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**The Mediterranean Eating in Scotland Experience
(MESE) project:
Evaluation of an Internet-based, tailored intervention
promoting the Mediterranean diet**

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MSc

**Submitted in fulfilment of the requirements for the
degree of Doctor of Philosophy**

**University of Glasgow
Faculty of Medicine
Division of Developmental Medicine
Human Nutrition Section**

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Author's declaration

I personally developed the educational content of an innovative healthy-eating website promoting the Mediterranean diet, which was designed by Mr. Joe Murray, Department of Human Nutrition, University of Glasgow. I was also responsible for the development of study recruitment materials, as well as the design/adaptation and validation of questionnaires.

I was responsible for participant recruitment, as well as scheduling and completion of assessment appointments, and carried out all assessments required by the project, including dietary analysis, anthropometric and biochemical measurements and focus group interviews. Biochemical analyses were performed by the Department of Clinical Biochemistry, Glasgow Royal Infirmary. I also developed the feedback letters for participants in the study, and conducted the statistical analyses reported, under the supervision of Dr Jane Scott.

Angeliki Papadaki

18/05/2005

Date

I certify that this thesis is the work of Angeliki Papadaki, as stated above.

Dr Jane A Scott, PhD

19/05/2005

Date

Senior Lecturer in Public Health Nutrition
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Abstract

A 6-month intervention study with a quasi-experimental design and a 3-month follow-up was conducted to evaluate the effectiveness of an Internet-based, step-wise, tailored-feedback intervention promoting four key components of the Mediterranean diet (vegetables, fruits, nuts and seeds, legumes and ratio of monounsaturated to saturated fat). Fifty-three (intervention group) and nineteen (control group) healthy females, aged 25-55 years, were recruited from the Universities of Glasgow and Glasgow Caledonian, Scotland, respectively. Participants in the intervention group received tailored dietary and psychosocial feedback and Internet nutrition education over a 6-month period, while participants in the control group were provided with minimally-tailored dietary feedback and general healthy-eating brochures. Internet education was provided via an innovative Mediterranean Eating website.

At baseline, 6 and 9 months, dietary changes were assessed with 7-day estimated food diaries, and nutrition knowledge, stages of behaviour change and psychosocial determinants of dietary behaviour with previously validated questionnaires. Anthropometric variables, blood pressure, blood lipid and urinary electrolyte levels were also assessed at these time points. Dietary data were analysed to calculate the Mediterranean Diet Score (MDS), a composite score based on the consumption of eight components of the traditional Mediterranean diet, whereas a series of validated short food frequency questionnaires were completed by the intervention group over the 6-month trial, in order to assess progress towards dietary change and inform the development of tailored feedback during the trial. At the end of the 6-month trial, use, appreciation and perceived impact of the nutrition materials provided over the study course were assessed by self-administered questionnaires for participants in both groups. Website usage patterns and user perceptions were also evaluated via website visit counts and focus group interviews, respectively.

Between group comparisons carried out on an "intention-to-treat" basis, providing the strongest evidence of the effect of the intervention, showed that participants in the intervention group had made more favourable changes to their fruit, nut and seed intake over the 6-month intervention, as well as increased their vegetable intake over the 9-month trial. Over both the 6-month intervention and 9-month trial, participants in the intervention group had more favourable levels of HDL-cholesterol and ratio of total:HDL-cholesterol, a higher proportion progressed through the stages of behavioural change regarding legumes and olive intake and self-efficacy skills were generally increased, compared with the control group. Participants in the control group however, showed more favourable urinary electrolyte levels throughout the study.

Within group comparisons showed that at 6 months, participants in the intervention group had significantly increased their intake of vegetables, fruits, legumes, as well as the MUFA:SFA ratio in their diet, had increased their mean total MDS and had significantly increased plasma HDL-cholesterol levels and a reduced ratio of total:HDL-cholesterol, as well as higher nutrition knowledge scores compared with baseline. In addition, a higher percentage of participants in this group were in the action and maintenance stage of behavioural change for vegetables, legumes and olive oil consumption, as well as generally showing more favourable attitudes and self-efficacy skills towards consumption of most of the food components promoted by the study at 6 months. These changes were generally maintained at 9 months, when additional decreases in blood pressure and an increase in total cholesterol, compared with baseline, were reported. Participants in the control group increased their intake of legumes, as well as their mean total MDS, and had significantly reduced urinary sodium levels at 6 months, compared with baseline. In addition, a higher proportion were in the action and maintenance stage of behavioural change for legumes, but self-efficacy skills generally decreased, compared with baseline. These changes were not maintained at 9 months, but at this time point participants in this group had a higher nutrition knowledge score, compared with baseline. Both groups had significantly lower waist circumference at 6 and 9 months, compared with baseline.

Participants in the intervention group were generally more positive and more satisfied with the nutrition education materials they accessed, whereas use of the general healthy-eating brochures by the control group was generally low. A higher proportion of participants in the control group thought the feedback letters were not attractive in appearance but intended to read the letters again in the future. More participants in the intervention group reported having changed their diets as a result of the feedback letters they received. Although website login frequency decreased over the 6-month study, most participants reported visiting the website once per month or more, and there was general agreement between frequency of use and perceived helpfulness for different website sections. The focus group interviews revealed that the website was generally well accepted. Several features that would improve this application, such as increased interactivity, were identified from the interviews and will inform future refinements of the website.

This Internet-based, step-wise tailored-feedback intervention used to promote healthy eating in the context of the traditional Mediterranean diet presents a realistic and reliable approach to dietary behaviour change and shows that the Mediterranean diet can be adopted by healthy individuals in northern European countries. The present findings can be used to improve the design of future Internet applications and facilitate the promotion of healthy eating to Western populations. Since an increasing number of people in Scotland have Internet access at work or at home and electronic access to health information increases, such interventions have the potential to promote greater

consumption of plant foods in Scotland, as well as decreasing saturated fat and increasing monounsaturated fat in the Scottish diet, in agreement with current dietary recommendations for health promotion and disease prevention.

List of abstracts and papers

Abstracts of oral and poster presentations:

- Scott, J.A., Papadaki, A. Mediterranean diet and Coronary Heart Disease: The epidemiological evidence of the protective qualities of the Mediterranean diet. Can the Mediterranean diet be achieved in Scotland? The Scottish Syndrome: Coronary Heart Disease as a Killer, a One Day Conference. University of Glasgow, Glasgow, UK. 16 September, 2004
- Papadaki, A., Scott, J.A. The Mediterranean Eating in Scotland Experience (MESE) project: impact of an internet-based, tailored intervention on dietary behaviour. Nutrition Society Summer Meeting, jointly with The Association for the study of Obesity. Obesity: taking theory into practice. Trinity College, Dublin, Ireland. 5-8 July, 2004
- Papadaki, A., Scott, J.A. The Mediterranean Eating in Scotland Experience (MESE) project: Use of the Mediterranean Diet Score to evaluate dietary change in an internet-based, tailored intervention. International Conference, Health benefits of Mediterranean diet: Obesity and Type II Diabetes prevention. Perpignan, France. 12-15 May, 2004

Papers submitted for publication in peer-reviewed journals

- Papadaki A & Scott JA (2005) The Mediterranean Eating in Scotland Experience project: evaluation of an Internet-based intervention promoting the Mediterranean diet. *Br J Nutr* **94**, 290-298.
- Papadaki, A. and Scott, J.A. The Mediterranean Eating in Scotland Experience (MESE) project: process evaluation and user perceptions of a Website promoting the Mediterranean diet. Health Education Research. Accepted.

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Definitions

Personalised feedback is feedback that uses an individual's name to draw attention to otherwise generic information (De Vries & Brug, 1999; Kreuter *et al.* 1999a).

Tailored feedback refers to the process of combining strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the behavioural outcome of interest and derived from an individual assessment (Rakowski *et al.* 1998; Bull *et al.* 1999b; De Vries & Brug, 1999; Kreuter *et al.* 1999a; Kreuter *et al.* 1999b).

Computer-tailored feedback refers to the adaptation of materials to one specific person and the provision of personalised and tailored feedback through a largely computerised process (Brug *et al.* 1998; De Vries & Brug, 1999).

Personal feedback refers to information that respondents obtain about answers they have provided on a tailoring questionnaire (De Vries & Brug, 1999).

Normative feedback refers to information that respondents obtain when comparing their responses with the responses of another group, usually similar in one or several characteristics (De Vries & Brug, 1999), or a standard (e.g. recommendations) (Ryan & Lauver, 2002).

Ipsative or iterative feedback refers to information that respondents obtain when comparing their most recent status and that found at previous assessments (Brug *et al.* 1998; De Vries & Brug, 1999).

Primary prevention trials are intervention trials designed to prevent initiation of disease in free-living, healthy individuals. They require the largest population size and the longest duration of therapy because of the lower risk of developing a disease (Hakim, 1998).

Secondary prevention trials are intervention trials designed to attempt to remove or affect disease promoting factors in individuals with high risk of developing disease. They are generally designed to compare promising therapies with no treatment or a placebo, or with standard treatment, or with each other (Hakim, 1998).

Tertiary prevention trials are intervention trials designed to attempt to improve treatment outcomes and prevent disease relapse in individuals with established disease (Hakim, 1998).

Abbreviations

ANOVA:	Analysis of Variance
BMI:	Body Mass Index
BP:	Blood pressure
CI:	Confidence interval
CHD:	Coronary Heart disease
CVD:	Cardiovascular disease
E-mail:	Electronic mail
F&V:	Fruits and vegetables
FEQ:	Food and Eating Questionnaire
FFQ:	Food Frequency Questionnaire
FST:	Forward Stage of Transition
HC:	Hip circumference
HDL:	High Density Lipoprotein
ID:	Identity
kcal:	kilocalories
kJ:	kilojoules
LDL:	Low Density Lipoprotein
MDS:	Mediterranean Diet Score
MESE:	Mediterranean Eating in Scotland Experience
MUFA:	Monounsaturated fatty acids
NCEP:	National Cholesterol Education Programme
NCI:	National Cancer Institute
OR:	Odds Ratio
PA:	Physical activity
PUFA:	Polyunsaturated fatty acids
SD:	Standard Deviation

SFA: Saturated fatty acids

UK: United Kingdom

USA: United States

v.: versus

WC: Waist circumference

WHR: Waist-to-hip ratio

y: years

1 Introduction

1.1. Significance of the study

It is well documented that the average Scottish diet is relatively low in fruit and vegetables and legumes and high in saturated fat, and is recognised as contributing to Scotland's high rates of coronary heart disease, stroke and cancer mortality (The Scottish Office, 1996). Since diet is responsible for approximately 30% of cancers in industrialised countries (World Health Organisation, 2002) and is associated with cardiovascular disease through its relationship to blood lipid concentrations (Kromhout, 1999), antioxidant status (Kushi *et al.* 1995a) and blood pressure (Appel *et al.* 1997), dietary interventions have the potential to reduce chronic disease incidence and mortality rates.

The Seven Countries study, conducted by Keys and his colleagues in the early 1960s, was the first study to raise interest in the Mediterranean diet, due to the very low mortality rates and high life expectancies demonstrated in southern Europe, compared to northern Europe and the United States (Keys, 1970). In particular, the dietary pattern of Crete was considered to be a healthy ideal, being low in saturated fat and rich in fruit, vegetables, legumes, nuts, grains and olive oil (Kromhout *et al.* 1989).

A number of researchers have used the Mediterranean diet recommendations as the nutritional basis of tertiary (Renaud *et al.* 1995; de Lorgeril *et al.* 1998), secondary (Esposito *et al.* 2003; Esposito *et al.* 2004) and primary (Castagnetta *et al.* 2002) interventions with promising results. These studies have shown that the Mediterranean diet can improve blood lipid profiles, protect against both cardiovascular diseases and cancer, and increase survival in people already suffering from chronic disease. The success of these studies suggests that basic components of the Mediterranean dietary pattern are transferable to both patients who are motivated to change their diet and healthy individuals in non-Mediterranean countries.

The health advantages of promoting the Mediterranean diet in Scotland are therefore obvious. In addition, the Mediterranean Diet is recognized as being highly palatable (Nestle, 1995), which is a characteristic not readily associated with healthy eating (Food Standards Agency Scotland, 2002). The traditional Mediterranean diet is consistent with the recommendations of the Scottish Diet Action Plan (The Scottish Office, 1996) but it may be more attractive to consumers since it is an established and thus, acceptable eating pattern. In addition, Scottish people regularly holiday in

Mediterranean countries. As a result, they have been exposed to, purportedly enjoy the Mediterranean cuisine and associate it with tastiness and good times. They may not however, realise that it is a healthy eating pattern, aspects of which can be relatively easily incorporated into their everyday lives in Scotland.

It is important however, to identify effective and feasible approaches to communicating dietary advice that would reach large numbers of individuals in a cost- and time-effective manner, in order to increase the potential impact of dietary interventions, sustain dietary adherence and optimally result in improved population health.

The Internet could offer such an opportunity, since it is widely accessible to the general public and is a primary method of obtaining health information (Patrick *et al.* 1999; Sastry & Carroll, 2002; Williams *et al.* 2002). The National Statistics Survey revealed that in the first quarter of 2004, 49% of households in the UK (12.1 million) could access the Internet from home, with just over a quarter of adults in Great Britain (26%) accessing the Internet everyday or almost everyday and 56% of adults having used the Internet at least once in the three months prior to the survey (National Statistics, 2004b). Between February 2002 and February 2004, Scotland, in particular, displayed the highest increase in Internet access in the UK (16%) (National Statistics, 2004a). These statistics provide evidence of the Internet's increasing opportunities to reach large numbers of people in a cost effective manner.

Feedback that is tailored to an individual's needs according to their specific behaviours and psychosocial and environmental factors that may affect these behaviours, is another strategy that can be used to modify eating habits in a relatively inexpensive and time-saving manner (Skinner *et al.* 1993; Dijkstra & De Vries, 1999; Brug & Van Assema, 2000). During the last decade, this approach has been applied in several computer-tailored nutrition interventions and has been shown to be more effective in promoting favourable dietary changes compared with general, non-tailored nutrition education (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1998; Brug, 1999; Brug *et al.* 1999b). Tailored feedback accounts for an individual's personal characteristics and thus it is likely to be less redundant than general nutrition information (Brug *et al.* 1999b; Brug & Van Assema, 2000), thereby facilitating the change of dietary behaviours that are potentially health threatening or maintaining food habits that are beneficial for health (Brug *et al.* 1999b).

Since the Internet is one of the most preferred nutrition information sources (van Dillen *et al.* 2003), its use seems to be a promising way of delivering nutrition education and could enhance the positive effect of tailored dietary and psychosocial feedback.

1.2. Justification of the study

The World Wide Web offers numerous resources providing healthy eating advice, recipes, and interactive tools for dietary assessment. In a recent study investigating preferences for sources of nutrition information, Dutch adults ranked the Internet highly for its accessibility and clarity of information. However, it was rated less favourably in terms of reliability and expertise (van Dillen *et al.* 2003). This is not surprising, as the vast majority of nutrition information on the Internet is posted by individuals or groups with vested interests and/or dubious expertise. Therefore, while the Internet appears to offer a promising medium for delivering nutrition education, the need to provide credible information via this channel must be addressed (Davison, 1997).

Combining the principles of information technology systems and tailored dietary and psychosocial feedback could present an effective and practical means of delivering reliable nutrition education and promoting dietary behaviour change. Since an increasing number of people in the United Kingdom have Internet access at work or at home (British Computer Society, 2003; Linke *et al.* 2004; National Statistics, 2004b) and electronic access to health information increases (Williams *et al.* 2002), Internet-based tailored interventions can be practical in delivering trustworthy nutrition education by reaching large numbers of people at a relatively low cost.

Although most tailored-feedback and Internet-technology nutrition interventions to date have proved successful in promoting dietary changes and/or improving psychosocial determinants of dietary behaviour, many studies have identified the following limitations:

- Selection bias (Brug *et al.* 1998; De Vries & Brug, 1999);
- Short intervention periods and short, or lack of, follow-up periods (Skinner *et al.* 1999);
- Long time span between assessment and tailored feedback delivery (Brug *et al.* 2003);
- Reliance on self-reported dietary intake and lack of objective biological measurements (i.e. body weight, blood lipid levels) for impact evaluation (Brug *et al.* 1999a);
- Evaluation of applications under highly controlled conditions (Oenema *et al.* 2001; Oenema & Brug, 2003b);
- Process evaluation based on retrospective data, instead of also including direct measures of application usage (e.g. tracking of number of website visits) and/or use of focus group interviews for extended feedback on such applications (Sciamanna *et al.* 2002);
- Analysis of results based on a “per protocol” instead of an “intention-to-treat” basis, which might overestimate the clinical implications of findings (Kruse *et al.* 2002).

The aim of the Mediterranean Eating in Scotland Experience (MESE) study therefore, was to design a tailored-feedback nutrition intervention utilizing Internet technology which addressed, where possible, these limitations. This study is novel in that no research has evaluated the combined effects of a healthy-eating website promoting the Mediterranean diet and tailored dietary and psychosocial feedback through e-mails, in order to encourage dietary change. This study also aimed to promote the Mediterranean diet by setting reasonable and realistic goals, in a step-wise manner, in order to encourage gradual dietary change, which is more likely to lead to long-term changes (Fletcher & Rogers, 1985). In addition, the MESE study contributes to previous research assessing consumers' information needs regarding nutrition and is the first study to our knowledge, to evaluate users' attitudes towards a specific nutrition website in a real life setting.

This work is important because health promotion websites appear to offer a cheap and effective way of delivering nutrition information to the general public. Combining this latter effect with the benefits of the traditional Mediterranean diet and tailored feedback might bring forward favourable dietary changes that would promote health.

1.3. Objectives and hypotheses of the study

The primary aims of the present study are:

- To develop and evaluate a step-wise, Internet-based tailored healthy eating intervention promoting four key components of the Mediterranean diet;
- To explore the immediate effects of this intervention on dietary behaviour;
- To explore the immediate effects of this intervention on anthropometric and blood pressure measurements, as well as biochemical biomarker levels.

Secondary aims include:

- To explore the immediate effects of this intervention on nutrition knowledge, stages of dietary behaviour change, importance of, and attitudes and self-efficacy skills towards dietary change of the four key components of the Mediterranean diet promoted by the study;
- To evaluate and examine users' perceptions and usage patterns of an innovative website promoting the traditional Mediterranean diet, as well as evaluate the use, appreciation and perceived impact of the tailored feedback provided.

We hypothesise that, compared with a control group receiving general nutrition information and minimally-tailored dietary feedback, participants in the intervention group receiving the Internet-based, tailored-feedback nutrition intervention will:

- Make more favourable changes to their diets;
- Have more favourable biochemical biomarker levels and no adverse effects would be reported on anthropometric and blood pressure measurements;
- Increase their nutrition knowledge, achieve forward progress through the stages of behavioural change, as well as improve their perceived attitudes and self-efficacy skills towards dietary change;
- Judge the nutrition information materials they access (i.e. Mediterranean Eating website) and receive (i.e. tailored dietary and psychosocial feedback) more positively, compared with the minimal intervention materials.

1.4. Benefits of the study

The MESE study will evaluate a tailored nutrition intervention which utilises an innovative healthy-eating website in order to promote the Mediterranean diet. User perceptions of this website will also be evaluated, contributing to previous research assessing consumers' information needs regarding nutrition. This information will help to identify effective ways of delivering nutrition information.

Once evaluated and refined, the Mediterranean Eating website could be evaluated among a larger group of free-living adults in the general community and/or a primary care setting. If shown to be effective, the Mediterranean Eating website could then be promoted to general practitioners and other health professionals as a reputable, non-commercial tool for use by their patients and clients wishing to make simple improvements to their diet. Since 45% of general practitioners in Scotland would consider referring patients to the Internet for further trustworthy information (Wilson, 1999), the proposed website could offer such an opportunity.

The proposed Internet-based, tailored nutrition education intervention could also be particularly effective in promoting dietary behaviour change in work-based settings. Educating employees about nutritional issues can help reduce their health care costs and the subsequent improvement in employees' health could help reduce absenteeism, increase productivity and performance and optimise work satisfaction (Heimendinger *et al.* 1995). Because this study presents a realistic approach to eating behaviour change and is practical, economical and efficient, employees' health

improvement is expected to be maintained in the long run. Therefore, other work settings could also benefit from this intervention.

Finally, the Mediterranean Eating website could also be disseminated on the World Wide Web, in order to make this Mediterranean nutrition education program accessible to larger population groups.

2 Literature Review

2.1. The Mediterranean diet

The Mediterranean diet is a dietary pattern that is recognised for both its health benefits and its palatability and can serve as a model for dietary improvement (Nestle, 1995). Its health promoting benefits are demonstrated by the increased longevity and lower rates of chronic diseases in countries in this region, compared with other developed countries in the world (Helsing, 1995), resulting in its recommendation to the Western world as a dietary pattern that is tasty, healthy and easily incorporated within a modern lifestyle (Willett *et al.* 1995).

2.1.1. Epidemiology of chronic disease in Mediterranean countries

Interest in the health promoting benefits of the Mediterranean diet derives from the results of the Seven Countries Study that was conducted by Ancel Keys and his colleagues in the early 1960s (Keys, 1970). It was found that overall mortality rates were lower in adult Greek men than in North Americans or northern Europeans (Helsing, 1995). After a follow-up of 5-15 years, it was found that mortality from all causes in the cohort from Crete, Greece was much lower when compared with the nine other cohorts from southern Europe and northern countries, as illustrated in Table 2.1.

Table 2.1 Ten-year total mortality rates per 100,000 men aged 50-69y, who participated in the Seven Countries Study

	Total mortality	CHD mortality
Crete	514	9
Mediterranean ^a	1090	184
Netherlands	1091	420
United States	1153	574

CHD= Coronary Heart Disease

^a 9 Mediterranean cohorts

Source: Renaud *et al.* (1995)

The Seven Countries Study specifically reported that diets consumed in Greece and southern Italy in the 1960s protected against the development of coronary heart disease. People in Crete, in particular, were found to have very low CHD mortality rates compared with other European and North American populations (Table 2.1) (Keys, 1970). The life expectancy displayed by people in Greece in the early 1960s was also among the highest in the world and the Greek population

displayed very low mortality rates from both cardiovascular and coronary heart disease, as presented in Table 2.2. The Mediterranean diet has also attracted considerable attention because of its apparent cancer-protective role, as evidenced by the relatively low cancer mortality rates in Mediterranean populations (Helsing, 1995). Specifically, it was observed that people living in Mediterranean countries and especially in Greece, displayed mortality rates from cancer that were among the lowest in the world (Table 2.2).

Since socio-economic factors in Mediterranean regions, including financial status, educational levels and medical services, were quite low at the time compared with those of more industrialised countries, diet has been proposed to be the main factor related to the excellent health status and high life expectancies of Mediterranean populations (Kromhout *et al.* 1995; Gjonca & Bobak, 1997). Longitudinal studies have suggested that people who follow the traditional Mediterranean pattern have a 17% to 60% reduced risk of dying from all causes than people with less traditional eating habits (Trichopoulou *et al.* 1995a; Trichopoulou *et al.* 1995b; Osler & Schroll, 1997; Kouris-Blazos *et al.* 1999; Lasheras *et al.* 2000; van Staveren *et al.* 2002; Trichopoulou *et al.* 2003; Knoops *et al.* 2004). It has also been suggested that adherence to a Mediterranean-style diet could reduce the overall incidence of cancer in northern Europe and the United States by 10% (Trichopoulou *et al.* 2000; Knoops *et al.* 2004), reduce cancer mortality risk by 24% to 60% (Knoops *et al.* 2004), reduce coronary heart disease and cardiovascular disease mortality risk by 31% to 64% (Trichopoulou *et al.* 2003; Knoops *et al.* 2004; Trichopoulou *et al.* 2005a), as well as be protective against obesity and promote greater food variety (Wahlqvist *et al.* 1999). These estimates are supported by findings from tertiary, secondary and primary prevention trials that have used the Mediterranean diet as an intervention strategy, highlighting the benefits of adopting this dietary pattern (see Section 2.2.).

Table 2.2 Life expectancy at 45y and age-standardised chronic disease mortality rates per 100,000 people aged 0-64y in various countries in the 1960s

	Life expectancy		CVD mortality		CHD mortality		Total cancers		Breast cancer	Gastric Cancer		Colorectal cancer	
	Males	Females	Males	Females	Males	Females	Males	Females	Females	Males	Females	Males	Females
Greece	31	34	26	23	33	14	83	61	8	10	6	3	3
United States	27	33	30	24	189	54	102	87	22	6	3	11	10
Japan	27	32	102	57	34	21	98	77	4	48	26	5	5

CVD= Cardiovascular Disease

CHD= Coronary Heart Disease

Source: Kushi *et al.* (1995b)

2.1.2. Definition of the Mediterranean diet

The Mediterranean Sea borders 16 countries, which differ greatly in culture, religion, geography, economic and political status and other factors that may influence food resources and eating habits. It is therefore difficult to establish a definition of the “typical” Mediterranean diet, since the variety of dietary patterns in Mediterranean countries leads to differences in terms of food consumption and consequently, nutrient intakes (Hakim, 1998).

Since Ancel Keys found the dietary pattern of the Greek island of Crete to be associated with extremely good health in the Seven Countries Study in the early 1960s, it is this pattern that has come to be regarded as the model Mediterranean diet (Keys, 1970; Renaud *et al.* 1995). Other researchers proposed a definition of the Mediterranean diet as the dietary pattern followed by people living in southern Italy in the 1960s (Ferro-Luzzi & Sette, 1989). Since in that period, olive oil was the principal source of fat in both Crete and southern Italy, the term “Mediterranean diet” has been extended to include dietary patterns similar to olive-growing Mediterranean locations, where olive oil is a major fat source in the diet (Willett *et al.* 1995).

Although it has been difficult to define one kind of Mediterranean diet, traditional Mediterranean dietary patterns share some basic characteristics that differentiate them from northern European food cultures. In particular:

- High ratio of monounsaturated to saturated fat (MUFA:SFA);
- High consumption of fruits, nuts and seeds;
- High consumption of vegetables (excluding potatoes);
- High consumption of legumes (including beans, lentils, chickpeas and peas);
- High consumption of (mainly unrefined) cereals;
- Moderate consumption of fish (depending on the proximity to the sea);
- Low consumption of meat, meat products and poultry;
- Low-to-moderate consumption of milk and dairy products;
- Moderate alcohol consumption (Trichopoulou *et al.* 1995a; Trichopoulou *et al.* 2003).

The high consumption of vegetables, legumes and other plant foods in raw salads, soups and cooked meals is facilitated by the use of olive oil, which is the most important fat source in this dietary pattern (Trichopoulou *et al.* 2000). The consumption of plant foods is also made easier by

the abundant use of garlic, onions and various herbs. In addition, foods consumed are generally seasonally fresh and minimally processed, so in most Mediterranean countries, only moderate amounts of salt are consumed. Fresh fruit is the standard dessert and cakes and puddings are usually consumed on special occasions only. Intake of alcohol is moderate for most people, mainly in the form of wine and almost always with meals (James, 1995; Keys, 1995; Hakim, 1998). The food consumption pattern of Mediterranean populations is indicated by the median intake of eight components of the traditional Mediterranean diet of a group of elderly Greeks consuming a traditional Greek diet (Table 2.3) (Trichopoulou *et al.* 1995b).

Table 2.3 Median daily intake of eight components of the traditional Greek diet

Food component ^a	Elderly Greeks	
	Men (<i>n</i> 91)	Women (<i>n</i> 91)
Vegetables (g/d) ^b	303.0	248.0
Fruits (g/d)	249.0	216.0
Legumes (g/d)	60.0	49.0
MUFA:SFA ratio (/d)	1.6	1.6
Cereals (g/d) ^c	291.0	248.0
Meat and meat products (g/d)	109.0	91.0
Milk and dairy products (g/d)	201.0	194.0
Alcohol (g/d)	10.0	0.0

^a Intakes were adjusted to 10450 kJ (2500 kcal) for men and 8368 kJ (2000 kcal) for women

^b Excluding potatoes

^c Includes cereals, potatoes and bread

Source: Trichopoulou *et al.* (1995b)

The minimal processing and usual methods of preparation, as well as the high proportion of fresh, seasonal foods related to Mediterranean diets guarantee a high intake of antioxidants, dietary fibre, monounsaturated fat, *n*-3 fatty acids, various micronutrients and several non-nutrient substances found in plant foods, as well as a low intake of saturated fat (Renaud *et al.* 1995; Gjonca & Bobak, 1997; Kafatos *et al.* 2000). Although the total fat content of the traditional dietary pattern of Crete remains controversial (Ferro-Luzzi *et al.* 2002), olive oil consumption resulted in an extremely favourable overall dietary fat profile of this eating pattern, as demonstrated in Table 2.4. Although factors other than diet may have contributed to the good health of Mediterranean populations, such as the after-lunch siesta, reduced stress and good climate (Renaud *et al.* 1995), the traditional Mediterranean diet appears to supply most of the essential elements identified to promote health (Willett, 1994; Hakim, 1998).

Table 2.4 Dietary fat profile in various countries in the 1960s^a

	Crete	United States	Japan
Total fat (% energy)	40.0	39.0	11.0
Saturated fat (% energy)	8.0	18.0	3.0
Monounsaturated fat (% energy)	29.0	12.4	5.0
Polyunsaturated fat (% energy)	3.0	8.6	3.0

^a Based in the average daily intake of men (aged 40-59y) who participated in the Seven Countries Study

Source: Kafatos *et al.* (1991); Kromhout *et al.* (1995); Kushi *et al.* (1995b)

2.1.3. Current chronic disease rates and dietary patterns in the United Kingdom

Cardiovascular and coronary heart disease are major causes of morbidity and premature mortality in the United Kingdom, leading to a lower life expectancy compared with Mediterranean countries, as demonstrated in Table 2.5. In addition, in the 1990s, mortality rates from both cardiovascular and coronary heart disease in the United Kingdom were higher compared with Mediterranean countries, as illustrated in Table 2.5. Despite the increasing rates displayed by Greece since the early 1960s, men and women in the United Kingdom have approximately double the rates of mortality from coronary heart disease compared with the Greek population.

Table 2.5 Life expectancy and cardiovascular and coronary heart disease mortality rates in selected European countries in 1990

	Life expectancy at birth (y)		CVD mortality ^a		CHD mortality ^a	
	Males	Females	Males	Females	Males	Females
Greece	74.6	79.9	100	37	55	11
Italy	73.5	80.0	81	29	44	9
Portugal	70.0	77.3	92	41	37	10
United Kingdom	72.7	78.3	133	48	102	28

^a Age-standardised death rates per 100,000 people aged 0-64y

Source: Gjonca & Bobak (1997)

In recent years, it has been estimated that in England and Wales, about one- third of all deaths are the result of coronary heart disease (Mann, 2000), while CHD mortality rates in Scotland are among the highest in the world (The Scottish Office, 1996). Heart disease in Scotland led to 14,164 deaths (age-standardised rate of 185.3/100,000population) in 2003, combined for both sexes, the majority of which were the result of coronary heart disease (11,441 deaths, age-standardised rate of

150.4/100,000 population) (Information and Statistics Division NHS National Services Scotland, 2004a). In the same year, mortality rates from cerebrovascular disease reached 2,411 deaths, combined for both sexes (aged-standardised rate of 83.4/100,000 population), the majority of which were the result of stroke (1,385 deaths, age-standardised rate of 48.1/100,000 population) (Information and Statistics Division NHS National Services Scotland, 2004b).

After diseases of the circulatory system, cancer is the second most common cause of death in developed countries, accounting for approximately 10 million new cases and over 6 million deaths in 2000 (World Health Organisation, 2002). In the United Kingdom, the most common sites for cancer are lung, breast, large bowel and prostate (Bingham, 2000). It has been estimated that in England and Wales, age-standardised incidence rates for all cancer sites are 274.1 and 221.0/100,000 of the population in men and women, respectively (Bingham, 2000). In addition, cancer is the second largest cause of death in the Scottish population, leading to approximately 15,000 deaths in 2003 (Information and Statistics Division NHS National Services Scotland, 2004c). Age-adjusted incidence rates for selected diet-related cancers in the United Kingdom are presented in Table 2.6, compared with Mediterranean and northern countries.

Table 2.6 Age-adjusted incidence rates for various cancer sites per 100,000 people in 1990

	Large bowel		Pancreas		Breast	Endometrium	Prostate
	Males	Females	Males	Females	Females	Females	Males
Mediterranean	18	14	6	4	43	10	17
Scandinavian	22	18	8	6	64	13	48
United Kingdom	31	22	8	6	70	10	30
United States	37	26	8	6	90	18	100

Source: Trichopoulou *et al.* (2000)

Dietary habits are one of the most important lifestyle behaviours related to chronic disease risk. The Scottish diet, in particular, has been recognised as contributing to Scotland’s high rates of coronary heart disease, stroke and cancer mortality (The Scottish Office, 1996). Consumption of the eight components of the Mediterranean diet by Scottish men and women is compared with the median intake of the group of elderly Greeks consuming a traditional Greek diet (Trichopoulou *et al.* 1995b) in Table 2.7. It is shown that the average Scottish diet contains lower amounts of vegetables,

fruits and legumes, as well as a lower MUFA:SFA ratio, compared with the Mediterranean diet. In contrast, the Mediterranean diet is lower in cereals, meat and meat products, dairy products (for men) and alcohol. The differences between the two eating patterns have resulted in a less favourable dietary fat profile of the Scottish diet, as presented in Table 2.8.

Table 2.7 Daily intake of the eight components of the Mediterranean diet for elderly Greeks and Scottish adults

Food component	Elderly Greeks ^a		Scottish adults ^b	
	Men (<i>n</i> 91)	Women (<i>n</i> 91)	Men (<i>n</i> 65)	Women (<i>n</i> 66)
Vegetables (g/d) ^c	303.0	248.0	83.0	79.0
Fruits, nuts and seeds (g/d)	249.0	216.0	110.0	139.0
Legumes (g/d)	60.0	49.0	0.0	2.0
MUFA:SFA ratio (/d)	1.6	1.6	0.9	0.8
Cereals (g/d) ^d	291.0	248.0	398.6	278.0
Cereals (g/d) ^e			268.0	181.6
Meat and meat products (g/d)	109.0	91.0	201.8	102.0
Milk and dairy products (g/d)	201.0	194.0	216.3	164.0
Alcohol (g/d)	10.0	0.0	22.2	10.4

^a Median intake, adjusted to 10450 kJ (2500 kcal) for men and 8368 kJ (2000 kcal) for women (Trichopoulou *et al.* 1995b)

^b Median intake of men and women (consumers, aged 19-64y) who participated in the National Diet and Nutrition Survey of British Adults (The Office for National Statistics, 2002)

^c Excludes potatoes

^d Includes cereals, potatoes and bread

^e Includes cereals and bread

Table 2.8 Dietary fat profile of the traditional diet of Crete and the Scottish diet

	Crete ^a	Scotland, men ^b	Scotland, women ^b
Total fat (% energy)	40.0	36.0	34.6
Saturated fat (% energy)	8.0	13.1	13.5
Monounsaturated fat (% energy)	29.0	12.3	11.2
Polyunsaturated fat (% energy)	3.0	6.7	6.0

^a Average daily intake of men (aged 40-59y) who participated in the Seven Countries Study in the 1960s (Kafatos *et al.* 1991; Kromhout *et al.* 1995; Kushi *et al.* 1995b)

^b Mean daily intake of men and women (aged 19-64y) who participated in the National Diet and Nutrition Survey of British Adults (The Office for National Statistics, 2002)

Considering the unfavourable dietary pattern of the Scottish population and its contribution to the high mortality rates of chronic disease, efforts to develop effective preventive measures appear most important. Since the Mediterranean diet appears to be transferable to populations with more westernised eating habits, who are not familiar with this diet (Kouris-Blazos *et al.* 1999; Lairon, 1999), intervention studies that focus on dietary modification in the context of the Mediterranean diet hold promise in promoting healthy and palatable eating patterns. In addition, due to the variety of food options this pattern offers, the Mediterranean diet could promote long-term dietary adherence and therefore, long-term health benefits (Trichopoulou, 2001).

For the following parts of the present review (intervention studies promoting the Mediterranean diet, tailored-feedback nutrition intervention studies and Internet-technology nutrition intervention studies), computerised literature searches were conducted using the databases MEDLINE and OVID. Titles and abstracts were searched for the following terms:

- Mediterranean diet, nutrition interventions, primary, secondary, tertiary (see Section 2.2.)
- Tailoring, tailored feedback, tailored interventions, individualized, nutrition, diet, computers, dietary behaviour (see Section 2.3.6.)
- Internet, World Wide Web, nutrition, diet, website evaluation, nutrition interventions (see Section 2.4.6.)

Abstracts were screened for potential relevance and following the identification of suitable journal papers, full texts were sought via electronic libraries or after contacting the authors. All references cited in these papers were also hand searched to locate appropriate papers.

Although a systematic review or meta-analysis of the studies identified would have been preferable in order to combine and analyse results across multiple studies, this was impractical taking into account the considerable variation between these studies in outcome measures, sample characteristics, comparison groups and types and evaluation of interventions. A further limitation of the present literature search is that searches were limited to articles published in the English language. In addition, although every attempt was made to locate relevant papers, the possibility of missing references, as well as the publication bias (e.g. bias against intervention studies presenting “negative” or “neutral” results) should be acknowledged.

2.2. Intervention studies promoting the Mediterranean diet

Intervention trials promoting the traditional Mediterranean diet or a Mediterranean-style diet have included tertiary (in people with established disease), secondary (in high-risk individuals) and primary (in free-living, healthy individuals) prevention studies. A summary of these studies, in order of year of publication, along with their methods and major findings is presented in Tables 2.9-2.11. Only studies that have included the term “Mediterranean” as part of their intervention approach were included.

A number of feeding trials have also investigated the effect of the Mediterranean diet, basic components of this eating pattern (e.g. olive oil, legumes, vegetables, whole grains, nuts etc.) or single nutrients abundant in this eating pattern (e.g. antioxidant vitamins, monounsaturated fat, *n*-3 fatty acids etc.) on several biological markers (e.g. blood lipids, LDL-cholesterol oxidation, blood antioxidant levels etc.) and recurrence of, or mortality from chronic disease. These studies have been undertaken under strictly controlled, in contrast to real-life setting conditions, by providing pre-prepared meals and/or supplements, or comparing diets of determined nutrient compositions. Free-living individuals, however, do not consume single nutrients or foods, but complex diets containing a combination of foods, nutrients and non-nutrient compounds. Research has advocated the importance of the whole dietary pattern, in contrast to particular dietary components, with regard to survival and reduced rates of chronic disease (Trichopoulou *et al.* 1995*b*; Osler & Schroll, 1997; de Lorgeril *et al.* 1998). This review, therefore, will focus on studies promoting the whole Mediterranean diet, or a Mediterranean-style diet, instead of specific components of this dietary pattern (e.g. fruits and vegetables).

Table 2.9 Tertiary prevention intervention trials

Authors	Sample characteristics	Study design	Intervention	Outcomes measured	Main results
Singh <i>et al.</i> (1992a,b,c)	South-Asian patients with unstable angina pectoris and past myocardial infarction (within 24-48 hours) (n 406; 204 intervention, 202 control, mean age=51 years)	Randomised single-blinded controlled trial; reduced-fat diet and increased fruit, vegetable, nut, legume, fish and grain intake, compared with step I NCEP diet	Individual counselling to promote reduced-fat diet and more fruit, vegetables, nuts, pulses, fish and grain products	Primary: Mortality from cardiac disease and other causes (assessed at 1 year) Secondary: Dietary adherence, body weight, serum glucose and lipids, blood pressure (assessed at baseline, 6, 8, 24, 36 weeks and 1 year)	At 6 and 12 weeks, significant intervention effect on total (-20.5 v. -8.6 and -26.4 v. -13.8 mg/dl, both P<.010) and LDL-cholesterol (-16.6 v. -6.4 and -20.0 v. -9.8 mg/dl, both P<.010), weight (-3.4 v. -1.3 kg), compared with control group. At 8 and 24 weeks, significant intervention effect on fibre intake (50.6 v. 24.6 and 50.8 v. 26.2 g/d, both P<.001). At 8, 24 and 36 weeks, significant intervention effect on F&V intake (582 v. 180, 590 v. 190 and 575 v. 186 g/d, all P<.001), compared with control group. At 1 year, significant intervention effect on incidence of cardiac events (50 v. 82, P<.001) and total CVD mortality (21 v. 38, P<.010), compared with control group. Significant intervention effect on HDL-cholesterol (+0.07 v. -0.04 mmol/l, P<.050), total cholesterol (-0.74 v. -0.32 mmol/l, P<.010), LDL-cholesterol (-0.54 v. -0.24 mmol/l, P<.010), glucose (-1.36 v. -0.65, P<.010), SBP (-13.4 v. -5.2 mmHg, P<.050), DBP (-9.3 v. -3.5 mmHg, P<.050), weight (-7.1 v. -3.0 kg, P<.010) and dietary adherence (123 v. 71 points, P<.001), compared with control group.
Salen <i>et al.</i> (1994)	French hypercholesterolemic men, heart transplant recipients (n 41, mean age=50 years)	Single group, pre-test post-test intervention trial; Mediterranean diet advice	Individual counselling to promote Mediterranean diet, with use of olive or canola oil	Assessed every 2 months and 1 year: Primary: Platelet aggregation, plasma lipids Secondary: Dietary intake	At 1 year, significant effect on total- (-1 mmol/l, P=.005) and LDL-cholesterol (-0.9 mmol/l, P=.004). Inverse correlation between α -linolenic acid and platelet aggregation ($r=-0.44$, P=.030). Significant effect on total energy (-19%, P=.001), saturated fat (-32%, P=.0001), α -linolenic acid (+62%, P=.0001) and oleic acid (+13.5%, P=.050) intakes.

Table 2.9 cont.: Tertiary prevention intervention trials

Authors	Sample characteristics	Study design	Intervention	Outcomes measured	Main results
de Lorgeril <i>et al.</i> (1994, 1996, 1998, 1999); Renaud <i>et al.</i> (1995); Kris-Etherton <i>et al.</i> (2001)	French patients, survivors of first acute myocardial infarction (within 6 months) (<i>n</i> 605; 302 intervention, 303 control, mean age=53.5 years)	Randomised single-blinded controlled trial; Mediterranean α -linolenic acid-rich diet, compared with step I NCEP diet	Individual counselling to promote Mediterranean diet (consisting of <35% of energy as fat, <10% of energy as saturated fat, \leq 4% of energy as linoleic acid, \geq 0.6% of energy as α -linolenic acid, PUFA:SFA ratio \leq 0.8) and canola oil-based margarine (similar in content to olive oil but higher in α -linolenic acid) to replace butter and cream	Assessed at 8 weeks and annually for 4 years: Primary: incidence of combined cardiac deaths and non-fatal acute myocardial infarction (also assessed non-cardiac deaths and overall deaths) Composite 2 nd outcome: primary outcome plus unstable angina, heart failure, stroke and embolism Composite 3 rd outcome: Preceding outcomes plus minor secondary events (recurrent stable angina, need for myocardial surgery and thrombophlebitis) Secondary: Plasma lipids, fatty acids and antioxidant vitamins, BP, BMI and dietary adherence Also assessed at 4 years: Occurrence of malignant and non-malignant tumours, overall survival	At 8 weeks, 12 and 27 months and 4 years, no between group differences in plasma lipids, BMI or BP. At 8 weeks, significant intervention increase in plasma antioxidant vitamins ($P<.050$), oleic ($P<.001$) and α -linolenic acid ($P<.001$) and reduction in linoleic acid ($P<.001$), compared with control group. Changes maintained at 1-3 years. At 27 months, significant intervention reduction in primary outcome (RR=0.27, $P=.001$), composite 2 nd outcome (RR=0.24, $P<.0001$) and composite 3 rd outcome (RR=0.63, $P<.005$) and increase in survival (RR=0.30, $P=.020$), compared with control group. At 4 years, significant intervention reduction in primary outcome (RR=0.35, $P=.010$), primary outcome including non-cardiac and overall deaths (RR=0.28, $P=.0001$), composite 2 nd outcome (RR=0.33, $P=.0001$), composite 3 rd outcome (RR=0.53, $P=.0002$), total deaths (RR=0.44, $P=.030$), cancers (RR=0.39, $P=.050$), combined deaths and cancers (RR=0.44, $P=.010$) and combined deaths, cancers and non-fatal myocardial infarctions (RR=0.38, $P<.001$), compared with control group. After 1-4 years, significant ($P<.001$) intervention reduction in dietary saturated fat, linoleic acid and cholesterol, increase in oleic and α -linolenic acid, compared with control group. After 1-3 years, significant intervention within-group increase in intake of bread ($P<.050$), legumes ($P<.001$), fruit ($P<.001$) and margarine ($P<.001$) and reduction in butter and cream ($P<.001$). Changes maintained at 4 years.

Table 2.9 cont.: Tertiary prevention intervention trials

Authors	Sample characteristics	Study design	Intervention	Outcomes measured	Main results
Singh <i>et al.</i> (2002b)	South-Asian patients with angina pectoris, past myocardial infarction or surrogate coronary artery disease risk factors (<i>n</i> 1000; 499 intervention, 501 control, mean age=48.5 years)	Randomised single-blinded controlled trial; Indo-Mediterranean diet, compared with step I NCEP diet	Individual counselling to promote step I NCEP diet plus: 250-300 g/d fruits, 125-150 g/d vegetables, 25-50 g/d nuts, 400-500 g/d wholegrains (legumes, rice, maize and wheat), 3-4 servings of mustard seed or soybean oil	Primary: Fatal or non-fatal myocardial infarction, sudden cardiac death and combined total of these events (assessed at 2 years) Secondary: Serum glucose and lipids, BMI, BP, dietary intake (assessed at baseline, 12 and 24 weeks and 2 years)	At 2 years, significant intervention reduction in total cardiac endpoints (RR= 0.48, <i>P</i> <.001), non-fatal MI (RR=0.47, <i>P</i> <.001) and sudden cardiac deaths (RR=0.33, <i>P</i> =.015). Significant intervention effect on increase in fruit, vegetable, legume and nut (+358 v. +25 g/d), grain (+132 v. +5 g/d), MUFA (+2.7 v. +1.5%), n-3 fatty acid (+1.33 v. +0.25), total fat (-1.5 v. +1.1%) and saturated fat (-4.8 v. -0.4%) intakes (all <i>P</i> <.0001), compared with control group. Significant intervention increase in HDL-cholesterol and reduction in other blood lipids, BMI, BP and glucose (all <i>P</i> <.0001).
Barzi <i>et al.</i> (2003)	Italian adults, survivors of recent (3 months or less) myocardial infarction (<i>n</i> 11,323, mean age=59.4 years)	Single group, pre-test post-test intervention trial; Mediterranean diet advice	Leaflet advice to increase fish, fruit, raw and cooked vegetable and olive oil intake	Primary: All-cause mortality (assessed at 6.5 years) Secondary: Consumption of promoted foods (10-scale dietary score assessed at baseline, 6, 18 and 42 months)	At 6 months, increased consumption of all foods promoted, maintained to end of study. At 6.5 years, higher consumption of each food significantly associated with reduced death risk (<i>P</i> <.002). One unit increase in diet score associated with 14% reduction in death risk.

Table 2.9 cont.: Tertiary prevention intervention trials

Authors	Sample characteristics	Study design	Intervention	Outcomes measured	Main results
Skoldstam <i>et al.</i> (2003) ; Hagfors <i>et al.</i> (2003)	Swedish patients with rheumatoid arthritis (n 51; 26 intervention, 25 control, mean age=58.5 years)	Randomised parallel trial; Mediterranean diet, compared with usual diet	Group sessions/phone consultations with dietician to promote the de Lorgeril <i>et al.</i> (1994) diet; olive and canola oil for food preparation; canola-based liquid and spreadable margarine; reduce dairy products/substitute with low-fat dairies	Assessed at baseline, 3, 6 and 12 weeks: Primary: Disease activity score, physical function score, pain severity, health-related quality of life, daily dose of non-steroid drugs Secondary: C-reactive protein, plasma antioxidants, blood thrombocyte count, pain severity, morning stiffness, functional impairment, grip ability, dietary antioxidants, dietary intake	At 12 weeks, significant intervention effect on disease activity ($P<.001$), physical function ($P=.020$), vitality ($P=.018$) and current vs. previous quality of life ($P=.016$), compared with baseline. Significant intervention effect on disease activity (-0.5 v. 0 points, $P=.047$), physical function (-0.1 v. 0, $P=.012$), pain severity (-12 v. +3 mm, $P=.006$) and C-reactive protein (-5 v. 0 mg/l, $P=.006$), compared with control group. Significant intervention effect on intake of legumes (6 v. 2 servings/m, $P=.002$), fish (16 v. 6 servings/m, $P<.001$), and cooked root vegetables (11 v. 2 servings/d, $P=.027$), raw green vegetables (21 v. 6 servings/m, $P=.001$), cooked green vegetables (26 v. 6 servings/m, $P<.001$), vitamin C ($P=.014$), vitamin E ($P=.007$) and selenium ($P=.004$) and lower intake of retinol ($P=.049$), compared with control group. No differences between the groups in plasma antioxidant levels.
Søndergaard <i>et al.</i> (2003)	Danish patients with ischemic heart disease and hyper-cholesterolemia (n 131; 68 intervention, 63 control, mean age=62.5 years)	Randomised controlled trial; Mediterranean dietary advice and statin treatment, compared with "heart-healthy diet" booklets and statin treatment	Individual counselling to promote ≥ 660 g/d fruit and vegetables, oily fish at least once/week, plenty of bread/cereals, canola oil instead of butter and hard margarines, modification of total and saturated fat from meat and dairy products	Assessed at baseline and 12 months: Primary: Endothelial function Secondary: dietary changes, serum lipids	At 12 months, significant intervention improvement in endothelial function ($P<.010$). Significant intervention effect on oily fish (67 v. 46 g/d, $P=.030$), red meat (84 v. 112 g/d, $P=.020$), total fat (26.2 v. 28.9%, $P=.030$), PUFA (13.0 v. 10.6%, $P=.030$), compared with control group. Significant intervention reduction in triglyceride levels (within-group, $P<.050$). Significant decrease in total- and LDL-cholesterol in both groups (within-group, $P<.001$).

Table 2.9 cont.: Tertiary prevention intervention trials

Authors	Sample characteristics	Study design	Intervention	Outcomes measured	Main results
Toobert <i>et al.</i> (2003)	North American post-menopausal women with type 2 diabetes (n 279; 163 intervention, 116 control, aged ≤ 75 years)	Randomised controlled trial; Mediterranean Lifestyle Programme, compared with usual care	Lifestyle programme to promote Mediterranean diet, stress management training, physical activity, group support and smoking cessation	Assessed at baseline and 6 months: HbA1c, serum blood lipids, plasma fatty acids, BMI and central obesity, BP, flexibility and quality of life	At 6 months, significant intervention effect on HbA1c (-0.36 v. -0.02%, $P < .001$), BMI (-0.37 v. +0.20 kg/m ² , $P = .009$), n-3 plasma fatty acids (+0.21 v. +0.05%, $P = .022$) and quality of life ($P = .021$), compared with control group.

Table 2.10 Secondary prevention intervention trials

Authors	Sample characteristics	Study design	Intervention	Outcomes measured	Main results
McManus <i>et al.</i> (2001)	North American overweight adults (BMI=26.5-46kg/m ²) (<i>n</i> 101; 50 intervention, 51 control, mean age=44 years)	Randomised controlled trial; Mediterranean moderate-fat diet, compared with low-fat diet, both controlled for energy	Weekly education classes to promote moderate fat diet (35% of energy as fat) compared with low-fat diet (20% of energy as fat) (nutrition counselling, goal setting, behaviour modification, exercise, follow-up visits, maintenance strategies)	Assessed at baseline, 6, 12 and 18 months: Primary: Body weight, waist and hip circumference, body fat Secondary: Dietary intake	At 18 months, significant intervention effect on participant retention in the programme (54% v. 20%, <i>P</i> <.002). Significant intervention effect on body weight (-4.1 v. +2.9kg), BMI (-1.6 v. 1.4 kg/m ²) and WC (-6.9 v. 2.6 cm) (all <i>P</i> ≤.001). At 30 months (additional follow-up), significant intervention reduction in body weight (3.5 kg, <i>P</i> =.030), compared with baseline. Significant intervention effect on vegetable (+1.2 v. -1 servings/d, <i>P</i> =.002), peanut butter (+0.7 servings/d, <i>P</i> =.002) and peanut and tree nut (+0.5 servings/d, <i>P</i> =.010), compared with control group (net differences).
Jula <i>et al.</i> (2002)	Finnish hypercholesterolemic men [<i>n</i> 120; 60 intervention (30 receiving simvastatin and 30 receiving placebo), 60 control (30 receiving simvastatin and 30 receiving placebo), mean age=48.2 years]	Randomised controlled trial; Mediterranean diet (single-blinded) and simvastatin or placebo (double-blinded cross-over), compared with usual diet (single-blinded) and simvastatin or placebo (double-blinded cross-over)	Individualised and group sessions to promote the Mediterranean diet and use of canola margarine and oil, oat bran and frozen berries (provided for free to participants)	Assessed at baseline and 12 weeks: Primary: Serum lipids, insulin sensitivity, serum antioxidants Secondary: Dietary intake	At 12 weeks, significant intervention effect on total cholesterol (-7.6%, <i>P</i> <.001), LDL-cholesterol (-10.8%, <i>P</i> <.001), HDL-cholesterol (-4.9%, <i>P</i> =.010), apolipoprotein B (-5.7%, <i>P</i> =.003), serum insulin (-14.0%, <i>P</i> =.020), and alpha-tocopherol (-3.5%, <i>P</i> =.040), compared with control group. Significant overall simvastatin effect on total cholesterol (-20.8%), LDL cholesterol (-29.7%), triglycerides (-13.6%), apolipoprotein B (-22.4%), alpha-tocopherol (-16.2%), beta-carotene (-19.5%), ubiquinol-10 (-22.0%), HDL cholesterol (+7.0%) (all <i>P</i> <.001) and serum insulin (+13.2%, <i>P</i> =.005) compared with placebo group. The effects of dietary treatment and simvastatin were independent and additive.

Table 2.10 cont.: Secondary prevention intervention trials

Authors	Sample characteristics	Study design	Intervention	Outcomes measured	Main results
Esposito <i>et al.</i> (2003)	Italian premenopausal obese women (BMI ≥ 30 kg/m ²) (<i>n</i> 120; 60 intervention, 60 control, mean age=34.6 years)	Randomised single-blinded controlled trial; Mediterranean diet and weight loss advice, compared with general healthy eating and exercise advice	Individualised dietary and exercise advice and behavioural counselling to promote a $\geq 10\%$ reduction in weight through a low-energy Mediterranean-style step I NCEP diet (goal setting, self-monitoring)	Assessed at baseline and 2 years: Primary: Body weight, vascular inflammatory markers, insulin resistance Secondary: WHR, dietary intake, physical activity levels, serum lipids and glucose, plasma fatty acids and insulin	At 2 years, significant intervention effect on intake of complex carbohydrates (+9%, $P < .001$), MUFA (+2%, $P = .009$), fibre (+7 g/d, $P < .001$), n-6:n-3 fatty acids (-5, $P < .001$), energy (-310 kcal/d, $P < .001$), SFA (-3.5%, $P = .007$) and cholesterol (-92 mg/d, $P < .001$), compared with control group. Significant intervention reduction in BMI (-4.2, $P < .001$) and markers of vascular inflammation (ranged from $P = .008$ to $P = .020$), compared with control group.
Esposito <i>et al.</i> (2004)	Italian adults with the metabolic syndrome (<i>n</i> 180; 90 intervention, 90 control, mean age=43.9 years)	Randomised single-blinded controlled trial; Mediterranean diet, compared with general healthy eating and exercise advice	Individualised dietary and exercise advice, group sessions and behavioural counselling to promote Mediterranean diet, rich in fruit, vegetables, whole grains, legumes, walnuts and olive oil (goal setting, self-monitoring)	Assessed at baseline and 2 years: Primary: Endothelial function, vascular inflammatory markers, nutrient intake Secondary: BMI, WC, BP, serum lipids and glucose, insulin sensitivity	At 2 years, significant intervention effect on intake of complex carbohydrates (+7%), MUFA (+3%), fibre (+16 g/d), n-6:n-3 fatty acids (-4.3), energy (-100 kcal/d), SFA (-5.3%) and cholesterol (-80 mg/d), total F&V, legume and nut (+289 v. +15 g/d), whole grain (+111 v. +8 g/d) and olive oil (+9.7 v. +1.5 g/d) (all $P < .001$) and PUFA (+0.9%, $P = .010$), compared with control group. Significant intervention reduction in body weight (-4.0 kg, $P < .001$), markers of vascular inflammation (ranged from $P = .010$ to $P = .040$) and insulin resistance ($P < .001$), and improvement in endothelial function ($P < .001$) compared with control group. Significant intervention effect on % of participants with features of the metabolic syndrome, compared with control group (44% v. 87% ; $P < .001$).

Table 2.11 Primary prevention intervention trials

Authors	Sample characteristics	Study design	Intervention	Outcomes measured	Main results
Singh <i>et al.</i> (2002a)	British older adults (<i>n</i> 56; 18 intervention, 18 control, 18 placebo, mean age=67 years)	Randomised controlled trial; healthy "Mediterranean-type" diet, compared with vitamin C supplement (1 g/d) or placebo (double blinded)	Advice to promote Mediterranean diet, based on the Lyon Heart Study (de Lorgeril <i>et al.</i> 1999), including increase of fruits and vegetables by 3 servings/d	Assessed at baseline and 6 weeks: Primary: Vascular function, plasma vitamin C Secondary: Plasma lipids, BP, BMI	At 6 weeks, significant intervention improvement in endothelium-dependent ($P=.043$) and endothelium-independent ($P=.011$) vascular function, compared with control group. Similar increases in plasma vitamin C levels in intervention and control groups ($P<.010$ for both).
Castagnetta <i>et al.</i> (2002)	South-Italian postmenopausal healthy women (<i>n</i> 113; 58 intervention, 55 control, age range=44-71 years)	Randomised controlled trial; Mediterranean diet, compared with WHO recommendations for fruit and vegetable intake	Weekly cooking courses to promote use of Mediterranean diet ingredients and instructions to follow the diet at home	Assessed at baseline, 6 and 12 months: Plasma lipids, hormone assays, BMI, WC, HC, dietary compliance Also to be assessed: Associations with breast cancer risk (not published)	Preliminary results: At 6 months, significant intervention reduction in weight and total cholesterol and improved feeling of well-being. At 12 months, excellent compliance with diets (85% of intervention and 81% of control groups).
Goulet <i>et al.</i> (2003)	French-Canadian healthy women (<i>n</i> 73; 73 intervention, mean age=46.8 years)	Single group, pre-test post-test intervention trial; Mediterranean diet advice	Group and individual sessions, cooking lessons to promote the Mediterranean diet	Assessed at baseline, 6 and 12 weeks: Primary: Plasma lipids and body weight Secondary: Dietary adherence through 11-scale MDS, based on the 11 components of the Mediterranean diet pyramid	At 6 weeks, significant intervention increase in total MDS (28.6 v. 21.1, $P<.0001$), reductions in total cholesterol (5.08 v. 5.21 mmol/l, $P<.050$), apolipoprotein B (0.93 v. 0.98 g/l, $P<.0001$), body weight (67.3 v. 67.7 kg, $P<.010$) and BMI (25.7 v. 25.8 kg/m ² , $P<.050$), compared with baseline. Changes remained significant at 12 weeks, apart from total cholesterol.

2.2.1. Tertiary prevention intervention trials

Eight tertiary prevention trials were identified, conducted in France, India, Italy, Denmark, Sweden and the United States, that used the Mediterranean diet recommendations as an intervention strategy, in order to prevent recurrence or improve quality of life in individuals with established chronic disease (Table 2.9). These studies differ in several characteristics that make comparisons of findings difficult to undertake. In particular:

- **Sample size and characteristics:** Sample sizes varied from 41 (Salen *et al.* 1994) to 11,323 (Barzi *et al.* 2003), with three studies including between 500 and 1,000 participants (Singh *et al.* 1992c; de Lorgeril *et al.* 1994; Singh *et al.* 2002b). Participants were, on average, approximately 55 years of age. Inclusion criteria differed slightly between the studies. Salen *et al.* (1994) recruited heart transplant recipients, whereas five studies recruited individuals with documented heart disease, as established by the presence of angina pectoris and/or recent myocardial infarction (within 1-2 days) (Singh *et al.* 1992c), recent/remote myocardial infarction (ranging from within three to within six months) (de Lorgeril *et al.* 1994; Barzi *et al.* 2003), or a combination of angina pectoris, myocardial infarction and surrogate heart disease risk factors (Singh *et al.* 2002b; Søndergaard *et al.* 2003). In addition, one study recruited patients with rheumatoid arthritis (Skoldstam *et al.* 2003) and one was carried out among patients with type 2 diabetes (Toobert *et al.* 2003).
- **Type and length of intervention and follow-up periods:** Five studies used individual counselling as their strategy to promote the Mediterranean diet (Singh *et al.* 1992a; Singh *et al.* 1992b; Singh *et al.* 1992c; de Lorgeril *et al.* 1994; Salen *et al.* 1994; de Lorgeril *et al.* 1996; Singh *et al.* 2002b; Søndergaard *et al.* 2003). In the remaining studies, advice was provided via a short leaflet (Barzi *et al.* 2003), group sessions (Toobert *et al.* 2003) and group sessions in combination with phone counselling (Skoldstam *et al.* 2003). In the study by Søndergaard *et al.* (2003), the Mediterranean diet (along with statin treatment) was compared with a “heart-healthy diet” booklet (along with statin treatment), whereas the study by Toobert *et al.* (2003) was a multi-component intervention, providing additional advice on physical activity and smoking cessation. In the studies not providing individual counselling, intervention periods were six weeks (Skoldstam *et al.* 2003) and six months (Barzi *et al.* 2003; Toobert *et al.* 2003). Six studies reported follow-up periods, which ranged from 12 weeks (Skoldstam *et al.* 2003) to 6.5 years (Barzi *et al.* 2003). In the studies providing individual dietary counselling, this was offered at every assessment during the intervention and follow-up periods. This resulted in the following number of sessions participants attended in each study: three sessions over two years (Singh *et al.*

2002b), four sessions over one year (Singh *et al.* 1992c), five sessions over four years (de Lorgeril *et al.* 1994) and six sessions over one year (Salen *et al.* 1994). No follow-up period was reported in the study by S ndergaard *et al.* (2003), where dietary counselling was provided every three months over a 1-year period.

- Comparison groups: Two studies had a single group, pre-test post-test evaluation design (Salen *et al.* 1994; Barzi *et al.* 2003). Three studies compared the Mediterranean diet with the reduced-fat diet (step I NCEP) of the American Heart Association (Singh *et al.* 1992c; de Lorgeril *et al.* 1994; Singh *et al.* 2002b). In the remaining studies, the Mediterranean diet was compared with a “heart-healthy diet” booklet (S ndergaard *et al.* 2003), a low-fat diet (Toobert *et al.* 2003) and usual diet (Skoldstam *et al.* 2003).
- Outcome measures: Two studies assessed platelet aggregation and plasma lipid levels (Salen *et al.* 1994) and endothelial function (S ndergaard *et al.* 2003) as primary outcomes. Four studies assessed the impact of the Mediterranean diet on all-cause mortality (Barzi *et al.* 2003), cardiac disease morbidity and mortality (Singh *et al.* 1992c), myocardial infarction recurrence, sudden cardiac death or a combination of these events (Singh *et al.* 2002b), and a combination of cardiac deaths and non-fatal myocardial infarction, along with unstable angina, heart failure, stroke and embolism, as well as minor cardiac events (de Lorgeril *et al.* 1994). The latter study also assessed occurrence of malignant and non-malignant tumours, as well as overall survival (de Lorgeril *et al.* 1998). With the exception of the study by Toobert *et al.* (2003), all studies assessed dietary adherence, whereas five studies aimed to result in favourable blood lipid levels (Singh *et al.* 1992c; de Lorgeril *et al.* 1994; Singh *et al.* 2002b; S ndergaard *et al.* 2003; Toobert *et al.* 2003). In addition, blood glucose levels were assessed by three studies (Singh *et al.* 1992c; Singh *et al.* 2002b; Toobert *et al.* 2003), whereas four studies measured blood pressure and body mass index (BMI) (Singh *et al.* 1992c; de Lorgeril *et al.* 1994; Singh *et al.* 2002b; Toobert *et al.* 2003). In addition, two studies assessed blood levels of antioxidant vitamins (de Lorgeril *et al.* 1994; Skoldstam *et al.* 2003) and fatty acids (de Lorgeril *et al.* 1994; Toobert *et al.* 2003).
- Type of dietary assessment instruments: In order to assess dietary adherence, two studies used a combination of 24-hour recall and 7-day food records (Singh *et al.* 1992c; Singh *et al.* 2002b), one study used 24-hour recall records (Salen *et al.* 1994) and one study used a food frequency questionnaire (Barzi *et al.* 2003). The remaining studies used a combination of 24-hour recall records and either food frequency questionnaires (de Lorgeril *et al.* 1994) or 4-day food records (S ndergaard *et al.* 2003), whereas one study used a combination of food frequency questionnaires and diet history interviews (Hagfors *et al.* 2003).

The findings from the tertiary prevention trials justify and provide an explanation for the epidemiologic evidence associating lower mortality from heart disease and cancer, as well as longevity, with the Mediterranean diet. Perhaps the most important finding is the reduction in overall mortality rates, as evidenced by two studies (de Lorgeril *et al.* 1999; Barzi *et al.* 2003). Participants who followed the Mediterranean diet also displayed significantly lower incidence of cardiac events and recurrent myocardial infarction, as well as lower rates of cardiovascular and coronary heart disease mortality, compared with participants who followed the 'standard care' low-fat diet, based on recommendations of the American Heart Association. Compared with the latter diet, the Mediterranean diet was also more protective against the occurrence of cancer events (de Lorgeril *et al.* 1998). These findings suggest that the health benefits enjoyed by populations living in Mediterranean countries in the 1960s (Keys, 1970) are transferable to non-Mediterranean populations forty years later.

Consistent favourable effects were also reported for blood glucose (Singh *et al.* 1992c; Singh *et al.* 2002b; Toobert *et al.* 2003), endothelial function (Søndergaard *et al.* 2003), as well as blood levels of antioxidant vitamins (de Lorgeril *et al.* 1994) and fatty acids (de Lorgeril *et al.* 1994; Toobert *et al.* 2003). Three of the four studies assessing body mass index and blood pressure (Singh *et al.* 1992c; Singh *et al.* 2002b; Toobert *et al.* 2003), as well as four of the six studies assessing blood lipid levels (Singh *et al.* 1992c; Salen *et al.* 1994; Singh *et al.* 2002b; Søndergaard *et al.* 2003) reported a significant favourable impact among participants in the intervention group. The Mediterranean diet also resulted in additional beneficial outcomes, such as improved quality of life (Skoldstam *et al.* 2003; Toobert *et al.* 2003) and increased physical function and reduced disease activity in arthritis (Skoldstam *et al.* 2003). All studies assessing dietary intake reported excellent adherence with the Mediterranean diet, even after long follow-up periods (Renaud *et al.* 1995; Barzi *et al.* 2003), suggesting that this is not only a healthy eating pattern, but also a palatable, purportedly easy to follow diet.

Individuals participating in tertiary prevention trials have already established chronic disease, and are therefore highly motivated patients, who are likely to be willing to comply with the requirements of such studies (Hakim, 1998). Nevertheless, de Lorgeril *et al.* reported that less than half of participants in their intervention group provided dietary data at the 4-year follow-up assessment (Kris-Etherton *et al.* 2001). Although the improvement in plasma fatty acid composition in this study suggested that adherence to the Mediterranean diet was sustained, and intention-to-treat analyses were conducted to deal with missing data, long-term dietary adherence still needs to be confirmed. In addition, due to their condition, participants in the control arm of tertiary prevention trials might make favourable changes to their eating habits, irrespective of the

intervention approach evaluated (Singh *et al.* 1992c). If this is the case however, the Mediterranean diet can be considered as extremely beneficial, since it outperformed the comparison diets in the majority of outcomes assessed. In addition, although in most studies participants in the intervention group already consumed a relatively healthy diet, due to their condition, more improvement was reported (Salen *et al.* 1994).

Considering the possible beneficial effects of the Mediterranean diet, it is important to establish the best approach to deliver Mediterranean diet advice to patients already suffering or under treatment for chronic disease, in order to ensure continuing compliance with this dietary pattern. Barzi *et al.* (2003) for example, showed that effective advice can be provided via simple printed materials (i.e. a leaflet), which would certainly be a less time-consuming approach, compared with face-to-face counselling. This however, needs to be examined further.

2.2.2. Secondary prevention intervention trials

Four secondary prevention trials were identified, conducted in the United States, Italy and Finland, that promoted the Mediterranean diet to individuals with increased risk for developing chronic disease (Table 2.10). These studies have several differences. In particular:

- Sample size and characteristics: Sample sizes varied from 101 (McManus *et al.* 2001) to 180 (Esposito *et al.* 2004). Participants were, on average, approximately 43 years of age. Inclusion criteria differed slightly between the studies. Two studies were conducted among overweight/obese adults (McManus *et al.* 2001; Esposito *et al.* 2003), one among hypercholesterolemic adults (Jula *et al.* 2002), whereas one study recruited individuals with the metabolic syndrome (Esposito *et al.* 2004).
- Type and length of intervention and follow-up periods: Two studies used individual counselling as their strategy to promote the Mediterranean diet (Esposito *et al.* 2003; Esposito *et al.* 2004), whereas one study used group sessions (McManus *et al.* 2001) and one used a combination of interpersonal and group counselling (Jula *et al.* 2002). Three studies were multi-component interventions, providing additional advice on physical activity (McManus *et al.* 2001; Esposito *et al.* 2003; Esposito *et al.* 2004). Intervention periods ranged from 12 weeks (Jula *et al.* 2002) to two years (Esposito *et al.* 2003; Esposito *et al.* 2004). Only one study reported a follow-up assessment period of 18 months (McManus *et al.* 2001).
- Comparison groups: Two studies compared the Mediterranean diet with general healthy eating and physical activity advice (Esposito *et al.* 2003; Esposito *et al.* 2004) and one with

a low-fat diet (McManus *et al.* 2001). In the study by Jula *et al.* (2002), the Mediterranean diet (along with simvastatin or placebo treatment) was compared with usual diet (along with simvastatin or placebo treatment).

- Outcome measures: All studies assessed dietary adherence. Three studies assessed blood lipids (Jula *et al.* 2002; Esposito *et al.* 2003; Esposito *et al.* 2004), three assessed anthropometric variables (McManus *et al.* 2001; Esposito *et al.* 2003; Esposito *et al.* 2004), one assessed blood antioxidant (Jula *et al.* 2002) and fatty acid (Esposito *et al.* 2003) levels and three assessed blood glucose levels and/or insulin resistance (Jula *et al.* 2002; Esposito *et al.* 2003; Esposito *et al.* 2004). Primary and secondary outcomes however, varied greatly across the studies.
- Type of dietary assessment instruments: In order to assess dietary adherence, studies used 3-day food records (Esposito *et al.* 2003; Esposito *et al.* 2004), food frequency questionnaires (McManus *et al.* 2001) and 7-day food records (Jula *et al.* 2002).

Despite the different goals of the secondary prevention trials reviewed, promoting the Mediterranean diet appeared to have a favourable impact on most of the biological outcomes each study assessed. Consistent findings were reported concerning reductions in body weight (McManus *et al.* 2001; Esposito *et al.* 2003; Esposito *et al.* 2004). Two of the three studies assessing blood glucose/insulin resistance (Jula *et al.* 2002; Esposito *et al.* 2004) and one of the three studies assessing blood lipid levels (Jula *et al.* 2002) found beneficial effects of the Mediterranean diet. Favourable changes were also reported for plasma fatty acids (Esposito *et al.* 2003). In the study by Jula *et al.* (2002), the Mediterranean diet added to the cholesterol-lowering impact of simvastatin, while at the same time preserved antioxidant levels, thereby showing potential for additional favourable impact even on individuals under pharmacological treatment. In addition, the studies assessing dietary intake reported that participants in the intervention group had generally made favourable changes to their diets, compared with participants in the control conditions. The Mediterranean diet also resulted in additional beneficial outcomes, such as reduced vascular inflammation (Esposito *et al.* 2003; Esposito *et al.* 2004) and improved endothelial function (Esposito *et al.* 2004).

As evidenced by these secondary prevention trials, the Mediterranean diet has apparent beneficial effects on chronic disease risk factors. However, as in tertiary prevention, participants in secondary prevention trials are high-risk individuals, who are likely to be motivated to change their diets and comply with study requirements (Hakim, 1998). Nevertheless, with recruitment restricted to individuals with high risk of developing chronic disease, secondary prevention trials are useful in promoting the Mediterranean diet in order to eliminate disease promoting factors, since relatively

small numbers of participants and therefore low costs are required to demonstrate potential effects (Hakim, 1998; Leaf, 1999).

Longer intervention trials and with longer follow-up periods are also needed, in order to examine the long-term efficacy of the Mediterranean diet on chronic disease risk factors. With only one study in this review reporting follow-up periods however, it is not sure whether adherence to the Mediterranean diet, and therefore beneficial impact on biological outcomes, would continue in the long-term. Esposito *et al.* (2003, 2004) demonstrated beneficial dietary changes and biological effects of this dietary pattern at 2 years, showing potential for long-term compliance and health benefits. Their approach however, was a relatively intensive intervention of monthly individual counselling sessions over the first year, conducted every two months thereafter.

Considering the need for long duration of intervention and follow-up periods (Esposito *et al.* 2003), as well as the possible time burden on both health professionals and patients, the question remains as to whether findings from secondary prevention trials are applicable to the general population (Hakim, 1998), as well as how costly and cost-effective such programmes would be in the real-life situation of providing counselling in a clinical setting, to the large number of individuals who require such advice.

2.2.3 Primary prevention intervention trials

Three primary prevention trials were identified, conducted in the United Kingdom, Italy and France, that promoted the Mediterranean diet to healthy individuals (Table 2.11). These studies differ in several characteristics that make comparisons of findings difficult to undertake. In particular:

- Sample size and characteristics: Sample sizes varied from 56 (Singh *et al.* 2002a) to 113 (Castagnetta *et al.* 2002). Participants were, on average, approximately 57 years of age.
- Type and length of intervention and follow-up periods: Two of the studies reported a 6-week (Singh *et al.* 2002a; Goulet *et al.* 2003), and one a 6-month (Castagnetta *et al.* 2002) intervention periods. The methods used to promote the Mediterranean diet were weekly cooking sessions (Castagnetta *et al.* 2002) and group and individual counselling (Goulet *et al.* 2003). Singh *et al.* (2002a) asked participants to eat in a Mediterranean style and increase their intake of fruits and vegetables by 3 servings/day, but did not specify how this advice was provided. Two of the studies reported follow-up periods, which were 12 weeks (Goulet *et al.* 2003) and 12 months (Castagnetta *et al.* 2002).

- Comparison groups: One study had a single group, pre-test post-test evaluation design (Goulet *et al.* 2003) and one study recruited a control group, who were advised to increase their fruit and vegetable intake to the 400g recommendation of the World Health Organisation (Castagnetta *et al.* 2002). In the third study, the Mediterranean diet was compared with a double-blind control condition of either vitamin C supplements or placebo (Singh *et al.* 2002a).
- Outcome measures: All studies assessed plasma lipids and BMI, whereas dietary adherence was assessed by two studies (Castagnetta *et al.* 2002; Goulet *et al.* 2003). Primary outcomes in the study by Singh *et al.* (2002a) were vascular function and plasma vitamin C levels.
- Type of dietary assessment instruments: The two studies assessing dietary adherence used a food frequency questionnaire (Goulet *et al.* 2003) and a combination of a food frequency questionnaire and a 24-hour recall record (Castagnetta *et al.* 2002).

Despite the differences in outcome measures and the methods used to assess dietary compliance, these primary prevention studies suggest that promoting the Mediterranean diet to healthy people has some beneficial impact, particularly concerning reductions in body weight and blood lipid levels (Castagnetta *et al.* 2002; Goulet *et al.* 2003), as well as improvement in vascular function (Singh *et al.* 2002a).

The number of studies promoting the Mediterranean diet to healthy individuals is too small however, to draw conclusions on the potential of this dietary pattern in preventing chronic disease. This is not surprising, considering that primary prevention trials are designed to prevent initiation of disease. They therefore require a large sample size, long intervention and long follow-up periods, due to the lower disease risk status of healthy population groups (Hakim, 1998). This requirement is likely to result in a high investment in time and monetary resources, as well as high programme attrition rates, since healthy individuals are not always as motivated as people with high risk of developing chronic disease. In addition, primary prevention, as all intervention trials, relies on sustained dietary adherence over long time periods, in order to examine the effect of a dietary pattern or specific food components on the development of chronic disease (Willett, 1994; Hakim, 1998). Castagnetta *et al.* (2002) reported excellent compliance with the Mediterranean diet at 1-year follow-up, but their study was conducted in a Mediterranean population. Despite recent changes in the dietary habits of Mediterranean people towards the adoption of more westernised cuisines (Renaud *et al.* 1995; Trichopoulou *et al.* 1995a), Mediterranean populations are more familiar with this traditional diet, which might increase continuing adherence once proper advice, demonstrations and counselling are provided. On the other hand, Goulet *et al.* (2003) found that the Mediterranean

diet is transferable to healthy Canadian women, but with a follow-up period of 12 weeks it is difficult to determine whether adherence would be sustained in the long-term.

The importance of the Mediterranean diet as a preventive measure against the development and/or recurrence of chronic disease, as well as the need for development of methods to promote this eating pattern, whether in clinical settings, among high-risk individuals or the general population, have been well emphasised (Kris-Etherton *et al.* 2001). In addition, adherence to this dietary pattern could be sustained in the long-term, because it's easy to follow, purportedly palatable and practically inexpensive (Azevedo, 1999). As the researchers of the Lyon Diet Heart Study comment, 'no deleterious effects are likely and in view of the frequency and severity of most cancers and the cardioprotective effect of this diet, there is no convincing argument against such a prudent attitude' (de Lorgeril *et al.* 1998).

Individual or group counselling intervention programmes promoting the Mediterranean diet however, will have minimal impact if they only reach a small proportion of the population of interest (Haire-Joshu *et al.* 2003). The question remains therefore, as to how nutrition intervention trials can become effective at communicating dietary advice and sustaining compliance with such advice, in order to produce longer-term dietary modifications that would decrease chronic disease risk.

2.3 Tailored-feedback nutrition interventions

2.3.1. Rationale

Despite the effect of dietary interventions and individual and/or group counselling in promoting dietary change (Contento *et al.* 1995), studies employing such an approach present additional weaknesses that should be accounted for when designing and implementing nutrition intervention programmes. In particular, health professionals and general practitioners often lack the time, nutrition knowledge and behavioural counselling skills required to assist the great number of individuals requesting dietary advice (Hiddink *et al.* 1995; Prochaska *et al.* 2000; Hunt *et al.* 2001; Anderson *et al.* 2003). Face-to-face counselling can also be time-consuming and costly for many people, who may be unable or unwilling to attend clinic-based appointments and might prefer to access such services from home (Jeffery & Gerber, 1982; Ramelson *et al.* 1999; Velicer & Prochaska, 1999; Prochaska *et al.* 2000). Additionally, it would be extremely time-consuming and costly for group education programmes to account for psychosocial characteristics and motivational stage of behaviour change of each individual participating, possibly making it difficult for any

positive changes to last in the long-term (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1998; Velicer & Prochaska, 1999; Brug & Van Assema, 2000; Brug *et al.* 2003).

A lower-cost, and with wider reach, alternative to individual and group nutrition education could be presented by targeting printed materials (e.g. leaflets, brochures etc.) to specific population groups, according to socio-demographic characteristics or disease risk factors of each group. However, Kreuter *et al.* (1999b) comment that such an “one-size-fits-all” approach of delivering nutrition education cannot take into account the unique characteristics of each individual that are responsible for health-related behaviours.

Considering the limitations of these approaches, it is important to identify effective and feasible intervention techniques that will address each individual’s specific characteristics in order to promote dietary behaviour change, while at the same time overcome the barriers of face-to-face and group counselling, as well as those of interventions involving mass-produced printed materials.

2.3.2. Computer-tailoring

A relatively new, time- and possibly cost-effective approach to deliver nutrition education is the provision of personalised feedback, tailored to an individual’s specific behaviours and factors that may affect these behaviours (Brug *et al.* 1999a; Dijkstra & De Vries, 1999; Skinner *et al.* 1999). In recent years, this approach has been used to develop computer-tailored interventions, in order to promote a variety of behaviour changes, including dietary change (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1998), weight loss (Kreuter *et al.* 1999a; Kreuter *et al.* 2000), smoking cessation (Dijkstra *et al.* 1999; Strecher, 1999; Velicer & Prochaska, 1999; Lennox *et al.* 2001) and physical activity (Bull *et al.* 1999a; Bull *et al.* 1999b). Computers have also been used to provide tailored health education for cancer (Jones *et al.* 1999) and asthma (Osman *et al.* 1994) patients, as well as to enhance participation in mammography screening (Skinner *et al.* 1994; Rakowski *et al.* 1998) and health risk appraisal (Kreuter & Strecher, 1996) programmes.

Computer-tailored nutrition interventions, in particular, provide people with personalised feedback that is tailored to their dietary behaviours and specific characteristics, such as beliefs, attitudes, self-efficacy skills, perceived barriers and intentions that are related to those behaviours (Brug *et al.* 1996; Brug *et al.* 1998; Brug *et al.* 1999a; Brug *et al.* 1999b; Oenema *et al.* 2001). Such interventions also suggest ways of changing dietary behaviours that are potentially health threatening or maintaining eating habits that are beneficial for health. To provide people with computer-tailored nutrition feedback, individuals are first interviewed/surveyed using appropriate questionnaires and their answers are entered, either manually or interactively, into a data file. This

data file contains all the nutrition education messages that may be needed in order to develop an individual treatment plan that informs the individual of the need to change and the possible ways to change harmful eating habits, or the ways to maintain healthy eating behaviours. Feedback information is then delivered through an algorithm that selects the messages tailored to the specific needs of the individual, according to the answers provided in the tailoring questionnaire. Tailored feedback information is usually distributed by means of printed materials, such as a personalised letter, newsletter or magazine, which can be delivered by regular post (Brug *et al.* 1996; Brug *et al.* 1999b; De Vries & Brug, 1999; Lutz *et al.* 1999; Campbell *et al.* 2002; Brug *et al.* 2003). By using this approach, different types of feedback can be provided, including personal (based on answers provided), normative (comparing personal behaviours with those of a comparable in characteristics population group or with current recommendations) and ipsative/iterative (comparing most recent status with status at previous assessments) feedback (Brug *et al.* 1998; De Vries & Brug, 1999; Vandelanotte *et al.* 2005).

2.3.3. Benefits of computer-tailoring

Information that is communicated through computer-tailoring imitates advice provided by interpersonal nutrition counselling, since it refers to an individual's personal characteristics, needs, beliefs and attitudes (Brug *et al.* 1998; Brug *et al.* 1999a; Brug *et al.* 1999b; Brug & Van Assema, 2000; Brug *et al.* 2003). Although computer tailoring lacks the direct social support and interactivity of interpersonal counselling (Brug *et al.* 1999a; Kreuter *et al.* 1999b; Oenema *et al.* 2001), it is suggested to be less expensive and less time consuming, since it does not require individual or group sessions and thus it can easily access large and diverse population groups (Skinner *et al.* 1993; Abrams *et al.* 1999; Velicer & Prochaska, 1999; Brug & Van Assema, 2000) and be practical for long-term use (Ramelson *et al.* 1999). In addition, the ongoing improvement of information technology systems makes it possible for novel applications to be developed, where an individual provides answers to a questionnaire directly into a computer and feedback is provided automatically on the computer screen (Anderson *et al.* 2001; Vandelanotte *et al.* 2004; Vandelanotte *et al.* 2005), thereby increasing the interactivity of the tailoring procedure. Use of computers for screening individuals, particularly about sensitive topics, might also produce more honest answers than in a personal interview and therefore increase the accuracy of the feedback provided (Locke *et al.* 1992; Paperny, 1997; McRoy *et al.* 1998; Marsden & Jones, 2001). Regarding health assessment about topics like substance abuse for example, Paperny (1997) showed that adolescents found it easier to talk honestly when the assessment was carried out by a computerised system than a person.

Computer-tailored feedback is also suggested to be more effective in promoting dietary change compared with general, non-tailored printed materials, such as general healthy-eating brochures, since tailored information is more relevant to an individual's personal behaviours and characteristics and therefore, possibly less redundant (Brug *et al.* 1998; Brug *et al.* 1999a). Thus, tailored messages are more likely to be read, remembered and discussed with others (Skinner *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1998; Kreuter *et al.* 1999a), as well as processed more intensively (Kreuter *et al.* 1999a) than general nutrition information. In addition, computer tailoring allows individuals to compare their dietary intake with recommendations (Brug *et al.* 1999a), as well as compare their current health status with that of their peers or with their status at previous assessments (De Vries & Brug, 1999), which could not be achieved by mass-produced printed materials.

2.3.4. Examples of computer-tailored nutrition education

Computer-tailored nutrition interventions conducted to date have aimed at reducing total fat and/or saturated fat intake (Bowen *et al.* 1994; Raats *et al.* 1999; Brug & Van Assema, 2000; De Bourdeaudhuij & Brug, 2000; De Bourdeaudhuij *et al.* 2002; Vandelanotte *et al.* 2005), increasing fruit and vegetable consumption (Lutz *et al.* 1999; Baker & Wardle, 2002; Block *et al.* 2004) and increasing dietary fibre intake (Brinberg *et al.* 2000). Computer tailoring has also been applied to promote a combination of lower fat and higher fruit and vegetable intake (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1998; Brug *et al.* 1999b; Stevens *et al.* 2002; Campbell *et al.* 2004), to promote healthy dietary patterns (Delichatsios *et al.* 2001a; Hunt *et al.* 2001) and to alter food shoppers' purchases towards nutritional guidelines (Winett *et al.* 1991b; Winett *et al.* 1997; Anderson *et al.* 2001). In addition, computer-tailored feedback has been used in combination with other intervention approaches, such as group/individual sessions, health risk appraisal or self-help materials (Kreuter & Strecher, 1996; Glasgow *et al.* 1997; Greene & Rossi, 1998; Havas *et al.* 1998; Marcus *et al.* 1998; Campbell *et al.* 1999; Bemelmans *et al.* 2000; Kristal *et al.* 2000; Siero *et al.* 2000; Calfas *et al.* 2002; Campbell *et al.* 2002; Havas *et al.* 2003).

2.3.5. Use of behaviour change theories in tailored nutrition education

Despite the varying outcome measures and different methods employed by tailored interventions (e.g. differences in population groups and settings targeted etc.), all studies that have used tailored feedback as a nutrition intervention strategy have been based on established theories of health-related behaviour change, in order to develop tailored messages and achieve the behavioural outcome of interest (Kreuter *et al.* 1999b). This is because the provision of dietary feedback alone

(e.g. providing information on current dietary intake) will make it unlikely for behaviour change to take place, since individuals do not always have the knowledge or skills to implement recommendations (Winett *et al.* 1999; Brinberg *et al.* 2000). In contrast, behavioural therapy can help explain an individual's behaviour (Veverka *et al.* 2003). Therefore, when additional, theory-based information, tailored to personal intentions, beliefs, knowledge structure, needs and attitudes of individuals, is provided, it is more likely to be evaluated positively and be effective in changing behaviours (Winett *et al.* 1991b; Campbell *et al.* 1994; Brug *et al.* 1996; Kreuter & Strecher, 1996; Winett *et al.* 1997; Brug *et al.* 1998; Brug *et al.* 1999a; Brug *et al.* 1999b; Brinberg *et al.* 2000; Brug & Van Assema, 2000; Anderson *et al.* 2001).

The major theoretical models that have been utilised in tailored nutrition interventions, in order to provide psychosocial tailored feedback and strategies to promote dietary behaviour change, will be briefly described in the following section of this chapter.

2.3.5.1. *Elaboration Likelihood Model*

The major concept of tailored feedback interventions is that people are more likely to actively and thoughtfully process information if they perceive it as personally relevant (Petty & Cacioppo, 1986).

Based on the Elaboration Likelihood Model, tailored feedback can help eliminate redundant information, therefore only providing information that is personally relevant. This increases the likelihood of recipients paying attention to the information, which will, in turn, increase the likelihood of considering changing the behaviour of interest. It is also more likely that personally relevant information will be retained longer, increase motivation and help acquire the skills necessary to enact and sustain behaviour change (Brug *et al.* 1999a; Kreuter *et al.* 1999b).

2.3.5.2. *Transtheoretical Model*

One of the most widely used theories for describing the process of behaviour change is based on the Transtheoretical Model (Prochaska *et al.* 1992). According to this model, and in order to adopt or change a health-related behaviour, people move through a series of stages of commitment to change this behaviour. The stages involved in this process include precontemplation (no intention to change in the foreseeable future/within the next six months), contemplation (intention to change within the next six months, but not within the next 30 days), preparation (intention to change within the next 30 days and sometimes attempts have been made in the recent past), action (recent change/currently enacting the behaviour) and maintenance (sustaining the behaviour for at least 6 months after

modification has started). Regression (i.e. reversal to an earlier stage of change) and relapse (i.e. regression from action or maintenance to an earlier stage) are also considered as stages of change, since in many cases individuals move back rather than forward through the stages of change (Prochaska & Velicer, 1997).

Movement along the stages is facilitated by changes in a number of psychosocial determinants that affect the decision to change a behaviour (Skinner *et al.* 1994). These include the processes of change, decisional balance, self-efficacy and temptations (Velicer & Prochaska, 1999).

The processes of change are cognitive and behavioural strategies that people use to facilitate behaviour change. Cognitive strategies are important in the early stages of behaviour change and include consciousness-raising (increasing awareness of risk behaviours), dramatic relief (increasing emotional experience regarding risk behaviour), self-reevaluation (personal evaluation of the risk behaviour), environmental reevaluation (how the behaviour affects others) and self-liberation (belief and commitment to change behaviour). Behavioural strategies, important in the later stages of behaviour change, include helping relationships (enabling social support), reinforcement management (rewarding oneself for practicing new behaviour), social liberation (increasing social opportunities to practice new behaviour), counter-conditioning (acquiring skills to substitute risk behaviours with new behaviours) and stimulus control (remove prompts for risk behaviours and supporting new behaviours) (Prochaska *et al.* 1992; Prochaska & Velicer, 1997).

The decisional balance represents the relative strength of the positive (pros) against the negative (cons) aspects of the behaviour of interest and of adopting or changing this behaviour (Rakowski *et al.* 1998). The pros and cons denote some of the cognitive changes that are required for progress in the early stages of change (Prochaska *et al.* 1992).

Self-efficacy signifies the confidence in the ability to enact and sustain a behaviour in challenging situations, whereas temptations involve an assessment of how tempted an individual would be to perform a risk behaviour in challenging situations. Self-efficacy usually increases and temptations decrease through the stages of change. These elements are important in the later stages of behaviour change and in predicting relapse in particular (Prochaska *et al.* 1992).

According to the Transtheoretical Model, behaviour change depends on doing the right things (processes of change) at the right time (stages of change) (Prochaska *et al.* 1992). Tailored feedback can help individuals progress along the stages by providing educational and motivational strategies for those in the earlier stages (precontemplation, contemplation, preparation), in order to raise awareness of personal behaviours, overcome perceived barriers, reinforce perceived benefits and

acquire practical skills to help adopt a behaviour. In contrast, behavioural strategies are provided to individuals in the later stages (action, maintenance), in order to reinforce already adopted behaviours, increase confidence, resist temptations and sustain favourable changes (Brug *et al.* 1998; Aveyard *et al.* 1999; Baker & Wardle, 2002; Shepherd, 2002).

2.3.5.3. *Social Cognitive Theory*

According to the Social Cognitive Theory (Bandura, 1986), adopting or changing a health-related behaviour is influenced by a combination of cognitive and behavioural factors, including the perceived benefits and barriers associated with behaviour change, the perceived social influences, attitudes, knowledge and beliefs about the behaviour of interest, goal-setting and self-monitoring, self-efficacy skills, as well as environmental factors (e.g. availability and costs) (Kristal *et al.* 2000; Revere & Dunbar, 2001; Havas *et al.* 2003). All these factors should be addressed in order to promote behaviour change.

Self-efficacy in particular, is a central component of the Social Cognitive Theory and an important predictor of behaviour change (Bandura, 1989; Brug *et al.* 1996). This part of the theory suggests that when people perceive they have increased confidence to perform a behaviour that will result in favourable outcome expectations, they are more likely to set challenging goals and commit to them, thereby also increasing their level of motivation towards and actual behaviour change. Therefore, 'it is partly on the basis of efficacy beliefs that people choose what challenges to undertake, how much effort to expend in the endeavor, how long to persevere in the face of obstacles and failures and whether failures are motivating or demoralising' (Bandura, 2001).

Based on this theory, tailored feedback can help increase perceived positive outcomes, decrease perceived negative outcomes and provide appropriate suggestions to increase self-efficacy skills in order to promote behaviour change (Dijkstra *et al.* 1999; Kreuter *et al.* 1999b; Anderson *et al.* 2001). In addition, and in keeping with the Social Cognitive Theory, individuals are encouraged to set small goals, which, when achieved, are reinforced to increase self-efficacy, in order to achieve gradual behaviour change (Demark-Wahnefried *et al.* 2003).

2.3.5.4. *Health Belief Model*

According to this model, an individual's likelihood of changing a behaviour is determined by the perceived personal risk and perceived outcome severity from practicing this behaviour, as well as the perceived benefits, barriers, and cues to action associated with behaviour change (Becker, 1974; Skinner *et al.* 1994). When the perceived susceptibility to an adverse health outcome associated

with a risk behaviour is high, and when the perceived benefits from changing this behaviour outweigh the perceived barriers to changing, people are more likely to take preventive measures in order to change this risk behaviour (Kreuter & Strecher, 1996).

Tailored feedback can help identify risk behaviours and their possible consequences, addresses the benefits to be expected from changing risk behaviours, identifies and reduces perceived barriers and suggests strategies in order to promote awareness and behaviour change (Kreuter *et al.* 1999b; Revere & Dunbar, 2001).

2.3.5.5. *Theory of Reasoned Action and Planned Behaviour*

According to the Theory of Reasoned Action, an individual's likelihood of changing a behaviour is determined by their intentions (i.e. motivation, willingness to attempt to change this behaviour), which in turn is determined by their attitudes (i.e. favourable or unfavourable evaluation of the behaviour) and social/subjective norms (i.e. the perceived social pressure to perform or not perform this behaviour) (Ajzen, 1991; Ajzen, 2001).

The Theory of Planned Behaviour extends the scope of the Theory of Reasoned Action to include perceived behavioural control (i.e. the perceived ease or difficulty of performing the behaviour of interest) as a determinant of behaviour change, which may or may not be mediated by intentions (Ajzen, 1991). Self-efficacy and controllability (i.e. the extent to which personal performance depends solely on the individual performer) are important components of perceived behavioural control (Ajzen, 2002). In addition, awareness of personal behaviour should be taken into account when applying the Theory of Planned Behaviour to promote behaviour change (Bogers *et al.* 2004).

In the case of nutrition interventions, people will be more likely to make dietary changes if they intend to make those changes, while the intention to change is more likely when positive attitudes and social norms, as well as perceived control over the dietary change are present (Ajzen, 1991). Tailored feedback can help increase intentions and improve attitudes, identifies and addresses the benefits to be expected from behaviour change and identifies and reduces perceived barriers. In addition, tailored feedback provides strategies to increase encouragement and approval from the social environment and increase self-efficacy skills and perceived control over a situation, in order to promote behaviour change (Revere & Dunbar, 2001).

2.3.5.6. *Precaution Adoption Process Model*

In order for individuals to move forward in the stages of change algorithm and achieve behaviour change, it is necessary for them to be aware of their risk behaviour (Oenema & Brug, 2003a). In the case of nutrition interventions, raising awareness of one's dietary intake would be the first step to dietary behaviour change, since lack of awareness is a major barrier to the motivation to change behaviours (Oenema *et al.* 2001; Oenema & Brug, 2003b).

According to the Precaution Adoption Process model, the decision to adopt a precaution measure (i.e. change a risk behaviour) is reached through a dynamic process that involves three cognitive stages (Weinstein, 1988). These include being aware of the risk associated with a particular behaviour, being aware of the prevalence of this behaviour and finally, being aware of personal engagement in this risk behaviour. In order for people to become fully aware of and become motivated to change this risk behaviour, they have to proceed through all three stages.

Based on this model, providing tailored feedback on personal dietary intake, as well as feedback on how one's intake compares with the intake of others, can help achieve the third stage of awareness (Oenema *et al.* 2001; Oenema & Brug, 2003b).

2.3.5.7. *Goal Setting Theory*

This theory suggests that, under certain conditions, individuals who set specific difficult goals will perform higher, regarding achievement of those goals, compared with setting a vague, non-quantitative goal (e.g. "do your best"), or setting no goals (Locke & Latham, 1990; Strecher *et al.* 1995; Lutz *et al.* 1999). In addition, breaking down difficult goals into smaller subgoals is suggested to further promote behaviour change (Strecher *et al.* 1995).

2.3.5.8. *Diet Individuation Model*

This model describes the process by which new foods are incorporated or eliminated from an individual's usual diet. According to this model, new foods are first added to the peripheral diet on a trial basis (e.g. eaten once per month or less frequently). The foods preferred are then incorporated in the core diet (eaten once per week or more often) and replace foods previously consumed. This process is achieved through several stages, which include "dietary expansion", "inclusion" and "variation", followed by "substitution", "replacement" and "stabilisation" (Bennett *et al.* 1943), cited in (Kristal *et al.* 2000).

2.3.5.9. Behavioural Alternatives Model

The Behavioural Alternatives Model attempts to describe the process of consumer choice and decision making. According to this model, individuals select a number of different behavioural alternatives based on their attitudes towards them, which in turn are the result of how these alternatives are evaluated. In the case of dietary behaviour change, the model describes individuals' attitudes towards different foods, the selection of which depends on these foods' perceived attributes (e.g. good or bad), and specifies which foods are most likely to be selected from a set of alternative foods. Based on this model, tailored feedback on food substitutions can be provided to promote the dietary outcome of interest (Jaccard, 1981), cited in (Brinberg *et al.* 2000).

Tailored feedback interventions can influence behaviour change by changing the psychosocial determinants of behaviour, including knowledge, beliefs, attitudes, self-efficacy, stages of change and intentions (Dijkstra & De Vries, 1999). By using the appropriate theoretical framework, it is also more likely for tailored feedback messages to increase an individual's motivation and commitment towards changing the behaviour of interest. Further likelihood of behaviour change can be achieved if personal characteristics (e.g. socio-demographic characteristics) are taken into account, in order to approximate face-to-face counselling (Revere & Dunbar, 2001).

In addition, because behaviour change is accomplished gradually, it has been suggested that multiple feedback tailored at an individual's stage of change would be more effective than single feedback, since it would increase the accuracy of the information provided. For example, people who have moved from contemplation to preparation between two assessments should receive feedback information tailored on their new stage of change (Rakowski *et al.* 1998).

2.3.6. Tailored-feedback nutrition education studies

Thirty-four studies were identified, conducted in the Netherlands, United States, United Kingdom and Belgium, that have used tailored feedback, as the only intervention or as part of a multi-component intervention, in order to promote dietary behaviour change and/or influence psychosocial determinants of dietary behaviour. A summary of these studies, in order of year of publication, along with their methods and major findings is presented in Table 2.12.

Table 2.12 Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Winett <i>et al.</i> (1991a,b)	North American healthy adults, supermarket customers (<i>n</i> 77; 40 intervention, 37 control, mean age=40 years)	Randomised controlled trial; Interactive, touchscreen intervention with computer-generated tailored food purchase (in response to intended food purchases) and psychosocial feedback, compared with no intervention	Increasing intended and actual low-fat and high-fibre, and reducing high-fat and low-fibre content of food purchases (assessed via intended food purchases and food purchase receipts)	Computer prints	Stages of Change, Social Cognitive Theory, Health Belief Model, Goal setting	<p>At 8 weeks, significant intervention effect on purchases of high-fat meat (intended: 329 v. 655g, $P<.010$; actual: 789 v. 1,360 g, $P<.001$), high-fat dairy products (intended: 1,134 v. 3,050 g, $P<.010$; actual: 2,027 v. 3,217 g, $P<.050$), high-fibre grains/cereals (intended: 1,391 v. 911 g, $P<.010$; actual: 1,224 v. 1,004 g, $P<.010$) and percentage of calories from fat (intended: 35.0 v. 41.3%, $P<.010$; actual: 34.3 v. 39.5%, $P<.010$), compared with control group.</p> <p>At 1 month follow-up, significant intervention effect on purchases of low-fat dairy products (actual: 3,679 v. 2,841 g, $P<.050$), high-fat dairy products (actual: 1,781 v. 2,520 g, $P<.050$) and high-fibre grains/cereals (actual: 1,063 v. 813 g, $P<.050$).</p>

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Bowen <i>et al.</i> (1994)	North American healthy undergraduate students (<i>n</i> 162, mean age=20.8 years)	Single group, pre-test post-test intervention trial; Tailored dietary feedback (derived via FFQ) and nutrition education booklet	Effect of fat intake on intentions, self-efficacy and knowledge of recommendations	Personal letter	Social Cognitive Theory, Precaution Adoption model, Stages of Change	At 1 week (immediate impact), higher fat intake (36-40%) associated with negative emotional distress ($P<.050$) and lower knowledge of high-fat foods ($P<.005$), compared with lower fat intake. At 1 month post-feedback (delayed impact), highest fat intake (>41%) inversely associated with intentions to reduce fat ($P<.010$).
Campbell <i>et al.</i> (1994)	North American adults, primary care patients (<i>n</i> 394; 134 tailored intervention group, 136 non-tailored intervention group, 124 control group, mean age=40.8 years)	Randomised controlled trial; Computer-tailored dietary (derived via food frequency instrument) and psychosocial feedback, compared with general nutrition information, and no intervention	Total and saturated fat reduction, increasing fruit and vegetable intake	Personal letters	Stages of Change, Health Belief Model	At 4 months, significant tailored intervention effect on total fat (-10.3 v. -1.3 g/d, $P=.033$) and saturated fat (-4.8 v. -0.5 g/d, $P=.036$) intake, compared with control group, but not with non-tailored intervention group. No effect on fruit and vegetable intake. Significant tailored intervention effect on message recall ($P<.0001$) and readership ($P<.050$).

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Brug <i>et al.</i> (1996)	Dutch healthy adults, employees of an oil company (<i>n</i> 347; 178 intervention, 169 control, mean age=39 years)	Randomised controlled trial; Computer-tailored dietary (derived via FFQ) and psychosocial feedback, compared with general nutrition information	Primary: Fat reduction, increasing fruit and vegetable intake Secondary: Improving attitudes, intentions, social influences and self-efficacy	Personal letters	Stages of Change, Theory of Planned Behaviour, Social Cognitive Theory, Precaution Adoption Process Model	At 3 weeks, significant intervention effect on fat intake (26.9 v. 27.2 points, $P<.010$), compared with control group. No effect on fruit and vegetable intake. Significant intervention effect on attitudes towards increasing fruits and vegetables (both $P<.010$) and intentions towards reducing fat and increasing fruit (both $P<.010$). Significant intervention effect on appreciation and use of feedback ($P<.010$).
Kreuter & Strecher (1996)	North American healthy adults, primary care patients (<i>n</i> 1317; 427 enhanced health risk appraisal feedback, 427 health risk appraisal feedback, 463 control, mean age=40 years)	Randomised controlled trial; Health risk appraisal and computer-tailored dietary (derived via FFQ) and psychosocial feedback, compared with health risk appraisal, and no intervention	Fat reduction	Personal letters	Stages of Change, Health Belief Model	At 6 months, enhanced health risk appraisal feedback effect on fat intake ($OR=1.84$, $P=.069$), compared with health risk appraisal and no-intervention groups combined.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Glasgow <i>et al.</i> (1997)	North American adults with type I or II diabetes, outpatients in medical office (<i>n</i> 206; 107 intervention, 96 control, mean age=62.4 years)	Randomised controlled trial; Brief, touchscreen computer-assisted intervention with tailored dietary (derived via FFQ and 4-day food records) and psychosocial feedback, individual counselling, motivational phone calls and self-help materials, compared with usual care	Improving dietary self-management and physiological outcomes (serum cholesterol and HbA _{1c} , BMI)	Computer print-out	Social Cognitive Theory, Goal setting	At 12 months follow-up, significant intervention effect on fat (-3.3 v. -0.9%, <i>P</i> =.023) and saturated fat (-1.5 v. -0.1%, <i>P</i> =.003) intake and serum cholesterol levels (-9 v. +3 mg/dl, <i>P</i> =.002), compared with control group. Significant intervention effect on patient satisfaction (<i>P</i> <.020).
Winett <i>et al.</i> (1997)	North American healthy adults, supermarket customers (<i>n</i> 105; 54 intervention, 51 control, median age=40 years)	Randomised controlled trial; Interactive, touchscreen intervention with computer-tailored psychosocial feedback and tailored food purchase coupons, compared with no intervention	Increasing low-fat, high-fibre and fruit and vegetable, and reducing high-fat and low-fibre content of food purchases (assessed via food purchase receipts)	Computer print-outs	Stages of Change, Social Cognitive Theory, Health Belief Model, Goal setting	At 8 weeks, significant intervention effect on content of food purchases: % of calories from fat (34.8 v. 39.4%, <i>P</i> <.010), fibre (7.48 v. 6.37 g/1000 kcal, <i>P</i> <.010) and fruits and vegetables (1.70 v. 1.36 servings/1000 kcal, <i>P</i> <.010), compared with control group. At 1 month follow-up, significant intervention effect on content of food purchases: % of calories from fat (32.7 v. 37.8%, <i>P</i> =.040), % of calories from fat from dairy foods (33.6 v. 47.6%, <i>P</i> =.001) and fibre (7.23 v. 6.19 g/1000 kcal, <i>P</i> <.010), compared with control group.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Brug <i>et al.</i> (1998)	Dutch healthy adults (<i>n</i> 646; 215 tailored and ipsative feedback, 211 tailored feedback, 220 control, mean age=44 years)	Randomised controlled trial; Computer-tailored dietary (derived via FFQ) and psychosocial feedback with ipsative feedback, compared with computer-tailored dietary (derived via FFQ) and psychosocial feedback, and general nutrition information	Fat reduction, increasing fruit and vegetable intake	Personal letters	Stages of Change, Theory of Planned Behaviour, Social Cognitive Theory, Precaution Adoption Process Model	<p>At 4 weeks, significant overall tailoring effect on fat (26.7 v. 28.3 points, $P<.001$), vegetable (1.13 v. 1.05 servings/d, $P<.001$) and fruit (2.33 v. 2.09, $P<.010$) intake, compared with control group.</p> <p>At 8 weeks, significant overall tailoring effect on fat (25.9 v. 27.5 points, $P=.001$), compared with control group.</p> <p>Significant tailored and ipsative feedback effect on vegetable (1.20 v. 1.08 servings/d, $P=.001$) and fruit (1.17 v. 1.06 servings/d, $P=.002$) intake, compared with control group.</p> <p>Significant tailoring and ipsative feedback effect on fat (25.6 v. 26.2 points, $P=.020$) and fruit (1.17 v. 1.10 servings/d, $P=.030$) intake, compared with tailored feedback group.</p> <p>Significant tailoring effect on appreciation and use of feedback ($P<.010$), but higher credibility of general information letters ($P<.010$).</p>

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Greene & Rossi (1998)	North American healthy non-smoking adults (<i>n</i> 296; 147 intervention, 149 control, mean age=46.4 years)	Randomised controlled trial; Tailored dietary feedback (derived via FFQ) and brief educational materials, compared with delayed intervention (provided at 12 months)	Primary: Fat reduction Secondary: Progressing in stages of change	Personal report	Stages of Change	At 6 months, significant tailoring effect on fat intake ($P<.001$) compared with control group, not sustained at 12 or 18 months. 9%, 12% and 24% of pre- and contemplators and preparators, respectively, progressed to the action stage by 18 months. Between 12 and 18 months, significant association of forward stage of change with reduction in fat intake ($P<.0001$).
Havas <i>et al.</i> (1998)	North American healthy women (<i>n</i> 3122; 1443 intervention, 1679 control, 67% <30 years)	Randomised trial; Group sessions, printed materials, visual reminders and tailored dietary (derived via food frequency instrument) and behavioural feedback, compared with 10min nutrition education	Primary: Increasing fruit and vegetable intake Secondary: Progressing in stages of change, improving knowledge of recommendations and attitudes, increasing self-efficacy and decreasing perceived barriers	Personal letters with tip sheets	Stages of Change, Social Cognitive Theory, Goal setting	At 2 months post-intervention, significant intervention effect on fruit and vegetable intake (+0.56 v. +0.13 servings/d, $P=.002$), compared with control group. Significant intervention effect on stages of change ($P=.003$), attitudes ($P=.003$), self-efficacy ($P=.0006$), knowledge ($P<.001$) and social support ($P=.002$). At 14 months post-intervention, significant intervention effect on fruit and vegetable intake (+0.83 v. +0.4 servings/d, $P=.004$), compared with control group.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Marcus <i>et al.</i> (1998)	North American healthy adults, callers to the Cancer Information Service, who did not seek diet and nutrition information as part of usual service (<i>n</i> 2118; 1054 intervention, 1064 control, 50% range 30-49 years, 22.1% \geq 60 years)	Randomised controlled trial; Brief tailored dietary (derived via short quiz) and behavioural feedback and tailored printed materials, compared with assessment only	Primary: Increasing fruit and vegetable intake Secondary: Improving predisposing and enabling psychosocial factors regarding fruit and vegetable intake	Telephone contacts, tailored letters and tailored printed materials	Transtheoretical Model, Theory of Reasoned Action, Health Belief Model, Social Cognitive Theory	Significant intervention increase in fruit and vegetable intake (+0.65 servings/d at 4 weeks, $P<.001$; +0.41 servings/d at 4 months, $P<.001$), compared with control group. No differences in psychosocial factors between groups. Significant intervention increase in % of participants aware of guidelines ($P=.003$) and trying to eat more fruits and vegetables ($P<.001$) at 4 weeks and 4 months, compared with control group. High intervention acceptability.
Brug <i>et al.</i> (1999b)	Dutch healthy adults, employees of a regional home care organisation (<i>n</i> 315; 152 experimental, 163 comparison, mean age=40 years)	Randomised controlled trial; Computer-tailored dietary (derived via FFQ) and psychosocial feedback (experimental), compared with computer-tailored dietary feedback (derived via FFQ) (comparison)	Primary: Fat reduction, increasing fruit and vegetable intake Secondary: Increasing intention to change diet	Personal letters	Stages of Change, Theory of Planned Behaviour, Social Cognitive Theory, Precaution Adoption Process Model	At 4 weeks, significant overall effect on fat (26.1 v. 27.0 points, $P<.010$), fruit (2.0 v. 1.6 servings/d, $P<.010$) and vegetable intake (0.9 v. 0.8 servings/d, $P<.010$, for participants with low baseline intake), compared with baseline. No differences in dietary intake between the groups. Significant experimental group effect on feedback being interesting ($P<.050$) and comprehensive ($P=.050$). Significant comparison group effect on changing fat intake due to the feedback ($P<.050$).

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Campbell <i>et al.</i> (1999a)	African-American rural adults, church members (n 459; 109 expert-oriented intervention, 108 pastor-oriented intervention, 242 control, 57.9% aged 38-65 years)	Randomised controlled trial; Scientific/expert-oriented computer-tailored dietary (derived via food frequency instrument and 3-day food records) and psychosocial information, compared with spiritual/pastor-oriented computer-tailored dietary (derived via food frequency instrument and 3-day food records) and psychosocial information, and no tailored information	Increasing fruit and vegetable intake (as part of a multi-component intervention including educational sessions, cooking classes, environmental interventions to increase fruit and vegetable availability at church and point-of-purchase)	Bulletins	Stages of Change, Health Belief Model, Theory of Reasoned Action	<p>At 1 year, significant pastor-oriented intervention effect on perceived message trustworthiness (63.5 v. 53.6%, $P<.050$) and perceived impact (58 v. 45%, $P=.020$), compared with expert-oriented intervention.</p> <p>Significantly higher trust in scientific research (48 v. 34%, $0<.001$) and lower trust in the pastor (31 v.45%, $P=.020$) as nutrition information sources reported by expert-oriented group, compared with pastor-oriented group.</p> <p>High message recall, similar between intervention groups.</p> <p>Significant overall intervention effect on F&V intake (+0.65 v. +0.00 servings/d, $P<.005$), compared with control group. No difference between the intervention groups.</p> <p>At 2 years, significant overall intervention effect on F&V intake (+0.8 servings/d, $P<.001$), compared with control group.</p>

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Lutz <i>et al.</i> (1999)	North American healthy adults, health maintenance ¹ organisation clients (<i>n</i> 573; 136 computer-tailoring, 146 computer-tailoring and goal setting, 140 non-tailoring, 151 control, mean age=39 years)	Randomised controlled trial; Computer-tailored dietary (derived via FFQ) and psychosocial feedback, compared with computer-tailored dietary (derived via FFQ) and psychosocial feedback with goal setting, non-tailored dietary feedback, and no intervention	Increasing daily intake and weekly variety of fruits and vegetables	Newsletters	Stages of Change, Social Cognitive Theory, Health Belief Model, Goal setting	At 6 months, significant effect of all newsletter groups on daily intake (+0.8 servings/d, $P<.002$) and variety scores (>1.5 kinds/week, $P=.001$), compared with control group. Non-significant trend of improved intake and variety with each added newsletter component. Significant effect of tailored and goal setting intervention on message recall ($P<.010$).
Raats <i>et al.</i> (1999)	UK healthy adults, University employees (<i>n</i> 113; 59 intervention, 54 control)	Randomised controlled trial; Computer-tailored dietary feedback (derived via 7-day food records), compared with no intervention	Fat reduction, improving attitudes	Personal letter	Theory of Planned Behaviour, Precaution Adoption Process Model	At 4 and 18 weeks, no intervention effect on fat intake or attitudes.

¹ A Health Maintenance Organisation is a private medical group that has the responsibility for providing all of the primary health care services to a company's employees.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Bemelmans <i>et al.</i> (2000, 2002, 2004)	Dutch hypercholesterol aemic adults with at least two other CVD risk factors [<i>n</i> 265; 103 intervention (52 receiving linoleic-acid rich and 51 receiving α -linolenic acid-rich margarine), 163 control (105 receiving linoleic-acid rich and 58 receiving α -linolenic acid-rich margarine), mean age=55 years]	Randomised controlled trial; Intensive group education, individualised tailored dietary feedback (derived via FFQ) intervention and nutritional guidelines (single-blinded) and linoleic-acid rich or α -linolenic acid-rich margarine (double-blinded), compared with general healthy eating leaflet (single-blinded) and linoleic-acid rich or α -linolenic acid-rich margarine (double-blinded)	Primary: Promoting the Mediterranean diet, reducing 10-year estimated rate of CVD events and deaths Secondary: Reducing levels of CVD risk factors and risk of CVD development	Personal letters	Theory of Planned Behaviour (for group education component only)	At 16 weeks, significant intervention effect on BMI (-0.06 v. +0.09 kg/m ²), compared with control group, not maintained at 1, 2 or 3 years. At 1 year, significant intervention effect on total fat (-2%), saturated fat (-0.9%), fruit (+39 v. -18 g/d), fish (+21 v. -1 g/d), poultry (+4 v. 0 g/d) and bread (+9 v. -8 g/d) (all <i>P</i> < .050), compared with control group. Favourable effect on saturated fat and fish intake maintained at 2 years. At 2 years, significant α -linolenic acid group effect on total:HDL-cholesterol ratio (+0.34, <i>P</i> < .001), triglycerides (+0.24 mmol/l, <i>P</i> = .030), HDL-cholesterol (-0.05 mmol/l, <i>P</i> = .040) and fibrinogen (-0.18 g/l, <i>P</i> = .001), compared with linoleic-acid group, not maintained at 3 years. At 3 years, significant intervention effect on total fat (-2%, <i>P</i> < .050), saturated fat (-1.2%, <i>P</i> < .010), fish (+12 v. +1 g/d, <i>P</i> < .010) and vegetables (+11 v. -10 g/d, <i>P</i> < .050), compared with control group. No difference in 10-year estimated CVD risk between the groups at 1, 2 or 3 years.
Brinberg <i>et al.</i> (2000)	North American healthy college students (<i>n</i> 133, mean age=21 years)	Randomised controlled trial; Tailored dietary (derived via FFQ) and behavioural feedback, compared with general message with tailored dietary feedback, general message with no dietary feedback, and no intervention	Increasing dietary fibre knowledge, improving food choices and increasing dietary fibre consumption	Brochure and nutrition educator	Behavioural Alternatives Model, Goal setting	At 6 months, significant tailored and behavioural intervention effect on fibre knowledge (<i>P</i> < .010), food choices (<i>P</i> < .010) and dietary fibre consumption (<i>P</i> < .010).

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Brug & van Assema (2000)	Dutch healthy adults, with low education and motivation to change (n 699; 459 intervention, 240 control, mean age=44.1 years)	Randomised controlled trial; Computer-tailored dietary (derived via FFQ) and psychosocial feedback, compared with general nutrition information	Primary: Progressing in stage of change regarding fat intake Secondary: Improving intentions	Printed letters	Stages of Change	<p>At 4 weeks, significant intervention effect on forward stage of change from pre-action (67 v. 48%, 95% CI=1.6-3.2) and precontemplation (29 v. 10%, 95% CI=1.5-2.9), compared with control group. No effect according to level of education.</p> <p>Among intervention group, participants in contemplation/preparation more likely to save feedback, think, eat and intend to eat differently because of feedback, eat less fat and rate feedback as relevant and credible, compared with participants in precontemplation or action/maintenance stage.</p> <p>Among intervention group, lower educated participants more likely to think differently and rate feedback as interesting and relevant, compared with medium or high level of education participants.</p>

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
De Bourdeaudhuij & Brug (2000)	Belgian healthy quartet families (both parents and two adolescents) [(n 140; 72 intervention (18 families), 68 control (17 families)]	Randomised controlled trial; Family-based manually-tailored dietary (derived via FFQ) and psychosocial feedback, compared with general nutrition information (both directed simultaneously at each family member)	Fat reduction, improving psychosocial determinants of fat intake	Personal letters	Precaution Adoption Process Model, Theory of Planned Behaviour, Social Cognitive Theory	<p>At 4 weeks, significant intervention effect on total fat (-2 v. -0.2%, $P<.050$) and saturated fat (-1.4 v. -0.1%, $P<.050$) intake when all family members were included, and total fat (-2.4 v. +2.4%, $P<.050$) and saturated fat (-1.6 v. +2.0%, $P<.005$) intake of mothers, compared with control group. No difference on intake of fathers and adolescents between the groups.</p> <p>Significant intervention effect on awareness of personal ($P<.010$) and family ($P<.005$) intake.</p> <p>Tailored intervention rated more personally relevant ($P<.005$) and novel ($P<.005$), but less credible ($P<.050$), was used more ($P<.050$) and increased intentions to change diet (69 v. 32%, $P<.001$), compared with control group.</p>

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Kristal <i>et al.</i> (2000)	North American healthy adults, members of a health maintenance organisation (<i>n</i> 1459; 729 intervention, 730 control, mean age=44.9 years))	Randomised controlled trial; Multi-tailored self-help intervention with computer-tailored dietary (derived via 24-hour recall and food frequency index) and behavioural feedback, compared with no intervention	Primary: Fat reduction, increasing fruit and vegetable intake Secondary: Weight changes, progressing in stages of change	Personal letter, self-help manual, tailored dietary change materials, behavioural feedback	Social Cognitive Theory, Stages of Change, Diet Individuation Model	At 3 months, significant intervention effect on fat (-0.09 v. -0.01 points, $P<.0001$) and fruit and vegetable (+0.41 v. +0.08 servings/d, $P<.0001$) intake, compared with control group. Significant intervention effect on stages of change ($P<.050$). At 12 months, significant intervention effect on fat (-0.09 v. -0.00 points, $P<.0001$) and fruit and vegetable (+0.47 v. +0.14 servings/d, $P<.0001$) intake, compared with control group. Similar results in dietary changes with intention-to-treat analyses.
Siero <i>et al.</i> (2000)	Dutch hypercholesterolaemic adults with at least two other CVD risk factors (<i>n</i> 230; 48 group education, 33 group plus tailored feedback education, 149 control, mean age=54.2 years)	Randomised controlled trial; Intensive group education, compared with intensive group education and tailored stage-matched dietary (derived via FFQ) feedback and nutritional guidelines, and general nutrition information leaflet	Promoting the Mediterranean diet and increasing intake of fish, fruits and vegetables in particular, improving attitudes, social norms and self-efficacy, increasing intentions, progressing in stages of change	Personal letters	Theory of Planned Behaviour, Stages of Change	At 16 weeks, significant overall intervention effect on attitudes ($P<.001$), social norms ($P<.010$), intentions ($P<.001$) and stages of stage ($P<.001$) regarding fish intake, and stages of change ($P<.050$) regarding fruits and vegetables, compared with control group. Significant effect of both interventions on fish (40.3 v. 42.1 v. 24.1 g/d, $P<.001$) and fruit and vegetable (464 v. 493 v. 398 g/d, $P<.010$) intake, compared with control group. No differences in dietary intake between the two interventions.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Anderson <i>et al.</i> (2001)	North American healthy adults, supermarket customers (<i>n</i> 277; 129 intervention, 148 control, mean age=40 years)	Randomised controlled trial; Interactive, touchscreen intervention with computer-tailored food purchase and psychosocial feedback and tailored food purchase coupons, compared with no intervention	Primary: Increasing low-fat, high-fibre and fruit and vegetable, and reducing high-fat and low-fibre content of food purchases and intake (assessed via food purchase receipts and FFQ) Secondary: Improving self-efficacy and outcome expectations	Computer prints	Stages of Change, Social Cognitive Theory, Health Belief Model, Goal setting	At 8 weeks, significant intervention effect on content of food purchases and actual intake (composite measure): % of calories from fat (30.1 v. 33.4%, $P<.001$), fibre (10.6 v. 8.9 g/1000 kcal, $P<.001$) and fruits and vegetables (3.4 v. 2.8 servings/1000 kcal, $P<.010$), compared with control group. Significant intervention effect on self-efficacy for reducing fat in meals ($P<.050$) and social outcome expectations ($P<.050$). At 4-6 months post-intervention, significant intervention effect on content of food purchases and actual intake (composite measure): % of calories from fat (31.0 v. 33.2%, $P<.050$) and fibre (10.6 v. 9.2 g/1000 kcal, $P<.010$), compared with control group.
Delichatsios <i>et al.</i> (2001a)	North American sedentary adults with suboptimal diet quality, primary care patients (<i>n</i> 298; 148 intervention, 150 control, mean age=45.9 years)	Randomised controlled trial; Interactive, computer-controlled telephone system with weekly tailored dietary (derived via FFQ and food frequency instrument) and psychosocial feedback, compared with interactive, computer-controlled telephone system with weekly tailored physical activity feedback	Primary: Increasing fruit, vegetable and whole grain food and decreasing red and processed meats and whole-fat dairy product intake, improving overall diet quality Secondary: Increasing dietary fibre and decreasing saturated fat intake, progressing in stage of change	Telephone voice system	Stages of Change, Social Cognitive Theory, Goal setting	At 6 months, significant intervention effect on fruits (+1.1 servings/d, 95% CI=0.4-1.7), diet quality (+8.9 points, 95% CI=4.4-13.4), dietary fibre (+4 g/d, 95% CI=0.1-7.8) and saturated fat intake (-1.7%, 95% CI=-2.7- -0.7), compared with control group. Significant effect of program usage on saturated fat, fruit and dietary fibre intake ($P<.050$). Significant intervention effect on forward stage of change for fruit (55 v. 37%, $P=.004$).

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Hunt <i>et al.</i> (2001); Delichatsios <i>et al.</i> (2001b)	North American adults, primary care patients (<i>n</i> 504; 230 intervention, 274 control, mean age=54 years)	Randomised controlled pilot trial; Computer-tailored dietary (derived via FFQ) and behavioural feedback, tailored printed materials and individual counselling compared with dietary intake report (derived via FFQ) and recommendations brochure	Primary: Increasing fruit and vegetable intake, reducing intake of red and processed meats and substituting whole-fat with low-fat dairy products Secondary: Progressing in stages of change	Tailored letters, stage-matched nutrition education booklets	Stages of Change, Goal setting	At 3 months, significant intervention effect on fruit and vegetable intake (+1.1 v. +0.4 servings/d, 95% CI=0.3-0.8), compared with control group. Significant intervention effect on stages of change for saturated fat (47 v. 29%, <i>P</i> =.002).
Marcus <i>et al.</i> (2001) [replication study of Marcus <i>et al.</i> (1998)]	North American healthy adults, callers to the Cancer Information Service, who did not seek diet and nutrition information as part of usual service (<i>n</i> 1717; 861 intervention, 856 control, 45.9% range 30-49 years, 24.8% ≥60 years)	Randomised controlled trial; Brief tailored dietary (derived via 24-hour recall and food frequency index) and behavioural feedback and tailored printed materials, compared with assessment only	Primary: Increasing fruit and vegetable intake Secondary: Improving predisposing and enabling psychosocial factors regarding fruit and vegetable intake	Telephone contacts, tailored letters and tailored printed materials	Transtheoretical Model, Theory of Reasoned Action, Health Belief Model, Social Cognitive Theory	Significant intervention effect on fruit and vegetable intake (+0.88 servings/d at 4 weeks, <i>P</i> <.001; +0.63servings/d at 4 months, <i>P</i> <.001 and +0.43 servings/d at 12 months, <i>P</i> <.001), compared with control group. No differences in psychosocial factors between the groups. Significant intervention increase in intention to change (<i>P</i> =.001) and knowledge of guidelines (<i>P</i> =.001). High intervention acceptability.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Baker & Wardle (2002)	UK adults, attending cancer screening clinics (<i>n</i> 742; 325 intervention, 316 control, age range=55-64 years)	Randomised controlled trial; Computer-tailored dietary (derived via short quiz) and psychosocial feedback, compared with no intervention	Primary: Increasing fruit and vegetable intake Secondary: Increasing knowledge of recommendations, improving attitudes	Personal letter	Stages of Change	At 6 weeks, significant intervention effect on fruit (+0.59 v. +0.14 servings/d, $P<.001$) and vegetable (+0.47 v. +0.12, $P<.001$) intake, compared with control group. Significant intervention increase in knowledge score (+0.75 v. +0.08, $P<.001$) and improvement in attitudes to fruit intake ($P<.001$), compared with control group.
Calfas <i>et al.</i> (2002)	North American healthy adults, primary care patients (<i>n</i> 173; 41 frequent phone and mail, 41 infrequent phone and mail, 45 mail only, 46 control, mean age=37.5 years)	Baseline interactive, computer-tailored immediate behavioural (derived via fat screener and food frequency instrument) and psychosocial feedback with goal setting and tailored physician counselling, preceding controlled randomisation in tailored behavioural: frequent phone and mail contact, compared with infrequent phone and mail contact, mail only contact, and no intervention	Improving one physical activity behaviour (progressing in stages of change regarding moderate or vigorous physical activity) and one nutrition behaviour (reducing fat intake, reducing overeating behaviours, increasing fruit and vegetable intake)	Computer print	Social Cognitive Theory, Stages of Change, Goal setting, determinants of physical activity research	At 4 months, significant effect on nutrition behaviour of all conditions (dietary fat: $P=.039$; fruits and vegetables: $P<.001$, overeating: $P=.017$), compared with control group. Significant effect of targeting a behaviour on behaviour change (moderate physical activity: 48.5 v. 20.0%, $P<.001$; vigorous physical activity: 50.7 v. 22.6%, $P<.001$; high fat: -1.05 v. -0.07, $P<.002$ servings/d; fruits and vegetables: +1.66 v. +0.34 servings/d, $P<.001$; overeating: habits/d, $P<.002$), compared with participants not targeting that behaviour. High participant and physician satisfaction with intervention components.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Campbell <i>et al.</i> (2002)	North American healthy women, blue-collar employees (<i>n</i> 538; 282 intervention, 256 control, 53% ≤40 years)	Randomised controlled trial; Computer-tailored health messages with dietary (derived via food frequency checklist) and psychosocial feedback and health advisor workplace programme, compared with delayed intervention (provided at 6 months)	Increasing fruit and vegetable intake, fat reduction	Personal booklet, magazine format	Ecological model of change (individual characteristics, social network/support, community/environmental influences), Social Cognitive Theory, Stages of Change, Goal setting	At 6 months, significant intervention effect on fat intake (-3.4 v. -1.5 g/d, <i>P</i> =.010), compared with control group. At 18 months, significant intervention effect on fruit (+0.5 v. +0.1 servings/d, <i>P</i> =.020) and vegetable (+0.2 v. -0.1 servings/d, <i>P</i> =.030) intake, compared with control group. Significant intervention effect on message recall (<i>P</i> =.009) and personal relevance (<i>P</i> =.001).
De Bourdeaudhuij <i>et al.</i> (2002)	Belgian healthy families, adults and adolescents (<i>n</i> 178; 44 parents and 44 adolescents family-based, 40 parents and 50 adolescents individual-based)	Quasi-experimental trial; Family-based manually-tailored dietary (derived via FFQ) and psychosocial feedback, compared with individual-based manually-tailored dietary (derived via FFQ) and psychosocial feedback	Primary: Fat reduction, improving psychosocial determinants of fat intake, progressing in stages of change Secondary: Effect of family- and individual-based feedback on fat intake and determinants of fat intake	Personal letters	Precaution Adoption Process Model, Stages of Change, Social Cognitive Theory, Theory of Planned Behaviour	At 4 weeks, significant tailoring interventions effect on psychosocial determinants of fat intake (<i>P</i> <.001) and reduction in fat intake (<i>P</i> <.001, for participants with high baseline intake), compared with baseline. Significant family-based intervention effect on parental social support scores (<i>P</i> <.050) and intentions (<i>P</i> <.050). Progress in stages of change achieved in both conditions. High use, appreciation and perceived impact of feedback in both conditions. No difference in fat intake between the groups.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Stevens <i>et al.</i> (2002, 2003)	North American healthy women, members of a health maintenance organisation (<i>n</i> 616; 308 intervention, 308 control, mean age=53.7 years)	Randomised single blinded controlled trial; Computer-assisted, touchscreen, interactive counselling intervention with tailored dietary (derived via FFQ and 24-hour recalls) and psychosocial feedback and phone contacts, compared with attention-control intervention unrelated to diet	Primary: Fat reduction, increasing fruit, vegetable and whole grain intake Secondary: Improving behavioural measures of fat and fibre intake, improving serum cholesterol levels (at 12 months only)	Computer print-out, nutrition educator	Social Cognitive Theory, Stages of Change, Goal setting	At 4 months, significant intervention effect on fat (-2.84 v. +0.48%, <i>P</i> =.009) and fruit and vegetable (+0.43 v. -0.51 servings/d, <i>P</i> <.001) intake and behavioural measure of fat intake (-0.35 v. +0.02 points, <i>P</i> <.001), compared with control group. At 12 months, significant intervention effect on fat (-5.7 v. 0.8%, <i>P</i> <.001) and fruit and vegetable intake (+1.24 v. +0.19 servings/d, <i>P</i> <.001), and behavioural measure of fat intake (-0.27 v. +0.04 points, <i>P</i> <.001), compared with control group. At 12 months, significant intervention decrease in serum cholesterol (-3.82 mg/dl, <i>P</i> <.006, for those completing both dietary and blood assessments), compared with control group.
Havas <i>et al.</i> (2003)	North American healthy women (<i>n</i> 2066; 1055 intervention, 1011 control, 66.8%<30 years)	Randomised trial; Group sessions, printed materials and tailored dietary (derived via FFQ) and behavioural feedback, compared with 10min nutrition education	Primary: Fat reduction, increasing fruit, vegetable and fibre intake Secondary: Progressing in stages of change, increasing knowledge of recommendations and self-efficacy	Personal letters with tip sheets and newsletters	Stages of Change, Social Cognitive Theory, Goal setting	At 2 months post-intervention, significant intervention effect on fat (-1.4 v. +0.22%, <i>P</i> <.0001), fruit and vegetable (+0.16 v. -0.24 servings/d, <i>P</i> =.0003) and fibre (+0.41 v. -0.6 g/d, <i>P</i> =.001) intake, compared with control group. Significant intervention effect on stages of change (not reported). At 14 months post-intervention, significant intervention effect on fat (-0.74 v. +0.87%, <i>P</i> =.030) and fruit and vegetable (+0.1 v. -0.32 servings/d, <i>P</i> =.030) intake, compared with control group.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Block <i>et al.</i> (2004)	North American healthy low-income women (<i>n</i> 481; 162 CD-ROM with reminder phone calls, 160 CD-ROM, 159 stress management CD-ROM, mean age=50.1 years)	Randomized placebo-controlled, parallel-group trial; Interactive, nutrition education CR-ROM program with single tailored dietary (derived via 24-hour recalls) and psychosocial feedback, compared with interactive, nutrition education CR-ROM program with single tailored dietary (derived via 24-hour recalls) and psychosocial feedback and two phone calls, and stress management CD-ROM (control group)	Primary: Increasing fruit and vegetable intake Secondary: Progressing in stages of change	CD-ROM	Stages of Change, Self-efficacy, Goal Setting Theory	At 2 months, significant CD-ROM and phone call (+1.32 servings/d, $P=.016$) and CD-ROM (+1.20 servings/d, $P=.052$) effect on fruit and vegetable intake, compared with control group. Significant intervention effect on forward stage of transition, compared with control group.
Campbell <i>et al.</i> (2004)	North American healthy women, receiving food assistance (<i>n</i> 307; 141 intervention, 166 control, mean age=27.4 years)	Randomised controlled trial; Interactive, touchscreen nutrition education CR-ROM program with single tailored dietary (derived via FFQ) and psychosocial feedback and printed materials, compared with delayed intervention	Primary: Fat reduction, increasing fruit and vegetable intake Secondary: Increasing knowledge of low-fat and infant feeding choices, self-efficacy, progressing in stages of change	CD-ROM	Stages of Change, Social Cognitive Theory	At immediate post-intervention, significant intervention effect on self-efficacy ($P<.010$). At 2 months, no intervention effect on fat, fruit and vegetable intake, compared with control group. Significant intervention effect on low-fat and infant feeding knowledge ($P<.050$), compared with control group. High programme acceptability, rated positively on helpfulness.

Table 2.12 cont.: Tailored-feedback nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Feedback tool	Theoretical background	Main results
Vandelanotte <i>et al.</i> (2004, 2005)	Belgian healthy adults [(n 771; PA intervention: 189 simultaneous, 180 sequential and 204 control; Fat intervention: 176 simultaneous, 194 sequential, 195 control, mean age=39.1 years)]	Randomised trial; Interactive, computer-tailored intervention with tailored behavioural and psychosocial feedback for physical activity and fat intake (derived via FFQ), delivered simultaneously for both behaviours at baseline, compared with physical activity intervention at baseline and fat intake intervention at 3 months, fat intake intervention at baseline and physical activity intervention at 3 months, and no intervention	Fat reduction, increasing physical activity	Computer prints	Theory of Planned Behaviour, Stages of Change	<p>At 6 months, significant effect of simultaneous and sequential interventions on physical activity (+173 v. +213 v. +14 min/wk, $P<.001$), total fat intake (-33 v. -25 v. -7 g/d, $P<.001$) and fat intake (-11.5 v. -8.6 v. -2.1%, $P<.001$) scores, compared with control group.</p> <p>Significant simultaneous intervention effect on fat intake ($P<.001$), compared with sequential intervention groups.</p> <p>High program acceptability, rated positively on quality, user-friendliness and applicability.</p>

2.3.6.1. *Characteristics of tailored-feedback nutrition education studies*

The tailored-feedback nutrition education studies summarised in Table 2.12 differ in several characteristics that make comparisons of findings difficult to undertake. In particular:

- **Sample size and characteristics:** Sample sizes varied from 77 (Winett *et al.* 1991a) to 3,122 (Havas *et al.* 1998), with 6 studies including more than 1,000 participants, eight studies including between 500 and 1,000 participants and 20 including less than 500 participants. In most studies, participants were or appeared to be healthy adults, since not all studies defined specific exclusion criteria concerning health status. Three studies targeted high-risk individuals (Glasgow *et al.* 1997; Bemelmans *et al.* 2000; Siero *et al.* 2000) and two studies targeted families with adolescents (De Bourdeaudhuij & Brug, 2000; De Bourdeaudhuij *et al.* 2002). Participants were, on average, approximately 43 years of age. In addition, in most studies participants were self-selected, well-educated and of high socioeconomic status individuals, and the majority were women and Caucasian. However, some studies targeted individuals with low education and/or lower income (Havas *et al.* 1998; Bemelmans *et al.* 2000; Brug & Van Assema, 2000; Siero *et al.* 2000; Havas *et al.* 2003; Block *et al.* 2004; Campbell *et al.* 2004), African-Americans (Campbell *et al.* 1999), or recruited equal numbers of ethnically diverse participants and participants of various socioeconomic backgrounds (Delichatsios *et al.* 2001a; Calfas *et al.* 2002; Campbell *et al.* 2002; Campbell *et al.* 2004).
- **Intervention settings:** Most studies recruited participants from work settings and primary care clinics. Three studies were conducted in supermarkets (Winett *et al.* 1991a; Winett *et al.* 1997; Anderson *et al.* 2001) and three studies were carried out in community settings (Havas *et al.* 1998; Campbell *et al.* 1999; Havas *et al.* 2003).
- **Length of intervention and follow-up periods:** The length of intervention periods employed varied from one week (Bowen *et al.* 1994) to six months (Kreuter & Strecher, 1996; Greene & Rossi, 1998; Havas *et al.* 1998; Lutz *et al.* 1999; Brinberg *et al.* 2000; Delichatsios *et al.* 2001a; Campbell *et al.* 2002; Vandelanotte *et al.* 2005), with 14 studies having intervention periods from three to eight weeks. Sixteen studies reported follow-up periods at some point after the end of the immediate post-intervention evaluation, which ranged from one month (Winett *et al.* 1991b) to two years (Campbell *et al.* 1999).
- **Comparison groups:** Only one study did not recruit a control group (Bowen *et al.* 1994). Twenty-three studies compared tailored feedback with one control group, which included assessment-only, general nutrition information letters, usual care, minimal counselling, generic brochures and delayed intervention conditions. In some studies, the control group

was provided with tailored feedback of varied intensity or content (e.g. dietary v. dietary and psychosocial, family- v. individual-based, tailored information delivered via the same medium but targeting a different behaviour). Ten studies recruited more than one control group, which included assessment-only, general nutrition information letters, tailored feedback facilitated by other interventions (e.g. health risk appraisal, general education materials, counselling, phone and/or mail contacts, more than one feedback materials), tailored feedback from a different source, tailored feedback with v. without goal setting and simultaneous or sequential feedback on different behaviours.

- Outcomes and process evaluation: Thirty studies reported dietary behaviour change as a primary outcome, two of which used tailored feedback to promote the Mediterranean diet (Bemelmans *et al.* 2000; Siero *et al.* 2000) and two to improve diet quality, by promoting an eating pattern similar to the Mediterranean diet (Delichatsios *et al.* 2001a; Hunt *et al.* 2001). Two studies aimed at altering food purchases (Winett *et al.* 1991a; Winett *et al.* 1997), one study was conducted to improve knowledge and psychosocial determinants of intake (Brug & Van Assema, 2000), and one study only reported mediating factors of fat intake (Bowen *et al.* 1994). In total, twenty-one studies reported psychosocial determinants of dietary behaviour (e.g. attitudes, intentions, self-efficacy etc.) and/or stages of change as a primary or secondary outcome. Only twenty-four studies provided information on the use, appreciation and/or perceived impact of the tailored feedback or the intervention assessed and only six studies provided objective blood lipid (Glasgow *et al.* 1997; Bemelmans *et al.* 2002; Stevens *et al.* 2003; Bemelmans *et al.* 2004) and/or weight (Glasgow *et al.* 1997; Bemelmans *et al.* 2000; Kristal *et al.* 2000; Campbell *et al.* 2002; Stevens *et al.* 2003) measurements for impact evaluation.
- Use of behaviour change theories: Most studies based the content of tailored feedback on a combination of established behaviour change theories, while only two studies used a single theory (stages of change) to provide tailored feedback (Brug & Van Assema, 2000; Baker & Wardle, 2002). Twenty-nine studies addressed the stages of change concept from the Transtheoretical Model, twenty-two used concepts from the Social Cognitive Theory and nine and twelve provided strategies according to the Health Belief Model and the Theory of Reasoned Action and/or Planned Behaviour, respectively. Only fourteen studies used concepts from the Goal Setting Theory.
- Type and distribution of assessment instruments: Of the thirty studies that assessed dietary intake, the majority carried out the assessment using food frequency questionnaires or food consumption scales. Some studies however, used 24-hour recalls (Block *et al.* 2004), a combination of FFQs and 24 hour-recalls (Kristal *et al.* 2000; Marcus *et al.* 2001; Stevens *et al.* 2002), a combination of FFQs and 3-day (Campbell *et al.* 1999) or 4-day (Glasgow *et al.*

al. 1997) dietary food records, and 7-day food records (Raats *et al.* 1999). Studies also differed in the number of dietary assessments conducted over their intervention periods, the length and number of items assessed by the instruments used, as well as the way these instruments were distributed. For example, although in most studies the FFQs were self-administered, four studies used computerised versions of these instruments, where participants completed the questionnaire directly on the computer (Brinberg *et al.* 2000; Anderson *et al.* 2001; Campbell *et al.* 2002; Vandelanotte *et al.* 2005). In addition, four studies used both self- and telephone-administered questionnaires (Bowen *et al.* 1994; Lutz *et al.* 1999; Hunt *et al.* 2001; Calfas *et al.* 2002), two studies used telephone-administered questionnaires (Marcus *et al.* 1998; Marcus *et al.* 2001), three studies used computerised and telephone-administered surveys (Glasgow *et al.* 1997; Stevens *et al.* 2002; Campbell *et al.* 2004) and two studies used both self- and computer-administered instruments (Glasgow *et al.* 1997; Delichatsios *et al.* 2001a). Questionnaires used to assess psychosocial determinants of dietary intake were distributed via the same channel as the dietary assessment instruments, for those studies that assessed both dietary and psychosocial variables. Assessment of use, appreciation and perceived impact of interventions was usually performed by self-administered questionnaires, telephone surveys (Campbell *et al.* 1999; Calfas *et al.* 2002), or a combination of these methods (Bowen *et al.* 1994). The two studies aimed at altering food purchases used computerised instruments to assess their outcome of interest (Winett *et al.* 1991a; Winett *et al.* 1997), while the study conducted to improve intentions and progress regarding stages of change used self-administered questionnaires (Brug & Van Assema, 2000).

- **Type and distribution of tailored feedback:** Studies differed in respect with the number of feedback materials provided over the intervention period, with twenty-two studies providing a single exposure to tailored feedback and twelve providing more than one (ranging from two (Brug *et al.* 1998; Marcus *et al.* 1998; Hunt *et al.* 2001; Marcus *et al.* 2001; Campbell *et al.* 2002) to eight (Winett *et al.* 1997)), while one study provided the possibility of up to 24 tailored messages over a period of six months (Delichatsios *et al.* 2001a). The type of feedback also varied, with thirty studies providing psychosocial, in addition to dietary feedback. In addition, the majority of studies used a computer-tailoring procedure to tailor feedback, whereas two studies tailored feedback manually (De Bourdeaudhuij & Brug, 2000; De Bourdeaudhuij *et al.* 2002) and nine studies did not specify how feedback was generated (Bowen *et al.* 1994; Greene & Rossi, 1998; Havas *et al.* 1998; Marcus *et al.* 1998; Bemelmans *et al.* 2000; Brinberg *et al.* 2000; Siero *et al.* 2000; Marcus *et al.* 2001; Havas *et al.* 2003). The length of feedback provided varied from one (Kreuter & Strecher, 1996; Glasgow *et al.* 1997; Raats *et al.* 1999) to nine (Brug *et al.*

1996) pages, with an average of approximately 3.6 pages. In nineteen studies, feedback was delivered in the form of personal letters, usually delivered by post. Some studies however, distributed feedback via personal newsletters (Lutz *et al.* 1999), bulletins (Campbell *et al.* 1999), magazines (Campbell *et al.* 2002), or a nutrition educator (Brinberg *et al.* 2000). For those studies that did not provide immediate, interactive feedback, the time span between assessment and provision of feedback varied from one week (Bowen *et al.* 1994) to seven months (due to changes in study's timeline) (Campbell *et al.* 1999). Most studies reported a period of 2-4 weeks before feedback was provided. Most studies providing interactive, on-screen feedback, offered the option of a print-out (Winett *et al.* 1991a; Glasgow *et al.* 1997; Winett *et al.* 1997; Anderson *et al.* 2001; Calfas *et al.* 2002; Stevens *et al.* 2002; Vandelanotte *et al.* 2005), whereas one study provided feedback via a computerised telephone system (Delichatsios *et al.* 2001a).

- Twenty studies used tailored feedback as part of a multi-component intervention. In these studies, other components of the intervention included individual counselling, self-help materials and phone contacts (Glasgow *et al.* 1997), brief educational materials (Bowen *et al.* 1994; Greene & Rossi, 1998; Campbell *et al.* 2004), group sessions, printed materials and visual reminders (Havas *et al.* 1998), tailored printed materials (e.g. booklets) (Marcus *et al.* 1998; Kristal *et al.* 2000; Marcus *et al.* 2001), tailored printed materials, individual counselling and phone contacts (Hunt *et al.* 2001), group sessions, cooking classes and community interventions (Campbell *et al.* 1999), group sessions and diet supplementation with foods provided by the researchers (Bemelmans *et al.* 2000), group sessions and printed materials (Siero *et al.* 2000; Havas *et al.* 2003), food purchase coupons (Winett *et al.* 1997; Anderson *et al.* 2001), health risk appraisal (Kreuter & Strecher, 1996), counselling and phone and/or mail contacts (Calfas *et al.* 2002; Stevens *et al.* 2002), community interventions (Campbell *et al.* 2002) and phone contacts (Block *et al.* 2004).

Despite these differences in the implementation and outcome measures of the studies reviewed in this chapter, the provision of tailored feedback appears to outperform standard, non-tailored education materials in most behavioural outcomes studied. Tailored feedback also appears to be used and appreciated more, compared with general nutrition information, and, when part of a multi-component intervention, is suggested to act as an important adjunct to other intervention components. The main findings of the studies reviewed will be outlined in the following sections.

2.3.6.2. *Effect on dietary intake*

Thirty of the studies reviewed reported dietary behaviour change outcomes and two reported food purchases (Winett *et al.* 1991a; Winett *et al.* 1997). In eighteen of these studies, participants who received tailored feedback, as the only intervention or as part of a multi-component intervention, had significantly more positive outcomes at post-intervention, compared with participants in a control condition, in all the behaviours of interest (Winett *et al.* 1991a; Glasgow *et al.* 1997; Winett *et al.* 1997; Brug *et al.* 1998; Greene & Rossi, 1998; Havas *et al.* 1998; Marcus *et al.* 1998; Campbell *et al.* 1999; Brinberg *et al.* 2000; De Bourdeaudhuij & Brug, 2000; Kristal *et al.* 2000; Anderson *et al.* 2001; Marcus *et al.* 2001; Baker & Wardle, 2002; Calfas *et al.* 2002; Havas *et al.* 2003; Block *et al.* 2004; Vandelanotte *et al.* 2005).

Three studies did not find differences between the tailored-feedback and control conditions (Kreuter & Strecher, 1996; Raats *et al.* 1999; Campbell *et al.* 2004). All these studies reported that participants in the intervention group had more positive outcomes than participants in the control group, but these differences were not significant. In addition, none of the studies reported a more favourable outcome for participants in the control, compared with the tailored-feedback condition.

Eleven studies found significant effects of tailored feedback, compared to a control condition, in some, but not for all behavioural outcomes measured (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1999b; Lutz *et al.* 1999; Bemelmans *et al.* 2000; Siero *et al.* 2000; Delichatsios *et al.* 2001a; Hunt *et al.* 2001; Campbell *et al.* 2002; De Bourdeaudhuij *et al.* 2002; Stevens *et al.* 2002). Brug *et al.* (1996) and Campbell *et al.* (1994, 2002) for example, found that tailored feedback resulted in a reduction in fat, but not an increase in fruit and vegetable intake. In one of the latter studies, tailored feedback resulted in a reduction in fat when compared with a no-intervention condition, but not with general nutrition information (Campbell *et al.* 1994). In addition, Stevens *et al.* (2002) found a positive effect in fat, fruit and vegetable intake, but not in whole grain foods, whereas in another study, a significant tailoring effect on fat reduction was reported, but only for participants with high baseline intake (De Bourdeaudhuij *et al.* 2002). Lutz *et al.* (1999) also found that tailored feedback resulted in increased intake of fruits and vegetables compared with a no-intervention condition, but not with non-tailored dietary feedback. In most of the studies however, the tailored intervention resulted in more favourable, but not statistically significant, outcomes. The four studies that aimed at promoting the Mediterranean diet or a Mediterranean-style diet showed that tailored feedback alone (Delichatsios *et al.* 2001a; Hunt *et al.* 2001), or in combination with other intervention approaches (Bemelmans *et al.* 2000; Siero *et al.* 2000), produced favourable changes in several of the food components assessed (e.g. fruits, vegetables, fish, fat), and therefore has potential in promoting healthy eating patterns instead of specific food groups.

Despite the different methodological approaches and different behavioural outcomes assessed, these studies suggest that tailored feedback is effective in promoting dietary behaviour change, in line with nutritional recommendations.

2.3.6.3. Effect on stages of change and psychosocial determinants of dietary behaviour

In total, twenty-one studies reported psychosocial determinants of dietary behaviour (e.g. attitudes, intentions, self-efficacy etc.) and/or stages of change as a primary or secondary outcome (Winett *et al.* 1991a; Brug *et al.* 1996; Greene & Rossi, 1998; Havas *et al.* 1998; Marcus *et al.* 1998; Brug *et al.* 1999b; Raats *et al.* 1999; Brinberg *et al.* 2000; Brug & Van Assema, 2000; De Bourdeaudhuij & Brug, 2000; Kristal *et al.* 2000; Siero *et al.* 2000; Anderson *et al.* 2001; Hunt *et al.* 2001; Marcus *et al.* 2001; Baker & Wardle, 2002; De Bourdeaudhuij *et al.* 2002; Stevens *et al.* 2002; Havas *et al.* 2003; Block *et al.* 2004; Campbell *et al.* 2004). The majority of these studies showed a positive impact of tailored feedback compared with a control condition, in at least one of the outcomes assessed.

Although comparison of these studies is difficult to undertake, due to the different psychosocial outcomes assessed, it appears that feedback, tailored to stages of behavioural change and/or psychosocial determinants of dietary behaviour, has a favourable impact on improving these outcomes, which is likely to facilitate dietary behaviour change.

2.3.6.4. Use, appreciation and perceived impact

Twenty-four of the studies reviewed provided information on the use, appreciation and/or perceived impact of the tailored feedback materials provided. These studies suggest that tailored feedback is more likely to be read, saved, remembered and discussed with others, compared with non-tailored, general information (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1998; De Bourdeaudhuij & Brug, 2000). In addition, some studies showed that tailored feedback is appreciated better than general nutrition information. It is more likely to attract attention and be perceived as personally relevant, novel, individualised and interesting (Brug *et al.* 1998; Brug *et al.* 1999b).

Studies have also suggested that tailored feedback induces more positive intentions to change dietary habits and encourages thinking about one's diet, as well as about behaviour change (Brug *et al.* 1996; Brug & Van Assema, 2000; Campbell *et al.* 2002; De Bourdeaudhuij *et al.* 2002). In addition, individuals who received tailored feedback were more likely to report that they have

changed their diet and their opinion about their diet, as a result of this feedback, compared with general nutrition information (Brug *et al.* 1996; Brug *et al.* 1998).

Some studies have reported that tailored feedback is less likely than non-tailored feedback to be perceived as credible (Brug *et al.* 1998; De Bourdeaudhuij & Brug, 2000). One explanation for this finding suggested by the authors is the inconsistency between participants' perceived dietary intake and the actual dietary intake reported in the feedback (i.e. participants are not likely to find the feedback credible if they think the information provided is not true, or is unexpectedly negative) (Brug *et al.* 1998; De Bourdeaudhuij & Brug, 2000; Oenema *et al.* 2005). However, one study showed that tailored feedback was perceived to be more credible than non-tailored feedback among individuals with low education, who are not motivated to change their diet (Brug & Van Assema, 2000), whereas in another study no significant effect on credibility was reported (Brug *et al.* 1996).

Interventions that have used tailored feedback, in addition to other strategies, to promote dietary behaviour change have generally been more appreciated and well accepted compared with various control conditions (Marcus *et al.* 1998; Hunt *et al.* 2001; Marcus *et al.* 2001; Campbell *et al.* 2002). High appreciation and satisfaction with interactive computer systems that provide tailored feedback, as well as high readability and use of the printed feedback have also been reported (Glasgow *et al.* 1997; Winett *et al.* 1997; Anderson *et al.* 2001; Campbell *et al.* 2004; Vandelanotte *et al.* 2004). Calfas *et al.* (2002) for example, reported that tailored feedback developed by an interactive computer program and aimed at facilitating physician counselling in a primary care setting was found very helpful by both patients and physicians. Physicians in this study also welcomed the opportunity to integrate the program in their routine and would recommend it to other health professionals, which shows potential for the applicability of such systems in primary care settings.

The high appreciation of tailored feedback, compared with non-tailored information, as well as the acceptability of more interactive tailored-feedback applications, are suggested to be possible mediating factors responsible for the positive effect of tailored nutrition interventions on dietary behaviour change (Brug *et al.* 1998).

2.3.6.5. *Effect on biochemical and anthropometric measurements*

Three of the studies reviewed conducted blood lipid measurements for impact evaluation, with varied results. Participants in the intervention group in the study of Glasgow *et al.* (1997) had decreased their intake of total fat and saturated fat 12 months after receiving tailored feedback, individual counselling, self-help materials and motivational phone calls and showed significant decreases in serum cholesterol levels, compared with participants receiving usual care. Participants

receiving interactive tailored dietary and psychosocial feedback and individual counselling also showed significant reductions in their serum cholesterol levels at 1 year, compared with participants in the control group (Stevens *et al.* 2003). In addition, Bemelmans *et al.* (2002) found significant intervention effect on blood lipids, two years after receiving intensive group education, self-help materials and tailored correspondence, but not after 16 weeks and one year (Bemelmans *et al.* 2000) or 3 years (Bemelmans *et al.* 2004). The changes reported at 2 years were an increase in the ratio of total:HDL-cholesterol and triacylglycerol levels, as well as a decrease in levels of HDL-cholesterol and fibrinogen. Considering that participants in the intervention group in this study had significantly reduced their intake of saturated fat and increased their intake of fish, it was surprising that a decrease in HDL-cholesterol was observed. However, participants in this study also received a polyunsaturated fat-enriched margarine, similar to the Lyon Heart Study (de Lorgeril *et al.* 1999), which did not find changes in blood lipid levels and reported that HDL-cholesterol levels tended to increase less in the intervention group.

Five studies provided information on body mass index measurements, two of which did not find a significant impact in participants in the intervention, compared with the control group (Glasgow *et al.* 1997; Campbell *et al.* 2002), whereas in the study by Kristal *et al.* (2000), a nearly significant reduction was observed at the 12-month follow-up among participants receiving tailored dietary and psychosocial feedback and a combination of tailored printed materials, compared with a no-intervention group (adjusted net difference of -0.76lb, $P=0.088$). Bemelmans *et al.* (2000) reported a significant intervention effect on BMI at 16 weeks, which was not maintained at 1 (Bemelmans *et al.* 2000), or 2 and 3 years of follow-up (Bemelmans *et al.* 2002; Bemelmans *et al.* 2004). No results on BMI were reported in the study by Stevens *et al.* (2002), although BMI measurements were carried out.

All the studies that have included biochemical and/or anthropometric measurements for impact evaluation however, were multi-component interventions and therefore it is difficult to conclude that any effects are attributable solely to the tailoring component of the intervention. In addition, the number of studies that have provided information on such measurements is too small for any conclusions to be drawn on the potential effect of tailored-feedback information on blood lipids or BMI.

2.3.6.6. Long-term impact

Fifteen studies reported dietary assessment results for both post-intervention and follow-up periods. In six of these studies the positive effects of tailored feedback, or an intervention that included tailored feedback as one of its components, persisted throughout the measurement periods for all the

dietary outcomes of interest (Havas *et al.* 1998; Marcus *et al.* 1998; Campbell *et al.* 1999; Kristal *et al.* 2000; Marcus *et al.* 2001; Stevens *et al.* 2003). In two studies, positive outcomes on fat intake were achieved initially but did not persist at follow-up (Greene & Rossi, 1998; Campbell *et al.* 2002), whereas one study showed no positive effect at either post-intervention or follow-up (Raats *et al.* 1999).

In six studies that promoted behaviour change in several food components, the positive effects displayed in the intervention, compared with the control group, persisted over time for some, but not all behaviours of interest (Winett *et al.* 1991a; Winett *et al.* 1997; Brug *et al.* 1998; Anderson *et al.* 2001; Bemelmans *et al.* 2002; Havas *et al.* 2003; Bemelmans *et al.* 2004). Brug *et al.* (1998) for example, reported that at a follow-up of 8 weeks, the post-intervention positive impact on fat, fruit and vegetable intake persisted for fat and fruit, but not for vegetables. In two other studies, positive effects on fat and fibre intake were maintained at follow-up, but fruit and vegetable intake did not (Winett *et al.* 1997; Anderson *et al.* 2001).

In four studies that promoted behaviour change in several food components, no positive effect of the intervention, compared with the control condition, was observed initially but positive outcomes were reported at follow-up (Winett *et al.* 1991a; Winett *et al.* 1997; Bemelmans *et al.* 2002; Campbell *et al.* 2002; Bemelmans *et al.* 2004). For example, Campbell *et al.* (2002) did not find a positive effect in increasing fruit and vegetable intake at post-intervention, but reported an increased intake among participants in the intervention group at the 18-month follow-up. Similarly, vegetable intake in the study by Bemelmans *et al.* (2002, 2004) was higher among participants in the intervention group at 3 years, but not at 1 or 2 years.

These findings suggest that the positive effect of tailored feedback persists over time, at least for some behaviours.

2.3.6.7. Effect of providing tailored psychosocial information on dietary behaviour

Thirty of the studies reviewed tailored feedback information to participants' psychosocial determinants of dietary behaviour and/or stage of behavioural change, in addition to participants' dietary intake. The majority of these studies showed a positive impact of this combined tailored feedback, compared with a control condition, in most of the behavioural outcomes of interest. The question remains however, of whether psychosocial feedback, tailored, for example, to an individual's attitudes, beliefs, perceived social support, intentions and self-efficacy skills, facilitates

tailored dietary feedback, or whether the provision of tailored dietary feedback alone would be enough to promote dietary behaviour change.

Brug and his colleagues (1999b) examined the impact of tailored dietary feedback, with or without tailored psychosocial information, on dietary behaviour change regarding fat, fruit and vegetable intake. The authors found that for the whole study population, tailored feedback was effective in reducing fat, as well as increasing fruit, and increasing vegetable intake among participants with a low vegetable intake at baseline. However, no significant additive effect on dietary changes was reported due to the psychosocial feedback provided. In this study, although the inclusion of psychosocial information resulted in tailored feedback being perceived as more interesting and more comprehensive than dietary feedback alone, participants who received feedback tailored only to their dietary intake were more likely to report that they had made changes to their fat intake. The authors comment that the inclusion of psychosocial information could obscure essential messages on the need for dietary behaviour change, due to the increased length of the feedback provided. Overall, this study suggested that providing tailored feedback on dietary intake alone is sufficient in promoting dietary change.

In the study by Raats *et al.* (1999) the provision of tailored dietary feedback, with no additional psychosocial information, was compared to a no-intervention group. Participants in the intervention group did not decrease their fat intake more than did participants in the control group. This finding applied to participants with a low baseline fat intake, as well as those with higher fat intakes, as compared with the population average levels. The authors suggested that one of the reasons for this lack of effect might be the provision of minimally-tailored feedback, which addressed only dietary intake levels and their comparison with recommendations, instead of additionally providing feedback on psychosocial factors affecting dietary behaviour.

Given the findings of the latter study, as well as the acceptability of tailored dietary and psychosocial feedback (Brug *et al.* 1999b), supplementing tailored feedback with psychosocial information is likely to be an important factor leading to successful tailored nutrition interventions.

2.3.6.8. *Effect by feedback dosage*

Twenty-two of the studies reviewed provided a one-time tailored feedback message to participants in their intervention group, whereas twelve provided more than one feedback messages. In order to examine the possible impact of multiple feedback messages, Brug *et al.* (1998) compared the effect on fat, fruit and vegetable intake, of two interventions receiving one and two tailored dietary and psychosocial feedback letters, with a control group receiving general nutrition information. The



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second feedback letter, provided to participants in intervention groups, was tailored to dietary and psychosocial changes made by these between their baseline and post-intervention assessment (ipsative feedback). This study providing ipsative feedback in this manner is more effective, compared with providing a tailored message, in reducing fat and increasing fruit intake, as well as resulting in net increases ($P=.070$) in vegetable intake. Campbell *et al.* (2002) also showed that two feedback messages, delivered in the form of magazines, were more effective in increasing fruit and vegetables, compared with one magazine.

In a second study by Campbell *et al.* (2004), a single tailored dietary and psychosocial feedback was not sufficient in reducing fat or increasing vegetable intake. In addition, it was suggested that more than one message possibly positive outcome regarding fat reduction, when this is not achieved by a single message (Greene & Rossi (1998) have also supported the potential beneficial effect of feedback in more than one occasions. In this study, a single tailored-feedback report led to a net fat intake at 6, but not in 12 or 18 months. The authors commented that the initial point might have been sustained if more frequent feedback had been provided.

The differences in outcome measures and methods employed in the studies does not allow for conclusions to be drawn on the number of tailored messages required, or is more effective, in order to promote dietary change. There is evidence however suggesting that more than one tailored messages would be more successful than a single message in promoting and sustaining dietary changes.

2.3.6.9. Effect of tailoring as part of a multi-component intervention

Twenty of the reviewed studies were multi-component interventions that included tailored feedback as an intervention strategy, as well as a variety of other components (see Section 2.3.6.1.). The intervention arms of these studies have produced positive results on all, or some of their outcomes of interest, compared with a control group. However, it is difficult to isolate effects achieved from the different components of these interventions. For example, it cannot be clearly determined whether it was the tailored dietary and psychosocial feedback, the individual counselling session, the motivational phone calls or the self-help materials, or even the combination of all these approaches, that were associated with the reduction in total fat and saturated fat intake made by the intervention group in the study by Glasgow *et al.* (1997).

There has also been some inconsistency between the studies, with one study showing that tailored feedback did not offer an additional protective effect on group education on the promotion of the Mediterranean diet (Siero *et al.* 2000), whereas Kreuter and Strecher (1996) showed that tailored information on fat intake increased the effectiveness of standard health risk appraisal feedback by decreasing fat intake, a change that did not occur in the group receiving health risk appraisal feedback alone. Nevertheless, research has shown that tailored feedback, provided as part of a multi-component intervention, is one of the components receiving high appreciation and recall (Campbell *et al.* 1999).

These findings suggest that a combination of intervention strategies, that includes tailored feedback as an important adjunct, is feasible and possibly effective in promoting dietary behaviour change.

2.3.6.10. Applicability to low-educated and non-motivated individuals

The majority of studies reviewed were conducted among predominantly Caucasian, relatively well-educated and self-selected participants, who might have been more motivated to make changes to their diets, than members of the general public. Therefore, the potential impact, as well as usage patterns, of tailored-feedback interventions on individuals with different ethnic, socioeconomic and educational backgrounds, should be further investigated.

Calfas *et al.* (2002) for example, reported that minority participants were more likely than Caucasian participants to withdraw from the intervention programme. This study included the use of an interactive computer system to deliver behavioural and psychosocial feedback, which might have caused usage difficulties among people with low education or low computer-literacy skills. In addition, a study using tailored dietary and psychosocial feedback as part of a multi-component intervention proved successful in increasing fruit and vegetable intake and achieving positive movement along the stages of change (Havas *et al.* 1998). However, Black and less educated individuals did not show significant changes towards those outcomes. It might therefore be difficult to implement such interventions in minority and low-educated populations.

Nevertheless, several studies have shown promising results regarding the applicability of tailored-feedback interventions to low-educated and non-motivated participants. In one study, computer-tailored feedback was more effective in encouraging low-educated and non-motivated people to progress through the stages of change regarding fat intake, compared with non-tailored general information (Brug & Van Assema, 2000). Tailored feedback in this study was also more likely to be used more and appreciated better by non-motivated and lower-educated participants, compared with participants who were more motivated to change their diet or have higher education. Siero *et al.*

(2000) also showed that individuals of a socioeconomically deprived background were more successful in progressing through stages of change and making dietary changes after receiving group education and tailored feedback, than general nutrition information. Similar results have been reported concerning intake of fruits and vegetables among rural, blue-collar women of lower educational level and different ethnic backgrounds (Campbell *et al.* 2002), as well as among low-income women of various ethnic backgrounds (Block *et al.* 2004). African-Americans have also been receptive of tailored-feedback interventions aiming at increasing fruit and vegetable intake and have shown positive dietary changes and appreciation of feedback materials (Campbell *et al.* 1999).

These studies show that people who are not motivated to change their diet are still interested in participating in nutrition intervention studies and receiving tailored feedback (Brug & Van Assema, 2000). In addition, one study showed high appreciation of an interactive computer system that provided tailored feedback for fat reduction, among older and non-motivated people (Vandelanotte *et al.* 2004). High acceptability of this program was also independent of low computer-literacy or low education. Tailored nutrition interventions therefore appear appropriate for low-educated, non-motivated and socio-economically and ethnically diverse individuals, particularly if these characteristics are considered during the feedback development (Brug & Van Assema, 2000).

2.3.6.11. Estimated costs of tailored-feedback interventions

Only two of the studies reviewed have provided cost analyses of their intervention programmes. Kristal and his colleagues (2000) reported the cost analyses of delivering their intervention, consisting of tailored self-help materials, a motivational phone call, behavioural feedback and newsletters, to 2,500 people. The person-per-year cost of this multi-tailored intervention, was \$57, including costs of staff training and supervision, intervention materials, mailing, motivational counselling and computers, but not costs for evaluation and material development. The authors reported that an intervention including only a baseline assessment, tailored self-help materials and behavioural feedback would cost \$37 per-person-per-year.

The second report of cost assessment was provided by a study that used an interactive computer system, self-help materials and individual counselling to promote dietary self-management among diabetic patients (Glasgow *et al.* 1997). The actual costs reported represented computer hardware, intervention materials, postage costs, phone calls and staff wages, and not costs for evaluation or material development and were \$137 per participant. If this intervention was delivered to 1,000 people, the person-per-year cost would be \$115, whereas the cost for per unit reduction in serum cholesterol and per 1% reduction in fat intake would be \$6.95 and \$52, respectively. The authors

comment that these costs are lower than interventions involving pharmacological treatment. The cost of the computer hardware platform and software was \$2,650.

Although costs would vary, depending on a program's interactivity and number of tailored materials and messages offered, the findings from the tailored nutrition intervention studies reviewed provide evidence of the opportunities of such interventions to reach large numbers of people in a cost-effective manner.

2.4. Internet-technology nutrition interventions

2.4.1. Rationale

To be effective, 'nutrition promotion strategies must be creative, engaging, inexpensive and widely disseminated' (DiSogra & Glanz, 2000). Novel on-line applications, such as the Internet and the World Wide Web, offer great potential for reaching large audiences in a cost effective manner, since they are widely accessible to the general public and are a primary method of obtaining health information (Patrick *et al.* 1999; Sastry & Carroll, 2002; Williams *et al.* 2002; National Statistics, 2004a).

Tailored-feedback interventions delivered interactively via the Internet might overcome some of the barriers associated with delivering feedback via personal printed materials (e.g. letters, newsletters). For example, with the Internet, the time required to provide tailored feedback following an assessment is reduced to a minimum, thereby increasing the feedback's accuracy (Oenema *et al.* 2001; Oenema *et al.* 2005). In addition, and considering the Internet's wide use, tailored-feedback interventions delivered via this medium may reach larger and more diverse populations, compared with providing feedback via letters. Internet-based tailored applications can also provide access to other online information sources and links to support and discussion groups, as well as opportunities to communicate with experts, in addition to the provision of tailored feedback (Maskens, 2002; Brug *et al.* 2003). Therefore, computer-tailored interventions delivered via the Internet might be even more effective in promoting behaviour change.

2.4.2. Advantages of Internet technology

For health education and promotion, the Internet offers several advantages over more traditional applications. In particular:

- Learning from widely diverse resources, since geographical barriers are eliminated (Gustafson *et al.* 1999), as well as a greater variety of information and navigation pathways for people with different learning styles and preferences (Robinson *et al.* 1998; Quintana *et al.* 2001; Maskens, 2002);
- Access of information at one's own convenience, novelty and appeal, speed and flexibility, freedom and openness of communication (Lewis, 1999; Duffy, 2000; Fotheringham *et al.* 2000; Fotheringham & Owen, 2000; Doshi *et al.* 2003);
- Opportunity to target and tailor information (Robinson *et al.* 1998; Lewis, 1999; Cline & Haynes, 2001; Doshi *et al.* 2003), as well as to collect and automatically process information and provide interactive feedback (Lewis, 1999; Fotheringham *et al.* 2000; Fotheringham & Owen, 2000; Cline & Haynes, 2001; Oenema *et al.* 2001; Quintana *et al.* 2001; Maskens, 2002), thereby imitating face-to-face counselling;
- Given the potential for anonymity of the Internet (Robinson *et al.* 1998; Cline & Haynes, 2001), use of this method to collect health assessment information has been shown to produce more reliable and honest responses than face-to-face interviews or standard, self-administered questionnaires (Locke *et al.* 1992; Gerbert *et al.* 1999), thereby increasing the accuracy of the feedback provided;
- Exchange of information between health professionals, sharing information and maintaining contact between health professionals and patients, as well as sharing life experiences between patients, through support groups (Eng *et al.* 1999; Kalten *et al.* 2000; Cline & Haynes, 2001). In this manner, health professionals may become more efficient in providing appropriate advice and support and patients will be more likely to participate in decision making, optimally leading to improved health and reduced health care costs (Robinson *et al.* 1998; Eng *et al.* 1999; Lewis, 1999).

Although the initial design, set-up and evaluation of interactive Internet applications might be costly, their widespread application will likely be more affordable than face-to-face counselling. Such systems can be easily updated, offering a cost-effective alternative to producing and distributing traditional printed materials (Robinson *et al.* 1998; Dijkstra & De Vries, 1999; Maskens, 2002; Oenema *et al.* 2005), and the effort and costs to tailor feedback will be minimum, as this will be done automatically (Prochaska *et al.* 2000; Oenema *et al.* 2001). Therefore, when large numbers of individuals require information, the set-up costs of such applications may be worthwhile (Bental *et al.* 1999; Dijkstra & De Vries, 1999).

2.4.3. Shortcomings of Internet technology

Despite the Internet's apparent qualities, several important weaknesses may hinder the use of its applications. In particular:

- There is concern that the Internet contains enormous amounts of information from sources of questionable reliability and expertise, that can be misleading, inaccurate, inappropriate and may even put consumers at risk (Impicciatore *et al.* 1997; Eysenbach *et al.* 1999; Cline & Haynes, 2001; Eysenbach & Jadad, 2001; Quintana *et al.* 2001; Benigeri & Pluye, 2003; Doshi *et al.* 2003; Kirk *et al.* 2003);
- Despite the increase in the number of people who use the Internet, social inequalities exist that result in many disadvantaged groups not having access, having difficulties finding and evaluating the information provided (Eysenbach *et al.* 1999; Fotheringham *et al.* 2000; Cline & Haynes, 2001; Eysenbach & Jadad, 2001; Oenema *et al.* 2001; Benigeri & Pluye, 2003), or having difficulties concerning navigational issues (e.g. information overload, lack of organisation, searching difficulties, technical language, lack of user friendliness, lack of permanence of information) (Cline & Haynes, 2001);
- It has been suggested that information read from a screen may not be as thoroughly processed as information provided in traditional printed materials (Ramelson *et al.* 1999; Oenema *et al.* 2001; Oenema *et al.* 2005).

These drawbacks have led health professionals to have limited trust in the Internet (Eysenbach & Jadad, 2001), despite their recognition of this medium's potential for health promotion (Wilson, 1999). Therefore, while the Internet appears promising for delivering health education, the need to provide credible and high-quality information via this channel must be addressed (Davison, 1997).

2.4.4. Quality criteria for evaluation of Internet-technology applications

The varying quality and credibility of health-related information on the Internet has led to the development of guidelines and indicators of quality that should be taken into account when designing web-based applications. These criteria can also be used to evaluate health-related websites and include:

- Transparency and honesty, authority, privacy and data protection, updated information, accountability, responsible partnering, editorial policy, accessibility (Commission of the European Communities, 2002);

- Candor and trustworthiness, quality, privacy and confidentiality, best commercial practices, best practices for provision of health care by health care professionals (e-Health Ethics Initiative, 2000);
- Content (structure, readability, comprehension), design and aesthetics, disclosure of authors and sponsors/developers, currency of information, authority of source, ease of use, confidentiality/privacy (Kim *et al.* 1999);
- Provision of accurate, current, valid, appropriate, intelligible and free of bias information (Delamothe, 2000; Doshi *et al.* 2003), which acknowledges sources of content (i.e. provides references) (Gagliardi & Jadad, 2002);
- Disclosure of purpose and target group, potential conflicts of interest, organisation, readability, interactivity (Cline & Haynes, 2001; Eysenbach & Jadad, 2001);
- Functions (easiness of access, easiness of finding relevant information, usage patterns) and impact (cost-effectiveness, clinical processes, patient outcomes) (Wyatt, 1997).

Accounting for these criteria of website evaluation, it is important for health professionals to familiarise themselves with Internet applications and direct their patients to good quality health information (Benigeri & Pluye, 2003), in order to facilitate shared decision making (Eysenbach & Jadad, 2001).

2.4.5. Examples of Internet-technology applications

Internet applications that have been evaluated to date include websites designed to provide information or promote change regarding several health-related behaviours or conditions. These include emergency contraception (Gainer *et al.* 2003), breast (Winefield *et al.* 2004), colorectal (Birchley *et al.* 2003) and prostate cancer (Pinnock *et al.* 2003), smoking cessation (Lenert *et al.* 2003), excessive alcohol consumption (Linke *et al.* 2004), depression (Christensen *et al.* 2004), rheumatology (Wilson *et al.* 2001), systemic lupus (Young *et al.* 2002), diabetes self-management (Glasgow *et al.* 2003), physical activity (Sciamanna *et al.* 2002; Marshall *et al.* 2003; Napolitano *et al.* 2003), weight loss (Kalten *et al.* 2000; Tate *et al.* 2001; Harvey-Berino *et al.* 2002a; Harvey-Berino *et al.* 2002b; Kirk *et al.* 2003; Tate *et al.* 2003; Womble *et al.* 2004) and eating disorders (Celio *et al.* 2000; Winzelberg *et al.* 2000). Websites have also been evaluated that were designed to provide education and support for patients on the cardiac surgery waiting list (Scherrer-Bannerman *et al.* 2000) and to promote general health among adolescents (Michaud & Colom, 2003). Regarding nutrition, several web-based applications have been designed, in order to increase intake of fruit, vegetable and fibre and reduce high-fat snacks and sodas among girls attending high

school (Winett *et al.* 1999), improve eating habits (Maskens, 2002) and diet quality (Carpenter *et al.* 2004), reduce fat intake (Long & Stevens, 2004), promote cholesterol reduction (Riva *et al.* 2000), increase personal awareness and intentions to change intake of fat, fruits and vegetables (Oenema *et al.* 2001; Oenema & Brug, 2003b), as well as increase fruit and vegetable and reduce saturated fat intake (Oenema *et al.* 2005).

These studies provide evidence of the Internet's opportunities to address a variety of health-related behaviours. A recent meta-analysis of studies that have evaluated web-based interventions against more traditional interventions (i.e. interpersonal counselling, printed materials) has shown that these applications can improve behavioural change outcomes, including weight loss and maintenance, participation in healthcare, physical activity, knowledge of nutritional status, smoking cessation rates, body shape perception and health decline (Wantland *et al.* 2004).

Successful Internet interventions are suggested to incorporate practical advice, encourage self-monitoring and include interactive features, such as assessment and provision of tailored feedback, instead of mainly providing information about the behavioural outcome of interest (Womble *et al.* 2004). In this manner, Internet interventions imitate face-to-face counselling. In addition, and similar to computer-tailored interventions, Internet applications can overcome barriers of face-to-face counselling, such as lack of time or resources (Kirk *et al.* 2003). Regarding the limited applicability of such tools to low computer-literate populations, research has shown that individuals with minimal computer experience have successfully used and felt satisfied with computer-based learning technologies (Lewis, 1999). In addition, it has been suggested that even when people are inexperienced in using the Internet, this can still be a feasible method of promoting health and providing education if motivation, technical demonstrations and support are provided (Eng *et al.* 1998; Scherrer-Bannerman *et al.* 2000).

2.4.6. Internet-technology nutrition education studies

Previous studies have described the design of web-based nutrition applications aimed at several behaviours regarding healthy eating. For example, Maskens (2002) has described the development and content of a website developed to provide information on the role of diet in the causation and prevention of cancer to the general public and health professionals. The site contained scientific information on diet and cancer and provided recommendations on preventive diets, recipe suggestions, results of workshops and meetings related to diet and cancer and links to websites that can provide complementary information (Maskens, 2002). Riva and his colleagues (2000) developed a sophisticated, interactive web-based system to promote cholesterol reduction to hypercholesterolemic individuals, by modifying food consumption, physical activity and food

shopping decisions. The system offered information and suggested weight control and healthy eating strategies according to motivation, readiness to change and psychological determinants of dietary behaviour, by providing interactive tailored feedback (Riva *et al.* 2000). However, no studies reporting evaluation of these sites, regarding usage monitoring, appreciation or impact on behavioural outcomes could be traced.

DiSogra and Glanz (2000) have developed an innovative, Internet-based nutrition programme to encourage children to advocate for policies that promote eating more fruits and vegetables and promote increased consumption of these foods, by facilitating group discussions, youth empowerment and activation strategies. This programme offered an opportunity to use the Internet to induce learning, discussions, problem solving and social action to promote healthful lifestyles, but did not aim to evaluate actual changes in eating habits (DiSogra & Glanz, 2000). An interactive Internet-based application has also been used to deliver tailored, stage-matched dietary and physical activity feedback (Veverka *et al.* 2003), in order to improve fitness levels among Air Force enlisted volunteers. Although the programme was effective in improving several physiological measures, compared with a no-intervention group, no results on dietary intake were published.

A summary of the Internet technology intervention studies that have attempted to promote dietary behaviour change and/or improve determinants of dietary behaviour, in order of year of publication, along with their methods and major findings is presented in Table 2.13.

Table 2.13 Internet-technology nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Theoretical background	Main results
Winett <i>et al.</i> (1999)	North American high school girls (<i>n</i> 180; 103 intervention, 77 control, mean age=15.4 years)	Quasi-experimental trial; Interactive, Internet-based, computer-tailored modules with feedback (derived via FFQ), adjunctive to weekly health and physical education curriculum, compared with usual health curriculum	Primary: Increasing regular meals, fruit, vegetable and fibre intake, reducing high-fat snacks, high-fat dairy products and regular sodas intake, and increasing frequency and duration of physical activity Secondary: Decreasing fat and calories consumed from fast food	Goal setting, Social Cognitive Theory	At 5 weeks, significant intervention increase in regular meals (+0.3 v. +0.0, $P<.001$), fruit and vegetable intake (+1.1 v. -0.2 servings/d, $P<.001$), bread and cereal intake (+1.0 v. -0.2 servings/d, $P<.001$) and physical activity ($P<.050$) and reduction in regular sodas (-0.7 v. -0.3 servings/d, $P<.050$), compared with control group. Significant intervention reduction in fat grams (44.4 v. 30.2 g, $P<.001$) and calories (1047 v. 786 kcal, $P<.001$) consumed from fast food (within group). Application well accepted and enjoyable.
Oenema <i>et al.</i> (2001)	Dutch adults, students and employees of adult education centres (<i>n</i> 197; 96 intervention, 102 control, mean age=44 years)	Randomised controlled trial; Interactive, web-based computer-tailored dietary and psychosocial information, compared with general nutrition information	Increasing personal awareness and intentions to change intake of fat, fruit and vegetables	Precaution Adoption Process model, Transtheoretical model, Social Cognitive Theory	At post-test (immediate impact), significant intervention increase in awareness of intake ($P=.010$) and intentions to change fat intake ($P=.008$), compared with control group. Tailored intervention rated more personally relevant ($P=.001$), novel ($P<.001$), matched to the individual ($P<.001$) and had more subjective impact on opinion about dietary intake ($P<.001$) and intention to change ($P<.001$).

Table 2.13 cont.: Internet-technology nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Theoretical background	Main results
Oenema & Brug (2003b)	Dutch adults, students and employees of adult education centres (<i>n</i> 298; 96 tailored intervention, 100 self-test, 102 control, mean age=44 years)	Randomised controlled trial; Interactive, web-based computer-tailored dietary and psychosocial information, compared with tailored dietary printed self-test forms and general nutrition information (all randomised according to high or medium/low educational level)	Increasing realism of self-rated intake of fat, fruit and vegetable intake and intentions to change	Precaution Adoption Process model, Transtheoretical model, Social Cognitive Theory	<p>At post-test (immediate impact), significant tailored intervention effect on realism of fat intake compared to others (OR=2.6, 95% CI=1.1-5.8 and OR=11.4, 95% CI=12.8-124.1 among medium/low educational level participants), realism of fruit intake compared to others (OR=2.2, 95% CI=1.0-4.6), realism of self-rated fat intake (OR=2.3, 95% CI=1.0-5.1) and intentions to eat less fat ($P<.010$) and more vegetables ($P<.050$), compared with self-test group.</p> <p>Significant tailored intervention effect on intentions to eat less fat ($P<.010$), compared with control group, and intentions to eat less fat ($P<.050$) and eat more vegetables and fruits (both $P<.010$), among participants not meeting recommendations at baseline.</p> <p>Tailored intervention rated more effective, personally relevant (fat: $P=.002$, vegetables: $P=.004$, fruit: $P=.054$), novel ($P<.001$) and individualised ($P<.001$), and had more subjective impact on opinion about dietary intake ($P<.001$) and intention to change diet ($P<.001$), compared with the other groups.</p>

Table 2.13 cont.: Internet-technology nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Theoretical background	Main results
Carpenter <i>et al.</i> (2004)	North American healthy adults, in the precontemplation, contemplation or preparation stage of readiness to change fat, fruit, vegetable, whole grain and dairy food intake (<i>n</i> 98; 30 weekly meeting group, 33 correspondence group, 35 usual care group, mean age=49.6 years)	Randomized controlled pilot trial; Face-to-face weekly group meetings and printed healthy-eating booklet, compared with mail correspondence, interactive website with tailored psychosocial information and printed healthy-eating booklet (correspondence), and printed healthy-eating booklet (usual care)	Primary: Increasing overall diet quality score Secondary: Increasing fruits, vegetables, whole grains and dairy and calcium-rich foods, reducing fat	Transtheoretical model, Social Cognitive Theory, Goal setting	At 6 months, significant weekly meeting group increase in overall diet quality and fruit score (+ 7.7 and +2.2 points) compared with correspondence (+2.3 points, <i>P</i> =.040 and -0.2 points, <i>P</i> =.0001) and usual care (-1.2 points, <i>P</i> =.002 and -0.5, <i>P</i> =.0006) groups. No differences between correspondence and usual care groups.
Long & Stevens (2004)	North American adolescents (<i>n</i> 121; 63 intervention, 58 control, median age=13 years)	Quasi-experimental trial; Classroom curriculum and web-based education, tailored to social and developmental preferences, compared with standard school curriculum	Primary: Self-efficacy for increasing fruit and vegetable and reducing fat intake Secondary: Improving dietary knowledge, food choices and food consumption	Social Cognitive Theory	At 1 month, significant intervention increase in self-efficacy for eating more fruits and vegetables (<i>P</i> <.010) and less fat (<i>P</i> <.001) and improvement in food choices (<i>P</i> <.001) and dietary knowledge for fat (<i>P</i> <.050), compared with control group. No differences between the groups in food consumption.

Table 2.13 cont.: Internet-technology nutrition interventions

Authors	Sample characteristics	Study design	Intervention goal	Theoretical background	Main results
Oenema <i>et al.</i> (2005)	Dutch employed adults (<i>n</i> 782; 261 tailored intervention, 260 non-tailored intervention, 261 control, mean age=42 years)	Randomised controlled trial; Interactive, web-based information with computer-tailored nutrition (derived via FFQ) and psychosocial feedback, compared with web-based general nutrition information, and no information	Primary: Saturated fat reduction, increasing fruit and vegetable intake Secondary: Investigating mediating effects of tailored intervention, increasing awareness and intention to change	Precaution Adoption Process model, Social Cognitive Theory	At 3 weeks, significant tailoring effect on awareness ($P<.010$) and intention to change ($P<.010$) fat and vegetable intake, compared with non-tailored and control groups. No effect on actual intake. Tailored intervention was rated as more personally relevant ($P<.001$ for fat and vegetables; $P<.010$ for fruit), individualised ($P<.001$), interesting ($P<.010$), novel ($P<.001$) and less credible ($P<.050$ for fruit; $P<.010$ for vegetables), and used less often (1.8 v. 2.6 times, $P=.001$), compared with non-tailored intervention group. Significant mediating effect of perceived relevance, individualization and interestingness on tailoring effects.

Six studies were identified, that have used a web-based application as a strategy to promote dietary change and/or improve the psychosocial determinants of dietary intake (Table 2.13). Three of these studies were conducted in the United States, and three in the Netherlands. The different characteristics of these studies are summarised as follows:

- **Sample size and characteristics:** Sample sizes varied from 98 (Carpenter *et al.* 2004) to 782 (Oenema *et al.* 2005). Two studies targeted adolescents, whose mean age was 14.2 years (Winett *et al.* 1999; Long & Stevens, 2004). In the studies recruiting adults, participants were, on average, approximately 45 years of age.
- **Intervention settings:** Two studies were conducted in a school setting (Winett *et al.* 1999; Long & Stevens, 2004) and two in adult education centres (Oenema *et al.* 2001; Oenema & Brug, 2003b). In the remaining studies, participants had free access to the intervention materials at home or at work (Carpenter *et al.* 2004; Oenema *et al.* 2005).
- **Type and length of intervention and follow-up periods:** The length of intervention periods employed varied from three weeks (Oenema *et al.* 2005) to six months (Carpenter *et al.* 2004), with two studies providing an immediate, post-test evaluation of their intervention (Oenema *et al.* 2001; Oenema & Brug, 2003b). The medium used to deliver the intervention was a CD-ROM that could be applied as a web-based application (Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005), a combination of the Internet, mail correspondence (12 mailings over six months) and a printed healthy-eating booklet (Carpenter *et al.* 2004), as well as a combination of the Internet and classroom curriculum, including five weekly Internet modules as part of the classroom curriculum (Winett *et al.* 1999) and five hours of Internet education, along with ten hours of classroom curriculum (Long & Stevens, 2004). One study was a multi-component intervention, providing additional advice on physical activity (Winett *et al.* 1999). All Internet/web-based applications in these studies were interactive and could provide tailored dietary and psychosocial feedback. None of the studies reported follow-up periods following the end of the immediate post-intervention evaluation.
- **Comparison groups:** Two studies compared their web-based application with usual school health curriculum (Winett *et al.* 1999; Long & Stevens, 2004) and one with general nutrition information (Oenema *et al.* 2001). The remaining studies recruited two control groups each. These included a combination of weekly group sessions and a printed healthy-eating booklet (Carpenter *et al.* 2004), general nutrition information and no information (Oenema *et al.* 2005), and self-test printed forms with tailored dietary feedback (including general suggestions to change behaviour) and general nutrition information (Oenema & Brug, 2003b).

- Outcomes and process evaluation: Four studies reported dietary behaviour change as an outcome (Winett *et al.* 1999; Carpenter *et al.* 2004; Long & Stevens, 2004; Oenema *et al.* 2005), two of which aimed at improving diet quality (Carpenter *et al.* 2004) and food choices (Long & Stevens, 2004). In total, four studies reported psychosocial determinants of dietary behaviour (e.g. personal awareness, intentions, self-efficacy, dietary knowledge etc.) as a primary or secondary outcome (Oenema *et al.* 2001; Oenema & Brug, 2003b; Long & Stevens, 2004; Oenema *et al.* 2005). Four studies provided information on appreciation, and/or perceived impact, of the application (Winett *et al.* 1999; Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005) and two studies reported program usage (Carpenter *et al.* 2004; Oenema *et al.* 2005). The two earlier studies by Oenema *et al.* (2001, 2003b) did not report usage of the application, since the program had to be completed in a predetermined sequence. In addition, three studies reported subjective measures of height and body weight, although not as an outcome measure (Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005).
- Use of behaviour change theories: Most studies based their intervention on a combination of established behaviour change theories, while only one study used a single theory (Social Cognitive Theory) (Long & Stevens, 2004). All studies used concepts from the Social Cognitive Theory, four studies addressed the stages of change concept from the Transtheoretical Model and three provided advice according to the Precaution Adoption Process model (Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005). Only two studies used concepts from the Goal Setting Theory (Winett *et al.* 1999; Carpenter *et al.* 2004).
- Type and distribution of assessment instruments: One study used 3-day food records to assess dietary intake (Carpenter *et al.* 2004). The remaining studies used food frequency questionnaires, which were either completed in a web-based version (Oenema *et al.* 2001; Oenema & Brug, 2003b), in a paper-and-pencil format (Long & Stevens, 2004), or a combination of on-line and paper-and-pencil versions (Winett *et al.* 1999; Oenema *et al.* 2005). Questionnaires used to assess psychosocial determinants of dietary behaviour were distributed via the same channel as the dietary assessment instruments. For those studies assessing appreciation and perceived impact of applications, appropriate questionnaires were self-administered in a paper-and-pencil format (Winett *et al.* 1999; Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005).

Although differences between these studies exist, the results reported show the potential of web-based applications in improving psychosocial determinants of dietary behaviour. Web-based interventions proved effective in increasing awareness of personal dietary intake (Oenema *et al.*

2001; Oenema & Brug, 2003b; Oenema *et al.* 2005), intentions to change dietary intake (Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005), self-efficacy skills (Long & Stevens, 2004) and dietary knowledge (Long & Stevens, 2004).

In addition, web-based interventions were significantly more likely to be considered as personally relevant, novel, interesting and individualised (Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005) and to be well accepted (Winett *et al.* 1999). This approach was also reported to have a positive impact on participants' opinion about their diets and on their intentions to change their diets (Oenema *et al.* 2001; Oenema & Brug, 2003b). Oenema *et al.* (2005) showed that the increased perceived relevance, individualization and interestingness of a web-based application providing tailored dietary and psychosocial feedback is a mediator of the positive effects on dietary awareness and intentions, thereby providing an explanation for the potential effectiveness of such programs. However, this study also showed that the feedback received through the web-based application was perceived as less credible.

Web-based interventions were also successful in increasing awareness among participants with a low or medium education, as well as increasing intentions of dietary change among less motivated participants, with unfavourable baseline eating habits (Oenema & Brug, 2003b). In addition, the level of participants' computer literacy does not seem to affect the increased appreciation of web-based applications (Oenema *et al.* 2001), which shows promise for the applicability of such approaches in populations of different backgrounds.

The findings of the studies reviewed concerning dietary behaviour change however, were not so consistent, with only one study evaluating dietary change reporting favourable changes among participants who received the web-based programs (Winett *et al.* 1999). Long and Stevens (2004) found an improvement in food choices among adolescents attending a web-based curriculum, but no differences in actual dietary intake were present, compared with adolescents attending standard health curriculum classes. In this study however, participants in the control condition were also provided with advice to increase skills and improve attitudes in order to promote healthy eating, which is likely to have attenuated the results. The authors also suggested that longer exposure to the study's website might possibly lead to beneficial dietary changes. In addition, Carpenter *et al.* (2004) reported that their website was underused due to lack of time or interest, which probably led to the lack of impact on dietary change among participants assigned to this intervention group. In the study by Oenema *et al.* (2005), the web-based tailored intervention was also used less often than the general information programme, which might be the reason for the lack of dietary changes in this group. In addition, the intervention period was too short for potential changes to take place. Further, the time participants used the interactive program was not determined. Therefore, if

participants had used the program shortly before the post-intervention assessment, the time would not have been enough for dietary changes to occur (Oenema *et al.* 2005).

These studies show the Internet's potential in producing a favourable short-term effect on psychosocial determinants of dietary behaviour. The possible impact of such applications on dietary behaviour change should be further investigated, with intervention studies of longer duration, websites that are appealing to the user and adequate contact and reminders to increase usage (Carpenter *et al.* 2004).

2.4.7. Limitations of previous tailored-feedback and Internet-technology nutrition intervention studies

While tailored-feedback and Internet-technology nutrition intervention studies appear to offer a promising approach to deliver nutrition education in an effective manner, many of the studies conducted to date have suffered several methodological weaknesses, which should be accounted for before the wider application of such programmes.

2.4.7.1. Selection of study population

The majority of studies to date have recruited self-selected participants, who were predominantly Caucasian, well-educated and of a higher socio-economic background (De Vries & Brug, 1999). This resulted in a sample that was often not representative of the general population and limited the generalisability of results (Oenema *et al.* 2001; Carpenter *et al.* 2004; Long & Stevens, 2004; Oenema *et al.* 2005). In addition, individuals volunteering to take part in nutrition intervention studies are likely to be health-concerned and motivated to make changes to their diet (Baker & Wardle, 2002). Although it has been shown that tailored-feedback and web-based applications can be effective irrespective of race (Campbell *et al.* 1999), age (Vandelanotte *et al.* 2004), income (Campbell *et al.* 2004), motivation (Brug & Van Assema, 2000; Vandelanotte *et al.* 2004), education (Brug & Van Assema, 2000; Vandelanotte *et al.* 2004) and computer literacy (Oenema *et al.* 2001; Vandelanotte *et al.* 2004), studies should attempt recruiting participants of diverse backgrounds (De Vries & Brug, 1999).

2.4.7.2. Short intervention and follow-up periods

Almost half of the studies reviewed evaluated their intervention programmes over a period of 3-8 weeks and reported follow-up evaluation at some point after the end of the immediate post-

intervention evaluation. None of the Internet-technology trials carried out follow-up assessments following the end of the post-intervention evaluation. Intervention periods of such duration however, might not be sufficient to produce dietary change, particularly if more than one food components is targeted and changes are to be sustained in the long-term. For example, a study aiming at reducing fat and increasing fruit and vegetable intake over three weeks was successful at changing fat, but not fruit and vegetable intake (Brug *et al.* 1996). In contrast, Baker and Wardle (2002) reported favourable changes in fruit and vegetable consumption over a period of six weeks. The authors suggested that their intervention was more successful in producing this change, compared with earlier studies, because it only addressed one, instead of multiple food components (e.g. fat reduction and increase in fruits and vegetables). In addition, studies should ideally include follow-up assessments at some point after the immediate post-intervention evaluation, in order to establish the longer term impact of intervention programmes (Brug *et al.* 1999a; Oenema *et al.* 2005).

2.4.7.3. *Time span between assessment and feedback delivery*

The majority of studies not providing interactive feedback reported that the time span between assessment and feedback delivery was two to four weeks. The time required for provision of feedback however, varied greatly, from one week (Bowen *et al.* 1994) to seven months (Campbell *et al.* 1999). The importance of rapid feedback delivery has been consistently described, since any major delays could decrease the feedback's accuracy (Campbell *et al.* 1999; Oenema *et al.* 2001). This is because, as dietary habits and/or psychosocial characteristics may change, the information provided might no longer be relevant at the time participants read their feedback (Brug *et al.* 2003). Ideally, feedback should be provided as soon as possible after assessment completion.

2.4.7.4. *Self-reported information*

The majority of the studies reviewed based their findings on self-reported information from study participants. Only six studies provided objective blood lipid (Glasgow *et al.* 1997; Bemelmans *et al.* 2002; Stevens *et al.* 2003; Bemelmans *et al.* 2004) and/or body weight (Glasgow *et al.* 1997; Bemelmans *et al.* 2000; Kristal *et al.* 2000; Campbell *et al.* 2002; Stevens *et al.* 2003) measurements for intervention impact evaluation. This lack of evaluation of more objective criteria of dietary intake could possibly introduce response bias and result in favourable reported changes, if participants reported what they thought might please the researchers (Havas *et al.* 2003). In addition, due to the non-blinded nature of nutrition interventions, it might be difficult to separate any potential favourable impact of the intervention from the possibility of biased self-reporting of

dietary habits (Kristal *et al.* 2000). The use of biological biomarkers could help overcome this limitation.

2.4.7.5. *Controlled conditions*

Some of the Internet-technology intervention trials reviewed evaluated their web-based application under highly controlled conditions (Winett *et al.* 1999; Oenema *et al.* 2001; Oenema & Brug, 2003b). For example, the studies by Oenema *et al.* (2001, 2003b) evaluated an on-site intervention, where participants were required to complete the whole web-based program in a pre-determined sequence. As the authors noted however, participants using a web-based program in a real life setting could easily be distracted by various situations that would possibly prevent them from completing the program or completing self-assessment instruments in order to receive feedback. In addition, participants might be intrigued to obtain information from other sources (e.g. other websites) while using the application of interest (Oenema *et al.* 2001; Oenema & Brug, 2003b). These 'distractions' might affect the evaluation of web-based applications and might overestimate the effects of such programmes.

2.4.7.6. *Process evaluation*

The web-based interventions reviewed have used self-administered questionnaires to evaluate their program's acceptability and/or usage. This method however, might be subject to recall bias and might not provide extensive information on a program's usefulness. A more direct measure of usage, by tracking the number of visits or time spent using the whole and/or different sections of the program would provide a more objective way of evaluating a program's effectiveness (Sciamanna *et al.* 2002). In addition, the conduct of focus group interviews might provide useful and more detailed feedback on a web-based application, which might also be used for refinement of such programs.

2.4.7.7. *"Intention-to-treat" versus "per protocol" analyses*

The majority of studies have based their statistical analyses on "per protocol" analyses, which consider the number of participants who have completed all assessments during the study period. This however, may lead to overestimation of the clinical implications of results, since participants who comply with, and complete all the requirements of a study, might be more motivated to change their dietary habits and enact dietary change than people who withdraw, therefore producing more favourable data (Kruse *et al.* 2002).

In contrast, the “intention-to-treat” principle in data analysis accounts for participants who have completed the baseline assessment, but withdrew from the study at some stage before its completion. Analysing data in this manner, usually by using the last available recorded values for those participants who withdrew from the study and within the group they were initially randomised, would minimise bias and provide consistent interpretation of treatment effects (Nich & Carroll, 2002), that would ‘permit the pragmatic evaluation of the benefit of a treatment change, and not the potential benefit in patients getting the pre-planned allocated treatment only’ (Soares & Carneiro, 2002).

Only six tailored-feedback studies (Havas *et al.* 1998; Kristal *et al.* 2000; Delichatsios *et al.* 2001a; Delichatsios *et al.* 2001b; Baker & Wardle, 2002; Havas *et al.* 2003) and one Internet-technology study (Carpenter *et al.* 2004) of those reviewed have reported “intention-to-treat” analyses, one of which reported both “intention-to-treat” and “per protocol” analyses (Kristal *et al.* 2000). Considering that some studies reported considerable attrition rates (Marcus *et al.* 1998; Anderson *et al.* 2001; Marcus *et al.* 2001; Oenema *et al.* 2005), presentation of results using the “intention-to-treat” principle is likely to produce a clearer indication of these programmes’ effectiveness.

Several of the major limitations of previous studies could therefore be tackled by:

- A longer intervention period, that would allow gradual behaviour change;
- Follow-up measurements, to investigate the intervention’s long-term impact;
- Investigating the intervention’s impact in a “real-life” setting;
- Eliminating the time span between dietary assessment and provision of tailored feedback;
- Use of prospective (i.e. food diaries) instead of retrospective (i.e. FFQs) methods of dietary assessment;
- Use of objective biochemical and anthropometrical measures for impact evaluation;
- Use of a “triangulation” approach for process evaluation of web-based applications (e.g. objective usage patterns, focus group interviews, evaluation questionnaires);
- Analysing results on a “per protocol”, as well as an “intention-to-treat” basis, in order to account for participants who withdraw from the study.

3 Methodology and Sample Characteristics

3.1. Overview

A 6-month intervention trial with a 3-month follow-up, employing a quasi-experimental design with a pretest-posttest evaluation was conducted between May 2003 and May 2004. Healthy females employed by two Universities in Glasgow were invited to participate in order to compare the effect on dietary behaviour change, towards the traditional Mediterranean diet, of two methods of delivering nutrition education. Respondents who agreed to participate received Internet-based nutrition education, via an innovative Mediterranean Eating website, and tailored dietary and psychosocial feedback via e-mail (intervention group) or general nutrition education, via healthy-eating brochures/booklets, and minimally-tailored dietary feedback via e-mail (control group). Dietary intake was assessed using 7-day estimated food diaries. Participants who completed the 6-month intervention were followed-up 3 months later to determine whether any dietary changes had been maintained.

Particular attention was focused on the promotion of four of the eight components of the Mediterranean diet (Mediterranean goals), namely: vegetables (excluding potatoes); fruits (including nuts and seeds); legumes (including beans, lentils, peas and chickpeas); and MUFA:SFA ratio, since intakes of vegetables, fruits and legumes are particularly low and intake of saturated fat is high in the Scottish diet (The Scottish Office, 1996). The study focused on setting reasonable and realistic dietary goals, in a step-wise manner, in order to encourage gradual dietary change regarding these four components, which is more likely to lead to long-term changes (Fletcher & Rogers, 1985). Participants in the intervention group were also asked to choose the order in which they would tackle their Mediterranean goals during the 6-month trial.

For ease of presentation the methods employed by the study will be presented in two sections:

Section A: Development of study materials

Section B: Data collection and study procedures

Section A: Development of study materials

3.2. Development of the Mediterranean Eating website

A Mediterranean Eating website was developed and was available to participants in the intervention group via the Department of Human Nutrition's web page during the 6-month intervention period. In order to develop the website, a web-based search was performed during September and October 2002 to identify the range and content of existing websites promoting healthy eating and the Mediterranean diet. Due to the time frame and because a systematic review of nutrition-related websites was beyond the scope of the study, approximately seventy Internet resources were accessed. The majority of these originated from the United Kingdom, United States, Canada, Australia and Greece and included sites developed by nutrition foundations, organisations and societies, government-funded and academic institutions, the food industry and medical and nutrition information libraries and services. Governmental and commercial nutrition information resources, as well as websites that contained solely recipes were also reviewed. A list of these websites is presented in Appendix I.

The majority of websites reviewed provided information on healthy eating in general, whereas some provided information on established eating patterns that are associated with good health, such as the Mediterranean diet. Most of the websites also provided eating, shopping and cooking tips for healthy eating, as well as recipes. Particular issues of focus in the majority of websites were ways to increase vegetables, fruits and dietary fibre and reduce total and saturated fat and salt in the diet, as well as ways to promote physical activity and reduce or control body weight. Some websites included interactive assessment quizzes, mostly focusing on the calculation of body mass index. The content in the majority of websites was delivered in lay terms, whereas some websites also provided scientific evidence and reports, in technical language, to support the information provided.

Previous research studies were also reviewed, in order to determine users' needs and expectations of Internet health resources (Feightner *et al.* 2001; Quintana *et al.* 2001; White, 2002). In addition, several criteria for evaluating health related websites that have been published to date were identified. These include content; design and aesthetics; disclosure of authors and sponsors/developers; currency of information; authority and credibility of source; ease of use; and confidentiality/privacy (Kim *et al.* 1999). Since the Internet can be a potential source of inconsistent nutrition information for the general public (Davison, 1997), the need to provide credible information via this channel and the above criteria were taken into account in the development of the Mediterranean Eating website.

The development of the website was a collaboration between the researcher (AP), who was responsible for the site's content and Mr. Joe Murray, who designed the layout and format of the site. The underlying concept behind the Mediterranean Eating website was that Scottish people regularly holiday in Mediterranean countries and are familiar with and allegedly enjoy the Mediterranean cuisine. Therefore, the website incorporated many pictures of Mediterranean settings, featuring sunny scenery, blue skies and seas, as well as many pictures of colourful dishes of the Mediterranean cuisine. The focus on colours aimed to refresh memories of Mediterranean holidays and create a relaxed mood that could attract participants to incorporating the Mediterranean diet into their everyday lives in Scotland.

The content of the website was written in non-technical, lay terms and in a friendly and encouraging tone. Although scientific evidence on the benefits of the Mediterranean diet and nutrition information (e.g. food labels, nutrients) was provided, effort was made to deliver this using easily understood terminology. Despite the provision of scientific information, the website mainly focused on the provision of practical tips for dietary change. In this respect and similar to other websites, the Mediterranean Eating website provided healthy eating, shopping and cooking tips, adjusted to reflect the Mediterranean diet. The "Recipes" section was also a major feature of the website and twenty new recipes were added every two weeks, in order to introduce participants to a Mediterranean-style way of eating. The recipes incorporated were mainly inspired from Greek and Mediterranean dishes. However, recipes for popular Scottish dishes, prepared in a Mediterranean style (e.g. with more and a greater variety of vegetables), were also included.

In contrast to other websites, the Mediterranean Eating website provided limited information on the importance of physical activity and obesity prevention, since the study aimed solely at dietary behaviour change. However, some practical advice on ways to increase physical activity and achieve/maintain a healthy weight was incorporated. In addition, while covering the importance and tips on the consumption of all the eight components of the Mediterranean diet, the website focused primarily on the four components promoted by the study (Mediterranean goals). For this purpose, shopping, cooking and eating tips were incorporated to promote the consumption of vegetables, fruits, nuts and seeds and legumes, as well as tips to increase the ratio of monounsaturated to saturated fat in the diet.

In order to increase support between participants, a page was incorporated in the "Recipes" section, where participants were encouraged to share their recipes with each other. For this purpose, an electronic bulletin board was also developed, where participants could communicate with each other and post their questions, suggestions and ideas. In addition, the website incorporated several

interactive self-test quizzes that were developed to test knowledge on different aspects of the Mediterranean diet described on the website.

The format and layout of the website were simple and easy to use. There were eleven main sections, presented as navigation links, leading to a total of 682 online pages that were developed for the whole study course (including pages that were updated over the 6-month trial). For ease of navigation, pages were linked to each other, where appropriate, and the size of each page was relatively small, in order to avoid having to scroll to access information. For this purpose, links to some pages also opened in a new window.

Overall, the website consisted of eleven sections, providing both the theoretical background on the traditional Mediterranean eating pattern as well as practical advice, as described in Table 3.1. Samples of the website pages can be found in Appendix II.

Table 3.1 Content of Mediterranean Eating website sections

Website section	Contents
About the project	Aim of the project and information on background of the researchers
Tip of the Day	Short tip for healthy eating, updated daily
What's New?	Information on updated sections and links to: dietary assessment instruments, a Website bulletin board (developed to facilitate social support among participants) and self-test quizzes (developed to test knowledge on different aspects of the Mediterranean diet described on the website and updated monthly)
Mediterranean diet	Information on the characteristics and health benefits of the Mediterranean diet
Foods and Nutrients	Information on: food components of the Mediterranean diet (description, importance, how much and what types should be consumed); macro- and micronutrients; dietary fibre; and phytochemicals (importance, food sources, how much should be consumed, ways to achieve recommended intakes)
Some Health Issues	Advice on issues such as physical activity, keeping a healthy weight, salt intake and "fast-food" choices
Better Eating Tips	Tips for simple, easy to make dietary changes, using a step-wise approach to change with particular focus on consumption of vegetables, fruits, legumes and MUFA:SFA ratio; tips on eating Mediterranean-style on different occasions, updated every two weeks; including an archive of eating tips
Better Buying Tips	Shopping tips, highlighting the availability of low-cost, seasonal items; information on food labels; seasonal fruits and vegetables for every month of the year (storage and preparation tips); tips on "building" a Mediterranean kitchen
Better Cooking Tips	Healthy-cooking ideas, including healthy recipe ingredient substitutions; using herbs and spices; using fats and oils and using fruits and vegetables
Food Safety	Tips for safe food storage, handling and cooking
Recipes	Mediterranean-style recipes (for breakfast, starters/side dishes, salads, soups/stews, main dishes and desserts), requiring minimal cooking skills and using seasonal produce, updated every two weeks; recipes contributed by participants; recipe archive

Several theoretical models informed the development of the Mediterranean Eating website. The Health Belief Model (Becker, 1974) guided behavioural suggestions regarding several barriers towards healthy eating. In addition, many of the behavioural suggestions to overcome barriers and increase self-efficacy skills regarding healthy eating can be inferred from the Social Cognitive Theory (Bandura, 2001), while advice was also provided in order to improve attitudes and social influences, as well as increase perceived behavioural control, in keeping with the concepts of the Theory of Planned Behaviour (Ajzen, 1991).

The Mediterranean Eating website specifically addressed the barriers to healthy eating identified in the Food Standards Agency Scotland report (Food Standards Agency Scotland, 2002). In order to overcome the barrier of cost and the perception that healthy eating is expensive, the website included a “Fruit and Vegetable of the Month” section, which provided information on low-cost, seasonal vegetables and fruits. Cost-effective food shopping and preparation tips, as well as low-cost recipes, focusing on the use of seasonal produce were also provided. To address the barrier of time and the perception that preparing healthy foods is time consuming, the website provided simple and quick to prepare recipes. In addition, time-saving eating tips were provided on how to adjust everyday diet to the Mediterranean diet (e.g. frozen vegetables, portable fruit, canned legume soups, advice when eating out).

In order to overcome the perception that healthy foods are boring and tasteless, the website encouraged participants to experiment with different flavours and tastes. Information was provided on the use of different herbs and spices, as well as on ways to add variety to meals (e.g. use vegetables of different colours in food, add legumes and different vegetables in soups). The “Fruit and Vegetable of the Month” section also included advice on how to prepare different vegetables and fruits that participants might not have been familiar with. To address the barrier of lack of cooking skills, the majority of recipes presented on the website were easy to prepare and required relatively few, and easy to obtain, ingredients. For participants with minimal cooking skills, the “Better Eating Tips” section also provided advice on ways to incorporate foods, particularly the four components of the Mediterranean diet the study focused on, in everyday life (fruit as a snack and dessert, ready-made salad and frozen or canned vegetables, vegetable- and legume-based dishes when eating out).

3.3. Assessment instruments

3.3.1. Demographics, nutrition knowledge, psychosocial and physical activity questionnaire

A 96-item self-administered Food and Eating questionnaire was used to assess socio-demographic and lifestyle characteristics, nutrition knowledge, psychosocial determinants of dietary behaviour and physical activity patterns of participants of both groups at baseline, 6 and 9 months (Appendix III). The questionnaire took approximately 30 minutes to complete.

The first part of this questionnaire (13 questions) included questions about participants’ ethnic origin, education, occupation, household composition, parity, household food shopping and

preparation responsibility, as well as whether participants were smokers, under any specific diet or medication or taking vitamin supplements. In order to improve the tailoring procedure for participants in the intervention group, a question was included about frequency of eating meals at several different settings (e.g. home, restaurants etc.).

In the second part of the questionnaire (44 questions), a previously validated nutrition knowledge questionnaire was incorporated (Parmenter & Wardle, 1999). This questionnaire has been pre-tested in an adult UK population and has proved to have high internal consistency (Cronbach's $\alpha = 0.7-0.97$), test-retest reliability (Pearson's $r = 0.98$) and good construct validity ($P < 0.001$)² to provide a measure of nutritional knowledge of UK adults (Parmenter & Wardle, 1999). The questionnaire is divided in four sections: knowledge on dietary recommendations (11 items); knowledge on sources of nutrients (69 items); knowledge on choosing everyday foods (10 items); and knowledge on diet-disease relationships (20 items). A score of 1 or 0 was given for each answer depending on whether it was correct or not. The total nutrition knowledge score range was 0-110, and the sub-section scores range, for each questionnaire section, were 0-11, 0-69, 0-10, and 0-20.

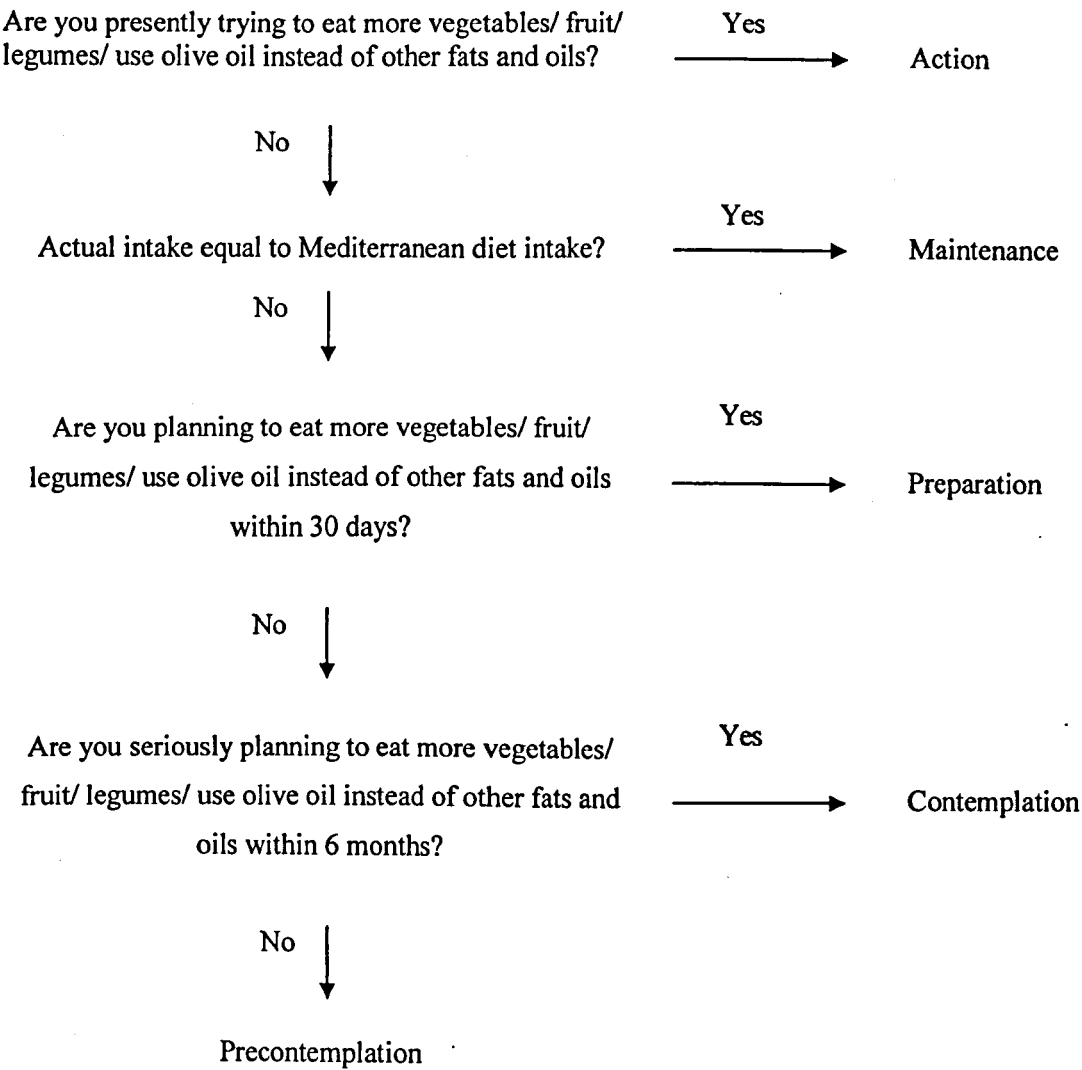
The third part of the questionnaire (37 questions) was adapted from a previously validated questionnaire measuring psychosocial factors influencing fat- and fibre-related dietary behaviour (Glanz *et al.* 1993) and was modified to account for consumption of vegetables, fruits and legumes and substituting olive oil for other fats and oils in the diet. For each of these dietary behaviours, psychosocial factors assessed included perceived benefits ("strongly agree" to "strongly disagree"); perceived barriers ("very important" to "not important at all"); perceived social norms ("strongly agree" to "strongly disagree"); self-rated intake ("very high" to "very low"); importance ("extremely important" to "not important at all"); and motivation ("very likely" to "very unlikely"). These variables were measured on 5-point scales. Categories of perceived benefits and barriers were based on the perceived benefits and barriers to healthy eating identified by respondents to an earlier pan-European study (De Graaf *et al.* 1997; Lopez-Azpiazu *et al.* 1999). Benefits of healthy eating included prevention of disease in general, staying healthy, better quality of life, weight control, keeping fit, living longer, having plenty of energy, doing well at sport and looking attractive. Perceived barriers to healthy eating included cost, lack of availability, lack of familiarity, limited cooking experience, appearance and quality of food, taste/smell, lack of time and length of preparation. Categories of motivators to healthy eating were derived from research on the most significant perceived reasons for eating healthily among UK consumers, which included personal health reasons, general improvement of health, weight loss, media/advertising and pressure from family/friends (Buttriss, 1997).

² When comparing two groups expected to differ in their nutrition knowledge, in this case dietetic and computer science students.

Questions were also included in this part of the questionnaire to assess social support (measured on 4-point scales: “very much” to “none”) and previous dietary change attempts and results (2-point scales: “yes”, “no” and 5-point scales: “extremely successful” to “not very successful”, respectively), as well as self-efficacy skills for dietary change (5-point scales: “extremely confident” to “not confident at all”).

Dietary behavioural intention (stages of change) to change (2-point scales: “yes”, “no”) was assessed based on the Transtheoretical model (Prochaska & Velicer, 1997). For this purpose, a series of questions were asked (Figure 3.1) that categorised participants in five stages of dietary behaviour change regarding the intake of the four components of the Mediterranean diet promoted by the study, namely: precontemplation (no intention to change within the next six months); contemplation (intention to change within the next six months, but not within the next thirty days); preparation (intention to change within the next thirty days); action (currently trying to change); and maintenance of behaviour change (Campbell *et al.* 1994; Brug & Van Assema, 2000). Only participants who already met the recommended intake of each food component (median intake of a group of elderly Greek women consuming a traditional Greek diet) (Trichopoulou *et al.* 1995b), based on 7-day estimated food diary completion (see Section 3.4.1.), were considered to be in the maintenance stage of change for the corresponding component.

Figure 3.1 Stages of dietary behaviour change



Questions on beliefs in diet-disease connections and knowledge, which were included originally (Glanz *et al.* 1993), were excluded from the present questionnaire as these were covered in the nutrition knowledge questionnaire items (Parmenter & Wardle, 1999), whereas a question on attitudes to increasing consumption of the four components of the Mediterranean diet promoted by the study (5-point scales: “extremely favourable” to “extremely unfavourable”) (Paisley *et al.* 1995) was incorporated. Three additional questions were included, where participants were asked to compare their dietary intake with that of their co-workers, family and friends, and people of the same age-gender group (Brug *et al.* 1998). The final part of the questionnaire (2 questions) assessed occupational and leisure physical activity patterns. These variables were measured on 3-point scales (“not very physically active”, “moderately physically active”, “very physically active”).

3.3.2. Food frequency questionnaires

Four short food frequency questionnaires were developed to assess intake of vegetables, fruits, legumes and the main contributors of fat in the diet (Appendix IV). These were self-administered and completed by participants in the intervention group at their baseline assessment meeting, in order to assess intake during the week prior to this meeting (week of food diary completion). It was intended that if these questionnaires provided a good estimate of dietary intake, once validated against the 7-day food diaries (see Section 3.3.2.5.), they would be designed as web-based questionnaires to be completed by participants online during the course of the study, in order to generate tailored feedback letters.

3.3.2.1. Vegetable questionnaire

The vegetable food frequency questionnaire comprised of seven items concerning the intake of raw and cooked vegetables, canned tomatoes, vegetable soup, vegetarian dishes, vegetables added to savoury dishes and pure vegetable juice. Each item was rated twice; the first rating reflected weekly frequency of intake (8-point scales, from “never” to “7 days/week”) and the second rating reflected the number of servings consumed on a day that the item was consumed (7-point scales, from “none”, “one serving” to “>5 servings”). Servings were described in household units, e.g. ½ cup of cooked vegetables, ½ cup of vegetable juice, 1 cup of vegetable soup etc. (Appendix IV).

For each item, servings consumed daily were calculated and multiplied by a nominal portion weight to generate a g/day figure. Portions were equal to 80g of raw and cooked vegetables, canned tomatoes and vegetarian dishes, 200g of soup and 200g of juice. One portion of soup and juice represented the nominal portion of 80g of vegetables each (Williams, 1995). Only one portion of vegetable juice consumed per day counted towards the estimated daily intake of vegetables (Williams, 1995). Total daily intake of vegetables was calculated by adding the daily intake (in grams) for each item.

Two questions were also included in this questionnaire in order to assess the variety of vegetables consumed on a typical day and the number of days when no vegetables were consumed. Potatoes, corn and peas were not assessed in the vegetable questionnaire, since in the original study that described the traditional Greek diet potatoes and corn were included in the cereal and peas in the legume groups (Trichopoulou *et al.* 1995b).

3.3.2.2. *Fruit questionnaire*

The fruit food frequency questionnaire consisted of six items concerning the intake of fresh, canned, frozen and dried fruit, fruit salad and pure fruit juice. Since the original study that defined the traditional Greek diet (Trichopoulou *et al.* 1995b) included nuts and seeds in the fruit group, four items assessing the consumption of nuts and seeds as a snack, added to mixed dishes and added to cakes, as well as peanut butter were incorporated in this questionnaire. The weekly frequency of intake was measured on 8-point scales (from “never” to “7 days/week”) and the number of servings consumed on a day that each item was consumed on 7-point scales (from “none”, “one serving” to “>5 servings”). Servings were described in household units, e.g. 1 medium-size piece of fruit, ½ cup of fruit juice, 1 small handful of nuts or seeds etc. (Appendix IV).

For each item, servings consumed daily were calculated and multiplied by a nominal portion weight to generate a g/day figure. Portions were equal to 80g of fresh, canned, frozen, dried fruit and fruit salad, 200g of juice and 30g of nuts and peanut butter. One portion of juice represented the nominal portion of 80g of fruit and only one portion of fruit juice consumed per day counted towards the estimated daily intake of fruit (Williams, 1995). Total daily intake of fruits, nuts and seeds was calculated by adding the daily intake (in grams) for each item.

Similar to the vegetable questionnaire, two questions were included in this questionnaire in order to assess the variety of fruits consumed on a typical day and the number of days when no fruits were consumed.

3.3.2.3. *Legume questionnaire*

The legume food frequency questionnaire comprised of five items concerning the intake of baked beans, legume soups, legumes added to mixed dishes, as well as soybeans/tofu and soy/veggie burgers. Weekly frequency of intake was measured on 8-point scales (from “never” to “7 days/week”) and the number of servings consumed on a day that each item was consumed on 5-point scales (from “none”, to “>3 servings”). Servings were described in household units, e.g. ½ cup of cooked legumes, 1 cup of soup, 1 burger etc. (Appendix IV).

For each item, servings consumed daily were calculated and multiplied by a nominal portion weight to generate a g/day figure. Portions were equal to 100g of baked beans, 200g of soup and 60g of legumes in other items. One portion of soup represented the nominal portion of 60g of legumes (Williams, 1995). Total daily intake of legumes was calculated by adding the daily intake (in grams) for each item.

Peas were assessed as part of this questionnaire, since in the original study that described the traditional Greek diet peas were included in the legume group (Trichopoulou *et al.* 1995b).

3.3.2.4. *Fat questionnaire*

The fat questionnaire was adapted from a previously validated food frequency questionnaire that assessed frequency of consumption, number of servings and types of the 19 most common food sources of fat in the Dutch diet (Van Assema *et al.* 2001). From this questionnaire, a total fat score could be computed, ranging from 0 to 95, that can classify individuals in broad categories of total fat intake (in grams). The design of the questionnaire was such that a high fat score indicated a high-fat diet. Since this questionnaire only included the most important sources of fat in the diet, a decrease in the total fat score cannot be directly translated to a decrease in percentage of energy from fat (Van Assema *et al.* 2001). This questionnaire was validated among Dutch adults and proved reliable and valid to rank individuals according to total fat intake.

The fat questionnaire comprised of three sections (Appendix IV). The first section was designed to assess weekly frequency of consumption (8-point scales, from “never” to “7 days/week”). For the purposes of the present study, the original questionnaire (Van Assema *et al.* 2001) was adapted to reflect the most important sources of fat in the Scottish diet (Ministry of Agriculture Fisheries and Food and the Department of Health, 1990). Two questions assessing gravy, as well as nuts and peanuts in the original questionnaire were excluded from the adapted questionnaire. Four questions were added to assess chicken and turkey dishes, meat pies, eggs, and fish. In the adapted questionnaire, chocolate and candy bars, as well as milk and chocolate milk were included as single categories (chocolate confectionery and milk, respectively). After refinement, 15 categories of food items were assessed, namely: meat and meat dishes; chicken and turkey dishes; meat pies and pastries; biscuits; buns and cakes; puddings and ice cream; fat spread on bread; milk; yoghurt; cheese; fried potatoes; savoury snacks (e.g. crisps); chocolate confectionery; eggs and egg dishes; and fish and fish dishes.

The second section assessed the number of servings of food items consumed on a day that those items were consumed (7-point scales, from “none”, “one serving” to “>5 servings”). Similar to the original questionnaire (Van Assema *et al.* 2001), number of servings were assessed for biscuits; puddings and ice cream; fat spread on bread; milk; yoghurt; cheese; fried potatoes; savoury snacks; and chocolate confectionery. Servings were described mainly in household units, e.g. 1 teaspoon of spread, 1 carton yoghurt, 1 small packet of crisps etc.

The third section of the adapted questionnaire assessed the quality of foods consumed. Questions were included to assess types of fat spreads, milk, cheese and yoghurt. Adjustments to the original questionnaire were made, where appropriate, in order to reflect products available in the UK market (Appendix IV).

Following appropriate adjustments to account for fat content of foods in the UK using the Diet5 program (Diet5 for Windows, Robert Gordon University, Aberdeen, UK), each category of food items received a score that ranged from 0 (lowest fat intake) to 5 (highest fat intake), based on the frequency of consumption and, where applicable, the number of servings and type of food consumed. Similar to the original questionnaire, the score for each category of food items should provide as close an indication as possible of the corresponding amounts of total fat (g) for these foods (Van Assema *et al.* 2001). The scoring system of the adapted fat questionnaire can be found in Appendix IV. The total fat score was calculated by adding up the fat scores for each category. Therefore, the total fat score calculated from the adapted questionnaire ranged from 0 to 75.

3.3.2.5. *Validation of food frequency questionnaires*

Relative validity of each food frequency questionnaire was assessed by comparing the results from its baseline administration with results from the baseline 7-day food diaries for fifty-one participants who provided data for both measures. Data on vegetable, fruit, legume and total fat intake (g/day) were recoded into tertiles and comparison of intakes and agreement within categories between the two dietary assessment methods were assessed using Pearson's correlation coefficients and weighted kappa statistics (with 95% confidence intervals), respectively. It has been suggested that kappa values from 0 to 0.20 indicate poor agreement, 0.21 to 0.40 fair agreement, 0.41 to 0.60 moderate agreement, 0.61 to 0.8 good agreement and 0.81 to 1 very good agreement (Altman, 1992).

The baseline mean daily intakes of vegetables, fruits, nuts and seeds, legumes and total fat, as assessed with the short food frequency questionnaires and the 7-day estimated food diaries are presented in Table 3.2. Compared with the food diaries, the vegetable and fruit short food frequency questionnaires tended to overestimate intake of vegetables and fruits, nuts and seeds. The legume short food frequency questionnaire produced an equal mean intake of legumes, whereas the fat food frequency questionnaire tended to underestimate total fat intake compared with the 7-day estimated food diaries. Correlations and measures of agreement between the baseline results of the food frequency questionnaires and the 7-day estimated food diaries are also listed in Table 3.2. Higher correlations were observed between the fruit food frequency questionnaire and fruits, nuts and seeds variables. Exact agreement within tertiles ranged from 49.0 to 56.9% and dissimilar classification

(into opposite tertiles) ranged from 7.8 to 11.8%. Weighted kappa statistics indicated fair agreement between the food diaries and all food frequency questionnaires. On the basis of these results, the food frequency questionnaires were considered acceptable as a means of assessing goal progress, which in turn informed the educational tailored feedback provided during the study course.

Table 3.2 Mean daily intake of food components assessed with 7-day estimated food diaries and food frequency questionnaires (with correlations and agreement within tertiles)

	FFQ		7-day estimated food diary		Correlation coefficient <i>r</i> (95% confidence interval)	Weighted kappa (95% confidence interval)	Similarly classified (%) ^a	Dissimilarly classified (%) ^b
Baseline (<i>n</i> 51)	Mean	SD	Mean	SD				
Vegetables (g/d)	222.4	116.9	156.6	68.8	0.371 (0.008, 0.011)	0.237 (0.016, 0.021)	49.0	11.8
Fruits, nuts and seeds (g/d)	286.2	146.0	180.1	119.1	0.522 (0.000, 0.000)	0.354 (0.000, 0.001)	56.9	7.8
Legumes (g/d)	14.9	20.2	14.9	17.8	0.353 (0.012, 0.016)	0.262 (0.013, 0.018)	54.9	9.8
Fat (g/d)	62.7 ^c	17.6	71.8	22.9	0.441 (0.001, 0.003)	0.235 (0.025, 0.031)	49.0	7.8

^a Percentage of participants classified into the same tertile of the distribution by the 7-day food diary and the FFQ

^b Percentage of participants classified into the opposite tertile of the distribution by the 7-day food diary and the FFQ

^c Indication of grams of fat corresponding to the total fat score calculated from the fat short food frequency questionnaire

3.3.3. Post-test process evaluation questionnaires

At the end of the 6-month intervention, all participants were asked to complete a self-administered post-test process evaluation questionnaire. Questions included in this questionnaire were adapted from previous research (Brug *et al.* 1996; Brug & Van Assema, 2000).

3.3.3.1. *Intervention group*

The post-test evaluation questionnaire administered to participants in the intervention group was divided into two sections (Appendix V). The first section consisted of questions about whether and how participants used (remembered receiving, read, saved, discussed with or shown to others) and appreciated (caught their attention, personal relevance and novelty of information, agreement with information, interesting, informative, trustworthy, easy to understand, useful, attractive, encouraging, time-saving, limited) the tailored feedback letters. Questions were also included to assess the perceived effects of the tailored feedback letters on changes of participants' opinions about their diets, actual dietary changes regarding the four components of the Mediterranean diet promoted by the study, intentions to make further dietary changes and participants' general satisfaction with the tailored feedback letters.

The second section of the post-test evaluation questionnaire consisted of questions about participants' reactions to the Mediterranean Eating website. Questions were included to rate the perceived helpfulness of the overall website and its specific sections, the overall satisfaction with the website and whether participants perceived the website to be interesting, informative, trustworthy, easy to understand, useful, attractive, encouraging, time-saving and limited. Participants were also asked whether they had used any of the recipes presented on the website and if applicable, to rate the easiness of preparing recipes, whether ingredients were easy to find, whether they perceived ingredients to be expensive and whether their friends/family enjoyed the sampled recipes. These variables were measured on 3-point scales ("very", "moderately", "not at all"). In addition, participants were asked to rate the frequency of use of the overall website and its sections ("a few times the first few weeks", "once a month", "once a fortnight", "more than once a fortnight"). Questions about perceived barriers to using the website and whether this combined method of tailored feedback and Internet nutrition education would be preferred to a consultation with a professional ("yes", "no", "not sure") were also included.

3.3.3.2. *Control group*

The post-test evaluation questionnaire administered to participants in the control group was also divided in two sections (Appendix V). In the first section the same variables were assessed as in the intervention post-test evaluation questionnaire (use and appreciation of the minimally-tailored feedback letters, effect of the letters on changes in participants' opinions about their diets, actual dietary changes, intentions and general satisfaction with the minimally-tailored feedback letters).

The second section of the post-test control evaluation questionnaire consisted of questions about participants' reactions to the general nutrition information brochures. Participants were asked whether they remembered receiving and whether brochure information caught their attention, as well as how much of the information they had read. Questions were also included to rate the perceived helpfulness ("very", "moderately", "not at all") and the frequency of reading ("never", "once", "more than once") the nutrition information brochures. In addition, questions were included to rate the general satisfaction with the brochures ("very", "moderately", "not at all") and whether this combined method of feedback letters and nutrition information brochures would be preferred to a consultation with a professional ("yes", "no", "not sure").

3.3.4. *Focus group interviews*

Following the return of the post-test process evaluation questionnaires, participants in the intervention group who completed the 6-month trial and those who withdrew before the end of the intervention period were invited to attend qualitative semi-structured focus groups, in order to evaluate the Mediterranean Eating website, as well as determine main areas of nutrition information needs.

An interview guide/schedule was developed, outlining questions about previous interest in obtaining nutrition information and previous sources accessed for information, as well as determinants of information credibility. Participants were asked their opinion about how the Mediterranean Eating website compared with other nutrition information sources and were asked to comment on website features that they liked and did not like, and whether they expected the website to contain features that were lacking or if there were any existing features that they would prefer changed. Barriers to using the website, effects of the information provided on everyday food choices and which website sections were perceived as most/least interesting were also discussed. The sequence and wording of the questions were modified, when appropriate, in order to explore emerging issues in more detail and allow participants to provide additional information. Interviews

were audiotaped with the permission of participants and audiotapes from each focus group were precisely transcribed.

Section B: Data collection and study procedures

3.4. Data collection

3.4.1. Primary outcome measures

Dietary behaviour was assessed by means of 7-day estimated food diaries, which were posted to participants. Detailed written instructions for completion of the food diaries were provided (Appendix VI) and participants were encouraged to contact the researcher if they had any questions regarding this procedure. Participants were also advised to start completing their diaries exactly one week prior to their assessment meeting (baseline, 6 and 9 months), at which time completed diaries were returned to the researcher. During the course of the study, dietary behaviour of participants in the intervention group, regarding the four Mediterranean goals, was assessed via four short food frequency questionnaires (see Section 3.3.2.), in order to generate the tailored feedback letters for individuals in this group.

Dietary data from the 7-day food diaries were checked for completeness and participants were contacted individually in order to clarify any queries (e.g. unknown food items). To avoid coding errors, data were computer entered and analysed by the same researcher, using the Diet5 program (Diet5 for Windows, Robert Gordon University, Aberdeen, UK). In the case when a consumed food item was not included in the Diet5 program, participants were either asked to provide specific recipes or food brand names, or it was substituted with an item of similar nutrient content.

Data from the 7-day food diaries were analysed at baseline, 6 and 9 months to calculate the Mediterranean Diet Score (MDS), a composite score based on the consumption of the eight components of the traditional Mediterranean diet. The cut-off point for each dietary component represents the median intake, specific for sex, of a group of elderly Greeks consuming a traditional Greek diet, on which the score was originally based (Trichopoulou *et al.* 1995b). Energy intake was adjusted to 8,368 kJ (2000 kcal) and a score of 1 or 0 was given for each of the food components depending on whether the cut-off point was met or not. Consequently, the total score range was 0-8, with a high score defined as ≥ 4 (Trichopoulou *et al.* 1995b). For the purpose of this thesis, the upper limit of intake of alcohol was increased from the median (0 g) to 5-25g/d (Trichopoulou *et al.* 2003).

Blood and urine samples were collected after an overnight fast (minimum 10h) in order to assess plasma lipid and urinary electrolyte levels at baseline, 6 and 9 months. Blood samples (approximately 10 ml) were drawn in EDTA sample tubes using standard venepuncture procedures. Plasma was harvested at 4°C by low-speed centrifugation, and aliquots for lipid and lipoprotein measurements were used immediately. Total-cholesterol, HDL-cholesterol and triglycerides were measured using enzymatic techniques and LDL-cholesterol was estimated using the Friedwald formula (Friedwald *et al.* 1972). The ratio of total:HDL-cholesterol was also calculated because it has been suggested that it is an important measure of coronary heart disease risk status (Kinosian *et al.* 1994).

Urine samples (first urine in the morning, approximately 50 ml) were collected in plain plastic containers without preservative at baseline, 6 and 9 months. Aliquots for urinary electrolytes were used immediately. Urinary potassium, as a biomarker of dietary potassium and fruit, vegetable and legume intake (Jones *et al.* 2001), and urinary sodium levels were assessed using ion-selective electrode-based methods. Creatinine was assessed with the Jaffé reaction method. The ratio of potassium:creatinine was also calculated because it has been associated with fruit and vegetable intake (Cappuccio *et al.* 2003).

All biochemical analyses were performed at the Department of Clinical Biochemistry, Glasgow Royal Infirmary, North Glasgow University Hospitals NHS Trust using standardised protocols and internationally agreed quality assurance procedures.

3.4.2. Secondary outcome measures

Body weight was measured with a digital scale with an accuracy of 500 g, in subjects with light clothing and without shoes. Standing height was measured with a stadiometre with an accuracy of 1 mm, in subjects without shoes, with shoulders relaxed and with heels adducted. Body Mass Index (BMI) was calculated as weight (kg) divided by height (m²). Waist circumference was measured with a flexible tape to the nearest mm, midway between the lowest rib and the iliac crest. Systolic and diastolic blood pressure were measured using a digital blood pressure monitor (AND Model UA-767, A&D, Tokyo, Japan), on the left arm, with subjects seating and after a five minute rest. Blood pressure measurements were taken two times with a one minute interval between the readings. The means of the two measurements were used for data analysis. All anthropometric and blood pressure measurements were performed at baseline, 6 and 9 months.

Nutrition knowledge, readiness to change, as well as importance of, and attitudes and self-efficacy skills towards dietary change were assessed at baseline, 6 and 9 months by means of a Food and

Eating questionnaire (see Section 3.3.1.). Although other psychosocial determinants of dietary behaviour (e.g. perceived benefits and barriers, perceived social support), as well as awareness of dietary intake were assessed via this questionnaire, these variables were used to tailor feedback in the intervention group and were not included as outcome measures.

During the 6-month trial, overall website login frequency for each participant in the intervention group and website usage patterns (total counts of visits to each website section) were measured via statistical summaries generated from the University of Glasgow web server. At the end of the 6-month intervention, appropriate post-test process evaluation questionnaires (see Section 3.3.3.) were also used to assess reactions towards the materials provided over the study course to participants in the intervention (tailored dietary and psychosocial feedback letters and Mediterranean Eating website) and control (minimally-tailored dietary feedback letters and general nutrition information brochures/booklets) groups. In addition, qualitative semi-structured focus group interviews were conducted with participants in the intervention group, in order to provide additional feedback on appreciation, perceptions and attitudes towards the Mediterranean Eating website.

3.5. Study procedures

3.5.1. Recruitment of sample

Using a level of 0.05 (two-tailed) and power of 80%, a sample size of 36 was needed to detect statistically significant differences in the mean MDS of the intervention group from baseline of the order of 0.5. It has been shown that a one unit increase in total MDS is associated with a significant 17% reduction in overall mortality (Trichopoulou *et al.* 1995b). As this study promoted only four components of the Mediterranean diet, a change of 0.5 was considered to be an important difference.

Fifty-three women were recruited from the University of Glasgow to serve as the intervention group and nineteen women from Glasgow Caledonian University, to serve as the control group. Recruitment strategies included advertisements in newsletters, flyers, postings on the worksites' Intranet and e-mail advertisements (Appendix VII). Eligibility criteria included females aged 25 to 55 years, with Internet and e-mail access at work and who were born or had lived in Scotland for more than 15 years. Participants were ineligible if they had a history of cardiovascular disease, cancer, diabetes or hypertension or if they were pregnant. Inclusion and exclusion criteria were clearly stated on the advertisements. Those who met the study criteria were sent an information sheet that described the study procedures in detail (VI). Once their willingness to participate was

verified, respondents were informed that they could participate in the study and were asked to sign an informed consent form (Appendix VII) during their baseline assessment meeting with the researcher.

3.5.2. Procedures

All participants were seen at baseline, 6 and 9 months, at which time their body weight, height, waist circumference, blood pressure, fasting plasma lipids and fasting urinary electrolytes were measured (see Section 3.4.1.). These assessments were carried out at the participants' worksite by the same researcher and a light breakfast was provided after blood samples had been drawn. At these time points, all participants provided a self-administered 7-day estimated food diary to determine current eating habits and the Food and Eating questionnaire to assess psychosocial determinants of dietary behaviour (see Section 3.3.1.). Intakes of vegetables, fruits, nuts and seeds, legumes and MUFA:SFA ratio, as calculated from the food diaries, were compared with the respective median intakes of a group of elderly Greek women consuming a traditional Greek diet (Trichopoulou *et al.* 1995b).

3.5.2.1. Intervention group

Depending on current dietary intake, participants in the intervention group were encouraged to attempt to increase or maintain the consumption of the four components of the Mediterranean diet promoted by the study (Mediterranean goals) over the 6-month intervention period, by focusing on a single goal for a period of 6 weeks. Each participant chose the order in which they would tackle their goals (e.g. focus on achieving the vegetable goal for the first 6 weeks, the legume goal for the next 6 weeks and so on).

Participants in this group received tailored dietary and psychosocial feedback via an e-mail letter, which was based on the results of their baseline dietary and psychosocial assessment (see Section 3.6.1.). Following receipt of their first tailored feedback letter, participants were given access to the Mediterranean Eating website, which they were requested to visit at least once a week.

Participants were sent a letter with detailed website login instructions (Appendix VI) and were encouraged to contact the researcher in case they encountered difficulties with the login procedure. A personal login identification password was assigned to each participant in order to monitor their entry into the website and to provide a measure of website login frequency and use. For this purpose, participants were specifically asked not to share their password, not to bookmark any

pages of the website and to always enter the website through the login page. In order to personalise the procedure, passwords were recognised by the web server and participants were greeted with their first name and a welcome message once they entered the home page of the website. Participants were e-mailed on a weekly basis and encouraged to visit the website and the sections that had been updated and also were directed to the website sections relevant to their current Mediterranean goal.

During the course of the intervention, participants completed a series of short food frequency questionnaires (see Section 3.3.2.), every 6 weeks, to assess their progress towards their selected Mediterranean goal. These food questionnaires were completed online while logged into the Mediterranean Eating website and responses were delivered to the researcher's e-mail address, from where they were analysed in order to generate the tailored feedback letters. Participants were then invited to tackle a second (third, fourth) goal in a step-wise manner. The 6-weekly assessments provided tailored feedback (see Section 3.6.1.), which gave information on achievement of previous selected goals and provided comparisons with previous levels of intake and encouragement to tackle a new goal in the manner described above.

Overall, participants in the intervention group received six tailored feedback letters over the 6-month intervention period. A seventh feedback letter was sent to participants in this group following their 3-month follow-up assessment.

3.5.2.2. *Control group*

Participants in the control group received minimally-tailored dietary feedback via an e-mail letter, which was based on the results of their baseline dietary assessment (see Section 3.6.2.). Following receipt of their first feedback letter, participants were sent three brochures/booklets containing general healthy-eating information, produced by the Health Education Board of Scotland. The leaflets provided information on the importance of eating healthily, suggestions for planning balanced meals and including more vegetables and fruits in the diet, as well as suggestions and recipes for low-cost, time-saving and healthy meals. No further contact was made with participants in this group until the end of the 6-month intervention, when they received a second feedback letter based on their 6-month dietary assessment.

Overall, participants in the control group received two minimally-tailored feedback letters over the 6-month intervention period. A third feedback letter was sent to participants in this group following their 3-month follow-up assessment.

3.6. Development and content of feedback letters

Feedback letters provided to participants in both groups were developed within a week of each dietary assessment and sent to participant's e-mail addresses. All participants were asked to confirm receipt of their letters. If receipt was not confirmed within a week, participants were contacted and the feedback letters were sent again. All letters were personalised, with participants' names written in the first paragraph and in several sections throughout the letters. All letters also had a similar format and layout, and featured the University of Glasgow's logo.

3.6.1. Intervention group

Tailored feedback letters sent to participants in the intervention group were developed using concepts from several behaviour change theories. Advice was provided on developing skills to improve food choices and changing dietary behaviour across stages of behaviour change, based on the stages of change concept from the Transtheoretical Model (Prochaska & Velicer, 1997). The letters also informed participants of their current dietary intake, and a comparison of current with perceived intake, as well as with the median intake of the Mediterranean diet, was provided, in order to increase awareness of personal dietary behaviour, based on the Precaution Adoption Process Model (Weinstein, 1988). In addition, suggestions tailored to perceived benefits and barriers were informed from the Health Belief Model (Becker, 1974), while the letters included advice on how to increase confidence towards achieving the Mediterranean goals, as well as obtain support from family and friends, in keeping with the principles of the Social Cognitive Theory (Bandura, 1986). The Theory of Reasoned Action and Planned Behaviour, with its focus on the importance of attitudes, social norms and perceived behavioural control in influencing intentions and behaviour change is also evident in the intervention (Ajzen, 1991; Ajzen, 2001).

The initial tailored feedback letter was approximately eight pages long, which included text and graphics. The letter started with an introductory paragraph describing the Mediterranean diet and its benefits. It then proceeded to compare participants' current intake of the four components of the Mediterranean diet promoted by the study with the median intake of a group of elderly Greek women consuming a traditional Greek diet (Trichopoulou *et al.* 1995b). These comparisons were explained in words, in addition to graphs. In order to increase awareness of intake, this section of the letter also provided a comparison of participants' perceived intake of each food component with the median intake of the Mediterranean diet (Trichopoulou *et al.* 1995b). The letter then focused on participants' first selected Mediterranean goal and provided advice to tackle perceived barriers,

improve attitudes and self-efficacy skills and tips to achieve or maintain the recommended intake of the selected food component, depending on current intake.

Different information was provided according to participants' selected goal, stage of change and perceived attitudes towards, and importance of consuming the selected food component. The letter also addressed participants' most important perceived benefits of, and motivators towards consumption of the selected food component and emphasised corresponding properties of the Mediterranean diet. In addition, the letter provided practical examples of how to increase or maintain current intake in order to achieve intake of the selected goal, as well as ways to improve taste of the current food component of interest. Further information was included depending on participants' perceived barriers towards consuming selected food components. Most important barriers for each participant were identified and advice was provided on how to overcome those. Moreover, information was provided according to participants' reasons for considering dietary change, self-efficacy expectations and confidence, and advice was given on how to achieve their goal when faced with challenging situations, as well as how to increase encouragement from their social environment. The final paragraph of the first feedback letter contained general tips on how to achieve intake of the selected Mediterranean goal. A sample of tailored feedback letters sent to participants in the intervention group at baseline, addressing each of the four Mediterranean goals, can be found in Appendix VIII.

Tailored feedback letters generated over the course of the 6-month intervention were similar to the first letter and were approximately seven pages long. A comparison, both in words and in graphs, was provided of participants' current intake of their previously selected food component with their baseline intake and with the Mediterranean diet and general advice was given on how to continue attempts in order to achieve or maintain that goal. Letters then proceeded with information on how to achieve or maintain intake of subsequent goals, according to baseline intake, and addressed psychosocial determinants of dietary intake in a similar manner.

Tailored feedback letters generated following the completion of the 6-month intervention and the 3-month follow-up were approximately six pages long and provided a comparison, in words and graphs, of current intake of all four food components with intake during previous assessments and with the Mediterranean diet. General tips on how to increase or maintain intake of these food components were provided at the end of those letters.

Information provided in all feedback letters was tailored to participants' dietary intake and perceived attitudes, beliefs and intentions, according to their ongoing dietary assessment and baseline psychosocial questionnaire. Throughout the letters, participants were encouraged to

attempt to achieve their Mediterranean goals in a step-wise manner by making gradual changes and to continue attempting to achieve or maintain the recommended intake of their previously selected goals. Where appropriate, letters directed participants to relevant sections of the Mediterranean Eating website, where additional information could be found.

3.6.2. Control group

The initial minimally-tailored feedback letter provided to participants in the control group was approximately five pages long, which included text and graphics. The letter started with an introductory paragraph describing the importance and benefits of a healthy diet, which incorporates vegetables, fruits and legumes and where olive oil substitutes other oils and fats. It then provided a comparison, in words and in graphs, of current intake of the four food components of the Mediterranean diet promoted by the study with the median intake of a group of elderly Greek women consuming a traditional Greek diet (Trichopoulou *et al.* 1995b). The final part of the letter contained general tips on how to achieve or maintain the recommended intake of these components, depending on current intake. A sample of a tailored feedback letter sent to participants in the control group at baseline can be found in Appendix IX.

Feedback letters generated following the completion of the 6-month and 3-month follow-up assessments were similar in length and content with the first feedback letter, but provided a comparison, in words and graphs, of current intake of the four food components with intake during all previous assessments and with the Mediterranean diet. The same general tips on how to achieve or maintain intake of these food components were provided at the end of those letters.

3.7. Ethical considerations

The study procedures and questionnaires were approved by the Ethics Committees of the Faculty of Medicine, University of Glasgow and North Glasgow University Hospitals NHS Trust (Appendix X). There were no obvious risks involved in participating in the study and the researcher received appropriate training before being qualified to perform venepuncture.

Participation was voluntary and participants were informed that they could withdraw from the study at any time and without giving any reason. After replying to the recruitment advertisement, all participants were sent a detailed information sheet (Appendix VII) that described the study procedures and requirements in detail and were encouraged to contact the researcher if they had additional questions or concerns. All participants signed an informed consent form prior to their

baseline assessment (Appendix VII). Participants were provided with their dietary, physical and biochemical results shortly after their assessment and were also informed that they would be notified if results of this study were published.

All information collected during the course of the study was kept strictly confidential and was only used for the study purposes. Participants were assigned a personal ID code, which was written on all their questionnaires. Although names and addresses were provided for correspondence purposes, these never appeared in any analyses or published reports. The focus group interviews were carried out anonymously and participants could not have been identified from the audiotapes. In addition, all documents sent to participants, including biochemical results and feedback letters via e-mails, were clearly marked as private and confidential. All results are presented as grouped data.

3.8. Analysis of data

All data analyses were performed using the Statistical Package for the Social Sciences (SPSS for Windows, release 11.5, 2002, SPSS, Chicago, Illinois). All data were computer-entered, reviewed and corrected by the same researcher, in order to avoid between-coder errors. Normality of distribution for all variables assessed was assessed using the Kolmogorov-Smirnov and skewness and kurtosis tests. Differences with $P < .050$ were considered to be significant.

Dietary, anthropometric and biochemical data were examined in three ways; first, for participants who completed both the baseline and the 6-month assessments; second, for participants who completed all three assessments (baseline, 6 months and 9 months); and third, on an intention-to-treat basis. Analysing data using the intention-to-treat principle takes into account participants who completed and withdrew from the study, according to their initial treatment group. Although this method cannot account for possible favourable changes in outcome measures, especially when withdrawal from a trial is not associated with the treatment received (e.g. geographical relocation) (Wright & Sim, 2003), this principle also minimises problems arising from missing values, which might bias and overestimate the clinical implications of results (Kruse *et al.* 2002). Between group comparisons carried out on an intention-to-treat basis in particular, provide the strongest evidence of the effect of an intervention, when compared to a control condition. For this study, intention-to-treat analyses used the last available recorded value for participants who withdrew from the study at some stage before the end of the 9-month follow up.

Comparisons of baseline socio-demographic and lifestyle characteristics between the intervention and control groups, as well as between participants in both groups who completed the 9-month

assessments and those who were lost to follow-up were performed using the Mann-Whitney U and Kruskal-Wallis tests for categorical variables.

For both the “per protocol” and the “intention-to-treat” analyses and in order to detect changes in mean food group intake, mean total MDS and mean anthropometric and biochemical measurements for both groups at baseline, 6 and 9 months, the Wilcoxon Signed Ranks test and paired-samples t test were used for non-normal and normally distributed variables, respectively. The Mann-Whitney U test was used to compare the changes from baseline in mean dietary intake, anthropometric and biochemical measurements between the intervention and control group. The McNemar test was performed to compare the within group differences in proportion of participants achieving a MDS of 1 for each food group, as well as the proportion of participants achieving a high MDS (≥ 4) at baseline, 6 and 9 months and the Kruskal-Wallis test to compare the differences between the groups in these variables.

One-way analysis of variance (ANOVA) with Bonferroni post-hoc multiple comparisons was performed to examine differences in dietary changes over 6 and 9 months, according to mean 6-month website login frequency, between high- and low-frequency users of the website (intervention group) and participants in the control group. Since participants in the intervention group were requested to visit the website at least once per week, a login frequency cut-off point of 20 times over the course of the 6-month intervention was used to determine high- and low-frequency users. To examine differences in dietary changes over 6 and 9 months, according to stage of dietary behaviour change for each food component, a dichotomous variable (forward stage of transition/FST and no forward stage of transition/no FST) was created for each participant by comparing her stage of change at baseline with that at 6 and 9 months (Brug & Van Assema, 2000). One-way analysis of variance was then performed between the intervention and control groups, with dietary changes as the dependent variable and forward-stage-of-transition as factor.

Within group differences in nutrition knowledge score and sub-section scores were examined using the Wilcoxon Signed Ranks test and paired-samples t test for non-normal and normally distributed variables, respectively. Between the groups, comparisons of changes from baseline in these variables were assessed with the Mann-Whitney U test. In order to examine changes in lifestyle characteristics and psychosocial determinants of dietary behaviour at all time points, questions measured on 4-point scales were collapsed into dichotomous variables and those measured on 5-point scales were recoded into variables with three values. Within the groups, differences in these variables were assessed with the use of the McNemar and Friedman tests. Between group comparisons in lifestyle characteristics and psychosocial determinants of dietary behaviour were examined with the use of the Mann-Whitney U and Kruskal-Wallis tests. Within group differences

in stages of dietary behaviour change were assessed with the use of the Friedman test and between group differences in forward-stage-of-transition for each food component were examined with the use of the Mann-Whitney U test.

Descriptive statistics were used to report website usage patterns and use, appreciation and perceived impact of the feedback letters and the nutrition education materials offered by the study. Between group comparisons of appreciation of study materials were made with the use of the Kruskal-Wallis test.

Transcripts from the focus group interviews were read in order to identify emerging themes, based on the interview guide, which were coded using appropriate keywords. All transcripts were then analysed, in order to examine similarities and differences within and among the focus groups, according to each theme, and to create a relevant to all groups summary of the findings. Findings from the focus group interviews are reported descriptively and issues that emerged are illustrated by quotations from participants.

3.9. Limitations of the study

There are a number of shortcomings to this study, which limit the generalisability of the findings and the external validity of the study. Despite employing similar recruitment techniques at both Universities, it proved difficult to recruit an equivalent sized control group. This is probably because the intervention offered to the control group was not innovative enough to motivate them to participate. The decision to recruit the intervention and control groups from different Universities was made to avoid the potential for cross-contamination between the groups. As several participants were often recruited from the same department, recruiting and randomising employees of the same department into an intervention and a control group might have resulted in participants in the intervention group sharing their personal Website passwords with friends assigned to the control group. In addition, no attempt was made to randomise the worksites into the intervention and control groups for reasons of convenience, as we had easy access to the intervention site's Intranet and associated website usage tracking procedures.

The study population consisted of a self-selected group of relatively well-educated and computer-literate women, who might have been more motivated to make dietary changes than average members of the general public. In addition, the total sample size was small, which was necessitated by the relatively labour-intensive dietary assessment and manual tailoring procedures. Taking this and the study's time frame into account, it was not feasible to assess psychosocial determinants of dietary behaviour during the study, which would also have been labour-intensive from the

participants' perspective. Therefore, tailored psychosocial feedback provided during the intervention period was based on the baseline psychosocial assessment.

A further limitation of the MESE study is that the time frame did not allow the conduct of focus group interviews prior to the website's development, in order to assess this population's nutrition information needs or a pilot-testing of the website before its launching. However, focus group interviews conducted after the end of the study provided valuable feedback on expectations concerning nutrition information on the Internet, which will inform the future refinement of the website. In addition, the study's time frame did not allow a validation of the short food frequency questionnaires and their web-based versions prior to the study beginning. However, the food frequency questionnaires were validated during the early weeks of the intervention and prior to their use in generating tailored dietary feedback and were found to have fair agreement with the respective 7-day estimated food diaries. Therefore, these instruments were considered acceptable to provide educational tailored feedback during the study course. Research also suggests that standard, hard-copy paper-and-pencil questionnaires produce comparable answers to their web-based versions (Davis, 1999; Eysenbach & Wyatt, 2002).

The time frame of the study did not permit the focused promotion of more components of the Mediterranean diet and therefore increase the number of Mediterranean goals participants of the intervention group would tackle over the 6-month trial. Earlier studies have examined the effect of tailored dietary and psychosocial feedback on dietary fat and/or fruit and vegetable intake over intervention periods lasting between one week (Bowen *et al.* 1994) and six months (Delichatsios *et al.* 2001a; Vandelanotte *et al.* 2005). Considering the step-wise approach the MESE study adopted, a 6-week period was considered to be appropriate for tackling a single Mediterranean goal, in order to encourage gradual dietary change, which is more likely to be maintained in the long-term (Fletcher & Rogers, 1985), therefore allowing the promotion of only four components of the Mediterranean diet. In addition, although the Mediterranean Eating website offered advice on the promotion of fish, and particularly oily fish consumption, according to current recommendations for healthy eating (The Scottish Office, 1996), fish was not included as one of the food components to contribute to the Mediterranean Diet Score. This is because fish consumption in the traditional Mediterranean diet depended on the proximity to the sea (Trichopoulou *et al.* 2003), and a median intake for fish was not defined in the original article describing the traditional Greek diet, on which the Mediterranean Diet Score was based (Trichopoulou *et al.* 1995b).

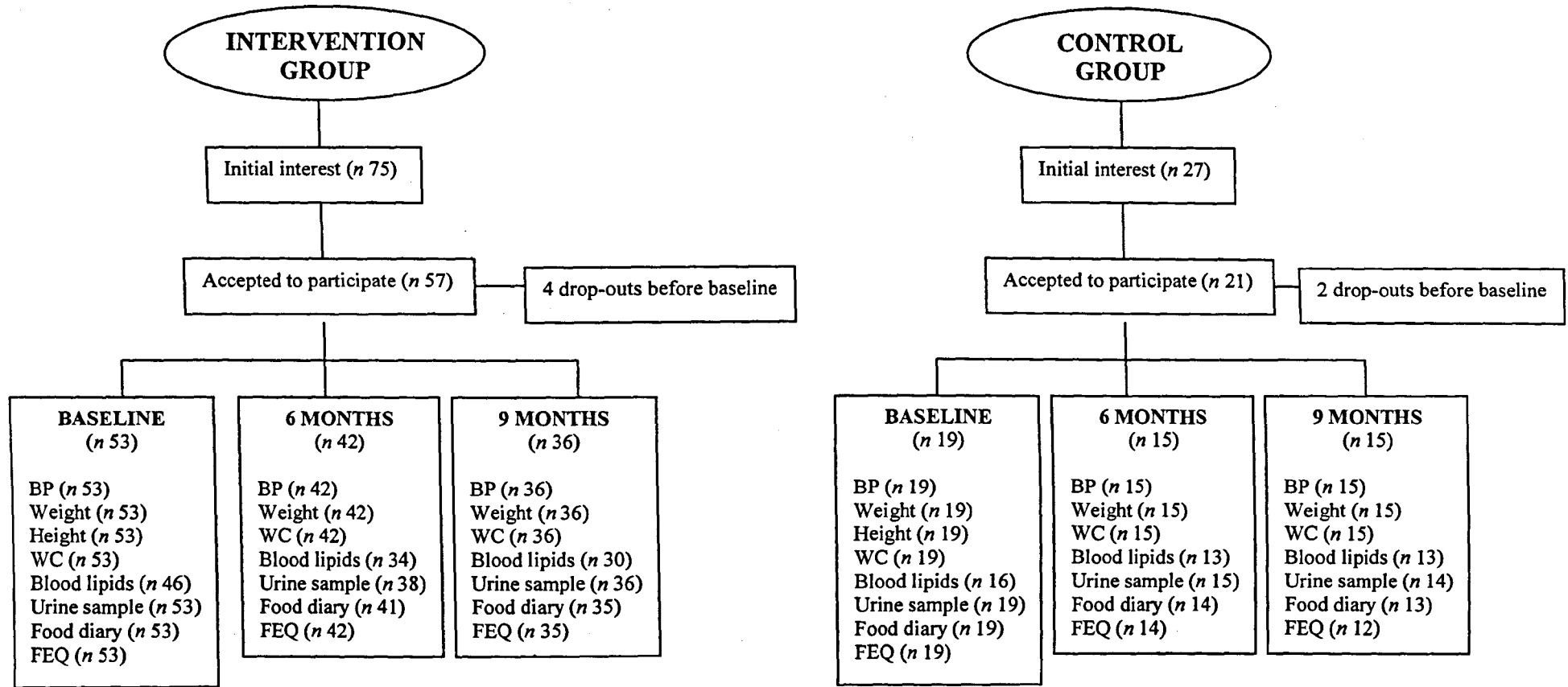
Finally, the time frame did not permit a longer follow-up period of six months. Some of the earlier studies, however, have not included follow-up assessments after the end of the immediate post-

intervention evaluation (Campbell *et al.* 1994; Brug *et al.* 1996; Brug, 1999; Campbell *et al.* 1999; Skinner *et al.* 1999).

3.10. Participation rate

Fifty-three women from the University of Glasgow and nineteen women from Glasgow Caledonian University replied to the study's advertisements and were recruited to serve as the intervention and control group, respectively. Participation flow and measurements provided by participants at baseline, 6 and 9 months are illustrated in Figure 3.1. By the end of the 6-month intervention, eleven participants (20.8%) in the intervention group and four participants (21.1%) in the control group had withdrawn from the study. Withdrawal reasons given from participants in the intervention group were lack of time to commit (*n* 4, 7.5% of consenters); employment relocation (*n* 3, 5.7% of consenters); illness (*n* 2, 3.8% of consenters); and no reason given (*n* 2, 3.8% of consenters). Withdrawal reasons given from participants in the control group were illness (*n* 2, 10.5% of consenters) and no reason given (*n* 2, 10.5% of consenters).

Figure 3.2 Study progress chart



BP, blood pressure; WC, waist circumference; FEQ, Food and Eating questionnaire

Overall, by the end of the 9-month study, seventeen participants (32.1%) in the intervention group and four participants (21.1%) in the control group had withdrawn from the study. Withdrawal reasons given from participants in the intervention group who withdrew between the end of the 6-month intervention and the 3-month follow-up were bereavement (n 2, 3.8% of consenters); employment relocation (n 1, 1.9% of consenters); and no reason given (n 3, 5.7% of consenters).

3.10.1. Socio-demographic and lifestyle characteristics of participants

The majority of recruited participants in both groups were less than 37 years of age, Caucasian, married and had a University or higher degree (Table 3.3). The age of participants in the intervention group ranged from 25 to 55 years (mean = 40.3 ± 7.2 years) and the age of participants in the control group ranged from 30 to 55 years (mean = 40.9 ± 6.9 years). There were slightly more participants of Indian origin in the control compared with the intervention group. Participants in the control group were also more likely to be better educated and belong to the managerial and professional occupation class (Table 3.3).

Table 3.3 Baseline socio-demographic and lifestyle characteristics of participants (n , % and P values)

	Intervention group (n 53)	Control group (n 19)	P
Age			
< 37 years	21 (39.6)	7 (36.8)	.978 ^a
37-43 years	14 (26.4)	6 (31.6)	
> 43 years	18 (34.0)	6 (31.6)	
Ethnicity			
Caucasian	53 (100.0)	17 (89.5)	.017 ^b
Indian	-	2 (10.5)	
Level of education			
Technical training	18 (34.0)	2 (10.5)	.052 ^b
University or higher	35 (66.0)	17 (89.5)	
Occupation			
Managerial and professional	32 (60.4)	17 (89.5)	.019 ^a
Intermediate	18 (34.0)	2 (10.5)	
Routine and manual	3 (5.7)	-	

Table 3.3 cont.: Baseline socio-demographic and lifestyle characteristics of participants (n, % and P values)

	Intervention group (n 53)	Control group (n 19)	P
Marital status			
Married/living with partner	35 (66.0)	12 (63.2)	.822 ^b
Single/divorced/widowed	18 (34.0)	7 (36.8)	
Has children			
Yes	24 (45.3)	7 (36.8)	.683 ^b
No	29 (54.7)	12 (63.2)	
Smoking			
Current smoker	8 (15.1)	3 (15.8)	.632 ^a
Never smoked	33 (62.3)	13 (68.4)	
Ex-smoker	12 (22.6)	3 (15.8)	
Vitamin supplement users			
Yes	16 (30.2)	8 (42.1)	.348 ^b
No	37 (69.8)	11 (57.9)	
Occupational physical activity			
Not very active	49 (92.5)	18 (94.7)	.739 ^b
Very/moderately active	4 (7.5)	1 (5.3)	
Leisure physical activity			
Not very active	13 (24.5)	6 (31.6)	.552 ^b
Very/moderately active	40 (75.5)	13 (68.4)	
Food shopping responsibility			
Full/shared responsibility	46 (86.8)	17 (89.5)	.763 ^b
Family members	7 (13.2)	2 (10.5)	
Food preparation responsibility			
Full/shared responsibility	43 (81.1)	16 (84.2)	.766 ^b
Family members	10 (18.9)	3 (15.8)	

^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

^b Levels of significance were assessed with the use of the Mann-Whitney U Test

When compared with participants who withdrew from the study at some stage, participants in the intervention group who completed the 9-month assessments were more likely to be better educated (Table 3.4). No baseline differences in any of the socio-demographic or lifestyle measurements were observed between participants in the control group who completed the 3-month follow-up and those who withdrew from the study.

Table 3.4 Baseline socio-demographic and lifestyle characteristics of participants who completed the study and those who were lost to follow-up (n, % and P values)

	Intervention group			Control group		
	Completers (n 36)	Drop- outs (n 17)	P	Completers (n 15)	Drop- outs (n 4)	P
Age						
< 37 years	13 (36.1)	8 (47.1)	.484 ^a	5 (33.3)	2 (50.0)	.596 ^a
37-43 years	10 (27.8)	4 (23.5)		5 (33.3)	1 (25.0)	
> 43 years	13 (36.1)	5 (29.4)		5 (33.3)	1 (25.0)	
Level of education						
Technical training	9 (25.0)	9 (52.9)	.047 ^b	1 (6.7)	1 (25.0)	.301 ^b
University or higher	27 (75.0)	8 (47.1)		14 (93.3)	3 (75.0)	
Occupation						
Managerial and professional	24 (66.7)	8 (47.1)	.207 ^a	13 (86.7)	4 (100.0)	.452 ^a
Intermediate	10 (27.8)	8 (47.1)		2 (13.3)	-	
Routine and manual	2 (5.6)	1 (5.9)		-	-	
Marital status						
Married/living with partner	25 (69.4)	10 (58.8)	.450 ^b	9 (60.0)	3 (75.0)	.591 ^b
Single/divorced/widowed	11 (30.6)	7 (41.2)		6 (40.0)	1 (25.0)	
Has children						
Yes	16 (44.4)	8 (47.1)	.759 ^b	4 (26.7)	3 (75.0)	.157 ^b
No	20 (55.6)	9 (52.9)		11 (73.3)	1 (25.0)	
Smoking						
Current smoker	5 (13.9)	3 (17.6)	.903 ^a	2 (13.3)	1 (25.0)	1.000 ^a
Never smoked	23 (63.9)	10 (58.8)		11 (73.3)	2 (50.0)	
Ex-smoker	8 (22.2)	4 (23.5)		2 (13.3)	1 (25.0)	
Vitamin supplement users						
Yes	11 (30.6)	5 (29.4)	.933 ^b	7 (46.7)	1 (25.0)	.448 ^b
No	25 (69.4)	12 (70.6)		8 (53.3)	3 (75.0)	
Occupational physical activity						
Not very active	33 (91.7)	16 (94.1)	.755 ^b	14 (93.3)	4 (100.0)	.606 ^b
Very/moderately active	3 (8.3)	1 (5.9)		1 (6.7)	-	

Table 3.4 cont.: Baseline socio-demographic and lifestyle characteristics of participants who completed the study and those who were lost to follow-up (n, % and P values)

	Intervention group			Control group		
	Completers (n 36)	Drop-outs (n 17)	P	Completers (n 15)	Drop- outs (n 4)	P
Leisure physical activity						
Not very active	10 (27.8)	3 (17.6)	.428 ^b	6 (40.0)	-	.137 ^b
Very/moderately active	26 (72.2)	14 (82.4)		9 (60.0)	4 (100.0)	
Food shopping responsibility						
Full/shared responsibility	31 (86.1)	15 (88.2)	.833 ^b	14 (93.3)	3 (75.0)	.301 ^b
Family members	5 (13.9)	2 (11.8)		1 (6.7)	1 (25.0)	
Food preparation responsibility			.555 ^b			.580 ^b
Full/shared responsibility	30 (83.3)	13 (76.5)		13 (86.7)	3 (75.0)	
Family members	6 (16.7)	4 (23.5)		2 (13.3)	1 (25.0)	

^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

^b Levels of significance were assessed with the use of the Mann-Whitney U Test

The results of the MESE study are presented in four chapters:

- Chapter 4: Dietary assessment
- Chapter 5: Anthropometric and biochemical assessment
- Chapter 6: Nutrition knowledge, stages of dietary behaviour change and psychosocial determinants of dietary behaviour
- Chapter 7: Process evaluation

4 Results: Dietary Assessment

4.1. Overview

Fifty-three, forty-two and thirty-six participants in the intervention group, and nineteen, fifteen and fifteen participants in the control group completed the baseline, 6-month and 9-month stages of the intervention, respectively.

During the three assessment time points (baseline, 6 months and 9 months), 7-day estimated food diaries for dietary assessment were provided by fifty-three, forty-one and thirty-five participants in the intervention group and nineteen, fourteen and thirteen participants in the control group. A summary of the dietary assessment results of participants providing food diaries at each time point is presented in Tables 4.1 and 4.2. Mean daily intake of the eight components of the Mediterranean diet, as well as the proportion of participants achieving a Mediterranean Diet Score (MDS) of 1³ for each food component and the total MDS (Trichopoulou *et al.* 1995b) were estimated after daily energy intake had been adjusted to 8368 kJ (2000 kcal).

³ The cut-off point for intake of each dietary component represents the median intake, specific for sex, of a group of elderly Greeks consuming a traditional Greek diet, on which the Mediterranean Diet Score was originally based (Trichopoulou *et al.* 1995b). Energy intake was adjusted to 8368 kJ (2000 kcal) and a score of 1 or 0 was given for each of the food components depending on whether the cut-off point was met or not.

Table 4.1 Mean daily consumption of the eight components of the Mediterranean diet of participants in both groups at baseline, 6 months and 9 months (mean values and standard deviations)

		Baseline				6 months				9 months			
		Intervention group (n 53)		Control group (n 19)		Intervention group (n 41)		Control group (n 14)		Intervention group (n 35)		Control group (n 13)	
Food component	Mediterranean diet	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Vegetables (g/d)	≥248 g/d	172.2	84.0	191.3	59.1	225.9	101.7	210.4	107.4	253.7	92.6	237.8	149.4
Fruits, nuts and seeds (g/d)	≥216 g/d	200.2	140.6	236.7	189.1	248.9	151.4	185.6	85.9	246.5	154.5	258.8	199.8
Legumes (g/d)	≥49 g/d	15.9	17.5	22.6	24.0	35.7	28.1	50.4	53.9	29.9	24.5	32.9	37.8
MUFA:SFA ratio (/d)	≥1.60 /d	1.47	0.48	1.48	0.42	1.83	1.01	1.69	0.68	1.79	1.04	1.64	0.54
Cereals (g/d)	≥248 g/d	251.3	73.6	213.3	45.1	233.4	91.5	239.1	79.8	233.7	78.9	216.9	96.3
Meat and meat products (g/d)	≤91 g/d	89.6	39.6	94.5	68.7	95.7	47.3	88.5	65.7	95.2	49.7	105.1	60.4
Milk and milk products (g/d)	≤194 g/d	231.1	115.9	209.7	130.9	230.4	121.3	225.3	111.3	256.5	108.5	189.4	121.2
Alcohol (g/d)	5-25 g/d	17.8	17.0	18.0	18.6	13.9	11.2	18.5	14.0	12.8	10.1	19.0	17.1

Table 4.2 Percentage of participants in both groups achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, a high Mediterranean Diet Score (≥ 4) and mean total score at baseline, 6 months and 9 months

Food component	Score criteria	Baseline		6 months		9 months	
		Intervention group (<i>n</i> 53)	Control group (<i>n</i> 19)	Intervention group (<i>n</i> 41)	Control group (<i>n</i> 14)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 13)
Vegetables	≥ 248 g/d	20.8	10.5	29.3	28.6	54.3	23.1
Fruits, nuts and seeds	≥ 216 g/d	39.6	47.4	46.3	35.7	48.6	53.8
Legumes	≥ 49 g/d	3.8	5.3	24.4	35.7	20.0	23.1
MUFA:SFA ratio	≥ 1.60 /d	34.0	36.8	51.2	42.9	54.3	46.2
Cereals	≥ 248 g/d	50.9	15.8	39.0	42.9	31.4	15.4
Meat and meat products	≤ 91 g/d	58.5	52.6	48.8	64.3	57.1	46.2
Milk and milk products	≤ 194 g/d	41.5	42.1	51.2	28.6	28.6	53.8
Alcohol	5-25 g/d	71.7	63.2	85.4	71.4	91.4	61.5
% achieving a score of ≥ 4		35.8	21.1	51.2	35.7	57.1	38.5
Mean Total Score (SD)		3.21 (1.21)	2.74 (1.45)	3.76 (1.46)	3.50 (1.45)	3.86 (1.46)	3.23 (1.64)

For ease of presentation, results on dietary assessment are presented in three sections:

Section A: Analysis for participants completing baseline and 6-month assessments

Section B: Analysis for participants completing baseline, 6-month and 9-month assessments

Section C: Analysis on an intention-to-treat basis

Section A: Analysis for participants completing baseline and 6-month assessments

4.2. Participants completing baseline and 6-month assessments

Forty-one participants in the intervention group and fourteen participants in the control group provided 7-day estimated food diaries for dietary assessment at both baseline and 6 months. Dietary intakes and components of the Mediterranean Diet Score were adjusted to 8368 kJ (2000 kcal) (Trichopoulou *et al.* 1995b).

4.2.1. Within group comparisons

4.2.1.1. Food components

Table 4.3 presents the comparison of daily consumption of the eight components of the Mediterranean diet at baseline and at the end of the 6-month intervention for both groups. Participants in the intervention group significantly increased the amount of vegetables, fruits, nuts and seeds, legumes and the MUFA:SFA ratio in their diet. Participants in the control group also showed a significant increase in legume and a less favourable increase in dairy product intake.

Table 4.3 Mean daily consumption of the eight components of the Mediterranean diet, based on participants in both groups completing the baseline and 6-month assessments (mean values, standard deviations and P values)

Food component	Intervention group (n 41)					Control group (n 14)				
	Baseline		6 months		P	Baseline		6 months		P
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Vegetables (g/d)	176.5	83.7	226.0	101.7	.002 ^b	196.5	66.7	210.4	107.4	.778 ^a
Fruits, nuts & seeds (g/d)	203.9	141.3	249.0	151.4	.020 ^a	217.1	155.1	185.6	85.9	.198 ^a
Legumes (g/d)	16.8	15.4	35.8	28.1	<.001 ^b	24.2	25.6	50.4	53.9	.013 ^a
MUFA:SFA ratio (/d)	1.43	0.41	1.84	1.01	<.001 ^a	1.53	0.47	1.69	0.68	.363 ^a
Cereals (g/d)	253.5	75.5	233.4	91.5	.104 ^a	219.7	49.3	239.1	79.8	.300 ^a
Meat & meat products (g/d)	85.9	36.0	95.7	47.3	.132 ^b	103.5	77.5	88.5	65.7	.221 ^a
Milk & milk products (g/d)	235.8	115.1	230.4	121.3	.755 ^b	167.9	92.6	225.3	111.3	.011 ^a
Alcohol (g/d)	17.0	18.4	14.0	11.2	.677 ^a	21.1	20.2	18.5	14.0	.530 ^a

^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

4.2.1.2. Mediterranean Diet Score

The proportions of participants in both groups achieving a MDS of 1 for each food component at baseline and 6 months are demonstrated in Table 4.4. In the control group, the proportion of participants achieving a score of 1 increased for five of the eight components, but none of these increases reached statistical significance. In contrast, the proportion of participants in the intervention group achieving a score of 1 at 6 months increased for six components, including the four “Mediterranean goals”. This increase was statistically significant for the legume and MUFA:SFA ratio components. There was no significant difference for the proportion of participants achieving a high MDS (≥ 4) at baseline compared with 6 months for either group (Table 4.4). There was, however, a significant post-intervention increase in the mean total MDS for both the intervention and control groups (Table 4.4).

Table 4.4 Percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, a high Mediterranean Diet Score (≥ 4) and mean total score, based on participants in both groups completing the baseline and 6-month assessments (P values)

Food component	Score criteria	Intervention group (n 41)			Control group (n 14)		
		Baseline	6 months	P	Baseline	6 months	P
Vegetables	≥ 248 g/d	19.5	29.3	.344 ^a	14.3	28.6	.625 ^a
Fruits, nuts and seeds	≥ 216 g/d	39.0	46.3	.375 ^a	50.0	35.7	.500 ^a
Legumes	≥ 49 g/d	2.4	24.4	.012 ^a	7.1	35.7	.125 ^a
MUFA:SFA ratio	≥ 1.6 /d	31.7	51.2	.039 ^a	42.9	42.9	1.000 ^a
Cereals	≥ 248 g/d	53.7	39.0	.180 ^a	21.4	42.9	.453 ^a
Meat and meat products	≤ 91 g/d	61.0	48.8	.267 ^a	42.9	64.3	.375 ^a
Milk and milk products	≤ 194 g/d	41.5	51.2	.424 ^a	50.0	28.6	.250 ^a
Alcohol	5-25 g/d	75.6	85.4	.289 ^a	57.1	71.4	.500 ^a
% achieving a score of ≥ 4		36.6	51.2	.238 ^a	21.4	35.7	.500 ^a
Mean Total Score (SD)		3.24 (1.32)	3.76 (1.46)	.035 ^b	2.86 (1.56)	3.50 (1.45)	.047 ^c

^a Levels of significance were assessed with the use of the McNemar Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

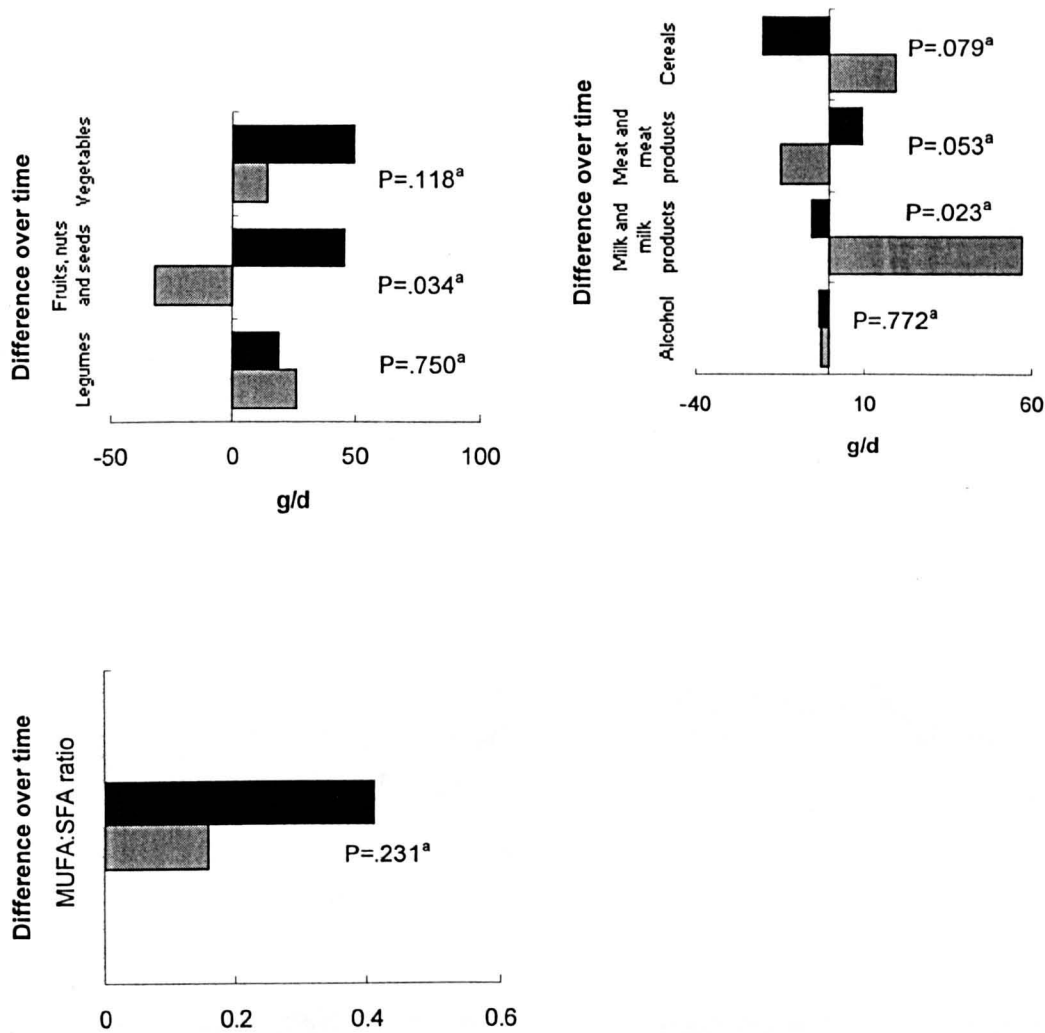
^c Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

4.2.2. Between group differences over time

4.2.2.1. Food components

The between group differences in changes in mean daily consumption of the eight components of the Mediterranean diet over the 6-month trial are presented in Figure 4.1. At the end of the trial, participants in the intervention group had significantly increased their intake of fruits, nuts and seeds, while participants in the control group had a reduced intake (45.0 v. -31.5 g/d; $P=.034$). There was also a less desirable significant increase in dairy product intake for participants in the control group (-5.0 v. 57.0 g/d; $P=.023$) and a slight, less desirable increase in meat and meat product intake for participants in the intervention group (9.9 v. -14.9 g/d; $P=.053$).

Figure 4.1 Between group comparison of changes over time in mean daily consumption of the eight components of the Mediterranean diet, based on participants in the intervention (■, *n* 41) and control (▨, *n* 14) groups completing the baseline and 6-month assessments (P values)



^a Levels of significance were assessed with the use of the Mann-Whitney U Test

4.2.2.2. *Mediterranean Diet Score*

For participants who completed both the baseline and 6-month assessments, the between group differences in proportions achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet are presented in Figure 4.2. A higher proportion of participants in the intervention group achieved a score of 1 for cereals at baseline, compared with participants in the control group (53.7 v. 21.4%; $P=.038$). There were no differences between the groups in proportions of participants achieving a score of 1 for any of the food components at 6 months.

Figure 4.2 Between group comparison of percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on participants in the intervention (■, n 41) and control (▨, n 14) groups completing the baseline and 6-month assessments

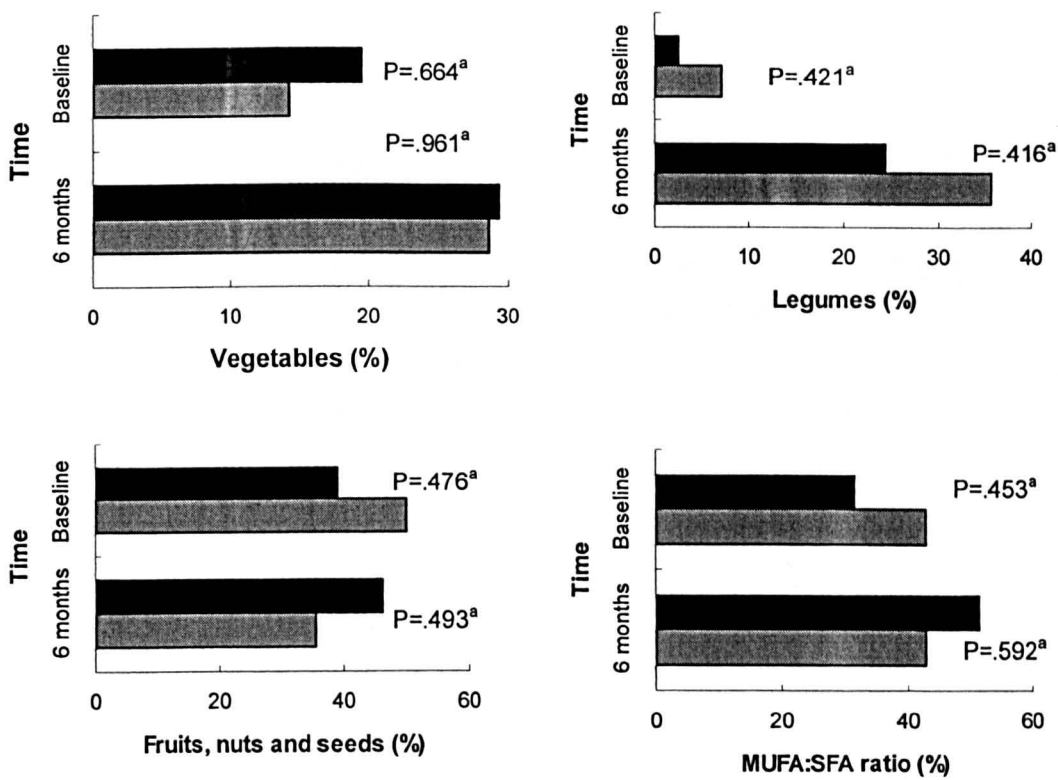
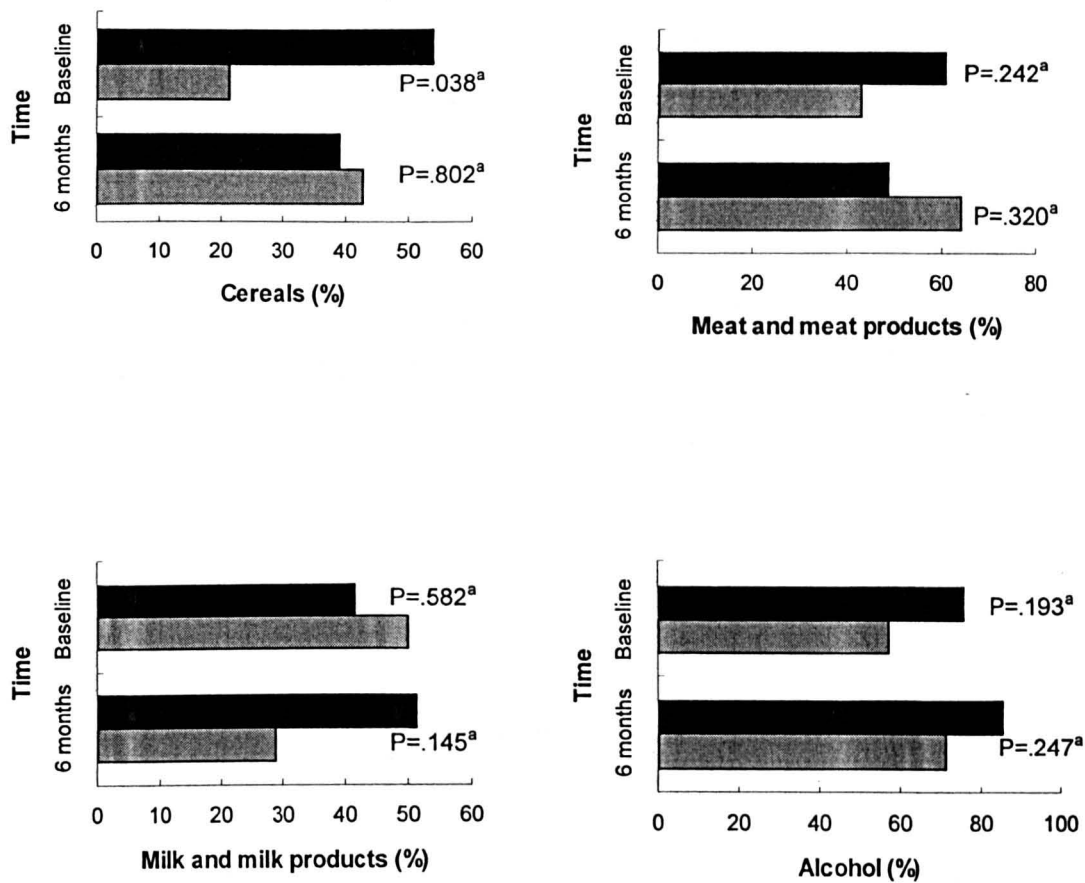


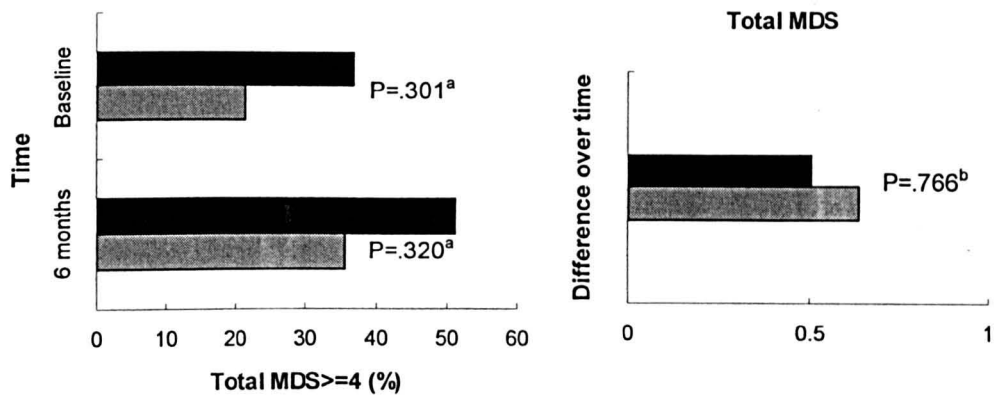
Figure 4.2 cont.: Between group comparison of percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on participants in the intervention (■, *n* 41) and control (▨, *n* 14) groups completing the baseline and 6-month assessments



^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

There were no significant between group differences in the proportions of participants achieving a high MDS (≥ 4) or in the changes in mean total MDS by the end of the trial, as illustrated in Figure 4.3.

Figure 4.3 Between group comparison of changes over time in percentage of participants achieving a high Mediterranean Diet Score (≥ 4) and mean total score, based on participants in the intervention (■, $n = 41$) and control (▨, $n = 14$) groups completing the baseline and 6-month assessments



^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

^b Levels of significance were assessed with the use of the Mann-Whitney U Test

Section B: Analysis for participants completing baseline, 6-month and 9-month assessments

4.3. Participants completing baseline, 6-month and 9-month assessments

Thirty-five participants in the intervention group and thirteen participants in the control group provided 7-day estimated food diaries for dietary assessment at all three assessment time points (baseline, 6 and 9 months). Mean daily food intake, the proportion of participants achieving a Mediterranean Diet Score (MDS) of 1 for each food component of the Mediterranean diet and the total MDS were estimated after daily energy intake had been adjusted to 8368 kJ (2000 kcal).

4.3.1. Within group comparisons

4.3.1.1. Food components

Figure 4.4 illustrates the comparison of daily consumption of the eight components of the Mediterranean diet at baseline, 6 and 9 months for participants in both groups completing all three assessments. At 6 months, participants in the intervention group had significantly increased the amount of vegetables (172.6 v. 224.5 g/d; $P=.002$), fruits, nuts and seeds (200.6 v. 259.3 g/d; $P=.004$) and legumes (15.9 v. 38.8 g/d; $P<.001$), as well as the MUFA:SFA ratio in their diet (1.34 v. 1.68; $P<.001$) compared with baseline. Participants in the control group also showed a significant increase in legume intake (23.4 v. 52.8 g/d; $P=.008$) and a less favourable increase in milk and milk product intake (170.6 v. 227.1 g/d; $P=.015$) at this time point. Consumption of vegetables between the end of the intervention and the 3-month follow-up further increased for participants in the intervention group (224.5 v. 282.3 g/d; $P=.035$). Overall, participants in the intervention group maintained their dietary changes at 9 months, showing significant increases in their mean intake of vegetables (172.6 v. 282.3 g/d; $P<.001$), fruits, nuts and seeds (200.6 v. 246.5 g/d; $P=.031$), legumes (15.9 v. 29.9 g/d; $P=.008$) and MUFA:SFA ratio (1.34 v. 1.79; $P<.001$) compared with baseline. No significant changes were observed for participants in the control group between the baseline and 3-month follow-up assessments.

Figure 4.4 Mean daily consumption of the eight components of the Mediterranean diet, based on participants in the intervention (—●—, *n* 35) and control (—○—, *n* 13) groups completing the baseline, 6-month and 9-month assessments (P values for comparison between baseline and 9-month assessments)

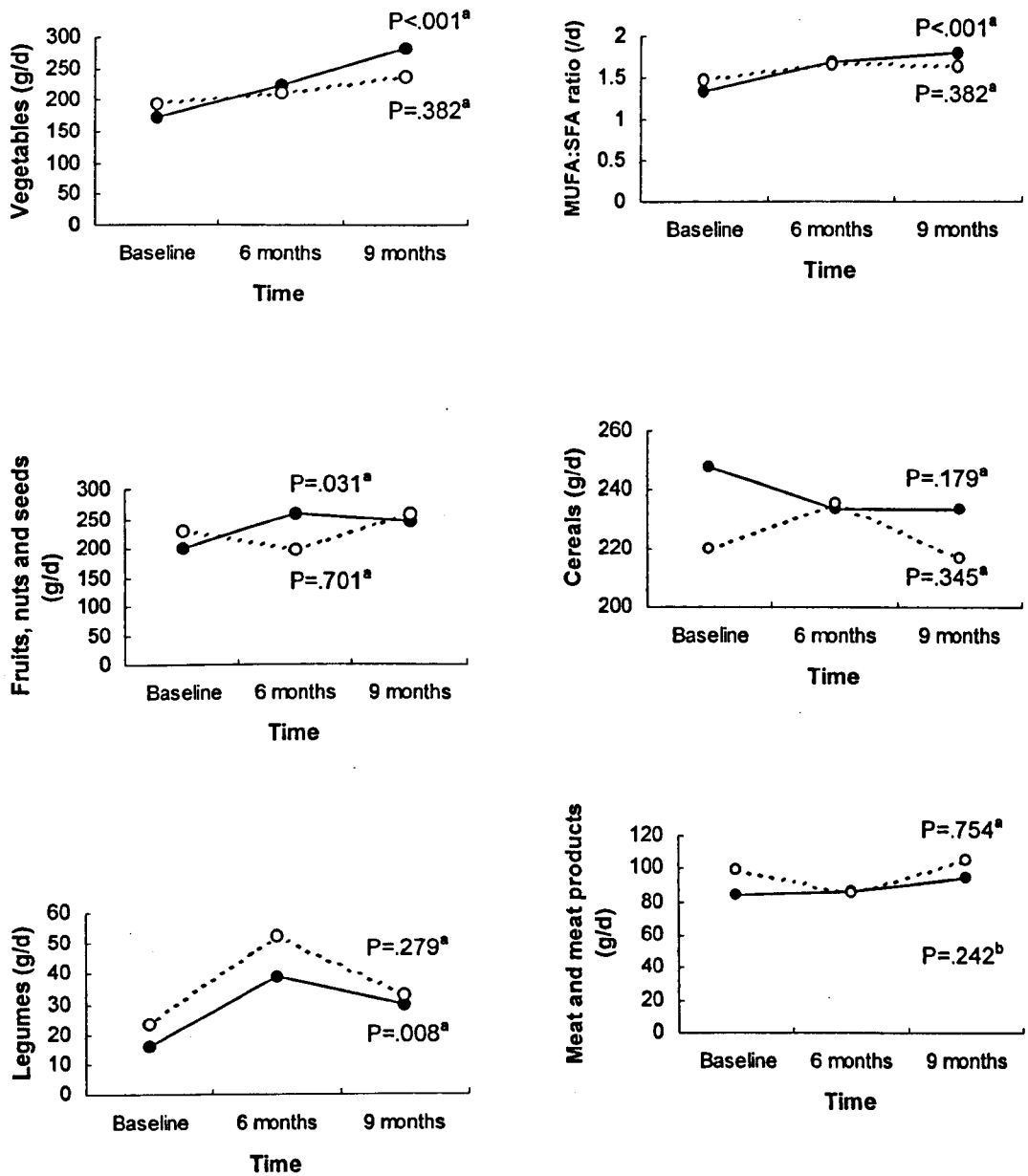
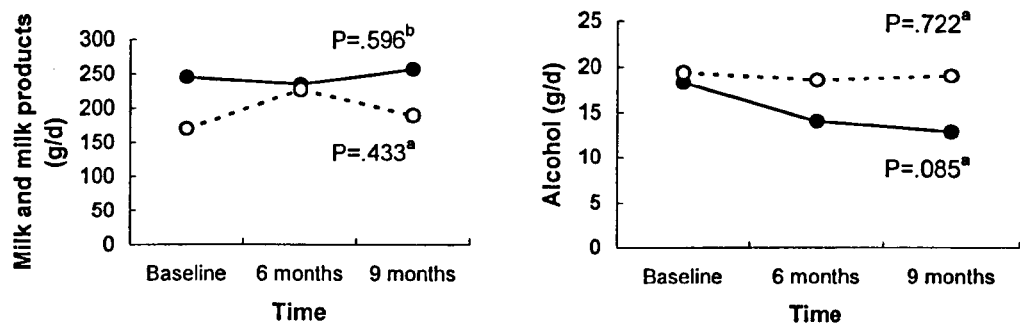


Figure 4.4 cont.: Mean daily consumption of the eight components of the Mediterranean diet, based on participants in the intervention (—●—, *n* 35) and control (---○---, *n* 13) groups completing the baseline, 6-month and 9-month assessments (P values for comparison between baseline and 9-month assessments)



^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

4.3.1.2. Mediterranean Diet Score

The proportions of participants in both groups achieving a MDS of 1 for each food component at baseline, 6 and 9 months are presented in Figure 4.5, for participants completing all three assessments. At 6 months, the proportion of participants in the control group achieving a score of 1 increased for five of the eight total components, but none of these increases reached statistical significance. In contrast, the proportion of participants in the intervention group achieving a score of 1 at 6 months increased for six components compared with baseline, including the four “Mediterranean goals”. This increase was statistically significant for legumes (2.9 v. 28.6%; $P=.012$) and MUFA:SFA ratio (22.9 v. 48.6%; $P=.012$). Between the end of the 6-month intervention and the 3-month follow-up, the proportion of participants in the intervention group achieving a score of 1 for vegetables further increased (31.4 v. 54.3%; $P=.057$). At 9 months, a significantly greater proportion of participants in the intervention group achieved a score of 1 for vegetables (20.0 v. 54.3%; $P=.002$), MUFA:SFA ratio (22.9 v. 54.3%; $P=.007$) and alcohol (74.3 v. 91.4%; $P=.031$) compared with baseline. There were no statistically significant changes in proportions of participants achieving a MDS of 1 for any food component in the control group over these time points.

Figure 4.5 Percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on participants in the intervention (—●—, *n* 35) and control (—○—, *n* 13) groups completing the baseline, 6-month and 9-month assessments (P values for comparison between baseline and 9-month assessments)

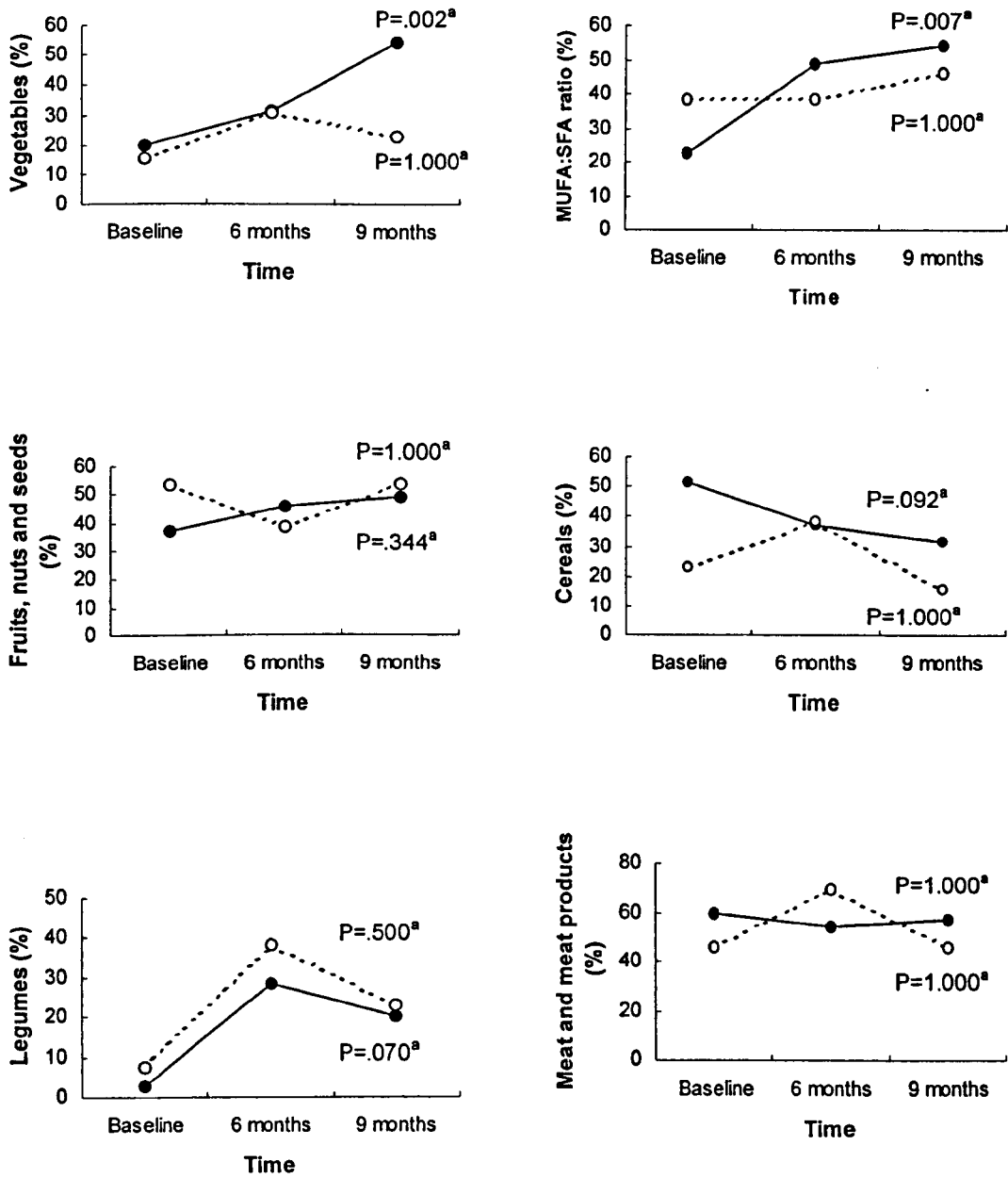
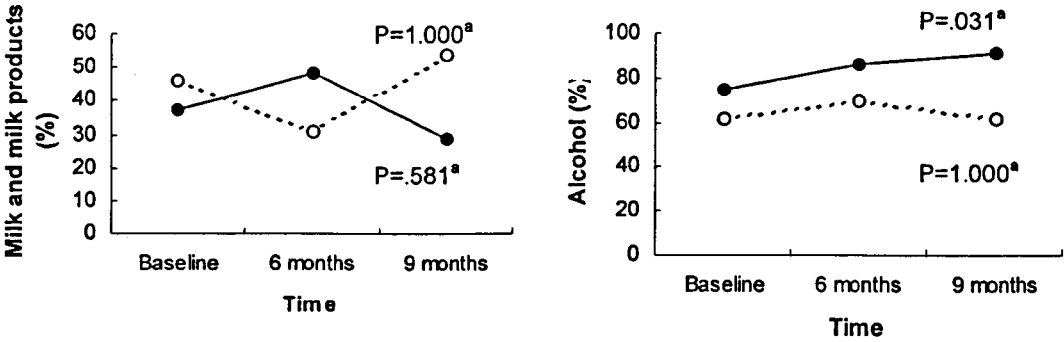


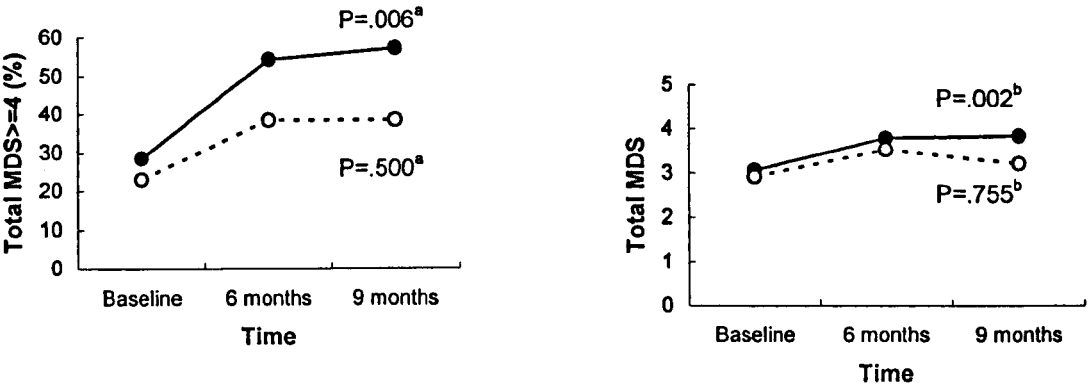
Figure 4.5 cont.: Percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on participants in the intervention (—●—, *n* 35) and control (---○---, *n* 13) groups completing the baseline, 6-month and 9-month assessments (P values for comparison between baseline and 9-month assessments)



^a Levels of significance were assessed with the use of the McNemar Test

A significantly higher proportion of participants in the intervention group achieved a high MDS (≥ 4) both at 6 months (28.6 v. 54.3%; $P=.035$) and 9 months (28.6 v. 57.1%; $P=.006$), compared with baseline (Figure 4.6), while there was also a significant increase in the mean total MDS at 6 months (3.06 v. 3.80; $P=.006$) and 9 months (3.06 v. 3.86; $P=.002$) for this group compared with baseline (Figure 4.6). No significant changes were observed for participants in the control group at any time point.

Figure 4.6 Percentage of participants achieving a high Mediterranean Diet Score (≥ 4) and mean total score, based on participants in the intervention (—●—, *n* 35) and control (---○---, *n* 13) groups completing the baseline, 6-month and 9-month assessments (P values for comparison between baseline and 9-month assessments)



^a Levels of significance were assessed with the use of the McNemar Test

^b Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

4.3.2. Between group differences over time

4.3.2.1. Food components

The between group differences in changes in mean daily consumption of the eight components of the Mediterranean diet over the 9-month trial are presented in Figure 4.7. At the end of the 6-month intervention, participants in the intervention group had significantly increased their intake of fruits, nuts and seeds, whereas participants in the control group had a reduced intake (58.7 v. -32.2 g/d; $P=.021$). Moreover, participants in the control group had significantly increased their intake of milk and milk products (-10.9 v. 56.5 g/d; $P=.025$).

Figure 4.7 Between group comparison of changes over time in mean daily consumption of the eight components of the Mediterranean diet, based on participants in the intervention (■, n 35) and control (▨, n 13) groups completing the baseline, 6-month and 9-month assessments

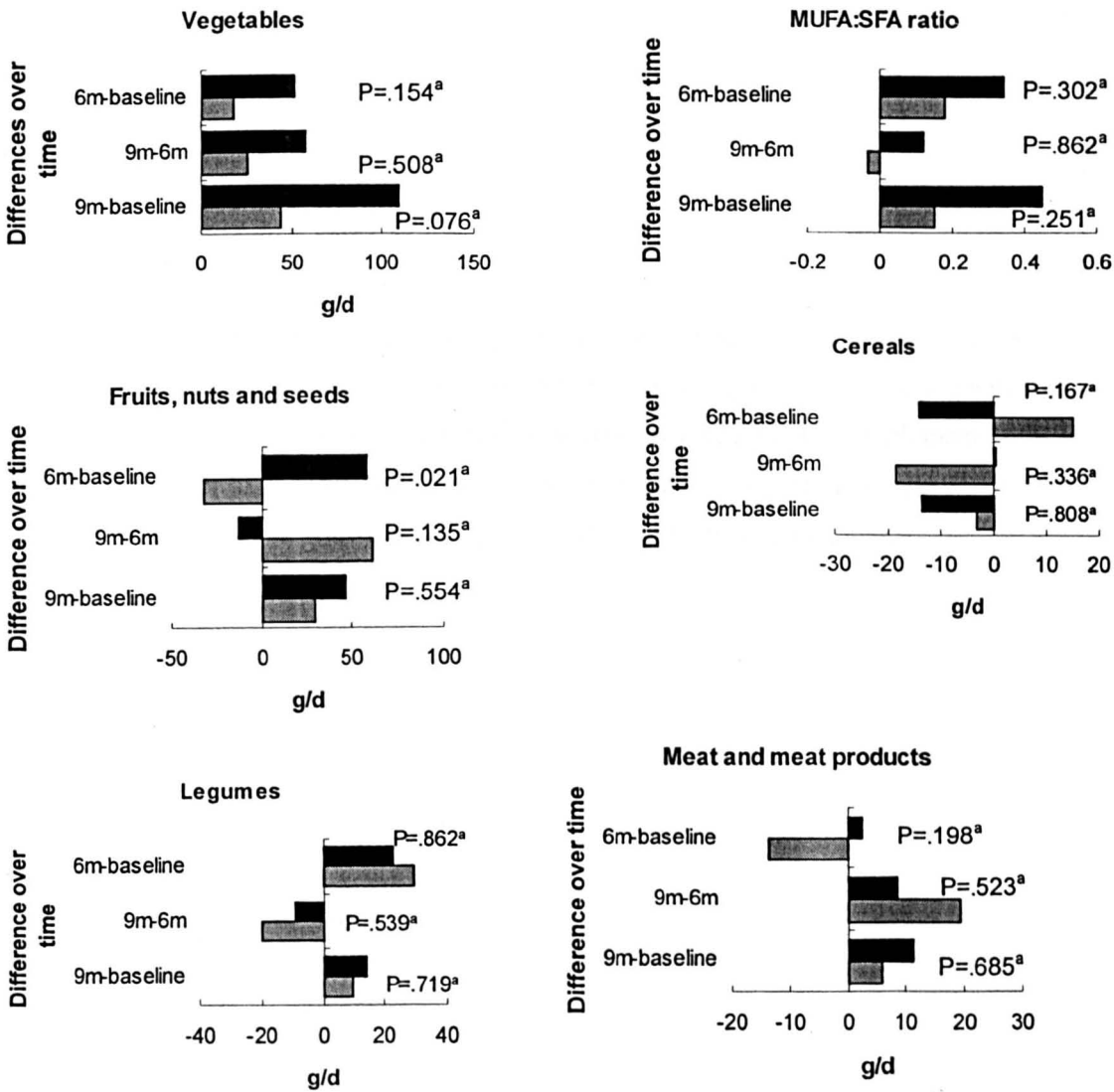
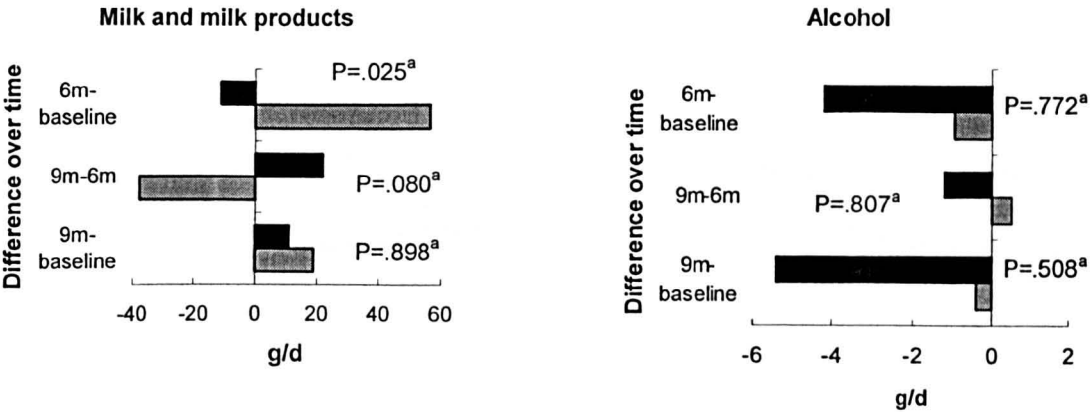


Figure 4.7 cont.: Between group comparison of changes over time in mean daily consumption of the eight components of the Mediterranean diet, based on participants in the intervention (■, *n* 35) and control (▨, *n* 13) groups completing the baseline, 6-month and 9-month assessments



^a Levels of significance were assessed with the use of the Mann-Whitney U Test

4.3.2.2. Mediterranean Diet Score

The between group differences in proportions of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet are presented in Figure 4.8, for participants who completed all three assessments (baseline, 6 and 9 months). Compared with participants in the control group, a higher proportion of participants in the intervention group achieved a score of 1 for vegetables (54.3 v. 23.1%; $P=.056$) and alcohol (91.4 v. 61.5%; $P=.015$) at 9 months.

Figure 4.8 Between group comparison of percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on participants in the intervention (■, *n* 35) and control (▨, *n* 13) groups completing the baseline, 6-month and 9-month assessments

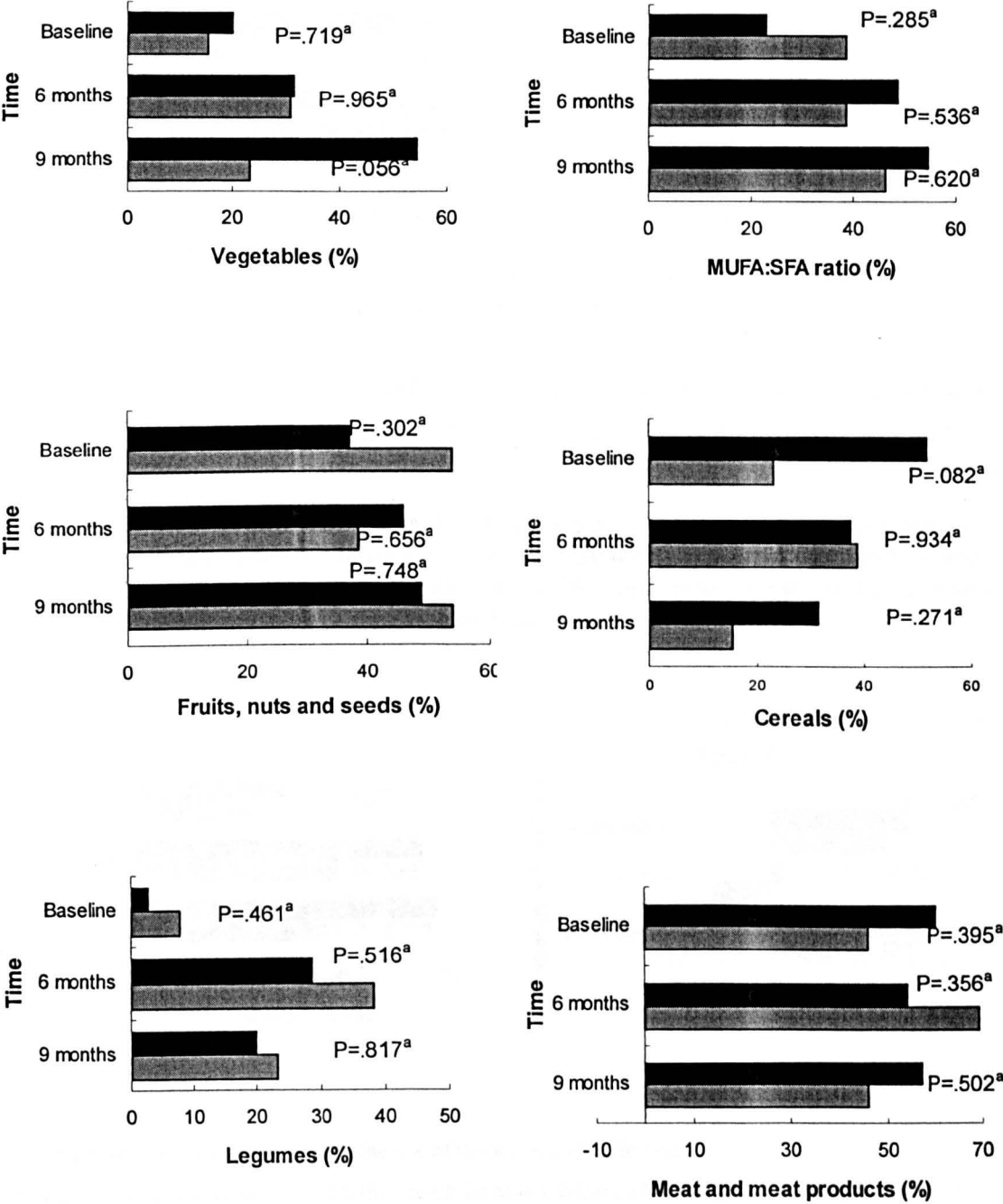
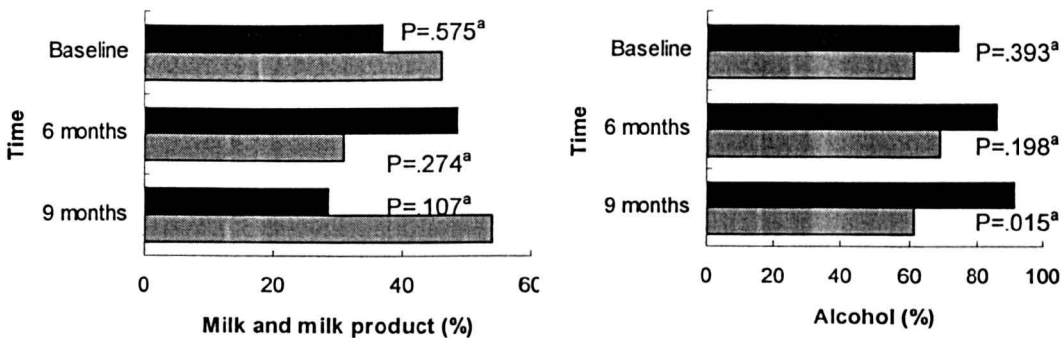


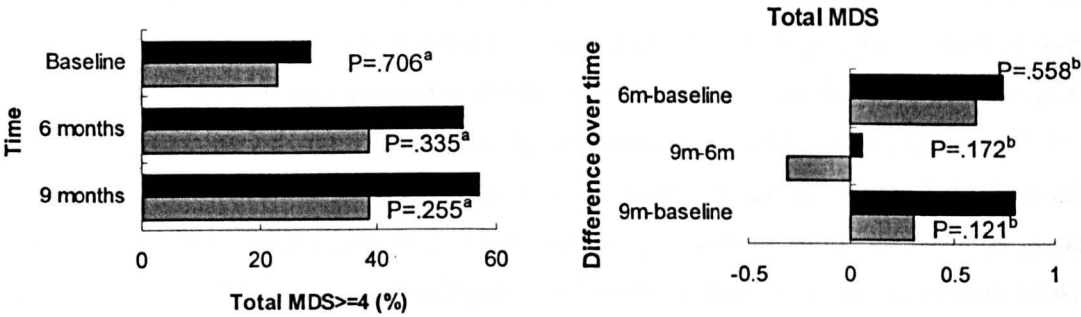
Figure 4.8 cont.: Between group comparison of percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on participants in the intervention (■, *n* 35) and control (▨, *n* 13) groups completing the baseline, 6-month and 9-month assessments



^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

There were no significant between group differences in the proportions of participants achieving a high MDS (≥ 4) or in changes in the mean total MDS at any time point, as illustrated in Figure 4.9.

Figure 4.9 Between group comparison of changes over time in percentage of participants achieving a high Mediterranean Diet Score (≥ 4) and mean total score, based on participants in the intervention (■, *n* 35) and control (▨, *n* 13) groups completing the baseline, 6-month and 9-month assessments



^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

^b Levels of significance were assessed with the use of the Mann-Whitney U Test

Section C: Analysis on an intention-to-treat basis

4.4. Intention-to-treat analysis: Participants completing baseline, 6-month and 9-month assessments

Intention-to-treat analyses were performed using the last available recorded value for participants in both groups who withdrew from the study at some stage before the end of the 3-month follow up. In this respect, analyses were performed for fifty-three and nineteen participants in the intervention and control group, respectively, who provided 7-day estimated food diaries for dietary assessment at baseline. Mean daily food intake, the proportion of participants achieving a Mediterranean Diet Score (MDS) of 1 for each food component of the Mediterranean diet and the total MDS were estimated after daily energy intake had been adjusted to 8368 kJ (2000 kcal).

4.4.1. Within group comparisons

4.4.1.1. *Food components*

Figure 4.10 illustrates the comparison of daily consumption of the eight components of the Mediterranean diet at baseline, 6 and 9 months. Intention-to-treat analyses showed that at 6 months, participants in the intervention group had significantly increased the amount of vegetables (172.2 v. 210.6 g/d; $P=.002$), fruits, nuts and seeds (200.2 v. 235.1 g/d; $P=.025$) and legumes (15.9 v. 30.6 g/d; $P=.001$), as well as the MUFA:SFA ratio in their diet (1.47 v. 1.79; $P<.001$) compared with baseline. Participants in the control group also showed a significant increase in legume intake (22.6 v. 41.9 g/d; $P=.026$), as well as a less favourable increase in milk and milk product intake (209.7 v. 252.0 g/d; $P=.018$) at 6 months. Between the end of the 6-month intervention and the 3-month follow-up, consumption of vegetables further increased for participants in the intervention group (210.6 v. 248.8 g/d; $P=.035$). Although participants in the intervention group increased their intake of meat and meat products between baseline and 9 months (89.6 v. 102.9 g/d; $P=.032$), this group also maintained most of their favourable dietary changes at this time point, showing significant increases in their mean intake of vegetables (172.2 v. 248.8 g/d; $P<.001$), legumes (15.9 v. 24.7 g/d; $P=.020$) and MUFA:SFA ratio (1.47 v. 1.86; $P=.001$) compared with baseline. No significant changes were observed for participants in the control group between baseline and 9 months.

Figure 4.10 Mean daily consumption of the eight components of the Mediterranean diet, based on intention-to-treat analyses for participants in the intervention (—●—, *n* 53) and control (---○---, *n* 19) groups (P values for comparison between baseline and 9-month assessments)

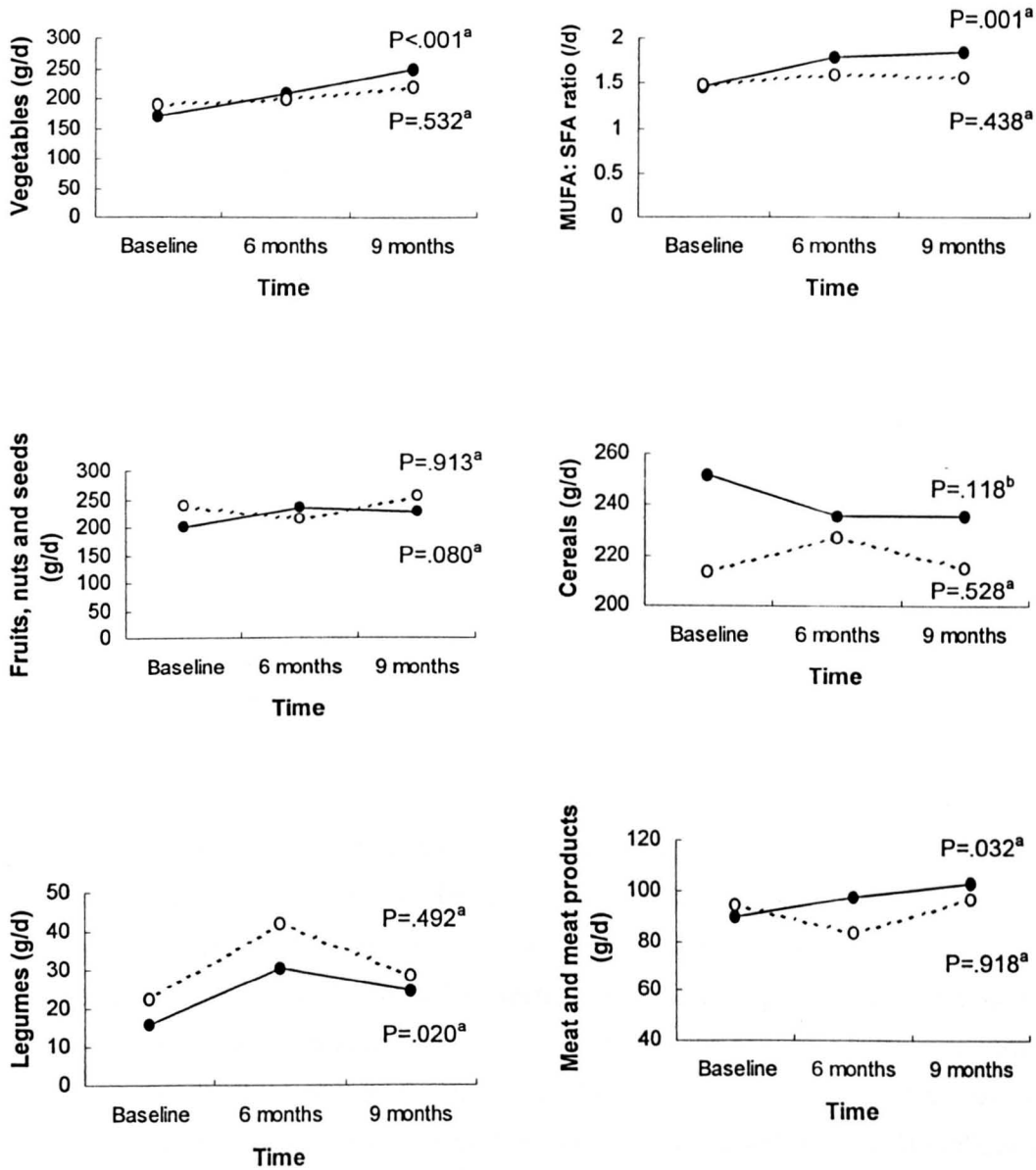
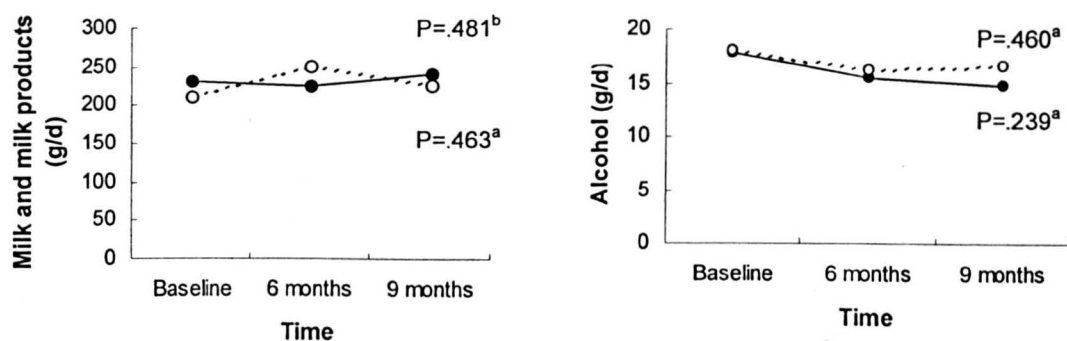


Figure 4.10 cont.: Mean daily consumption of the eight components of the Mediterranean diet, based on intention-to-treat analyses for participants in the intervention (—•—, n 53) and control (---○---, n 19) groups (P values for comparison between baseline and 9-month assessments)



^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

4.4.1.2. Mediterranean Diet Score

The proportions of participants in both groups achieving a MDS of 1 for each food component at baseline, 6 and 9 months are presented in Figure 4.11. The intention-to-treat analysis showed that at 6 months, the proportion of participants in the control group achieving a score of 1 increased for five of the eight total components, but none of these increases reached statistical significance. In contrast, the proportion of participants in the intervention group achieving a score of 1 at 6 months increased for six components compared with baseline, including the four “Mediterranean goals”. This increase was statistically significant for legumes (3.8 v. 20.8%; $P=.012$) and MUFA:SFA ratio (34.0 v. 49.1%; $P=.039$). Between the end of the 6-month intervention and the 3-month follow-up, the proportion of participants in the intervention group achieving a score of 1 for vegetables further increased (28.3 v. 43.4%; $P=.057$). At 9 months, a significantly greater proportion of participants in the intervention group achieved a score of 1 for vegetables (20.8 v. 43.4%; $P=.004$) and MUFA:SFA ratio (34.0 v. 52.8%; $P=.021$), compared with baseline. In addition, there was a decrease in the proportion of participants in the intervention group achieving a score of 1 for cereals (50.9 v. 35.8%; $P=.057$) between baseline and 9 months. There were no statistically significant changes in proportions of participants achieving a MDS of 1 for any food component in the control group over these time points.

Figure 4.11 Percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on intention-to-treat analyses for participants in the intervention (—●—, $n = 53$) and control (---○---, $n = 19$) groups (P values for comparison between baseline and 9-month assessments)

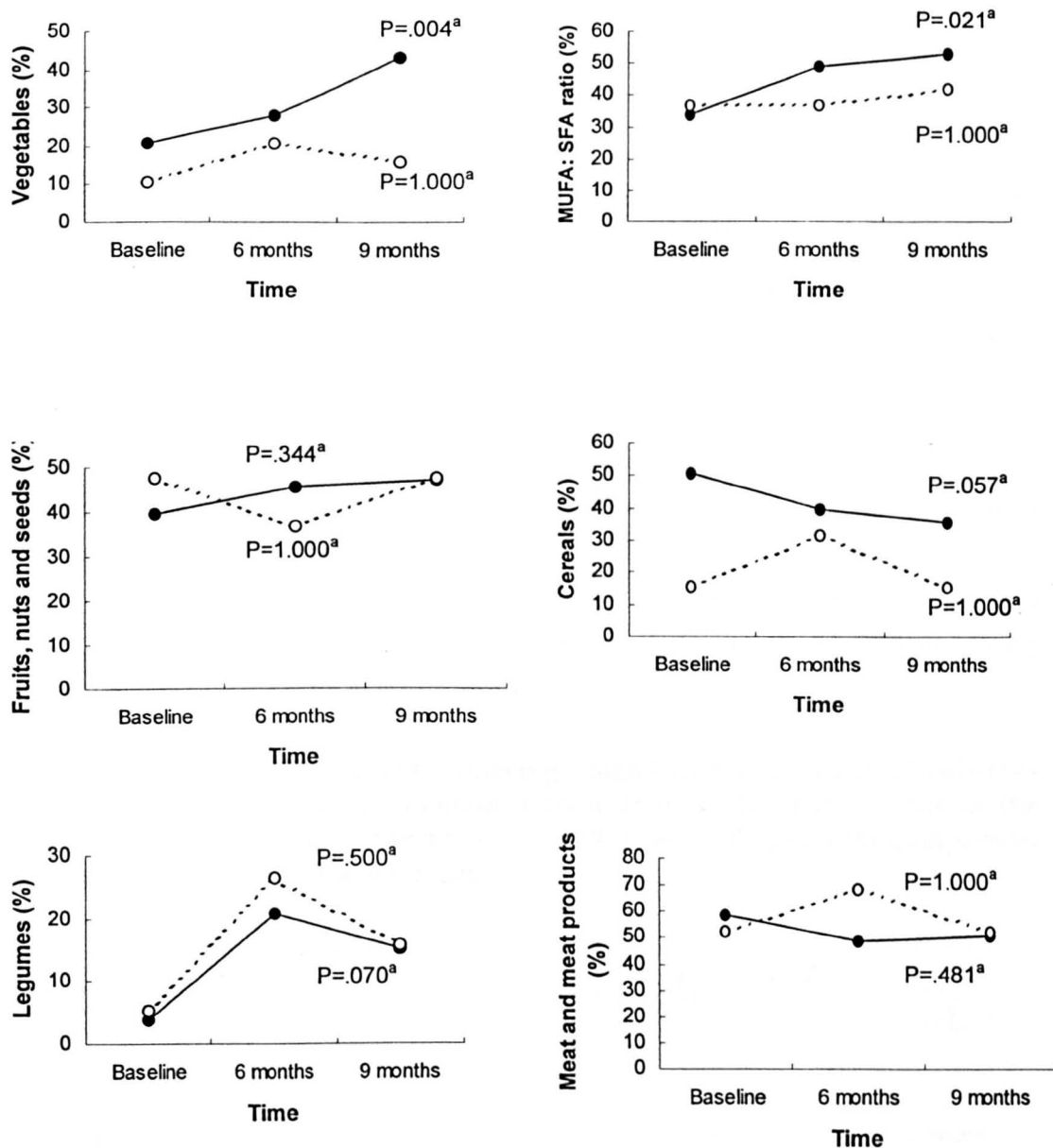
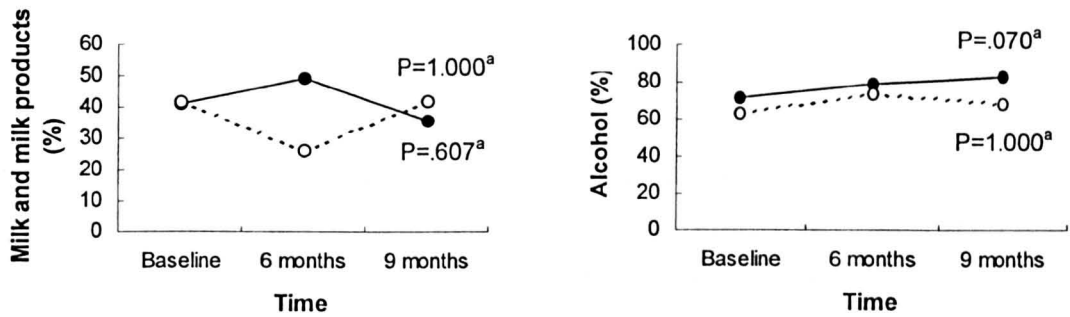


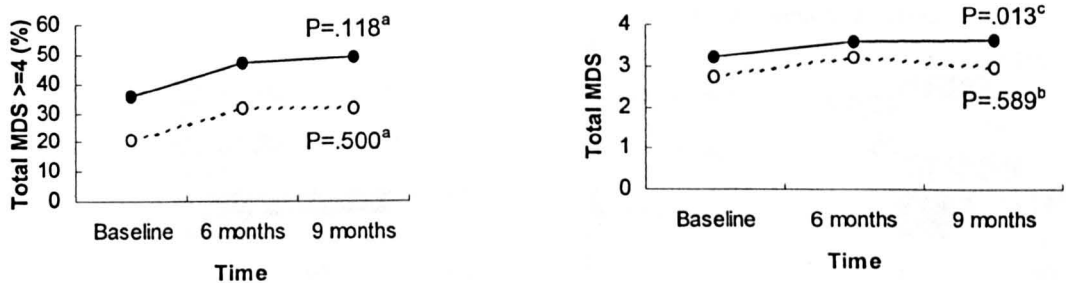
Figure 4.11 cont.: Percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on intention-to-treat analyses for participants in the intervention (—●—, *n* 53) and control (---○---, *n* 19) groups (P values for comparison between baseline and 9-month assessments)



^a Levels of significance were assessed with the use of the McNemar Test

There were no intention-to-treat differences in the proportions of participants achieving a high MDS (≥ 4) in either group at any time point (Figure 4.12). At 6 months, mean total MDS increased for participants in both the intervention (3.21 v. 3.60; $P=.035$) and control (2.74 v. 3.21; $P=.047$) groups, but this favourable change was maintained at 9 months only for participants in the intervention group (3.21 v. 3.64; $P=.013$) (Figure 4.12).

Figure 4.12 Percentage of participants achieving a high Mediterranean Diet Score (≥ 4) and mean total score, based on intention-to-treat analyses for participants in the intervention (—●—, *n* 53) and control (---○---, *n* 19) groups (P values for comparison between baseline and 9-month assessments)



^a Levels of significance were assessed with the use of the McNemar Test

^b Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^c Levels of significance were assessed with the use of the Paired-Samples T Test

4.4.2. Between group differences over time

4.4.2.1. Food components

The between group differences in changes in mean daily consumption of the eight components of the Mediterranean diet over the 9-month trial are presented in Figure 4.13. At the end of the 6-month intervention, intention-to-treat analyses showed that participants in the intervention group had significantly increased their intake of fruits, nuts and seeds, whereas participants in the control group had a reduced intake (34.9 v. -23.2 g/d; $P=.022$). At this time point, participants in the control group had also slightly increased their intake of cereals (-15.6 v. 14.3 g/d; $P=.059$) and increased their intake of milk and milk products (-4.1 v. 42.3 g/d; $P=.033$) compared with participants in the intervention group. Between the end of the 6-month intervention and the 3-month follow-up, participants in the intervention group had shown a less desirable increase in milk and milk products (14.4 v. -25.8 g/d; $P=.049$) compared with participants in the control group. In addition, there was a favourable increase in vegetable intake in the intervention compared with the control group (76.5 v. 27.7 g/d; $P=.050$) between baseline and 9 months.

Figure 4.13 Between group comparison of changes over time in mean daily consumption of the eight components of the Mediterranean diet, based on intention-to-treat analyses for participants in the intervention (■, n 53) and control (▨, n 19) groups (P values)

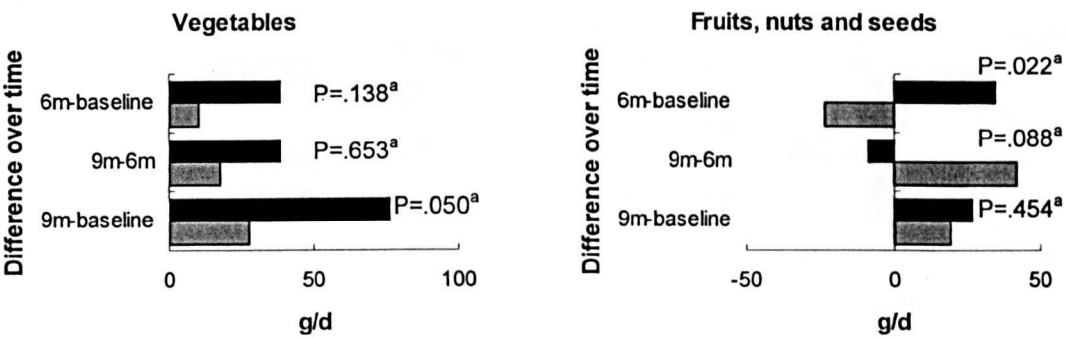
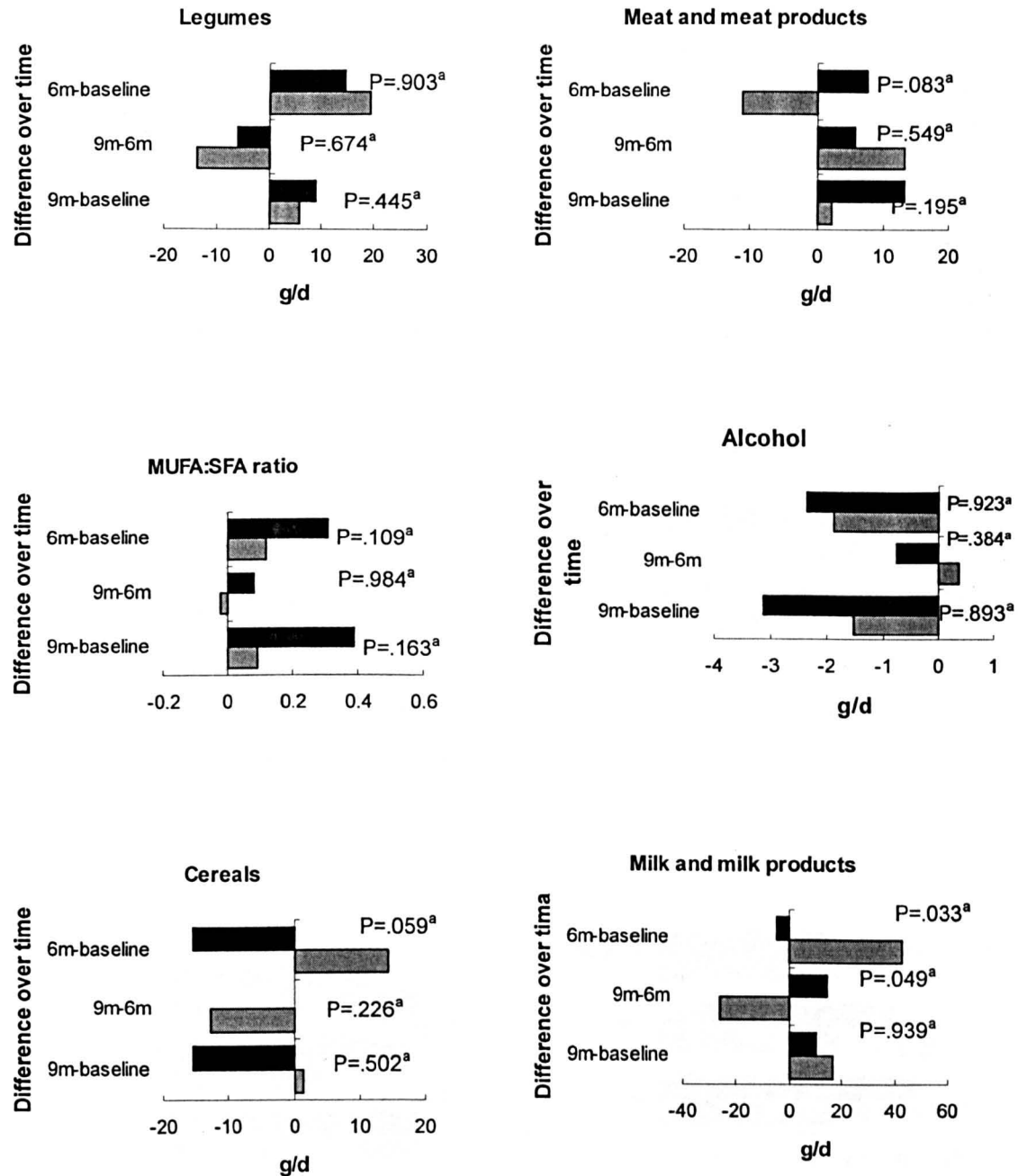


Figure 4.13 cont.: Between group comparison of changes over time in mean daily consumption of the eight components of the Mediterranean diet, based on intention-to-treat analyses for participants in the intervention (■, *n* 53) and control (▨, *n* 19) groups (P values)



^a Levels of significance were assessed with the use of the Mann-Whitney U Test

4.4.2.2. *Mediterranean Diet Score*

The between group differences in proportions of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet are presented in Figure 4.14. On an intention-to-treat basis, a higher proportion of participants in the intervention, compared with the control, group achieved a score of 1 for cereals at baseline (50.9 v. 15.8%; $P=.008$). Compared with participants in the control group, a higher proportion of participants in the intervention group achieved a score of 1 for vegetables (43.4 v. 15.8%; $P=.033$) at 9 months.

Figure 4.14 Between group comparison of percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on intention-to-treat analyses for participants in the intervention (■, $n = 53$) and control (▨, $n = 19$) groups (P values)

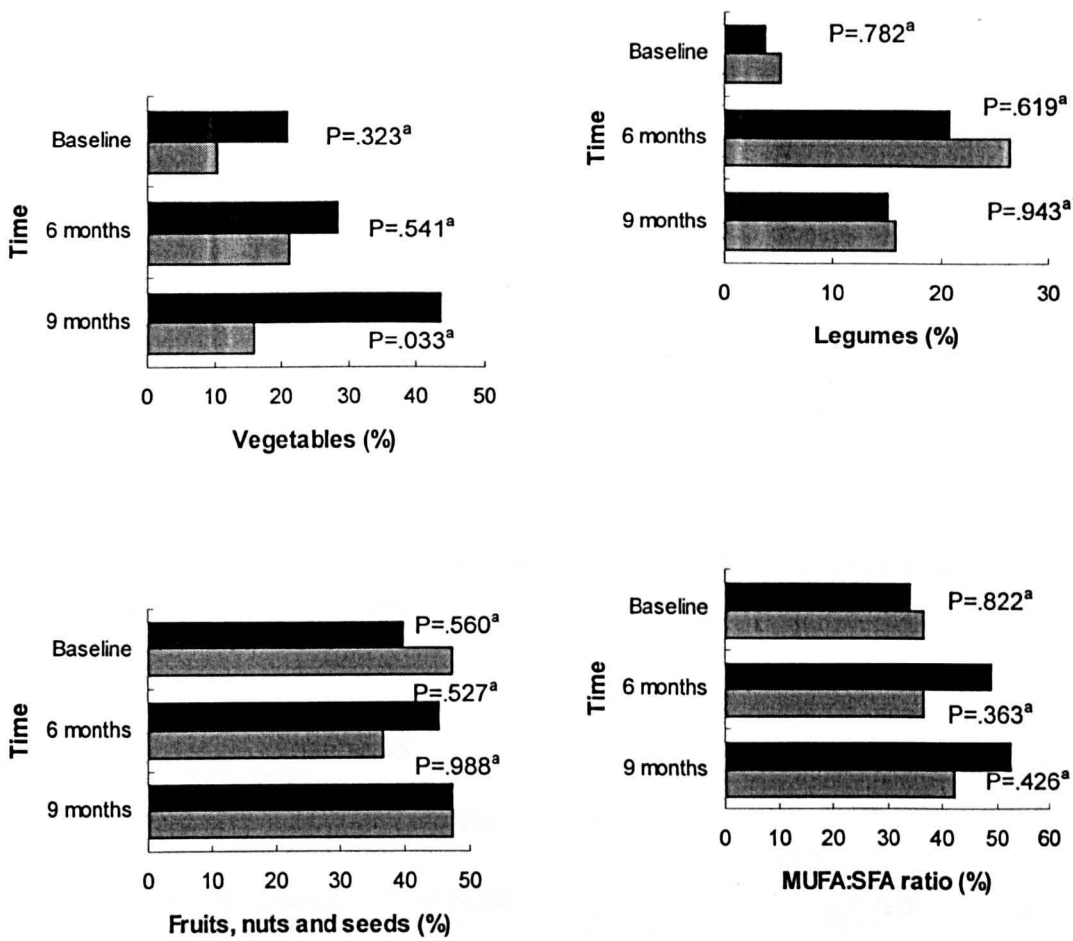
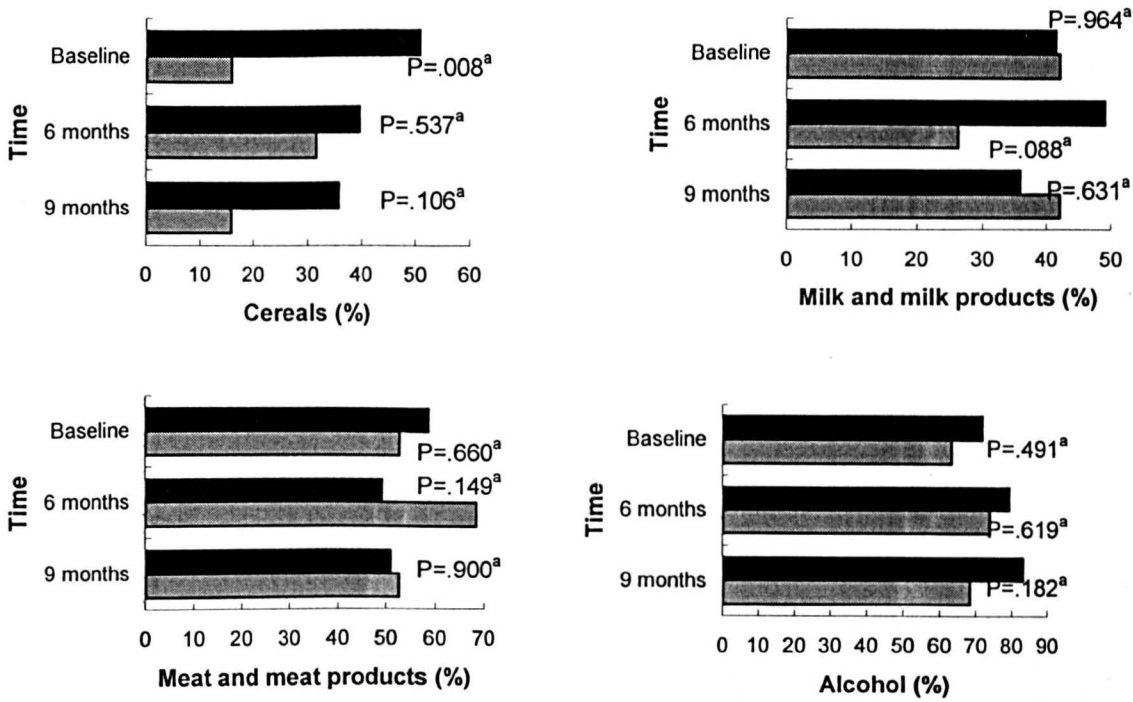


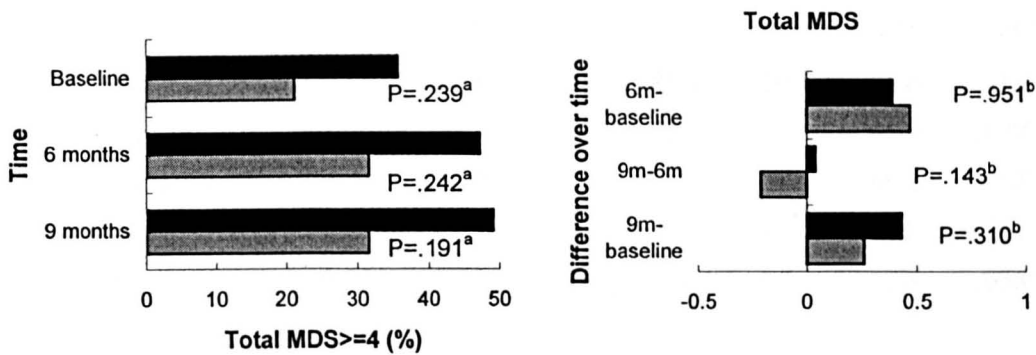
Figure 4.14 cont.: Between group comparison of percentage of participants achieving a Mediterranean Diet Score of 1 for each component of the Mediterranean diet, based on intention-to-treat analyses for participants in the intervention (■, n 53) and control (▨, n 19) groups (P values)



^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

There were no significant between group differences in the proportions of participants achieving a high MDS (≥ 4) or in the changes in the mean total MDS changes at any time point, as illustrated in Figure 4.15.

Figure 4.15 Between group comparison of changes over time in percentage of participants achieving a high Mediterranean Diet Score (≥ 4) and mean total score, based on intention-to-treat analyses for participants in the intervention (■, n 53) and control (▨, n 19) groups (P values)



^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

^b Levels of significance were assessed with the use of the Mann-Whitney U Test

4.5. Associations between dietary changes and website login frequency

During the 6-month trial, overall website login frequency for each participant in the intervention group was measured via statistical summaries generated from the University of Glasgow web Server. Since participants were requested to visit the website at least once per week, a login frequency cut-off point of 20 times over the course of the 6-month intervention was used to determine high- and low-frequency users of the website.

Table 4.5 presents the comparison of changes in mean daily consumption of the eight components of the Mediterranean diet and in the total MDS from baseline to 6 months between the high- and low-frequency website users (intervention group) and participants in the control group, for participants in all groups who completed the baseline and 6-month dietary assessments. No differences were observed between any of the three groups in these variables.

Table 4.5 Between group comparison of changes in mean daily consumption of the eight components of the Mediterranean diet from baseline to 6 months according to expected website login frequency (20 times/6 months), based on participants in both groups completing the baseline and 6-month assessments (mean values, standard deviations and P values)

Food component	Intervention group (n 41)				Control group (n 14)		
	Website login frequency						
	Low (n 30) ^a		High (n 11) ^b				
	Mean	SD	Mean	SD	Mean	SD	P
Vegetables (g/d)	48.7	91.7	51.7	101.8	13.9	96.4	.482 ^c
Fruits, nuts and seeds (g/d)	29.4	108.7	87.9	156.4	-31.5	108.3	.053 ^c
Legumes (g/d)	12.2	28.7	37.4	33.9	26.3	37.1	.073 ^c
MUFA:SFA ratio (/d)	0.37	0.9	0.49	0.5	0.16	0.56	.548 ^c
Cereals (g/d)	-22.0	83.3	-14.9	86.5	19.4	85.0	.318 ^c
Meat and meat products (g/d)	14.5	40.2	-2.9	42.4	-14.9	40.9	.079 ^c
Milk and milk products (g/d)	3.8	106.3	-30.5	117.7	57.4	69.2	.093 ^c
Alcohol (g/d)	-4.3	23.1	0.6	6.4	-2.5	9.8	.741 ^c
Mean Total Mediterranean	0.20	1.35	1.36	1.63	0.64	1.08	.056 ^c
Diet Score							

^a <20 times/ 6 months

^b ≥20 times/ 6 months

^c Levels of significance were assessed with the use of One-Way ANOVA

For those participants who completed all three dietary assessments (baseline, 6 and 9 months), there were no differences between any of the three groups in changes in mean daily consumption of the eight components of the Mediterranean diet or in the total MDS from baseline to 9 months (Table 4.6).

Table 4.6 Between group comparison of changes in mean daily consumption of the eight components of the Mediterranean diet from baseline to 9 months according to expected website login frequency (20 times/6 months), based on participants in both groups completing the baseline, 6-month and 9-month assessments (mean values, standard deviations and P values)

Food component	Intervention group (<i>n</i> 35)				Control group (<i>n</i> 13)		
	Website login frequency						
	Low (<i>n</i> 25) ^a		High (<i>n</i> 10) ^b				
	Mean	SD	Mean	SD	Mean	SD	P
Vegetables (g/d)	81.1	85.9	81.1	93.6	44.1	128.4	.530 ^c
Fruits, nuts and seeds (g/d)	26.6	161.0	94.3	102.5	29.4	189.8	.505 ^c
Legumes (g/d)	10.6	26.6	22.5	34.7	9.6	29.0	.495 ^c
MUFA:SFA ratio (/d)	0.47	1.27	0.41	0.39	0.15	0.62	.645 ^c
Cereals (g/d)	-17.1	81.4	-5.2	86.9	-3.3	98.6	.876 ^c
Meat and meat products (g/d)	14.9	58.7	1.7	47.1	5.8	51.4	.776 ^c
Milk and milk products (g/d)	11.1	131.1	10.2	90.5	18.8	79.7	.976 ^c
Alcohol (g/d)	-7.9	22.8	1.1	7.1	-0.4	9.5	.276 ^c
Mean Total Mediterranean	0.72	1.27	1.00	1.33	0.31	1.60	.479 ^c
Diet Score							

^a <20 times/ 6 months

^b ≥20 times/ 6 months

^c Levels of significance were assessed with the use of One-Way ANOVA

4.6. Associations between dietary changes and stages of dietary behaviour change

For participants who completed the baseline and 6-month dietary assessments, Table 4.7 presents the comparison of changes in mean daily consumption of the four components of the Mediterranean diet promoted by the study from baseline to 6 months between participants in the intervention and control groups who had achieved a forward stage of transition (see Chapter 3, Section 3.8.) from baseline to 6 months and those who had not. Bonferroni post-hoc multiple comparisons showed that at 6 months, participants in the intervention group who had achieved a forward stage of transition

for vegetables had increased their vegetable intake more than participants in this group who had not (101.1 v. 19.8 g/d; $P=.042$). There was also a higher increase in intake of fruits, nuts and seeds for participants in the intervention group who had achieved a forward stage of transition for this food component compared with those participants in the intervention (121.0 v. 5.7 g/d; $P=.018$) and control (121.0 v. -30.9 g/d; $P=.007$) groups who had not.

Table 4.7 Between group comparison of changes in mean daily consumption of the four Mediterranean goals from baseline to 6 months according to stage of dietary behaviour transition for each goal, based on participants in both groups completing the baseline and 6-month assessments (mean values, standard deviations and P values)

Food component	Intervention group (n 41)				Control group (n 14)				
	Stage of behavioural transition								
	FST (n 15)		No FST (n 26)		FST (n 4)		No FST (n 10)		P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Vegetables (g/d)	101.1	88.3	19.8	83.8	11.5	75.3	14.8	107.4	.031 ^a
Fruits, nuts and seeds (g/d)	Intervention group (n 41)				Control group (n 14)				
	Stage of behavioural transition								
	FST (n 14)		No FST (n 27)		FST (n 2)		No FST (n 12)		P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Fruits, nuts and seeds (g/d)	121.0	136.3	5.7	98.2	-34.9	18.3	-30.9	117.6	.005 ^a
Legumes (g/d)	Intervention group (n 41)				Control group (n 14)				
	Stage of behavioural transition								
	FST (n 37)		No FST (n 14)		FST (n 8)		No FST (n 6)		P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Legumes (g/d)	20.3	31.7	6.3	34.5	28.3	38.0	23.6	39.2	.755 ^a
MUFA:SFA ratio (/d)	Intervention group (n 41)				Control group (n 14)				
	Stage of behavioural transition								
	FST (n 28)		No FST (n 13)		FST (n 3)		No FST (n 11)		P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
MUFA:SFA ratio (/d)	0.52	0.95	0.17	0.42	0.18	0.33	0.15	0.62	.424 ^a

FST, forward stage of transition.

^a Levels of significance were assessed with the use of One-Way ANOVA

For those participants who completed all three dietary assessments (baseline, 6 and 9 months), intake of vegetables for participants in the intervention group who had achieved a forward stage of transition for this food component had significantly increased at 9 months compared with participants in the control group who had not moved forward (126.8 v. 14.3 g/d; $P=.046$), as presented in Table 4.8.

Table 4.8 Between group comparison of changes in mean daily consumption of the four Mediterranean goals from baseline to 9 months according to stage of dietary behaviour transition for each goal, based on participants in both groups completing the baseline, 6-month and 9-month assessments (mean values, standard deviations and P values)

Food component	Intervention group (<i>n</i> 35)				Control group (<i>n</i> 12)				
	Stage of behaviour transition								
	FST (<i>n</i> 10)		No FST (<i>n</i> 24)		FST (<i>n</i> 4)		No FST (<i>n</i> 8)		P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Vegetables (g/d)	126.8	85.8	56.8	77.6	27.0	67.7	14.3	108.4	.039 ^a
Fruits, nuts and seeds (g/d)	Intervention group (<i>n</i> 35)				Control group (<i>n</i> 12)				
	Stage of behaviour transition								
	FST (<i>n</i> 9)		No FST (<i>n</i> 25)		FST (<i>n</i> 3)		No FST (<i>n</i> 9)		P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Fruits, nuts and seeds (g/d)	132.6	197.7	9.3	115.1	99.2	110.7	33.4	203.9	.211 ^a
Legumes (g/d)	Intervention group (<i>n</i> 35)				Control group (<i>n</i> 12)				
	Stage of behaviour transition								
	FST (<i>n</i> 26)		No FST (<i>n</i> 8)		FST (<i>n</i> 5)		No FST (<i>n</i> 7)		P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Legumes (g/d)	17.8	29.9	-0.3	24.3	21.7	31.0	-4.5	21.1	.146 ^a
MUFA:SFA ratio (/d)	Intervention group (<i>n</i> 35)				Control group (<i>n</i> 12)				
	Stage of behaviour transition								
	FST (<i>n</i> 26)		No FST (<i>n</i> 8)		FST (<i>n</i> 2)		No FST (<i>n</i> 10)		P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
MUFA:SFA ratio (/d)	0.52	1.25	0.26	0.19	0.12	0.17	0.06	0.63	.645 ^a

FST, forward stage of transition.

^a Levels of significance were assessed with the use of One-Way ANOVA

4.7. Summary

Results based on the “intention-to-treat” analyses generally agreed with results from the “per protocol” analyses. Both analyses showed that at 6 months, participants in the intervention group had increased their intake of vegetables, fruits, nuts and seeds and legumes, as well as the MUFA:SFA ratio in their diet and their mean total MDS, compared with baseline. At 6 months, a higher percentage of participants in this group also achieved a MDS of 1 for legumes and MUFA:SFA ratio, while for participants who completed all three dietary assessments, “per protocol” analyses additionally showed that a higher percentage of participants in this group

achieved a high MDS (≥ 4), compared with baseline. Between the end of the 6-month intervention and the 3-month follow-up, consumption of vegetables, as well as the percentage of participants achieving a MDS of 1 for vegetables increased for the intervention group. All analyses revealed an increase in the consumption of vegetables, legumes, MUFA:SFA ratio and mean total MDS, as well as an increase in the percentage of participants achieving a MDS of 1 for vegetables and MUFA:SFA ratio for the intervention group at 9 months, compared with baseline. The “intention-to-treat” analysis additionally showed that meat intake in the intervention group had slightly increased and that a lower percentage of participants in this group achieved a MDS of 1 for cereals at 9 months, compared with baseline. In addition, “per protocol” analysis for participants completing all three dietary assessments showed that at 9 months, fruit, nut and seed intake of participants in the intervention group had increased and that a higher percentage of participants in this group achieved a MDS of 1 for alcohol, as well as a high MDS (≥ 4), compared with baseline.

All analyses showed that at 6 months, participants in the control group had increased their intake of legumes, as well as milk and milk products, compared with baseline. The “per protocol” analysis for participants completing the baseline and 6-month dietary assessments, as well as the “intention-to-treat” analysis further revealed that the mean total MDS for participants in this group had also increased at the end of the 6-month intervention.

All analyses on the between group differences over the 6-month intervention showed that participants in the intervention group had increased their intake of fruits, nuts and seeds, while participants in the control group had a decreased intake. Over this period, participants in the latter group had increased their intake of milk and milk products, while the “intention-to-treat” analysis additionally revealed that they had increased their intake of cereals, compared with participants in the intervention group. For participants who completed the baseline and 6-month dietary assessments, “per protocol” analyses showed an increase in meat and meat product intake for participants in the intervention, compared with the control group. Between the end of the 6-month intervention and the 3-month follow-up, “intention-to-treat” analyses showed an increase in milk and milk product intake for the intervention, compared with the control group. The “intention-to-treat” analyses revealed that between baseline and 9 months, vegetable intake in the intervention, compared with the control group, had increased. In addition, both the “intention-to-treat” and the “per protocol” analyses showed that at 9 months, a higher percentage of participants in the intervention, compared with the control group, achieved a MDS of 1 for vegetables, while the “per protocol” analyses additionally showed that more participants in the intervention group achieved a MDS of 1 for alcohol.

No association was found between website login frequency and dietary changes over the 6-month intervention or with dietary changes between the beginning of the study and the 3-month follow-up. However, participants in the intervention group who had achieved a forward stage of dietary behavioural transition regarding vegetables over the 6-month study, increased their vegetable intake more than participants in the same group who had not achieved a forward stage of change. In a similar manner, at the end of the 6-month intervention, participants in the intervention group who had moved forward in the stages of change algorithm regarding fruit, nuts and seeds, had increased their intake of this food component more than participants in both the intervention and control groups who had not achieved a forward stage of transition. In addition, at the end of the 3-month follow-up, participants in the intervention group who, over the trial (baseline to 9 months), had moved forward in the stages of change algorithm regarding vegetables, had increased their intake of this food component more than participants in the control group who had not achieved a forward stage of transition.

5 Results: Anthropometric, Blood Pressure and Biochemical Assessment

5.1. Overview

Fifty-three, forty-two and thirty-six participants in the intervention group, and nineteen, fifteen and fifteen participants in the control group completed the baseline, 6-month and 9-month stages of the intervention, respectively.

During these three assessment time points (baseline, 6 months and 9 months), anthropometric and blood pressure measurements were provided by all participants in both groups who completed these stages. Forty-six, thirty-four and thirty participants in the intervention group, and sixteen, thirteen and thirteen participants in the control group provided fasting plasma lipid measurements at each time point. Fasting urinary electrolyte measurements were provided by fifty-three, thirty-eight and thirty-six participants in the intervention group and nineteen, fifteen and fourteen participants in the control group at each assessment time point. A summary of the anthropometric and biochemical assessment results of participants providing measurements at each time point is presented in Tables 5.1-5.3.

Table 5.1 Mean anthropometric and blood pressure measurements of participants in both groups at baseline, 6 months and 9 months (mean values and standard deviations)

Measurement	Baseline				6 months				9 months			
	Intervention group		Control group		Intervention group		Control group		Intervention group		Control group	
	(n 53)		(n 19)		(n 42)		(n 15)		(n 36)		(n 15)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Weight (kg)	69.2	15.0	68.7	12.9	68.4	14.8	70.0	11.4	66.2	13.8	70.2	12.0
Body Mass Index (kg/m ²)	26.1	4.9	25.2	4.5	25.5	4.7	25.3	4.6	24.8	4.2	25.4	4.9
Waist circumference (cm)	83.2	11.9	82.6	11.1	80.5	11.2	81.7	9.5	78.3	10.0	81.0	10.8
Systolic Blood Pressure (mmHg)	120.8	14.5	118.3	9.5	118.2	9.2	120.6	8.0	113.9	10.0	119.2	13.9
Diastolic Blood Pressure (mmHg)	79.9	9.2	78.9	9.4	79.8	7.2	78.4	9.4	76.2	8.4	79.2	12.9

Table 5.2 Mean fasting plasma lipid measurements of participants in both groups at baseline, 6 months and 9 months (mean values and standard deviations)

Measurement	Baseline				6 months				9 months			
	Intervention group		Control group		Intervention group		Control group		Intervention group		Control group	
	(n 46)		(n 16)		(n 34)		(n 13)		(n 30)		(n 13)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Total cholesterol (mmol/l)	5.11	0.82	5.19	0.75	5.06	0.81	5.19	0.90	5.34	0.89	5.22	0.91
LDL-cholesterol (mmol/l)	3.10	0.75	2.89	0.90	2.86	0.80	2.86	1.09	3.03	0.86	2.89	1.09
HDL-cholesterol (mmol/l)	1.42	0.27	1.75	0.44	1.71	0.33	1.83	0.47	1.75	0.33	1.81	0.41
Triglycerides (mmol/l)	1.16	0.55	1.18	0.55	1.07	0.45	1.09	0.36	1.21	0.52	1.12	0.42
Total: HDL-cholesterol ratio	3.71	0.91	3.19	1.10	3.07	0.84	3.07	1.15	3.13	0.75	3.10	1.19

Table 5.3 Mean fasting urinary electrolyte measurements of participants in both groups at baseline, 6 months and 9 months (mean values and standard deviations)

Measurement	Baseline				6 months				9 months			
	Intervention group		Control group		Intervention group		Control group		Intervention group		Control group	
	(n 53)		(n 19)		(n 38)		(n 15)		(n 36)		(n 14)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Sodium (mmol/l)	102.1	39.9	115.8	48.3	96.7	43.2	92.0	31.7	97.6	48.1	101.1	41.4
Potassium (mmol/l)	46.1	23.7	42.1	22.2	54.9	29.9	45.8	25.5	48.0	25.9	50.1	20.1
Creatinine (mmol/l)	9.7	5.0	10.9	4.1	10.8	5.3	10.5	4.3	11.2	5.5	10.3	4.9
Potassium:creatinine ratio	5.8	3.9	3.9	1.4	5.6	3.5	4.6	2.4	4.9	2.9	5.5	2.5

For ease of presentation, results on the anthropometric and biochemical assessment are presented in three sections:

Section A: Analysis for participants completing baseline and 6-month assessments

Section B: Analysis for participants completing baseline, 6-month and 9-month assessments

Section C: Analysis on an intention-to-treat basis

Section A: Analysis for participants completing baseline and 6-month assessments

5.2. Participants completing baseline and 6-month assessments

Forty-two participants in the intervention group and fifteen participants in the control group provided anthropometric and blood pressure measurements at both baseline and 6 months. Fasting blood samples for blood lipid measurements at both time points were provided by thirty-four and thirteen participants in the intervention and control groups, respectively, and thirty-eight participants in the intervention group and fifteen participants in the control group provided fasting urine samples, to assess urinary electrolytes, at both baseline and 6 months.

5.2.1. Within group comparisons

5.2.1.1. Anthropometric and blood pressure measurements

Table 5.4 illustrates the comparison of mean anthropometric and blood pressure measurements at baseline and at the end of the 6-month intervention for both groups. Participants in the intervention group significantly decreased their waist circumference at 6 months, but showed no other significant differences compared with baseline. Participants in the control group also showed a significant decrease in waist circumference at 6 months.

Table 5.4 Mean anthropometric and blood pressure measurements, based on participants in both groups completing the baseline and 6-month assessments (mean values, standard deviations and P values)

Measurement	Intervention group (n 42)					Control group (n 15)				
	Baseline		6 months		P	Baseline		6 months		P
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Weight (kg)	69.0	15.5	68.4	14.8	.100 ^a	70.8	11.8	70.0	11.4	.343 ^a
Body Mass Index (kg/m ²)	25.7	4.9	25.5	4.7	.100 ^a	25.6	4.7	25.4	4.6	.456 ^a
Waist circumference (cm)	82.8	11.7	80.6	11.2	.001 ^a	84.7	11.3	81.7	9.5	.041 ^a
Systolic Blood Pressure (mmHg)	118.9	12.4	118.2	9.3	.767 ^a	119.9	9.3	120.6	8.0	.328 ^a
Diastolic Blood Pressure (mmHg)	79.8	7.7	79.8	7.2	.991 ^b	79.8	9.4	78.4	9.4	.280 ^a

^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

5.2.1.2. Blood lipids

Mean fasting plasma lipid levels at baseline and 6 months are presented in Table 5.5 for both groups. Despite a slight increase in total cholesterol levels at the end of the 6-month intervention in both groups, participants in the intervention group displayed significantly higher plasma HDL-cholesterol levels and a lower total: HDL-cholesterol ratio compared with baseline. Participants in the control group did not show any significant differences in fasting blood lipid levels at the end of the 6-month intervention compared with baseline.

Table 5.5 Mean fasting plasma blood lipids, based on participants in both groups completing the baseline and 6-month assessments (mean values, standard deviations and P values)

Measurement	Intervention group (n 34)					Control group (n 13)				
	Baseline		6 months		P	Baseline		6 months		P
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Total cholesterol (mmol/l)	4.99	0.74	5.06	0.81	.795 ^a	5.16	0.77	5.19	0.91	.780 ^a
LDL-cholesterol (mmol/l)	3.05	0.65	2.86	0.80	.077 ^b	2.87	0.98	2.86	1.10	.806 ^a
HDL-cholesterol (mmol/l)	1.41	0.27	1.71	0.33	<.001 ^b	1.76	0.48	1.83	0.47	.262 ^a
Triglycerides (mmol/l)	1.14	0.63	1.07	0.45	.606 ^a	1.16	0.61	1.10	0.36	.700 ^a
Total:HDL-cholesterol ratio	3.66	0.84	3.07	0.84	<.001 ^b	3.20	1.23	3.07	1.15	.329 ^a

^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

5.2.1.3. Urinary electrolytes

Table 5.6 illustrates the comparison of mean fasting urinary electrolytes at baseline and at the end of the 6-month intervention for both groups. No significant differences were found for participants in either group between baseline and 6 months, apart from a decrease in urinary sodium levels among participants in the control group.

Table 5.6 Mean fasting urinary electrolytes, based on participants in both groups completing the baseline and 6-month assessments (mean values, standard deviations and P values)

Measurement	Intervention group (n 38)					Control group (n 15)				
	Baseline		6 months		P	Baseline		6 months		P
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Sodium (mmol/l)	99.1	43.3	96.7	43.2	.727 ^b	126.9	48.1	92.0	31.7	.007 ^a
Potassium (mmol/l)	46.4	21.7	54.9	29.9	.157 ^a	43.1	20.9	45.8	25.5	.820 ^a
Creatinine (mmol/l)	9.8	5.2	10.8	5.3	.582 ^a	11.5	3.3	10.5	4.3	.397 ^a
Potassium:creatinine ratio	5.8	3.7	5.6	3.5	.890 ^a	3.8	1.4	4.6	2.4	.609 ^a

^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

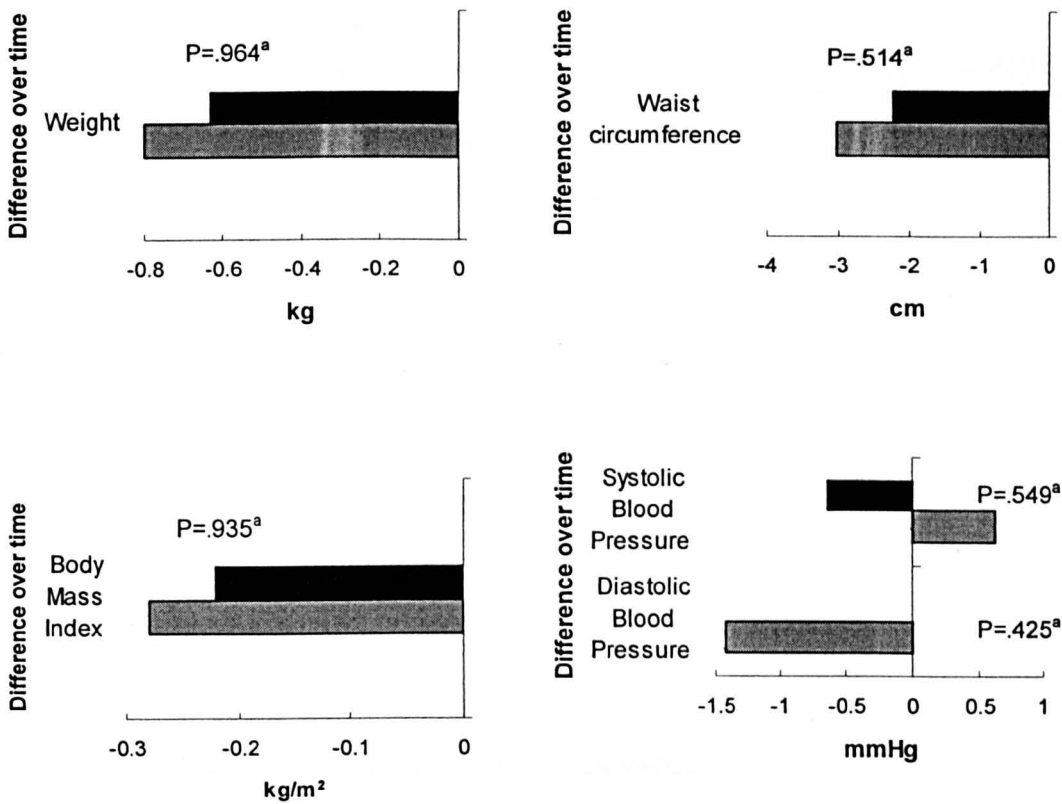
^b Levels of significance were assessed with the use of the Paired-Samples T Test

5.2.2. Between group differences over time

5.2.2.1. Anthropometric and blood pressure measurements

The between group differences in changes in mean anthropometric and blood pressure measurements over the 6-month intervention period are illustrated in Figure 5.1. There were no statistically significant differences between the groups by the end of the trial.

Figure 5.1 Between group comparison of changes over 6 months in mean anthropometric and blood pressure measurements, based on participants in the intervention (■, *n* 42) and control (▨, *n* 15) groups completing the baseline and 6-month assessments (*P* values)

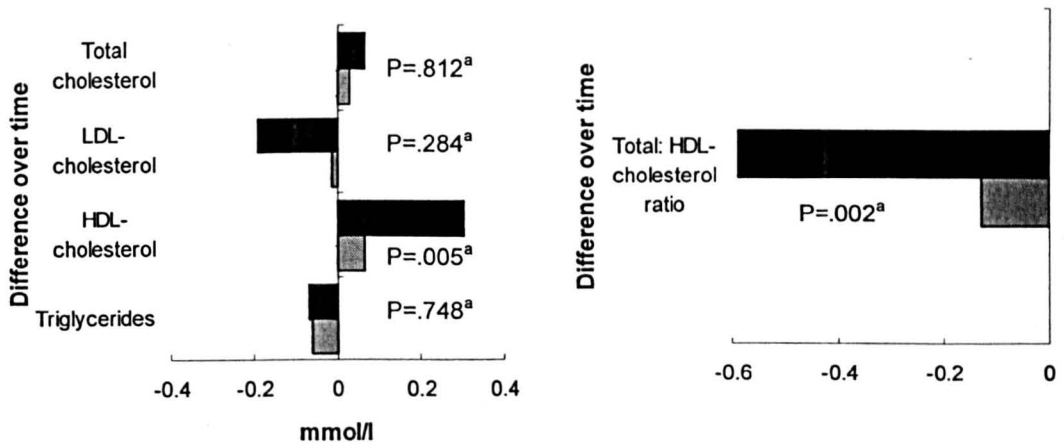


^a Levels of significance were assessed with the use of the Mann-Whitney U Test

5.2.2.2. Blood lipids

At the end of the trial, participants in the intervention group had shown a significantly higher increase in HDL-cholesterol levels (0.30 v. 0.07 mmol/l; $P=.005$), as well as a greater decrease in the total:HDL-cholesterol ratio (-0.59 v. -0.13; $P=.002$) compared with the control group, as illustrated in Figure 5.2.

Figure 5.2 Between group comparison of changes over 6 months in mean fasting plasma blood lipid levels, based on participants in the intervention (■, n 34) and control (▨, n 13) groups completing the baseline and 6-month assessments (P values)

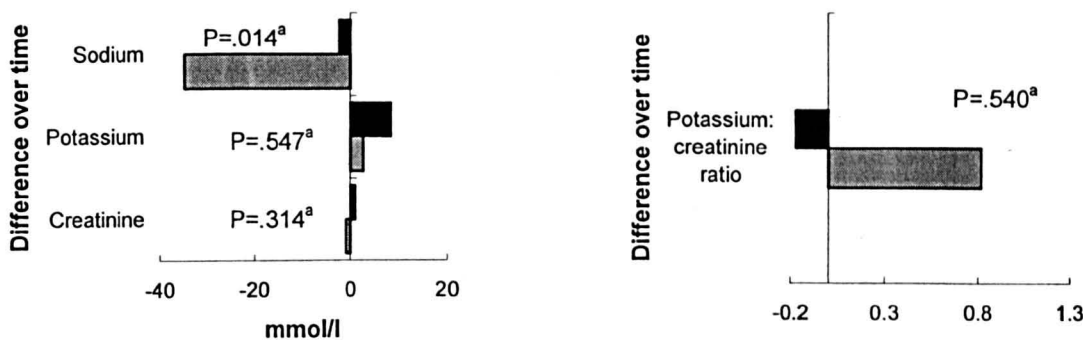


^a Levels of significance were assessed with the use of the Mann-Whitney U Test

5.2.2.3. Urinary electrolytes

The between group differences in mean fasting urinary electrolyte levels over the 6-month intervention period are illustrated in Figure 5.3. At the end of the trial, participants in the control group had shown a greater unexplained decrease in urinary sodium levels compared with participants in the intervention group (-2.4 v. -34.9 mmol/l; $P=.014$).

Figure 5.3 Between group comparison of changes over 6 months in mean fasting urinary electrolyte levels, based on participants in the intervention (■, n 38) and control (■, n 15) groups completing the baseline and 6-month assessments (P values)



^a Levels of significance were assessed with the use of the Mann-Whitney U Test

Section B: Analysis for participants completing baseline, 6-month and 9-month assessments

5.3. Participants completing baseline, 6-month and 9-month assessments

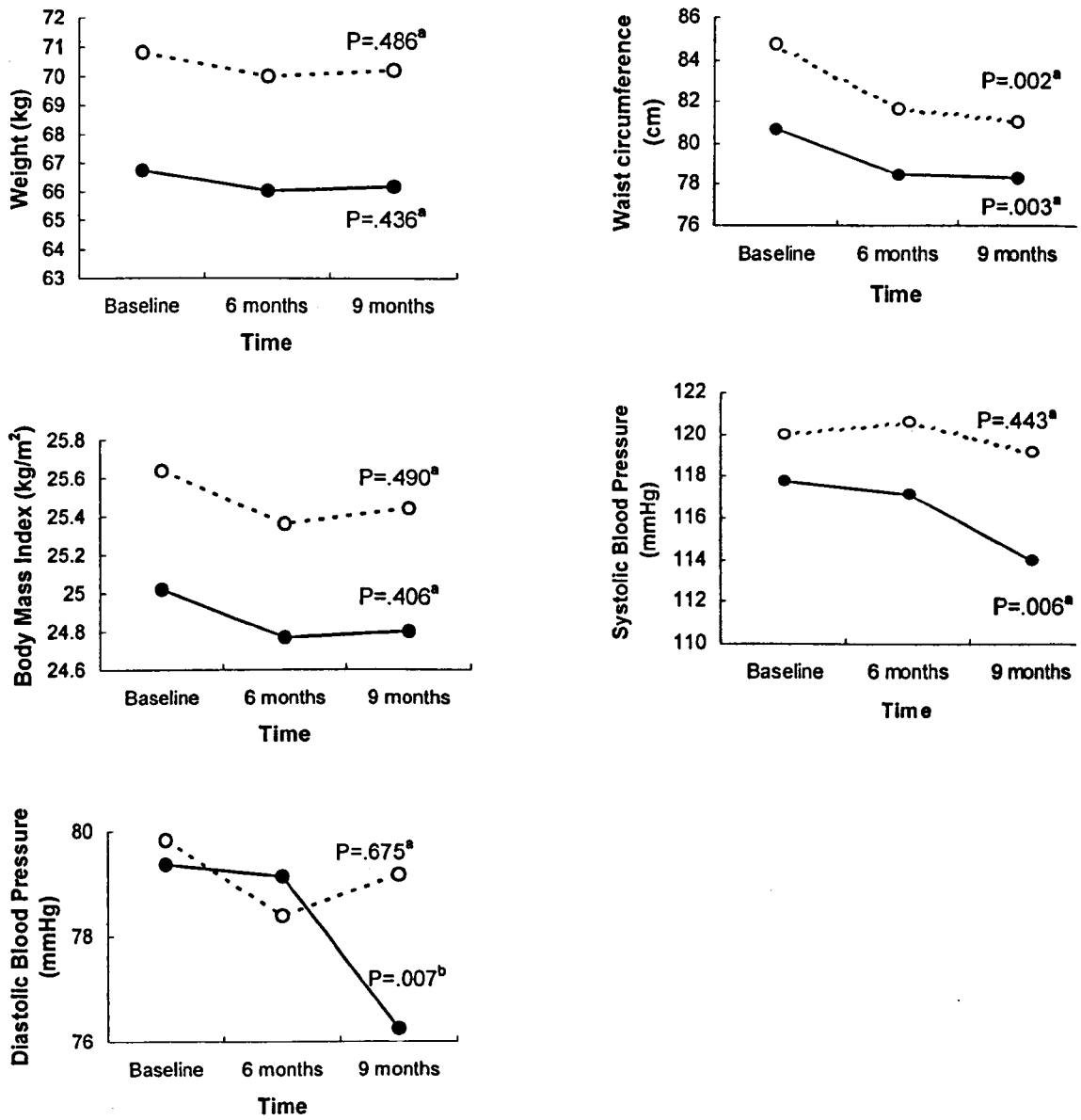
Thirty-six participants in the intervention group and fifteen participants in the control group provided anthropometric and blood pressure measurements at all three assessment time points (baseline, 6 and 9 months). Fasting blood samples for blood lipid measurements at all these time points were provided by twenty-nine and twelve participants in the intervention and control groups, respectively, and thirty-three participants in the intervention group and fourteen participants in the control group provided fasting urine samples, to assess urinary electrolytes, at all assessment points (baseline, 6 and 9 months).

5.3.1. Within group comparisons

5.3.1.1. Anthropometric and blood pressure measurements

Mean anthropometric and blood pressure measurements at baseline, 6 and 9 months are illustrated in Figure 5.4, for participants in both groups completing all three assessments. At 6 months, participants in the intervention and control groups significantly decreased their waist circumference compared with baseline (80.7 v. 78.4 cm; $P=.001$ and 84.7 v. 81.7 cm; $P=.041$, respectively). Between the end of the intervention and the 3-month follow-up participants in the intervention group also showed significant decreases in systolic (117.2 v. 113.9 mmHg; $P=.006$) and diastolic (79.1 v. 76.2 mmHg; $P=.026$) blood pressure. Overall, participants in both groups maintained lower waist circumference at 9 months compared with baseline (80.7 v. 78.3 cm; $P=.003$ for the intervention group and 84.7 v. 81.0 cm; $P=.002$ for the control group). In addition, participants in the intervention group displayed significantly lower systolic (117.8 v. 113.9 mmHg; $P=.006$) and diastolic (79.4 v. 76.2 mmHg; $P=.007$) blood pressure at 9 months compared with baseline.

Figure 5.4 Mean anthropometric and blood pressure measurements, based on participants in the intervention (—●—, *n* 36) and control (---○---, *n* 15) groups completing the baseline, 6-month and 9-month assessments (P values for comparison between baseline and 9-month assessments)



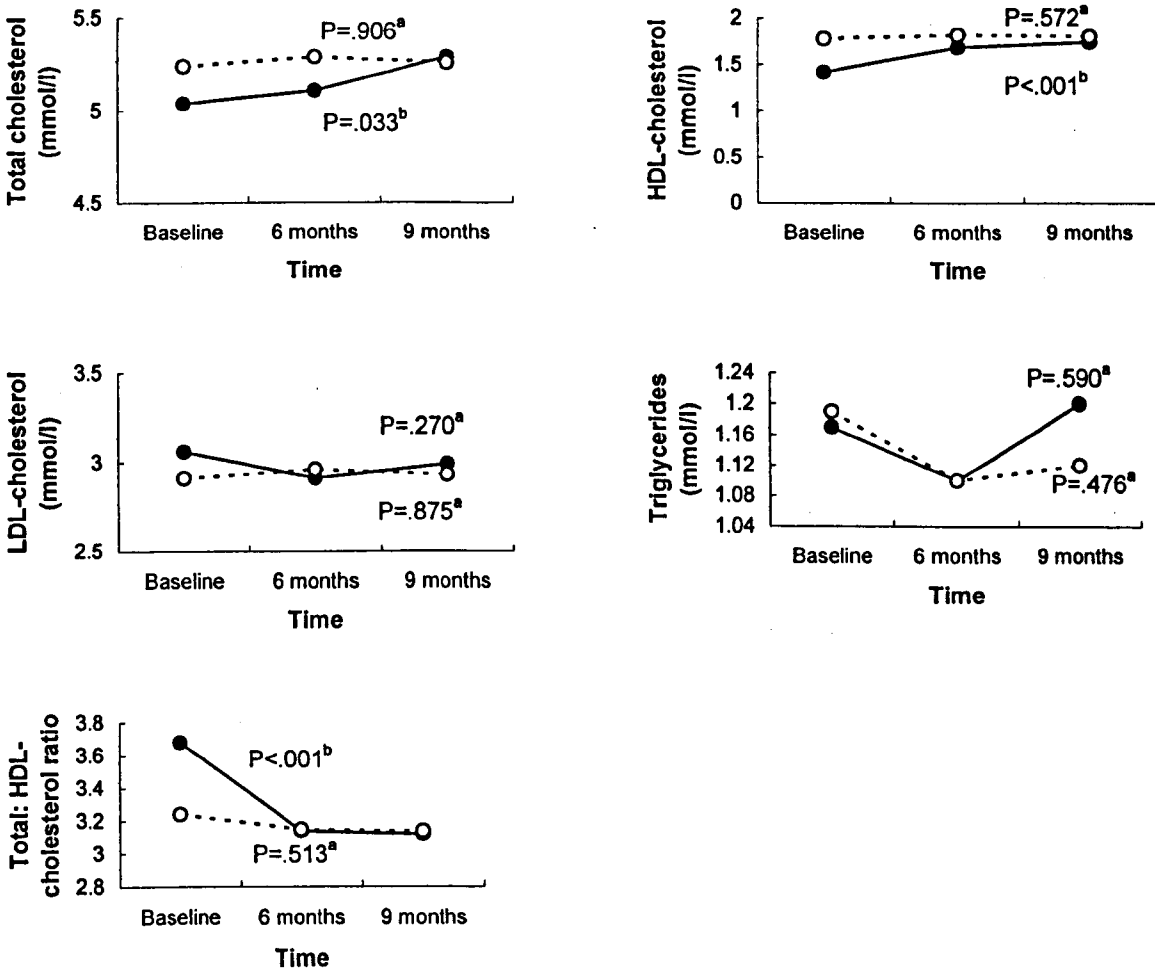
^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

5.3.1.2. Blood lipids

Figure 5.5 illustrates the comparison of mean fasting blood lipid levels at baseline, 6 and 9 months, for participants in both groups completing all three assessments. At 6 months, participants in the intervention group displayed significantly higher HDL-cholesterol levels (1.42 v. 1.69 mmol/l; $P<.001$), as well as a lower total:HDL-cholesterol ratio (3.68 v. 3.14; $P<.001$) compared with baseline. However, levels of total cholesterol in the intervention group increased between the end of the 6-month intervention and the 3-month follow-up (5.11 v. 5.29 mmol/l; $P=.031$). Overall, although total cholesterol levels in the intervention group increased (5.04 v. 5.29 mmol/l; $P=.033$), participants in this group displayed higher HDL-cholesterol levels (1.42 v. 1.75 mmol/l; $P<.001$) and a lower total:HDL-cholesterol ratio (3.68 v. 3.12; $P<.001$) at 9 months compared with baseline. No significant differences in mean blood lipid levels were observed among participants in the control group at any time points.

Figure 5.5 Mean fasting plasma blood lipids, based on participants in the intervention (—●—, $n = 29$) and control (---○---, $n = 12$) groups completing the baseline, 6-month and 9-month assessments (P values for comparison between baseline and 9-month assessments)



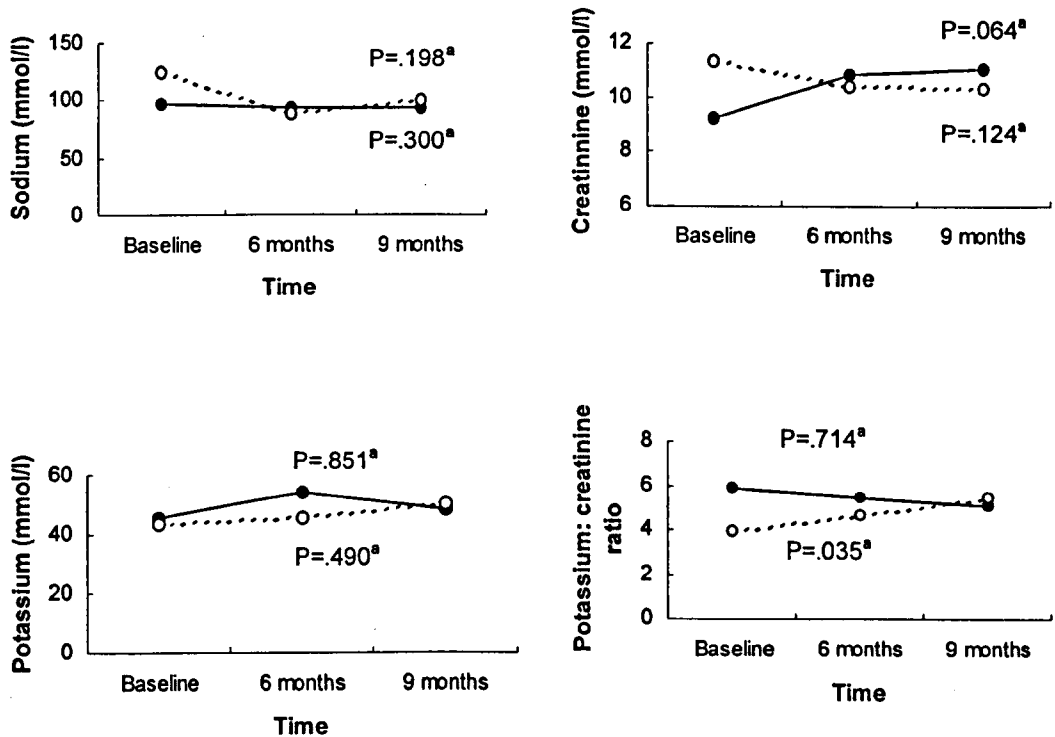
^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

5.3.1.3. Urinary electrolytes

Mean urinary electrolyte levels at baseline, 6 and 9 months are illustrated in Figure 5.6, for participants in both groups completing all three assessments. At the end of the 6-month intervention, mean urinary sodium in the control group had significantly decreased compared with baseline (125.3 v. 89.0 mmol/l; $P=.010$). However, there was no significant difference in urinary sodium levels at 9 months compared with baseline for this group. Participants in the control group also displayed higher levels of urinary potassium:creatinine ratio at the end of the 3-month follow-up compared with baseline (3.9 v. 5.5; $P=.035$).

Figure 5.6 Mean fasting urinary electrolytes, based on participants in the intervention (—●—, n 33) and control (---○---, n 14) groups completing the baseline, 6-month and 9-month assessments (P values for comparison between baseline and 9-month assessments)



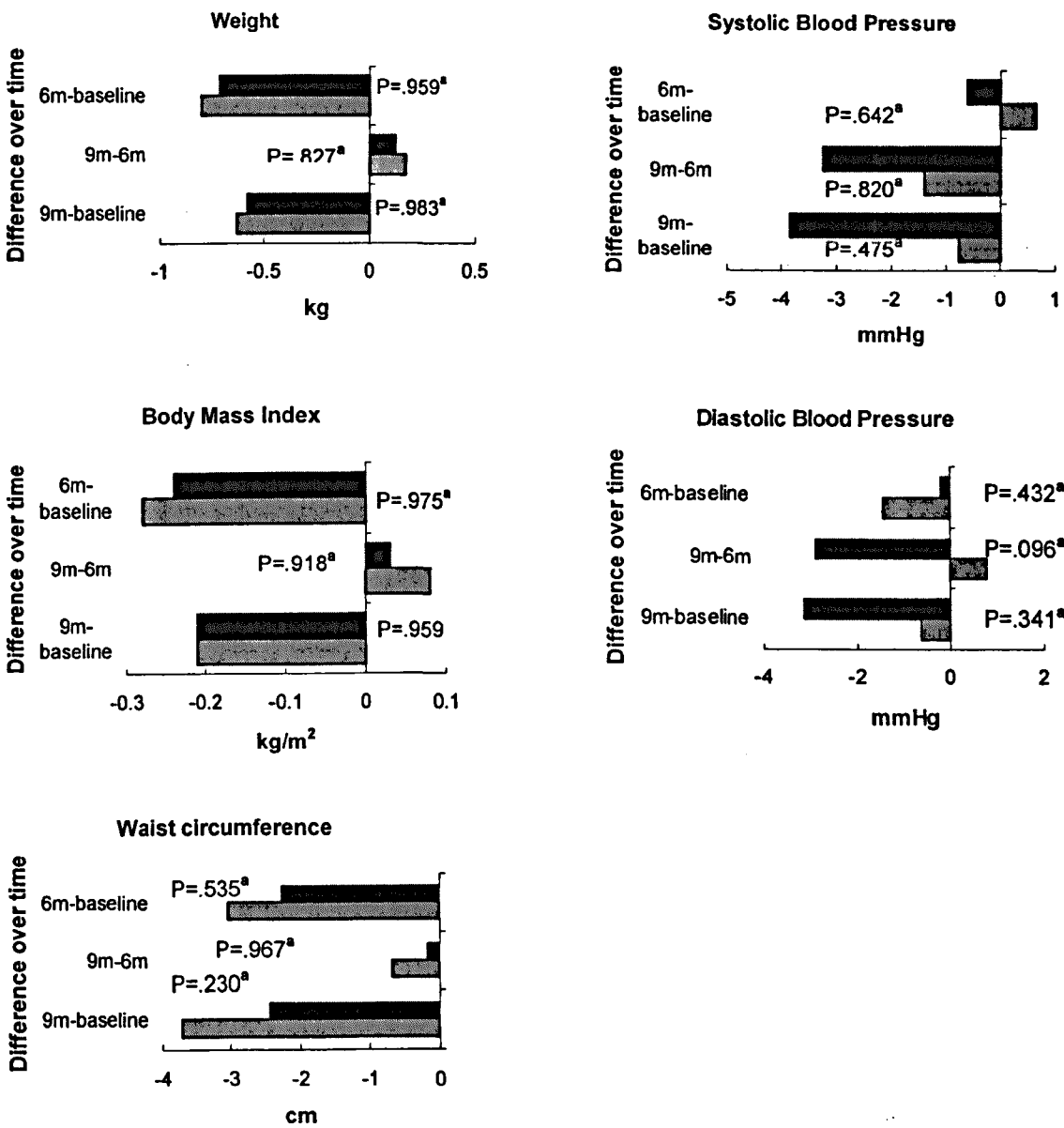
^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

5.3.2. Between group differences over time

5.3.2.1. Anthropometric and blood pressure measurements

The between group differences in changes in mean anthropometric and blood pressure measurements over the 9-month trial are illustrated in Figure 5.7, for participants completing all three assessments (baseline, 6 and 9 months). There were no statistically significant differences between the groups at any time point.

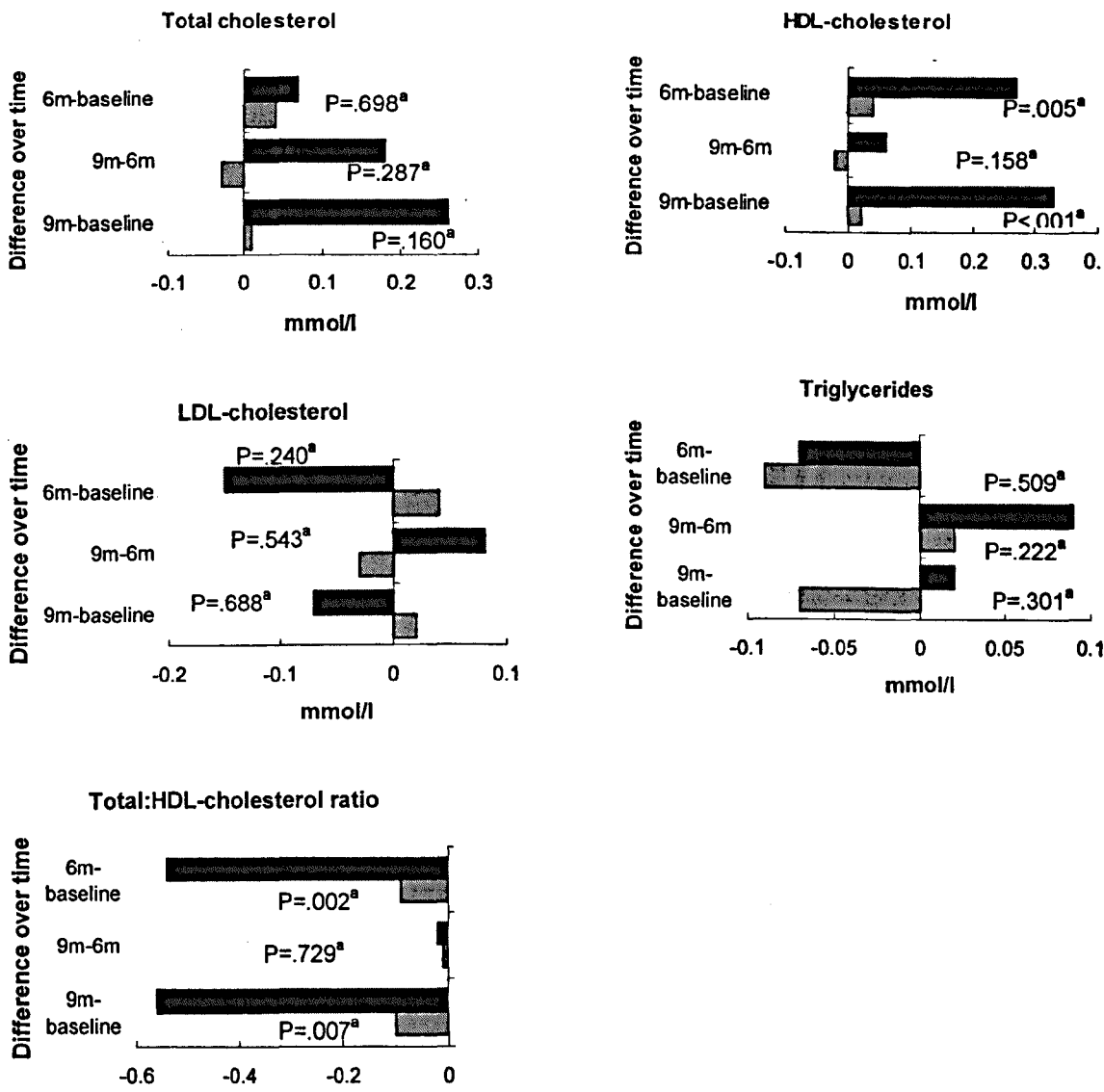
Figure 5.7 Between group comparison of changes over time in mean anthropometric and blood pressure measurements, based on participants in the intervention (■, *n* 36) and control (□, *n* 15) groups completing the baseline, 6-month and 9-month assessments (P values)



5.3.2.2. Blood lipids

Figure 5.8 illustrates the between group differences in changes in mean fasting blood lipid levels over the 9-month trial for these participants. At the end of the 6-month intervention, participants in the intervention group had shown a significantly higher increase in HDL-cholesterol levels (0.27 v. 0.04 mmol/l; $P=.005$), as well as a greater decrease in the total:HDL-cholesterol ratio (-0.54 v. -0.09; $P=.002$) compared with baseline than participants in the control group. In addition, there was a greater increase in HDL-cholesterol levels (0.33 v. 0.02 mmol/l; $P<.001$) and a greater decrease in the total:HDL-cholesterol ratio (-0.56 v. -0.10; $P=.006$) in the intervention compared with the control group between baseline and 9 months.

Figure 5.8 Between group comparison of changes over time in mean fasting plasma blood lipid levels, based on participants in the intervention (■, n 29) and control (□, n 12) groups completing the baseline, 6-month and 9-month assessments (P values)

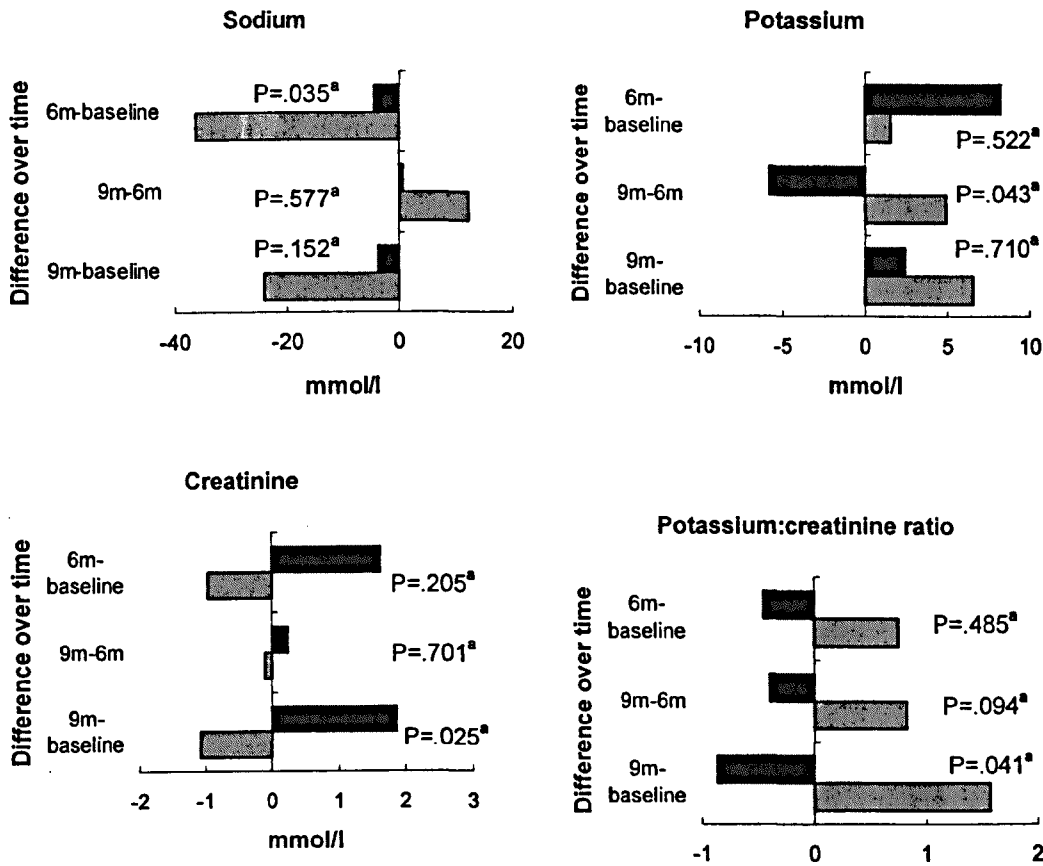


^a Levels of significance were assessed with the use of the Mann-Whitney U Test

5.3.2.3. *Urinary electrolytes*

The between group differences in changes in mean urinary electrolyte levels over the 9-month trial, for participants completing all three assessments (baseline, 6 and 9 months) are illustrated in Figure 5.9. At the end of the 6-month intervention, participants in the control group had shown a significantly greater decrease in urinary sodium levels (-4.7 v. -36.3 mmol/l; $P=.035$) compared with baseline than participants in the intervention group. Between the end of the 6-month intervention and the 3-month follow-up, favourable increases in urinary potassium (-5.8 v. 4.9 mmol/l; $P=.043$) were also observed among participants in the control compared with the intervention group. In addition, there was a decrease in urinary creatinine levels (1.9 v. -1.1 mmol/l; $P=.025$) and an increase in the potassium:creatinine ratio (-0.9 v. 1.6; $P=.041$) in the control compared with the intervention group between baseline and 9 months.

Figure 5.9 Between group comparison of changes over time in mean fasting urinary electrolyte levels, based on participants in the intervention (■, n 33) and control (▨, n 14) groups completing the baseline, 6-month and 9-month assessments (P values)



^a Levels of significance were assessed with the use of the Mann-Whitney U Test

Section C: Analysis on an intention-to-treat basis

5.4. Intention-to-treat analysis: Participants completing baseline, 6-month and 9-month assessments

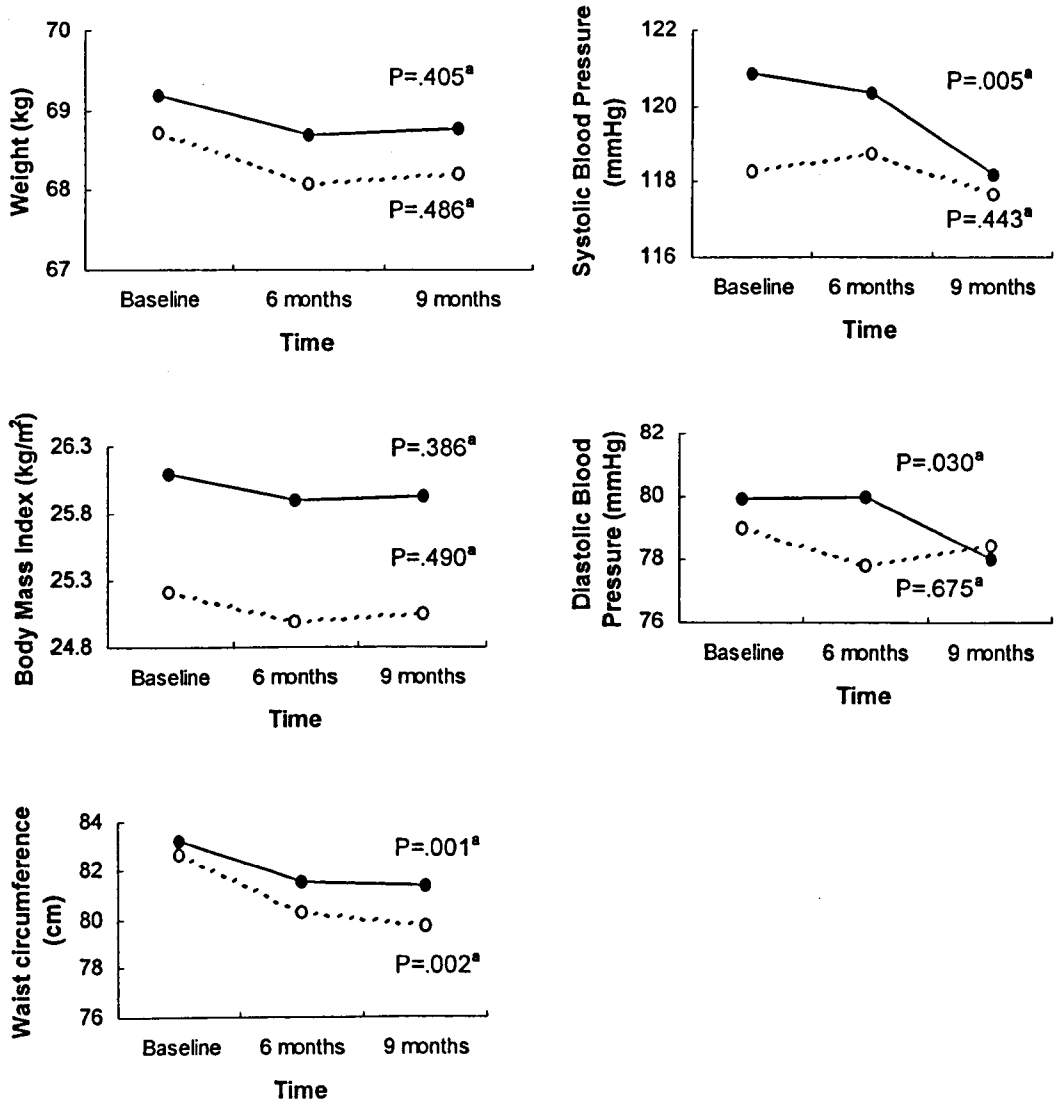
Intention-to-treat analyses were performed using the last available recorded value for participants of both groups who withdrew from the study at some stage before the end of the 3-month follow up. In this respect, analyses were performed for fifty-three and nineteen participants in the intervention and control group, respectively, who provided baseline anthropometric, blood pressure and urinary electrolyte measurements, as well as for forty-six and sixteen participants in the respective groups who provided fasting blood lipid measurements at baseline.

5.4.1. Within group comparisons

5.4.1.1. *Anthropometric and blood pressure measurements*

Mean anthropometric and blood pressure measurements at baseline, 6 and 9 months are illustrated in Figure 5.10. The intention-to-treat analysis showed that at 6 months, participants in the intervention and control groups significantly decreased their waist circumference compared with baseline (83.2 v. 81.5 cm; $P=.001$ and 82.6 v. 80.3 cm; $P=.041$, respectively). Between the end of the 6-month intervention and the 3-month follow-up participants in the intervention group also showed significant decreases in systolic (120.3 v. 118.1 mmHg; $P=.006$) and diastolic (79.9 v. 78.0 mmHg; $P=.012$) blood pressure. Overall, participants in both groups maintained lower waist circumference at 9 months compared with baseline (83.2 v. 81.3 cm; $P=.001$ for the intervention group and 82.6 v. 79.7 cm; $P=.002$ for the control group). In addition, participants in the intervention group displayed significantly lower systolic (120.9 v. 118.1 mmHg; $P=.005$) and diastolic (79.9 v. 78.0 mmHg; $P=.030$) blood pressure at 9 months compared with baseline.

Figure 5.10 Mean anthropometric and blood pressure measurements, based on intention-to-treat analyses for participants in the intervention (—•—, $n = 53$) and control (—○—, $n = 19$) groups (P values for comparison between baseline and 9-month assessments)

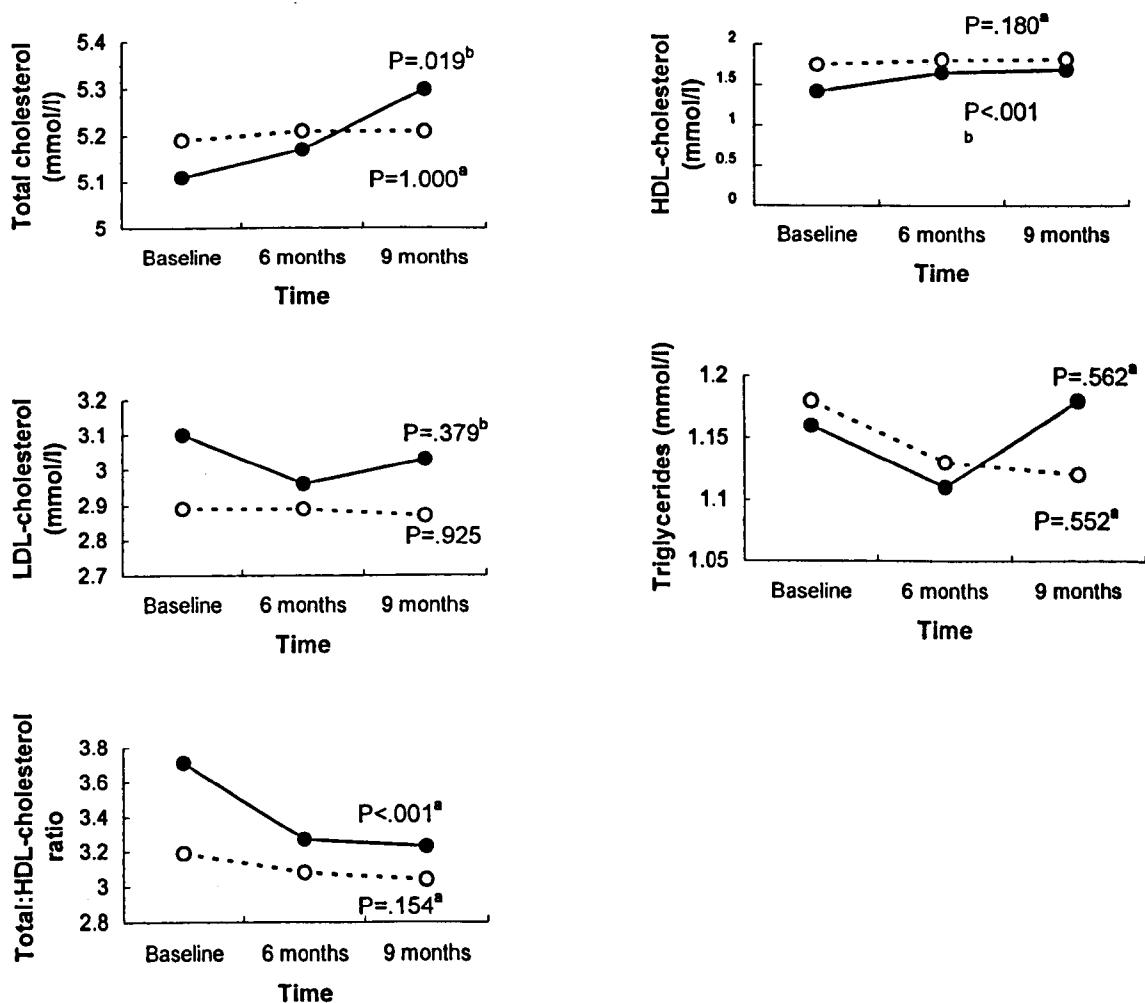


^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

5.4.1.2. Blood lipids

Figure 5.11 illustrates the intention-to-treat comparisons of mean fasting plasma lipid levels at baseline, 6 and 9 months. At 6 months, participants in the intervention group displayed significantly higher HDL-cholesterol levels (1.42 v. 1.65 mmol/l; $P<.001$), as well as a lower total:HDL-cholesterol ratio (3.71 v. 3.27; $P<.001$), compared with baseline. Despite levels of total cholesterol in the intervention group increasing between the end of the 6-month intervention and the 3-month follow-up (5.17 v. 5.30 mmol/l; $P=.018$), levels of HDL-cholesterol further increased (1.65 v. 1.69 mmol/l; $P=.053$) between these time points. Overall, although total cholesterol levels in the intervention group increased (5.11 v. 5.30 mmol/l; $P=.019$), participants in this group displayed higher HDL-cholesterol levels (1.42 v. 1.69 mmol/l; $P<.001$) and a lower total:HDL-cholesterol ratio (3.71 v. 3.23; $P<.001$) at 9 months compared with baseline. No significant differences in mean plasma lipid levels were observed among participants in the control group at any time points.

Figure 5.11 Mean fasting plasma blood lipids, based on intention-to-treat analyses for participants in the intervention (—●—, n 46) and control (---○---, n 16) groups (P values for comparison between baseline and 9-month assessments)



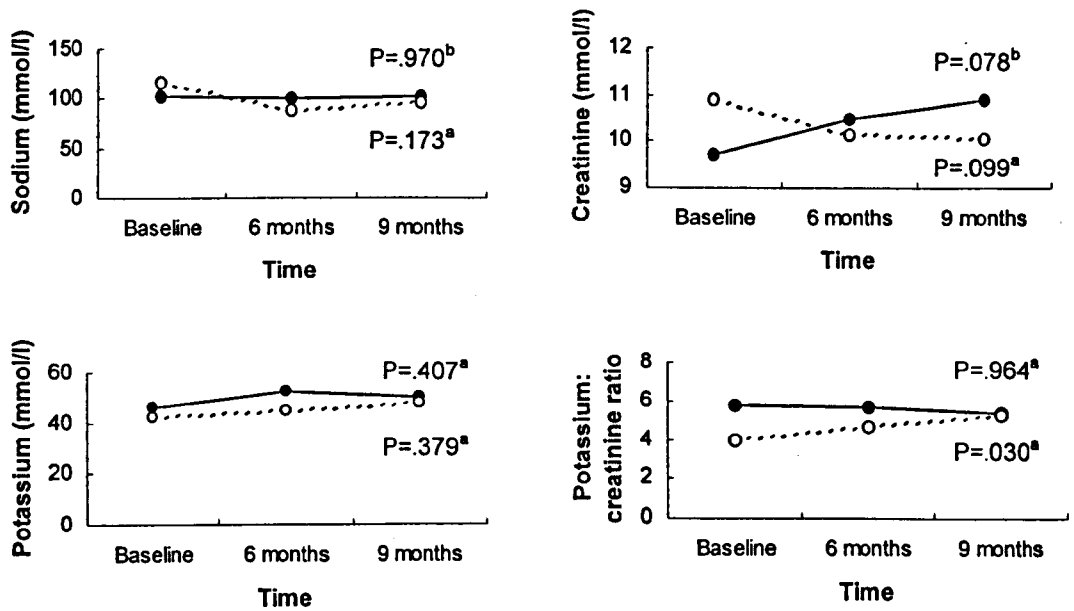
^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

5.4.1.3. Urinary electrolytes

Mean urinary electrolyte levels at baseline, 6 and 9 months are illustrated in Figure 5.12. The intention-to-treat analysis showed that at the end of the 6-month intervention, mean urinary sodium in the control group had significantly decreased compared with baseline (115.8 v. 88.3 mmol/l; $P=.007$). However, there was no significant difference in urinary sodium levels at 9 months compared with baseline for this group. Participants in the control group also displayed a higher urinary potassium:creatinine ratio at the end of the 3-month follow-up compared with baseline (3.9 v. 5.2; $P=.030$).

Figure 5.12 Mean fasting urinary electrolytes, based on intention-to-treat analyses for participants in the intervention (—●—, n 53) and control (—○—, n 19) groups (P values for comparison between baseline and 9-month assessments)



^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

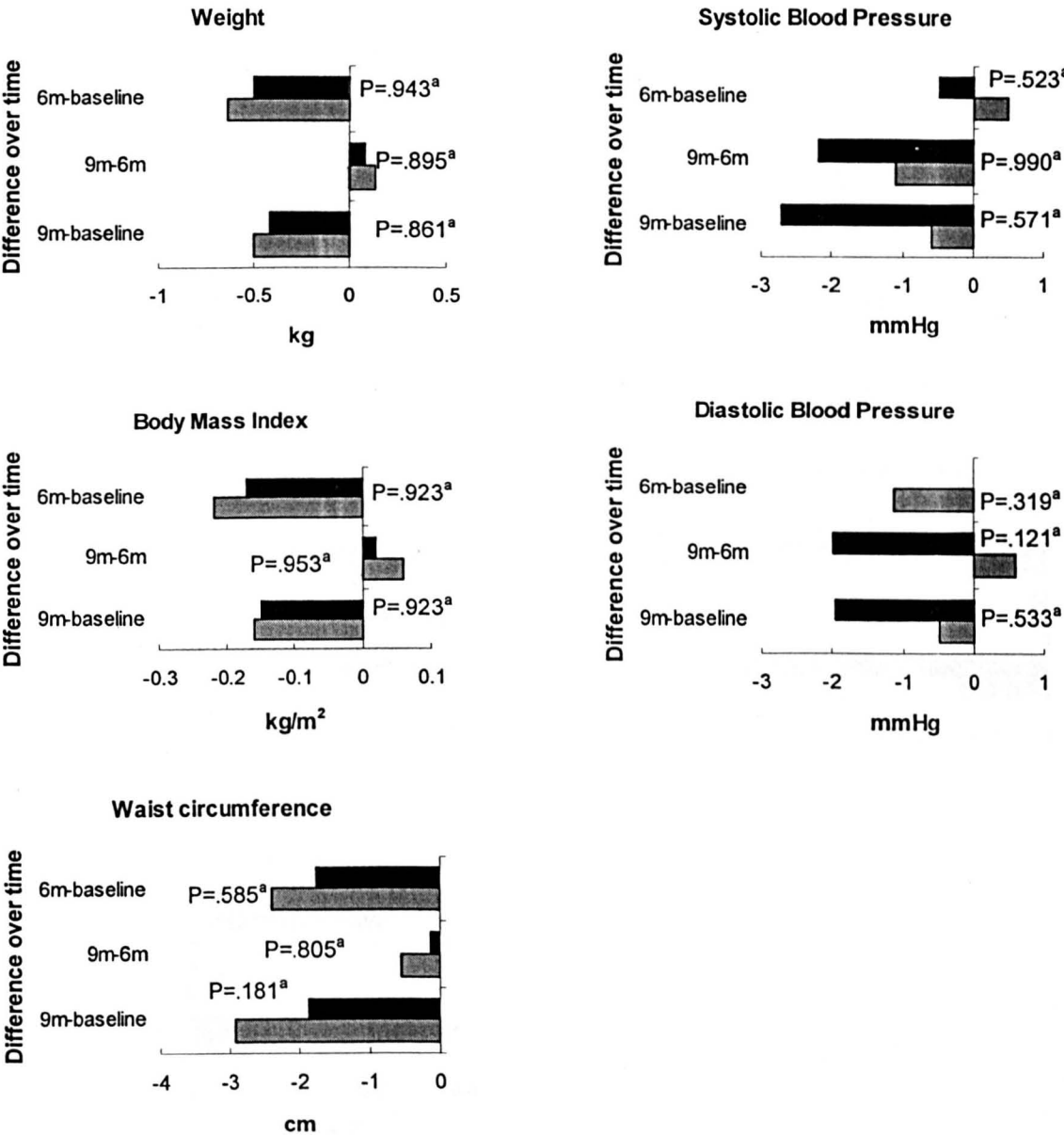
^b Levels of significance were assessed with the use of the Paired-Samples T Test

5.4.2. Between group differences over time

5.4.2.1. Anthropometric and blood pressure measurements

The between group differences in changes in mean anthropometric and blood pressure measurements over the 9-month trial are illustrated in Figure 5.13. On an intention-to-treat basis, there were no statistically significant differences between the groups in any of the variables at any time point.

Figure 5.13 Between group comparison of changes over time in mean anthropometric and blood pressure measurements, based on intention-to-treat analyses for participants in the intervention (■, *n* 53) and control (▨, *n* 19) groups (P values)

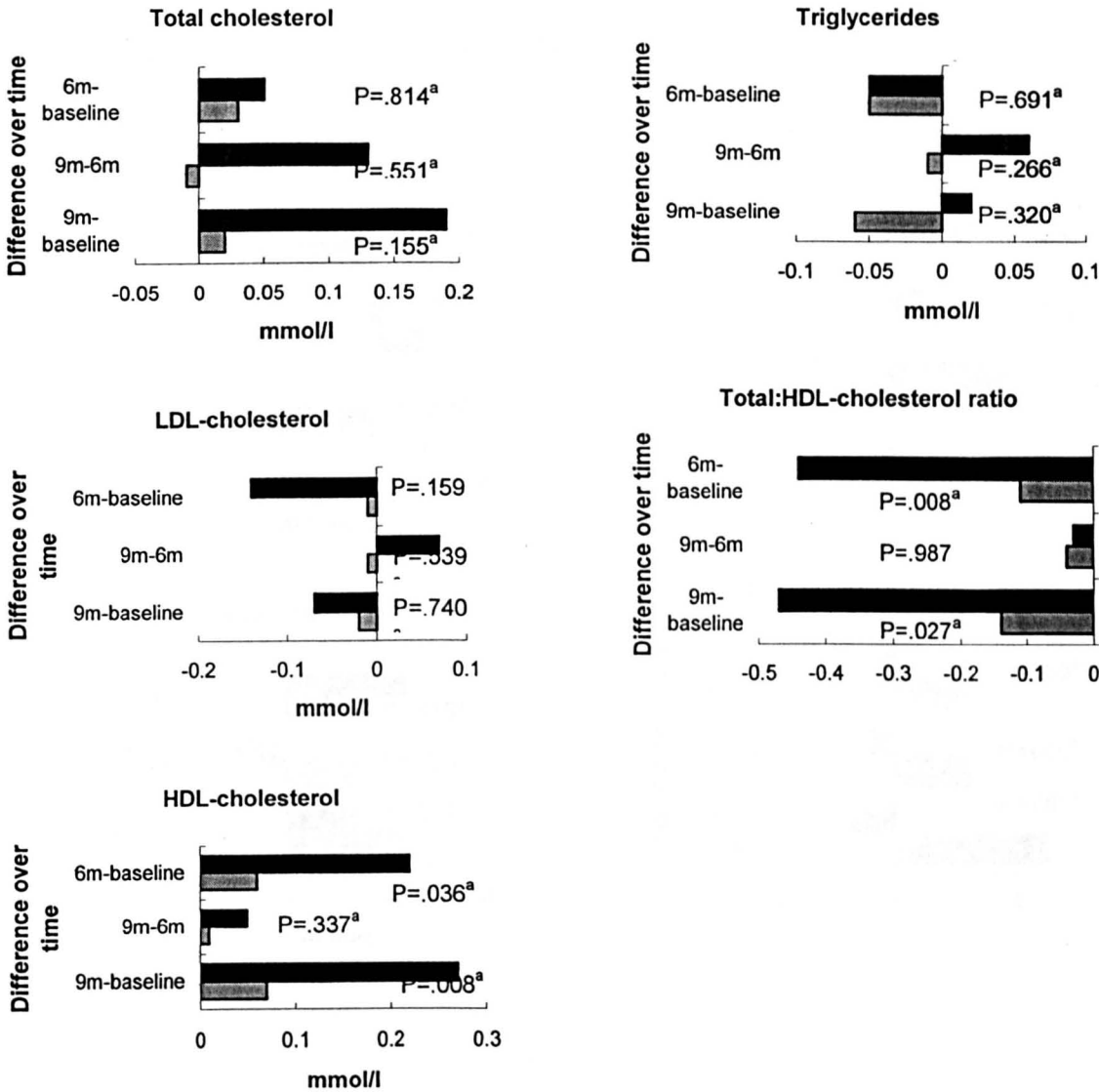


^a Levels of significance were assessed with the use of the Mann-Whitney U Test

5.4.2.2. Blood lipids

Figure 5.14 illustrates the between group differences in changes in mean fasting blood lipid levels over the 9-month trial. At the end of the 6-month intervention, participants in the intervention group had shown a significantly higher increase in HDL-cholesterol levels (0.22 v. 0.06 mmol/l; $P=.036$), as well as a greater decrease in the total:HDL-cholesterol ratio (-0.44 v. -0.11; $P=.008$) compared with baseline, than participants in the control group. In addition, there was a greater increase in HDL-cholesterol levels (0.27 v. 0.07 mmol/l; $P=.008$) and a greater decrease in the total:HDL-cholesterol ratio (-0.47 v. -0.14; $P=.027$) in the intervention compared with the control group between baseline and 9 months.

Figure 5.14 Between group comparison of changes over time in mean fasting plasma blood lipid levels, based on intention-to-treat analyses for participants in the intervention (■, $n = 46$) and control (▨, $n = 16$) groups (P values)

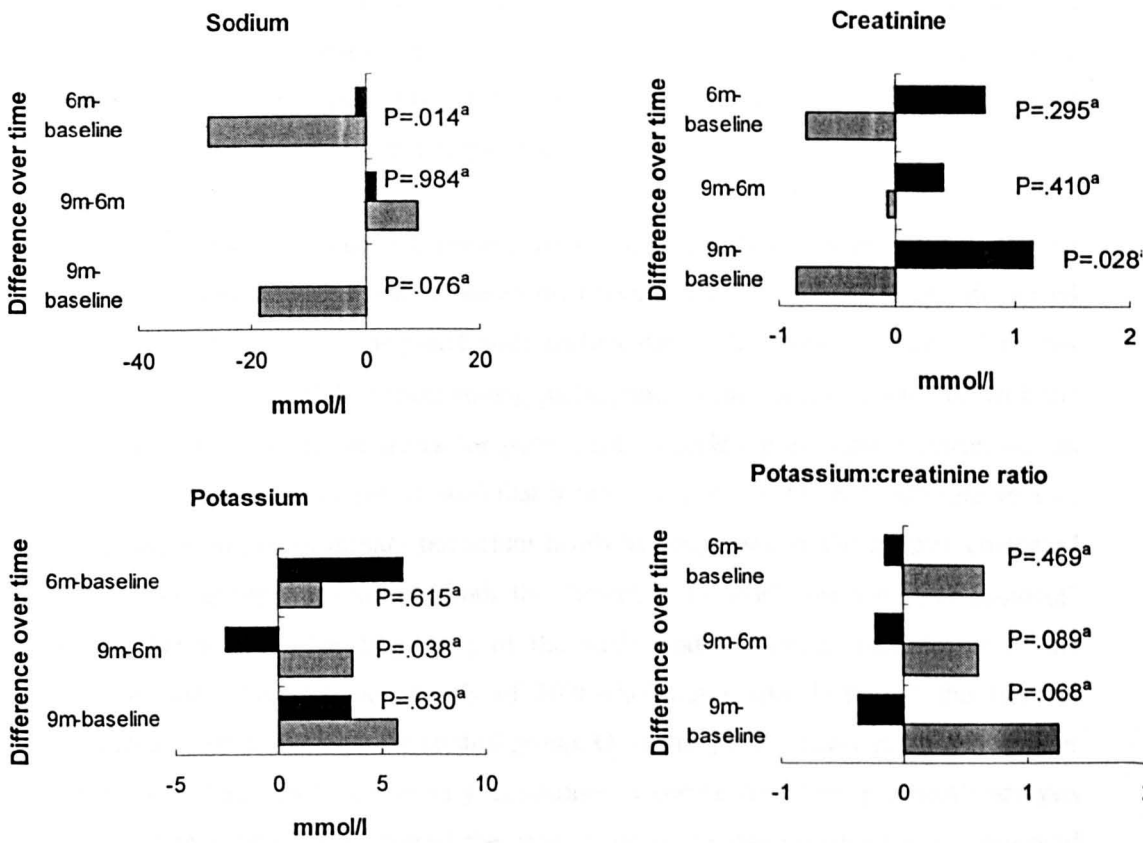


^a Levels of significance were assessed with the use of the Mann-Whitney U Test

5.4.2.3. *Urinary electrolytes*

The intention-to-treat analyses on between group differences in changes in mean urinary electrolyte levels over the 9-month trial are illustrated in Figure 5.15. At the end of the 6-month intervention, participants in the control group had shown a significantly greater decrease in urinary sodium levels (-1.7 v. -27.5 mmol/l; $P=.014$) compared with baseline, than participants in the intervention group. Between the end of the 6-month intervention and the 3-month follow-up, a favourable increase in urinary potassium levels (-2.6 v. 3.6 mmol/l; $P=.038$) was also observed among participants in the control compared with the intervention group. There was also a decrease in urinary creatinine levels (1.2 v. -0.8 mmol/l; $P=.028$) in the control compared with the intervention group between baseline and 9 months.

Figure 5.15 Between group comparison of changes over time in mean fasting urinary electrolyte levels, based on intention-to-treat analyses for participants in the intervention (■, n 53) and control (■, n 19) groups (P values)



5.5. Summary

Results based on the “intention-to-treat” analyses generally agreed with results from the “per protocol” analyses. Both analyses showed that at 6 months, participants in the intervention group had decreased their waist circumference and their ratio of total:HDL-cholesterol, and had increased their HDL-cholesterol levels, compared with baseline. Between the end of the 6-month intervention and the 3-month follow-up, systolic and diastolic blood pressure had decreased and total cholesterol levels had increased, while the “intention-to-treat” analyses additionally showed an increase in HDL-cholesterol levels among this group over this time period. All analyses showed that at 9 months, participants in the intervention group had lower waist circumference, systolic and diastolic blood pressure and ratio of total:HDL-cholesterol, as well as higher total cholesterol and HDL-cholesterol levels, compared with baseline.

All analyses showed that at 6 months, participants in the control group had lower waist circumference and lower urinary sodium levels, compared with baseline. “Per protocol” analyses for participants completing all three assessments, as well as the “intention-to-treat” analyses showed that at 9 months, participants in this group had decreased their waist circumference and increased their ratio of urinary potassium:creatinine, compared with baseline.

All analyses on the between group differences over the 6-month intervention showed that participants in the intervention group had increased their levels of HDL-cholesterol and decreased the ratio of total:HDL-cholesterol, compared with participants in the control group. Over this period, urinary sodium levels had decreased among participants in the control, compared with the intervention, group. “Per protocol” analyses for participants completing all three assessments, as well as the “intention-to-treat” analyses showed that between the end of the 6-month intervention and the 3-month follow-up, mean urinary potassium levels had increased in the control, compared with the intervention, group. In addition, both the “intention-to-treat” and the “per protocol” analyses showed that between the beginning of the study and 9 months, participants in the intervention group had increased their levels of HDL-cholesterol and decreased the ratio of total:HDL-cholesterol, compared with the control group. Over this period, participants in the latter group had decreased their levels of urinary creatinine, whereas the “per protocol” analysis additionally showed that they had increased the ratio of urinary potassium:creatinine, compared with participants in the intervention group.

6 Results: Nutrition Knowledge, Stages of Dietary Behaviour Change and Psychosocial Determinants of Dietary Behaviour

6.1. Overview

During the three assessment time points (baseline, 6 months and 9 months), Food and Eating questionnaires were completed by fifty-three, forty-two and thirty-five participants in the intervention group and nineteen, fourteen and twelve participants in the control group, in order to assess nutrition knowledge, stages of dietary behaviour change and psychosocial determinants of dietary behaviour. Baseline socio-demographic characteristics of participants in both groups were described in detail in the Methodology and Sample Characteristics chapter (see Chapter 3, Section 3.10.1.).

For ease of presentation, results on nutrition knowledge, stages of dietary behaviour change and psychosocial determinants of dietary behaviour will be presented in two sections:

Section A: Analysis for participants completing baseline and 6-month assessments

Section B: Analysis for participants completing baseline, 6-month and 9-month assessments

Section A: Analysis for participants completing baseline and 6-month assessments

6.2. Participants completing baseline and 6-month assessments

Forty-two participants in the intervention group and fourteen participants in the control group provided Food and Eating questionnaires at both baseline and 6 months, in order to assess nutrition knowledge, stages of dietary behaviour change and psychosocial determinants of dietary behaviour.

6.2.1. Within group comparisons

6.2.1.1. *Nutrition knowledge*

Mean total nutrition knowledge scores, as well as mean sub-section scores, at baseline and 6 months are presented in Table 6.1 for both groups. Participants in the control group did not show any significant differences in total or sub-section knowledge scores at the end of the 6-month intervention compared with baseline. In contrast, participants in the intervention group significantly increased their total knowledge score, as well as their score for knowledge of dietary recommendations and knowledge of sources of nutrients at 6 months, compared with baseline.

Table 6.1 Comparison of total and sub-section nutrition knowledge scores, based on participants in both groups completing the baseline and 6-month assessments (mean values, standard deviations and P values)

	Intervention group (n 42)						Control group (n 14)				
	Baseline			6 months			Baseline		6 months		P
	Maximum score	Mean	SD	Mean	SD	P	Mean	SD	Mean	SD	
Nutrition knowledge score											
Total score	110	83.7	11.0	87.2	10.4	<.001 ^a	83.3	9.7	85.7	9.8	.168 ^b
Section 1/ Dietary recommendations	11	9.3	1.1	9.8	0.8	.009 ^b	9.5	0.6	9.8	0.6	.194 ^b
Section 2/ Sources of nutrients	69	54.9	8.3	57.6	7.4	.002 ^b	55.1	6.2	57.1	5.8	.123 ^b
Section 3/ Choosing everyday foods	10	8.7	1.3	8.8	1.2	.160 ^a	8.6	1.3	8.5	1.0	.655 ^b
Section 4/ Diet-disease relationships	20	10.7	2.8	10.9	2.9	.487 ^a	10.1	2.9	10.3	4.2	.858 ^b

^a Levels of significance were assessed with the use of the Paired-Samples T Test

^b Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

6.2.1.2. Stages of dietary behaviour change

At the end of the 6-month intervention, a significantly higher proportion of participants in the intervention group were in the maintenance and action stage of behaviour change regarding vegetable ($P=.050$), legume ($P<.001$) and olive oil/ MUFA:SFA ratio ($P<.001$) consumption compared with baseline, as presented in Table 6.2. In addition, more participants in the control group were in the maintenance, action and preparation stage of change regarding legume consumption at 6 months compared with baseline ($P=.005$).

Table 6.2 Comparison of stages of change regarding the four Mediterranean goals at baseline and 6 months, based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Food component	Intervention group (n 42)			Control group (n 14)		
	Baseline	6 months	P	Baseline	6 months	P
Vegetables						
Maintenance	7 (16.7)	10 (23.8)	.050 ^a	2 (14.3)	2 (14.3)	.705 ^a
Action	20 (47.6)	27 (64.3)		7 (50.0)	8 (57.1)	
Preparation	7 (16.7)	1 (2.4)		2 (14.3)	-	
Contemplation	3 (7.1)	1 (2.4)		1 (7.1)	-	
Precontemplation	5 (11.9)	3 (7.1)		2 (14.3)	4 (28.6)	
Fruits, nuts and seeds						
Maintenance	14 (33.3)	13 (31.0)	.074 ^a	7 (50.0)	5 (35.7)	1.000 ^a
Action	18 (42.9)	28 (66.7)		4 (28.6)	6 (42.9)	
Preparation	6 (14.3)	-		1 (7.1)	-	
Contemplation	1 (2.4)	1 (2.4)		-	1 (7.1)	
Precontemplation	3 (7.1)	-		2 (14.3)	2 (14.3)	
Legumes						
Maintenance	1 (2.4)	8 (19.0)	<.001 ^a	1 (7.1)	4 (28.6)	.005 ^a
Action	2 (4.8)	28 (66.7)		2 (14.3)	4 (28.6)	
Preparation	8 (19.0)	-		1 (7.1)	2 (14.3)	
Contemplation	9 (21.4)	5 (11.9)		5 (35.7)	-	
Precontemplation	22 (22.4)	1 (2.4)		5 (35.7)	4 (28.6)	

Table 6.2 cont.: Comparison of stages of change regarding the four Mediterranean goals at baseline and 6 months, based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Food component	Intervention group (n 42)			Control group (n 14)		
	Baseline	6 months	P	Baseline	6 months	P
Olive oil/ MUFA:SFA ratio	3 (7.1)	9 (21.4)	<.001 ^a	5 (35.7)	2 (14.3)	.480 ^a
Maintenance	3 (7.1)	23 (54.8)		2 (14.3)	3 (21.4)	
Action	7 (16.7)	-		2 (14.3)	1 (7.1)	
Preparation	10 (23.8)	4 (9.5)		-	-	
Contemplation	19 (45.2)	6 (14.3)		5 (35.7)	8 (57.1)	
Precontemplation						

^aLevels of significance were assessed with the use of the Friedman Test

6.2.1.3. Psychosocial determinants of dietary behaviour

6.2.1.3.1. Importance and attitudes

The comparisons of importance of, and attitudes towards eating vegetables, fruits and legumes and using olive oil instead of other fats and oils at baseline and 6 months are presented in Table 6.3 and Table 6.4 for participants in both groups. At the end of the 6-month intervention, a significantly higher proportion of participants in the intervention group reported that eating vegetables was very important to them and that their attitude towards using olive oil was very favourable.

Table 6.3 Comparison of importance of eating vegetables/fruit/legumes and using olive oil instead of other fats/oils at baseline and 6 months, based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Importance	Intervention group (n 42)			Control group (n 14)		
	Baseline	6 months	P	Baseline	6 months	P
Vegetables						
Very important	31 (73.8)	38 (90.5)	.020 ^a	11 (78.6)	11 (78.6)	.157 ^a
Neutral	10 (23.8)	4 (9.5)		1 (7.1)	3 (21.4)	
Not important	1 (2.4)	-		2 (14.3)	-	
Fruits, nuts and seeds						
Very important	34 (81.0)	34 (81.0)	1.000 ^a	10 (71.4)	11 (78.6)	1.000 ^a
Neutral	8 (19.0)	7 (16.7)		2 (14.3)	2 (14.3)	
Not important	-	1 (2.4)		2 (14.3)	1 (7.1)	
Legumes						
Very important	19 (45.2)	26 (61.9)	.225 ^a	6 (42.9)	5 (35.7)	.705 ^a
Neutral	19 (45.2)	13 (31.0)		6 (42.9)	6 (42.9)	
Not important	4 (9.5)	3 (7.1)		2 (14.3)	3 (21.4)	
Olive oil						
Very important	19 (45.2)	23 (54.8)	.275 ^a	8 (57.1)	6 (42.9)	.655 ^a
Neutral	19 (45.2)	16 (38.1)		2 (14.3)	4 (28.6)	
Not important	4 (9.5)	3 (7.1)		4 (28.6)	4 (28.6)	

^a Levels of significance were assessed with the use of the Friedman Test

Table 6.4 Comparison of attitudes towards eating vegetables/fruit/legumes and using olive oil instead of other fats/oils at baseline and 6 months, based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Attitudes	Intervention group (n 42)			Control group (n 14)		
	Baseline	6 months	P	Baseline	6 months	P
Vegetables						
Very favourable	40 (95.2)	40 (95.2)	.564 ^a	14 (100.0)	14 (100.0)	1.000 ^a
Neutral	1 (2.4)	1 (2.4)		-	-	
Not favourable	1 (2.4)	1 (2.4)		-	-	
Fruits, nuts and seeds						
Very favourable	41 (97.6)	41 (97.6)	1.000 ^a	14 (100.0)	14 (100.0)	1.000 ^a
Neutral	1 (2.4)	-		-	-	
Not favourable	-	1 (2.4)		-	-	
Legumes						
Very favourable	31 (73.8)	33 (78.6)	.405 ^a	8 (57.1)	10 (71.4)	1.000 ^a
Neutral	7 (16.7)	7 (16.7)		6 (42.9)	2 (14.3)	
Not favourable	4 (9.5)	2 (4.8)		-	2 (14.3)	
Olive oil						
Very favourable	33 (78.6)	39 (92.9)	.020 ^a	11 (78.6)	11 (78.6)	1.000 ^a
Neutral	7 (16.7)	1 (2.4)		2 (14.3)	2 (14.3)	
Not favourable	2 (4.8)	2 (4.8)		1 (7.1)	1 (7.1)	

^a Levels of significance were assessed with the use of the Friedman Test

6.2.1.3.2. Self-efficacy skills

Table 6.5 presents participants' confidence of consuming vegetables, fruits and legumes under challenging situations at baseline and 6 months. At the end of the 6-month intervention, a significantly higher proportion of participants in the intervention group reported they were very confident of eating vegetables and fruit when eating out, whereas their confidence to consume legumes had increased for both when eating out and when snacking, compared with baseline. In contrast, a significantly lower proportion of participants in the control group reported they felt confident of eating fruit when they were eating alone at 6 months compared with baseline.

Table 6.5 Comparison of confidence of "eating vegetables/fruit/legumes in the following situations" at baseline and 6 months, based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Vegetables	Intervention group (n 42)			Control group (n 14)		
	Baseline	6 months	P	Baseline	6 months	P
Eating out						
Very confident	12 (28.5)	24 (57.1)	.001 ^a	4 (28.6)	5 (35.7)	.739 ^a
Neutral	14 (33.3)	9 (21.4)		5 (35.7)	3 (21.4)	
Not confident	16 (38.1)	9 (21.4)		5 (35.7)	6 (42.8)	
As a snack						
Very confident	26 (61.9)	27 (64.3)	1.000 ^a	6 (42.8)	5 (35.7)	.317 ^a
Neutral	8 (19.0)	7 (16.7)		1 (7.1)	5 (35.7)	
Not confident	8 (19.0)	8 (19.0)		7 (50.0)	4 (28.6)	
When in a hurry						
Very confident	15 (35.7)	15 (35.7)	.705 ^a	4 (28.6)	5 (35.7)	.317 ^a
Neutral	13 (31.0)	14 (33.3)		2 (14.3)	5 (35.7)	
Not confident	14 (33.3)	13 (31.0)		8 (57.1)	4 (28.6)	
Eating alone						
Very confident	34 (81.0)	34 (81.0)	1.000 ^a	10 (71.4)	9 (64.3)	.705 ^a
Neutral	6 (14.3)	6 (14.3)		2 (14.3)	2 (14.3)	
Not confident	2 (4.8)	2 (4.8)		2 (14.3)	3 (21.4)	

Table 6.5 cont.: Comparison of confidence of “eating vegetables/fruit/legumes in the following situations” at baseline and 6 months, based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Fruit	Intervention group (n 42)			Control group (n 14)		
	Baseline	6 months	P	Baseline	6 months	P
Eating out						
Very confident	14 (33.3)	23 (54.8)	.001 ^a	8 (57.1)	5 (35.7)	1.000 ^a
Neutral	12 (28.6)	10 (23.8)		2 (14.3)	5 (35.7)	
Not confident	16 (38.1)	9 (21.4)		4 (28.6)	4 (28.6)	
As a snack						
Very confident	36 (85.7)	37 (88.1)	1.000 ^a	14 (100.0)	11 (78.6)	.102 ^a
Neutral	6 (14.3)	3 (7.1)		-	1 (7.1)	
Not confident	-	2 (4.8)		-	2 (14.3)	
When in a hurry						
Very confident	30 (71.4)	33 (78.5)	.371 ^a	11 (78.6)	10 (71.4)	.414 ^a
Neutral	8 (19.0)	4 (9.5)		2 (14.3)	3 (21.4)	
Not confident	4 (9.6)	5 (11.9)		1 (7.1)	1 (7.1)	
Eating alone						
Very confident	36 (85.7)	34 (80.9)	.317 ^a	13 (92.9)	9 (64.3)	.008 ^a
Neutral	4 (9.5)	6 (14.3)		1 (7.1)	3 (21.4)	
Not confident	2 (4.8)	2 (4.8)		-	2 (14.3)	
Legumes	Intervention group (n 42)			Control group (n 14)		
	Baseline	6 months	P	Baseline	6 months	P
Eating out						
Very confident	7 (16.7)	11 (26.2)	.002 ^a	3 (21.4)	2 (14.3)	.180 ^a
Neutral	7 (16.7)	12 (28.6)		4 (28.6)	1 (7.1)	
Not confident	24 (66.7)	19 (45.3)		7 (50.0)	11 (78.6)	
As a snack						
Very confident	5 (11.9)	13 (31.0)	.034 ^a	2 (14.3)	1 (7.1)	.083 ^a
Neutral	12 (28.6)	13 (31.0)		3 (21.4)	1 (7.1)	
Not confident	25 (59.6)	16 (38.0)		9 (64.3)	12 (85.7)	
When in a hurry						
Very confident	5 (11.9)	8 (19.1)	.157 ^a	2 (14.3)	2 (14.3)	.414 ^a
Neutral	10 (23.8)	13 (31.0)		2 (14.3)	1 (7.1)	
Not confident	27 (64.3)	21 (50.0)		10 (71.4)	11 (78.6)	
Eating alone						
Very confident	18 (42.9)	20 (47.6)	.086 ^a	4 (28.6)	6 (42.8)	.739 ^a
Neutral	10 (23.8)	13 (31.0)		5 (35.7)	4 (28.6)	
Not confident	14 (33.4)	9 (21.5)		5 (35.7)	4 (28.6)	

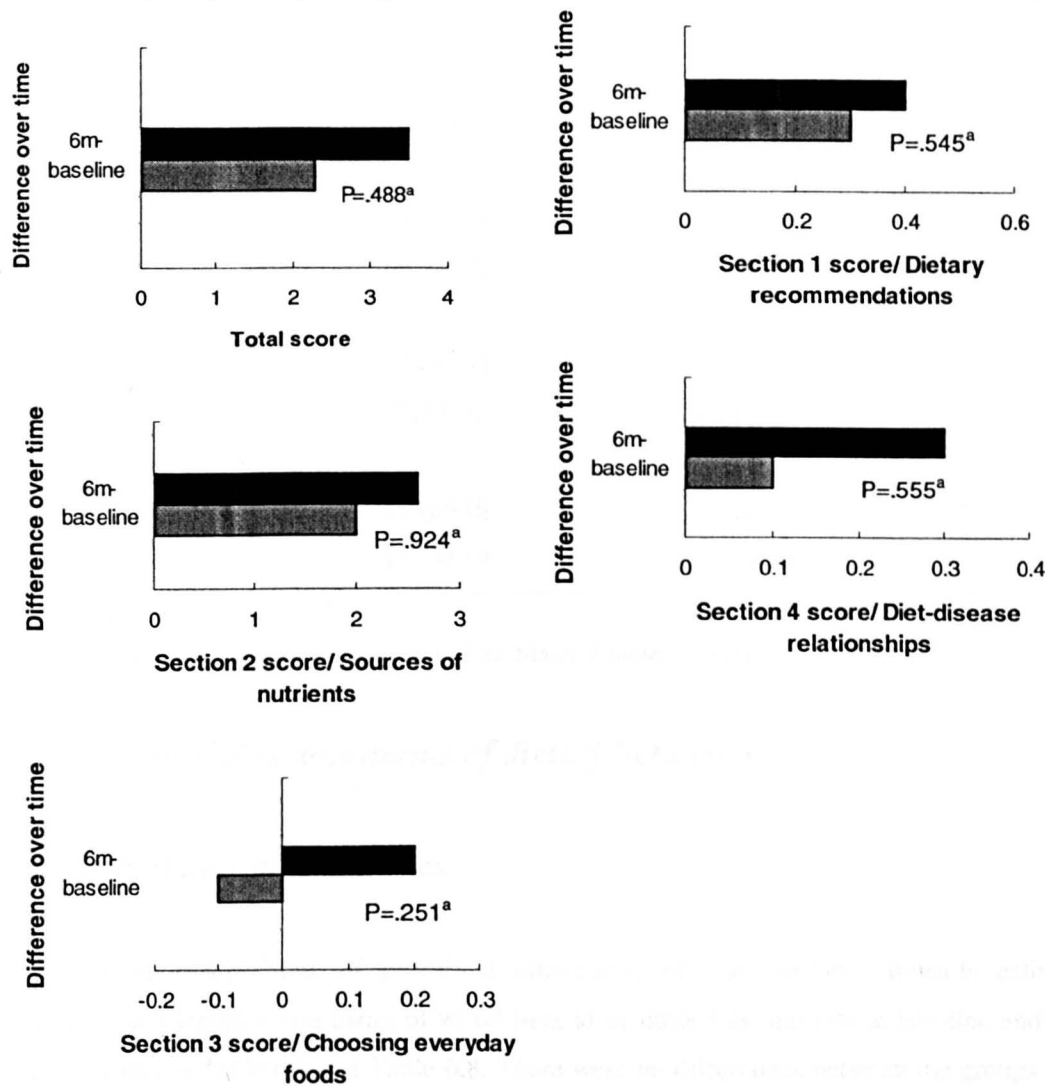
^aLevels of significance were assessed with the use of the Friedman Test

6.2.2. Between group comparisons

6.2.2.1. Nutrition knowledge

The between group differences in changes in mean total and sub-section nutrition knowledge scores over the 6-month intervention are illustrated in Figure 6.1, for participants completing both the baseline and 6-month assessments. There were no statistically significant differences between the groups by the end of the trial.

Figure 6.1 Between group comparison of changes over time in total and sub-section nutrition knowledge scores, based on participants in the intervention (■, *n* 42) and control (▨, *n* 14) groups completing the baseline and 6-month assessments (P values)



^a Levels of significance were assessed with the use of the Mann-Whitney Test

6.2.2.2. *Stages of dietary behaviour change*

The between group comparison of stages of behavioural transition from baseline to the end of the 6-month intervention is presented in Table 6.6. A significantly higher proportion of participants in the intervention compared with the control group achieved a forward stage of transition (FST) regarding legume and olive oil/ MUFA:SFA ratio consumption.

Table 6.6 Between group comparison of stages of behavioural transition regarding the four Mediterranean goals from baseline to 6 months, based on participants in both groups completing the baseline and 6-month assessments (*n*, % and *P* values)

Food component	Intervention group (<i>n</i> 42)	Control group (<i>n</i> 14)	<i>P</i>
Vegetables			
FST	15 (35.7)	4 (28.6)	.628 ^a
No FST	27 (64.3)	10 (71.4)	
Fruits, nuts and seeds			
FST	14 (33.3)	2 (14.3)	.176 ^a
No FST	28 (66.7)	12 (85.7)	
Legumes			
FST	37 (88.1)	8 (57.1)	.012 ^a
No FST	5 (11.9)	6 (42.9)	
Olive oil/ MUFA:SFA ratio			
FST	29 (69.0)	3 (21.4)	.002 ^a
No FST	13 (31.0)	11 (78.6)	

FST, Forward stage of transition.

^a Levels of significance were assessed with the use of the Mann-Whitney U Test

6.2.2.3. *Psychosocial determinants of dietary behaviour*

6.2.2.3.1. *Importance and attitudes*

The between group comparisons of perceived importance of, and attitudes towards eating vegetables, fruits and legumes and using olive oil instead of other fats and oils at baseline and 6 months are presented in Table 6.7 and Table 6.8. There were no differences between the groups at any time point.

Table 6.7 Between group comparison of importance of eating vegetables/fruit/legumes and using olive oil instead of other fats/oils, based on participants in both groups completing the baseline and 6-month assessments (*n*, % and *P* values)

Importance	Baseline			6 months		
	Intervention group (<i>n</i> 42)	Control group (<i>n</i> 14)	<i>P</i>	Intervention group (<i>n</i> 42)	Control group (<i>n</i> 14)	<i>P</i>
Vegetables						
Very important	31 (73.8)	11 (78.6)	.910 ^a	38 (90.5)	11 (78.6)	.248 ^a
Neutral	10 (23.8)	1 (7.1)		4 (9.5)	3 (21.4)	
Not important	1 (2.4)	2 (14.3)		-	-	
Fruits, nuts and seeds						
Very important	34 (81.0)	10 (71.4)	.340 ^a	34 (81.0)	11 (78.6)	.795 ^a
Neutral	8 (19.0)	2 (14.3)		7 (16.7)	2 (14.3)	
Not important	-	2 (14.3)		1 (2.4)	1 (7.1)	
Legumes						
Very important	19 (45.2)	6 (42.9)	.770 ^a	26 (61.9)	5 (35.7)	.063 ^a
Neutral	19 (45.2)	6 (42.9)		13 (31.0)	6 (42.9)	
Not important	4 (9.5)	2 (14.3)		3 (7.1)	3 (21.4)	
Olive oil						
Very important	19 (45.2)	8 (57.1)	.983 ^a	23 (54.8)	6 (42.9)	.201 ^a
Neutral	19 (45.2)	2 (14.3)		16 (38.1)	4 (28.6)	
Not important	4 (9.5)	4 (28.6)		3 (7.1)	4 (28.6)	

^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

Table 6.8 Between group comparison of attitudes towards eating vegetables/fruit/legumes and using olive oil instead of other fats/oils, based on participants in both groups completing the baseline and 6-month assessments (*n*, % and *P* values)

Attitudes	Baseline			6 months		
	Intervention group (<i>n</i> 42)	Control group (<i>n</i> 14)	<i>P</i>	Intervention group (<i>n</i> 42)	Control group (<i>n</i> 14)	<i>P</i>
Vegetables						
Very favourable	40 (95.2)	14 (100.0)	.410 ^a	40 (95.2)	14 (100.0)	.410 ^a
Neutral	1 (2.4)	-		1 (2.4)	-	
Not favourable	1 (2.4)	-		1 (2.4)	-	
Fruits, nuts and seeds						
Very favourable	41 (97.6)	14 (100.0)	.564 ^a	41 (97.6)	14 (100.0)	.564 ^a
Neutral	1 (2.4)	-		-	-	
Not favourable	-	-		1 (2.4)	-	

Table 6.8 cont.: Between group comparison of attitudes towards eating vegetables/fruit/legumes and using olive oil instead of other fats/oils, based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Attitudes	Baseline			6 months		
	Intervention group (n 42)	Control group (n 14)	P	Intervention group (n 42)	Control group (n 14)	P
Legumes						
Very favourable	31 (73.8)	8 (57.1)	.385 ^a	33 (78.6)	10 (71.4)	.504 ^a
Neutral	7 (16.7)	6 (42.9)		7 (16.7)	2 (14.3)	
Not favourable	4 (9.5)	-		2 (4.8)	2 (14.3)	
Olive oil						
Very favourable	33 (78.6)	11 (78.6)	.968 ^a	39 (92.9)	11 (78.6)	.153 ^a
Neutral	7 (16.7)	2 (14.3)		1 (2.4)	2 (14.3)	
Not favourable	2 (4.8)	1 (7.1)		2 (4.8)	1 (7.1)	

^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

6.2.2.3.2. *Self-efficacy skills*

Table 6.9 presents the between group comparison of participants' confidence of consuming vegetables, fruits and legumes under challenging situations at baseline and 6 months. At the end of the 6-month intervention, a significantly higher proportion of participants in the intervention group reported they were very confident of eating legumes as a snack, compared with participants in the control group.

Table 6.9 Between group comparison of confidence of "eating vegetables/fruit/legumes in the following situations", based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Vegetables	Baseline			6 months		
	Intervention group (n 42)	Control group (n 14)	P	Intervention group (n 42)	Control group (n 14)	P
Eating out						
Very confident	12 (28.5)	4 (28.6)	.906 ^a	24 (57.1)	5 (35.7)	.083 ^a
Neutral	14 (33.3)	5 (35.7)		9 (21.4)	3 (21.4)	
Not confident	16 (38.1)	5 (35.7)		9 (21.4)	6 (42.8)	
As a snack						
Very confident	26 (61.9)	6 (42.8)	.293 ^a	27 (64.3)	5 (35.7)	.144 ^a
Neutral	8 (19.0)	1 (7.1)		7 (16.7)	5 (35.7)	
Not confident	8 (19.0)	7 (50.0)		8 (19.0)	4 (28.6)	

Table 6.9 cont.: Between group comparison of confidence of “eating vegetables/fruit/legumes in the following situations”, based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Vegetables	Baseline			6 months		
	Intervention group (n 42)	Control group (n 14)	P	Intervention group (n 42)	Control group (n 14)	P
When in a hurry						
Very confident	15 (35.7)	4 (28.6)	.547 ^a	15 (35.7)	5 (35.7)	.921 ^a
Neutral	13 (31.0)	2 (14.3)		14 (33.3)	5 (35.7)	
Not confident	14 (33.3)	8 (57.1)		13 (31.0)	4 (28.6)	
Eating alone						
Very confident	34 (81.0)	10 (71.4)	.261 ^a	34 (81.0)	9 (64.3)	.388 ^a
Neutral	6 (14.3)	2 (14.3)		6 (14.3)	2 (14.3)	
Not confident	2 (4.8)	2 (14.3)		2 (4.8)	3 (21.4)	
Fruit						
	Baseline			6 months		
	Intervention group (n 42)	Control group (n 14)	P	Intervention group (n 42)	Control group (n 14)	P
Eating out						
Very confident	14 (33.3)	8 (57.1)	.275 ^a	23 (54.8)	5 (35.7)	.238 ^a
Neutral	12 (28.6)	2 (14.3)		10 (23.8)	5 (35.7)	
Not confident	16 (38.1)	4 (28.6)		9 (21.4)	4 (28.6)	
As a snack						
Very confident	36 (85.7)	14 (100.0)	.933 ^a	37 (88.1)	11 (78.6)	.183 ^a
Neutral	6 (14.3)	-		3 (7.1)	1 (7.1)	
Not confident	-	-		2 (4.8)	2 (14.3)	
When in a hurry						
Very confident	30 (71.4)	11 (78.6)	.631 ^a	33 (78.5)	10 (71.4)	.824 ^a
Neutral	8 (19.0)	2 (14.3)		4 (9.5)	3 (21.4)	
Not confident	4 (9.6)	1 (7.1)		5 (11.9)	1 (7.1)	
Eating alone						
Very confident	36 (85.7)	13 (92.9)	.757 ^a	34 (80.9)	9 (64.3)	.127 ^a
Neutral	4 (9.5)	1 (7.1)		6 (14.3)	3 (21.4)	
Not confident	2 (4.8)	-		2 (4.8)	2 (14.3)	
Legumes						
	Baseline			6 months		
	Intervention group (n 42)	Control group (n 14)	P	Intervention group (n 42)	Control group (n 14)	P
Eating out						
Very confident	7 (16.7)	3 (21.4)	.191 ^a	11 (26.2)	2 (14.3)	.077 ^a
Neutral	7 (16.7)	4 (28.6)		12 (28.6)	1 (7.1)	
Not confident	24 (66.7)	7 (50.0)		19 (45.3)	11 (78.6)	
As a snack						
Very confident	5 (11.9)	2 (14.3)	.643 ^a	13 (31.0)	1 (7.1)	.016 ^a
Neutral	12 (28.6)	3 (21.4)		13 (31.0)	1 (7.1)	
Not confident	25 (59.6)	9 (64.3)		16 (38.0)	12 (85.7)	

Table 6.9 cont.: Between group comparison of confidence of “eating vegetables/fruit/legumes in the following situations”, based on participants in both groups completing the baseline and 6-month assessments (n, % and P values)

Legumes	Baseline			6 months		
	Intervention group (n 42)	Control group (n 14)	P	Intervention group (n 42)	Control group (n 14)	P
When in a hurry						
Very confident	5 (11.9)	2 (14.3)	.676 ^a	8 (19.1)	2 (14.3)	.245 ^a
Neutral	10 (23.8)	2 (14.3)		13 (31.0)	1 (7.1)	
Not confident	27 (64.3)	10 (71.4)		21 (50.0)	11 (78.6)	
Eating alone						
Very confident	18 (42.9)	4 (28.6)	.541 ^a	20 (47.6)	6 (42.8)	.704 ^a
Neutral	10 (23.8)	5 (35.7)		13 (31.0)	4 (28.6)	
Not confident	14 (33.4)	5 (35.7)		9 (21.5)	4 (28.6)	

^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

Section B: Analysis for participants completing baseline, 6-month and 9-month assessments

6.3. Participants completing baseline, 6-month and 9-month assessments

Thirty-five participants in the intervention group and twelve participants in the control group completed Food and Eating questionnaires at all three assessment time points (baseline, 6 and 9 months), in order to assess nutrition knowledge, stages of dietary behaviour change and psychosocial determinants of dietary behaviour.

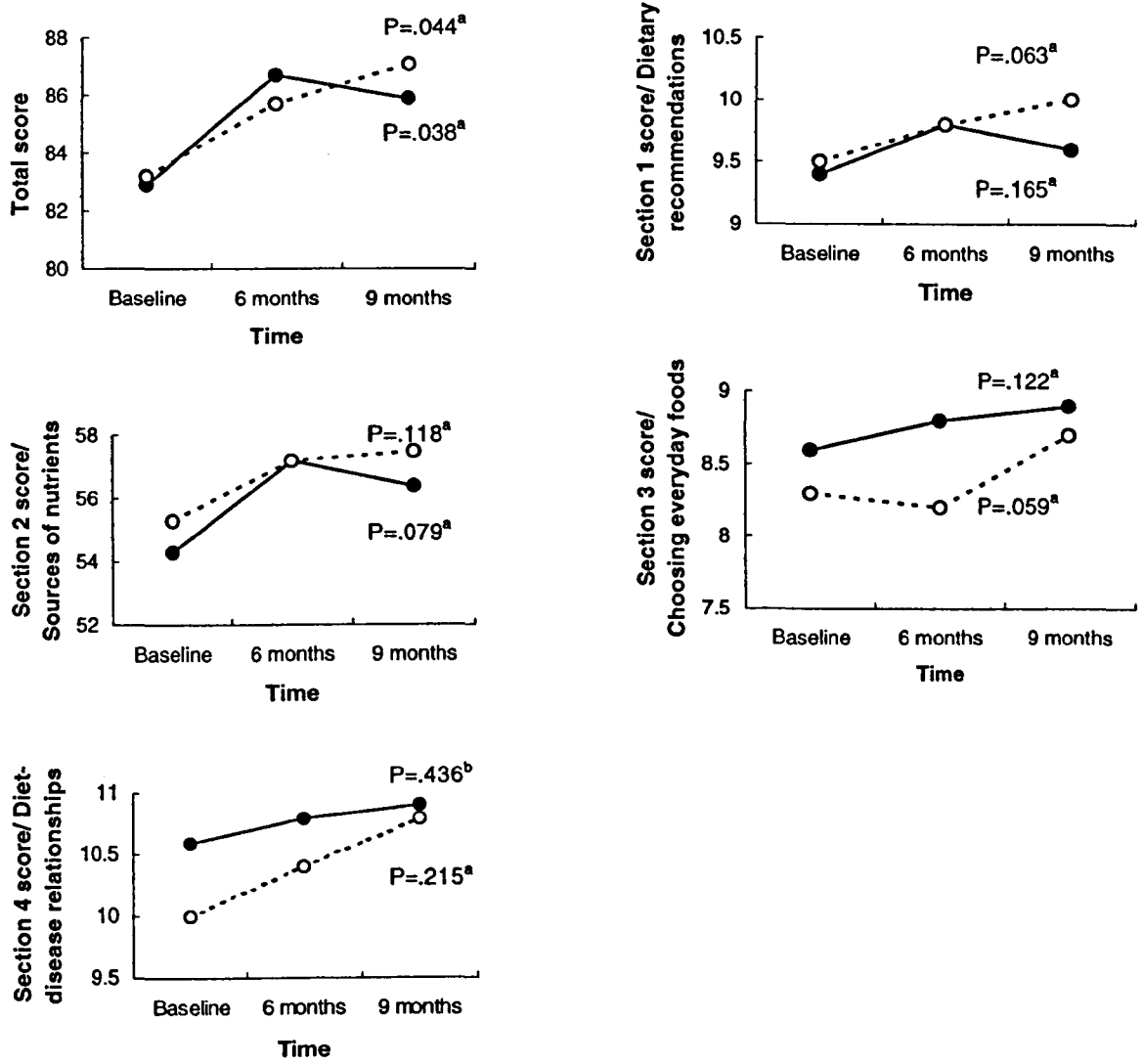
6.3.1. Within group comparisons

6.3.1.1. Nutrition knowledge

Mean total and sub-section nutrition knowledge scores at baseline, 6 and 9 months are illustrated in Figure 6.2, for participants in both groups completing all three assessments. At 6 months, participants in the intervention group significantly increased their total knowledge score (82.9 v. 86.7; $P<.001$), as well as their score for knowledge of dietary recommendations (9.4 v. 9.8; $P=.019$) and knowledge of sources of nutrients (54.3 v. 57.2; $P=.004$), compared with baseline, whereas no differences were observed for participants in the control group between the two time points. Between the end of the 6-month intervention and the 9-month follow-up, participants in the control group showed a slight increase in their score for knowledge of choosing everyday foods (8.8 v. 8.9;

P=.058). At 9 months, participants in the intervention group maintained higher total knowledge scores (82.9 vs. 85.9; P=.038) compared with baseline, whereas participants in the control group also had higher total knowledge scores (83.2 v. 87.1; P=.044), as well as slightly higher scores for choosing everyday foods (8.3 v. 8.7; P=.059) at 9 months compared with baseline.

Figure 6.2 Comparison of total and sub-section nutrition knowledge scores, based on participants in the intervention (—●—, *n* 35) and control (---○---, *n* 12) groups completing the baseline, 6-month and 9-month assessments (P values for comparison between baseline and 9-month assessments)



^a Levels of significance were assessed with the use of the Wilcoxon Signed Ranks Test

^b Levels of significance were assessed with the use of the Paired-Samples T Test

6.3.1.2. Stages of dietary behaviour change

The comparison of stages of dietary change regarding the four Mediterranean goals at baseline, 6 and 9 months is presented in Table 6.10 for participants in both groups. At 6 months, a significantly higher proportion of participants in the intervention group were in the maintenance and action stage of change regarding vegetable ($P=.029$), legume ($P<.001$) and olive oil/ MUFA:SFA ratio ($P<.001$) intake, compared with baseline. These favourable changes were maintained at 9 months (vegetables, $P=.046$; legumes, $P<.001$; and olive oil/MUFA:SFA ratio, $P<.001$, compared with baseline). In addition, a higher proportion of participants in the control group were in the maintenance and action stage of change regarding legume consumption ($P=.008$) at 6 months compared with baseline.

Table 6.10 Comparison of stages of change regarding the four Mediterranean goals, based on participants in both groups completing the baseline, 6-month and 9-month assessments (n and %)

Food component	Intervention group (n 35)			Control group (n 12)		
	Baseline	6 months	9 months	Baseline	6 months	9 months
Vegetables						
Maintenance	5 (14.3)	9 (25.7) ^a	11 (31.4) ^b	2 (16.7)	2 (16.7)	2 (16.7)
Action	16 (45.7)	21 (60.0)	16 (45.7)	5 (41.7)	7 (58.3)	6 (50.0)
Preparation	7 (20.0)	1 (2.9)	1 (2.9)	2 (16.7)	-	1 (8.3)
Contemplation	3 (8.6)	1 (2.9)	1 (2.9)	1 (8.3)	-	-
Precontemplation	4 (11.4)	3 (8.6)	6 (17.1)	2 (16.7)	3 (25.0)	3 (25.0)
Fruits, nuts and seeds						
Maintenance	12 (34.3)	12 (34.3)	10 (28.6)	6 (50.0)	5 (41.7)	7 (58.3)
Action	15 (42.9)	22 (62.9)	20 (57.1)	4 (33.3)	5 (41.7)	3 (25.0)
Preparation	5 (14.3)	-	1 (2.9)	-	-	-
Contemplation	1 (2.9)	1 (2.9)	-	-	1 (8.3)	-
Precontemplation	2 (5.7)	-	4 (11.4)	2 (16.7)	1 (8.3)	2 (16.7)
Legumes						
Maintenance	-	8 (22.9) ^a	4 (11.4) ^b	-	3 (25.0) ^a	2 (16.7)
Action	2 (5.7)	22 (62.9)	21 (60.0)	2 (16.7)	4 (33.3)	4 (33.3)
Preparation	7 (20.0)	-	2 (5.7)	1 (8.3)	1 (8.3)	-
Contemplation	7 (20.0)	4 (11.4)	2 (5.7)	4 (33.3)	-	1 (8.3)
Precontemplation	19 (54.3)	1 (2.9)	6 (17.1)	5 (41.7)	4 (33.3)	5 (41.7)

Table 6.10 cont.: Comparison of stages of change regarding the four Mediterranean goals, based on participants in both groups completing the baseline, 6-month and 9-month assessments (*n* and %)

	Intervention group (<i>n</i> 35)			Control group (<i>n</i> 12)		
	Baseline	6 months	9 months	Baseline	6 months	9 months
Olive oil/ MUFA:SFA ratio						
Maintenance	2 (5.7)	7 (20.0) ^a	7 (20.0) ^b	5 (41.7)	2 (16.7)	3 (25.0)
Action	2 (5.7)	18 (51.4)	16 (45.7)	1 (8.3)	3 (25.0)	3 (25.0)
Preparation	6 (17.1)	-	5 (14.3)	2 (16.7)	-	-
Contemplation	9 (25.7)	4 (11.4)	1 (2.9)	-	-	1 (8.3)
Precontemplation	16 (45.7)	6 (17.1)	6 (17.1)	4 (33.3)	7 (58.3)	5 (41.7)

Levels of significance were assessed with the use of the Friedman Test

^a Significant difference between baseline and 6-month assessments, $P < .050$

^b Significant difference between baseline and 9-month assessments, $P < .050$

6.3.1.3. Psychosocial determinants of dietary behaviour

6.3.1.3.1. Importance and attitudes

The comparisons of importance of, and attitudes towards eating vegetables, fruits and legumes and using olive oil instead of other fats and oils at baseline, 6 and 9 months are presented in Table 6.11 and Table 6.12 for participants in both groups. At the end of the 6-month intervention, a significantly higher proportion of participants in the intervention group reported that eating vegetables was very important to them ($P = .020$) and that their attitude towards using olive oil was very favourable ($P = .014$), compared with baseline. At 9 months, the proportion of participants in this group who thought eating vegetables was very important further increased ($P = .011$, compared with baseline) and more participants thought that eating legumes was important compared with baseline ($P = .046$). In addition, a higher proportion of participants in the control group thought using olive oil was very important at 9, compared with 6 months ($P = .046$).

Table 6.11 Comparison of importance of eating vegetables/fruit/legumes and using olive oil instead of other fats/oils, based on participants in both groups completing the baseline, 6-month and 9-month assessments (*n* and %)

Importance	Intervention group (<i>n</i> 35)			Control group (<i>n</i> 12)		
	Baseline	6 months	9 months	Baseline	6 months	9 months
Vegetables						
Very important	25 (71.4)	32 (91.4) ^a	33 (94.3) ^c	10 (83.3)	10 (83.3)	11 (91.7)
Neutral	9 (25.7)	3 (8.6)	2 (5.7)	1 (8.3)	2 (16.7)	1 (8.3)
Not important	1 (2.9)	-	-	1 (8.3)	-	-
Fruits, nuts and seeds						
Very important	28 (80.0)	28 (80.0)	30 (85.7)	9 (75.0)	9 (75.0)	10 (83.3)
Neutral	7 (20.0)	6 (17.1)	4 (11.4)	2 (16.7)	2 (16.7)	1 (8.3)
Not important	-	1 (2.9)	1 (2.9)	1 (8.3)	1 (8.3)	1 (8.3)
Legumes						
Very important	13 (37.1)	22 (62.9)	23 (65.7) ^c	4 (33.3)	3 (25.0)	6 (50.0)
Neutral	18 (51.4)	10 (28.6)	8 (22.9)	6 (50.0)	6 (50.0)	5 (41.7)
Not important	4 (11.4)	3 (8.6)	4 (11.4)	2 (16.7)	3 (25.0)	1 (8.3)
Olive oil						
Very important	15 (42.9)	19 (54.3)	21 (60.0)	7 (58.3)	5 (41.7)	7 (58.3) ^b
Neutral	16 (45.7)	14 (40.0)	10 (28.6)	2 (16.7)	3 (25.0)	3 (25.0)
Not important	4 (11.4)	2 (5.7)	4 (11.4)	3 (25.0)	4 (33.3)	2 (16.7)

Levels of significance were assessed with the use of the Friedman Test

^a Significant difference between baseline and 6-month assessments, $P < .050$

^b Significant difference between 6-month and 9-month assessments, $P < .050$

^c Significant difference between baseline and 9-month assessments, $P < .050$

Table 6.12 Comparison of attitudes towards eating vegetables/fruit/legumes and using olive oil instead of other fats/oils, based on participants in both groups completing the baseline, 6-month and 9-month assessments (*n* and %)

Attitudes	Intervention group (<i>n</i> 35)			Control group (<i>n</i> 12)		
	Baseline	6 months	9 months	Baseline	6 months	9 months
Vegetables						
Very favourable	33 (94.3)	33 (94.3)	35 (100.0)	12 (100.0)	12 (100.0)	12 (100.0)
Neutral	1 (2.9)	1 (2.9)	-	-	-	-
Not favourable	1 (2.9)	1 (2.9)	-	-	-	-
Fruits, nuts and seeds						
Very favourable	34 (97.1)	34 (97.1)	34 (97.1)	12 (100.0)	12 (100.0)	12 (100.0)
Neutral	1 (2.9)	-	-	-	-	-
Not favourable	-	1 (2.9)	1 (2.9)	-	-	-

Table 6.12 cont.: Comparison of attitudes towards eating vegetables/fruit/legumes and using olive oil instead of other fats/oils, based on participants in both groups completing the baseline, 6-month and 9-month assessments (n and %)

Attitudes	Intervention group (n 35)			Control group (n 12)		
	Baseline	6 months	9 months	Baseline	6 months	9 months
Legumes						
Very favourable	24 (68.6)	28 (80.0)	28 (80.0)	6 (50.0)	8 (66.7)	7 (58.3)
Neutral	7 (20.0)	5 (14.3)	4 (11.4)	6 (50.0)	2 (16.7)	5 (41.7)
Not favourable	4 (11.4)	2 (5.7)	3 (8.6)	-	2 (16.7)	-
Olive oil						
Very favourable	28 (80.0)	33 (94.3) ^a	30 (85.7)	10 (83.3)	10 (83.3)	10 (83.3)
Neutral	5 (14.3)	1 (2.9)	3 (8.6)	1 (8.3)	1 (8.3)	1 (8.3)
Not favourable	2 (5.7)	1 (2.9)	2 (5.7)	1 (8.3)	1 (8.3)	1 (8.3)

Levels of significance were assessed with the use of the Friedman Test

^a Significant difference between baseline and 6-month assessments, $P < .050$

^b Significant difference between baseline and 9-month assessments, $P < .050$

6.3.1.3.2. Self-efficacy skills

Table 6.13 presents participants' confidence of consuming vegetables, fruits and legumes under challenging situations. At the end of the 6-month intervention, a significantly higher proportion of participants in the intervention group reported they were very confident of eating vegetables ($P < .001$), fruit ($P = .001$) and legumes ($P = .005$) when eating out, as well as eating legumes when snacking ($P = .034$), compared with baseline. However, the proportion of participants in this group who were confident of eating fruit when eating out and when snacking decreased between 6 and 9 months ($P = .009$ and $P = .033$, respectively), whereas more participants felt confident of having legumes when eating alone at 9 months compared with baseline ($P = .033$).

A lower proportion of participants in the control group felt confident to have fruit when eating alone ($P = .025$) at 6 months compared with baseline, as well as to have vegetables when eating alone at 9 compared to 6 months ($P = .014$).

Table 6.13 Comparison of confidence of “eating vegetables/fruit/legumes in the following situations”, based on participants in both groups completing the baseline, 6-month and 9-month assessments (*n* and %)

Vegetables	Intervention group (<i>n</i> 35)			Control group (<i>n</i> 12)		
	Baseline	6 months	9 months	Baseline	6 months	9 months
Eating out						
Very confident	11 (31.5)	22 (62.9) ^a	14 (40.0)	4 (33.3)	5 (41.7)	3 (25.0)
Neutral	11 (31.5)	6 (17.1)	12 (34.3)	3 (25.0)	2 (16.7)	4 (33.3)
Not confident	13 (37.0)	7 (20.0)	9 (25.7)	5 (41.7)	5 (41.7)	5 (41.7)
As a snack						
Very confident	23 (65.7)	25 (71.4)	22 (62.9)	5 (41.7)	4 (33.3)	4 (33.3)
Neutral	5 (14.3)	4 (11.4)	7 (20.0)	1 (8.3)	4 (33.3)	3 (25.0)
Not confident	7 (20.0)	6 (17.1)	6 (17.1)	6 (50.0)	4 (33.3)	5 (41.7)
When in a hurry						
Very confident	12 (34.3)	12 (34.3)	14 (40.0)	4 (33.3)	5 (41.7)	4 (33.3)
Neutral	13 (37.1)	13 (37.1)	13 (37.1)	1 (8.3)	3 (25.0)	2 (16.7)
Not confident	10 (28.6)	10 (28.6)	8 (22.9)	7 (58.3)	4 (33.3)	6 (50.0)
Eating alone						
Very confident	28 (80.0)	29 (82.8)	30 (85.7)	8 (66.7)	9 (75.0)	5 (41.7) ^b
Neutral	5 (14.3)	5 (14.3)	2 (5.7)	2 (16.7)	2 (16.7)	3 (25.0)
Not confident	2 (5.7)	1 (2.9)	3 (8.6)	2 (16.7)	1 (8.3)	4 (33.3)
Fruit	Intervention group (<i>n</i> 35)			Control group (<i>n</i> 12)		
	Baseline	6 months	9 months	Baseline	6 months	9 months
Eating out						
Very confident	13 (37.1)	20 (57.2) ^a	13 (37.1) ^b	8 (66.7)	5 (41.7)	4 (33.3)
Neutral	9 (25.7)	7 (20.0)	9 (25.7)	-	4 (33.3)	4 (33.3)
Not confident	13 (37.1)	8 (22.9)	13 (37.1)	4 (33.3)	3 (25.0)	4 (33.3)
As a snack						
Very confident	31 (88.5)	31 (88.5)	29 (82.8) ^b	12 (100.0)	10 (83.4)	10 (83.4)
Neutral	4 (11.4)	2 (5.7)	4 (11.4)	-	1 (8.3)	2 (16.7)
Not confident	-	2 (5.7)	2 (5.7)	-	1 (8.3)	-
When in a hurry						
Very confident	26 (74.3)	28 (80.0)	27 (77.1)	10 (83.4)	9 (75.0)	9 (75.0)
Neutral	7 (20.0)	3 (8.6)	6 (17.1)	1 (8.3)	2 (16.7)	2 (16.7)
Not confident	2 (5.7)	4 (11.4)	2 (5.7)	1 (8.3)	1 (8.3)	1 (8.3)
Eating alone						
Very confident	29 (82.8)	29 (82.8)	29 (82.8)	12 (100.0)	9 (75.0) ^a	10 (83.4)
Neutral	4 (11.4)	5 (14.3)	4 (11.4)	-	3 (25.0)	2 (16.7)
Not confident	2 (5.7)	1 (2.9)	2 (5.7)	-	-	-

Table 6.13 cont.: Comparison of confidence of “eating vegetables/fruit/legumes in the following situations”, based on participants in both groups completing the baseline, 6-month and 9-month assessments (n and %)

Legumes	Intervention group (n 35)			Control group (n 12)		
	Baseline	6 months	9 months	Baseline	6 months	9 months
Eating out						
Very confident	6 (17.1)	10 (28.5) ^a	4 (11.4)	3 (25.0)	2 (16.7)	1 (8.3)
Neutral	7 (20.0)	11 (31.4)	14 (40.0)	3 (25.0)	1 (8.3)	3 (25.0)
Not confident	22 (62.9)	14 (40.0)	17 (48.6)	6 (50.0)	9 (75.0)	8 (66.7)
As a snack						
Very confident	4 (11.4)	12 (34.3) ^a	10 (28.5)	2 (16.7)	1 (8.3)	3 (25.0)
Neutral	11 (31.4)	11 (31.4)	11 (31.4)	3 (25.0)	1 (8.3)	1 (8.3)
Not confident	20 (57.2)	12 (34.3)	14 (40.0)	7 (58.3)	10 (83.4)	8 (66.7)
When in a hurry						
Very confident	4 (11.4)	7 (20.0)	8 (22.9)	2 (16.7)	2 (16.7)	2 (16.7)
Neutral	9 (25.7)	10 (28.6)	14 (40.0)	2 (16.7)	1 (8.3)	2 (16.7)
Not confident	22 (62.9)	18 (51.4)	13 (37.1)	8 (66.7)	9 (75.0)	8 (66.7)
Eating alone						
Very confident	15 (42.9)	16 (45.7)	19 (54.3) ^c	3 (25.0)	6 (50.0)	4 (33.3)
Neutral	8 (22.9)	12 (34.3)	10 (28.6)	5 (41.7)	3 (25.0)	3 (25.0)
Not confident	12 (34.3)	7 (20.0)	6 (17.1)	4 (33.3)	3 (25.0)	5 (41.7)

Levels of significance were assessed with the use of the Friedman Test

^a Significant difference between baseline and 6-month assessments, $P < .050$

^b Significant difference between 6-month and 9-month assessments, $P < .050$

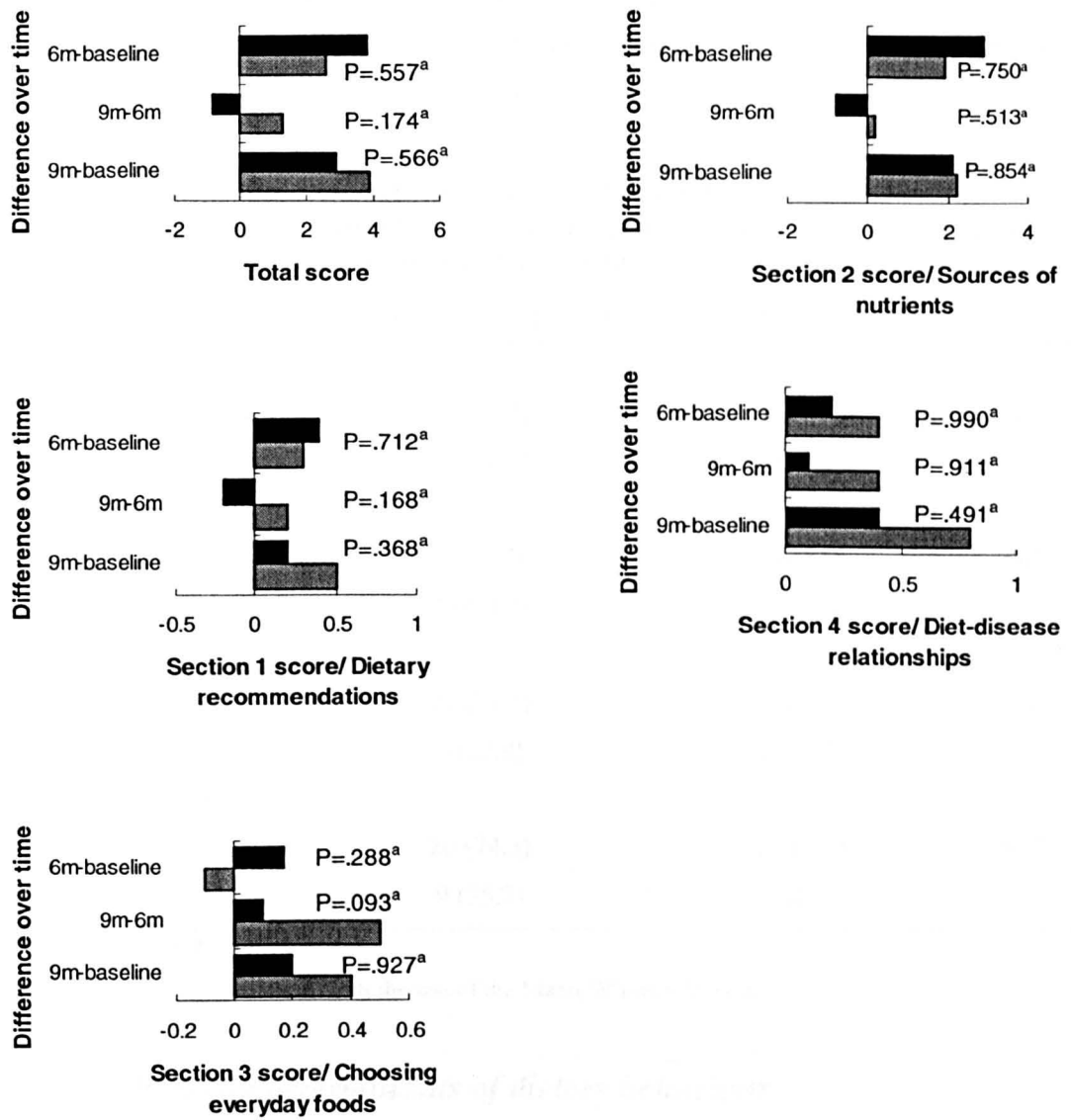
^c Significant difference between baseline and 9-month assessments, $P < .050$

6.3.2. Between group comparisons

6.3.2.1. Nutrition knowledge

The between group differences in mean total and sub-section nutrition knowledge scores over the 9-month trial are illustrated in Figure 6.3, for participants completing all three assessments (baseline, 6 and 9 months). There were no statistically significant differences between the groups at any time point.

Figure 6.3 Between group comparison of changes over time in total and sub-section nutrition knowledge scores, based on participants in the intervention (■, *n* 35) and control (▨, *n* 12) groups completing the baseline, 6-month and 9-month assessments (P values)



^a Levels of significance were assessed with the use of the Mann-Whitney U Test

6.3.2.2. *Stages of dietary behaviour change*

The between group comparison of stages of behavioural transition from baseline to 9 months is presented in Table 6.14. Over this period, a significantly higher proportion of participants in the intervention compared with the control group achieved a forward stage of transition regarding legume and olive oil/ MUFA:SFA ratio consumption.

Table 6.14 Between group comparison of stages of behavioural transition regarding the four Mediterranean goals from baseline to 9 months, based on participants in both groups completing the baseline and 9-month assessments (*n*, % and *P* values)

Food component	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	<i>P</i>
Vegetables			
FST	11 (31.4)	4 (33.3)	.904 ^a
No FST	24 (68.6)	8 (66.7)	
Fruits, nuts and seeds			
FST	9 (25.7)	3 (25.0)	.961 ^a
No FST	26 (74.3)	9 (75.0)	
Legumes			
FST	27 (77.1)	5 (41.7)	.024 ^a
No FST	8 (22.9)	7 (58.3)	
Olive oil/ MUFA:SFA ratio			
FST	26 (74.3)	2 (16.7)	.001 ^a
No FST	9 (25.7)	10 (83.3)	

FST, Forward stage of transition.

^a Levels of significance were assessed with the use of the Mann-Whitney U Test

6.3.2.3. *Psychosocial determinants of dietary behaviour*

6.3.2.3.1. *Importance and attitudes*

The between group comparisons of perceived importance of, and attitudes towards eating vegetables, fruits and legumes and using olive oil instead of other fats and oils at baseline, 6 and 9 months are presented in Table 6.15 and Table 6.16. There were no differences between the groups at any time point, but a higher proportion of participants in the intervention, compared with the control, group thought that eating legumes was very important at 6 months ($P=.020$).

Table 6.15 Between group comparison of importance of eating vegetables/fruit/legumes and using olive oil instead of other fats/oils, based on participants in both groups completing the baseline, 6-month and 9-month assessments (*n* and %)

Importance	Baseline		6 months		9 months	
	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)
Vegetables						
Very important	25 (71.4)	10 (83.3)	32 (91.4)	10 (83.3)	33 (94.3)	11 (91.7)
Neutral	9 (25.7)	1 (8.3)	3 (8.6)	2 (16.7)	2 (5.7)	1 (8.3)
Not important	1 (2.9)	1 (8.3)	-	-	-	-
Fruits, nuts and seeds						
Very important	28 (80.0)	9 (75.0)	28 (80.0)	9 (75.0)	30 (85.7)	10 (83.3)
Neutral	7 (20.0)	2 (16.7)	6 (17.1)	2 (16.7)	4 (11.4)	1 (8.3)
Not important	-	1 (8.3)	1 (2.9)	1 (8.3)	1 (2.9)	1 (8.3)
Legumes						
Very important	13 (37.1)	4 (33.3)	22 (62.9)	3 (25.0) ^a	23 (65.7)	6 (50.0)
Neutral	18 (51.4)	6 (50.0)	10 (28.6)	6 (50.0)	8 (22.9)	5 (41.7)
Not important	4 (11.4)	2 (16.7)	3 (8.6)	3 (25.0)	4 (11.4)	1 (8.3)
Olive oil						
Very important	15 (42.9)	7 (58.3)	19 (54.3)	5 (41.7)	21 (60.0)	7 (58.3)
Neutral	16 (45.7)	2 (16.7)	14 (40.0)	3 (25.0)	10 (28.6)	3 (25.0)
Not important	4 (11.4)	3 (25.0)	2 (5.7)	4 (33.3)	4 (11.4)	2 (16.7)

Levels of significance were assessed with the use of the Kruskal-Wallis Test

^a Significant difference between the groups, $P < 0.050$

Table 6.16 Between group comparison of attitudes towards eating vegetables/fruit/legumes and using olive oil instead of other fats/oils, based on participants in both groups completing the baseline, 6-month and 9-month assessments (*n* and %)

Attitudes	Baseline		6 months		9 months	
	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)
Vegetables						
Very favourable	33 (94.3)	12 (100.0)	33 (94.3)	12 (100.0)	35 (100.0)	12 (100.0)
Neutral	1 (2.9)	-	1 (2.9)	-	-	-
Not favourable	1 (2.9)	-	1 (2.9)	-	-	-

Table 6.16 cont.: Between group comparison of attitudes towards eating vegetables/fruit/legumes and using olive oil instead of other fats/oils, based on participants in both groups completing the baseline, 6-month and 9-month assessments (*n* and %)

Attitudes	Baseline		6 months		9 months	
	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)
Fruits, nuts and seeds						
Very favourable	34 (97.1)	12 (100.0)	34 (97.1)	12 (100.0)	34 (97.1)	12 (100.0)
Neutral	1 (2.9)	-	-	-	-	-
Not favourable	-	-	1 (2.9)	-	1 (2.9)	-
Legumes						
Very favourable	24 (68.6)	6 (50.0)	28 (80.0)	8 (66.7)	28 (80.0)	7 (58.3)
Neutral	7 (20.0)	6 (50.0)	5 (14.3)	2 (16.7)	4 (11.4)	5 (41.7)
Not favourable	4 (11.4)	-	2 (5.7)	2 (16.7)	3 (8.6)	-
Olive oil						
Very favourable	28 (80.0)	10 (83.3)	33 (94.3)	10 (83.3)	30 (85.7)	10 (83.3)
Neutral	5 (14.3)	1 (8.3)	1 (2.9)	1 (8.3)	3 (8.6)	1 (8.3)
Not favourable	2 (5.7)	1 (8.3)	1 (2.9)	1 (8.3)	2 (5.7)	1 (8.3)

Levels of significance were assessed with the use of the Kruskal-Wallis Test

6.3.2.3.2. Self-efficacy skills

Table 6.17 presents the between group comparison of participants' confidence of consuming vegetables, fruits and legumes under challenging situations at baseline, 6 and 9 months. At the end of the 6-month intervention, a significantly higher proportion of participants in the intervention group reported they were very confident of eating vegetables ($P=.041$) and legumes ($P=.044$) when eating out, as well as eating vegetables ($P=.036$) and legumes ($P=.004$) when snacking, compared with participants in the control group. In addition, more participants in the intervention, compared with the control, group felt confident that they would eat vegetables when eating alone ($P=.007$) at 9 months.

Table 6.17 Between group comparison of confidence of “eating vegetables/fruit/legumes in the following situations”, based on participants in both groups completing the baseline, 6-month and 9-month assessments (*n* and %)

Vegetables	Baseline		6 months		9 months	
	Intervention	Control	Intervention	Control	Intervention	Control
	group (<i>n</i> 35)	group (<i>n</i> 12)	group (<i>n</i> 35)	group (<i>n</i> 12)	group (<i>n</i> 35)	group (<i>n</i> 12)
Eating out						
Very confident	11 (31.5)	4 (33.3)	22 (62.9)	5 (41.7) ^a	14 (40.0)	3 (25.0)
Neutral	11 (31.5)	3 (25.0)	6 (17.1)	2 (16.7)	12 (34.3)	4 (33.3)
Not confident	13 (37.0)	5 (41.7)	7 (20.0)	5 (41.7)	9 (25.7)	5 (41.7)
As a snack						
Very confident	23 (65.7)	5 (41.7)	25 (71.4)	4 (33.3) ^a	22 (62.9)	4 (33.3)
Neutral	5 (14.3)	1 (8.3)	4 (11.4)	4 (33.3)	7 (20.0)	3 (25.0)
Not confident	7 (20.0)	6 (50.0)	6 (17.1)	4 (33.3)	6 (17.1)	5 (41.7)
When in a hurry						
Very confident	12 (34.3)	4 (33.3)	12 (34.3)	5 (41.7)	14 (40.0)	4 (33.3)
Neutral	13 (37.1)	1 (8.3)	13 (37.1)	3 (25.0)	13 (37.1)	2 (16.7)
Not confident	10 (28.6)	7 (58.3)	10 (28.6)	4 (33.3)	8 (22.9)	6 (50.0)
Eating alone						
Very confident	28 (80.0)	8 (66.7)	29 (82.8)	9 (75.0)	30 (85.7)	5 (41.7) ^a
Neutral	5 (14.3)	2 (16.7)	5 (14.3)	2 (16.7)	2 (5.7)	3 (25.0)
Not confident	2 (5.7)	2 (16.7)	1 (2.9)	1 (8.3)	3 (8.6)	4 (33.3)
Fruit	Baseline		6 months		9 months	
	Intervention	Control	Intervention	Control	Intervention	Control
	group (<i>n</i> 35)	group (<i>n</i> 12)	group (<i>n</i> 35)	group (<i>n</i> 12)	group (<i>n</i> 35)	group (<i>n</i> 12)
Eating out						
Very confident	13 (37.1)	8 (66.7)	20 (57.2)	5 (41.7)	13 (37.1)	4 (33.3)
Neutral	9 (25.7)	-	7 (20.0)	4 (33.3)	9 (25.7)	4 (33.3)
Not confident	13 (37.1)	4 (33.3)	8 (22.9)	3 (25.0)	13 (37.1)	4 (33.3)
As a snack						
Very confident	31 (88.5)	12 (100.0)	31 (88.5)	10 (83.4)	29 (82.8)	10 (83.4)
Neutral	4 (11.4)	-	2 (5.7)	1 (8.3)	4 (11.4)	2 (16.7)
Not confident	-	-	2 (5.7)	1 (8.3)	2 (5.7)	-
When in a hurry						
Very confident	26 (74.3)	10 (83.4)	28 (80.0)	9 (75.0)	27 (77.1)	9 (75.0)
Neutral	7 (20.0)	1 (8.3)	3 (8.6)	2 (16.7)	6 (17.1)	2 (16.7)
Not confident	2 (5.7)	1 (8.3)	4 (11.4)	1 (8.3)	2 (5.7)	1 (8.3)

Table 6.17 cont.: Between group comparison of confidence of “eating vegetables/fruit/legumes in the following situations”, based on participants in both groups completing the baseline, 6-month and 9-month assessments (*n* and %)

Fruit	Baseline		6 months		9 months	
	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)
Eating alone						
Very confident	29 (82.8)	12 (100.0)	29 (82.8)	9 (75.0)	29 (82.8)	10 (83.4)
Neutral	4 (11.4)	-	5 (14.3)	3 (25.0)	4 (11.4)	2 (16.7)
Not confident	2 (5.7)	-	1 (2.9)	-	2 (5.7)	-
Legumes						
	Baseline		6 months		9 months	
	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)	Intervention group (<i>n</i> 35)	Control group (<i>n</i> 12)
Eating out						
Very confident	6 (17.1)	3 (25.0)	10 (28.5)	2 (16.7) ^a	4 (11.4)	1 (8.3)
Neutral	7 (20.0)	3 (25.0)	11 (31.4)	1 (8.3)	14 (40.0)	3 (25.0)
Not confident	22 (62.9)	6 (50.0)	14 (40.0)	9 (75.0)	17 (48.6)	8 (66.7)
As a snack						
Very confident	4 (11.4)	2 (16.7)	12 (34.3)	1 (8.3) ^a	10 (28.5)	3 (25.0)
Neutral	11 (31.4)	3 (25.0)	11 (31.4)	1 (8.3)	11 (31.4)	1 (8.3)
Not confident	20 (57.2)	7 (58.3)	12 (34.3)	10 (83.4)	14 (40.0)	8 (66.7)
When in a hurry						
Very confident	4 (11.4)	2 (16.7)	7 (20.0)	2 (16.7)	8 (22.9)	2 (16.7)
Neutral	9 (25.7)	2 (16.7)	10 (28.6)	1 (8.3)	14 (40.0)	2 (16.7)
Not confident	22 (62.9)	8 (66.7)	18 (51.4)	9 (75.0)	13 (37.1)	8 (66.7)
Eating alone						
Very confident	15 (42.9)	3 (25.0)	16 (45.7)	6 (50.0)	19 (54.3)	4 (33.3)
Neutral	8 (22.9)	5 (41.7)	12 (34.3)	3 (25.0)	10 (28.6)	3 (25.0)
Not confident	12 (34.3)	4 (33.3)	7 (20.0)	3 (25.0)	6 (17.1)	5 (41.7)

Levels of significance were assessed with the use of the Kruskal-Wallis Test

^a Significant difference between the groups, $P < .050$

6.4. Summary

Both “per protocol” analyses showed that at 6 months, participants in the intervention group had a higher total nutrition knowledge score, as well as a higher score for knowledge of dietary recommendations and sources of nutrients, compared with baseline. At 9 months, total nutrition knowledge score remained higher than baseline. In addition, more participants in this group were in the action and maintenance stage of stage for vegetables, legumes and olive oil/ MUFA:SFA ratio at both 6 and 9 months, compared with baseline.

At 6 months, more participants in the intervention group, compared with baseline, thought eating vegetables was very important and had a favourable attitude to using olive oil. At 9 months, a higher proportion of participants in this group also thought that eating vegetables, as well as legumes, was very important, compared with baseline. Self-efficacy skills at 6 and 9 months generally increased for participants in this group, compared with baseline.

Between the end of the 6-month intervention and the 3-month follow-up, participants in the control group had increased their score for knowledge of choosing everyday foods, which, at 9 months, was higher compared with baseline. In addition, total nutrition knowledge score was higher at this time point, compared with baseline. More participants in this group were in the action and maintenance stage of stage for legumes at 6 months, compared with baseline. Between the end of the 6-month intervention and the 3-month follow-up, the percentage of participants in this group who thought using olive oil is very important increased. In addition, both analyses showed that at 6 months, a lower proportion of participants in this group felt confident of eating fruit when eating alone, compared with baseline, while between the end of the 6-month intervention and the 3-month follow-up, the percentage who felt confident of eating vegetables when eating alone decreased.

Between group comparisons showed that at 6 and 9 months, a higher proportion of participants in the intervention, compared with the control, group had achieved a forward stage of behaviour change regarding legumes and olive oil/ MUFA:SFA ratio. In addition, for participants who completed all three assessments, a higher proportion of participants in the intervention, compared with the control, group, thought that eating legumes was very important at 6 months. Self-efficacy skills were generally increased among the intervention, compared with the control group.

7 Results: Process Evaluation

7.1. Overview

At the end of the 6-month intervention trial, reactions towards the materials provided over the study course to participants in the intervention (tailored feedback letters and Mediterranean Eating website) and control (minimally-tailored feedback letters and general nutrition information brochures) groups were evaluated using a triangulation approach of process evaluation questionnaires, statistical summaries of overall website login frequency and website usage patterns and qualitative semi-structured focus group interviews.

7.2. Post-test process evaluation questionnaires

At the end of the 6-month intervention, usefulness and appreciation of the study materials (nutrition education materials and feedback letters) provided to participants in both groups were evaluated via self-administered questionnaires (Appendix V). These questionnaires were completed by thirty-one participants in the intervention group (58.5% of those who started the study; 73.8% of those who completed the 6-month intervention) and twelve participants in the control group (63.1% of those who started the study; 80.0% of those who completed the 6-month intervention).

7.2.1. Nutrition education materials

Reactions to the nutrition education materials (Mediterranean Eating website and general nutrition information brochures/booklets) are presented in Table 7.1. No difference in trustworthiness and easiness to understand was found between the Mediterranean Eating website and the general nutrition information brochures. However, participants in the intervention group were more positive about the nutrition education materials they received, with the majority finding them extremely interesting, informative, useful, attractive, encouraging, time saving, helpful and not limited in information. A lower proportion of participants in the intervention compared with the control group reported that the nutrition education materials were “somewhat limited” or “extremely limited”, whereas 29% of participants in the intervention group, compared to no participants in the control group, reported that the materials were “extremely time-saving”. In addition, a higher proportion of participants in the intervention group felt extremely satisfied with the nutrition education materials they received, compared with participants in the control group.

Table 7.1 Participants' reactions to the nutrition education materials (percentage of participants who agreed with the provided statements and P values)

	Intervention group (n 31)	Control group (n 12)	P
The nutrition education materials were...			
... extremely interesting	77.4%	16.7%	<.001 ^a
... extremely informative	77.4%	25.0%	.001 ^a
... extremely trustworthy	74.2%	50.0%	.104 ^a
... extremely easy to understand	77.4%	58.3%	.216 ^a
... extremely useful	67.7%	16.7%	.002 ^a
... extremely attractive	67.7%	25.0%	.008 ^a
... extremely encouraging	64.5%	16.7%	.003 ^a
... not time-saving at all	22.6%	41.7%	.047 ^a
... not limited at all	48.4%	16.7%	.050 ^a
... extremely helpful	58.1%	0.0%	<.001 ^a
I felt extremely satisfied with the nutrition education materials	67.7%	33.3%	.021 ^a

^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

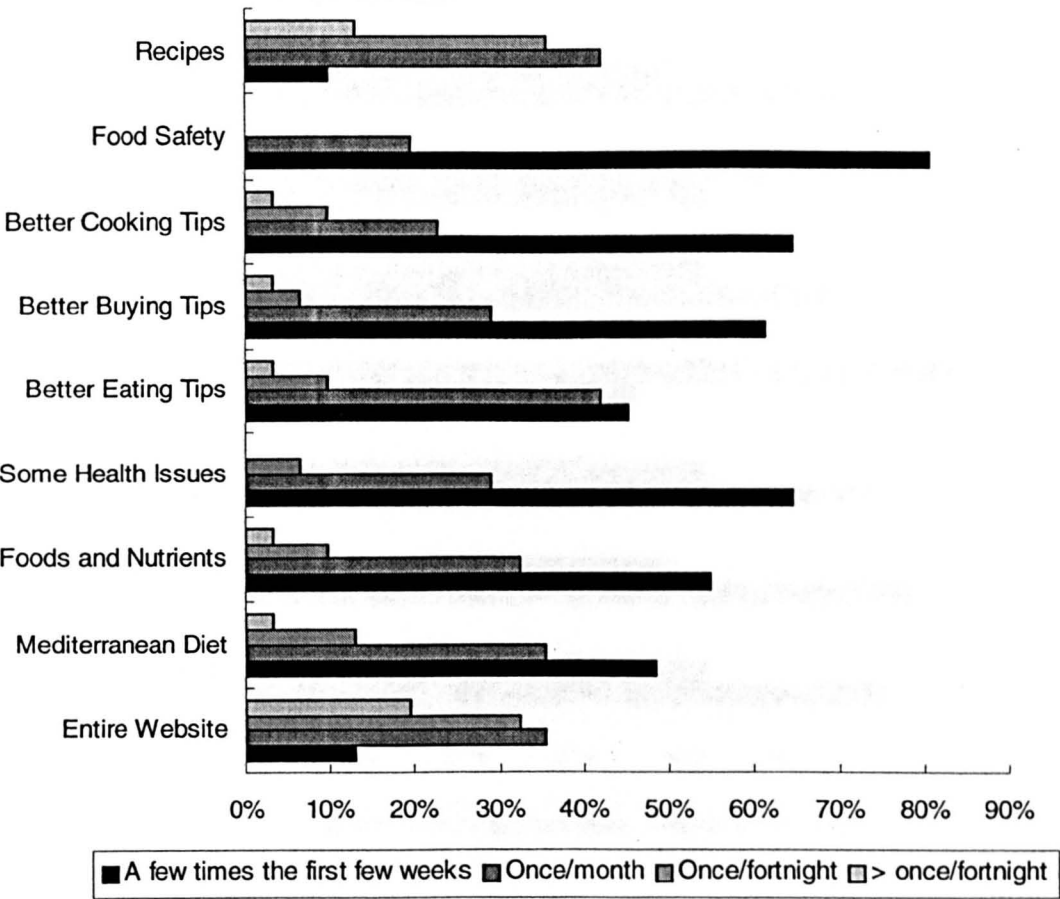
Just under one third (32.3%) of participants in the intervention group reported they would prefer such a tailored, Internet-based intervention to personal counselling compared with 45.2% who were not sure, whereas 16.7% of participants in the control group reported they would prefer a minimally-tailored intervention accompanied by general nutrition education materials, to personal counselling, compared with 50.0% who were not sure.

7.2.1.1. Self-reported Mediterranean Eating website login frequency and usage patterns

The frequencies of visiting the Mediterranean Eating website and the specific website sections, as reported in the evaluation questionnaire completed by participants in the intervention group, are illustrated in Figure 7.1. The majority of participants reported visiting the website once per month or more. The most popular sections appeared to be the "Recipes" and the "Better Eating Tips", with

a substantial number of participants reporting visiting these sections once per month or more. The majority of participants visited the remaining sections only a few times during the first weeks after the website was launched. These were also the sections of the website that were not updated with new information during the 6-month study. However, a relatively large number of participants visited these sections on a monthly basis or more often.

Figure 7.1 Self-reported frequency of visiting the Mediterranean Eating website and specific website sections (n 31)

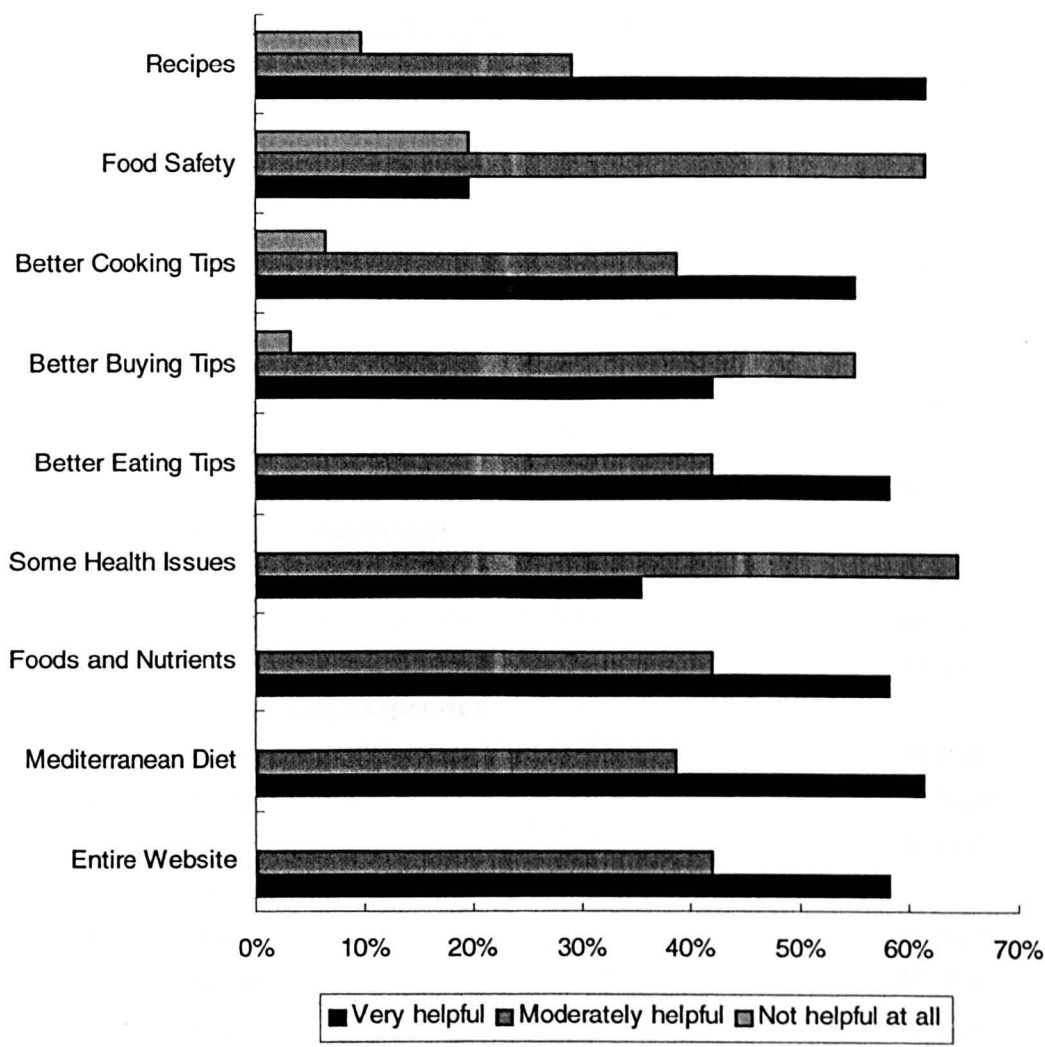


7.2.1.2. Perceived helpfulness of the Mediterranean Eating website and its sections

Figure 7.2 illustrates the perceived helpfulness of the Mediterranean Eating website and the specific website sections, as reported in the evaluation questionnaire completed by participants in the intervention group. The overall website was generally viewed as “very helpful” (58.1%) or “moderately helpful” (41.9%). The majority of participants found most of the individual sections of the website “very helpful”, with some sections regarded as “moderately helpful” by a greater

proportion of participants (“Some Health Issues”, “Better Buying Tips” and “Food Safety”). A relatively large number of participants (19.4%) thought the “Food Safety” section was “not helpful at all”, while the same opinion was reported by a slightly lower proportion of participants (9.7%) regarding the “Recipes” section.

Figure 7.2 Perceived helpfulness of the Mediterranean Eating website and specific website sections (n 31)



7.2.1.3. Attitudes towards trying recipes presented on the Mediterranean Eating website

The attitudes of participants in the intervention group towards trying recipes presented on the Mediterranean Eating website, as reported in the post-test evaluation questionnaires, are presented in Table 7.2. The majority of participants reported trying recipes presented on the website, with just over half trying some recipes more than once, suggesting that they incorporated them into their

menu repertoire. The recipes were generally perceived as “very easy” or “moderately easy” to prepare and the ingredients generally “very easy to find”. Almost a quarter of participants reported that ingredients for the recipes were “moderately expensive” and the majority reported that their friends/family enjoyed the sampled recipes.

Table 7.2 Attitudes to trying recipes from the Mediterranean Eating website (*n* and %)

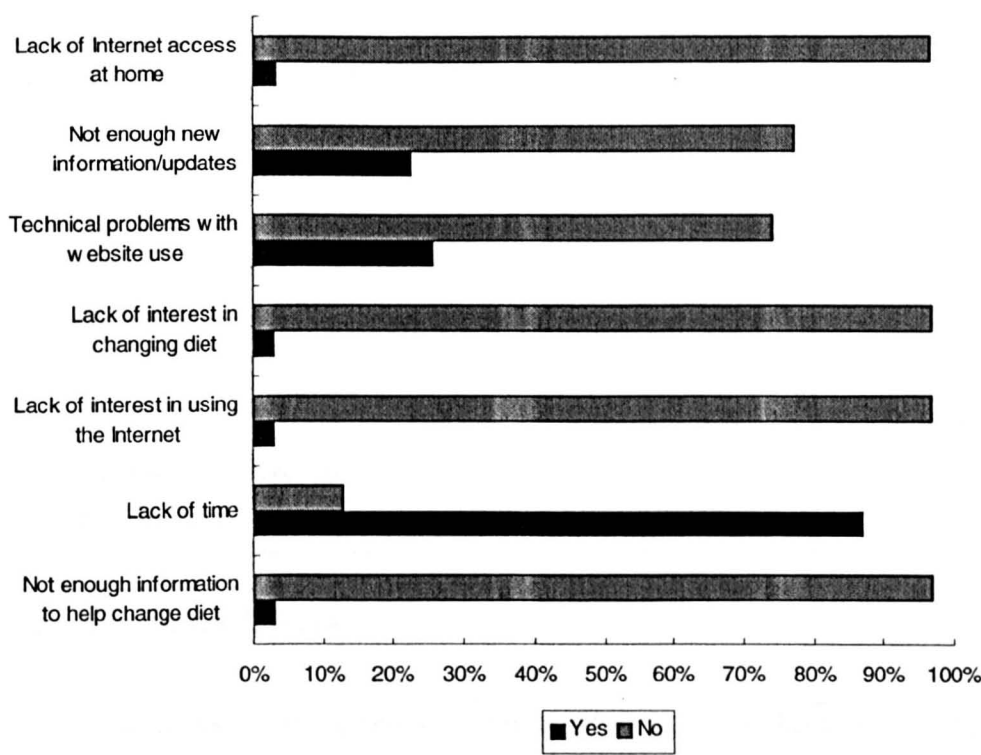
	Intervention group (<i>n</i> 31)
Have you used any of the recipes on the website?	
Yes	25 (80.6)
No	6 (19.4)
Have you tried any recipes more than once?	
Yes	16 (51.6)
No	9 (29.0)
Not applicable	6 (19.4)
Were the recipes generally easy to make?	
Very easy	17 (54.8)
Moderately easy	8 (25.8)
Not applicable	6 (19.4)
Were the ingredients generally easy to find?	
Very easy	19 (61.3)
Moderately easy	6 (19.3)
Not applicable	6 (19.4)
Were the ingredients for the recipes expensive?	
Moderately expensive	8 (25.8)
Not expensive at all	17 (54.8)
Not applicable	6 (19.4)
Did family/friends enjoy the recipes you tried?	
Enjoyed very much	13 (41.9)
Moderately enjoyed	11 (35.5)
Didn't enjoy at all	1 (3.2)
Not applicable	6 (19.4)

7.2.1.4. Perceived barriers to using the Mediterranean Eating website

Perceived barriers to using the Mediterranean Eating website are illustrated in Figure 7.3. For the majority of participants (87.1%), “lack of time” was a barrier to using the website weekly, as recommended, while few participants noted the barriers “lack of interest in changing my diet” (3.2%), “lack of interest in using the Internet” (3.2%), “lack of Internet access at home” (3.3%) and “not enough information to help me change my diet” (3.2%). Approximately a quarter of

participants regarded “not enough new information/updates” and “technical problems” as being barriers to using the website (22.6% and 25.8%, respectively).

Figure 7.3 Perceived barriers to using the Mediterranean Eating website (n 31)



7.2.1.5. Attitudes towards the general nutrition information brochures

The attitudes towards the general nutrition information brochures are presented in Table 7.3, as reported in the post-test evaluation questionnaires completed by participants in the control group. Although the majority of participants reported that the information in the brochures caught their attention, approximately one third read all the information, whereas the majority read the brochures only once after they were posted.

Table 7.3 Attitudes towards the general nutrition information brochures (*n* and %)

	Control group (<i>n</i> 12)
Do you remember receiving nutrition information brochures?	
Yes	12 (100.0)
No	-
Did the information in the brochures catch your attention?	
Yes	9 (75.0)
No	3 (25.0)
How much of the brochure information did you read?	
I didn't read any of the information	-
I read some of the information	4 (33.3)
I read most of the information	4 (33.3)
I read all the information	4 (33.3)
How often did you read the nutrition information brochures over the last 6 months?	
Never	1 (8.3)
Once, when I received them	9 (75.0)
More than once	2 (16.7)

7.2.2. Feedback letters

Attitudes towards the feedback letters are presented in Table 7.4, based on participants in both groups who completed the post-test process evaluation questionnaires. A higher proportion of participants in the control group reported intending to read the feedback letters again in the future, compared with participants in the intervention group. In addition, participants in the control group were more likely not to find the feedback letters attractive in appearance. There were no other differences in use or appreciation of the feedback letters between the intervention and control groups.

Table 7.4 Participants' attitudes towards the feedback letters (percentage of participants who agreed with the provided statements and P values)

	Intervention group (<i>n</i> 31)	Control group (<i>n</i> 12)	P
I remember receiving feedback letters	100.0%	100.0%	1.000 ^a
The feedback letters caught my attention	100.0%	100.0%	1.000 ^a
I read all the information in the feedback letters	58.1%	58.3%	.913 ^a
The information in the feedback letters applied to me specifically	93.5%	100.0%	.373 ^a
I agreed with the information in the feedback letters	96.8%	83.3%	.125 ^a
I have saved the feedback letters	93.5%	100.0%	.373 ^a
I will read the feedback letters again in the future	61.3%	91.7%	.043 ^a
I have shown the feedback letters to others	41.9%	25.0%	.308 ^a
I have talked about the feedback letters to others	87.1%	83.3%	.752 ^a
The feedback letters contained new information about my diet	90.3%	75.0%	.199 ^a

Table 7.4 cont.: Participants' attitudes towards the feedback letters (percentage of participants who agreed with the provided statements and P values)

	Intervention group (n 31)	Control group (n 12)	P
The feedback letters were extremely interesting	54.8%	33.3%	.211 ^a
The feedback letters were extremely informative	64.5%	41.7%	.178 ^a
The feedback letters were extremely trustworthy	64.5%	66.7%	.896 ^a
The feedback letters were extremely easy to understand	64.5%	58.3%	.710 ^a
The feedback letters were extremely useful	48.4%	50.0%	.925 ^a
The feedback letters were not attractive at all	6.5%	25.0%	.029 ^a
The feedback letters were extremely encouraging	58.1%	41.7%	.339 ^a
The feedback letters were not time-saving at all	41.9%	33.3%	.603 ^a
The feedback letters were not limited at all	67.7%	58.3%	.566 ^a
I felt extremely satisfied with the feedback letters	80.6%	83.3%	.841 ^a

^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

The subjective impact of the feedback letters on participants' opinions about and changes made to their diets is presented in Table 7.5. A higher proportion of participants in the intervention compared with the control group reported changing their diets as a result of the feedback letters they received.

Table 7.5 Subjective impact of the feedback letters (percentage of participants who agreed with the provided statements and P values)

	Intervention group (<i>n</i> 31)	Control group (<i>n</i> 12)	P
As a result of the feedback letters...			
I changed my opinion about my diet	71.0%	83.3%	.410 ^a
I changed my diet	100.0%	66.7%	.001 ^a
I switched to using olive oil instead of other fats and oils	80.6%	83.3%	.841 ^a
I increased my vegetable intake	77.4%	83.3%	.673 ^a
I increased my fruit, nut and seed intake	61.3%	58.3%	.860 ^a
I increased my legume intake	77.4%	50.0%	.083 ^a

^a Levels of significance were assessed with the use of the Kruskal-Wallis Test

7.3. Mediterranean Eating website login frequency

During the 6-month trial, overall website login frequency for each participant in the intervention group and website usage patterns (total counts of visits to each website section) were measured via statistical summaries generated from the University of Glasgow web server.

Login frequency for participants in the intervention group who completed both the baseline and 6-month dietary assessment (*n* 41) was tracked over the 6-month trial, in order to obtain an objective measure of website use. Participants visited the website an average of 15.5 times over the 6-month trial. Usage patterns of the overall website and its sections, as obtained by statistical summaries of the University of Glasgow web server, are presented in Table 7.6. On average, there were 150 hits to the website each month, with "Recipes" and "Food Safety" being the most and least visited

sections, respectively. For both the overall website and its different sections, the number of visits tended to decrease over the course of the study.

Table 7.6 Mediterranean Eating website usage patterns

Website section	Times pages accessed ^a						Actual visits/month (average)
	Jun	Jul	Aug	Sept	Oct	Nov	
Overall website	271	215	126	117	90	116	150
Recipes	270	176	130	83	81	73	135
Tip of the Day	241	125	91	67	61	2	98
Better Eating Tips	110	50	36	20	25	18	43
Better Buying Tips	104	38	26	14	24	11	36
Mediterranean Diet	79	37	25	19	16	11	31
Foods and Nutrients	80	24	30	16	16	14	30
Better Cooking Tips	80	33	23	11	15	7	28
Some Health Issues	65	38	21	17	14	10	27
Food Safety	37	16	13	5	5	0	13

^a Based on statistical summaries generated from the University of Glasgow web server

These monitoring statistical summaries generated from the University of Glasgow web server were in agreement with the self-reported website usage patterns (see Section 7.2.1.1.). The self-reported and actual frequency of visits, as well as the perceived helpfulness of the Mediterranean Eating website and the specific website sections, are presented in Table 7.7. It is shown that sections of the website that were perceived as “very helpful” by the majority of participants in the intervention group were also visited more frequently.

Table 7.7 Self-reported^a and actual^b frequency of use and perceived helpfulness^a of the Mediterranean Eating website and specific sections

Website section	Rated as “very helpful” (<i>n</i> 31)	Visited ≥ once/month (<i>n</i> 31)	Actual visits/month (average)	Actual number of visits over 6-months
Overall website	58.1%	87.2%	150	900
Recipes	61.3%	90.3%	135	810
Mediterranean diet	61.3%	51.6%	31	186
Better Eating Tips	58.1%	54.8%	43	258
Foods and Nutrients	58.1%	45.2%	30	180
Better Cooking Tips	54.8%	35.5%	28	168
Better Buying Tips	41.9%	38.7%	36	216
Some Health Issues	35.5%	35.5%	27	162
Food Safety	19.4%	19.4%	13	78

^a Based on evaluation questionnaires

^b Based on statistical summaries generated from the University of Glasgow web server

7.4. Mediterranean Eating website evaluation: Results from focus group interviews

After return of the post-test process evaluation questionnaires, participants in the intervention group were invited to attend qualitative semi-structured focus group interviews in order to evaluate the Mediterranean Eating website, as well as determine main areas of nutrition information needs.

Four interviews, lasting approximately one hour, were conducted at participants’ worksite during their lunchtime. A light lunch was provided to facilitate and encourage attendance at the interviews. Of the original sample recruited for the study (*n* 53), eighteen women participated in the focus group interviews (mean age = 39.6y). None of the participants who withdrew before the end of the 6-month intervention accepted the invitation to attend an interview.

7.4.1. Previous experience, sources sought for nutrition information and determinants of source credibility

Most participants had not actively sought nutrition information prior to the study. However, some mentioned that they had done so if they had a specific problem or when their children were young, in which case they would seek information on healthy-eating or recipes from books and magazines.

"If I came across something in a magazine I would read it but I didn't actively search information. That wouldn't be a reason for me to buy a magazine"

"If I had a specific problem, I would seek information from books"

"When you have young children you'd like them to eat properly so then healthy eating books are helpful"

Some participants had used the Internet to find nutrition information, mainly for recipes, on-line diets and healthy-eating advice.

"Mainly for diets (e-diet). On-line diets, how to lose weight 'painlessly'"

I would only search the Internet if I had a specific problem"

"I've sometimes sought the Internet for recipes"

The most often mentioned criteria to assess information credibility were websites from official authorities and provision of scientific evidence to support information.

"If it comes from a medical/nutrition Association or a University then it must be trustworthy"

"Depends on how websites support information, if they defend information with scientific evidence"

"Some sources have a disclaimer, like if you're not happy go and see your doctor first before you try something or change your eating plan"

7.4.2. Comparison of Mediterranean Eating website with other sources of nutrition information

When asked to compare the information on the Mediterranean Eating website with other sources of nutrition information, most participants mentioned that it was clearly set-up, well-organised, reliable, attractive and easy to use.

“I liked the way it was clearly set up in different sections. If you wanted to check a recipe you would go to that link. If you sought general information you would go directly to that. You could find the information you wanted more quickly rather than searching for what you want”

“I liked all the blue, Mediterranean colours. It was nice, bright and cheery”

“I liked it that it was personalised and I was welcomed by my name. Made me feel I belong”

7.4.3. Perceived qualities of the website

A summary of the major themes that emerged from the interviews, concerning the evaluation of the Mediterranean Eating website, is presented in Table 7.8.

Table 7.8 Summary of themes from focus group interviews (n 18)

Emerging themes	Typical quote
Qualities of the website	
• Updates	<p>“The ‘What’s New?’ window, it directs you to updates instead of having to look for them”</p> <p>“The updates in the recipe section were refreshing”</p>
• Layout and navigation	<p>“I like the layout and the navigation. It’s clear and intuitive, as well as attractive”</p> <p>“The structure was nice”</p>
• Way of writing	<p>“It was friendly”</p>
• Appearance	<p>“It looks great and it’s easy to use”</p> <p>“With all the pictures and attractive colours, you feel positive when you visit it, and happy”</p> <p>“I didn’t think it would be as attractive as it was. I thought it was just going to be a couple of basic pages of text...”</p>
• Information content	<p>“...well-organised and trustful. It wasn’t promoting anything. Some websites promote particular foods which makes you wonder whether someone from the food industry is behind them”</p> <p>“It had lots of information, particularly the background stuff. Although I read that once or twice, I was looking up for new recipes”</p> <p>“The recipes were useful [...] you think ‘I’ll buy this food’, instead of someone telling you ‘buy more vegetables’, without you knowing how to use them”</p> <p>“I liked the quizzes. Little tests of knowledge. I think they helped quite a lot”</p>

Table 7.8 cont.: Summary of themes from focus group interviews (n 18)

Emerging themes	Typical quote
Barriers to using the website more often	
<ul style="list-style-type: none"> Lack of time during working hours 	<p>"I usually only have time during lunch"</p> <p>"I didn't want my colleagues to see me visiting a website; they might think I'm skiving"</p>
<ul style="list-style-type: none"> Inability to access the Internet at home 	<p>"I could have visited it at home, but I don't want to do anything that reminds me of work [...] usually busy to search it as much as I'd like"</p> <p>"I don't access the web at home. And I'm away from the office during lunchtime"</p>
<ul style="list-style-type: none"> Technical/connection problems at work 	<p>"I don't have a printer at work so I had to write the recipes down"</p>
Effect on everyday food choices	
<ul style="list-style-type: none"> Limited cooking skills 	<p>"It's good if you cook more but it's difficult if you're not used to it"</p>
<ul style="list-style-type: none"> Family impact 	<p>"I didn't find that my family came along with the diet so most of the time I was on my own. And it's more impractical and difficult when you have to prepare different foods. It's best if we all eat the same meals"</p> <p>"The recipes, especially with legumes, are a little more difficult to incorporate at the moment as I have two small children who are very fussy, but I will keep persevering"</p> <p>"It's difficult with the rest of the family, like when my children's friends visit and they ask for the crisps"</p> <p>"I realised that my kids actually like pulses"</p> <p>"My husband liked some of the recipes so that made it easier"</p> <p>"I cooked for my friends [...] we had more dishes based on vegetables and they enjoyed it and were interested in the diet"</p> <p>"It was nice trying to cook things we haven't tried before"</p>

Table 7.8 cont.: Summary of themes from focus group interviews (n 18)

Emerging themes	Typical quote
Effect on everyday food choices	
<ul style="list-style-type: none"> Eating out 	<p>"Mostly affected my choices at home. [...] still problematic to stick to what you should eat when you go out"</p> <p>"It's difficult at lunchtime [...] the food in canteens is rubbish. It's difficult to find something that doesn't have mayonnaise in it. If I'm organized I would bring food from home but that didn't always happen"</p> <p>"When I eat out, I usually have a curry and it's not very easy to find healthy Indian food"</p> <p>"I have been enjoying the recipes and the project has certainly made me think more - especially when I'm eating out"</p> <p>"It made me think when I ate out and try to go for vegetable dishes and tomato sauces instead of cream"</p> <p>"I think it has made me more aware of the importance of taking care not to overdo the good things in life and even when I do too much of something at least I am aware of it and can take steps to rectify it"</p>
Attitudes towards different website sections	
<ul style="list-style-type: none"> Most interesting sections 	<p>"I would go back especially for the recipes and occasionally for the general information or more specific information e.g. how to use herbs"</p> <p>"Everything that got updated and changed, like the recipes and the eating tips was more interesting"</p> <p>"The Food Safety should be there in case someone was a first-time-cook"</p> <p>"I liked the Foods and Nutrients section although I didn't visit it as often as the recipes"</p> <p>"The Health Issues were also interesting, especially the parts on weight control and physical activity"</p> <p>"The seasonal fruit and vegetables were very useful for what to buy when and how to categorise them. Since you can find anything in the supermarket these days all year round, it's nice to know what actually is in season"</p> <p>"When the study started I went and read through everything on the website but I didn't go back to the Foods and Nutrients and the Mediterranean Diet section. I sometimes used the Better Buying Tips but I mainly went back for the Recipes"</p>

Table 7.8 cont.: Summary of themes from focus group interviews (n 18)

Emerging themes	Typical quote
Attitudes towards different website sections	
<ul style="list-style-type: none"> Less/least interesting sections 	<p>"I read the theoretical part once the first week or two and then didn't go back"</p> <p>"I just visited Some Health Issues once and didn't go back. It's easy to be skipped. It could have more links to other websites with more expansive information"</p> <p>"[...] Food Safety. It could be more extensive, with links to Environmental Health guidelines [...] covered the surface of issues"</p> <p>"The Food Safety wasn't really necessary; it made the website look more 'educational' and you don't want that"</p>
<ul style="list-style-type: none"> Bulletin board 	<p>"The web-board was an interesting idea but I didn't like that I had to search for it. It would be nice to find out what people thought of some of the recipes"</p>

Features of the Mediterranean Eating website considered particularly helpful were the relatively regular, highlighted updates; easiness of finding specific information (layout and navigation); friendly and trustworthy writing; bright and happy appearance; theoretical background information (e.g. food groups); novelty and easiness of recipes; and inclusion of self-test knowledge quizzes (Table 7.8).

7.4.4. Barriers to using the website more often

Several barriers to using the website emerged from the interviews, as presented in Table 7.8. The most often mentioned barriers were lack of time during working hours; inability to access the Internet at home; and occasional lack of Internet access or technical problems at work. In particular, some participants mentioned they did not want their colleagues to see them visit a website during working hours.

7.4.5. Effect of the website on everyday food choices

Some participants thought that the information provided was not enough for people who have minimal cooking skills, while participants with young children mentioned having difficulties incorporating recipes in their everyday lives (Table 7.8). For others, however, family encouragement made incorporating new foods easier. In addition, although keeping to healthy eating when eating out was difficult for some participants, most found that the information on the website helped them try to make healthier choices.

7.4.6. Attitudes towards Mediterranean Eating website sections

Most participants thought the “Recipes”, “Foods and Nutrients” and “Better Buying Tips” were the most interesting sections of the website, whereas the “Food Safety” section was perceived as the least interesting. Generally, sections that were regularly updated were perceived as being the most interesting, whereas sections that mainly contained theoretical information were more likely to be considered less interesting. Although the website bulletin board was thought to be an interesting idea, most participants recommended that easier access to it would have increased its use (Table 7.8).

7.4.7. Perceived features that would improve the website

Several themes emerged concerning features that would improve the website, as presented in Table 7.9. Some participants mentioned that more prompting to visit the website would have been desirable. Some participants also would have preferred some of the information on food choices to appear permanently on the website instead of as updates or for the updates to be more regular. In addition, discussions highlighted how additional features could enhance the usefulness of such a website. In particular, participants would have liked the website to include links to other trustworthy websites for more extensive information and recipes, as well as more links between the different sections, which would prompt visits to other sections of the site. Most participants also mentioned that a seasonal ingredient/recipe search index and inclusion of nutritional information and fruit and vegetable serving content of recipes, as well as a site-map, would be helpful. In addition, suggestions for people who are dieting, more information and tips on physical activity/weight control and weekly prompts on buying tips before weekend shopping and suggestions of weekly meal planners would be additional useful features. More interactive features, such as dietary assessment quizzes that would provide support during the study and raise awareness of dietary intake would be particularly welcomed, as would tips on places to find healthier food choices (e.g. restaurants, around campus etc.) and more background information on Mediterranean traditions and foods eaten on special occasions.

Table 7.9 Features that would improve the website- summary from focus group interviews (n 18)

Emerging themes	Typical quote
Visit prompts	<p>"The website prompted you to go in; but more prompting would be desirable"</p> <p>"More e-mails reminding there are new updates would be helpful"</p>
Up-to-date information	<p>"More updates would be useful"</p> <p>"I liked the Recipe section. [...] instead of having to wait for the next updates, I wished I could have them all at once"</p> <p>"Updates in the Foods and Nutrients section too. You can't absorb all the information at once and you can easily forget the information you read at the beginning"</p> <p>"Updates in theoretical information wouldn't be useful because we might miss something we need answered immediately"</p>
External links	<p>"[...] links to other credible websites, like on exercise and chronic disease or food"</p> <p>"[...] links to other websites, on the basis of 'here is an example of a Mediterranean-style dish from this website...' "</p>
Internal links between sections	<p>"The recipes could have links to other sections [...]. I tend to go to the practical parts first"</p> <p>"The Tip of the Day [...] you had to remember and have a look. Can they automatically pop up when you go in the Recipes?"</p> <p>"How to make informed choices when eating out. Make that more obvious"</p> <p>"Make the 'less used' areas more obvious"</p> <p>"I would have liked easier access to the web-board and the food questionnaires. They weren't completely sign-posted"</p> <p>"The navigation could have been better. Especially with the recipes"</p> <p>"It would save time if you didn't have to go through so many channels to find something. Just click once and be able to access everything from one main page"</p> <p>"A site map would be useful to find what you're looking for immediately"</p>

Table 7.9 cont.: Features that would improve the website- summary from focus group interviews (n 18)

Emerging themes	Typical quote
Recipe features	<p>“A search index for the recipes [..], where you would put the key ingredients you want and all the relevant recipes would come out”</p> <p>“Listing the information by starters/main dishes/sweets/snacks rather than by month [..]. It took a while to navigate [..]”</p> <p>“Why this recipe is good for you: it contains this food, which contains this nutrient [..] this many portions of fruit and veg...”</p> <p>“Portion sizes are still confusing. Could you put specific information on different types of vegetables? [..] how many portions are there in 1 carrot? How do you count portions if vegetables are in a sauce?”</p>
Eating/buying tips features	<p>“It would be helpful if there was a weekly prompt, before the weekend shopping, on advice on what to buy for the week”</p> <p>“[..] weekly menus with combination of the recipes [..] maybe for losing weight. Many people might have done this more as a losing weight than healthy eating pattern and it might be good to combine these two. [..] people go to websites like this more for losing weight”</p> <p>“Make suggestions like ‘if you want an energy boost, have a salad’ [..] food has a really big impact on how you’re feeling and what you’re doing [..] this might encourage us more to eat a healthy diet”</p> <p>“[..] suggestions of restaurants with addresses instead of us having to search for healthy options”</p>
Health issues	<p>“More suggestions on physical activity, like if you eat a chocolate bar or a ready-made meal it will give you this amount of calories, fat etc. and it will take you ... minutes/hours of doing a certain exercise to work it off”</p> <p>“Some of the recipes were really tasty and because you know they’re healthy you think that you can eat some more. So it would be helpful to say ‘If you want to lose weight, here are some suggestions’”</p> <p>“[..] information on how the Atkins diet and any kind of diet compares to the Mediterranean diet”</p>
Food-related traditions	<p>“[..] know where the recipes came from, which part of the country. It helps to set that recipe somewhere in your head”</p> <p>“[..] more information on traditions and festivals. Like, foods eaten at specific times of the year and why that is”</p>
Interactivity	<p>“[..] small exercises, like food diaries, just to keep you aware of what you eat [..] with interactive feedback and comments on your faults and goods like, ‘Oops, you should eat more...’ [..] also print this feedback [..] feels like somebody cares for you [..] you’re not on your own”</p>

7.4.8. Encouragement provided through the website over the study course

The majority of participants thought the information provided through the Mediterranean Eating website was encouraging and that the reminder e-mails to visit the website were useful. However, some participants mentioned that more prompting to visit the website would have been desirable.

"I love getting your e mails - they make me more determined to try harder - maybe it's just guilt that I don't always try as hard as I should"

"The encouragement was very good throughout the study but the website needed more information, especially on snacks/sandwiches, foods to choose at lunchtime. Definitely more snacking"

"To be honest I don't feel as if I have changed anything much by way of my diet. I did think there would be more ongoing encouragement and prompting, follow up etc. on a regular basis which hasn't been the case. Unfortunately the 'push' I've needed hasn't been there"

7.4.9. General participant comments

Some participants recommended that this Internet intervention should form part of a health promotion programme in the University of Glasgow, in association with food suppliers and canteens, where all employees would be prompted to visit the website on a weekly basis and encouraged to make healthier food choices.

"It would be a good idea if this was the start of a University's health promotion programme. Where there would be prompts for all employees to visit the website weekly. In association with healthier food choices, including legumes, in the University canteens and restaurants"

7.5. Summary

Compared with participants in the control group, participants in the intervention group were more positive about the nutrition education materials they accessed (website), with the majority finding them extremely interesting, informative, useful, attractive, encouraging, time saving, helpful and not limited in information. In addition, a higher proportion of participants in the intervention, compared with the control, group felt extremely satisfied with the nutrition education materials they

accessed, and the majority reported visiting the website once per month or more. Sections that were updated regularly during the 6-month trial were reported to have received more visits. In addition, lack of time was the most often reported barriers to using the website weekly, as recommended. Although the majority of participants in the control group reported that the information in the brochures/booklets caught their attention, use of these materials was generally low.

There were no differences in use or appreciation of the feedback letters between the intervention and control groups. A higher proportion of participants in the control group found the letters not to be attractive in appearance. However, they also reported intending to read the feedback letters again in the future. Perceived impact of the feedback letters was higher in the intervention group, with more participants reporting having changed their diets as a result of the feedback letters they received.

Participants visited the website an average of 15.5 times over the 6-month trial. On average, there were 150 hits to the website each month and there was general agreement between frequency of use and perceived helpfulness for different sections of the website. For both the overall website and its different sections, the number of visits tended to decrease over the course of the study.

The focus group interviews showed that source credibility and provision of scientific evidence to support information were important criteria to assess a website's trustworthiness. The Mediterranean Eating website was generally well accepted and was considered well-organised, easy to use, novel, attractive, friendly, encouraging and trustworthy. In addition, several features that would improve such an application, such as increased interactivity, nutritional analysis and fruit and vegetable serving content of recipes, more regular updates and more prompting to visit the site, were identified from the interviews and will inform future refinements of the website.

8 Discussion

8.1. Overview

The Seven Countries study was the first study to raise interest in the health-promoting benefits of the Mediterranean diet, due to the low overall and coronary heart disease mortality rates and high life expectancies demonstrated by people living in Greece and southern Italy, compared with northern Europe and the United States (Keys, 1970). In recent years, a number of researchers have used the Mediterranean diet recommendations as the nutritional basis of tertiary (de Lorgeril *et al.* 1994; Singh *et al.* 2002b) and secondary (Esposito *et al.* 2004) interventions and shown that this eating pattern can be successfully adopted by patients who are motivated to change their diet. Similar to an earlier primary prevention study promoting the Mediterranean diet to healthy women (Goulet *et al.* 2003), the MESE study showed that this eating pattern is also transferable to healthy, free-living women living in a non-Mediterranean country. Internet education and tailored dietary and psychosocial feedback led to more favourable dietary changes towards the traditional Mediterranean diet at 6 months, compared with general healthy-eating information and minimally-tailored dietary feedback. Moreover, these favourable changes were maintained during the 3-month follow-up. The dietary changes displayed by the intervention group were reflected in blood lipid profiles, indicating the health benefits of a Mediterranean-style diet, while additional favourable effects in nutrition knowledge, stages of dietary behaviour change and psychosocial determinants of dietary behaviour were found. In addition, the significant differences for the majority of outcomes identified in the “per protocol” analysis were not attenuated to any great degree by the “intention-to-treat” analysis, providing further evidence of the strength of these findings. Overall, the MESE study suggests that step-wise dietary changes towards the Mediterranean diet can be achieved by a northern European population.

8.2. Dietary behaviour

Previous studies examining the effect of tailored dietary and psychosocial feedback on dietary behaviour have focused mainly on fat and/or fruit and vegetable intake. To our knowledge, this is the first study to investigate the combined effect of a healthy-eating website, in the context of the traditional Mediterranean diet, and tailored dietary and psychosocial feedback delivered via electronic mail, on dietary behaviour change. In addition, this is the first web-based, tailored-

feedback intervention study to promote consumption of legumes, as well as a combination of increased intake of monounsaturated and decreased intake of saturated fat.

8.2.1. Vegetables and fruits, nuts and seeds

At the end of the 6-month intervention, participants in the intervention group had increased their mean vegetable intake by 0.5 servings per day⁴, while an increase of 0.4 servings of fruits per day was also found. Not only were these changes sustained after the intervention but by the end of the 3-month follow-up, participants in the intervention group had increased their mean vegetable intake by 0.9 servings overall. At both 6 and 9 months, mean fruit intake in the intervention group was higher than the median intake of 216 g/d observed in elderly Greek women (Trichopoulou *et al.* 1995b). In addition and based on intention-to-treat analyses, higher increases in fruit and vegetable intake were reported in the intervention, compared with the control, group, confirming our hypothesis that an Internet-based, tailored-feedback intervention would result in more favourable dietary changes compared with general nutrition information and minimally-tailored dietary feedback.

Participants in the intervention group in the MESE study achieved greater increases in the mean daily consumption of both vegetables and fruits compared with employees of an oil company who received computer-generated feedback letters tailored to their dietary behaviour, attitudes, perceived social influences, self-efficacy expectations and awareness levels (Brug *et al.* 1996). This study reported an increase of 0.04 daily servings of vegetables and 0.08 daily servings of fruit. Participants in the control group receiving general nutrition information did not make significant changes to their vegetable and fruit consumption and there were no significant differences observed between the two groups (Brug *et al.* 1996). In another study conducted by Brug *et al.* (1999b), it was found that providing tailored dietary feedback in a work-based setting led to an increase of 0.4 servings in the intake of fruit, which is consistent with our findings, and a decrease of 0.07 servings in vegetable intake. The MESE project also reported greater changes in mean combined vegetable and fruit consumption compared with studies employing tailored dietary and psychosocial feedback and involving primary care adult patients (-0.3 servings/d) (Campbell *et al.* 1994) and volunteers (+0.37 servings/d) (Brug *et al.* 1998). In addition, the present study reported more favourable changes compared with studies using a web-based program to provide interactive tailored feedback (+0.2 servings/d) (Oenema *et al.* 2005), as well as using interactive feedback along with phone counselling (+0.4 servings/d) (Stevens *et al.* 2002). Further, the MESE study reported similar changes in fruit and vegetable intake with studies employing tailored dietary and psychosocial feedback (+1.1. servings/d) (Delichatsios *et al.* 2001b) and using an interactive, telephone voice

⁴ Based on an 80g portion of fruits or vegetables.

system to provide tailored feedback (+1.1. servings/d) (Delichatsios *et al.* 2001a) in order to promote a Mediterranean-style diet.

A study by Siero *et al.* (2000) compared the impact of group education, group education plus tailored dietary and psychosocial feedback and general nutrition information on dietary changes towards the Mediterranean diet, with a particular focus on fish, fruit and vegetable consumption. It was reported that after 4 months, participants in the group education and tailored feedback group had increased their fruit and vegetable intake by almost one serving, which is similar to our findings. Compared to group education, the addition of tailored feedback led to an increase in fruit and vegetable intake that was in the desired direction, although not statistically significant. Tailored feedback as part of a multi-component intervention was also more effective in increasing intake of this food component, compared with general nutrition information, which is consistent with the present study.

The present study also showed that forward progress through the stages of behaviour change is a mediator of the favourable dietary changes in fruit and vegetable intake. Participants in the intervention group who had achieved a forward stage of dietary behavioural transition regarding vegetables and fruits over the study course, generally increased their intake of these food components more than participants in the intervention group who had not achieved a forward stage of transition. This finding underpins the potential benefits of providing appropriate stage-matched tailored nutrition education, in order to promote forward transition through the stages of dietary behaviour change, which is likely to lead to dietary changes.

Although the baseline fruit and vegetable consumption of participants in the MESE study was higher than the baseline consumption reported in most previous studies, the increase we observed in mean intake of these food components was also higher. In addition, the intervention period in the present study was longer than in a similar study using a web-based, tailored-feedback intervention (Oenema *et al.* 2005), as well as several earlier tailored-feedback nutrition interventions (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1999b), which might have allowed our participants more time to make changes in their intake of all food components promoted by the study, including fruit and vegetables. These findings suggest that Internet technology enhances the positive effect of tailored feedback, with a potentially more beneficial impact when sufficient time is allowed for dietary behaviour change to take place.

Another possible explanation for the greater effect of the intervention employed in the MESE study on vegetable and fruit intake, compared with previous research, might derive from the manual procedure employed to tailor feedback messages. It is noteworthy that the majority of studies to date have used computer programs in order to generate tailored dietary and/or psychosocial

feedback. In these cases, a computer is programmed to read responses provided to a tailoring questionnaire and automatically generate individualised feedback messages, based on these responses (Brug, 1999). The results of the MESE study therefore, cannot be directly compared with these earlier studies, as feedback e-mail letters in the MESE study were tailored manually and, while more time consuming, may have provided more individualised feedback messages than computer-generated messages. However, tailoring feedback messages manually cannot be sustained in the long-term, particularly when larger population samples are involved. It will be necessary therefore, for future studies to sacrifice possibly some of the favourable changes associated with manually-generated feedback in favour of a more sustainable intervention.

Siero *et al.* (2000) note that the public has already been exposed to campaigns promoting fruit and vegetable consumption and therefore, dietary changes in these food components might be harder to achieve. In addition, a potential limitation of intervention studies is that participants, prompted by the intervention, may access other sources of relevant information, which could affect the outcome of interest (Lanza *et al.* 2001; Eysenbach, 2002; Napolitano *et al.* 2003). In the MESE study, it was assumed that both the intervention and control groups had the same prospect of accessing external to the study sources of nutrition information, since it is difficult to account for this factor and the majority of participants in both groups were highly-educated and relatively motivated women. However, mean intake of fruits and vegetables increased only in the intervention group, suggesting that combined Internet nutrition education and tailored dietary and psychosocial feedback is an effective method of promoting fruit and vegetable consumption.

Another factor that has been suggested to be responsible for the lack of effect on fruit and vegetable intake in earlier computer-tailored nutrition intervention studies is seasonal variation (Campbell *et al.* 1994). In the MESE study, baseline intake for participants in the intervention and control groups was recorded in late spring and early summer months, respectively and immediate post-intervention intake was recorded in early and mid-winter, respectively. It is therefore possible that participants in the control group had seasonally adjusted their mean fruit and vegetable intake by the immediate post-intervention assessment. This seasonal trend for participants in the control arm of an intervention study has been noted before (Havas *et al.* 2003). Similar to the study by Havas *et al.* (2003) however, participants in our intervention group overcame the barrier of seasonality, showing increased intake of fruits and vegetables at the immediate post-intervention assessment and additionally maintaining an increased intake by the early spring follow-up assessment.

Some of the earlier tailored-feedback intervention studies promoting fruit and vegetables as a combined goal have found that changes are usually seen, or are greater, in fruit, compared with vegetable intake (Brug *et al.* 1999b; Baker & Wardle, 2002; Campbell *et al.* 2002). An important finding of the MESE project however, is that at 6 months, participants in the intervention group

achieved significant increases in both fruit and vegetable intake, which were also maintained at the 3-month follow-up. It was therefore considered a strength of the present study that fruits and vegetables were promoted as two different goals and were assessed separately, since these foods have different nutritional properties. In addition, it has been previously reported that there are more low-vegetable than low-fruit consumers (Trichopoulou, 2000). This study supports the hypothesis of Trichopoulou (2000) that the efficiency of strategies promoting fruit and vegetable consumption would probably increase if these components were promoted separately.

8.2.2. Legumes

Most interventions promoting healthy eating to free-living individuals focus on increasing intake of fruits and vegetables and decreasing total and saturated fat intake, but the number of interventions suggesting a regular consumption of legumes is limited (Leterme, 2002) and mainly involves tertiary prevention trials (Renaud *et al.* 1995; Singh *et al.* 2002b). In addition, it is usual practice in the United Kingdom and the United States for legumes to be included in the fruit and vegetable category (Block *et al.* 1986; Williams, 1995). Legumes however, have always formed an important part of the traditional Mediterranean diet and were consumed frequently and independently of vegetables (Trichopoulou *et al.* 1995b; Kafatos *et al.* 2000). In the traditional diet of Crete for example, legumes were consumed four times per week (Kafatos *et al.* 2000). Such frequency of legume consumption has been associated with a significant 22% reduction in risk of coronary heart disease and 11% reduction in risk of cardiovascular disease (Bazzano *et al.* 2001). In addition, a recent study showed that legumes are the most important predictor of survival among older people, with a 7-8% reduction in mortality risk for every 20g increase in daily intake (Darmadi-Blackberry *et al.* 2004).

To our knowledge, the MESE project was the first web-based, tailored-feedback intervention study to promote consumption of legumes, as a separate component of a healthy diet. In addition, previous studies providing tailored feedback as part of a multi-component intervention to promote the Mediterranean diet have either focused on increasing consumption of fish, fruits and vegetables (Siero *et al.* 2000) or have not made any specific report on legume intake (Bemelmans *et al.* 2000). The present study reported a significant increase in mean legume intake among participants in the intervention group at 6 months, a change that was sustained at the 3-month follow-up evaluation. These findings suggest that the provision of Internet nutrition education and tailored dietary and psychosocial feedback, with a step-wise approach to dietary change, is an effective method of promoting the consumption of legumes, to individuals who might not be so familiar with this food component. Considering the potential health promoting benefits of legumes (Messina, 1999; Bazzano *et al.* 2001; Darmadi-Blackberry *et al.* 2004), the importance for dietary intervention

studies to promote legume consumption as part of a healthy diet, independently of vegetable consumption, should be well emphasised.

The personalised, minimally-tailored feedback letters sent to participants in the control group included suggestions on how to eat more vegetables, fruits and legumes, as well as advice on how to increase the MUFA:SFA ratio in their diet. This might have accounted for the dietary changes towards the Mediterranean diet made by the control group, particularly the significant increases in legume consumption and mean total MDS from baseline to the end of the 6-month intervention. It has been suggested that the provision of minimally-tailored feedback would be sufficient to promote behaviour change, if it is personalised (Lennox *et al.* 2001), and that even completing a questionnaire on a particular behaviour may increase interest in changing that behaviour (Kreuter & Strecher, 1996; Block *et al.* 2004). In addition, the general public has been widely exposed to campaigns promoting increased fruit and vegetable and decreased fat consumption (Siero *et al.* 2000). Therefore, the significant increase in mean legume intake displayed by the control group might have resulted from the novelty of this particular intervention.

8.2.3. MUFA:SFA ratio

At the end of the 6-month intervention, participants in the intervention group had increased the mean MUFA:SFA ratio in their diet to 1.79, well above the median intake of 1.6 observed in the group of elderly Greeks consuming a traditional Greek diet (Trichopoulou *et al.* 1995b). Not only was this change sustained after the intervention but by the end of the 3-month follow-up, participants in the intervention group had increased their mean intake to 1.86. This favourable increase has likely resulted from an increase in intake of olive oil and/or foods high in monounsaturated fat (e.g. monounsaturated fat-based margarines), since only slight actual dietary changes in other foods contributing to fat intake (e.g. meat, dairy products) were observed in this group.

Previous research has reported decreases in total fat and saturated fat intake after providing participants with tailored dietary and psychosocial feedback on fat and/or saturated fat consumption (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1998; Brug *et al.* 1999b). Direct comparisons regarding fat intake cannot be made, however, since the present study focused on increasing the MUFA:SFA ratio in the diet and not decreasing total and/or saturated fat intake. In addition, this is the first web-based, tailored-feedback intervention study to promote a combination of increased intake of monounsaturated and decreased intake of saturated fat. Considering that olive oil has been the principal source of dietary fat in the traditional Mediterranean diet, with no documented adverse effects (Keys, 1995; Willett *et al.* 1995), there is great potential for such studies to promote the

substitution of saturated fat for monounsaturated oils and fats in the diet, with a focus on olive oil in particular.

8.2.4. Mediterranean Diet Score

The favourable dietary changes made by participants in the intervention group resulted in a significant increase in the mean total Mediterranean Diet Score at 6 months, a change that was sustained at the end of the 3-month follow-up evaluation. In addition, a higher proportion of participants in this group had mean vegetable, legume, and MUFA:SFA ratio intake that was equal or higher than the relevant median intake observed in elderly Greek women (Trichopoulou *et al.* 1995b) at 6 and/or 9 months, compared with baseline. This finding is important, as it suggests that the MESE project was successful in promoting the Mediterranean diet and particularly the consumption of food components that are not so regularly tackled in nutrition intervention studies, or for which dietary changes are not so often reported.

Several studies have used adaptations of the original Mediterranean Diet Score proposed by Trichopoulou *et al.* (1995b) and found significant inverse associations with overall mortality (Osler & Schroll, 1997; Lasheras *et al.* 2000; Trichopoulou *et al.* 2003; Knoop *et al.* 2004). In a recent cohort study, the Mediterranean Diet Score was adapted to account for the minimal consumption of monounsaturated fat from olive oil reported in non-Mediterranean populations, by substituting monounsaturated fat (as the numerator of the MUFA:SFA ratio) with the sum of monounsaturated and polyunsaturated fat in the diet (Trichopoulou *et al.* 2005b). This study also reported that increases in the modified score were significantly associated with lower overall mortality and increased survival among healthy older people. These findings suggest that the Mediterranean diet can be adapted to take into account cultural differences regarding dietary habits and that a Mediterranean-style diet is just as likely to have a beneficial impact on health, as the traditional dietary pattern of the 1960s.

Several unfavourable changes were reported among participants in the intervention group for components of the Mediterranean diet not specifically promoted by the study (i.e. they were not promoted as Mediterranean goals). Thus, although mean intake of meat/meat products and milk/milk products increased and mean intake of cereals decreased over the study course, these changes would unlikely be of clinical significance, since intake of these components was still relatively close to the median intakes observed in elderly women consuming a traditional Greek diet (Trichopoulou *et al.* 1995b).

The time frame of the MESE study did not permit the focused promotion of more components of the Mediterranean diet. The inclusion of additional goals related, for example, to cereal, meat and dairy product intake would have either increased the duration of the intervention from 6 months to almost 12 months, or reduced the length of time that participants had to attempt and achieve their goals. This study adopted a step-wise approach and a 6-week period was considered to be appropriate for tackling a single Mediterranean goal, in order to encourage gradual and sustained dietary change, therefore allowing the promotion of only four components of the Mediterranean diet in the 6-month intervention period. Although a longer intervention would allow the more extensive focus on all eight components of the Mediterranean diet, such an intervention would probably not be sustainable from a participant's perspective, resulting in increased attrition rates. However, since earlier successful studies promoting dietary changes in more than one food component have employed shorter intervention periods (Kristal *et al.* 2000; Siero *et al.* 2000; Calfas *et al.* 2002; Havas *et al.* 2003), future applications of the MESE project could include the promotion of other components of the Mediterranean diet by reducing the time assigned to tackle each goal to 4 weeks. This might also result in a more favourable post-intervention effect on the total MDS for participants in the intervention group.

The procedure of asking and encouraging participants in the intervention group to make dietary changes, instead of just providing dietary feedback and behaviour change strategies might have contributed to the favourable effects observed. Raats *et al.* (1999) for example, noted this factor as a possible reason for the lack of effect of their intervention on fat reduction, where participants in the intervention group were provided with tailored dietary feedback but were not asked to make changes to their fat intake.

Participants in the intervention group in the MESE study might also have been more successful in making favourable dietary changes in all food components promoted by the study, compared with earlier research, because of the relatively short time span between each dietary assessment and the provision of feedback based on that assessment. Excluding studies providing immediate, interactive feedback, the majority of computer-tailored nutrition interventions to date have distributed feedback messages not earlier than two to four weeks following assessment, and in two studies where feedback messages were tailored manually, these were distributed to participants at two (De Bourdeaudhuij & Brug, 2000) and six (De Bourdeaudhuij *et al.* 2002) weeks after assessment completion. As the time span between completion of an assessment instrument and feedback delivery based on the answers provided increases however, the likelihood that this feedback is accurate and relevant decreases, since the assessed variables of interest might change (Campbell *et al.* 1999; Oenema *et al.* 2001; Brug *et al.* 2003). Therefore, it is important for the time between assessment and feedback delivery to be as short as possible. Despite the manual tailoring procedure

employed by the present study, tailored feedback letters were e-mailed to participants within one week of dietary assessment, and often within one to three days, which might have increased feedback relevance and led to favourable changes in the food components promoted by the study.

In addition, participants in the intervention group were allowed to choose the order in which they would tackle their Mediterranean goals and focused on a single goal at a time. Although Vandelanotte *et al.* (2005) showed that intervening on different behaviours can be effective when done simultaneously as well as sequentially, research has shown that changing more than one behaviour simultaneously might be difficult to accomplish. It is suggested that tackling one behaviour at a time prevents information overload, which will in turn help achieve behaviour change (Emmons *et al.* 1994; Strecher *et al.* 2002). Participants in the intervention group in the present study were also encouraged to set their own sub-goals for dietary behaviour change, in order to achieve the median intake observed in elderly women consuming a traditional Greek diet (Trichopoulou *et al.* 1995b). Although in an earlier study, the combination of tailored dietary and psychosocial feedback and goal setting did not prove more effective in promoting the consumption of five daily portions of fruits and vegetables than provision of tailored feedback without goal setting (Lutz *et al.* 1999), setting goals to achieve dietary behaviour change is generally considered an important component of nutrition interventions (Winett *et al.* 1999; Block *et al.* 2004). In addition, setting specific goals and sub-goals is suggested to be more effective in promoting behaviour change compared with setting general, non-quantitative goals (Strecher *et al.* 1995). Participants in the MESE study were encouraged to set sub-goals, in order to make gradual, small changes to their diet and reach each Mediterranean goal, but no attempt was made to assess whether in fact participants set themselves sub-goals. In a future application of the MESE project, it would be interesting to examine individual processes of goal setting and their impact on dietary behaviour change.

Finally, the need for nutrition intervention programmes to promote gradual, step-wise dietary changes should not be underestimated. As Block *et al.* (2004) comment, 'we cannot expect people to make wholesale changes in their behaviour, and they may fear to undertake any change if they believe it will be too difficult'. Similar to this earlier study, which used an interactive CD-ROM to promote an increase in fruit and vegetable intake, by offering easy tips to move participants towards their dietary goals (Block *et al.* 2004), the MESE project offered easy, practical advice on dietary change and participants were encouraged to make gradual changes to their eating habits.

Although the results on dietary behaviour change from the MESE study are promising, the sample consisted of a self-selected group of relatively well-educated women, who might have been more motivated to make dietary changes than average members of the general public. Using a quasi-experimental design, instead of randomising the two Universities into the intervention and control

groups, might also have led to selection bias, with women with already healthy diets being over-recruited. It is noteworthy that participants in this study had, at baseline, a more favourable average daily consumption of the four components of the Mediterranean diet the study promoted compared with the Scottish average intakes (The Office for National Statistics, 2002). However, their intakes were still lower compared with the median intakes of elderly Greek women consuming a traditional Greek diet (Trichopoulou *et al.* 1995b), as presented in Table 8.1. In addition, no major statistically significant differences in baseline dietary intake were observed between the intervention and control groups. Therefore, although it is difficult to generalise to the Scottish population, these findings should apply to Scottish women with dietary intakes not meeting recommendations.

Table 8.1 Daily intake of the eight components of the Mediterranean diet for participants in the MESE project, elderly Greeks and Scottish adults

Food component	MESE project ^a		Elderly Greeks ^b	Scottish adults ^c
	Intervention (n 53)	Control (n 19)	Women (n 91)	Women (n 66)
Vegetables (g/d) ^d	172.2	191.3	248.0	79.0
Fruits, nuts and seeds (g/d)	200.2	236.7	216.0	139.0
Legumes (g/d)	15.9	22.6	49.0	2.0
MUFA:SFA ratio (/d)	1.47	1.48	1.6	0.8
Cereals (g/d) ^e	251.3	213.3	248.0	278.0
Meat and meat products (g/d)	89.6	94.5	91.0	102.0
Milk and dairy products (g/d)	231.1	209.7	194.0	164.0
Alcohol (g/d)	17.8	18.0	0.0	10.4

^a Baseline mean intake, adjusted to 8368 kJ (2000 kcal)

^b Median intake, adjusted to 8368 kJ (2000 kcal) for women (Trichopoulou *et al.* 1995b)

^c Median intake of women (consumers, aged 19-64y) who participated in the National Diet and Nutrition Survey of British Adults (The Office for National Statistics, 2002)

^d Excludes potatoes

^e Includes cereals, potatoes and bread

A further limitation of this study is that it is difficult to isolate effects achieved from the two components of the intervention. Therefore, it cannot be clearly determined whether it was the Mediterranean Eating website or the theory-based, step-wise behaviour change approach with tailored dietary and psychosocial feedback, or the combination of the two approaches that were associated with the dietary changes in the intervention group. Previous studies have found usage of interactive programs to be associated with favourable changes in consumption of fruits and vegetables (Anderson *et al.* 2001), in addition to saturated fat and fibre intake (Delichatsios *et al.* 2001a). Website login frequency in the present study was not associated with dietary changes at the

end of the 6-month intervention. If frequency of website visits had remained high or increased over the study course, perhaps this variable would have been related to dietary changes and the Mediterranean Eating website, as an autonomous intervention, would be successful in promoting dietary change. However, attempting to associate login frequency with dietary change cannot account for participants who might have used the website once, printed information to read at a time convenient for them and still made changes to their diets. Nevertheless, it appears that the favourable dietary changes made by participants in the intervention group were the result of the combined exposure to the Mediterranean Eating website and tailored dietary and psychosocial feedback.

8.3. Anthropometric, blood pressure and biochemical measurements

In order to overcome the possibility of response bias, resulting from self-reported data (Campbell *et al.* 1994; Hunt *et al.* 2001), anthropometric, blood pressure and biochemical markers were assessed. This is a strength of the MESE project over earlier research, since the majority of web-based and/or tailored nutrition interventions to date have not conducted such impact evaluation measurements.

The hypothesis that participants in the intervention group would have more favourable blood lipid profiles at the end of the 6-month intervention period, compared with participants in the control group, was confirmed. At the end of the 6-month intervention, as well as the 3-month post-intervention follow-up assessment, participants in the intervention group showed a higher increase in HDL-cholesterol levels and a greater decrease in the ratio of total:HDL-cholesterol than participants in the control group. This finding is consistent with an earlier study promoting the Mediterranean diet by means of a multi-component intervention that included tailored feedback (Bemelmans *et al.* 2002). In contrast to two earlier multi-component intervention studies that reported decreases in total cholesterol levels among participants in the intervention group following interactive tailored feedback, individual counselling and self-help materials (Glasgow *et al.* 1997) and interactive tailored feedback and telephone contacts (Stevens *et al.* 2003) however, the present study did not have any significant post-intervention impact on total cholesterol. Plasma cholesterol is suggested to be an effective biomarker of a low saturated fat intake (Lanza *et al.* 2001). The lack of effect on total cholesterol levels in this study might have therefore resulted from the different outcomes of the present study, i.e. the focus on increasing the MUFA:SFA ratio instead of reducing total fat and/or saturated fat intake. Thus, although total cholesterol levels significantly increased following the post-intervention evaluation and were higher at 9 months, compared with baseline, the ratio of total:HDL-cholesterol remained favourable over the entire study course. As this measure has been suggested to be a better predictor of coronary heart disease risk status than total cholesterol

levels (Kinosian *et al.* 1994), the present intervention programme can be considered effective in promoting a cardio-protective diet to a non-Mediterranean population.

The hypothesis that no adverse effects would be observed in anthropometric and blood pressure measurements was also confirmed. No between group differences were observed in these variables, a finding consistent with the majority of earlier studies assessing body weight for impact evaluation (Glasgow *et al.* 1997; Kristal *et al.* 2000; Campbell *et al.* 2002; Stevens *et al.* 2003). Only one study using tailored feedback as part of a multi-component intervention to promote the Mediterranean diet reported decreases in BMI at the post-intervention assessment of 16 weeks, but this change was not maintained at follow-up assessments of one, two or three years (Bemelmans *et al.* 2000; Bemelmans *et al.* 2002; Bemelmans *et al.* 2004).

While the Mediterranean Eating website offered some advice on physical activity and body weight control, the MESE study did not actively promote weight loss. Nevertheless, it is noteworthy that although the study did not promote a decrease in fat intake, but substitution with olive oil of other fats and oils (in moderation) and low intake of meat and meat products, no weight increases were observed in participants in the intervention group. In addition, within group comparisons showed that participants in the intervention group had decreased systolic and diastolic blood pressure at 6 and 9 months, compared with baseline, possibly reflecting their increased intake of potassium-rich fruits, vegetables and legumes.

The hypothesis that participants in the intervention group would have more favourable urinary electrolyte levels was rejected. At the end of the 6-month intervention, participants in the control group had reduced their mean sodium excretion significantly more than participants in the intervention group. In addition, between the immediate post-intervention evaluation and the 3-month follow-up assessment, urinary potassium excretion increased significantly more in the control group. Urinary potassium excretion has previously been positively associated with intake of foods rich in potassium, such as vegetables and legumes, but particularly fruit (Jones *et al.* 2001; Cappuccio *et al.* 2003), and feeding studies have shown that this is a useful biomarker of fruit and vegetable intake (Appel *et al.* 1997; Smith-Warner *et al.* 2000). Between the immediate post-intervention and the 3-month follow-up assessment, participants in the control group had increased their fruit, nut and seed intake, whereas participants in the intervention group had a decreased intake (-8.4 v. 42.2 g/d; $P=.088$). Although this change in intake of fruits, nuts and seeds did not reach statistical significance, it might have accounted for the increase in urinary potassium excretion observed among participants in the control group.

The decrease in urinary sodium observed in the control group is difficult to explain. In an earlier secondary prevention trial promoting increased consumption of vegetables and fruits, no changes in

sodium excretion were observed in either the intervention or control groups (Smith-Warner *et al.* 2000), while in another study, potassium, but not sodium excretion, was associated with increased intake of fruits and vegetables (Cappuccio *et al.* 2003). Assessing other biological markers, such as antioxidant levels, would possibly produce more valid information on changes in fruit and vegetable consumption. Blood levels of antioxidants, such as ascorbic acid, carotenoids and vitamins A and E have been previously found to be closely related to intake of fruit and vegetables and therefore, they are considered reliable indicators of intake (Hu *et al.* 1999; Block *et al.* 2001; van Kappel *et al.* 2001). However, assessing antioxidant levels in this study would be too costly, taking into account the limited funds available for biochemical evaluation.

A limitation of the present study might lie in that results of the blood lipid and urinary electrolyte assessments were sent to participants in both groups as soon as samples were analysed in the laboratory. Providing this information while participants were still actively involved in the study might have resulted in dietary modifications, independent of the intervention provided. Goulet *et al.* (2003), in an earlier primary prevention study promoting the Mediterranean diet, noted that blood lipid results were sent to participants at the end of the study, in order to avoid potential bias that this information might have on dietary changes. However, providing this information was part of the initial agreement between the researchers and potential participants in the MESE project, as this acted as an incentive to take part in the study. Most importantly, it was considered unethical not to provide participants with feedback on their biochemical results. In addition, providing feedback on these variables would be unlikely to lead to dietary changes in favour of the intervention group, since feedback was provided to participants in both groups. Moreover, no attempt was made to investigate which of the food components promoted by the study were more responsible for changes in biochemical markers, since this was beyond the scope of the study and earlier research has supported the importance of the whole diet, instead of any nutrient or food component in particular, regarding reducing disease risk status (Osler & Schroll, 1997; de Lorgeril *et al.* 1998; Kouris-Blazos *et al.* 1999; Trichopoulou, 2000).

8.4. Nutrition knowledge, stages of dietary behaviour change and psychosocial determinants of dietary behaviour

The hypothesis that participants in the intervention group would achieve more favourable changes in their nutrition knowledge scores, achieve forward progress through the stages of behavioural change, as well as improve their perceived attitudes and self-efficacy skills towards dietary change more than participants in the control group was partly confirmed. Although within group changes for participants in the intervention group were in the desired direction for most of these variables over the study course, significant between group differences, in favour of the intervention group,

were only reported for forward stage of behaviour change regarding legumes and olive oil/MUFA:SFA ratio, perceived importance of eating more legumes and self-efficacy skills for consumption of some of the food components promoted by the study in challenging situations. In addition, a higher proportion of participants in the control group were in the action or maintenance stage of behaviour change for legumes at 6 months, compared with baseline, which probably explains this group's increase in legume intake over this period. However, self-efficacy skills generally decreased over the study period for participants in the control group.

Previous studies evaluating web-based nutrition applications have shown that such programs are effective in promoting favourable changes in several determinants of dietary behaviour, such as awareness of personal dietary intake (Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005), intentions to change dietary intake (Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005) and self-efficacy skills (Long & Stevens, 2004). In addition, many of the earlier tailored-feedback nutrition interventions have found a positive impact of tailored feedback, compared with a control condition, on many of the psychosocial factors they assessed, such as attitudes (Brug *et al.* 1996; Siero *et al.* 2000), intentions (Brug *et al.* 1996; De Bourdeaudhuij & Brug, 2000; Siero *et al.* 2000) and self-efficacy skills (Havas *et al.* 1998; Campbell *et al.* 2004), and reported forward progress through the stages of behavioural change for participants who received tailored messages (Greene & Rossi, 1998; Havas *et al.* 1998; Brug & Van Assema, 2000; Siero *et al.* 2000; Delichatsios *et al.* 2001b).

In the present study, several psychosocial determinants of dietary behaviour, such as perceived social support, intentions, perceived benefits and barriers, as well as awareness of dietary intake, were assessed in order to tailor feedback for participants in the intervention group, but were not included as outcome measures. However, our findings on the favourable impact of the intervention on stages of dietary behaviour change, attitudes and self-efficacy skills are generally consistent with earlier research, suggesting that web-based, tailored interventions are effective in modifying psychosocial determinants of dietary behaviour, which is likely to facilitate dietary changes.

It has been suggested that forward movement through the stages of behavioural change (i.e. from precontemplation to maintenance) can be used as an indicator of an intervention's effectiveness (Kristal *et al.* 1999). Some earlier studies have categorised participants into stages of behavioural change based on self-reported information of perceived dietary intake, instead of actual intake (Greene & Rossi, 1998; Kristal *et al.* 2000). People often have low awareness of their actual dietary behaviour however, and therefore using objectively assessed dietary intake to classify participants into stages of change will increase the accuracy and validity of stage categorisation (Brug & Van Assema, 2000; Havas *et al.* 2003).

Similar to the study by Campbell *et al.* (1994), participants in the MESE study were classified in the action stage of behaviour change if they reported that they were currently trying to change their diet. In contrast to this earlier study however, which also classified participants currently trying to change in the maintenance stage (Campbell *et al.* 1994), participants in the present study were considered to be in the maintenance stage if they were meeting dietary recommendations, based on their 7-day food diaries. According to the Transtheoretical model of behaviour change, the maintenance stage is reached when behaviour change is sustained for at least six months after modification has started (Prochaska & Velicer, 1997). Similar to what Campbell *et al.* (1994) noted however, the follow-up assessments in the MESE study might not have been long enough to allow classification in the maintenance stage using this criterion.

In addition, similar to an earlier study, participants in the MESE study were classified into the appropriate stage of behaviour change based on the assessment of both their perceived reported dietary intake (derived via psychosocial questionnaire) and their actual dietary intake (derived via food diaries) (Havas *et al.* 2003). For example, participants who reported not intending to increase their vegetable intake within the next 6 months (i.e. precontemplation) but who actually consumed the recommended daily amount of vegetables, were classified into the maintenance stage of change for this component. It is clear that if only perceived dietary intake was taken into account for behaviour stage classification, results on this variable would not be accurate since, in this example, participants who already eat the recommended amount of vegetables might not wish to further increase their intake.

A limitation of the MESE project is that psychosocial feedback provided to participants in the intervention group over the study course was based on the baseline psychosocial screening. This is because the questionnaire assessing these variables was quite long, and its completion on 6-weekly intervals would increase participants' burden and possibly increase attrition rates. In addition, the time frame of the study did not allow the development of a shorter, on-line version of this questionnaire, which would be used to inform tailored feedback letters during the 6-month intervention, similar to the short food frequency questionnaires. Participants in the intervention group however, were asked and encouraged to focus on a single Mediterranean goal at a time, and were provided with psychosocial feedback to achieve the recommended intake of the relevant food component. Therefore, it was considered unlikely that baseline psychosocial determinants of intake of their remaining goals would have changed before those specific goals were actually tackled. In future applications of the study, this limitation will be overcome by the development of a short psychosocial instrument, which will be completed on-line to provide interactive psychosocial feedback, which will likely also increase this feedback's accuracy.

8.5. Process evaluation

The Internet plays an important role in making information accessible to, and educating, the general public (Eysenbach *et al.* 1999; Eysenbach, 2000). With the demand for online nutrition information resources increasing, the need is emerging to provide quality, evidence-based information (Eysenbach *et al.* 1999; White, 2002), which is acceptable and has been evaluated against a target audience's needs (Delamothe, 2000; Pinnock *et al.* 2003; Gustafson & Wyatt, 2004). One of the aims of the MESE project was to evaluate an innovative healthy eating website promoting the Mediterranean diet. Results from this evaluation showed that the Internet can be a feasible and trustworthy tool to deliver nutrition education. Moreover, this study provides important insights into users' attitudes and perceptions towards this type of nutrition information resource.

8.5.1. Feedback letters

The hypothesis that participants in the intervention group would judge the nutrition information materials they received (i.e. tailored dietary and psychosocial feedback letters) more positively, compared with participants in the control group (i.e. minimally-tailored dietary feedback letters) was partly confirmed. Perceived impact of the feedback letters on dietary behaviour was higher in the intervention group, with a significantly higher proportion reporting that they had changed their diets as a result of the feedback letters they received, compared with the control group. No between group differences were reported however, in use or appreciation of the feedback letters, with the exception that participants in the control group were more likely to intend to read their letters again in the future, and more likely not to find the letters attractive in appearance, compared with participants in the intervention group.

Earlier studies have generally shown that tailored materials are more likely to be perceived as personally relevant, compared with non-tailored materials (Brug *et al.* 1998; Brug *et al.* 1999b). However, Brug *et al.* (1996) found that only half of participants thought that the tailored dietary and psychosocial feedback they received was personally relevant. In addition, some of the earlier studies evaluating tailored-feedback interventions reported lower perceived credibility of the tailored feedback messages, compared with general nutrition information (Brug *et al.* 1998; De Bourdeaudhuij & Brug, 2000). As the authors noted, this can occur when participants have low awareness of their actual personal behaviour (i.e. they believe their fat intake is low) and they are confronted about their unfavourable habits (i.e. that their fat intake is actually high). This difference between perceived behaviour and information on the actual behaviour provided with tailored feedback might also result in reduced perceived personal relevance of the feedback messages (Kreuter *et al.* 2000). No differences in perceived credibility or personal relevance were reported

between the groups in the present study and relatively high proportions of participants in both groups thought the letters were credible and personally relevant, suggesting that participants generally agreed with the information provided.

Some of the earlier studies have also shown that tailored materials are more likely to be read and remembered than non-tailored materials (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1998). Nevertheless, Campbell *et al.* (1994) reported that a large proportion of participants in their study did not read the tailored feedback messages they received. This finding is consistent with the present study, which showed that just under half of participants in the intervention group failed to read all the information provided in the feedback letters. Feedback letters in the MESE study were delivered to participants in electronic format, via e-mails, which might have affected the readability or processing of information provided (Oenema *et al.* 2005). However, participants were strongly encouraged to print their letters and keep them for future reference. More likely, the low readability of feedback letters was the result of the length of the letters in the present study, which, at six to eight pages, were longer than tailored materials provided in many of the earlier studies (Campbell *et al.* 1994; Brug *et al.* 1999b; De Bourdeaudhuij & Brug, 2000). This is also consistent with the finding that almost half of participants thought that the feedback letters were not time saving. Despite the length of feedback provided however, and the possibility that long feedback might “hide” important messages (Brug *et al.* 1999b), participants in the intervention group made favourable changes to the consumption of all food components promoted by the study.

In a study reporting the impact of tailored feedback on physical activity, tailored feedback messages were just as likely to be read, remembered and perceived as personally relevant as general nutrition information (Bull *et al.* 1999b). The authors reported that this lack of intervention effect might occur due to feedback being tailored on variables with little variation, thereby resulting in tailored and general messages looking quite similar. The tailored dietary and psychosocial feedback letters provided in the present study were similar in appearance with the minimally-tailored letters (e.g. both were personalised, included the University of Glasgow logo and had the same format), which is also consistent with earlier studies evaluating tailored-feedback nutrition interventions (Campbell *et al.* 1994; Brug *et al.* 1996). Similar to the findings by Brug *et al.* (1996) however, participants in the intervention group might have rated the appearance of letters more positively, compared with the control group, because they were more satisfied with the arm of the study they were assigned to and the intervention they received.

It has been suggested that highly-educated people are less likely to find the feedback they receive to be interesting, as the feedback may not be challenging enough for this group (Brug & Van Assema, 2000). This finding might also apply to the MESE study, which was carried out among a sample of relatively well-educated women, and showed that only just over a half of participants in the

intervention group thought that their feedback letters were interesting. In addition, the finding that more participants in the intervention, compared with the control, group reported having changed their diet as a result of the feedback they received, is consistent with earlier studies (Brug *et al.* 1996; Brug *et al.* 1998).

A possible explanation for the lack of between group differences in use and appreciation of feedback letters in the present, compared with earlier, studies is that the letters provided to participants in the control group contained minimally-tailored dietary feedback, instead of general nutrition information (Campbell *et al.* 1994; Brug *et al.* 1996; Brug *et al.* 1998). As a result, all participants in the control group thought the letters were personally relevant, which might have attenuated the between group results. The additional intervention component provided to participants in this group (i.e. three healthy-eating booklets) was fairly minimal and not very well accepted, compared with the Mediterranean Eating website. In addition, participants in the control group had no contact with the researcher until the end of the 6-month intervention. Participants in the control group therefore, might have focused more of their attention on the content of their feedback letters, thereby reporting positive use, appreciation and perceived impact of these materials, compared with earlier research.

The majority of participants in the intervention group felt extremely satisfied with the feedback letters they received, which has likely contributed to their favourable changes towards the Mediterranean diet. Of interest is that a higher proportion of participants in the control, compared with the intervention, group felt satisfied with their feedback letters and letters attracted the attention of all participants in both groups, which has been reported to be an important factor determining the impact of tailored feedback (Brug *et al.* 1999a). However, participants in the intervention group made more favourable changes to their diet, compared with participants in the control group. This finding possibly reflects the efficiency of the combined approach of Internet education and tailored dietary and psychosocial feedback employed by the MESE study in promoting dietary behaviour change.

8.5.2. Nutrition education materials

The hypothesis that participants in the intervention group would judge the nutrition education materials they accessed more positively, compared with participants in the control group, was confirmed. The Mediterranean Eating website was perceived to be more interesting, informative, useful, attractive, encouraging, time saving and not limited, compared with the general healthy-eating brochures/booklets. In addition, a significantly higher proportion of participants in the intervention, compared with the control group, felt extremely satisfied with the nutrition education

materials they accessed, suggesting that such applications are an acceptable method of delivering nutrition information.

Earlier studies evaluating web-based programs developed to promote dietary behaviour change and/or influence psychosocial determinants of dietary behaviour were often conducted under highly controlled conditions. These applications were generally well accepted, and perceived to be relevant, interesting, novel and individualised (Winett *et al.* 1999; Oenema *et al.* 2001; Oenema & Brug, 2003b; Oenema *et al.* 2005). Results from the MESE study cannot be readily compared to earlier research however, since this is the first study, to our knowledge, to investigate users' attitudes and perceptions towards a healthy-eating website, promoting the Mediterranean diet, in a real life setting and using a "triangulation" approach for process evaluation, including questionnaires, statistical summaries of usage and focus group interviews. It has been suggested that it is insufficient to assess the quality of a web-based program by only counting website visits and that qualitative information should supplement quantitative measures of usage, in order to examine users' attitudes and the impact of these applications on users' lives and choices (Gustafson & Wyatt, 2004).

The entire website and most of its sections were generally found to be very helpful, while it is noteworthy that none of the participants in the control group considered the brochures they received to be helpful. This finding is important, since mass-produced printed materials are widely used in clinical or primary care settings. In addition, there was general agreement between reports of website frequency of use and perceived helpfulness. The "Recipes", "Better Eating Tips" and "Better Buying Tips" were the sections most regularly visited by the majority of participants and were perceived to be the most helpful sections. This finding indicates the need to include practical advice when promoting dietary behaviour change (i.e. how to eat more healthy on different occasions) instead of only providing information on the benefits of healthy eating. Although we tried to provide simple, timesaving recipes, and included popular Scottish dishes prepared in a Mediterranean style (i.e. with more and a greater variety of vegetables), a small proportion of participants did not find the "Recipes" section to be helpful. This stresses the need for future studies to identify ways to tackle the barrier of lack of cooking skills, perhaps by including recipe demonstrations. More than half of participants however, found the recipes easy to prepare and thought that the ingredients were not expensive, suggesting that eating healthily, in a Mediterranean style, does not have to be difficult or expensive.

The greatest barrier to using the website was lack of time, which is consistent with findings from earlier studies examining participants' perceptions of weight loss (Tate *et al.* 2001), physical activity (Sciamanna *et al.* 2002) and healthy eating (Carpenter *et al.* 2004; Oenema *et al.* 2005) promotion websites. In addition, the study by Oenema *et al.* (2005) reported that the web-based

tailored intervention was also perceived as less credible than general nutrition information, possibly because people might process information read from a screen less thoroughly than information read from a printed material. The authors comment that this factor might have resulted in their web-based application being used less often than general nutrition information materials (Oenema *et al.* 2005). Although no differences in perceived credibility were observed between the materials accessed by the intervention and control groups in the present study, the barrier of time might have resulted in the decrease in login frequency over the 6-month study, which was also somewhat expected due to the length of the intervention period. However, it is difficult to conclude that the website was not efficient due to the decreased login frequency over the study course, since some participants might have used the website once and printed information to read at a time convenient for them or keep for future reference. This was possible even with website sections that were regularly updated (i.e. Recipes, Better Eating Tips), since the website provided archives for this information. However, it would be useful for future applications of the MESE study to account for this factor and assess the number of, and which website pages are printed off by users via appropriate statistical usage summaries.

It is also noteworthy that pages that were not updated over the 6-month study were more often rated as moderately helpful or not helpful and received fewer visits by many participants. This finding shows the importance of providing regularly updated information, which will likely keep users interested in using such a website. This is also in agreement with insufficiency of updates being one of the regularly mentioned barriers to using the website more often and the wish of many participants for the website to have more regular updates.

It has been advocated that 'websites should not only be judged by the accuracy and readability of the information provided, but also by whether they meet the needs of their target audience' (Pinnock *et al.* 2003). A limitation of the MESE study is that the time frame did not allow for focus group interviews to be conducted prior to the development of the Mediterranean Eating website, in order to assess nutrition information needs of the particular population group the website targeted. However, published criteria for evaluating health related websites (Kim *et al.* 1999) were taken into consideration to inform the content of the website and several themes emerged from interviews conducted at the end of the study that provided additional valuable information to the quantitative results of the process evaluation questionnaires.

The majority of participants mentioned source credibility and provision of scientific evidence to support information as important criteria to assess a website's trustworthiness. This finding is consistent with previous research on users' expectations of Internet health resources (Feightner *et al.* 2001; Quintana *et al.* 2001; White, 2002). Criteria for evaluating health related websites that have been published to date include content, design and aesthetics, disclosure of authors,

sponsors/developers, currency of information, authority of source, ease of use and confidentiality/privacy (Kim *et al.* 1999; Eysenbach & Köhler, 2002). Although the focus group interviews revealed that the Mediterranean Eating website was well accepted concerning these criteria, some issues were identified that will be considered for future refinement of the website. For example, most participants felt the website was clearly set-up, easy to use and that finding specific information on the site was easy. However, approximately a quarter of participants did not find the website time-saving. It was suggested that easier access to some sections (e.g. specific recipes, bulletin board), possibly facilitated by a site index or site-map, by increasing the links between the pages or by making contents more noticeable on the website's homepage, might have increased their use and participants' ability to locate relevant information.

A finding of interest is that although provision of scientific, evidence-based information was considered a quality of a nutrition-related website, the interviews revealed that these sections were less likely to be considered interesting and based on the evaluation questionnaires, received less visits compared with sections providing more practical information. Although some participants explained that practical information is easier to absorb, it was suggested that theoretical features could be improved by providing links to other trustworthy Internet sources for more extensive information, in addition to making access to these sections easier via multiple pages within the website. This would probably also increase the likelihood of users returning to these sections. For example, if a recipe contained a specific type of vegetable, a direct link in that page would prompt users to visit the "Food and Nutrients" section, to be reminded of the nutritional qualities of this vegetable.

Findings from the focus group interviews are generally consistent with earlier research on consumers' information needs from nutrition websites, particularly the need for inclusion of weight loss/control information, simple, convenient and healthy recipes, meal planning (Buller *et al.* 2001; Cousineau *et al.* 2004), as well as serving size information (Buller *et al.* 2001). Participants in the present study consistently suggested that inclusion of nutritional information and fruit and vegetable serving content of recipes would increase the usefulness of the website. In addition, meal planners for people who are dieting, as well as more information and suggestions on physical activity and weight control would also be useful features. The comment that people often relate nutrition websites with weight loss was of particular interest. Although the Mediterranean Eating website was not designed to promote weight loss, providing additional information on weight control and meal planners for different energy needs might improve the appeal and use of such a site.

It has been suggested that for a web-based application to be successful and promote dietary behaviour change, it needs to incorporate interactive features, including record keeping, assessment and provision of tailored feedback on an ongoing basis, instead of primarily providing nutrition

information (Noell & Glasgow, 1999; Marcus *et al.* 2000; Womble *et al.* 2004). With technology systems improving, the inclusion of such features enables web-based programs to imitate traditional face-to-face counselling interventions (Doshi *et al.* 2003). Although the Mediterranean Eating website did not provide interactive dietary and psychosocial assessment and provision of dietary feedback based on that assessment in real time, this feedback was available via the tailored letters e-mailed to participants. Winett *et al.* (1999) suggest that usage and effectiveness of nutrition related websites would increase with more interactive features. This is consistent with findings from the interviews in the present study, where most participants suggested that more interactive features, such as dietary assessment quizzes that would provide support during the study and raise awareness of dietary intake, would be particularly welcomed.

Despite attempting to conduct a focus group for participants who didn't complete the study, only those who had completed the study accepted the invitation to attend a focus group. Therefore, they represent a self-selected group of relatively well-educated female employees who are likely to have favourable attitudes towards the website. Nevertheless, attrition from the study was relatively low with only 20% of individuals ($n = 11$) not completing the 6-month impact evaluation measurements, suggesting that the intervention was successful in engaging and maintaining the interest of participants. Nevertheless, obtaining these participants' perceptions towards the Mediterranean Eating website would have provided useful information as to whether these participants dropped out because the website failed to meet their expectations.

Furthermore, the findings from the present study cannot be generalised to non-computer literate populations. An increasing number of people use computers and the Internet (National Statistics, 2004b) and web-based tailored interventions are suggested to reach more people at a lower cost compared with interpersonal counselling (Oenema *et al.* 2001). Nevertheless, a considerable proportion of the population, particularly low-literacy groups, have limited Internet access (Eysenbach *et al.* 1999; Brodie *et al.* 2000) or difficulty in searching and finding relevant health information on the Internet (Benigeri & Pluye, 2003). It is these groups however, that are also more likely to need such information (Eysenbach & Jadad, 2001). Similar to the present study, the majority of published reports on Internet-based interventions and/or evaluation of health promotion websites have been on participants with existing Internet access (Glasgow *et al.* 2003). The acceptability of such programs from the general population and individuals with low general or computer literacy skills, of low socio-economic status and different age groups therefore, remains to be investigated. However, research has shown that elderly people with little computer experience have successfully used and felt satisfied with Internet-based applications promoting health management and self-care, possibly due to the individualised instruction pace offered by this medium (Lewis, 1999). In addition, it has been suggested that even when participants are

inexperienced in using the Internet or a computer-based program, this can be a feasible method of promoting health and providing education if motivation, technical demonstrations and support are provided (Eng *et al.* 1998; Scherrer-Bannerman *et al.* 2000; Block *et al.* 2004).

The barrier of low-literacy has also been proposed to be overcome by more interactive web-based applications that focus on a more visual design (Benigeri & Pluye, 2003). In addition, considering that people may provide more honest answers when completing computer-based, instead of self-administered paper-and-pencil questionnaires (Locke *et al.* 1992; Paperny, 1997), a website providing interactive tailored feedback might prove efficient in promoting behavioural change (Wantland *et al.* 2004).

Although results of the MESE project should be interpreted with caution, due to the limitations discussed, this Internet-based, step-wise tailored intervention used to promote healthy eating in the context of the traditional Mediterranean diet presents a realistic approach to dietary behaviour change. In addition, the Mediterranean Eating website was well accepted and once refined, could present an effective and practical means of delivering reliable nutrition education and promoting dietary behaviour change.

9 Conclusions and Recommendations

9.1. Overview

The Internet offers a novel approach to health information delivery, enabling unlimited access to help and advice (Duffy, 2000). Tailored-feedback nutrition interventions delivered interactively via the Internet, in particular, have great potential in promoting health, since they can purportedly reach large and diverse populations, at relatively moderate costs, in order to promote healthy eating patterns (Kreuter *et al.* 1999a; Brug & Van Assema, 2000). In addition, interactive, tailored-feedback programs satisfy three important criteria for effective nutrition interventions, further supporting their potential as a feasible method of promoting healthy eating. In particular:

- Opportunity to provide tailored feedback, by focusing on motivating and reinforcing factors affecting dietary behaviour;
- Opportunity for self-assessment and self-evaluation, by providing appropriate tailored feedback;
- Opportunity to actively participate in the intervention, by using a computer to receive interactive feedback (Contento *et al.* 1995; Brug *et al.* 1999a; Brug *et al.* 2003).

Much of the health and dietary information available on the Internet however, is unregulated or not written by qualified health professionals, making it difficult to assess its quality and credibility (Davison, 1997; Boyer *et al.* 1998; Pearson *et al.* 2000; Bessell *et al.* 2002; Kirk *et al.* 2003). As the concern regarding the reliability and often, potential for harm of information on the Internet increases (Eysenbach *et al.* 1999; Cline & Haynes, 2001; Benigeri & Pluye, 2003), the potential exists for health professionals to provide credible and evaluated programs via this channel, in order to promote healthy eating and dietary behaviour change (Davison, 1997; DiSogra & Glanz, 2000; Kirk *et al.* 2003).

Based on intention-to-treat analyses, the MESE study showed that the combined approach of Internet education and provision of tailored dietary and psychosocial feedback was more successful in promoting the consumption of vegetables, as well as fruits, nuts and seeds, and leading to more favourable blood lipid profiles, compared with minimally-tailored dietary feedback and general healthy-eating brochures. Psychosocial determinants of dietary behaviour generally improved more in the intervention, compared with the control group, while additional favourable within group differences were reported among the intervention group regarding all four components of the

Mediterranean diet promoted by the study. Along with the general acceptability of the Mediterranean Eating website, these findings suggest that an interactive website, which would include assessment tools and automatically provide on-screen tailored feedback, could be a valuable means of promoting and sustaining a Mediterranean-style diet, a dietary pattern recommended to the Western world for its palatability, health properties and easy incorporation within a modern lifestyle (Willett *et al.* 1995). The focus group interviews showed that such a website would increase user satisfaction, which is likely to result in increased adherence and improved long-term health outcomes (Glasgow *et al.* 1997). In addition, and considering the shortcomings of Internet technology applications (Eysenbach *et al.* 1999; Cline & Haynes, 2001; Benigeri & Pluye, 2003), the Mediterranean Eating website could present a feasible and credible tool for nutrition information and tailored feedback delivery.

9.2. Refinement of the Mediterranean Eating website

This thesis reports the results of the evaluation of a nutrition intervention which utilised the first prototype of a Mediterranean Eating website. However, before the intervention can be widely disseminated on the World Wide Web, the Mediterranean Eating website needs to be further refined. Based on the process evaluation findings, future refinement will attempt to make the Mediterranean Eating website more appealing and user-friendly, which might also increase its frequency of use. Particular changes that will be considered include:

- Increased interactive features, with inclusion of dietary and psychosocial assessment instruments and automatic, on-screen provision of tailored feedback;
- Easier access to all, but particularly theoretical, sections by increasing the number of internal links in multiple pages within the website;
- Links to other credible websites and sources of nutrition information for more extensive information;
- More regular updates;
- Inclusion of nutrient and fruit and vegetable serving content of recipes, allowing users a more effective indication of dietary intake;
- Inclusion of more extensive information and suggestions to promote physical activity and body weight control.

In addition, several methodological flaws of the present study will be tackled in future applications. In particular:

- Using a randomised controlled, instead of a quasi-experimental design, in order to reduce the possibility of selection bias;
- Recruiting a larger and more diverse population, taking into consideration regional, socio-economic, educational and other demographic characteristics, as well as recruiting participants with different levels of computer literacy. In the present study, female participants were recruited because research suggests that women are more responsible for meal planning, food shopping and preparation (Harnack *et al.* 1998; Stevens *et al.* 2003) and more likely than men to use the Internet to access health information (Brodie *et al.* 2000). It would however, be useful to examine the effect of such an intervention on male participants. In the past, men have also been receptive to tailored nutrition education (Brug *et al.* 1996);
- Promoting more, or all, food components of the Mediterranean diet, including fish, by reducing the time assigned to tackle each Mediterranean goal to four, instead of six weeks;
- Using additional objective statistical usage summaries to assess the number of website pages printed off by users, which, in combination with assessing website visits, will provide a better insight into website usage patterns;
- Evaluating the post-intervention outcome over a longer-term period of six months or one year;
- Evaluating the costs and cost-effectiveness of the intervention.

9.3. Applicability of the MESE project

The present findings can be used to improve the design of future Internet nutrition applications and facilitate the promotion of healthy eating to Western populations. In addition, considering the limited accessibility of face-to-face counselling and the potential for Internet-based, tailored interventions to reach large population groups (Brug *et al.* 1999a), the refined MESE project could have several implications for nutrition education practice. This project could be a particularly feasible means of promoting dietary behaviour change in primary care and work-based settings.

9.3.1. Primary care settings

Research has shown that general practitioners are regarded as the most trustworthy source of information on diet and health by the general public, whereas general practitioners often feel that they lack the skills and time to provide their patients with nutrition information (Hiddink *et al.* 1995). Incorporating evaluated web-based, tailored-feedback interactive programs in medical practices may overcome the barrier of lack of time from general practitioners' perspective (Brug *et*

al. 1999a). At the same time, this will ensure the delivery of trustworthy nutrition education to facilitate interpersonal counselling and shared decision making, which will likely result in reduced health care costs (Eng *et al.* 1999).

Siero *et al.* (2000) comment on earlier tailored-feedback nutrition interventions, that 'the lack of usual care control groups on behavioural impact is worrisome, since they reflect usual care in the health sector'. This underlies the importance of facilitating general practice interpersonal counselling with interactive, tailored-feedback information. This can be achieved by placing computers in the waiting room of a general practice, where patients can be encouraged to access a web-based application and receive tailored feedback. The feedback report can be printed off and discussed with the general practitioner, thereby saving time and providing effective, personalised advice (Skinner *et al.* 1993; Brug *et al.* 1998; Prochaska *et al.* 2000).

Research to date has shown that general practitioners and health professionals acknowledge the Internet's potential for health information delivery and are willing to encourage its use by their patients if the accuracy and credibility of this information can be ensured (Wilson, 1999; Feightner *et al.* 2001; Kirk *et al.* 2001). Expectations from health-related websites, according to health professionals, include source credibility, disclosure of authors, unbiased information content, easy accessibility and access of information and professional design (Feightner *et al.* 2001; Kirk *et al.* 2001). The Mediterranean Eating website satisfied these criteria and could present a feasible tool of facilitating dietary interpersonal counselling in general practices.

Following the appropriate refinement and methodological design of the MESE project, the next step would therefore involve its evaluation among a larger group of free-living adults in a primary care setting. If shown to be effective, the Mediterranean Eating website could be promoted to general practitioners and other health professionals as a reputable, non-commercial tool for use by their patients and clients wishing to make simple improvements to their diet. Since 45% of general practitioners in Scotland would consider referring patients to the Internet for further trustworthy information (Wilson, 1999), the proposed website could offer such an opportunity.

9.3.2. Work-based settings

Work-based settings are considered to be good channels of promoting dietary change since 'they offer accessibility to large populations and the use of existing organisational structures for information delivery and social and co-worker support' (Patterson *et al.* 1998). In worksites participants can also be repeatedly reached for surveys and frequent assessments and tailored feedback and nutrition education can be included in the examinations undertaken as part of occupational health programmes in many sites. In addition, worksites offer a good alternative to

other settings, since they reduce the time needed for participants to travel to and from research sites (Brug, 1999).

In recent years, worksite-based nutrition interventions have proved to be effective in promoting dietary change (Abrams *et al.* 1994; Tilley *et al.* 1999). Although the MESE project was not exactly a worksite intervention, since no attempt was made to influence environmental factors (e.g. food served in University restaurants and canteens), it offered the convenience of evaluating the intervention by means of existing worksite structures (i.e. University of Glasgow web server). Targeting social norms and eating environments might further increase the effectiveness of web-based, tailored interventions, in order to promote dietary behaviour change. It was encouraging that participants in the MESE project suggested that a refined version of the Mediterranean Eating website should form the beginning of a health promotion programme in the University of Glasgow. In such a case, employees would be encouraged to visit the website on a weekly basis, which might lead to even more beneficial results on dietary behaviour change.

9.4. Conclusions

This Internet-based, step-wise tailored-feedback intervention used to promote healthy eating in the context of the traditional Mediterranean diet presents a realistic and reliable approach to dietary behaviour change and shows that the Mediterranean diet can be adopted by healthy individuals in northern European countries. Although results of the MESE project should be interpreted with caution, due to the limitations discussed, the present intervention was effective in encouraging higher consumption of vegetables, fruits and legumes, as well as increasing the monounsaturated to saturated fat ratio in the diet. Since an increasing number of people in Scotland have Internet access at work or at home (National Statistics, 2004a) and electronic access to health information increases (Velicer & Prochaska, 1999; Williams *et al.* 2002), such interventions have the potential to promote healthy eating habits in Scotland, in agreement with current dietary recommendations for health promotion and disease prevention (The Scottish Office, 1996).

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