	<ol style="list-style-type: none"> 1. Nutrition, physical activity, alcohol consumption and tobacco use of patients in 2006 and 2007 according to gender and age (divided in two age groups <54 and ≥54) 2. Willingness to change health behaviour in 2006 and 2007 according to gender and age (divided in two age groups <54 and ≥54) 3. Change in the behaviour and in the willingness to change behaviour between 2006 and 2007 according to gender in repeated measures setting 4. Use of the counselling during 2006 and 2007 according to gender 	<p>First questionnaire in 2006 + follow-up questionnaire in 2007</p> <p>n=1211 in 2006</p> <p>n=599 in 2007</p> <p>n=559 in repeated measures (outcome 3)</p>	<p>Chi-Square test (outcomes 1, 2, 4)</p> <p>Cohen's kappa (outcome 3)</p>
EVI-STUDY (Kuninkaanniemi et al. 2011)	Influence of intervention in patients' (i) consumption of fish, whole grain products, and fruits and vegetables; (ii) nutrition index; and (iii) health outcomes in terms of metabolic syndrome definers	<ol style="list-style-type: none"> 1. Change in the consumption of fish, whole grain products, and fruits and vegetables 2. Change in the overall nutrition: nutrition index (fish at least two times a week; whole grain products daily; vegetables, fruits or berries daily) 3. Changes in metabolic syndrome definers (SBP, DBP, total cholesterol, HDL, triglyceride, fasting plasma glucose, self-reported BMI and waist circumference) 	<p>Study patients who had received intervention on nutrition during 2006 and 2007: n=218</p> <p>Data included:</p> <ul style="list-style-type: none"> - First questionnaire from 2006 - Follow-up questionnaire from 2007 - Clinical values SBP, DBP, total cholesterol, HDL, triglyceride, fasting plasma glucose, and self-reported BMI and waist circumference from 2006 and 2008 	<p>Cohen's kappa (outcomes 1, 2 and 3)</p> <p>Logistic Regression (outcomes 1 and 2)</p> <p>Multivariate Analysis of Variance (MANOVA) for Repeated Measures (outcome 3)</p>

APPENDIX 4: Flowchart of the EVI study patients who received the intervention on nutrition

Presented originally in Kuninkaanniemi et al. (2011)



APPENDIX 5: MANOVA for Repeated Measures for the effect of the intervention group and effect of time on the clinical values

Presented originally in Kuninkaanniemi et al. (2011)

	Brief intervention	Extended intervention	Effect of the group		Effect of time†	
	2006/2008	2006/2008	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>
SBP (mmHg)	141.3/139.3	135.9/138.3	0.814	0.369	1.057	0.306
DBP (mmHg)	85.8/85.2	81.6/83.9	2.491	0.118	1.758	0.188
Total cholesterol	4.682/4.515	4.327/4.216	1.053	0.307	0.010	0.921
HDL	1.577/1.495	1.351/1.319	3.262	0.074	0.136	0.713
LDL	2.412/2.343	2.642/2.467	0.311	0.579	0.030	0.863
Triglyceride	1.429/1.364	1.260/1.215	0.832	0.364	0.016	0.901
Fasting glucose	5.559/5.470	6.140/5.354	0.303	0.583	0.595	0.442
BMI‡	27.7/27.7	29.9/30.8	7.180	0.008	4.260	0.040
Waist circumference‡	93.2/92.4	100.1/99.3	4.243	0.042	0.000	0.992

SBP=Systolic Blood Pressure, DBP=Diastolic Blood Pressure, HDL=High Density Lipoprotein, LDL=Low Density Lipoprotein, BMI=Body Mass Index

† Adjusted by intervention

‡ Self-reported

APPENDIX 6: Total search result and inclusion and exclusion phases and criteria of the primary systematic search

Databases: EBM Reviews - ACP Journal Club <1991 to October 2016>, EBM Reviews - Cochrane Central Register of Controlled Trials <September 2016>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to October 19, 2016>, EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2015>, EBM Reviews - Health Technology Assessment <3rd Quarter 2016>, Ovid MEDLINE(R) Epub Ahead of Print <October 21, 2016>, Ovid MEDLINE(R) <1946 to October Week 2 2016>

Exclusion Phase: T=title, A=abstract, F=full text

Exclusion criteria: a=Study theme not appropriate, b=Setting or intervention trial not appropriate, c=Target group not appropriate, d=Not an intervention trial, e.g. a guideline, e=Review article or a comment on an article, f=Follow-up <6 month

ID	Exclusion phase	Exclusion criteria	Duplicate to search CT 2	Data-base	Article number	Authors	Title	Source	Pub. year
1	T	a	No	CCTR	CN-01173166 NEW	Battaglia Y, Forcellini S, Cojocar E, Fiorini F, Granata A, Morrone L, Di Iorio B, Russo L, Storari A, Russo D	Anthropometric indicators and hypertension in Italian young adults from the word kidney days 2010 - 2011.	Nephrology Dialysis Transplantation. Conference. Publication: (var.pagings) Vol.30, pp.iii98-iii99, 2015.	2015
2	T	a	Yes	CCTR	CN-01165852 NEW	Ramirez-Velez R, Hernandez A, Castro K, Tordecilla-Sanders A, Gonzalez-Ruiz K, Correa-Bautista JE, Izquierdo M, Garcia-Hermoso A	High Intensity Interval- vs Resistance or Combined- Training for Improving Cardiometabolic Health in Overweight Adults (Cardiometabolic HIIT-RT Study): Study protocol for a randomised controlled trial.	Trials. 17(1) (no pagination):2016.	2016
3	T	b	Yes	CCTR	CN-01152742 NEW	Baer HJ, Wee CC, DeVito K, Orav EJ, Frolkis JP, Williams	Design of a cluster-randomized trial of electronic health record-based tools to	Clinical trials (London, England). 12(4):374-83, 2015 Aug.	2015

						DH, Wright A, Bates DW	address overweight and obesity in primary care.		
4	T	b	Yes	CCTR	CN-00553146 UPDATE	Scott F, Beech R, Smedley F, Timmis L, Stokes E, Jones P, Roffe C, Bowling TE	Prospective, randomized, controlled, single-blind trial of the costs and consequences of systematic nutrition team follow-up over 12 mo after percutaneous endoscopic gastrostomy.	Nutrition (Burbank, Los Angeles County, Calif.). 21(11-12):1071-7, 2005 Nov-Dec.	2005
5	T	b	Yes	CCTR	CN-00786408 UPDATE	Goode AD, Winkler EA, Lawler SP, Reeves MM, Owen N, Eakin EG	A telephone-delivered physical activity and dietary intervention for type 2 diabetes and hypertension: does intervention dose influence outcomes?	American journal of health promotion : AJHP. 25(4):257-63, 2011 Mar-Apr.	2011
6	T	a	Yes	CCTR	CN-00895252 UPDATE	Logue EE, Bourguet CC, Palmieri PA, Scott ED, Matthews BA, Dudley P, Chipman KJ	The better weight-better sleep study: a pilot intervention in primary care.	American journal of health behavior. 36(3):319-34, 2012 Mar.	2012
7	T	c	Yes	CCTR	CN-01117687 NEW	Martinez-Andrade GO, Cespedes EM, Rifas-Shiman SL, Romero-Quechol G, Gonzalez-Unzaga MA, Benitez-Trejo MA, Flores-Huerta S, Horan C, Haines J, Taveras EM, Perez-Cuevas R, Gillman MW	Feasibility and impact of Creciendo Sanos, a clinic-based pilot intervention to prevent obesity among preschool children in Mexico City.	BMC pediatrics. Vol.14, pp.77, 2014.	2014
8	T	b	Yes	CCTR	CN-00331458 UPDATE	Glasgow RE, Toobert DJ	Brief, computer-assisted diabetes dietary self-management counseling: effects on behavior, physiologic outcomes, and quality of life.	Medical care. 38(11):1062-73, 2000 Nov.	2000

9	T	b	Yes	CCTR	CN-01101391 NEW	Khanna R, Stoddard PJ, Gonzales EN, Villagran-Flores M, Thomson J, Bayard P, Palos Lucio AG, Schillinger D, Bertozzi S, Gonzales R	An automated telephone nutrition support system for Spanish-speaking patients with diabetes.	Journal of diabetes science and technology. 8(6):1115-20, 2014 Nov.	2014
10	included		No	CCTR	CN-01080212 NEW	Ackermann RT, Liss DT, Finch E, Hays L, Marrero DG, Saha C	A randomized comparative effectiveness trial of a primary care-community linkage for preventing type 2 diabetes.	Journal of general internal medicine. Vol.30, pp.S88-S89, CONFERENCE START: 2015 Apr 22 CONFERENCE END: 2015 Apr 25, 38th Annual Meeting of the Society of General Internal Medicine Toronto, ON Canada.,	2015
11	T	a	Yes	CCTR	CN-01001458 UPDATE	Sanders LM, Perrin EM, Yin HS, Bronaugh A, Rothman RL	"Greenlight study ": A controlled trial of low-literacy, early childhood obesity prevention.	Pediatrics. 133 (6):e1724-e1737, 2014.	2014
12	A	a	No	CCTR	CN-01003471 UPDATE	Mertens J, Weisner C, Sterling S, Chi FW, Pating D	Structural and attitudinal factors affecting sbirt implementation in adult primary care.	Alcoholism: Clinical and Experimental Research. Vol.35, pp.285A, CONFERENCE START: 2011 Jun 25 CONFERENCE END: 2011 Jun 29, 34th Annual Scientific Meeting of the Research Society on Alcoholism, RSA Atlanta, GA United States.,	2011
13	F	d	No	CCTR	CN-01007832 UPDATE	Simovska V, Vidin M	Public health and lifestyle interventions to reduce cardiovascular risk in macedonia: Evaluation and recommendations.	Circulation. 125 (19):e812-e813, CONFERENCE START: 2012 Apr 18 CONFERENCE END: 2012 Apr 21, World Congress of Cardiology Scientific Sessions 2012, WCC 2012 Dubai United Arab Emirates.,	2012
14	T	e	No	CCTR	CN-01009858 UPDATE		3rd World Congress on Vascular Access, WoCoVA 2014.	Journal of Vascular Access. (pp. 193-239). 15 (3):193, CONFERENCE START: 2014 Jun 18 CONFERENCE END: 2014 Jun 20, 3rd World Congress on Vascular Access, WoCoVA 2014 (3rd)Germany.,	2014
15	F	d	No	CCTR	CN-01009912	Lewis A, Jolly K, Adab P, Daley A, Jebb S,	A randomised controlled trial to test the effectiveness of a	Obesity reviews. Vol.15, pp.148, CONFERENCE START: 2014 Mar 17	2014

					UPDATE	Lycett D, Farley A, Aveyard P	brief intervention for weight management in primary care.	CONFERENCE END: 2014 Mar 20, 12th International Congress on Obesity, ICO 2014 Kuala Lumpur Malaysia.,	
16	T	b	No	CCTR	CN-01011395 UPDATE	Sherrington A, Newham J, Araujo-Soares V, Adamson A, McColl E, Bell R	Systematic review of internet-based interventions providing individualised feedback for weight loss in overweight adults.	Proceedings of the Nutrition Society. Vol.72, pp.E220, CONFERENCE START: 2013 Jul 15 CONFERENCE END: 2013 Jul 18, Nutrition Society Summer Meeting 2013 Newcastle-upon-Tyne United Kingdom.,	2013
17	T	b	Yes	CCTR	CN-01050357 UPDATE	Martinez-Andrade GO, Cespedes EM, Rifas-Shiman SL, Romero-Quechol G, Gonzalez-Unzaga MA, Benitez-Trejo MA, Flores-Huerta S, Horan C, Haines J, Taveras EM, Perez-Cuevas R, Gillman MW	Feasibility and impact of Creciendo Sanos, a clinic-based pilot intervention to prevent obesity among preschool children in Mexico City.	BMC pediatrics. 14(1):2014.	2014
18	T	d	No	CCTR	CN-01059267 NEW	Barrett-Connor E	Looking back on the look ahead trial.	Cardiology (Switzerland). Vol.128, pp.422, CONFERENCE START: 2014 Jul 25 CONFERENCE END: 2014 Jul 28, International Academy of Cardiology 19th World Congress on Heart Disease Annual Scientific Sessions 2014 Boston, MA United States.,	2014
19	T	a	No	CCTR	CN-01065155 NEW	Cho AH, Killeya-Jones LA, Suchindran S, O'Daniel JM, Kawamoto K, Haga S, Lucas JE, Trujillo GM, Joy S, Ginsburg GS	Preliminary outcomes of genetic risk testing in primary care for common DNA variants associated with type 2 diabetes.	Journal of general internal medicine. Vol.27, pp.S278, CONFERENCE START: 2012 May 9 CONFERENCE END: 2012 May 12, 35th Annual Meeting of the Society of General Internal Medicine, SGIM 2012 Orlando, FL United States.,	2012
20		duplicate to ID 11		CCTR	CN-01053784 NEW	Sanders LM, Perrin EM, Yin HS, Bronaugh A, Rothman RL, Greenlight Study Team	"Greenlight study": a controlled trial of low-literacy, early childhood obesity prevention.	Pediatrics. 133(6):e1724-37, 2014 Jun.	2014

21	A	b	Yes	CCTR	CN-00168679 UPDAT E	Ammerman A, Caggiula A, Elmer PJ, Kris EP, Keyserling T, Lewis C, Luepker R, Pearson T, Schucker B, Shannon B, Simpson RJJ, Watson J	Putting medical practice guidelines into practice: The cholesterol model.	American journal of preventive medicine. 10(4):209-16, 1994.	1994
22	F	f	No	CCTR	CN-01008047 NEW	Kulick D, Langer RD, Gans KM, Schlauch K, Feller C	Live well: An effective physician-delivered low-intensity dietary counseling intervention for patients with dyslipidemia.	Circulation. 127(12 Meeting Abstracts):CONFERENCE START: 2013 Mar 19 CONFERENCE END: 2013 Mar 22, American Heart Association's Epidemiology and Prevention/Physical Activity, Nutrition and Metabolism 2013 Scientific Sessions New Orleans, LA United States.,	2013
23		duplicate to ID 15		CCTR	CN-01011893 NEW	Lewis AL, Jolly K, Adab P, Daley A, Lycett D, Farley A, Jebb S, Thompson B, Aveyard P	A randomised controlled trial to test the effectiveness of a brief intervention for weight management for obese adults in primary care.	Obesity facts. Vol.6, pp.155, CONFERENCE START: 2013 May 12 CONFERENCE END: 2013 May 15, 20th European Congress on Obesity, ECO 2013 Liverpool United Kingdom.,	2013
24	A	b	Yes	CCTR	CN-00699146 UPDAT E	O'Neill SM, Rubinstein WS, Wang C, Yoon PW, Acheson LS, Rothrock N, Starzyk EJ, Beaumont JL, Galliher JM, Ruffin MT, Family Healthware Impact Trial group	Familial risk for common diseases in primary care: the Family Healthware Impact Trial.	American journal of preventive medicine. 36(6):506-14, 2009 Jun.	2009
25	F	d	Yes	CCTR	CN-00869281 UPDAT E	Blair SN, Applegate WB, Dunn AL, Ettinger WH, Haskell WL, King AC, et al	Activity Counseling Trial (ACT): rationale, design, and methods. Activity Counseling Trial Research Group	Medicine and science in sports and exercise. 30(7):1097-106, 1998.	1998
26	F	b	Yes	CCTR	CN-00139487 UPDAT E	Beresford SA, Curry SJ, Kristal AR, Lazovich D, Feng Z, Wagner EH	A dietary intervention in primary care practice: the Eating Patterns Study.	American journal of public health. 87(4):610-6, 1997 Apr.	1997

27	T	a	Yes	CCTR	CN-00640404 UPDATE	Counterweight Project Team	Influence of body mass index on prescribing costs and potential cost savings of a weight management programme in primary care.	Journal of health services research & policy. 13(3):158-66, 2008 Jul.	2008
28	T	b	Yes	CCTR	CN-00688147 UPDATE	Eakin E, Reeves M, Lawler S, Graves N, Oldenburg B, Del Mar C, Wilke K, Winkler E, Barnett A	Telephone counseling for physical activity and diet in primary care patients.	American journal of preventive medicine. 36(2):142-9, 2009 Feb.	2009
29	F	f	Yes	CCTR	CN-00349955 UPDATE	Delichatsios HK, Hunt MK, Lobb R, Emmons K, Gillman MW	EatSmart: efficacy of a multifaceted preventive nutrition intervention in clinical practice.	Preventive medicine. 33(2 Pt 1):91-8, 2001 Aug.	2001
30	A	b	Yes	CDSR	00075320 - 100000000-04498.	Omidvari AH, Vali Y, Murray SM, Wonderling D, Rashidian A	Nutritional screening for improving professional practice for patient outcomes in hospital and primary care settings [Systematic Review]	Cochrane Database of Systematic Reviews 2016;(5)	2016
31	F	b	Yes	Ovid MEDLINE(R)		Hirshfield S, Downing MJ Jr, Horvath KJ, Swartz JA, Chiasson MA	Adapting Andersen's Behavioral Model of Health Service Use to Examine Risk Factors for Hypertension Among U.S. MSM.	American Journal of Mens Health. , 2016 Apr 19.	2016
32	T	a	Yes	Ovid MEDLINE(R)		van Dalen EC, Mank A, Leclercq E, Mulder RL, Davies M, Kersten MJ, Van de Wetering MD	Low bacterial diet versus control diet to prevent infection in cancer patients treated with chemotherapy causing episodes of neutropenia. [Review][Update of Cochrane Database Syst Rev. 2012;(9):CD006247; PMID: 22972091]	Cochrane Database of Systematic Reviews. 4:CD006247, 2016.	2016
33	A	c	Yes	Ovid MEDLINE(R)		Nava LT, Zambrano JM,	Nutrition-based interventions to address metabolic	Journal of Clinical Nursing. 24(21-22):3024-45, 2015 Nov.	2015

						Arviso KP, Brochetti D, Becker KL	syndrome in the Navajo: a systematic review. [Review]		
34	T	a	Yes	Ovid MEDLINE(R)		Grant JF, Chittleborough CR, Taylor AW	Parental Midlife Body Shape and Association with Multiple Adult Offspring Obesity Measures: North West Adelaide Health Study.	PLoS ONE [Electronic Resource]. 10(9):e0137534, 2015.	2015
35	T	a	Yes	Ovid MEDLINE(R)		Smith S, Seeholzer EL, Gullett H, Jackson B, Antognoli E, Krejci SA, Flocke SA	Primary Care Residents' Knowledge, Attitudes, Self-Efficacy, and Perceived Professional Norms Regarding Obesity, Nutrition, and Physical Activity Counseling.	Journal of Graduate Medical Education. 7(3):388-94, 2015 Sep.	2015
36	T	b	Yes	Ovid MEDLINE(R)		Baer HJ, Wee CC, DeVito K, Orav EJ, Frolkis JP, Williams DH, Wright A, Bates DW	Design of a cluster-randomized trial of electronic health record-based tools to address overweight and obesity in primary care.	Clinical Trials. 12(4):374-83, 2015 Aug.	2015
37	F	b	Yes	Ovid MEDLINE(R)		Ruzicka M, Ramsay T, Bugeja A, Edwards C, Fodor G, Kirby A, Magner P, McCormick B, van der Hoef G, Wagner J, Hiremath S	Does pragmatically structured outpatient dietary counselling reduce sodium intake in hypertensive patients? Study protocol for a randomized controlled trial.	Trials [Electronic Resource]. 16:273, 2015.	2015
38	T	d	Yes	Ovid MEDLINE(R)		Apovian CM, Garvey WT, Ryan DH	Challenging obesity: Patient, provider, and expert perspectives on the roles of available and emerging nonsurgical therapies.	Obesity. 23 Suppl 2:S1-S26, 2015 Jul.	2015
39	T	e	Yes	Ovid MEDLINE(R)		Maderuelo-Fernandez JA, Recio-Rodriguez JL, Patino-Alonso MC, Perez-Arechaederra D, Rodriguez-Sanchez E,	Effectiveness of interventions applicable to primary health care settings to promote Mediterranean diet or healthy	Preventive Medicine. 76 Suppl:S39-55, 2015 Jul.	2015

						Gomez-Marcos MA, Garcia-Ortiz L	eating adherence in adults: A systematic review. [Review]		
40	T	a	Yes	Ovid MEDLINE(R)		Fiscella K, Goodwin MA, Stange KC	Does patient educational level affect office visits to family physicians?.	Journal of the National Medical Association. 94(3):157-65, 2002 Mar.	2002
41	T	e	Yes	Ovid MEDLINE(R)		Booth HP, Prevost TA, Wright AJ, Gulliford MC	Effectiveness of behavioural weight loss interventions delivered in a primary care setting: a systematic review and meta-analysis. [Review]	Family Practice. 31(6):643-53, 2014 Dec.	2014
42	T	b	Yes	Ovid MEDLINE(R)		Khanna R, Stoddard PJ, Gonzales EN, Villagran-Flores M, Thomson J, Bayard P, Palos Lucio AG, Schillinger D, Bertozzi S, Gonzales R	An automated telephone nutrition support system for Spanish-speaking patients with diabetes.	Journal of Diabetes Science & Technology. 8(6):1115-20, 2014 Nov.	2014
43	T	b	Yes	Ovid MEDLINE(R)		Sanders LM, Perrin EM, Yin HS, Bronaugh A, Rothman RL, Greenlight Study Team	"Greenlight study": a controlled trial of low-literacy, early childhood obesity prevention.	Pediatrics. 133(6):e1724-37, 2014 Jun.	2014
44	T	e	Yes	Ovid MEDLINE(R)		Shrewsbury VA, Baur LA, Nguyen B, Steinbeck KS	Transition to adult care in adolescent obesity: a systematic review and why it is a neglected topic. [Review]	International Journal of Obesity. 38(4):475-9, 2014 Apr.	2014
45	T	c	Yes	Ovid MEDLINE(R)		Martinez-Andrade GO, Cespedes EM, Rifas-Shiman SL, Romero-Quechol G, Gonzalez-Unzaga MA, Benitez-Trejo MA, Flores-Huerta S, Horan C, Haines J, Taveras EM	Feasibility and impact of Creciendo Sanos, a clinic-based pilot intervention to prevent obesity among preschool children in Mexico City.	BMC Pediatrics. 14:77, 2014.	2014
46	A	a	Yes	Ovid MEDLINE(R)		Rosa Fortin MM, Brown C, Ball GD,	Weight management in Canada: an environmental	BMC Health Services Research. 14:69, 2014.	2014

						Chanoine JP, Langlois MF	scan of health services for adults with obesity.		
47	F	b	Yes	Ovid MEDLI NE(R)		Lebrun LA, Chowdhury J, Sripipatana A, Nair S, Tomoyasu N, Ngo- Metzger Q	Overweight/obesity and weight-related treatment among patients in U.S. federally supported health centers.	Obesity Research & Clinical Practice. 7(5):e377-90, 2013 Sep-Oct.	2013
48	T	a	Yes	Ovid MEDLI NE(R)		Farran N, Ellis P, Lee Barron M	Assessment of provider adherence to obesity treatment guidelines.	Journal of the American Association of Nurse Practitioners. 25(3):147-55, 2013 Mar.	2013
49	T	e	Yes	Ovid MEDLI NE(R)		Omidvari AH, Vali Y, Murray SM, Wonderling D, Rashidian A	Nutritional screening for improving professional practice for patient outcomes in hospital and primary care settings. [Review]	Cochrane Database of Systematic Reviews. 6:CD005539, 2013.	2013
50	A	a	Yes	Ovid MEDLI NE(R)		Rose SA, Gokun Y, Talbert J, Conigliaro J	Screening and management of obesity and perception of weight status in Medicaid recipients.	Journal of Health Care for the Poor & Underserved. 24(2 Suppl):34-46, 2013.	2013
51	T	a	Yes	Ovid MEDLI NE(R)		Wedlake LJ, Shaw C, Whelan K, Andreyev HJ	Systematic review: the efficacy of nutritional interventions to counteract acute gastrointestinal toxicity during therapeutic pelvic radiotherapy. [Review]	Alimentary Pharmacology & Therapeutics. 37(11):1046-56, 2013 Jun.	2013
52	A	a	Yes	Ovid MEDLI NE(R)		Toth-Capelli KM, Brawer R, Plumb J, Daskalakis C	Stage of change and other predictors of participant retention in a behavioral weight management program in primary care.	Health Promotion Practice. 14(3):441-50, 2013 May.	2013
53	A	e	Yes	Ovid MEDLI NE(R)		Kraschnewski JL, Sciamanna CN, Stuckey HL, Chuang CH, Lehman EB, Hwang KO,	A silent response to the obesity epidemic: decline in US physician weight counseling.	Medical Care. 51(2):186-92, 2013 Feb.	2013

						Sherwood LL, Nembhard HB			
54	T	a	Yes	Ovid MEDLI NE(R)		Logue EE, Bourguet CC, Palmieri PA, Scott ED, Matthews BA, Dudley P, Chipman KJ	The better weight-better sleep study: a pilot intervention in primary care.	American Journal of Health Behavior. 36(3):319-34, 2012 Mar.	2012
55	A	e	Yes	Ovid MEDLI NE(R)		Chale A, Unanski AG, Liang RY	Nutrition initiatives in the context of population aging: where does the United States stand?. [Review]	Journal of Nutrition in Gerontology & Geriatrics. 31(1):1-15, 2012.	2012
56	T	c	Yes	Ovid MEDLI NE(R)		Halfon N, Verhoef PA, Kuo AA	Childhood antecedents to adult cardiovascular disease. [Review]	Pediatrics in Review. 33(2):51-60; quiz 61, 2012 Feb.	2012
57	T	a	Yes	Ovid MEDLI NE(R)		Hawk C, Ndetan H, Evans MW Jr	Potential role of complementary and alternative health care providers in chronic disease prevention and health promotion: an analysis of National Health Interview Survey data.	Preventive Medicine. 54(1):18-22, 2012 Jan.	2012
58	T	b	Yes	Ovid MEDLI NE(R)		Baer HJ, Wee CC, DeVito K, Orav EJ, Frolkis JP, Williams DH, Wright A, Bates DW	Design of a cluster- randomized trial of electronic health record-based tools to address overweight and obesity in primary care.	Clinical Trials. 12(4):374-83, 2015 Aug.	2015
59		duplicate to ID 30	Yes	Ovid MEDLI NE(R)		Omidvari AH, Vali Y, Murray SM, Wonderling D, Rashidian A	Nutritional screening for improving professional practice for patient outcomes in hospital and primary care settings. [Review]	Cochrane Database of Systematic Reviews. (6):CD005539, 2013.	2013
60		duplicate to ID 55	Yes	Ovid MEDLI NE(R)		Chale A, Unanski AG, Liang RY	Nutrition initiatives in the context of population aging: where does the United States stand?. [Review]	Journal of Nutrition in Gerontology & Geriatrics. 31(1):1-15, 2012.	2012

61		duplicate to ID 5	Yes	Ovid MEDLINE(R)		Goode AD, Winkler EA, Lawler SP, Reeves MM, Owen N, Eakin EG	A telephone-delivered physical activity and dietary intervention for type 2 diabetes and hypertension: does intervention dose influence outcomes?.	American Journal of Health Promotion. 25(4):257-63, 2011 Mar-Apr.	2011
62	F	b	Yes	Ovid MEDLINE(R)		Thorpe LE, Gwynn RC, Mandel-Ricci J, Roberts S, Tsoi B, Berman L, Porter K, Ostchega Y, Curtain LR, Montaquila J, Mohadjer L, Frieden TR	Study design and participation rates of the New York City Health and Nutrition Examination Survey, 2004.	Preventing Chronic Disease. 3(3):A94, 2006 Jul.	2006
63	T	a	Yes	Ovid MEDLINE(R)		Halfon N, Verhoef PA, Kuo AA	Childhood antecedents to adult cardiovascular disease. [Review]	Pediatrics in Review. 33(2):51-60; quiz 61, 2012 Feb.	2012
64	T	b	Yes	Ovid MEDLINE(R)		Khanna R, Stoddard PJ, Gonzales EN, Villagran-Flores M, Thomson J, Bayard P, Palos Lucio AG, Schillinger D, Bertozzi S, Gonzales R	An automated telephone nutrition support system for Spanish-speaking patients with diabetes.	Journal of Diabetes Science & Technology. 8(6):1115-20, 2014 Nov.	2014
65	A	a	Yes	Ovid MEDLINE(R)		Apovian CM, Garvey WT, Ryan DH	Challenging obesity: Patient, provider, and expert perspectives on the roles of available and emerging nonsurgical therapies.	Obesity. 23 Suppl 2:S1-S26, 2015 Jul.	2015
66	included		Yes	Ovid MEDLINE(R)		Kuninkaanniemi H, Villberg J, Vanhala M, Poskiparta M	Behaviour-change interventions in primary care: influence on nutrition and on the metabolic syndrome definers.	International Journal of Nursing Practice. 17(5):470-7, 2011 Oct.	2011

67	T	a	Yes	Ovid MEDLINE(R)		Kones R	Primary prevention of coronary heart disease: integration of new data, evolving views, revised goals, and role of rosuvastatin in management. A comprehensive survey. [Review]	Drug design, development & therapy. 5:325-80, 2011.	2011
68	T	a	Yes	Ovid MEDLINE(R)		Lim MY, Pruthi RK	Cardiovascular disease risk factors: prevalence and management in adult hemophilia patients.	Blood Coagulation & Fibrinolysis. 22(5):402-6, 2011 Jul.	2011
69	A	a	Yes	Ovid MEDLINE(R)		Smith AW, Borowski LA, Liu B, Galuska DA, Signore C, Klabunde C, Huang TT, Krebs-Smith SM, Frank E, Pronk N, Ballard-Barbash R	U.S. primary care physicians' diet-, physical activity-, and weight-related care of adult patients.	American Journal of Preventive Medicine. 41(1):33-42, 2011 Jul.	2011
70		duplicate to ID 5	Yes	Ovid MEDLINE(R)		Goode AD, Winkler EA, Lawler SP, Reeves MM, Owen N, Eakin EG	A telephone-delivered physical activity and dietary intervention for type 2 diabetes and hypertension: does intervention dose influence outcomes?.	American Journal of Health Promotion. 25(4):257-63, 2011 Mar-Apr.	2011
71	T	c	Yes	Ovid MEDLINE(R)		Wang RH, Chen SW, Tang SM, Lee SL, Jian SY	The relationship between selected developmental assets and health-promoting behaviours of adolescents in Southern Taiwan.	Journal of Clinical Nursing. 20(3-4):359-68, 2011 Feb.	2011
72	T	a	Yes	Ovid MEDLINE(R)		Pomeroy SE, Cant RP	General practitioners' decision to refer patients to dietitians: insight into the clinical reasoning process.	Australian Journal of Primary Health. 16(2):147-53, 2010.	2010
73	T	c	Yes	Ovid MEDLINE(R)		McKee MD, Deen D, Maher S, Fletcher J,	Implementation of a pilot primary care lifestyle change intervention for families of	Patient Education & Counseling. 79(3):299-305, 2010 Jun.	2010

						Fornari A, Blank AE	pre-school children: lessons learned.		
74	T	e	Yes	Ovid MEDLI NE(R)		Berghella V, Buchanan E, Pereira L, Baxter JK	Preconception care. [Review] [65 refs]	Obstetrical & Gynecological Survey. 65(2):119-31, 2010 Feb.	2010
75	T	a	Yes	Ovid MEDLI NE(R)		Gowin E, Avonts D, Horst-Sikorska W, Ignaszak-Szczepaniak M, Michalak M	Gender makes the difference: the influence of patients' gender on the delivery of preventive services in primary care in Poland.	Quality in Primary Care. 17(5):343-50, 2009.	2009
76	T	a	Yes	Ovid MEDLI NE(R)		Virta LJ, Kaukinen K, Collin P	Incidence and prevalence of diagnosed coeliac disease in Finland: results of effective case finding in adults.	Scandinavian Journal of Gastroenterology. 44(8):933-8, 2009.	2009
77	T	a	Yes	Ovid MEDLI NE(R)		Decker SL, Burt CW, Sisk JE	Trends in diabetes treatment patterns among primary care providers.	Journal of Ambulatory Care Management. 32(4):333-41, 2009 Oct-Dec.	2009
78	F	b	Yes	Ovid MEDLI NE(R)		Jovanovic Z, Crncevic-Orlic Z, Stimac D, Kokic S, Persic V, Ruzic T, Goll-Baric S	Effects of obesity reduction on cardiovascular risk factors: comparison of individual and group treatment--substudy of the Croatian Healthy Weight Loss Programme.	Collegium Antropologicum. 33(3):751-7, 2009 Sep.	2009
79	A	a	Yes	Ovid MEDLI NE(R)		Waring ME, Roberts MB, Parker DR, Eaton CB	Documentation and management of overweight and obesity in primary care.	Journal of the American Board of Family Medicine: JABFM. 22(5):544-52, 2009 Sep-Oct.	2009
80	T	a	Yes	Ovid MEDLI NE(R)		Lamb CA, Parr J, Lamb EL, Warren MD	Adult malnutrition screening, prevalence and management in a United Kingdom hospital: cross-sectional study.	British Journal of Nutrition. 102(4):571-5, 2009 Aug.	2009
81	T	a	Yes	Ovid MEDLI NE(R)		O'Neill SM, Rubinstein WS, Wang C, Yoon PW, Acheson LS, Rothrock N, Starzyk EJ, Beaumont JL, Galliher JM,	Familial risk for common diseases in primary care: the Family Healthware Impact Trial.	American Journal of Preventive Medicine. 36(6):506-14, 2009 Jun.	2009

						Ruffin MT 4th, Family Healthware Impact Trial group			
82	T	b	Yes	Ovid MEDLINE(R)		Eakin E, Reeves M, Lawler S, Graves N, Oldenburg B, Del Mar C, Wilke K, Winkler E, Barnett A	Telephone counseling for physical activity and diet in primary care patients.	American Journal of Preventive Medicine. 36(2):142-9, 2009 Feb.	2009
83	A	a	Yes	Ovid MEDLINE(R)		Fransen GA, Hiddink GJ, Koelen MA, van Dis SJ, Drenthen AJ, van Binsbergen JJ, van Woerkum CM	The development of a minimal intervention strategy to address overweight and obesity in adult primary care patients in The Netherlands.	Family Practice. 25 Suppl 1:i112-5, 2008 Dec.	2008
84	A	a	Yes	Ovid MEDLINE(R)		Holtrop JS, Dosh SA, Torres T, Thum YM	The community health educator referral liaison (CHERL): a primary care practice role for promoting healthy behaviors.	American Journal of Preventive Medicine. 35(5 Suppl):S365-72, 2008 Nov.	2008
85	T	a	Yes	Ovid MEDLINE(R)		Cant RP, Aroni RA	Exploring dietitians' verbal and nonverbal communication skills for effective dietitian-patient communication.	Journal of Human Nutrition & Dietetics. 21(5):502-11, 2008 Oct.	2008
86	A	a	Yes	Ovid MEDLINE(R)		Ornstein S, Nietert PJ, Jenkins RG, Wessell AM, Nemeth LS, Rose HL	Improving the translation of research into primary care practice: results of a national quality improvement demonstration project.	Joint Commission Journal on Quality & Patient Safety. 34(7):379-90, 2008 Jul.	2008
87	T	a	Yes	Ovid MEDLINE(R)		Taveras EM, Gortmaker SL, Mitchell KF, Gillman MW	Parental perceptions of overweight counseling in primary care: the roles of race/ethnicity and parent overweight.	Obesity. 16(8):1794-801, 2008 Aug.	2008

88	A	a	Yes	Ovid MEDLI NE(R)		Counterweight Project Team	Influence of body mass index on prescribing costs and potential cost savings of a weight management programme in primary care.	Journal of Health Services & Research Policy. 13(3):158-66, 2008 Jul.	2008
89	A	a	Yes	Ovid MEDLI NE(R)		Greenwood JL, Stanford JB	Preventing or improving obesity by addressing specific eating patterns. [Review] [51 refs]	Journal of the American Board of Family Medicine: JABFM. 21(2):135-40, 2008 Mar-Apr.	2008
90	A	a	Yes	Ovid MEDLI NE(R)		Rohrer JE, Anderson GJ, Furst JW	Obesity and pre-hypertension in family medicine: implications for quality improvement.	BMC Health Services Research. 7:212, 2007.	2007
91	T	c	Yes	Ovid MEDLI NE(R)		Steinbeck K	Adolescent overweight and obesity--how best to manage in the general practice setting. [Review] [22 refs]	Australian Family Physician. 36(8):606-12, 2007 Aug.	2007
92	T	c	Yes	Ovid MEDLI NE(R)		Haney EM, Huffman LH, Bougatsos C, Freeman M, Steiner RD, Nelson HD	Screening and treatment for lipid disorders in children and adolescents: systematic evidence review for the US Preventive Services Task Force. [Review] [266 refs]	Pediatrics. 120(1):e189-214, 2007 Jul.	2007
93	T	c	Yes	Ovid MEDLI NE(R)		Millan T, Morera I, Vargas NA	[Teenager counselling in primary care]. [Spanish]	Revista Medica de Chile. 135(4):457-63, 2007 Apr.	2007
94	T	a	Yes	Ovid MEDLI NE(R)		Clase CM, Kiberd BA, Garg AX	Relationship between glomerular filtration rate and the prevalence of metabolic abnormalities: results from the Third National Health and Nutrition Examination Survey (NHANES III).	Nephron. 105(4):c178-84, 2007.	2007
95	T	a	Yes	Ovid MEDLI NE(R)		Roux L, Kuntz KM, Donaldson C, Goldie SJ	Economic evaluation of weight loss interventions in overweight and obese women.	Obesity. 14(6):1093-106, 2006 Jun.	2006

96	A	b	Yes	Ovid MEDLI NE(R)		Thorpe LE, Gwynn RC, Mandel-Ricci J, Roberts S, Tsoi B, Berman L, Porter K, Ostchega Y, Curtain LR, Montaquila J, Mohadjer L, Frieden TR	Study design and participation rates of the New York City Health and Nutrition Examination Survey, 2004.	Preventing Chronic Disease. 3(3):A94, 2006 Jul.	2006
97	T	a	Yes	Ovid MEDLI NE(R)		Bradley R, Oberg EB	Naturopathic medicine and type 2 diabetes: a retrospective analysis from an academic clinic.	Alternative Medicine Review. 11(1):30-9, 2006 Mar.	2006
98	T	a	Yes	Ovid MEDLI NE(R)		Scott F, Beech R ,Smedley F, Timmis L, Stokes E, Jones P, Roffe C, Bowling TE	Prospective, randomized, controlled, single-blind trial of the costs and consequences of systematic nutrition team follow-up over 12 mo after percutaneous endoscopic gastrostomy.	Nutrition. 21(11-12):1071-7, 2005 Nov- Dec.	2005
99	T	a	Yes	Ovid MEDLI NE(R)		Lin SX, Larson E	Does provision of health counseling differ by patient race?.	Family Medicine. 37(9):650-4, 2005 Oct.	2005
100	T	c	Yes	Ovid MEDLI NE(R)		Whitlock EP, Williams SB, Gold R, Smith PR, Shipman SA	Screening and interventions for childhood overweight: a summary of evidence for the US Preventive Services Task Force. [Review] [127 refs]	Pediatrics. 116(1):e125-44, 2005 Jul.	2005
101	T	a	Yes	Ovid MEDLI NE(R)		Kirk S, Scott BJ, Daniels SR	Pediatric obesity epidemic: treatment options. [Review] [37 refs]	Journal of the American Dietetic Association. 105(5 Suppl 1):S44-51, 2005 May.	2005
102	A	a	Yes	Ovid MEDLI NE(R)		Kennen EM, Davis TC, Huang J, Yu H, Carden D, Bass R Arnold C	Tipping the scales: the effect of literacy on obese patients' knowledge and readiness to lose weight.	Southern Medical Journal. 98(1):15-8, 2005 Jan.	2005







103	T	a	Yes	Ovid MEDLI NE(R)		Singh RB, Pella D, Mechirova V, Otsuka K	Can brain dysfunction be a predisposing factor for metabolic syndrome?. [Review] [118 refs]	Biomedicine & Pharmacotherapy. 58 Suppl 1:S56-68, 2004 Oct.	2004
104	T	a	Yes	Ovid MEDLI NE(R)		Peters RM	Theoretical perspectives to increase clinical effectiveness of lifestyle modification strategies in diabetes. [Review] [27 refs]	Ethnicity & Disease. 14(4):S2-17-22, 2004.	2004
105	T	a	Yes	Ovid MEDLI NE(R)		Pearce KA, Love MM, Barron MA, Matheny SC Mahfoud Z	How and why to study the practice content of a practice- based research network.	Annals of Family Medicine. 2(5):425-8, 2004 Sep-Oct.	2004
106	T	a	Yes	Ovid MEDLI NE(R)		Webb R, Brammah T Lunt M, Urwin M, Allison T Symmons D	Opportunities for prevention of 'clinically significant' knee pain: results from a population-based cross sectional survey.	Journal of Public Health. 26(3):277-84, 2004 Sep.	2004
107	T	a	Yes	Ovid MEDLI NE(R)		Fiscella K, Goodwin MA, Stange KC	Does patient educational level affect office visits to family physicians?.	Journal of the National Medical Association. 94(3):157-65, 2002 Mar.	2002
108	T	a	Yes	Ovid MEDLI NE(R)		Bachmann P, Marti- Massoud C, Blanc- Vincent MP, Desport JC, Colomb V, Dieu L, Kere D, Melchior JC, Nitenberg G, Raynard B, Roux-Bournay P, Schneider S, Senesse P	[Standards, options and recommendations: nutritional support in palliative or terminal care of adult patients with progressive cancer]. [Review] [137 refs] [French]	Bulletin du Cancer. 88(10):985-1006, 2001 Oct.	2001
109	F	f	Yes	Ovid MEDLI NE(R)		Delichatsios HK, Hunt MK, Lobb R, Emmons K, Gillman MW	EatSmart: efficacy of a multifaceted preventive nutrition intervention in clinical practice.	Preventive Medicine. 33(2 Pt 1):91-8, 2001 Aug.	2001
110	A	b	Yes	Ovid MEDLI NE(R)		Glasgow RE, Toobert DJ	Brief, computer-assisted diabetes dietary self- management counseling:	Medical Care. 38(11):1062-73, 2000 Nov.	2000

							effects on behavior, physiologic outcomes, and quality of life.		
111	A	b	Yes	Ovid MEDLINE(R)		Mahabir D, Gulliford MC	A 4-year evaluation of blood pressure management in Trinidad and Tobago.	Journal of Human Hypertension. 13(7):455-9, 1999 Jul.	1999
112		duplicate to ID 25	Yes	Ovid MEDLINE(R)		Blair SN, Applegate WB, Dunn AL, Ettinger WH, Haskell WL, King AC, Morgan TM, Shih JA, Simons-Morton DG	Activity Counseling Trial (ACT): rationale, design, and methods. Activity Counseling Trial Research Group.	Medicine & Science in Sports & Exercise. 30(7):1097-106, 1998 Jul.	1998
113	T	a	Yes	Ovid MEDLINE(R)		Macario E, Emmons KM, Sorensen G, Hunt MK, Rudd RE	Factors influencing nutrition education for patients with low literacy skills.	Journal of the American Dietetic Association. 98(5):559-64, 1998 May.	1998
114	T	a	Yes	Ovid MEDLINE(R)		Kleerekoper M	Detecting osteoporosis. Beyond the history and physical examination. [Review] [5 refs]	Postgraduate Medicine. 103(4):45-7, 51-2, 62-3 passim, 1998 Apr.	1998
115		duplicate to ID 26	Yes	Ovid MEDLINE(R)		Beresford SA, Curry SJ, Kristal AR, Lazovich D, Feng Z, Wagner EH	A dietary intervention in primary care practice: the Eating Patterns Study.	American Journal of Public Health. 87(4):610-6, 1997 Apr.	1997
116	T	d	Yes	Ovid MEDLINE(R)		Ammerman A, Caggiula A, Elmer PJ, Kris-Etherton P, Keyserling T, Lewis C, Luepker R, Pearson T, Schucker B, Shannon B, et al	Putting medical practice guidelines into practice: the cholesterol model.	American Journal of Preventive Medicine. 10(4):209-16, 1994 Jul-Aug.	1994
117	A	a	Yes	Ovid MEDLINE(R)		Hahn DL	Systematic cholesterol screening during acute care visits.	Journal of the American Board of Family Practice. 6(6):529-36, 1993 Nov-Dec.	1993

118	T	a	Yes	Ovid MEDLI NE(R)		Marquez Contreras E, Casado JJ, Sanchez Ramos JL	[Epidemiology of dyslipidemias in a general adult population of the basic health area "La Orden de Huelva"]. [Review] [20 refs] [Spanish]	Atencion Primaria. 12(6):319-24, 1993 Oct 15.	1993
119	T	a	Yes	Ovid MEDLI NE(R)		Bradley A, Elliott J, White H	Attitudes and practice of New Zealand doctors in the management of patients with dyslipidaemia.	New Zealand Medical Journal. 106(958):243-7, 1993 Jun 23.	1993
120	A	a	Yes	Ovid MEDLI NE(R)		Arneson T, Luepker R, Pirie P, Sinaiko A	Cholesterol screening by primary care pediatricians: a study of attitudes and practices in the Minneapolis- St Paul metropolitan area.	Pediatrics. 89(3):502-5, 1992 Mar.	1992
121	A	a	Yes	Ovid MEDLI NE(R)		Tannenbaum TN, Sampalis JS, Battista RN, Rosenberg ER, Joseph L	Early detection and treatment of hyperlipidemia: physician practices in Canada.	CMAJ Canadian Medical Association Journal. 143(9):875-81, 1990 Nov 1.	1990

APPENDIX 7: QUALITY ASSESSMENT OF THE INCLUDED STUDIES USING THE QUALITY ASSESSMENT TOOL (The Effective Public Health Practice Project 2008b)






Quality Assessment of included study: Ackermann et al. 2015

COMPONENTS AND QUESTIONS	JUDGEMENT
SELECTION BIAS	
Are the individuals selected to participate in the study likely to be representative of the target population?	Somewhat likely
What % of selected individuals agreed to participate?	<60% agreement
STUDY DESIGN	
Was the study described as randomized?	Yes
If Yes, was the method of randomization described?	Yes
If Yes, was the method appropriate?	Yes
CONFOUNDERS	
Were there important differences between groups prior to the intervention?	No
BLINDING	
Was the outcome assessor(s) aware of the intervention or exposure status of participants?	Yes
Were the study participants aware of the research question?	No
DATA COLLECTION METHODS	
Were data collection tools shown to be valid?	Can't tell
Were data collection tools shown to be reliable?	Can't tell
WITHDRAWALS AND DROP-OUTS	
Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?	No
Indicate the % of participants completing the study. (If the % differs by groups, record the lowest).	<60% agreement
INTERVENTION INTEGRITY	
What % of participants received the allocated intervention or exposure of interest?	80-100%
Was the consistency of the intervention measured?	Can't tell
Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?	No
ANALYSES	
Indicate the unit of allocation and unit of analysis	Both individual
Are the statistical methods appropriate for the study design?	Yes
Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?	Yes

Quality Assessment of included study: Hardcastle et al. 2008

COMPONENTS AND QUESTIONS	JUDGEMENT
SELECTION BIAS	
Are the individuals selected to participate in the study likely to be representative of the target population?	Somewhat likely
What % of selected individuals agreed to participate?	<60% agreement
STUDY DESIGN	
Was the study described as randomized?	Yes
If Yes, was the method of randomization described?	Yes
If Yes, was the method appropriate?	Yes
CONFOUNDERS	
Were there important differences between groups prior to the intervention?	No
BLINDING	
Was the outcome assessor(s) aware of the intervention or exposure status of participants?	No
Were the study participants aware of the research question?	Yes
DATA COLLECTION METHODS	
Were data collection tools shown to be valid?	Yes
Were data collection tools shown to be reliable?	Can't tell
WITHDRAWALS AND DROP-OUTS	
Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?	No
Indicate the % of participants completing the study. (If the % differs by groups, record the lowest).	60-79%
INTERVENTION INTEGRITY	
What % of participants received the allocated intervention or exposure of interest?	60-79%
Was the consistency of the intervention measured?	Can't tell
Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?	No
ANALYSES	
Indicate the unit of allocation and analysis	Both individual
Are the statistical methods appropriate for the study design?	Yes
Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?	Yes

Quality Assessment of included study: Kuninkaanniemi et al. 2011

COMPONENTS AND QUESTIONS	JUDGEMENT
SELECTION BIAS	
Are the individuals selected to participate in the study likely to be representative of the target population?	Somewhat likely
What % of selected individuals agreed to participate?	<60% agreement
STUDY DESIGN	
Was the study described as randomized?	No
CONFOUNDERS	
Were there important differences between groups prior to the intervention?	Yes, pre-intervention score on outcome measures, 80-100%
If yes, indicate the percent of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?	
BLINDING	
Was the outcome assessor(s) aware of the intervention or exposure status of participants?	No
Were the study participants aware of the research question?	No
DATA COLLECTION METHODS	
Were data collection tools shown to be valid?	No
Were data collection tools shown to be reliable?	No
WITHDRAWALS AND DROP-OUTS	
Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?	N/A
Indicate the % of participants completing the study. (If the % differs by groups, record the lowest).	N/A
INTERVENTION INTEGRITY	
What % of participants received the allocated intervention or exposure of interest?	N/A
Was the consistency of the intervention measured?	No
Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?	Yes
ANALYSES	
Indicate the unit of allocation and analysis	Both individual
Are the statistical methods appropriate for the study design?	Yes
Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?	Yes

Quality Assessment of included study: Sacerdote et al. 2006

COMPONENTS AND QUESTIONS	JUDGEMENT
<p>SELECTION BIAS</p> <p>Are the individuals selected to participate in the study likely to be representative of the target population?</p> <p>What % of selected individuals agreed to participate?</p>	<p></p> <p>Somewhat likely</p> <p>80-100%</p>
<p>STUDY DESIGN</p> <p>Was the study described as randomized?</p> <p>If Yes, was the method of randomization described?</p> <p>If Yes, was the method appropriate?</p>	<p></p> <p>Yes</p> <p>Yes</p> <p>Yes</p>
<p>CONFOUNDERS</p> <p>Were there important differences between groups prior to the intervention?</p>	<p></p> <p>No</p>
<p>BLINDING</p> <p>Was the outcome assessor(s) aware of the intervention or exposure status of participants?</p> <p>Were the study participants aware of the research question?</p>	<p></p> <p>Yes</p> <p>No</p>
<p>DATA COLLECTION METHODS</p> <p>Were data collection tools shown to be valid?</p> <p>Were data collection tools shown to be reliable?</p>	<p></p> <p>Yes</p> <p>Can't tell</p>
<p>WITHDRAWALS AND DROP-OUTS</p> <p>Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?</p> <p>Indicate the % of participants completing the study. (If the % differs by groups, record the lowest).</p>	<p></p> <p>No</p> <p>80-100%</p>
<p>INTERVENTION INTEGRITY</p> <p>What % of participants received the allocated intervention or exposure of interest?</p> <p>Was the consistency of the intervention measured?</p> <p>Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?</p>	<p>80-100%</p> <p>Can't tell</p> <p>No</p>
<p>ANALYSES</p> <p>Indicate the unit of allocation and analysis</p> <p>Are the statistical methods appropriate for the study design?</p> <p>Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?</p>	<p>Both individual</p> <p>Yes</p> <p>Yes</p>

Quality Assessment of included study: Steptoe et al. 2003

COMPONENTS AND QUESTIONS	JUDGEMENT
SELECTION BIAS	
Are the individuals selected to participate in the study likely to be representative of the target population?	Somewhat likely
What % of selected individuals agreed to participate?	<60% agreement
STUDY DESIGN	
Was the study described as randomized?	Yes
If Yes, was the method of randomization described?	No → clinical trial
CONFOUNDERS	
Were there important differences between groups prior to the intervention?	No
BLINDING	
Was the outcome assessor(s) aware of the intervention or exposure status of participants?	Yes
Were the study participants aware of the research question?	Can't tell
DATA COLLECTION METHODS	
Were data collection tools shown to be valid?	Yes
Were data collection tools shown to be reliable?	Can't tell
WITHDRAWALS AND DROP-OUTS	
Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?	No
Indicate the % of participants completing the study. (If the % differs by groups, record the lowest).	80-100%
INTERVENTION INTEGRITY	
What % of participants received the allocated intervention or exposure of interest?	80-100%
Was the consistency of the intervention measured?	Yes
Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?	No
ANALYSES	
Indicate the unit of allocation and analysis	Both individual
Are the statistical methods appropriate for the study design?	Yes
Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?	Yes