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An Individually Tailored Behaviour Change Programme for Cardiovascular Prevention: Effectiveness and Cost-Effectiveness

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Nele JACOBS

Promotor: prof. dr. Neree Claes
Copromotor: prof. dr. Ilse De Bourdeaudhuij

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AN INDIVIDUALLY TAILORED BEHAVIOUR CHANGE PROGRAMME FOR CARDIOVASCULAR PREVENTION: EFFECTIVENESS AND COST-EFFECTIVENESS

Nele Jacobs

Promotor:	Prof Dr N Claes
Co-promotor:	Prof Dr I De Bourdeaudhuij
Supervisory board:	Prof Dr N Claes Prof Dr I De Bourdeaudhuij Prof Dr P Dendale Prof Dr H Thijs
Examination board:	Prof Dr G De Backer Prof Dr N De Vries Prof Dr S Evers Prof Dr N Claes Prof Dr I De Bourdeaudhuij Prof Dr P Dendale Prof Dr H Thijs

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General summary

Cardiovascular disease (CVD) is the main cause of death and disability in Europe and 10% of the total health care costs in the European Union is due to CVD. This thesis provides original research on a cardiovascular prevention programme focused on medical risk factors and risk behaviours such as an unhealthy diet, low levels of physical activity, and smoking in a highly educated sample. The behavioural interventions, namely a website and one-on-one coaching were part of an individually tailored behaviour change programme. The effectiveness of this programme was evaluated compared to a medical intervention only condition with total CVD risk assessment, communication, and follow-up.

After 36 months improvements in most of the medical risk factors such as blood pressure and cholesterol were found in both study conditions. The effects of the programme on behaviour were evaluated at 6, 12, and 24 months and improvements in fat intake and physical activity were found in both conditions.

The studies of this thesis corroborated the knowledge on intervention exposure. The dose-response analyses showed that a higher intervention dose led to better results in behaviour and determinants of behaviour. The study on exposure to the website showed that the surfing depth was low in general but an effect of use of tailored physical activity advice on physical activity was found.

The participants of this study self-selected the intervention dose and delivery modes of the intervention. For physical activity and dietary behaviours, different delivery modes were effective. The Internet and e-mail were better for physical activity while face-to-face contacts were better for dietary behaviours.

Nevertheless, there were no significant differences between both study conditions, suggesting that a medical screening with follow-up is sufficient to change important CVD risk factors in the highly educated. The behaviour change programme was effective in influencing key risk factors but screening was as effective in this population. However, we should consider that partial effects might be attributable to spontaneous changes of risk factors in the community due to community interventions and health policy initiatives (e.g., smoking, diet). Nevertheless, based on these results the organisation of screening events with follow-up in the primary care setting is a good action in CVD prevention in the highly educated.

Chapter 1: General Introduction

Interventions for the prevention of chronic diseases such as cardiovascular disease (CVD) are preferably focused on changing medical risk factors and multiple risk behaviours at the same time. This thesis provides original research on a cardiovascular prevention programme focused on medical risk factors and risk behaviours. The programme was evaluated on its effectiveness and cost-effectiveness in a sample of highly educated adults. The general introduction starts with an overview of CVD and its causing factors, both medical and behavioural. This is followed by an overview of behavioural determinants and procedures for intervention development. The third part of the general introduction summarises prior health promotion interventions. Although many interventions wherein single health behaviours were targeted exist, special attention was given to interventions focusing on changing multiple behaviours, especially to those additionally targeting medical risk factors. The last part of the introduction describes how economic evaluations of interventions are performed.

I. Cardiovascular disease (CVD) and its risk factors

Cardiovascular disease (CVD) (International Classification of Diseases (ICD)/10 codes I00–I99, Q20–Q28) covers all diseases that affect the heart and the blood vessels. This includes diseases such as coronary heart disease (CHD) and stroke. CHD refers to the failure of the coronary circulation to supply adequate circulation to the cardiac muscle and the surrounding tissue. In Belgium, large cross-sectional epidemiological studies about CVD and risk factors were carried out during the past 20 years. These include the BIRNH Study, the MONICA Surveys, and the BELSTRESS Project (5-7). The Belgian interuniversity Research on Nutrition and Health (BIRNH) study is a population-based survey to investigate the association between nutritional patterns, clinical and biochemical characteristics and cause-specific mortality (5). Data for this study were gathered between 1980 and 1984. The World Health Organization Multinational Monitoring of Trends and Determinants in Cardiovascular Diseases study (MONICA Project) is also a population-based study about the trends in incidence and risk factors of CVD (6). The data were gathered between 1985 and 1992. Finally, the Belgian Jobstress Project (BELSTRESS) is a large-scale study dealing with the relationship between perceived job stress and the incidence of CHD and sick leave (7). The baseline data were gathered between 1994 and 1998. The combination of these datasets showed that, in Belgium, the prevalence of CHD is 2.8% in men and 1.2% in women (8). It should be noted, however, that these prevalence figures are strongly age-dependent and thus only applicable to the age groups of the specific studies and not to the overall population.

CVD is the main cause of death in Europe and nearly half of all deaths are due to CVD (9). CVD mortality rates vary with age, gender, socio-economic status, ethnicity, and geographical region (10). Men, older people, people with a family history of CVD, and people with a low socio-economic status are more likely to die from CVD than others (10). The incidence of coronary vascular events is 1.91 per 1,000 population years (11). The personal burden CVD causes is substantial and can be expressed in disability adjusted life years (DALYs), i.e. the number of years of life lost due to ill-health and premature death. In 2002, cardiovascular disease was responsible for 22.0% of the DALYs in Europe (9). CVD is associated with impaired quality of life, with more severe disease states having a worse quality of life (12). Quality of life means suboptimal levels of physical, mental, role- and social functioning, and personal perceptions of health, fitness, life satisfaction, and well-being (13). Clusters of CVD risk factors are associated with a lower quality of life (14). CVD develops mostly through modifiable medical risk factors and risk behaviours (10). A preventive strategy in clinical practices is needed because the underlying atherosclerosis develops insidiously over years and is usually advanced when symptoms occur (10).

Next to a personal burden, CVD is responsible for a large societal burden since it consumes about 10.0% of the health care expenditures across the European Union (9). In 2003, the estimated total cost of CVDs in the countries of the European Union was €168,757 million (15). The main cost driver is health care, followed by productivity losses (16). Productivity losses are foregone earnings related to CVD-attributable mortality and morbidity. Interventions to manage CVD risk factors can reduce the burden that CVDs impose on the health care budget.
The CVD risk factors that should be targeted are medical risk factors such as blood pressure, cholesterol, diabetes, blood glucose, overweight and obesity. Moreover, risk behaviours such as smoking, physical activity, fitness and diet should be targeted by health promotion interventions.

Medical risk factors
Figure 1 represents a model of the risk factor-CVD relationship (3).

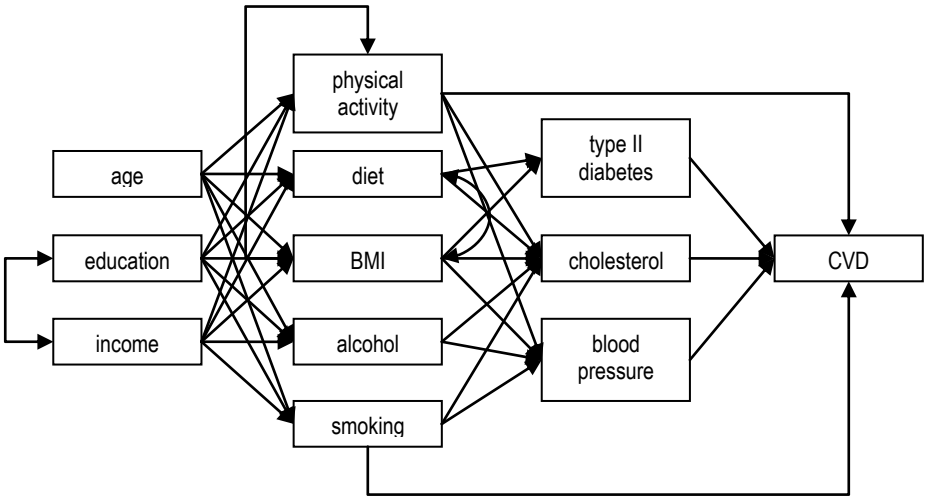

Figure 1: Risk factors for CVD (3)

Blood pressure

Relation with CVD

A high blood pressure or hypertension has been described as an epidemic and a primary risk factor for CVD (17, 18). A history of hypertension was found to contribute for 22.0% to the risk of a first myocardial infarction in Western Europe and for 25.0% in Central and Eastern Europe(19). CHD and stroke mortality increase linearly from blood pressure levels as low as 115 mmHg systolic and 75 mmHg diastolic upward (18).

Relation with other risk factors

An elevated blood pressure is related to alterations in blood glucose and cholesterol (20-22). Hypertension is also associated with overweight and low levels op physical activity (23).

Recommendations and guidelines

Systolic blood pressure (SBP) and diastolic blood pressure (DBP) levels (in mmHg) can be characterised as optimal (SBP<120.0 and DBP<80.0), normal (120.0<SBP<129.0 and/or 80.0<DBP<84.0), high normal (130.0<SBP<139.0 and/or 85.0<DBP<89.0), grade 1 hypertension (140.0<SBP<159.0 and/or 90.0<DBP<99.0), grade 2 hypertension (160.0<SBP<179.0 and/or 100.0<DBP<109.0), grade 3 hypertension (180.0≤SBP and/or 110.0≤DBP), and isolated systolic hypertension (140.0≤SBP and 90.0<DBP)(24). Drug therapy for hypertension should be

initiated promptly in individuals with a sustained SBP≥180.0 mmHg and/or DBP≥110.0 mmHg regardless of their total CVD risk(25). Antihypertensive treatment translates into significant reductions of cardiovascular morbidity and mortality (24). Individuals with SBP of ≥ 140.0 mmHg and/or DBP ≥ 90.0 mmHg also require drug therapy. Drug treatment for hypertension includes prescription of diuretics, beta-blockers, ACE inhibitors, calcium channel blockers and angiotensin II antagonists (25). For most people, the norm for blood pressure equals 140.0/90.0 mmHg (10). Some authors state that for patients with diabetes and high-risk individuals this norm should be even lower but this is questioned by others (25, 26). Lifestyle advice for the treatment of hypertension includes: weight reduction in overweight/obese individuals, reduction of salt intake, restriction of alcohol consumption, regular physical activity, reduction of saturated/total fat and cholesterol intake and increase of fruit and vegetable intake (27). Results from large epidemiological studies showed that 8.4% of the men and 13.5% of the women in the Belgian population use antihypertensive drugs (8).

Epidemiology

The prevalence of hypertension was 44.0% in men and 36.0% in women(8). The mean SBP values in the general Belgian population are 133.7 mmHg (SD 16.2) for men and 129.3 mmHg (SD 18.7) for women (8). The mean DBP values in the general Belgian population are 83.9 mmHg (SD 10.6) for men and 79.8 mmHg (SD 11.2) for women (8). It can be concluded that the values of SBP and DBP are suboptimal in the general Belgian population.

Measurement

The diagnosis of hypertension should be based on multiple blood pressure measurements because blood pressure is characterised by large spontaneous variations during the day and between days. Blood pressure can be measured by a mercury sphygmomanometer. Other non-invasive devices (auscultatory or oscillometric semiautomatic devices) can also be used. Several devices (mostly oscillometric) are available for automatic blood pressure measurements.

Cholesterol

Relation with CVD

The INTERHEART study found high blood lipids to contribute for 45.0% to the risk of an initial myocardial infarction in Western Europe and for 35.0% in Central and Eastern Europe (19). A high cholesterol or dyslipidemia or hypercholesterol is one of the top 5 major risk factors for CVD (28). People with abnormal lipids are at over three times the risk of a heart attack compared to those with normal lipids (19). A 10.0% reduction of blood cholesterol reduces the incidence of coronary artery disease by 25.0% after 5 years (29). Furthermore, with each 1 mmol/L reduction in LDL cholesterol, the annual rate of major vascular events is reduced by just over a fifth (30).

Relation with other risk factors

Hypercholesterol and hypertension often co-occur (21, 22). In a Belgian population study this was the case in 38.0% of the men and 32.0% of the women (8). Hypercholesterol is also related to impaired glucose tolerance (8). Cholesterol is also associated with overweight and low levels of physical activity (23).

Recommendations and guidelines

Total cholesterol (TC) should be lower than 5.0 mmol/l (190 mg/dl) and low density lipids-cholesterol (LDL-C) should be lower than 3.0 mmol/l (115.0 mg/dl)(25). In the highest risk subjects, especially those with clinically established coronary artery disease, atherosclerotic CVD and in patients with diabetes, the treatment goal should be lower (TC<4.5 mmol/l (175.0 mg/dl) and LDL-C<2.5 mmol/l (100.0 mg/dl)). If patients exceed one of these thresholds, dyslipidemia is assumed. There is a general trend to recommend low treatment targets for TC and LDL-C in all major guidelines (28). Available treatments include pharmacotherapy and lifestyle interventions. Drug therapy for high blood cholesterol can be performed using statins. Other drugs that can be considered in the prevention of CVD include: aspirin or other platelet-modifying drugs, beta blockers, ACE-inhibitors and anti-coagulants (25). Patients with a high cholesterol are advised to improve their lifestyle habits with regard to diet and physical activity (25). Results from large epidemiological studies in the past showed that 3.3% of the men and 1.0% of the women in the Belgian population use lipid-lowering drugs and nowadays these figures will even be increased (8).

Epidemiology

In Belgium, the prevalence of TC levels above the optimal levels is 84.0% in men and 82.0% in women (8). The German Metabolic and Cardiovascular RiSk Project (GEMCAS) showed that 76.4% of the patients in general practice met the criteria for dyslipidemia (28). The mean TC values in the general Belgian population are 228.8 mg/dl (SD 41.6) for men and 230.5 mg/dl (SD 45.6) for women (8). It can be concluded that the values of TC are suboptimal in the general Belgian population.

Measurement

Cholesterol measurement usually takes place using venous blood samples that are analysed in the laboratory. Next to this golden standard, a point of care lipid analyser using fasting finger stick samples can be successfully employed in practice but care should be given to the selection of an analyser with a good reliability and validity compared to laboratory testing (31).

Diabetes and blood glucose

Relation with CVD

Diabetes mellitus is a metabolic disorder characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat, and protein metabolism resulting from defects of insulin secretion, insulin action, or a combination of both (32). Type I diabetes is due to a lack of insulin

production, whereas in type II diabetes, the rising blood glucose results from a combination of factors such as genetic predisposition, an unhealthy diet, physical inactivity, and increasing weight with a central distribution (33). The risk for CVD increases along a spectrum of blood glucose concentrations (34). A close interrelation between hyperglycaemia, diabetes, and CVD has been confirmed in various populations (35). People with diabetes have a risk on CVD that is two to three times higher than among people without diabetes (36).

Relation with other risk factors

Overweight or obesity predict diabetes (37). The primary factors responsible for weight loss are diet and physical activity (37).

Recommendations and guidelines

Glucose regulation is classified into different stages ranging from normoglycaemia to diabetes. Values of fasting plasma glucose (FPG) below 6.1 mmol/l (110.0 mg/dl) are considered to be normal (10, 34). Values from 6.1 (109.8 mg/dl) to 7.0 mmol/l (126.0 mg/dl) indicate impaired fasting glucose (IFG). Values of FPG lower than 7.0 mmol/l and 2h post load plasma glucose from 7.8 (140.4 mg/dl) to 11.0 mmol/l (198.0 mg/dl) indicate impaired glucose tolerance (IGT). Diabetes mellitus is indicated by a FPG value of 7.0 mmol/l or higher and 2 h post load plasma glucose of 11.0 mmol/l or higher. In subjects with IGT, the progression to diabetes can be prevented or delayed by lifestyle interventions (10). Targets for blood pressure and cholesterol are usually more ambitious in patients with diabetes than in non-diabetic subjects (10).

Epidemiology

The lifetime risk of diabetes in the European population is 20.0-40.0% (33). BIRNH, MONICA and BELSTRESS showed that the prevalence of diabetes was 1.8% in men and 1.7% in women, respectively (8).

Measurement

In general, FPG is determined in an accredited clinical laboratory but point of care glucose meters are increasingly used. In a recent study, 14 glucose meters were tested and 11 received a quality mark for adequate analytical and technical quality (38).

Overweight and obesity

Relation with CVD

It is estimated that worldwide over 1 billion people are overweight and over 300 million obese (10). Overweight and obesity partially increase the risk of CVD through adverse effects on blood pressure and cholesterol (39). In Western Europe, 63.0% of heart attacks are due to abdominal obesity (a high waist to hip ratio), and those with abdominal obesity are at over twice the risk of heart attack compared to those without (19). In Central and Eastern Europe abdominal obesity was responsible for 28.0% of the heart

attacks (19). CVD risk is independently associated with an increased waist to hip ratio and Body Mass Index (BMI) (40).

Relation with other risk factors

Body fat is associated with a high blood pressure and cholesterol (23). The joint prevalence of hypertension and hypercholesterol strongly depends on the BMI (8). Abdominal obesity and overweight are, on their turn, strongly associated with risk behaviours (e.g., an unhealthy diet and inadequate levels of physical activity) (10). Weight loss can effectively lower blood pressure (18). There is also an association between overweight and education and income (41).

Recommendations and guidelines

In adults, overweight is defined by an increased BMI ranging from 25.0 to 29.9 kg/m² and obesity by BMI ≥ 30.0 kg/m². The BMI should be lower than 25.0 kg/m². The waist circumference should be lower than 94.0 cm in men and 80.0 cm in women. A waist circumference of 94.0 cm or more in men and 80 cm or more in women is defined as central or abdominal obesity (10).

Epidemiology

In 2004, 44.0% of the Belgian population had overweight (42). Authors reported slightly different figures from BIRNH, MONICA and BELSTRESS, namely 49.2% in men and 33.9% in women (8). Fourteen percent of the men and 17.0% of the women were obese, respectively (8).

Measurement

BMI can be used to define groups of body weight [kg/height (m)²] using classifications suggested by the World Health Organization (WHO). Body fat percentage can be determined using bioelectrical impedance analysis, skin fold measurements and hydrostatic weighing tasks.

Risk behaviours

Smoking

Relation with medical risk factors and CVD

There is an association between smoking and CVD (43). The effects of smoking on CVD interact synergistically in the presence of other CVD risk factors such as age, gender, arterial hypertension, and diabetes. In Europe, about 20.0% of deaths from CVD in men and about 3.0% of deaths from CVD in women are due to smoking (9). Furthermore, 29.0% of heart attacks in Western Europe are due to smoking (9). Smoking is not only a risk behaviour for the development of CVD, about half of all regular smokers will eventually die of their habit(9).

Recommendations and guidelines

The recommendation for smoking used in this thesis was for smokers to quit smoking (44, 10). The recommendation of the WHO at national level is to achieve that at least 80.0% of the people of 15 and older should be non-

smokers (45). Recommendations to achieve the latter goal are to ban smoking in all public places and to increase taxes on tobacco.

Epidemiology

BIRNH, MONICA and BELSTRESS showed that the percentage of smokers was 30.1% in men and 20.7% in women (8). In Belgium, the percentage of daily smokers was 25.0% in 2008 (46). The number of smokers decreased in Belgium over the past 11 years (46).

Measurement

Smoking behaviour can be measured by use of self-report measures or more objectively by CO or cotinine measurement.

Physical activity and physical fitness

Relation with medical risk factors and CVD

Distinguishing between physical activity and fitness is important because physical activity is a behaviour, whereas fitness is a physiological measure that reflects a combination of physical activity behaviours, genetic potential, and functional health of various organ systems (47). Physical inactivity or performing less than 2.5 hours per week of moderate exercise or 1 hour per week of vigorous exercise contributes to the development of CHD and CVD (48, 49). Physical activity has beneficial effects on the course of atherosclerosis, resulting in a 20.0-25.0% reduction in overall mortality (50). Being more physically active provides some protection from CVD mortality, even in the presence of multiple CVD risk factors (51).

Physical fitness is expressed as the maximum capacity of an individual's body to transport and utilize oxygen during incremental exercise (VO2max). The association between physical fitness and all-cause mortality is stronger than the relationship between physical activity and all-cause mortality (52). Only high levels of physical activity that raise fitness may be sufficient to lower the risk of developing hypertension (47). Thus, the association between fitness and CVD is considered to be stronger than the association between physical activity and CVD.

Recommendations and guidelines

To reduce the risk of CVD, the WHO recommends at least 30 minutes of regular moderate-intensity physical activity on most days of the week (53). Other recommendations for physical activity were described: to do sports 3 times per week for at least 20 minutes or to be moderately active for at least 6 days per week for a minimum of 30 minutes (44, 54-56).

Epidemiology

In 2008, 38.0% of the population performed at least 30 minutes of physical activity of moderate or intensive intensity per day (57). Only 18.0% of adults in different European countries reported daily moderate level physical activity, the frequency WHO suggests is required to reduce CHD (48). It can be concluded that the physical activity levels are suboptimal in the general Belgian population.

Measurement
For the assessment of physical activity, different methods are available such as activity monitors (pedometers, accelerometers), heart rate monitors and questionnaires, or activity diaries. Physical activity can be measured in total minutes per week with the International Physical Activity Questionnaire (IPAQ) (long version, usual week) (58). For physical fitness and exercise capacity, maximal incremental exercise testing is the golden standard for measurement (59). Sub maximal tests, such as step tests using a bench, are cheaper and more feasible in practice. However, there is a lack of standardization and validation of step tests.

Diet and alcohol consumption
Relation with medical risk factors and CVD
It is generally known that a diet which is high in fat, salt and free sugars, and low in complex carbohydrates, fruit and vegetables increases the risk of chronic diseases, especially CVD and cancer (9, 60). Thirty-one percent of CHD is due to fruit and vegetable consumption levels below 600.0 grams per day (48). Fruit and vegetable consumption is inversely linked to body weight and fat mass (61, 62). Fatty acids affect cholesterol, blood pressure levels, and body weight (10). Salt intake influences arterial blood pressure and therefore the risk of arterial hypertension, stroke, CHD, and heart failure (10). A reduction in salt intake and alcohol intake can effectively lower the blood pressure (18).
Recommendations and guidelines
The WHO recommends that average fruit and vegetable intake should be at least 400.0 grams of fruit and vegetables per day (39). Furthermore, the average fat intake should maximally be 30.0% of total energy intake and saturated fat intake shouldn't be more than 10.0% of total energy intake (39, 10). A varied diet rich in fruit and vegetables, monounsaturated fatty acid-rich oil (such as olive oil), wholegrain cereals and bread, fish (especially oily), lean meat, and low fat dairy products lowers the risk of CVD (10). Salt intake should be limited if blood pressure is raised. The recommendations for diet used in this thesis were: to limit the saturated fat intake to a maximum of 10.0% and the total fat to a maximum of 30.0% of the total energy intake per day; and to eat 4 portions of fruit and vegetables every day (44, 55, 63, 56). Moderate alcohol consumption reduces the risk of CVD, at high levels of intake, however, the risk of CVD is increased (9).
Epidemiology
In Belgium, in 2004, the mean amount of energy from total fat equalled 37.9% and 16.0% from saturated fat (64). In Europe, in 2003, the percentage of total energy from fat was 36.9% (65). Two thirds of the Belgian population eats fruits on a daily basis and one thirds eats 2 portions per day (66). Two thirds of the Belgian population eats 200.0 grams of

vegetables per day (66). It can be concluded that the fat intake is too high and the fruit intake is too low in the general Belgian population.

Measurement

Types of measurement include diet assessment by a dietician, 24 hour recalls and food frequency lists. Fruit- and vegetable intake can be measured in portions per day with a short food frequency questionnaire (1 portion = 80 grams) (67). Fat intake can be measured in grams per day with a computerised fat intake questionnaire with a good reliability and adequate validity (68). The distinction between saturated and unsaturated fat intake can be made using the latter questionnaire. Therefore the above mentioned questionnaires were selected for measuring fruit, vegetable and fat intake in the present thesis.

Total CVD risk

In total, 70.0-76.0% of the CVD burden in the world can be attributed to a combination of the medical risk factors and risk behaviours mentioned above (69). Risk tables were developed to estimate the total CVD risk and provide options for multiple risk management. In 2003, a risk chart called SCORE (Systematic Coronary Risk Evaluation) was developed and allowed the estimation of 10-year risk of cardiovascular death (70, 10). This is the risk of a fatal atherosclerotic event, whether heart attack, stroke aneurysm of the aorta, or other. All ICD codes that could reasonably be assumed to be atherosclerotic are included. The factors taken into account in this algorithm are age, gender, smoking status, cholesterol level, and blood pressure level. People can have a low, average or high risk score. It is advised to adapt interventions to the magnitude of this risk but no information is available on the implementation of this guideline in clinical practice, certainly not across the whole spectrum of primary prevention (people at *all* risk levels) (71). Individuals with a high CVD risk gain most by active risk factor management (10). However, the relative risk reduction of certain interventions (e.g., treatment with statins) is independent of the baseline risk. Consequently, interventions shouldn't be limited to high risk individuals but should be combined with national public health strategies aimed at whole populations (10). Interventions at the population-level are critical to reduce the overall incidence of CVD (72). When high-risk strategies are compared to population-targeted interventions, the latter appear to be the winner with a 45.0% decrease in CVD in contrast to 11.0% for high risk-strategies (73). Most deaths in a community come from those at lower levels of risk, simply because they are more numerous compared with high risk individuals who, paradoxically, develop fewer events in absolute terms (Rose paradox) (10). To prevent one single cardiovascular event, it is necessary to intervene in many patients with no apparent benefit (prevention paradox)(10, 74). Importantly, the overall objectives of cardiovascular prevention are to reduce morbidity and mortality in those at high absolute risk and to assist

those at low absolute risk to maintain this state, through a healthy lifestyle (10).
In spite of the evidence for the importance of CVD risk factor management, the implementation of cost-effective interventions in an organized way is lacking. An optimal CVD risk profile is characterised by the absence of a number of medical risk factors and risk behaviours. The medical risk factors should be managed to obtain optimal SBP, DBP, TC, FPG, BMI levels (10). Cardio protective drug therapy can be used in high risk individuals to achieve the medical targets. The risk behaviours should be managed to obtain smoking abstinence, healthy food choices and daily moderate physical activity (75, 76).

CVD Risk factor management: an implementation model
The practice guidelines on risk factor management for CVD acknowledge the existence of three components of CVD prevention: a primordial, a primary, and a secondary prevention strategy (77, 78). The **primordial prevention strategy** deals with actions to prevent the development of risk factors (e.g., prevent people from becoming obese, prevent the raise of blood pressure with age). Measures at this level include population policies for smoking cessation, promotion of a healthy diet, and physical activity. Moreover, this level involves public health financing, changes in medical education, and national CVD health programmes. The **high-risk primary prevention strategy** deals with risk factor reduction in asymptomatic people and the **secondary prevention** strategy deals with CVD patients. High risk individuals gain most by active risk factor management (10). However, interventions should not be limited to high risk individuals but should be combined with national health strategies aimed at whole populations to reduce the overall incidence of CVD (10, 72).
The implementation of prevention strategies can be performed using an implementation model. Grol et al. (2001) proposed a model of Change Implementation wherein a number of key points can be distinguished (79). These key points were: development of guidelines, analysis of the target group and setting, development and application of strategies and an implementation plan, and evaluation. For CVD prevention, specifically, Wan et al. (2008) and Gupta et al. (2011) provided more advices for implementation (77, 80). An implementation model should consist of three types of support, support for the general practitioner (GP), the patient and support by the government (77).

- The GPs can be supported to follow the guidelines by tackling the barriers they experience to do so. These barriers include: lack of time, lack of awareness, lack of agreement with the guidelines, lack of outcome expectancy, lack of reminders, and lack of reimbursement (81, 82).

- The patients can be supported to accept and act on the preventive advice of the GP by increasing awareness (80). Awareness, on its turn, can be increased by facilitating self-assessment, follow-up, and referral (80). Active patient participation should be encouraged because it leads to shared risk management and decision making.
- The government can support the shared risk management by reimbursing the use of supportive CVD risk management tools and preventive actions in primary care (80). In Belgium, the state recently started to financially reward GPs for using an improved medical record with a prevention module in patient consultations.

Conclusion:
Medical risk factors and risk behaviours such as smoking, low levels of physical activity and an unhealthy diet contribute to an increased total CVD risk. Risk factor management for high and low risk individuals always includes the advice to adopt a healthy lifestyle through behaviour change. CVD risk factor management asks for a specific implementation model.

II. Behavioural determinants and intervention development

Change of risk behaviours for CVD can be stimulated by well designed health promotion interventions. Several models for health promotion planning exist, with the Precede – Proceed model and the Intervention Mapping protocol as the most influential examples (83). However, an integrated, simple model with 5 steps can be used to explain the desired procedure for health promotion planning (Figure 2) (2).

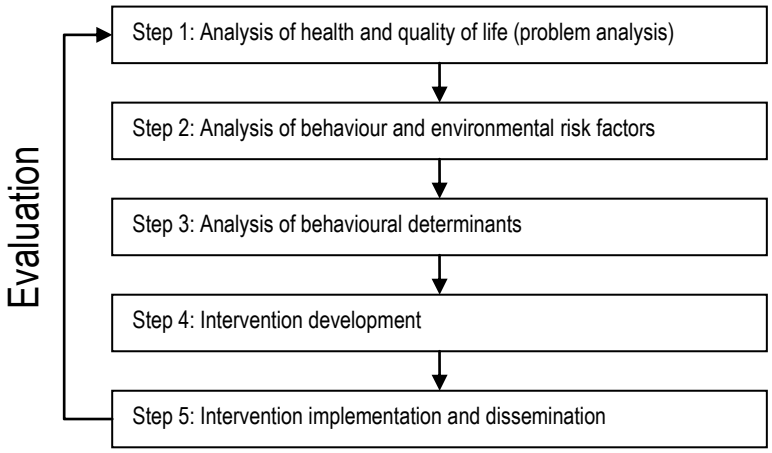

Figure 2: A model for Planned Health Education (2)

The first two steps include a health problem and risk behaviour analysis. The health problem should be serious and/or prevalent enough to justify spending time, money and other resources on it. From the first part of this introduction it can be concluded that CVD is a major public health problem. In the second step of health promotion planning, the risk behaviours associated with the health problem need to be identified. The risk behaviours associated with CVD were described in the prior paragraphs as well. The third step includes an analysis of the behavioural determinants and this step is described below. In the fourth step interventions should be developed that target the most important and modifiable behavioural determinants. In the fifth step, interventions should be implemented and disseminated after effectiveness has been established. Each step should be evidence-based and evaluated. The original research in this thesis is based on this planning model.

Behavioural determinants

Behavioural determinants are "causal factors that are hypothesised to affect health behaviour" (84, 1). These include demographic and biological factors (age, gender, socio-economic status); psychological, cognitive and emotional factors; social and cultural factors, and environmental factors. The relationships between determinants and health behaviour have led to the construction of health behaviour theories. These theories can be placed

along a continuum of personal level theories on one end of the continuum and environmental theories on the other end. Personal or social psychological theories focus primarily on cognitions that determine behaviour; whereas environmental theories are related to the physical, social or institutional environment. Psychological and social determinants are most likely to be modifiable by means of health education interventions. This can be done in an evidence-based manner using two prominent personal level theories, the TransTheoretical Model (TTM) and the Theory of Planned Behaviour (TPB) (85, 84, 86).

TransTheoretical Model (TTM)

The TTM describes behaviour change as a multistage process (84, 86). It is a brief model with a high face validity that can easily be explained to non-behavioural scientists, general practitioners and patients. Although the model was originally developed to describe change of addictive behaviours, it has also been applied to health-promoting behaviours. In the model 5 stages are distinguished: precontemplation, contemplation, preparation, action, and consolidation. In the precontemplation stage, benefits of behaviour change are not being considered and people do not intend to change their behaviour. In the contemplation stage, individuals consider change, but they don't take action yet. In the preparation stage, individuals are ready to change and make plans to change. In the action stage, individuals change their behaviour but not yet for a longer period. In the consolidation stage, individuals change their behaviour and the change is maintained on the long-term. The TTM has two major sets of constructs: the stages mentioned above and processes of change (87). Some processes can be considered as determinants of moving to the next stage while others are rather methods to promote stage transition. Examples of processes of change are: mobilizing social support; improving self-efficacy; relevance, tailoring, and individualization. Self-efficacy is a concept that has been borrowed from Bandura's Social Cognitive Theory (SCT) (88). Tailored materials are "intended to reach one specific person, are based on characteristics that are unique to that person, are related to the outcome of interest, and have been derived from an individual assessment" (89, 90). Nevertheless, the evidence for TTM comes solely from cross-sectional studies that showed that certain processes of change are associated with stage transitions but not that they can predict stage transitions (91). The TTM has been subject to criticism, for instance, because the distinction between the stages is chosen in an arbitrary way (92).

Theory of Planned Behaviour (TPB)

The TPB can be seen as an expectancy value theory and has successfully been applied to many types of health behaviour (1, 93). TPB states there are distal and proximal predictors of health behaviour (87, 94). The distal

predictors are three conceptually different belief-based perceptions on behaviour: attitudes, subjective norms, and perceived behavioural control (PBC) (Figure 3). Attitudes reflect beliefs as to whether the behaviour (e.g., physical activity and dietary behaviour) will lead to desirable outcomes. Subjective norms summarise beliefs about whether salient others want an individual to participate in the behaviour. The concept of PBC is similar to Bandura's concept of self-efficacy and reflects whether a person believes he/she has the resources or capacity to engage in the behaviour (95, 96). According to TPB, the effect of these distal predictors is mediated by intentions. Intentions are the tendency of a person to demonstrate a certain behaviour. However, PBC or self-efficacy is considered to be a direct predictor of behaviour as well. Current developments in TPB include an increased interest in the intention-behaviour link (e.g., for implementation intentions) in addition to the moderating factors of skills and barriers described by the Attitude, Social influence and Self-Efficacy (ASE) model (4, 97).

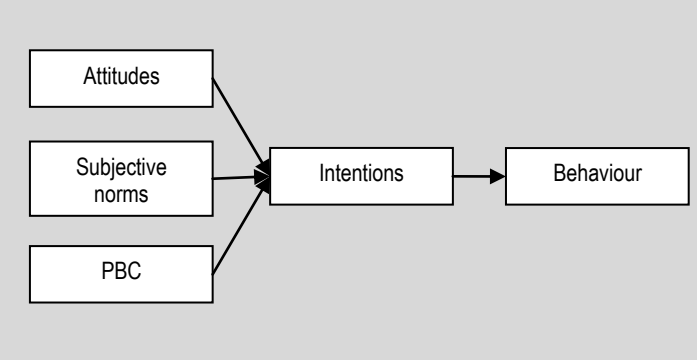

Figure 3: Theory of planned behaviour (TPB) (1)

Self-Determination Theory (SDT)

TPB has recently and successfully been integrated in a theoretical model together with the Self-Determination Theory (SDT) (4). The SDT has focused on social-contextual conditions that facilitate or impede the natural processes of self-motivation (98). On the one hand it is concerned with psychological needs within the individual but on the other hand SDT describes how social environments can fulfil these needs and increase motivation towards behaviour change (4). SDT pays more attention to the

environment than TTM and TPB. Ryan and Deci (2000) stated that "motivation concerns energy, direction, persistence and equifinality – all aspects of activation and intention"(4). People can feel externally pressured versus have an internal motivation to act. Accordingly, SDT distinguishes between distinct types of motivation on a continuum from amotivation, controlled types of motivation (non-selfdetermined) over more self-determined types of motivation with intrinsic motivation at the end of the continuum (Figure 4) (99, 4, 100, 101). When people are amotivated, they lack the intention to act. The regulation of behaviour becomes more autonomous from the left end to the right end of the continuum. As people internalize regulations and assimilate them to the self, they experience greater autonomy in action.

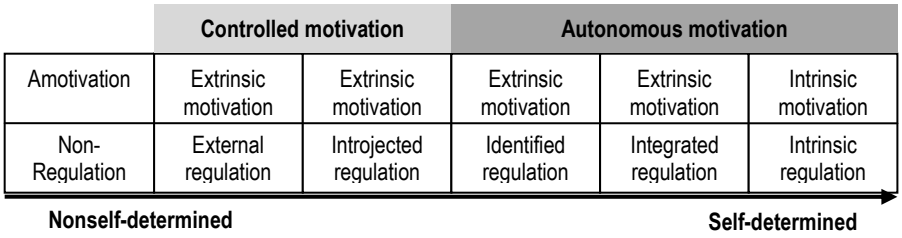

Figure 4: The Self-Determination Continuum (4)

The extrinsically motivated behaviours that are least autonomous are referred to as externally regulated. These behaviours are performed because of external reward or avoidance of punishment. People are interpersonally controlled. A second type of extrinsic motivation is defined as introjected regulation. In this case, behaviours are performed to avoid feelings of guilt or anxiety or to feel proud. People are intrapersonally controlled. These two types of motivation are labelled as controlled motivation (Figure 4). The next type of extrinsic motivation is characterised by identified regulation. This means that the behaviour is considered to be of personal importance. The next type of extrinsic motivation is regulation through integration. This means that the behaviour is not only considered to be important but it is valued and integrated in a network of other values and needs. Lastly, when people are intrinsically motivated they perform a behaviour for its inherent satisfactions. Identified regulation, Integrated regulation and intrinsic motivation form an autonomous motivation composite.
The aim of health promotion interventions should be to support internalization of regulations and thus stimulate autonomous motivation to achieve behavioural effectiveness and persistence (4). This support ideally

consists of efforts to satisfy three innate psychological needs: the need for autonomy, the need for competence, and the need for relatedness (102). The need for autonomy refers to the need to experience oneself as an initiator and regulator of one's actions. The need for competence refers to the innate need to master one's environment. The need for relatedness refers to people's innate need to seek close and intimate relationships with others. Using an autonomy-supportive style to stimulate behaviour change was found to lead to better behavioural outcomes than a more controlling style (4). An autonomy-supportive style is characterised by providing a rationale for the proposed behaviour, offer choice, take the perspective of the individual and acknowledge difficulties associated with changing behaviour (97). Perceived autonomy support directly influences self-determined motivation and indirectly the distal behavioural determinants from TPB (Figure 3) (103-105, 98). Because the motivation theory of SDT can identify the origins of TPB constructs theoretically-integrated models of TPB and SDT have been developed and tested (76). It is proposed that individuals with a self-determined motivational orientation towards a health-related behaviour will tend to form positive attitudes and more self-efficacy, two key determinants of intention from the TPB.

Intervention development and implementation

The health behaviours that need to be changed in order to improve health and reduce total CVD risk or maintain a low total CVD risk are: not smoking, being physically active, and eating a healthy diet. A first step in the intervention development should be to determine the behavioural outcomes. In other words, to describe what the health promotion intervention needs to result in (106-108). The process of intervention development can be summarised in a matrix. After the behavioural outcomes have become clear, one should come to sub-behaviours which are the performance objectives. Then the behavioural determinants that are important and changeable should be listed together with change objectives. These change objectives are what the health promotion intervention should actually contribute or realise. Next, the general methods on how to do this are listed and the next step is to determine the practical strategies that match the target group. Then intervention themes and materials should be developed and pretested, and delivery modes should be selected. An implementation plan and an effect and process evaluation plan should be developed. Finally, the intervention can be implemented.

Conclusion:
Behavioural determinants predict behaviour and interventions should be designed to influence these determinants using effective strategies so that healthy behaviours are adopted and maintained on the long-term.

III. Interventions

People's adherence to the recommendations and guidelines mentioned in the first part of this introduction can be stimulated by interventions including messages that convey why and how to achieve multiple behavioural recommendations. First a summary of intervention effectiveness studies, targeted at multiple behaviours (with or without an additional focus on medical risk factors) is given. Next, some general features that can increase intervention effectiveness are discussed. These include tailoring, delivery mode and intervention dose.

Interventions targeting multiple behaviours and medical risk factors

A recent review summarised the effects of health promotion interventions at the workplace to reduce CVD risk (109). The effectiveness of interventions that were aimed to improve blood pressure, cholesterol, glucose, body weight, waist circumference, physical activity and diet were reviewed. The three intervention strategies most frequently used in the included studies were individual coaching, group education, and supervised exercise. Interventions were effective in reducing overall body fat but not in changing blood pressure, cholesterol, glucose levels and body weight. The authors state that the effectiveness of a lifestyle intervention often depends on the level of risk. Interventions with mixed populations (i.e., making no use of CVD risk-related inclusion criteria) had no effect on most outcomes. A weakness of this study is that it only included interventions at the worksite.

Another review on interventions for the primary prevention of CVD concluded that multiple risk factor interventions have no effect on CVD mortality (110). Furthermore they found that lifestyle interventions are not effective in low-risk populations for the prevention of clinical events. Importantly, this review has been criticised for mixing very heterogeneous trials. Moreover, there were only two trials that had sufficient statistical power to examine the intervention effects on total mortality and CHD incidence. Additional analyses showed that lifestyle changes are effective in terms of CHD prevention.

Individual trials that target multiple behaviours and medical risk factors are Hartslag Limburg, the Swedish Bjorknas study, the Improving Patients' Adherence to Lifestyle Advices (IMPALA) study, and EUROACTION (111-113). Hartslag Limburg was a community-based intervention that started in The Netherlands in 1998. The aim of the project was to reduce the prevalence of CVD in the general population of the Maastricht region by health promotion interventions (smoking-cessation, physical activity, diet). This region was compared to a reference group from another region. Examples of materials that were used are: computer-tailored diet education, television programmes, walking and cycling campaigns, and pamphlets. The study included a five-year follow-up and the main outcome measures were blood pressure, cholesterol, serum glucose, BMI, and waist circumference.

Blood pressure, BMI, and waist circumference changed more favourably in the intervention group compared to the reference group (114). With regard to risk behaviours the conclusion was that changes for time spent bicycling and fat intake were more favourable in the intervention group, especially in the lower educated (112).
The Swedish Bjorknas study was a randomised controlled trial conducted from 2003 to 2006 with a follow-up on cardiovascular risk factors at 3, 12, 24 and 36 months (113). The intervention consisted broadly on a Diabetes Prevention Program and was administered during three months in the primary care setting using physical activity and diet sessions. The control group received general advice. Main outcome measures were changes in blood pressure, metabolic traits, anthropometrics, self-reported physical activity, aerobic fitness, and tobacco habits. The lifestyle intervention was effective in changing blood pressure, waist circumference, waist-to hip ratio, smoking-cessation, physical activity, and aerobic fitness. No effects were found for cholesterol or glucose (113). A weakness of the study is the mere inclusion of participants at moderate and high total CVD risk, discordant with the guidelines on CVD prevention.
The IMPALA study is a cluster-randomised controlled trial of an intervention to reduce CVD risk with the practice nurse as a key figure. The nurse gave patients face-to-face consultations and a follow-up telephone call (111). CVD risk-related inclusion criteria were used. The main outcome measures were smoking and alcohol use, physical exercise, saturated fat intake, and fruit and vegetable consumption. No differences between both study groups were found for the outcome measures after twelve weeks. The authors explain this can be due to the practice nurse being available in both study conditions; a problem formerly described in the literature (115). A weakness of the study is its short duration of only three months.
EUROACTION was another nurse-coordinated CVD prevention programme for patients with CHD and asymptomatic individuals with a high total CVD risk (116). It was a matched, cluster-randomised controlled trial. The main outcome measures were blood pressure, cholesterol, glucose level, and lifestyle change (smoking cessation, physical activity, diet). The conclusions were that the intervention resulted in a higher chance of reaching blood pressure targets, a decreased fat consumption, and an increased consumption of fruit and vegetables and oily fish.

Interventions targeting multiple behaviours
Targeting multiple behaviours at the same time seems logical in the context of cardiovascular prevention. From the studies of Vandelanotte et al. (2005; 2008) it can be concluded that there is no need to work on different risk behaviours sequentially (117, 118). The evidence is thus not in line with the intuitive idea that working on multiple behaviours at the same time may become overwhelming for people. Moreover, interventions targeting multiple

behaviours seem to lead to better results. A trend was found for increasing effect sizes of tailored interventions that targeted one, two, and three behaviours (119). Targeting multiple behaviours at the same time was advocated by prior research on clusters of behaviours (120). These results show that there are two clusters, one of addictive behaviours and one of health promoting behaviours. The authors argue that tailoring interventions to multiple behaviours in the same cluster may lead to better effects. Smeets et al. (2007) indeed showed that tailored feedback for smoking, physical activity, fruit and vegetable intake was effective in changing behaviour, except for smoking-cessation (121). Nevertheless, small effect sizes were found, the follow-up period was no longer than three months and only one tailored feedback letter was used in that study. De Vries et al. (2008) confirmed the effectiveness of tailored printed letters to improve multiple behaviours (108). In the latter study, dynamic tailoring for smoking, physical activity, fruit and vegetable intake and fat intake was used. At post-test participants improved for all behaviours, except for smoking-cessation. Oenema et al. (2008) evaluated the effect of a computer-tailored intervention targeted at smoking cessation, physical activity and diet (122). After a one-month follow-up, saturated fat intake was reduced and more participants met the recommendations for physical activity. Again, no effects for smoking-cessation were found.

Tailoring

In the present study, tailoring was defined as *any combination of information or change strategies intended to reach one specific person, based on specific characteristics of that person that have been measured in a formal assessment* (123). Tailoring increases message relevance, the chance that the information is read and remembered, and the impact of the message on behaviour (124-128). This was examined and confirmed in randomised studies using generic or non-tailored information in the control conditions (129). Computer-tailoring means that the content is selected using data-driven decision rules or IF-THEN algorithms that automatically produce advice from a feedback message library (Figure 5).

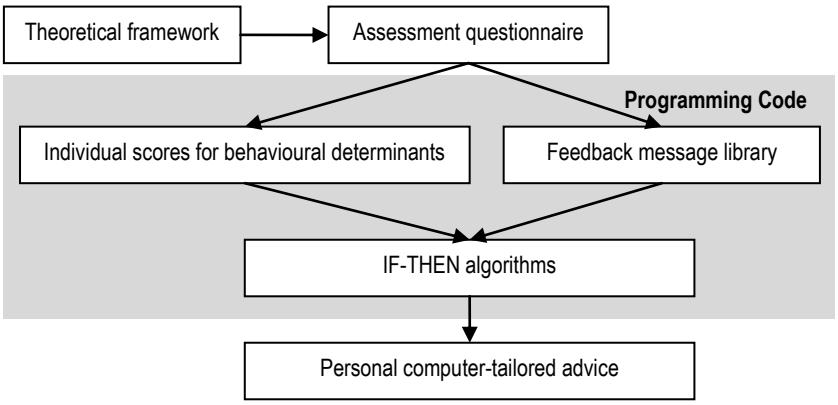

Figure 5: The process of computer-tailoring

Computer-tailored messages can be delivered through different modes such as print, website, and e-mail. Early computer-tailored interventions were disseminated by print, but nowadays website and mobile technology are popular. A recent review summarised the effect sizes for tailoring (119). For smoking cessation, the mean effect size was g=0.16 (95% CI=0.12-0.19, p<.001). A value of g=0.10 (OR=1.18) is assumed to be a meaningful effect in population-based interventions. For physical activity, the mean effect size was g=0.16 (95% CI=0.10-0.21, p<.001). For dietary fat reduction this was g=0.22 (95% CI=0.18-0.26), p<.001) and for fruit and vegetable intake the effect size was g=0.16 (95% CI=0.10-0.21, p<.001). Other reviews corroborate these findings with positive results for computer-tailored diet (especially on the short-term) and for smoking-cessation education (130-132, 127). In contrast, the evidence for computer-tailored physical activity interventions is inconclusive (133).

Delivery mode

Research on the optimal delivery mode (e.g., print, website, telephone) has been summarized and evaluated. In a recent review on the effectiveness of tailored interventions, no significant differences between delivery modes were found (p=.89) (119). This review included computer-delivered, print-delivered, and messages delivered by an automated phone. The same conclusion was drawn in a review on sequential and simultaneous tailored interventions for physical activity and diet (118). However, some studies reported some intervention modes to be superior to others (134, 135).

Bartholomew et al. (2006) described different delivery modes or "channels and vehicles" with their advantages and disadvantages (76). No definite conclusions about the effectiveness of different delivery modes can be drawn from the literature. In the next paragraphs the evidence on the effectiveness of different delivery modes is summarised.

Print
Print materials such as pamphlets and brochures can enhance skill training, modelling, knowledge and can persuade (76). Posters can raise awareness, draw attention and be a cue to action but learning opportunities are more limited than with brochures. Print materials are believed to lead to higher costs than messages delivered through a website or e-mail. Most studies included in a recent review were delivered by means of letters, pamphlets or brochures and were found to be effective, especially for dietary behaviours (127). Another study showed that multiple tailored print materials were more effective in increasing fruit and vegetable consumption than single untailored print materials or messages (136). Tailored print materials for smoking cessation can be useful in addition to one-on-one coaching by telephone (137).

Website and e-mail
Bartholomew et al. (2006) state that the current computer environment in health education is one of great promise (76). A high level of interactivity enables the user to modify the form and content of the intervention. Nowadays, internet-delivered interventions are widely used to deliver behaviour change interventions. However, mixed results were found for the effectiveness of computer-tailored interventions delivered through the Internet (138, 139). Interventions delivered online should be refined and evaluated more rigorously (140).
A number of studies showed that e-mail interventions for improving physical activity and diet were effective (141, 142). Coaching by e-mail in combination with telephone coaching or a website is effective to reduce body weight, waist circumference, fat intake and increase physical activity and fruit and vegetable intake (143, 144). However, one study pointed out that e-mails in addition to a website yielded no effect on physical activity (145, 144).

Telephone
One-on-one coaching by telephone is an interpersonal way of message delivery. When delivered by health care providers, the typical methods and strategies that are used are skill training, social reinforcement, modelling, and counselling (76). An advantage of this delivery mode is that experts in patient counselling can greatly influence and persuade people to behaviour change. Of course this mode is time-consuming and therefore expected to be

more costly than the previous ones. Coaching by telephone is an effective mode to deliver interventions to promote fruit and vegetable consumption and physical activity compared to printed mailed self-help materials in a working population (146). A review confirmed that telephone-based coaching is an effective mode to improve fruit and vegetable consumption and fat intake in adults (147). Another development in this respect is the Telephone Linked Communication (TLC) system that enables a real-time assessment and delivery of messages from a audio taped feedback library (148, 149). This system was found to be effective for physical activity promotion and for smoking cessation (148, 150).

Face-to-face

Another interpersonal form of message delivery is face-to-face coaching, individually or in group. Behaviour therapy and cognitive behaviour therapy, forms of individual coaching, were found to be effective in changing dietary habits, weight, and cardiovascular and diabetes risk factors(151). A cognitive behaviour therapy group session for lifestyle change and individual coaching were more effective to change weight than a control condition consisting of print booklets with general information after three and twelve months (152). No differences between individual coaching and group coaching were found in the latter study.

Intervention dose

The intervention dose that is actually delivered and received by participants should be considered when evaluating the effectiveness of health promotion interventions. The review of Krebs et al. (2010) on the effectiveness of tailoring mentioned the intervention dose (i.e., operationalised by the number of intervention contacts) (119). The authors found that the effect size was related to the number of intervention contacts and that every additional contact increased the effect size by an average of g=0.01. A higher dose leads to better results for diet and physical activity compared to a low intervention dose (153). Multiple intervention contacts give the opportunity to use dynamic tailoring (feedback based on multiple assessments) instead of static tailoring (feedback based on one baseline assessment). Dynamic tailoring is more effective than static tailoring (g=0.19 *vs* g=0.14; p=.01), especially on the long-term.

A failure of researchers to describe their interventions with enough detail makes a meaningful comparison in terms of the intervention dose impossible (127). In the literature it is advised to include information on the elements of intervention intensity such as number of contacts or exposures, delivery modes, length of active intervention period, environmental exposures or manipulations (154). Information on the dose and dose-response effects of health promotion interventions is lacking. Recently, however, the

intervention dose or actual exposure to website content received more attention (155).

Conclusion:
Behaviour change can be promoted by tailored interventions and interventions targeting multiple CVD risk factors have been proven to be effective. However, the effectiveness is dependent on the level of tailoring, the delivery mode, and the intervention dose. These factors should be taken into account in intervention development and evaluation.

IV. Economic evaluation

Cost-, cost-utility and cost-effectiveness analyses

Next to an evaluation of the effectiveness of health promotion interventions, an economic evaluation can be performed. Drummond et al. (2005) define economic evaluation as *the comparative analysis of alternative courses of action in terms of both their costs and consequences* (156). Different consequences can be considered and correspond with different types of economic evaluation. When no consequences are considered, a mere cost analysis is performed. Possible consequences can be measured as changes in natural units (e.g., life-years gained, points of blood pressure reduction, cases correctly diagnosed…), this is labelled as a cost-effectiveness study (CEA). When the consequences are measured in terms of quality-adjusted life years (QALYs), it is a cost-utility analysis (CUA). In this type of analysis, the consequences of interventions are adjusted by health state preference scores or utility weights. Lastly, if the outcomes of the intervention are measured in terms of monetary units, it is a cost-benefit analysis (CBA). In this part of the introduction, these different types are discussed together with examples from the literature relevant to the theme of this thesis.

Cost analysis

A cost analysis is common to all types of economic evaluation (156). The viewpoint for the economic analysis is important. An item may be a cost from one point of view, but not from another. Analyses can be performed from the perspective of the individual patient, the specific institution, the target group, the Ministry of Health, the government, or the society as a whole (156). For the evaluation of costs it is important to know that costing has two elements: measurement of the quantities of resource use (q) and the assignment of unit costs or prices (p). If an economic evaluation is conducted alongside a trial, information on resource quantities can be registered easily and prospectively. When conducting a cost analysis alongside a clinical trial, three steps are required: identification,

quantification and valuation (156). In the identification phase, the aspects of an intervention that have to be included and excluded in the cost analyses will be determined. These are costs of the material and staffing input. Next, in the quantification phase a description will be given of the methods used to obtain an overview of the material and personnel resources necessary for the intervention to be implemented. Finally, in the valuation phase, pricing methods will be applied. Market prices will be available for many of the resource items. Volunteer, patient and family time are non-market items and for these resources market wage rates can be used. Other choices that have to be made for a cost analysis are: the follow-up time, whether or not to include health care costs unrelated to the intervention, how to handle overhead costs, the level of precision for cost estimates (e.g., average daily cost *vs* micro-costing), and discounting of costs. Discounting is a way of taking into account that individuals prefer benefits today rather than in the future.

Relevant examples from the literature

The most relevant example from the literature is the cost analysis of Hartslag Limburg mentioned earlier in this introduction (157). This was the first study that presented a detailed cost analysis of a large-scale community intervention programme, including the material and staff input for every single intervention and following the guidelines for economic evaluation. The costs were calculated from the societal perspective. Costs were prospectively registered. The total cost for a five-year community programme was €900.000. A recent cost analysis of a web-based behavioural intervention to increase fruit and vegetable intake was conducted alongside a randomised controlled trial with three intervention arms. These study conditions included an untailored website program, a tailored website program, and a tailored website program with additional personalised counselling via e-mail (158). The tailored arms of the study cause an additional cost of $12-$115 per participant compared to the untailored website only. It is important to note that the costs of tailored message interventions have not been documented extensively yet (159).

Cost-effectiveness analysis

A cost-effectiveness analysis relates a cost difference (C_i-C_c) to a difference in effects (E_i-E_c) between two alternative interventions, often an intervention and control condition (156). The outcome measure of a cost-effectiveness analysis is the incremental effectiveness ratio (ICER):

$$\text{ICER} = \frac{\text{Cost intervention} - \text{Cost control condition } (C_i\text{-}C_c)}{\text{Effect intervention} - \text{Effect control condition } (E_i\text{-}E_c)}$$

In CEA outcome measures are noticeable effects of interventions such as life years gained or blood pressure reduction (156). However, intervention outcomes are often proxy or intermediate outcomes instead of measures for the ultimate goal of the intervention or the final outcome. For example, blood pressure reduction instead of avoided CVD events is used. A link should be established between the intermediate and the final outcome. Decisions between alternative interventions is impossible because of the use of different outcome measures. Because measuring costs and effects is subject to error, sensitivity analyses can be performed to account for this source of uncertainty. Furthermore, one should decide whether to include an estimation of avoided costs using modelling techniques based on data from the literature. The latter remark is also relevant for the other types of economic evaluation.

Relevant examples from the literature

A cost-effectiveness analysis of a randomised controlled trial for secondary prevention of CHD was performed (160). Nurse led clinics seem to be cost-effective compared with most interventions in health care, with the main gains in life years saved. A study on the cost-effectiveness of face-to-face smoking interventions concluded that a minimal counselling intervention by the general practitioner was cost saving compared to usual care (161).

Cost-utility analysis

Drummond et al. (2005) recommend the use of CUA for health treatments or programmes that extend life combined with certain costs (i.e., loss of quality of life) (162). In CUA the outcome measures are QALYs, which are calculated by multiplying the additional life years gained with a *utility weight* or a *health state preference* score between zero and one, where zero is death and one is full health. Using QALYs, comparison of interventions is possible. Comparison is even possible with completely different interventions for another disease or another target. This is undoubtedly an appealing feature of CUA. According to CUA an intervention is cost-effective if the ICER is below the pre-determined threshold. However, thresholds differ between countries and there is much discussion on how to determine these thresholds (163). In Belgium, no official threshold exists but an arbitrary threshold of €20,000 per QALY gained is mentioned in the literature (164). In neighboring countries, the thresholds range from £20,000-£30,000 per QALY (United Kingdom) to a maximum threshold of €80,000 (The Netherlands) (165).

Relevant examples from the literature

A recent review was positive about the cost-utility of behaviour change interventions targeted at high risk groups (166). The interventions that were analysed were intensive face-to-face interventions and did not make use of cheaper alternatives such as computer-tailored interventions. A recent cost-

utility analysis investigated the cost-utility of physical activity compared to no physical activity (164). In this study only modelling techniques were used, it was not performed alongside an actual trial. Lastly, Bemelmans et al. (2008) determined the cost-utility of community interventions (90% of the general population), combined with an intensive lifestyle intervention for an overweight subgroup (10% of overweight adults) (167). The conclusion was that these interventions were cost-effective.

Cost-benefit analysis: Willingness to pay

CBA requires that the consequences of interventions are valued in monetary terms (156). Whereas CEA and CUA reveal the price of achieving a particular goal, CBA reveals whether a programme on itself is worthwhile (156). The outcome measure is the Net Social Benefit (NSB):

NSB =	Benefits of the intervention (in monetary terms) – Costs of the intervention (in monetary terms)

The primary goal of CBA is to identify interventions where NSB>0. The major issue for health care CBA is the valuation of health outcomes in money. One approach to do this is that of stated preferences or willingness to pay (WTP), also known as contingent valuation (156). In contingent valuation individuals are directly asked what they are willing to pay for a service or benefit. This can be done using a questionnaire with an open-ended or close-ended format. In the case of an open-ended format, situations are presented where individuals are free to fill in an amount of money they are willing to pay. In the case of a close-ended format, people are asked to give a yes or no answer to a pre-set amount of WTP. The maximal WTP is the maximum amount an individual is willing to pay for the intervention or treatment which improves health while maintaining the same utility. Variety exists because of social differences, knowledge about the disease, seriousness of the disease and ability to trade money for health. It can therefore be said that the WTP for an intervention or treatment is dependent on the socio-economic status. A major merit of CBA is that it enables comparison of projects beyond health care boundaries.

Relevant examples from the literature

To date, no CBA was conducted in the context of health promotion including one or more risk behaviours for CVD. However, the WTP for health improvements of physical activity on description was recently determined alongside a randomised trial (168). Other authors concluded that people want to participate in interventions to prevent diabetes if the interventions are subsidised, but they are unwilling to pay the full program cost (169).

Conclusion:
Policy makers need to invest the scarce health care resources in cost-effective interventions only. At the moment, however, there is a lack of economic analyses that were conducted alongside randomised trials targeting multiple risk factors for CVD and involving computer-tailored interventions.

V. GENERAL AIM OF PRECARDIO

The **aim of the general project** was to study the effects of a multidisciplinary intervention for cardiovascular prevention, a cardiovascular prevention programme called PreCardio (or the PreCardio project). The interventions consisted of medical interventions and an individually tailored behaviour change programme targeted at changing medical risk factors and risk behaviours for CVD.
The **aim of the present thesis** was to study the **effect** and the **cost-effectiveness** of the **behaviour change programme on risk behaviours for CVD**. The main goal was to summarise the findings with regard to behaviour and behaviour change. Notwithstanding the fact that this thesis falls within the domain of health psychology -in line with the author's expertise- the choice was made to additionally include information on the medical interventions and the effects on the medical outcomes to give a complete overview of the broader context wherein this (cost-)effectiveness study took place.

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Chapter 2: Adapted protocol of PreCardio

Based on:
Claes N, Jacobs N. The PreCardio-study protocol: a randomised clinical trial of a multidisciplinary electronic cardiovascular prevention programme. BMC Cardiovascular Disorders 2007;7:27
and
Jacobs N, Claes N. An autonomy supportive cardiovascular prevention programme: practical recommendations from Self-Determination Theory. The European Health Psychologist 2008;10(4):74-76

Aims

Overall aims of the thesis
The overall aim of the thesis was to examine the (cost-)effectiveness of an individually tailored behaviour change programme.

Medical aims
This thesis concisely describes the medical interventions and the effect on the medical risk factors (blood pressure, cholesterol, overweight and obesity, fat percentage, and physical fitness) for the completeness of the project description. Further descriptions of the medical interventions and effects on medical outcomes fall beyond the scope of this thesis.

Primary aims
The primary aims of the thesis can be summarised as follows:

1. BEHAVIOUR:
   To examine **the effectiveness** of the individually tailored behaviour change programme on smoking, physical activity, saturated, unsaturated and total fat intake, and fruit and vegetable intake. Furthermore, the aim was to examine the dose-response effects and the effects on determinants of behaviour.
2. ECONOMIC EVALUATION:
   To perform an **economic evaluation** of the individually tailored behaviour change programme consisting of:
   a. a **cost-effectiveness** (i.e. a cost-utility analysis) to determine the costs of the tailored behaviour change programme and the cost per QALY gained
   b. a **willingness to pay** analysis to examine the willingness of the participants to pay for the individually tailored behaviour change programme

Secondary aims

1. To validate a step test for physical fitness assessment in a population sample
2. To perform an in-depth analysis of the use of the intervention by the participants
3. To determine the costs of an electronic prevention programme to support the general practitioner

Methods and design

Study population

PreCardio was financially supported by the Chair "De Onderlinge Ziekenkas-Preventie" established at Hasselt University. De Onderlinge Ziekenkas (OZ)

is an insurance company that insures self-employed professionals (e.g., lawyers) against loss of income due to sickness. The potential participants for the PreCardio study were customers of this company. They were self-employed and highly educated (i.e. Master degree in Law, 5 years of study at university level in Belgium). The inclusion criteria were age between 25-75 years, insured by OZ, have Internet access and sign an informed consent. The study took place in the East of Belgium (province of Limburg) from February 2007 to April 2010.

Recruitment
Recruitment or study enrolment took place from February 2007 to April 2007. Potential participants (*n*=737) received an e-mail with an invitation to take part in the PreCardio study. Because of the specific study population, the worksite could be used as a recruitment setting. The lawyers in Limburg are affiliated with the Bar of Hasselt or Tongeren which have their own administration and secretariat where lawyers meet each other. This was beneficial during recruitment and throughout the complete trial. For instance, promotional activities such as fruit distribution and healthy breakfasts were organized at the Bars. Furthermore, the cardiovascular prevention programme could be targeted to this specific and highly educated study population. At April 2007, 314 participants agreed to take part in the study and signed an informed consent form. The participation rate is less than 50%; it should be noted that this might limit the external validity of the study. Nevertheless, the hypothesis is that most of the non-respondents did not participate due to time constraints and this would in fact also be the case if this intervention would be implemented in real-life.

Design and randomisation
The study was a randomised controlled trial that ran from February 2007 to April 2010. The participants (*n*=314) were randomised using a nonstratified randomisation technique (Figure 1). The names of the participants were written on papers that were put in sealed envelopes. Next, the envelopes were randomly assigned by hand to two baskets for the control and intervention condition with a ratio of 1/2 to be able to study the dose-response effects of the intervention. Each participant had a 67% chance of being allocated to the intervention condition.

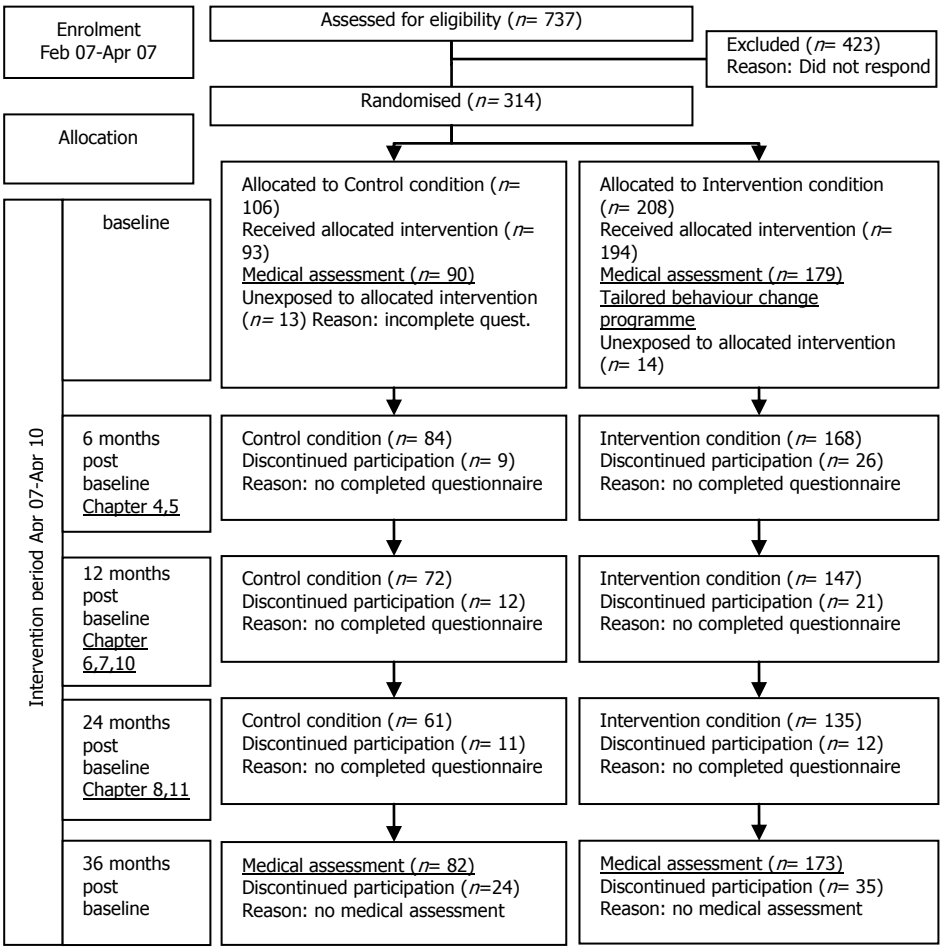

Figure 1: participant flow chart

Power calculation

A power calculation was performed to determine the number of study participants needed to detect a significant effect of PreCardio with a power of 80%. The main sample size calculation was based on the population standard deviation of the primary outcome measure for PreCardio, namely the systolic blood pressure (SBP). However, the power calculation was carried out for multiple behavioural parameters as well (see below) to fulfil the primary aims of this thesis. Kelley et al. (2000) found a mean SBP of 125 mmHg (SD 14) (1). The sample size calculation was performed with

Nquery Advisor 4.0®. A two group t-test with a 0.05 two-sided significance level would have 80% power to detect the difference between a control condition mean of 125 mmHg and an intervention condition mean 120 mmHg. Assuming a common standard deviation of 14 mmHg, a total sample size of 282, 93 in the control condition and 186 in the intervention condition would be sufficient to examine the study's effect on SBP. Other outcome measures were also used to determine the necessary sample size. A study on the effect of a computer-tailored intervention to reduce fat intake included at post-test a mean fat intake of 85 grams/day (SD 35) (2). A two group t-test with a 0.05 two-sided significance level would have 80% power to detect the difference between a control condition mean of 97 grams/day and an intervention condition mean of 85 grams/day. Assuming that the common standard deviation is 34.5 grams/day, a total sample size of 294, 98 in the control condition and 196 in the intervention condition would be sufficient to examine the study's effect on fat intake. Another study evaluating a website-delivered computer-tailored intervention for increasing physical activity increased physical activity with a mean of 77 minutes per week in the intervention condition (3). In this study the total moderate- and vigorous-intensity physical activity was chosen as an outcome measure. This measure was used to determine the necessary sample size. At follow up, this measure had a mean of 241 minutes (SD 269) in the control condition and 363 minutes (SD 323) in the intervention condition. Assuming that the common standard deviation is 323 minutes, a total sample size of 252, 84 in the control condition and 168 in the intervention condition would be sufficient to examine the study's effect on physical activity.

I. Intervention

The participants were randomised to a control and intervention condition. The control condition consisted of total CVD risk assessment, communication and follow-up. The intervention condition additionally consisted of a tailored behaviour change programme and is defined as a cardiovascular prevention programme (PreCardio).

Total CVD risk assessment, communication and follow-up

The participants with a signed informed consent (*n*=314) were invited to Hasselt University for a medical or total CVD risk assessment during a screening event. This risk assessment consisted of different measurements of medical risk factors and was conducted by general practitioners. These practitioners used the SCORE risk table to determine total CVD risk; this could be low, average or high (4). To determine the total CVD risk the following medical risk factors were measured at the screening event: blood pressure, cholesterol, diabetes and blood glucose, weight and fat percentage, and the fitness level. More information on the instruments used for these measurements can be found under the paragraph Measurements

below. The participants, who failed to attend the screening event, were asked to contact their own general practitioner for a cardiovascular prevention consultation. The general practitioners that performed the measurements at the screening event and the general practitioners of the participants had the opportunity to use an electronic prevention programme (EPP) with a risk calculator based on the European guidelines on CVD prevention. The EPP calculates the total CVD risk and generates standardised therapeutic goals and behavioural advice based on the participants' stage of behaviour change. The general practitioners of the participants in the trial could download and install the EPP. After installation, the EPP was automatically linked to the existing electronic medical files on the general practitioner's computer. Furthermore, the general practitioners who participated in the study had access to an informational website.

After the risk assessment, this risk was communicated to the patient. Firstly, immediate medical and behavioural feedback could be given by the general practitioner performing the assessment. This was of course easier for general practitioners using the EPP. Next, the medical CVD risk factors and the total CVD risk were summarised on a printed profile per participant. These profiles were sent to the participants by the study secretariat by regular mail.

Lastly, medical follow-up was given to participants with a medium and high CVD risk, irrespective of the study condition. Therefore, the risk profile also included advice on when to have a next cardiovascular prevention consultation. This advice could also be to go immediately to their general practitioner for drug treatment or to have a next cardiovascular prevention consultation within 4 months, one year or three years. The follow-up consultations could be performed by the participant's general practitioner or by a general practitioner of the PreCardio-study. The patients with a low risk were advised to have a next prevention consultation three years post baseline. The patients with a medium risk received the advice to have a next consultation one year post baseline. Lastly, the patients with a high risk were advised to have a next consultation immediately following baseline assessment and/or 4 months post baseline. The **therapeutic goals for medical CVD risk factors** were different for each risk group and these goals were based on the Boland algorithm (Table 1) (5). The Boland algorithm was used because it was specifically developed to be implemented in the primary care setting.

Table 1: therapeutic goals medical CVD risk factors based on the Boland algorithm

	High risk	**High risk 1 exuberant risk factor**	**Medium risk**	**Low risk**
Criteria for risk determination	SCORE risk ≥ 5% or Diabetes or a personal ischemic event	Cholesterol ≥ 320 mg/dl Blood pressure ≥ 180/110 mmHg LDL cholesterol ≥ 240 mg/dl	SCORE risk 2-4%	SCORE risk ≤ 2
Parameters				
BMI	< 25 kg/m²	<25 kg/m²	<25 kg/m²	<25 kg/m²
SBP	< 140 mmHg	< 140 mmHg	< 140 mmHg	
DBP	< 80 mmHg	< 90 mmHg	< 90 mmHg	
TC	< 175 mg/dl	< 190 mg/dl	< 190 mg/dl	
LDL cholesterol	< 115 mg/dl	< 115 mg/dl	< 115 mg/dl	

The **recommendations for behaviour** used in the present thesis were:

- Smoking: smoking abstinence
- Physical activity: engage in sports 3 times per week for at least 20 minutes or be moderately active for at least 6 days per week for a minimum of 30 minutes
- Diet: limit the saturated fat intake to a maximum of 10.0% and the total fat to a maximum of 30.0% of the total energy intake per day; and to eat 4 portions of fruit and vegetables every day (+/- 400 grams)

Individually tailored behaviour change programme

The tailored behaviour change programme or the intervention of the present study was a theory-based intervention and it was developed using the model for planned health education (6). Table 2 gives an overview of the matrix that was used for intervention development. As can be seen in table 2, the website and one-on-one coaching were important strategies to reach the change objectives by employing the adequate method. The individually tailored behaviour change programme consisted of a tailored behaviour change website and one-on-one coaching that are described in greater detail below.

Table 2: behavioural determinants, methods and strategies used in the behaviour change programme

Behaviour	Behavioural outcomes	Performance objectives	Behavioural determinants	Change objectives	Methods	Strategies
Not smoking	Smoking abstinence in smokers	Monitor smoking behaviour Plan smoking cessation Select smoking cessation drugs Quit smoking Deal with early relapse	Knowledge	Give information on CVD and smoking, low level of physical activity and an unhealthy diet as a risk factors that can be avoided leading to a decreased CVD risk	Tailoring and individualisation Feedback	Website Pamphlets Posters One-on-one coaching
Being physically active	Do sports 3 times per week for at least 20 minutes or Be moderately active for at least 6 days per week for a minimum of 30 minutes	Monitor own level of physical activity Increase total weekly physical activity by: -selecting a physical activity -planning (achievable goals in combination with profession) -maintenance -weight loss if overweight/obese	Awareness and risk perception	Inform about personal risk	Information about personal risk Consciousness raising	Screening event Printed profile
Eating a healthy diet	Limit the saturated fat intake to a maximum of 10% and the total fat intake to a maximum of 30% of the total energy intake per day. Eat 4 portions of fruit and vegetables every day.	Monitor own food intake Decrease daily total/saturated fat intake by: -buying and eating low-fat products -substitution of calorie-rich snacks by healthy alternatives Decreasing meat consumption -increasing (fatty) fish consumption -select low-fat food at receptions or dinners -goal-setting (in line with recommendations) -weight loss if overweight/obese Increase daily fruit and vegetable intake by: -eating vegetables for lunch -eating fruit as snacks or at breakfast -goal setting (in line with recommendations) -weight loss if overweight/obese	Attitudes and outcome expectations	Develop more positive attitudes about smoking cessation, being more physically active, eating less fat and more fruit and vegetables	Give information on the effect of smoking cessation Give information on the effect of being more physically active (e.g., to achieve a health benefit or to increase physical fitness) Give information on the effect of eating less fat (e.g., to lose weight, avoid atherosclerosis or a	Website One-on-one coaching

					high cholesterol) Give information on the effect of eating more fruit and vegetables (e.g., vitamins for health and resistance)	
			Perceived subjective norms	Recognise that colleagues are involved with their health and lifestyle	Belief selection, arguments, direct experience, repeated exposure	Screening event Tailored information with information about group results on the website.
			Self-efficacy	Express confidence in ability to quit smoking when following a good plan Express confidence in ability to be more physically active in combination with work when making physical activity a priority Expressing confidence in the ability to select healthy foods and substitute calorie-rich snacks with alternatives (also at receptions and dinners with colleagues or clients)		One-on-one coaching
			Capabilities, skills	Help with planning to increase chance on	Skills training with guided	Group sessions Behaviour change guidelines on

				success (easy goals to start with) Organise group training (e.g., start to run) Encourage physical training at home, at the office or the fitness centre Organise group training or encourage practicing at home/super market (e.g., reading food labels)	practice and feedback, modelling, goal setting, planning coping responses	the website One-on-one coaching
			Barriers	Help to determine barriers for change	Modelling	Dissemination of barriers for behaviour change in the target group
			Self-determined motivation	Using an autonomy-supportive interpersonal intervention style	Avoiding controlling language Take the perspective of the participant Offer choice Offer a rationale for requested behaviour change	One-on-one coaching Website
			Social norms	Try to influence the view of the professional group towards a healthy lifestyle	Social comparison, behavioural journalism (role models from the community)	Messages or interviews about lifestyle disseminated through pamphlets delivered by e-mail and regular mail
			Social support	Coach individuals to change behaviour, even when change is difficult	Stimulate communication and mobilising social support, skill building for	One-on-one coaching

					resistance to social pressure	
			Reinforcement	Try to reinforce small changes that participants make	Praise small, positive changes (e.g., decrease in the number of cigarettes smoked, car parked further away from destination than one usually would, eating one portion of fruit extra)	One-on-one coaching

Tailored behaviour change website
The participants of the intervention condition received access to a tailored behaviour change website. Figure 2 shows the site plan of this website. The website consisted of various sections that were one click away from the homepage, more detailed information asked for 2 or more clicks starting from the homepage. The content of the website was personalised and tailored to theoretical constructs (behavioural determinants) and behaviour. The tailored advice included advice on fat intake and physical activity and was evaluated and found to be effective in changing behaviour in prior research (7,8). On the homepage and in the separate sections personal messages could be given to the participants by a health psychologist (part of the one-on-one coaching, see below). The theoretical underpinning of the website content was based on TTM, TPB, and SDT (9-11). Operant learning principles (e.g., stimulus control, contingency management), principles from behavioural cognitive therapy (e.g., decisional balance exercises, problem-solving techniques) and relapse prevention techniques were used for the manuals (9, 12).

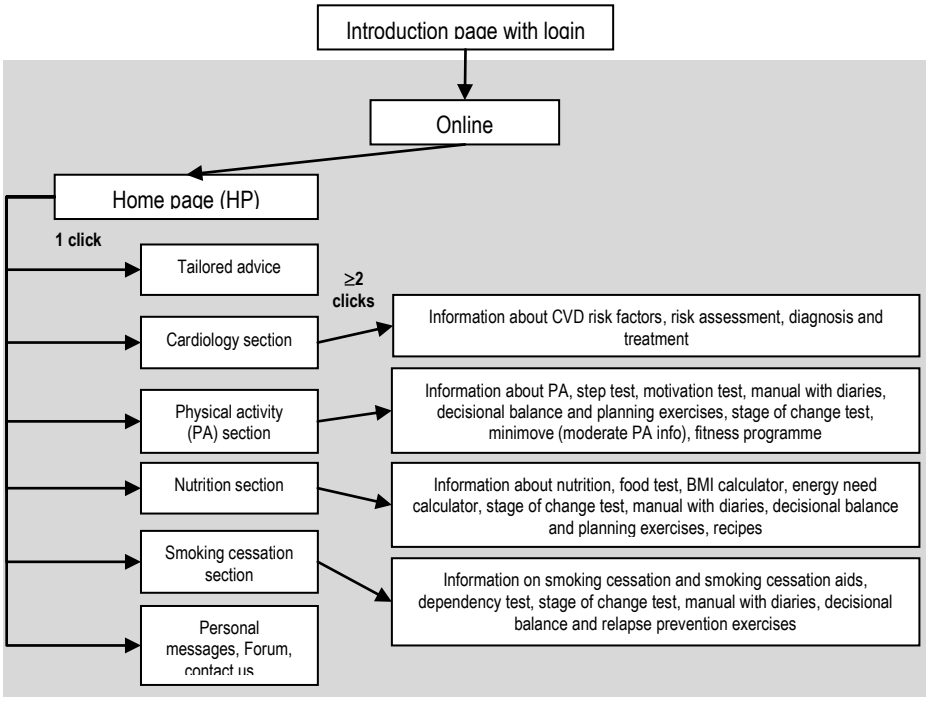

Figure 2: Site plan of the tailored behaviour change website

A first version of the tailored behaviour change website was evaluated in a small pilot study with eight highly educated volunteers. They were asked to surf on the website guided by a document. The volunteers were asked to give feedback on different factors related to user experience (e.g., look and feel, attractiveness, understandability, the ability to interact with the website). This feedback was used to improve the content of the website and an adapted version was evaluated in the present study. The website remained online from April 2007 to the end of the trial. In the last intervention year it was restyled and changes were made in accordance to the study findings.

One-on-one coaching
The one-on-one coaching consisted of contacts between the participants and a member of the multidisciplinary PreCardio team (health psychologist, physical therapist, cardiologist, general practitioner, and last-year students (dietician, sports coach)). All behavioural interventions were supervised by the trained health psychologist involved in the study. The interventions were theory-based and targeted at changing the determinants by the methods and strategies mentioned in table 2. Thus, the contact of the one-on-one coaching could take place via: the website (personal messages), per e-mail, per regular mail, per telephone or face-to-face (screening event, individual session or group session). Group sessions were organised for physical activity (e.g., start to run, spinning session), for nutrition, and for smoking cessation. During the first intervention year, the one-on-one coaching was completely adapted to the preferences of the participants in accordance with recommendations that can be derived from SDT (13). These preferences were registered by a health psychologist that telephoned the participants at the start of the study. The participants were asked for which behaviours they wanted coaching, how intensive they wanted this coaching to be (intervention dose, frequency and duration), and which delivery mode they preferred for this coaching (website, e-mail, regular mail, telephone, face-to-face). Combinations of multiple behaviours and multiple delivery modes were possible. The dose and delivery mode of the one-on-one coaching was self-selected during the first intervention year. This period will be referred to as the first stage of the behaviour change programme. However, based on findings of the first intervention year (April 2007-April 2008), the intervention dose of the one-on-one coaching was fixed to 10 tailored messages that were delivered by a limited number of modes (regular mail and e-mail) during the second intervention year (from April 2008-April 2009). This period will be referred to as the second stage of the behaviour change programme. The tailored behaviour change website was still available to the participants during the second intervention year. During the

third intervention year the tailored website was kept online and was restyled and ameliorated based on research findings of the first intervention year.

The PreCardio Implementation Model
The total CVD risk assessment, communication, and follow-up, and the individually tailored behaviour change programme were implemented in practice as shown in Figure 3.

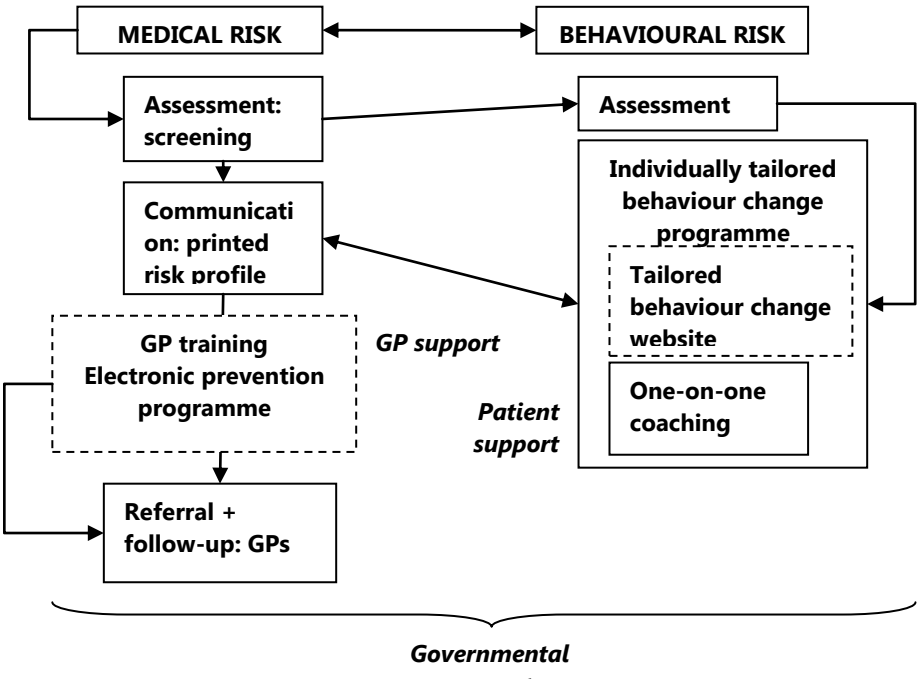

Figure 3: PreCardio Implementation model (intervention). Broken lines represent e-health support tools. GP; General practitioner

Within PreCardio, the emphasis is on behavioural and medical risk factors alike in a mixed population (primordial, primary, and secondary prevention). The aim of the PreCardio implementation model was to achieve an optimal CVD risk profile characterised by the absence of medical and behavioural risk factors in as many participants as possible. Consequently, a medical and a behavioural intervention path co-existed together (Figure 3). Both paths were supported by electronic tools; one to aid the shared-decision making during the consultation (electronic prevention programme) and a

personalised behaviour change website for the patient. In line with the theory on implementation discussed in the introduction of this thesis, the PreCardio model includes GP support (for adequate follow-up), patient support, and governmental since in Belgium GPs are rewarded to use an electronic prevention programme in practice.

II. Measurements

Time of assessment

The effects on medical risk factors were examined after three years of intervention. The effect of PreCardio on risk behaviours and determinants of behaviour were examined at different points in time, namely at 6 months, 12 months and 24 months post baseline. These moments of measurement are slightly different than mentioned in the published protocol. For instance, in the protocol published in 2007, we included a measurement moment for behaviour and determinants of behaviour at 18, 30 and 36 months as well. However, when performing the study, this wasn't feasible because the participants were tired and bored of filling out lengthy questionnaires.

Medical risk factors

The measurements of medical risk factors were performed at the screening event at baseline and after 36 months, and during individual consultations by a general practitioner affiliated with PreCardio or the general practitioner of the participant. Blood pressure (mmHg) was measured by an oscillometric semiautomatic device. For cholesterol measurement (mg/dl), the Accu-Chek InstantPlus Meter© (Roche Diagnostics, Basel, Switzerland) was selected (14). For glucose measurement (mg/dl), the Accu-Check Aviva System© (Roche Diagnostics, Basel, Switzerland) was used (15). Weight (kg) and fat percentage (%) were measured using the Tanita TBF-215 leg-to-leg analyser© (Tanita, Tokyo, Japan) (16).

Risk behaviours

In this thesis the smoking status (abstinence or no abstinence) was determined with a self-report national health questionnaire (17). Physical activity (minutes per week) was measured with the International Physical Activity Questionnaire (IPAQ) (long version, usual week). It was found to be a reliable and reasonably valid physical activity assessment tool for the general Belgian adult population (18). For physical fitness an adapted version of the Harvard Step Test was validated and used and validated for this specific study sample (19). Fat intake (grams/day) was measured with a validated food frequency questionnaire with 48 items divided into 7 categories of food items (20). This questionnaire was tested in a Belgian sample and has an acceptable reliability and validity. Originally, this questionnaire was designed to result in a total fat intake score. However,

only the saturated fats contribute to the risk on CVD. Consequently, we recalculated the coefficients to be able to determine the saturated and unsaturated fat intake (21,22).

Determinants of behaviour

With regard to the determinants from TTM, stages of change were measured for the following behaviours: 30 minutes of moderate physical activity daily or 3 times of intensive physical activity per week; low fat diet and 5 portions fruit and vegetables daily, and not smoking. Answer possibilities were: I'm not performing the behaviour and I do not intend to in the next 6 months (precontemplation); I'm not performing the behaviour but I plan to in the next 6 months (contemplation); I'm not performing the behaviour but I plan to in the next 30 days (preparation); I perform the behaviour but no longer than 6 months (action); I perform the behaviour but already longer than 6 months (consolidation). These items were formulated taking into account the advice about standardisation mentioned in a recent meta-analysis (23). With regard to the determinants of behaviour from TPB, much more items were included (24). General-affective and instrumental attitudes towards changing physical activity (4 items), dietary behaviours (4 items), and quitting smoking (4 items) were assessed using bipolar adjectives (7-point Likert scale). For physical activity, participants were asked whether being active every day for 30 minutes or do sports 3 times per week is 'pleasant-unpleasant', 'bad-good', 'stressing-relaxing', and 'unhealthy-healthy'. For dietary behaviours and smoking similar items were used. Because of the lower predictive quality of subjective norms and to limit the length of the questionnaire, data on subjective norms was not collected. Perceived behavioural control was measured with 1 item per behaviour. For physical activity, participants had to answer the item "I have the feeling that daily 30 minutes of moderate physical activity or 3 times sports per week is completely in my control in the next month". For dietary behaviours and smoking the items were comparable. For self-efficacy for changing physical activity and dietary behaviours 2 items were used for each behaviour using a 7-point Likert scale ranging from strongly disagree to strongly agree. For physical activity, an example of an item used is: "I am sure that, when it's up to me, I am capable to be physically active every day or to do sports 3 times per week in the coming month, also on days when I'm very busy or family and friends ask time from me". For dietary behaviours and smoking similar items were used. The intentions towards changing physical activity (1 item), dietary behaviours (1 item), and quitting to smoke (1 item) were measured on a 7-point Likert Scale ranging from strongly disagree to strongly agree. An example of an item for physical activity is: "I plan to be active every day or do sports 3 times per week in the coming month". For dietary behaviours and smoking a similar item was used. With regard to the items of SDT, three questionnaires were included for the 3 risk behaviours.

For the measurement of autonomous and controlled motivation the Behavioural Regulation Exercise Questionnaire II (BREQII) and the Treatment Self-Regulation Questionnaire (TSRQ) for dietary behaviours and smoking were used (25-27). The items for autonomous motivation for changing physical activity included, for example, "A reason to be physically active every day or to do sports 3 times per week is: (i) because it is fun, and (ii) because I find being physically active a pleasurable activity". The items were answered on a 7-point Likert scale ranging from strongly disagree to strongly agree.

Health related quality of life
The health related quality of life (HRQoL) was measured to be able to perform a cost-utility analysis. HRQoL was measured with the Dutch translation of the Short Form 36 second version (SF-36v2). This version was successfully tested in a Belgian and Dutch population with a Chronbach's alpha coefficient ranging from 0.81 to 0.92 (28, 29).

Intervention dose
Information on the contacts of the one-on-one coaching was prospectively registered throughout the trial by the members of the PreCardio team using an online activity registration form. The team members needed to fill out questions for each contact. These questions included items on the participant, the target behaviour (or behaviours) of the contact, the duration of the contact and the content of the contact (e.g., information giving, motivational). The intervention dose of the one-on-one coaching was determined as the frequency of contacts per delivery mode; the total duration/intervention time per behaviour or delivery mode. The total duration per delivery mode is a measure for its level of intensity, elaborateness, and tailoring.

Website traffic
The log-on rate percentage, the number of log-ons and hits by different subjects and the surfing depth were electronically registered. For individual surfing depth, the deepest layer that was visited was used as an outcome measure. Page view duration per participant was estimated using the time registration of subsequent hits after log-on. Unrealistically high durations of page views were changed into a maximum page view duration for that specific page which was determined by an independent person in advance of the study. This person was asked to read each page on the website and time this with a chronometer. This duration was multiplied by 2 to determine the maximum page view duration. The total page view duration per website section and the median number of hits and the median page view duration per subject and website section were determined.

Problem analyses and outline of the thesis

This thesis consists of a collection of articles that are published, in press, under review or submitted for publication.
Chapter 3 consists of a validation study of a step test for large-scale fitness assessment. When reviewing the instruments for measurement, the only instrument that was missing was a physical fitness measurement, validated in an overall healthy adult study sample. Physical fitness can lower the risk of hypertension more effectively than physical activity. Therefore, a simple, adapted version of the Harvard step test to assess physical fitness was validated for PreCardio and used during the screening events. Comparable studies were performed but were limited by small sample sizes and inclusion of very specific samples such as college students or elderly people aged 65 years or older (30-32).
Chapter 4 describes the effect evaluation of the tailored behaviour change programme on BMI, physical activity, fat intake and smoking 6 months post baseline. Because of the importance of the intervention dose for the intervention effect, special attention was given to a study of the dose-response effects on physical activity and fat intake (33, 34).
Chapter 5 describes an in-depth analysis of the use of the tailored behaviour change website during the first 6 months of the trial. In this chapter, objective data on the use of the website are presented. Previous studies pointed out that website use declines over time and that actual exposure to Internet-delivered interventions is important (35,36). The main aim of this study was to predict surfing depth and its effect on physical activity and fat intake.
Chapter 6 describes the effect evaluation of the tailored behaviour change programme on individual lifestyle factors (weight, smoking, physical activity, saturated fat intake, fruit and vegetable intake) and on a composite lifestyle change score. In prior research, it was concluded that it is important for multiple behaviour change interventions to find a way of communicating the complete behaviour change effect (37). They can be evaluated accordingly using a composite lifestyle score, but no randomised controlled trial of a behaviour change intervention for mixed populations (high, medium and low risk individuals) has used a composite lifestyle score as outcome measure yet. The dose-response effect was taken into account in this study.
Chapter 7 consists of an in-depth analysis of the underlying theoretical framework of the behaviour change programme. As was mentioned in the general introduction, integrated models of TPB and SDT were evaluated and confirmed by mainly correlational studies (38). However, no study has evaluated the model in an RCT in the dietary context yet (39). The study described in chapter 7 tests the model in the physical activity and dietary context 12 months post baseline. The intervention dose was included in the

model as a moderating factor of the relations within the model and to test effects on determinants of behaviour.
Chapter 8 describes the effect of the behaviour change programme 24 months post baseline. The difference between the control and intervention condition of the trial was examined for physical activity, saturated fat intake and smoking.
In **Chapter 9** the implementation costs of the EPP in practices of the participating general practitioners are described. The guidelines on CVD prevention are clear but not always followed by general practitioners in the field because of barriers such as lack of time (40). These barriers can be overcome by implementing electronic tools in general practice that can aid the general practitioner to follow the guidelines in an easy and time-efficient way. However, to date, no figures are available on the true implementation costs of such a tool.
Chapter 10 is an economic evaluation of the first intervention year of the behaviour change programme. A cost-utility analysis was performed and hereby fills in a gap in the literature because to date no cost-utility analysis of a multiple behaviour change programme was performed alongside an RCT in the field of CVD prevention.
Chapter 11 also looks into an economic aspect of the behaviour change programme, namely the willingness to pay of the participants for the programme. To date, only one other RCT evaluated the WTP of its participants but did this in a patient sample, thus not in a mixed sample that is advised to be targeted by the European guidelines on CVD prevention (41).

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Chapter 3

Validation of a step test for the prediction of physical fitness in population samples

Based on:
Jacobs N, Hansen D, D'Haene G, Bex S, Dendale P, Thijs H, Claes N. Validation of a fixed-rate step test for the prediction of physical fitness in healthy adults (submitted)

ABSTRACT
Objective. To asses, the validity of a fixed-rate step test to estimate maximal oxygen uptake capacity (VO_{2max}) and ventilatory threshold (VT).
Design. Experimental design with maximal cardiopulmonary exercise testing (CPET) using a cycle ergometer test and a fixed-rate single-stage step test.
Setting. Rehabilitation and Health Centre (Heart Centre Hasselt), Jessa Hospital, Hasselt, Belgium (March 2010 - June 2010).
Participants. 112 adults (45 +/- 13 yrs, 53 women, 59 men).
Main outcome measures and methods: VO_{2max} and VT during CPET, and heart rate during and after a single-stage step test. Linear regression analysis using Bland Altman 95% limits of agreement and a Jackknife procedure were used to test the validity of the step test prediction for CPET VO_2max and VT. The intraclass correlation coefficient (ICC) was calculated.
Results. The linear regression model (with age, BMI, gender, height, fitness index and maximal heart rate during step test as dependent variables) explained 78% of the variance in CPET VO_{2max} ($F=66.15$, $df=6$, $p=.00$). The Bland-Altman plot and the ICC showed a high level of agreement ($ICC=.94$; $p<.00$). On the other hand, the step test outcomes explained only 58% of the variance in CPET VT ($F=27.84$, $df=5$, $p=.00$)and a lower level of agreement ($ICC=.86$; $p<.00$).
Conclusion. In healthy adults a fixed-rate single-stage step test is a valid instrument to estimate VO2max, but to a lesser extent VT .

1. INTRODUCTION
In Europe, cardiovascular disease (CVD) is the main mortality cause and second most important cause of physical disability (1). CVD prevention is therefore needed to improve patients' CVD risk factors, hereby lowering disease burden. In this regard, the promotion of physical activity ca, be effective to increase physical fitness and lower CVD disease risk (2). Increasing the patients' physical activity is an important responsibility of general practitioners. Exercise prescription in general practice can be effective to assess and improve the physical fitness in older adults (3, 4). Fortunately, 70% of general practitioners provide verbal promotion for physical activity (5).
When designing effective exercise programmes, the exercise capacity needs to be assessed to obtain the baseline exercise tolerance and quantify changes in exercise tolerance. In general practice, however, exercise tests are infrequently executed (5). This lack of assessment could, at least partially be due to time investment, cost of equipment, and/or required technical skills. As a result, general practitioners are in need of physical fitness tests with limited time investment, need for equipment, and technical skills. Furthermore, they are in need of physical fitness tests that are safe to be carried out in clinical practice (6).
Decades ago, fixed-rate or single-stage step tests were introduced (7). In these tests, the patient steps up and down a bench at a fixed rate for a few

minutes. Next, the test duration as well as heart rate during and after exercise is used to predict the maximal oxygen uptake capacity (VO2max), which is considered as the gold standard surrogate for maximal exercise capacity.

However, the validity of step tests to estimate VO2max remains questionable. Even though some authors reported an acceptable VO2max estimation when using step tests, (3, 8-11), others reported a systematic under or overestimation of VO_2max (12, 13). Moreover, previous studies were limited by small sample sizes (50 subjects or less) (14-19), inclusion of non-representative samples (college students, subjects $\geq$ 65 years (3, 9, 18-21), patients (11, 22-24)) and/or lack VO_2max data (16, 25).

Furthermore, the prediction of the ventilatory threshold (VT) by step tests might also be of interest. VT is used to estimate the anaerobic threshold by ventilatory data, which is the exercise intensity at which lactic acid starts to accumulate in the circulation. This threshold is used to determine aerobic exercise intensity, as well as aerobic exercise capacity. The use of step test data to predict VT has, however, not been studied before and might be relevant for aerobic exercise programmes.

The aims of the present study were to assess the validity of a single-stage step test to estimate the VO_2max and VT in healthy individuals.

2. METHODS

Participants

Study participants were recruited in different workplace settings. E-mails with the request for participation were sent to the personnel lists of Hasselt University, Jessa Hospital, the city of Hasselt, and the city of Genk. Furthermore, participants engaged in a larger cardiovascular prevention trial (PreCardio) had the opportunity to participate in this study (26). Participants who signed an informed consent form, who were not excluded for safety reasons (see exclusion criteria below) and who completed a cardiopulmonary exercise test (CPET) and a step test were included in this study. In this study, a sample of 112 participants consisting of 53 women and 59 men with a mean age of 45+-13 years was included.

Procedure

The ethics committee of Jessa Hospital approved the study protocol. Subjects were excluded in case of any acute and/or chronic disease, and/or orthopaedic injury/dysfunction, and/or in case of heart rate-altering pharmacologic treatment. Following subject inclusion, subjects filled out a physical activity questionnaire and performed a CPET and step test on 2 separate days interspersed by a 1-week recovery. All measurements were performed by the same investigator at the same time of the day.

Measurement

Personal factors. Age, gender, height and weight, body mass index (BMI) were self-reported by the participants.

Cardiopulmonary exercise capacity. All subjects performed a maximal incremental 1-min stage CPET (27). Following criteria were used to define maximal exercise effort during exercise testing: respiratory exchange ratio >1.10 and/or heart rate >90% of maximal predicted value. During the cyclo ergometer test, an electronically braked Ergo 1500 cycle (ErgoFit®, Pirmasens, Germany) was used. The cycling frequency was set at 70 rpm and the test was ended when the subject failed to maintain a cycling frequency of at least 60 rpm (28). Before every test, an automatic gas and volume calibration was performed. During the exercise tests, pulmonary gas exchange analysis was performed by a cardiopulmonary ergospirometry device (Schiller CS200®, Schiller AG, Switzerland). Oxygen uptake capacity (VO_2) and carbon dioxide output (VCO_2) were collected breath-by-breath and averaged every 10s. VO_{2max} is the maximum capacity of an individual's body to transport and utilize oxygen during incremental exercise, which reflects the physical fitness of the individual. Predicted VO_{2max} was calculated from age, gender, height, and weight and compared to the actually achieved VO_{2max} (expressed in %predicted VO_{2max}) (29). Ventilatory threshold (VT) was calculated by V-slope method (30). VT is used to estimate the anaerobic threshold by ventilatory data, which is the exercise intensity at which lactic acid starts to accumulate in the circulation. Using a 12-lead ECG device, heart rate (HR) was recorded and averaged every ten seconds. Subjects presenting myocardial ischaemia (ST segment depression >0.1 mV and/or angina pectoris) and/or severe ventricular arrhythmias during exercise testing were excluded.

Step test. The step test was an adapted version of the Harvard step test (31). The step test consisted of stepping up and down a bench at a rate indicated by a metronome (90 beats/min, corresponding to 22.5 steps/min). Each beat initiates the movement of one leg up or down the bench. The stepping period lasted for 5 min. The height of the bench was determined according to patients' height. For individuals with a height up to 170 cm (5.6 ft) a bench of 33 cm (13.0 inch) was used. For individuals with a height above 170 cm (5.6 ft) a bench of 40 cm (15.7 inch) was used. The HR was continuously recorded by a commercially available ambulatory system (Polar©, Oy, Finland). The HR was recorded immediately post exercise (HRmax; measured immediately after 5 min or after early cessation because of physical exhaustion), and during recovery in sitting position between 1 min and 1:30 min after completing the step test (HR1), between 2 min and 2:30 min (HR2), between 3 min and 3:30 min (HR3). A fitness index (FI) based on the step test data was calculated using the following formulae: duration of exercise in sec. x 100/sum of the three pulse counts x 2 (32).

Statistical analyses

Descriptive statistics were performed, average values and standard deviations (SD) for the outcome measures are reported. Pearson's product moment correlations were calculated between the maximal CPET outcomes

(VO_{2max}, W_{max}, VT) and the step test outcomes (HR recordings immediately post cessation, and during recovery, and the fitness index as a continuous variable).

Linear regression analysis (backward procedure) was used for the prediction of the VO_{2max} and VT. For this analysis, increments and mean values were calculated using the HR recordings during step test recovery. The increments were calculated as follows: (HR2-HR1)/2 *(increment 1)*; (HR3-HR2)/2 *(increment 2)*; and (HR3-HR1)/2 *(increment 3)*. The mean values were calculated as follows: (HR2+HR1)/2 *(mean1)*; (HR3+HR2)/2 *(mean2)*; and (HR3+HR1)/2 *(mean3)*. Independent variables included in the model were by demographic variables (age, gender, height, weight, BMI), raw step test outcome measures (test duration and HRmax) and calculated values (FI, *increments*, *means*). The linear regression models for VO_{2max} and VT were completed with a jackknife method in order to check whether the model was robust. Furthermore, a Bland-Altman plot was created to explore the agreement between actual and predicted VO_{2max} and VT values. Additionally, the intraclass correlation coefficient (ICC) was calculated to determine agreement between actual and predicted VO_{2max}/VT values. Statistical significance was set at α=0.05 (two-tailed) and all analyses were performed using SPSS 16.0 for Windows.

3. RESULTS

Descriptive statistics

The sample consisted of 59 men (53%) and 53 women (47%) (mean age 45+-13 years). The participants had a normal weight (mean BMI 23.9+-3.5 kg/m²) and VO_{2max} (94.0+-24% of predicted maximum). The subjects reached 98+-6% of their maximal predicted HR, indicating that subjects cycled until exhaustion during CPET. As result of the single-stage step test, HR rose from 89+-15 beats/min at rest up to 151+-20 beats/min (Table 1).

Univariate correlations

Significant negative correlations were found between VO_{2max} and step test HR ($p<.05$). The highest correlation was found between VO_{2max} and HR 1 minute post step test ($r=-0.48$, $p=.00$).

Significant positive correlations were found between VO_{2max} and step test duration ($r=0.52$, $p=.00$). VO_{2max} was positively correlated with FI as a continuous variable ($r=0.52$, $p=.00$).

VT was negatively associated with step test HR ($p<.05$) with the highest correlation between HR 1 minute post step test ($r=-0.48$, $p=.00$). VT was positively associated with step test duration ($r=0.22$, $p=.03$) and FI as a continuous variable ($r=0.50$, $p=.00$).

Prediction of VO_{2max}

The linear regression model explained 78% of the variation in CPET VO_{2max} values ($F=66.15$, $df=6$, $p=.00$). Included variables in the regression equation using the backward method were age, gender, height, BMI, step test HR_{max} and FI (continuous) (Table 2).

A significant positive correlation was found between CPET VO_{2max} and predicted VO_{2max} (r=0.89, p=.00). There was no significant difference between CPET VO_{2max} and predicted VO_{2max} (t=0.00, df=111, p=1.00, mean difference 0.0+-0.4 L/min. Figure 1 shows the agreement between CPET and predicted VO_{2max}. The ICC was high (ICC=.94, p<.00) between CPET and predicted VO_{2max}. The Jackknife procedure showed that, even when the model was developed using all but one subject and the predicted value was calculated per person that was excluded from the model, the CPET and predicted VO_{2max} showed high levels of agreement (Figure 2).
The equation to predict VO_{2max} from step testing is:

-3,475 - 0,011(age) + 0,054(BMI) + 0,612(gender)*+ 3,359(height) + 0,019(FI) -0,012(HRmax)
*0=female, 1=male

Prediction of VT

The linear regression model explained 58% of the variation in CPET VT (F=27.84, df=5, p=.00) . Included variables in the regression equation using the backward method were height, BMI, HR_{max}, *mean 2* and FI (continuous) (Table 2). A significant positive correlation was found between CPET VT and predicted VT (r=0.78, p=.00). There was no significant difference between CPET VT and predicted VT (t=0.00, df=97, p=1.00, mean difference 0.0+-0.5 L/min. Figure 3 shows the agreement between CPET and predicted VT. The ICC was high (ICC=.86, p<.00) between measured and predicted values. The Jackknife procedure showed that the CPET and predicted VT were comparable (Figure 4).
The equation to predict VT from step testing is:

-5,156 + 0,042(BMI) + 3,447(height in m) + 0,026(FI) -0,021(HRmax)+ 0,018(*mean 2*)

4. DISCUSSION AND CONCLUSION

The present study showed that a single-stage fixed-rate step test is a valid instrument to estimate maximal oxygen uptake capacity (VO_{2max}) in healthy adults. This can be valuable for general practitioners to adequately prescribe exercise in general practice. These step tests seem, on the other hand, less valid to estimate the ventilatory threshold (VT).
According to our results, a single-stage fixed-rate step test is a valid instrument to estimate VO_{2max}. The VO_2max during maximal cardiopulmonary exercise testing (CPET) was 3.2+-0.8 L/min in men, and 1.9+-0.5 L/min in women, as opposed to a predicted VO_{2max} of 3.2+-0.6 L/min in men and 1.9+-0.4 L/min in women (no significant difference between CPET and predicted VO_{2max}). The agreement between CPET and predicted VO_{2max} was confirmed by the high ICC value. In extent, the linear regression model explained 78% of the variance of CPET $VO_{2max.}$ Therefore, general practitioners might have the opportunity to assess the patient's

physical fitness without any need for expensive equipment, technical skills, and/or great time investment.

Current literature on the validity of step testing to estimate VO_{2max} reports contrasting findings. D'Alonzo et al. (2006) reported that the Queen's College step test (QCT) can be used to predict VO_{2max} in males (16), even though the individuals had a mean age of 23 years. Siconolfi et al. (1985) showed a high correlation between CPET VO_{2max} and predicted VO_{2max} (13), although a slight overestimation of CPET VO_{2max} was noticed. Kasch et al. (1966) reported no significant difference between CPET and predicted VO_{2max} (14). In accordance, Keren et al. (1980) found no difference between CPET and predicted VO_{2max} in 15 non-professional sportsmen (17). According to Petrella et al. (2001) a self-paced step test is a valid instrument to predict the VO_{2max} but in older adults (3). Recently, Chatterjee et al. (2004, 2005) described regression models to adequately estimate VO_2max in university students using the QCT (9, 10). In contrast, Buckley et al. (2004) reported Chester step test data to lead to an over estimation of actual CPET VO_{2max} values (12). The variance explained by the linear regression model for VO_2max (L/min) was 78%, which is a figure comparable to the results from Petrella et al. (2001) (ranging 62% to 75%) (3). Their final model included the following variables: age, BMI, O_2 pulse (oxygen consumption per heart beat), heart rate at the end of the step test, and test duration. In contrast, the model of the present study also included body height as a significant predictor in addition to BMI. This might be due to the height of the bench used in this study, 13 inch or 15.7 inch (for a body height $\leq$ 5.6 ft or above, respectively) compared to a bench of 7.85 inch in the study of Petrella et al. (2001) (3).

The step test seems less valid to estimate the ventilatory threshold (VT). The linear regression model explained 58% of the variance of CPET VT. The mean CPET VT was 2.0+-0.8 L/min in men and 1.2+-0.4 L/min in women, as opposed to predicted VT of 2.0+-0.5 L/min in men and 1.2+-0.3 L/min in women. The predicted VT also show a good agreement with CPET VT. As a result, even though a high ICC was found, and the CPET vs predicted VT was not significantly different, only 58% of the variance of CPET VT could be explained by regression analysis. This indicates that the error on VT estimation could be too high, limiting its application in current sports/family medicine. To our knowledge, no prior studies examined the validity of the step test to estimate VT. As a result, we were unable to contrast our findings with previous studies.

The present study is the first to confirm the validity of a single-stage fixed-rate step test to estimate VO_{2max} in a large population. As a result, our data indicate that step tests can be used in epidemiologic studies to estimate VO_{2max}, without the need of expensive equipment and/or technical skills. In addition, the step test can be used by general practitioners for exercise prescription/evaluation (33). The study was limited by the absence of a

reliability test. We only considered the validity of the step test as the main focus of research.
A single-stage fixed-rate step test is a valid instrument to predict VO_{2max} and a fairly adequate instrument to predict VT in healthy adults.

FIGURES

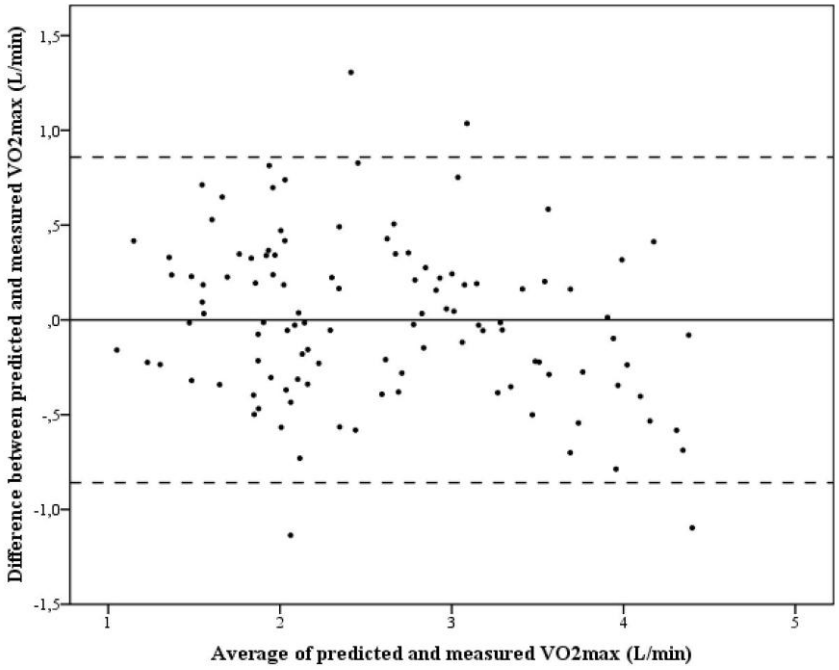

Figure 1: Bland-Altman plot of maximal oxygen uptake capacity (VO_{2max}) predicted by the step test outcome measures against the direct measurement of VO_{2max} during the cycling test. The solid line within the graph represents the bias; the broken lines represent the upper and lower 95% limits of agreement.

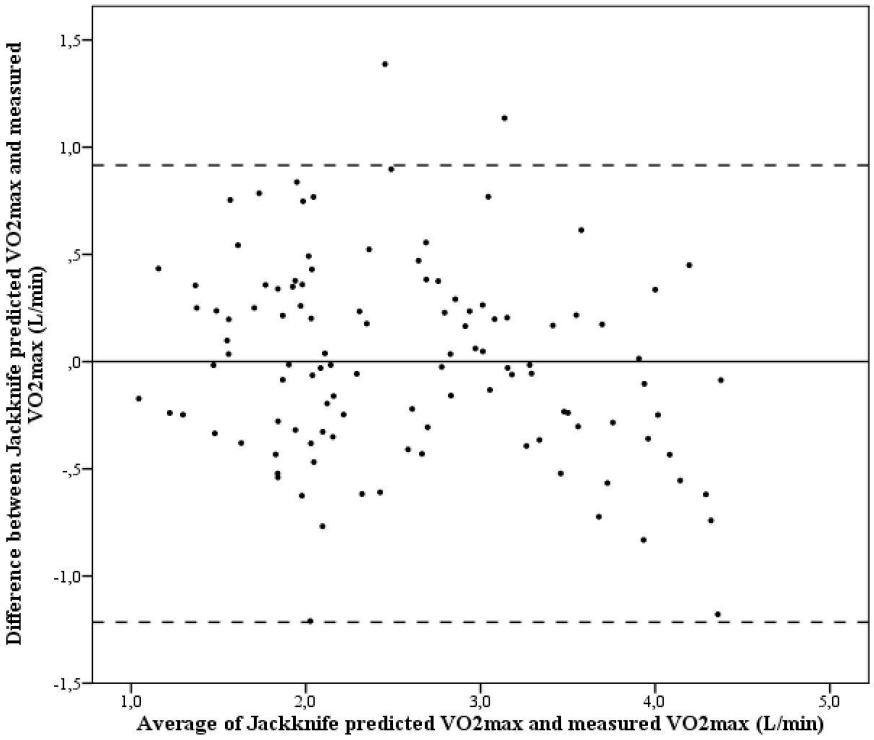

Figure 2: Bland-Altman plot of maximal oxygen uptake (VO_{2max}) predicted by the step test outcome measures using a Jackknife procedure against the direct measurement of VO_{2max} during the cycling test. The solid line within the graph represents the bias; the broken lines represent the upper and lower 95% limits of agreement.

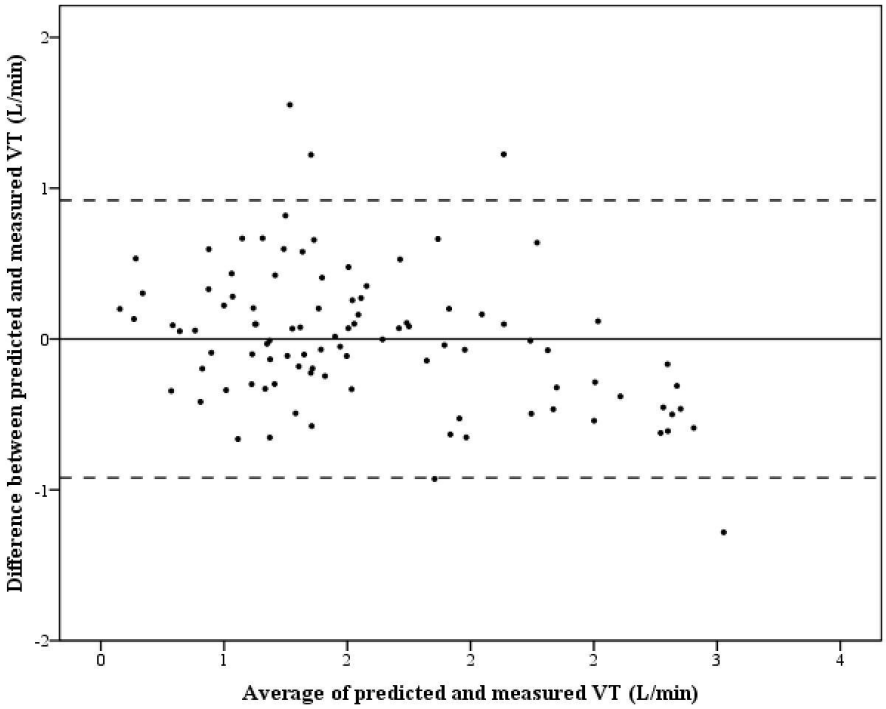

Figure 3: Bland-Altman plot of Ventilatory threshold (VT) predicted by the step test outcome measures against the direct measurement of VT during the cycling test. The solid line within the graph represents the bias; the broken lines represent the upper and lower 95% limits of agreement

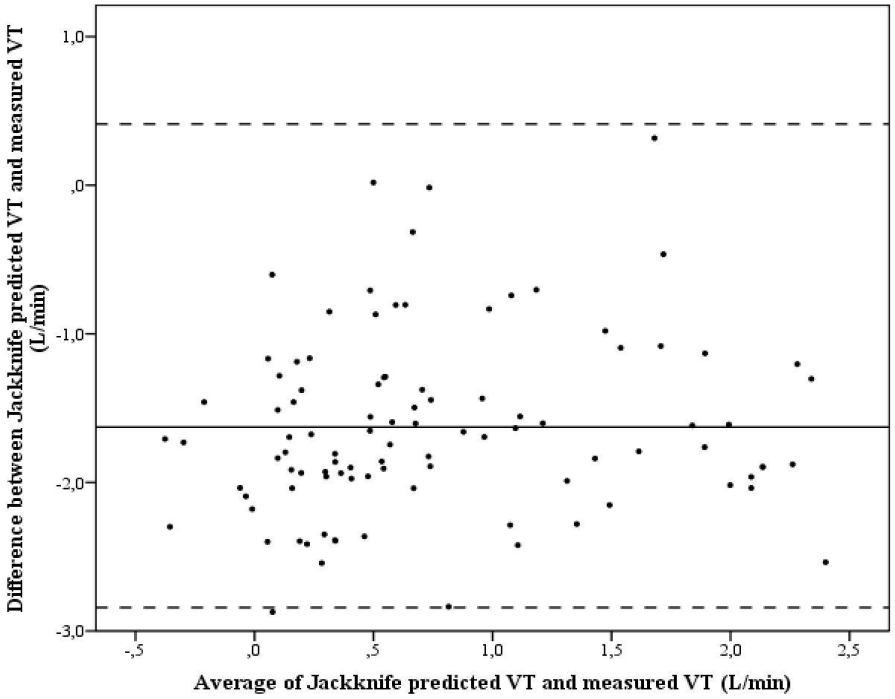

Figure 4: Bland-Altman plot of Ventilatory threshold (VT) predicted by the step test outcome measures using a Jackknife procedure against the direct measurement of VT during the cycling test. The solid line within the graph represents the bias; the broken lines represent the upper and lower 95% limits of agreement.

TABLES

Table 1 Demographics and results from the maximal CPET and the step test by gender

	Men (N = 59) Mean (SD)	**Women (N = 53) Mean (SD)**
demographic variables		
age	44.08 (12.67)	45.72 (12.66)
BMI	24.19 (3.14)	23.59 (3.81)
exercise capacity		
VO_{2max} (L/min)	3.22 (0.79)	1.88 (0.48)
%predicted* VO_{2max}	98.52 (24.12)	88.96 (23.51)
W_{max}	268.47 (70.24)	160.00 (35.33)
HR_{max} (beats/min)	172.29 (14.68)	170.83 (12.62)
% predicted HR_{max}	98.02 (6.06)	98.16 (5.53)
ventilatory threshold (L/min)	1.98 (0.76)	1.16 (0.39)
step test data		
resting heart rate	86.44 (14.29)	92.30 (15.80)
HR_{max} (beats/min)	147.83 (22.22)	153.89 (15.95)
HR recovery after 1 min (beats/min)	105.14 (28.39)	111.98 (18.93)
HR recovery after 2 min (beats/min)	94.07 (25.10)	94.64 (16.40)
HR recovery after 3 min (beats/min)	89.31 (20.60)	98.68 (15.47)
test duration (sec)	293.19 (27.55)	271.30 (64.04)
predicted values		
predicted VO_{2max}	3.22 (0.57)	1.88 (0.39)
predicted VT	1.97 (0.47)	1.16 (0.35)

*based on formulae from Fairbarn et al. (1994)
Abbreviations: BMI, Body Mass Index; VO_{2max}, maximal oxygen uptake capacity; W_{max}, maximal cycling power output; HR_{max}, maximal heart rate; VT, ventilatory threshold

Table 2 Linear regression model for CPET VO_2max and VT estimation

Linear regression model for VO2max					
	Unstandardised coefficients (Beta, SE Beta)		**Standardised coefficients (Beta)**	***t***	***P***
Constant	-3.48	1.44		-2.41	.02
Age	-.01	.00	-.15	-2.99	.00
BMI	.05	.01	.20	3.96	.00
Gender	.61	.13	.33	4.87	.00
Height	3.36	.65	.35	5.21	.00
FI	.02	.00	.31	4.71	.00
HR_{max}	-.01	.00	-.25	-4.16	.00
Linear regression model for VT					
	Unstandardised coefficients (Beta, SE Beta)		**Standardised coefficients (Beta)**	***t***	***P***
Constant	-5.16	1,10		-4.67	.00
BMI	.04	.02	.20	2.73	.01
Height	3.45	.49	.46	6.98	.00
FI	.03	.01	.53	5.34	.00
HR_{max}	-.02	.00	-.56	-4.89	.00
Mean 2	.02	.01	.47	3.56	.00

Abbreviations: BMI, Body Mass Index; FI, fitness index; HR_{max}, maximal heart rate achieved during the step test
Mean 2 = mean of heart rate between 2 min and 2:30 min and between 3 min and 3:30 min during step test recovery

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Chapter 4

Effect of a tailored behaviour change programme in highly educated adults: a randomised controlled trial

Based on:
Jacobs N, De Bourdeaudhuij I, Thijs H, Dendale P, Claes N. Effect of a cardiovascular prevention program on health behavior and BMI in highly educated adults: a randomized controlled trial. Patient Educucation and Counseling 2011 Oct; 85(1): 122-6. Epub 2010 Oct 2

ABSTRACT
Objective. To examine the effects and dose-response effects of an intervention on health behaviour (fat intake, physical activity, and smoking) and Body Mass Index (BMI) in a sample of highly educated adults.
Methods. Participants were randomised to a 'usual care' condition (= medical assessment) (*n* = 106) and an intervention condition (= cardiovascular prevention programme) that additionally included a website and one-on-one coaching (by e-mail, telephone, and/or face-to-face) (*n* = 208). The participants could select their own intervention dose and delivery mode.
Results. Participants completed questionnaires at baseline (*n* = 93; *n* = 194) and six months post baseline (*n* = 84; *n* = 168). The intervention wasn't more effective than 'usual care' but a higher intervention dose led to better outcomes for fat intake and physical activity, independent of baseline motivation. Furthermore, the effect of combining different delivery modes was dependent on the behavioural context.
Conclusion. A higher intervention dose led to better results but allowing people to select their own intervention dose probably undermined the potential intervention effect.
Practice implications. The present study highlights the importance of intervention dose and delivery mode for the development, evaluation, and optimisation of health promotion programmes.

1. INTRODUCTION

Cardiovascular disease (CVD) is a major cause of death and disability and its risk factors should be detected and managed at the population-level (1). Amongst these risk factors, multiple health behaviours play an important role in the development and exacerbation of CVD. Positive associations were confirmed between the consumption of a fat-rich diet, having inadequate levels of physical activity, smoking, being overweight or obese and CVD (2-5). Improvement of these risk factors reduces medical risk factors for CVD (e.g., blood pressure, cholesterol) and CVD (6-9).
Adaptive health behaviours can be successfully promoted by theory-based behaviour change interventions with content tailored to the individual (e.g., based on the The Theory of Planned Behaviour (TPB) and the Self-Determination Theory (SDT)) (10-19). In addition to the tailored content, the intervention dose and delivery mode can be adapted to the characteristics or preferences of the individual (20).
The primary aim of the present study was to examine the effects of a cardiovascular prevention programme on health behaviour (fat intake, physical activity, and smoking) and Body Mass Index (BMI) compared to 'usual care' in a sample of highly educated adults. The secondary aim was to study the dose-response effects for changes in fat intake and physical activity within the intervention condition.

2. METHODS

2.1. Study design

Randomised controlled trial carried out between February and October 2007 in Belgium (Figure 1). Participants were randomized to a 'usual care' and intervention condition using a 1/2 ratio to study the dose-response effects (21). A sample size calculation showed that a total sample size of 300 was needed (21). The Hasselt University Ethics Committee approved this study (ISRCTN23940498).

2.2. Setting and participants

The study participants were insured by De Onderlinge Ziekenkas and highly educated (Master degree in law). This sample was selected because the insurer funded the Chair wherein this study took place and wanted their clients to benefit from it (eligibility criteria: a signed informed consent form, age between 25 and 75 years, and internet access).

2.3. Intervention

Participants of both study conditions were invited to Hasselt University for a baseline medical assessment (22). Additionally, the participants of the intervention condition had access to a tailored website and one-on-one coaching by a psychologist (23). The website consisted of different sections such as a homepage, tailored fat intake advice (24), Minimove (moderate physical activity), and tailored physical activity advice (25). Behaviour change techniques targeted at determinants of behaviour derived from TPB and SDT were used (e.g., knowledge, skills, beliefs about capabilities (self-efficacy); beliefs about consequences (anticipated outcomes/attitude)) (14, 16, 26). The intervention was developed to stimulate a 'sense of choice' to increase motivation and behavioural engagement (16). The intervention dose (frequency, duration) and delivery mode (e-mail, telephone, face-to-face) of the coaching were self-selected by the participants who could combine different target behaviours and delivery modes.

2.4. Measures

Health behaviour and BMI were primary outcome measures gathered at baseline and 6 months post baseline. Outcome measures for dietary behaviour, physical activity, and smoking were the daily fat intake (g/day), the total physical activity (min/week), and the number of quitters, respectively (27-29). Motivation at baseline was also measured (30-32). Self-reported weight and height were used for BMI calculation. The secondary outcome measure was the intervention dose. This dose was automatically registered for the website (number of hits per section) and by a study collaborator for the coaching (frequency of contacts per delivery mode; total duration/intervention time per behaviour or delivery mode). The total duration per delivery mode is a measure for its level of intensity, elaborateness, and tailoring.

2.5. Statistical analyses

Repeated measures ANOVAs with time (within) and study condition (between) as factors were used to fulfil the primary aim of the study (effects on fat intake, physical activity, smoking, and BMI) (SPSS 14.0); Linear Mixed Effects models and One-Way ANOVAs and post hoc Dunnett tests were used to fulfil the secondary aim (dose-response effects on changes in fat intake/physical activity, controlling for baseline motivation) (SAS 9.1). Participants of the intervention condition were categorised in three intervention dose groups using the 25^{th}, 50^{th} and 75^{th} percentile of dietary/physical activity intervention time (α=.05).

3. RESULTS

Participants (*n* = 287) completed the questionnaire at baseline and 6 months post baseline (*n* = 252) (Figure 1, Table 1). There were no differences between dropouts and non-dropouts or between study conditions for socio-demographic characteristics, health behaviours, and BMI but there were significant time effects (Table 2). In spite of the fact that there were no significant differences between study conditions, important clinical differences between study conditions were found (e.g., 11% vs. 19% smokers in both conditions). Six smokers quitted smoking in the intervention condition compared to none in the 'usual care' condition. About half of the participants visited the homepage (95%), the tailored fat intake advice (52%), and the tailored physical activity advice (45%). Only 10% visited the Minimove section. Participants selected to be coached by e-mail (100%), telephone (97%), and/or face-to-face (10%). The mean intervention time was 22 minutes (SD±18) for diet and 37 minutes (SD±18) for physical activity.

A higher intervention dose led to better outcomes for fat intake and physical activity (Table 3). However, the effect of more coaching (i.e. intervention time) was different in both behavioural contexts. In the dietary context, more coaching led to a larger decrease in fat intake ($P < .01$) (Figure 2) but there was no positive main effect of intervention time on changes in physical activity. Positive dose-response effects when combining delivery modes were present in both behavioural contexts but also varied by behaviour. In the dietary context, frequent face-to-face sessions combined with frequent coaching by telephone was effective in reducing the daily fat intake ($P < .05$). For physical activity, website use combined with coaching ($P < .05$), and intensive coaching by e-mail and telephone were effective to increase physical activity ($P < .01$).

4. DISCUSSION AND CONCLUSION

4.1. Discussion

Six months post baseline, the cardiovascular prevention program wasn't more effective than 'usual care' in changing health behaviours and BMI. The dose-response analyses, however, showed that a higher intervention dose led to better responses. The effect of a higher intervention dose delivered by different modes was dependent on the behavioural context.

Potential explanations for the lack of intervention effect are: the selection of a healthy (70%) and highly educated sample (perhaps more empowered to risk take) (33); a medical assessment in both study conditions; an insufficient sample size; lack of changes in psychosocial determinants of behaviour (14, 16); and the high level of choice options might have overwhelmed the participants and led them to select an insufficient intervention dose. The dose-response analyses corroborate the latter hypothesis. Nevertheless, the present study has important advantages. The intervention was targeted at multiple behaviours and the study explored the effect of the self-selected intervention dose and combinations of different delivery modes (33). In spite of these advantages, the present study has several weaknesses: the specific sample and the small group of smokers limit the external validity, and self-report measures were used. Furthermore, a low amount of variance was explained (7-9%) and the dose-response effects were highly dependent on the operationalisation of intervention dose in terms of frequency or duration. For instance, intensive coaching by telephone combined with elaborate e-mails predicted an increase in physical activity whereas the combination with frequent e-mails predicted a decrease. Future research is needed to explore if these operationalisation differences systematically lead to different responses.

A higher website use combined with individual coaching resulted in better responses for physical activity but not for fat intake. This is surprising since there is more evidence on the effectiveness of tailored diet education than for tailored physical activity education, however, positive results were found (18, 34). In line with prior research, a higher dose of one-on-one coaching led to better responses for fat intake (35). If more one-on-one coaching is better to change behaviour than, for instance, a website only, this raises questions on the real-world applicability of the intervention. However, the fact that the participants could choose their own intervention 'dose' did not automatically lead to an overconsumption of the more intensive *or expensive* delivery modes at all. On the contrary, the amount of choice led to people under using the programme, limiting its effectiveness. The limited resources available for CVD prevention augment the importance of cost-effectiveness studies. One year post baseline, the present intervention was cost-effective compared to 'usual care' (36).

4.2. Conclusion

Six months post baseline, our results showed that 'usual care' was as effective as a cardiovascular prevention programme in changing health behaviour and BMI in highly educated adults. However, a higher intervention dose led to better responses than a lower dose.

4.3. Practice Implications

The present study highlights the importance of the intervention dose and delivery mode for the development, evaluation, and optimization of health promotion programs. Based on the results from the present study, practitioners are advised to combine online coaching (website and e-mail) and coaching by other delivery modes for physical activity. Practitioners who want to decrease the fat intake are advised to combine frequent face-to-face sessions and coaching by telephone.

FIGURES

Figure 1: Flow of the participants throughout the study

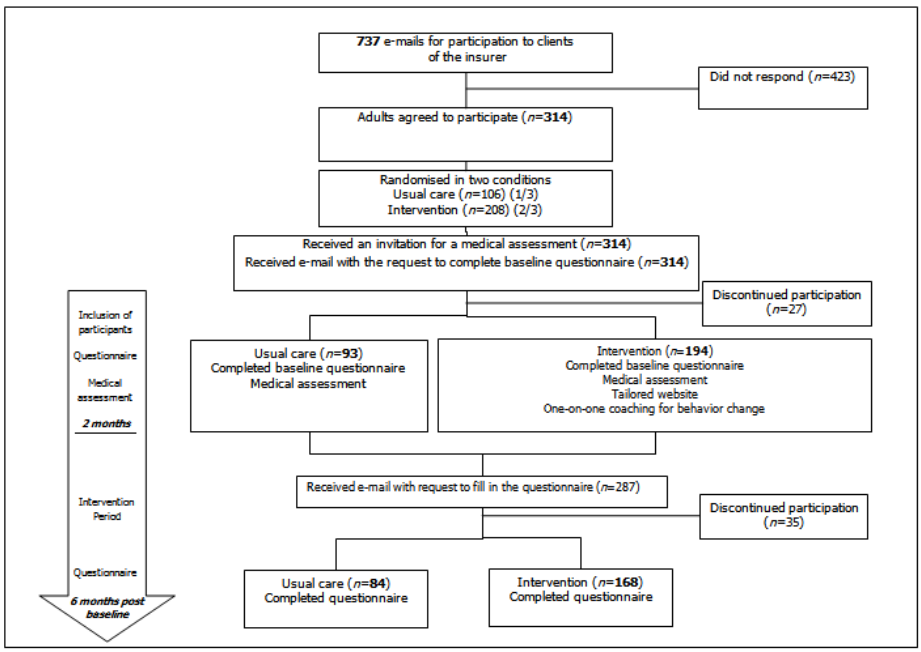
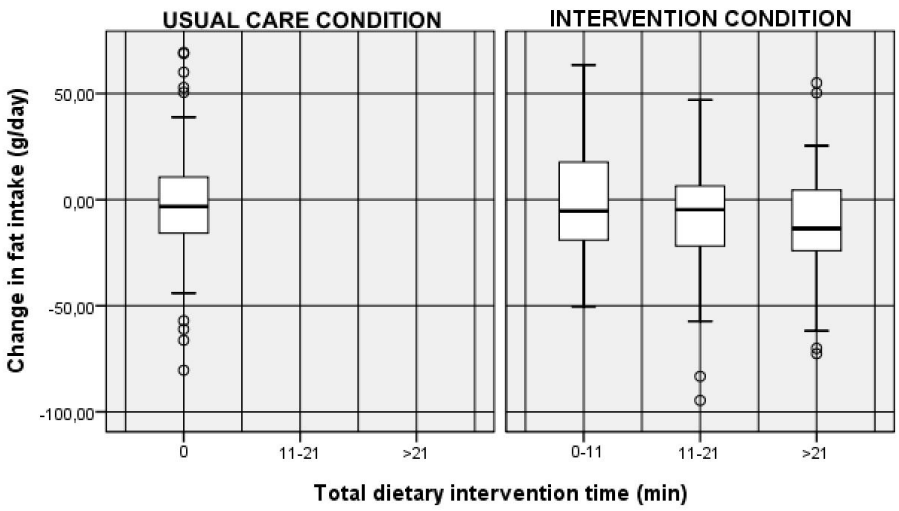


Figure 2: Dose-response relationship for dietary intervention time and change in fat intake



Negative values represent a decrease of fat intake, measured in g/day

TABLES

Table 1: Baseline characteristics for the total sample and intervention and usual care conditions			
Characteristic	Total sample (*n*=287)	Usual Care (*n*=93)	Intervention (*n*=194)
Age (±SD)	40 (±11)	40 (±11)	41 (±11)
Gender (%male)	67%	68%	66%
BMI (±SD)	25 (±5)	25 (±5)	25 (±4)
Cardiovascular risk			
Unknown (%)	30 (11%)	7 (7%)	23 (12%)
Low (%)	202 (70%)	66 (71%)	136 (70%)
Average (%)	31 (11%)	8 (9%)	23 (12%)
High (%)	24 (8%)	12 (13%)	12 (6%)
Smokers (%)	46 (16%)	10 (11%)	36 (19%)
Fat intake (in grams/day) (±SD)	106 (±38)	105 (±36)	107 (±40)
Physical activity (in minutes/week) (±SD)	350 (±232)	350 (±212)	351 (±241)
Motivation for changing dietary behaviour (Relative Autonomy Index) (±SD)	2 (±1)	2 (±1)	2 (±1)
Motivation for changing physical activity (Relative Autonomy Index) (±SD)	9 (±6)	8 (±6)	9 (±6)

BMI; Body Mass Index

Table 2: Mean fat intake, physical activity, and BMI outcome measures at baseline and six months post baseline for the total sample and the usual care and intervention conditions

	Total sample (n=252)			**Usual care (n=84)**	**Intervention (n=168)**	**Time X group**
	Mean ± SD	**Change (±SD)**	***F* time**	**Mean ± SD**	**Mean ± SD**	***F***
Total Fat intake (g/day)	107 ± 38	-5 (±27)	5.08*	107 ± 36	106 ± 39	1.58
6 months post baseline	102 ± 37			105 ± 37	100 ± 37	
Total physical activity	346 ± 228	+7 (±214)	.12	352 ± 215	343 ± 234	.14
6 months post baseline	353 ± 231			351 ± 200	353 ± 246	
BMI ***Baseline***	25 ± 5	-.6 (±4)	7.01**	25 ± 5	25 ± 5	.46
6 months post baseline	25 ± 4			24 ± 3	25 ± 4	

* < .05; ** <.01, *** <.0001

Table 3: Results of the linear modelling for changes in fat intake and physical activity				
Dependent variable	**Independent variables**	**Estimate**	**Standard error**	**P-value**
Change in fat intake[◙]				
Model: R-square=0.09; p<.001	C Dietary intervention time	-0.32	0.11	.003
	C by telephone (frequency) × face-to-face session (frequency)	-178.30	74.12	.017
	C by telephone (duration) × face-to-face session (duration)	-0.25	0.11	.019
	C by telephone (frequency) × face-to-face session (duration)	3.23	1.43	.024
	C by telephone (duration) × face-to-face session (frequency)	14.03	5.61	.013
Change in total PA[✱]				
Model: R-square=0.07; p<.05	C PA intervention time x hits for the Minimove website section	2.87	0.88	.001
	C by telephone (duration) x C by e-mail (duration)	0.85	0.32	.007
	C by telephone (frequency) x total number of hits	26.08	11.71	.027
	C by telephone (frequency) x C by telephone (duration)	-3.01	1.09	.006
	C by telephone (frequency) x C by e-mail (duration)	-10.74	4.69	.023
	C by telephone (duration) x C by e-mail (frequency)	-3.16	1.40	.025
	hits for the Minimove website section × hits for the PA advice website section	-19.74	9.10	.031

PA; Physical Activity; C: coaching
◙ Negative values represent a decrease of fat intake; measured in g/day
✱ Positive values represent an increase of physical activity (PA); measured in min/week

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Chapter 5

Chapter 5

Surfing depth on a behaviour change website: predictors and effects on behaviour

Based on:
Jacobs N, De Bourdeaudhuij I, Claes N. Surfing Depth on A Behaviour Change Website: Predictors and Effects on Behaviour. Informatics for Health and Social Care 2010 Mar; 35(2): 41-52

ABSTRACT
Objectives: The primary objectives of the present study were to gain insight into website use and to predict the surfing depth on a behaviour change website and its effect on behaviour.
Design: Two-hundred and eight highly educated adults from the intervention condition of a randomised trial received access to a medical intervention, individual coaching (by e-mail, post, telephone or face-to-face) and a behaviour change website.
Measurements: Website use (e.g., surfing depth, page view duration) was registered. Online questionnaires for physical activity and fat intake were filled out at baseline and after 6 months. Hierarchical linear regression was used to predict surfing depth and its effect on behaviour.
Results: Seventy-five percent of the participants visited the website. Fifty-one and 56% consulted the physical activity and fat intake feedback, respectively. The median surfing depth was 2. The total duration of interventions by e-mail predicted deeper surfing (β=.36; P<.001). Surfing depth did not predict changes in fat intake (β=-.07; P=.45) or physical activity (β=-.03; P=.72). Consulting the physical activity feedback led to more physical activity (β=.23; P=.01).
Conclusion: The findings from the present study can be used to guide future website development and improve the information architecture of behaviour change websites.

INTRODUCTION
Cardiovascular disease is only one of the diseases that can be, at least partially, prevented by making positive health behaviour changes (1). Various behaviour change interventions have been developed and have targeted one or more behaviours using one or more delivery modes (2, 3). An increasing number of interventions use the internet as a delivery mode (4-6). The effectiveness of website-delivered physical activity interventions is mostly tested in highly educated volunteers (7). It is believed that internet interventions are most effective for the highly educated who intensively use the Internet at work. Nevertheless, there is no conclusive evidence for this.
In spite of positive results on the effectiveness of internet interventions, objective data on exposure to different website subsections are scarce (7, 8). Most authors reported log-on rates and percentages of continued use, showing a decline over time (5, 6, 7, 9, 10, 11, 12). To improve log-on rates and continued use, reminders per e-mail or mobile phone text messaging can be used (11, 13). Methods to improve intervention exposure mainly focus on stimulating first and follow-up visits. However, instead of a mere focus on drawing people to the existing websites, the focus should shift to the content and the form of behaviour change websites. Indeed, some authors have mentioned possible content improvements by including more powerful behaviour change strategies (5). Furthermore, Ferney et al. (2008)

organised post trial focus group discussions to explore the participants' experience with the website with regard to lay-out, information and usefulness (12). The aim should be to create a positive user experience that stimulates users to stay. User experience refers to how a person acts and what a person thinks and feels during and after a visit (14).
Instead of using self-reported data, however, it is possible to gather objective and more detailed data on website use to improve both the content and the form of behaviour change websites (7). Only a limited number of studies reported on the mean duration per log-on or visit (13, 16, 17, 18, 19). More interesting data on website use are, for instance, the median page view duration for specific website subsections and the surfing depth. Only one other study made notice of the average page view duration for specific website subsections, but none of surfing depth (16). The surfing depth is a measure for the extent to which people visit deeper levels of the website. It can be used to ameliorate the structure of website information, also called the information architecture (IA). The IA is an important but often overlooked factor in the development of behaviour change websites (20). Different designs can be used: a matrix design, a tunnel design, a hierarchical design or a combination of the previous designs, a hybrid design (20). A matrix design allows users to use multiple hyperlinks to explore the website content. A tunnel design guides the user through a series of websites (e.g., e-learning modules). In a hierarchical design, the content is arranged in a top-down manner. Lastly, a hybrid design includes components that use matrix, tunnel and/or hierarchical designs (20). The IA is related to the navigation structure of a website. The navigation structure consists of methods to help users find their way around a website (e.g., hyperlinks). A matrix design includes pages with more hyperlinks than, for instance, a tunnel design.
The behaviour change website from the present study was used in a randomised cardiovascular prevention trial targeted at three behavioural risk factors (a sedentary lifestyle, an unhealthy diet and smoking) (2). The effects of a cardiovascular prevention programme (access to a medical intervention, individual coaching and a tailored behaviour change website) in comparison to usual care (access to a medical intervention) were evaluated. In the present study, tailoring was defined as any combination of information or change strategies intended to reach one specific person, based on specific characteristics of that person that have been measured in a formal assessment (21). The participants in the intervention condition could choose their own intervention dose (frequency/duration) and delivery mode (by e-mail, post, telephone or face-to-face). There were no significant differences between the two study conditions for physical activity, fat intake or smoking "submitted paper: Jacobs, N., Claes, N., Thijs, H., Dendale, P., De Bourdeaudhuij, I. Effect of a tailored behaviour change programme in highly educated adults: a randomised clinical trial".

The fact that the participants could compose their own intervention programme complicates the study. However, it increases its ecological validity since people in real life are confronted with many options to improve their lifestyles as well. Most interventions at population level make use of a lifestyle website. It is important to get insight into the possible reinforcing or counteracting effects of combinations of interventions of a different intervention dose or delivered by different modes. Studying only an intervention delivered through a website might not resemble reality in an adequate way. This was confirmed in a recent study that looked at the use of non-assigned treatments by participants during a web-based randomised trial for smoking cessation (22). Participants enrolled in the study made use of individual coaching next to the intervention delivered through a website. In our study, these possibilities are included in the assigned programme. This can lower the chance of people seeking non-assigned treatments.
The primary objectives of the present study were to gain more insight into the website use, to predict the surfing depth and its effect on physical activity and fat intake in combination with other intervention components (the medical intervention, individual coaching).

SUBJECTS AND RESEARCH DESIGN

The subjects in the study were 208 highly educated participants from the intervention condition of a randomised cardiovascular prevention trial (2). All participants obtained a Master's degree in Law which takes 5 years of study at university level in Belgium. The mean age of the subjects in the study was 41 years (SD 10) and 68% were male. For this trial, 737 potential participants insured by De Onderlinge Ziekenkas (a company that offers income protection insurance in case of illness or an accident) received an invitation to take part in the study. 314 signed an informed consent and were randomised to usual care and intervention conditions using a 1/2 ratio to keep enough power to study the dose-response effects of the intervention. The non stratified randomisation was performed by an independent person using sealed envelopes. The participants were blinded to group assignment. It was a representative sample of overall healthy adults. The study was approved by the Hasselt University Ethics Committee and was registered (ISRCTN23940498).

EXPERIMENTAL INTERVENTIONS

Intervention condition

The usual care condition existed only of a medical intervention to determine the risk of dying from cardiovascular disease within 10 years (1). Patients with an increased risk were referred to their own general practitioner (2). Participants in the intervention condition additionally received access to individual coaching and a behaviour change website.

The individual coaching was based on a needs assessment that was performed by a psychologist at baseline. The psychologist telephoned the participants and asked them what their preferred individual coaching would look like with regard to the target behaviour(s), the intervention dose (frequency/duration) and the delivery mode (e-mail, post, telephone and/or face-to-face). Combinations were possible because participants could prefer being approached by multiple modes and the literature shows that one mode can increase the exposure to another intervention mode (5). Elaborate e-mails to stimulate behaviour change are one example of individual coaching. These e-mails included advice tailored on psychosocial determinants and became more elaborate when targeting more determinants. The duration to compose an elaborate e-mail was higher because the psychologist had to look at prior communication reports (by any mode) and data on psychosocial determinants from the baseline measurement to sufficiently tailor the e-mail. Furthermore, the e-mail could include some advice to visit relevant subsections of the website. This also counted for individual coaching by telephone and face-to-face individual coaching. The psychologist explained to participants why this particular subsection might be relevant for them.

The conceptual framework underpinning the individual coaching and the behaviour change website was mainly based on the Theory of Planned Behavior (TPB) (23) and Self-Determination Theory (SDT) (24, 25). Psychosocial determinants from TPB (e.g., intention, attitude) and SDT (e.g., autonomous motivation) were used to tailor the content of the individual coaching and the behaviour change website to the individual. The behaviour change website included physical activity and fat intake feedback. An elaborate description of the measures for these determinants is outlined in detail elsewhere (2). Furthermore, SDT served as an inspiration for the design of the intervention. In SDT, the assumptions are made that choice should be offered to participants; that these choices should be respected and that controlling language should be avoided. These practical recommendations from SDT were applied in the interventions of the present study. How the recommendations were translated into practice is described in detail elsewhere (25).

The individual coaching was conducted by an experienced psychologist assisted by undergraduate students Sports and Nutrition.

Behaviour change website

The behaviour change website was developed using a hybrid design. When logging on to the homepage, the users had free access to multiple website subsections for the different behaviours (a matrix design). When following a link it was organised in a top-down manner, offering broad themes (e.g., information on nutrition, food diary,…) people could drill down into for more detailed information (a hierarchical structure).

A first version of the behaviour change website was evaluated in a small pilot study of the cardiovascular prevention programme. For this pilot study, 8

highly educated volunteers were invited to Hasselt University and they were informed about the program. They had different educational backgrounds: cardiology, chemistry, sports psychology, communication science, civil engineering, personal training and 2 specialised in computer science. Five of them obtained a Master's degree; the others received non-university level higher education. These volunteers were fairly representative of the intended audience with regard to education level, sex and age. Nevertheless, none of them obtained a Master's degree in Law. They were asked to surf to the website guided by a document. This document was used to stimulate the participants to surf to all the website subsections. They were asked to give feedback on different factors related to user experience (e.g., look and feel, attractiveness, understandability, the ability to interact with the website) and the IA (14). The feedback of these volunteers was intensively used to improve the content, the user experience and the IA. The improved version of the website was investigated in the present study.

Fig 1 shows the homepage of the behaviour change website (layer 0). The homepage included links to news items, a cardiology section, a physical activity section, a nutrition section, a smoking cessation section and tailored physical activity and fat intake feedback (layer 1) (8). The tailored feedback on physical activity and fat intake was adopted from a prior study and was mainly based on the TPB (8, 23). The feedback on physical activity included normative feedback, next a part of advice on how to increase physical activity at work, in leisure time and transportation. This was followed by feedback on psychosocial determinants (e.g., attitudes). The feedback on fat intake consisted of normative feedback, next a part of advice that indicated what fatty foods they consumed and tips on how they could reduce or replace these foods. Finally, the feedback ended by giving information on their psychosocial determinants of fat intake (e.g., self-efficacy). A detailed description of the items that were used to measure these constructs can be found elsewhere (2).

(Figure 1 about here)

Layer 1 required one additional click starting from the homepage. Layer 2 consisted of more detailed information such as specific programs for physical activity of low intensity, diaries for self-monitoring and motivational tests. Layer 2 required 2 extra clicks starting from the homepage. Layer 3 contained comprehensive behaviour change manuals (with decisional balance exercises, instructions for planning, organizing social support and relapse prevention). Layer 3 required 3 extra clicks starting from the homepage. Layer 4 and layer 5 consisted of specific tests and exercises and required 4 or 5 clicks starting from the homepage. Each layer included multiple links to information in the same and/or other layers.

METHODS AND PROCEDURES

Measures of website use

The log-on rate percentage, the number of log-ons by different subjects per week and the surfing depth were registered. For individual surfing depth, the deepest layer that was visited was used as an outcome measure. Page view duration per participant was estimated using the time registration of subsequent hits after log-on. Unrealistically high durations of page views were changed into a maximum page view duration for that specific page which was determined by an independent person in advance of the study. This person was asked to read each page on the website and time this with a chronometer. This duration was multiplied by 2 to determine the maximum page view duration. The total page view duration per website subsection and the median number of hits and the median page view duration per subject and website subsection were determined.

Changes in physical activity and fat intake

Physical activity (min/week) was measured at baseline and after 6 months using the International Physical Activity Questionnaire (IPAQ). This Dutch version was validated for the Belgian population (26). The IPAQ was scored using the manual but household activities were left out of the analyses and total weekly physical activity was multiplied with a constant (.80) to correct for over reporting (27). Fat intake in grams per day (g/day) was measured at baseline and after 6 months using a validated fat intake questionnaire (28). Changes in physical activity and fat intake were used as outcome measures by subtracting the values at baseline from the values at 6 months. The Behavioural Regulation in Exercise Questionnaire-II (BREQ-II) was used as a measure of autonomous motivation for changing physical activity. This instrument has good psychometric properties (29, 30). The Treatment Self-Regulation Questionnaire (TSRQ) was used to measure autonomous motivation for changing nutrition (31).

Measures for the medical intervention and individual coaching

Outcome measures for the medical intervention and individual coaching (by delivery mode) were the total duration of interventions by e-mail, the total duration of interventions by telephone and the total duration of face-to-face interventions. Outcome measures for individual coaching (by target behaviour) were the total duration of physical activity interventions, the total duration of nutrition interventions and the total duration of all interventions (also medical interventions). Outcome variables for individual coaching were also frequencies of interventions by the different delivery modes.

Prediction of surfing depth

For the prediction of surfing depth, a hierarchical regression analysis was performed. The independent variables were entered into the model in two blocks. Initially gender, age and baseline self-determined motivation for physical activity and nutrition were entered using a stepwise method and removed if $P > .10$. Next, measures for the medical intervention and

individual coaching (see above) were entered using a stepwise method and removed if *P* >.10.

Effect of surfing depth on physical activity and fat intake

For the prediction of changes in physical activity and fat intake, hierarchical regression analyses were performed. The independent variables were entered into the models in three blocks. Initially gender, age and baseline self-determined motivation for physical activity and nutrition were entered using a stepwise method and removed if *P* >.10. Next, measures for the medical intervention and individual coaching (see above) were entered using a stepwise method and removed if *P* >.10. Finally, measures of website use were entered using a stepwise method and removed if *P* >.10. The measures of website use included in the analyses were: surfing depth and total page view duration per website subsection. *P*-values <.05 were considered to be significant. Data were analyzed in 2009 using SPSS version 16.

MAIN OUTCOME AND RESULTS

Subjects

168 participants from the intervention group filled out the questionnaires on physical activity, fat intake and self-determined motivation after 6 months. The mean age was 41 (SD 11). 66% (N=110) were male and 34% (N=58) were female.

Website use

Among the study group, 75,0% (N=156) logged on to the behaviour change website. Fig 2 shows the pattern of website use (number of log-ons or visits by different subjects per week) and reinstating interventions during the 26 first weeks of the intervention. The reinstating interventions were interventions that caused an increase of the number of log-ons by different subjects at a given point in time.

(Figure 2 about here)

Table I shows the visits to the website subsections, the mean/median page view duration, the mean/median number of hits and the mean/median surfing depth per subsection.

(Table I about here)

Twenty-five percent (N=39) of the people who logged on to the website only visited the homepage and 51% (N=80) and 56% (N=88) consulted the physical activity and fat intake feedback, respectively. The physical activity and nutrition section were consulted by 60% (N=93) and 65.4% (N=102) of the participants, respectively. The median page view duration for no feedback pages ranged from 7 to 20 seconds and the median page view duration for feedback pages was 110 seconds for fat intake feedback and 123 seconds for physical activity feedback. The mean surfing depth was 1.91 with a standard deviation 1 and the median surfing depth was 2 (2 extra clicks after log-on). Less than 10% (N=15) made four extra clicks or more. The section wherein participants clicked the most was the physical activity

section, followed by the nutrition and the smoking section. However, these sections had a lower median page view duration compared to the feedback pages. The median number of hits and the median page view duration seem to be distinct measures of website use.

Changes in physical activity and fat intake

The mean increase of weekly physical activity was 19 minutes (SD 174). The mean decrease of daily fat intake was -6 grams (SD 27).

Prediction of surfing depth

The total duration of interventions per e-mail (β=.36, P<.001) was a significant predictor of the surfing depth. Elaborate e-mails led to participants visiting deeper laying levels of the website. Participants received elaborate e-mails if they were highly motivated to change behaviour and chose for a higher intervention dose during the initial needs assessment. The model explained 12% of the variance of the surfing depth.

Effect of surfing depth on physical activity and fat intake

Surfing depth did not predict changes in physical activity (β=-.03; P=.72). The physical activity feedback was the most significant positive predictor of desired changes in weekly physical activity (β=.23, P=.01). There was a positive relation between changes in weekly physical activity and age (β=.16, P=.06). This model explained 7% of the variance in changes in physical activity.

The hierarchical regression analysis showed that surfing depth did not predict changes in fat intake (β=-.07; P=.45). The total duration of nutrition interventions (e.g., face-to-face interventions, e-mail with tailored nutrition feedback) was a significant predictor of a decrease of fat intake (β=-.21, P=.02). This model explained 4% of the variance in changes in fat intake.

DISCUSSION

The study was designed to gain insight into the website use, the predictors of surfing depth and its effect on behaviour. The results showed that most website users visited the behaviour change website (75%) but that the median surfing depth was limited to a layer two page; this requires two extra clicks after log-on. There are very few manuscripts that report surfing depth figures and none in the field of health promotion. However, the average surfing depth on a specific corporate website was found to be 4 and for a pool of websites this was 8 (32). Although the present study shows that interventions by e-mail are significantly associated with deeper surfing, no conclusion can be drawn. The surfing depth was possibly too small to find an effect. The significant positive effect of tailored feedback on changes in physical activity is an important result for future website development. Nevertheless, the variance explained by the models was rather limited.

The median surfing depth found in the present study was low. The lack of effect that was found for behaviour change websites compared to other media may be partially attributed to the number of layers used or other

aspects of the IA (33). The importance of the IA and navigation structure of the website was stressed by other authors before (34, 35). These authors suggested that further research is needed to identify possible exposure-related factors. We believe that the inclusion of the surfing depth and the page view duration for specific website subsections in the present study complies with this advice.

As found in previous studies the website use showed a decline over time (15). However, peaks at several months show that the website use can be reinstated by additional interventions. In week 4, for instance, the participants received a tailored printed profile by post with the results of the medical intervention. In week 15, the participants received a motivating e-mail to visit the website and read about a start to run program. This e-mail included a link to the website and personal log-on information. In weeks 23 and 25, the participants were asked to fill out a questionnaire and received tailored feedback by e-mail. This e-mail also included a link to the website and personal log-on information. Most of the website users at these peaks visited the website before in the first two weeks of the intervention. These findings are in line with previous research showing a positive effect from e-mail on follow-up visits and the importance of tailored feedback (11, 5).

The present study gives information on the page view duration per website subsection. The page view duration was longer for feedback pages than for no feedback pages. However, the information on the feedback pages was quite elaborate and this might have caused the longer page view duration. In comparison to another study reporting information on page view duration (average duration), the present study reports much lower levels (16). For tailored information, for example, Lewis et al. (2008) found a mean page view duration of 21 minutes compared to 3 minutes in the present study. Lewis et al. (2008), however, did not correct for unrealistically high page view durations. A sound comparison of both studies is impossible due to a lack of detailed information (e.g., number of words). Perhaps the difference can be explained by predictors of page view duration such as age, gender, number of words, text complexity or functionality (36). Our study included mainly males whereas that of Lewis included mainly females. Females have been found to have a higher visit duration but not a higher page view duration (36). Nevertheless, the mean page view duration of more than 100 seconds for the feedback pages suggests that the participants at least consulted the page long enough to use and process the information. Of course, this tailored information was more relevant to them. It has been suggested before that tailored information might increase website exposure (37, 38). The present study showed a discrepancy between median number of hits and median page view duration suggesting both measures of website use should be included in future research.

The strengths of the present study are the inclusion of objective data on website use and follow-up measures of 26 weeks. This is the first study in

which the page view duration was estimated using subsequent hits and in which the surfing depth was registered. The effect of surfing depth on behavioural outcomes was studied including self-determined motivation at baseline in the models. In contrast to most studies, where women predominated, our sample consists for the major part of men.
The study has several limitations. The sample consisted of highly educated participants and this might limit the generalisability of the present findings. Since the participants were included in a cardiovascular prevention trial, they might have been more motivated than the general population and the effect of physical activity feedback on behaviour might be an overestimation. Furthermore, this study was not designed as an experiment or randomised controlled trial analyzing the direct comparison of websites with different IAs or different website subsections. The direct comparison of behaviour change websites with different IAs should be subject to future research. We have tried to optimize the user experience of the behaviour change website. However, the small pilot study included only a limited number of volunteers and we didn't involve a design staff in the development phase of the website. Next, we only focused on quantitative measures of website use. An additional qualitative process measurement or usability analysis during the intervention could have given more insight into the reasons of the participants to visit certain pages more than others. Furthermore, one concern could be that the small sample size could have caused the lack of effect for surfing depth on behavioural outcomes. Post-hoc power analyses, however, revealed that there was sufficient power (above 80%) for all regressions. Lastly, the page view duration gives an idea of the time that participants stayed on the page and this might be long enough to use and process the information. However, we do not know whether they actually read the information. Nevertheless, exposure is defined as the combination of three elements: accessing the website, staying on the website long enough to use and process the information and revisiting the intervention website (14). We can only conclude that the participants were exposed to the behaviour change website.

CONCLUSION

Considering the results of this study, the IA of future behaviour change websites can be improved. A behaviour change website preferably consists of a homepage with one or maximally two deeper layers. Newspaper websites can serve as an excellent example. The homepage can summarise information about different health behaviours based on questionnaires and the page view duration after one click. After each log-on, the homepage will become more personally relevant. Furthermore, tailored feedback including progress information should be placed on a prominent web page, preferably a short summary on the homepage with detailed information on a deeper layer. E-mail and post can be used to stimulate log-on to the website.

FIGURES

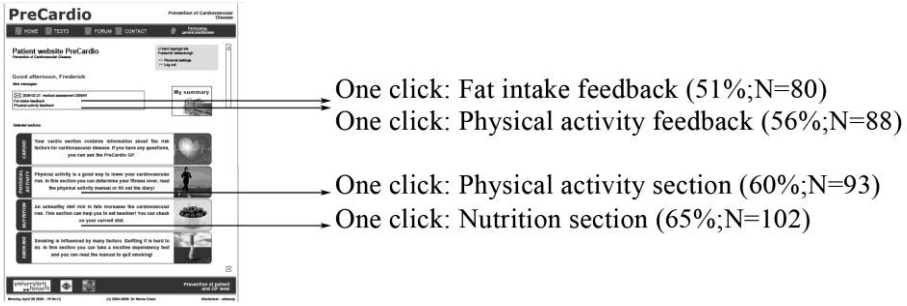

Figure 1: homepage of the behaviour change website

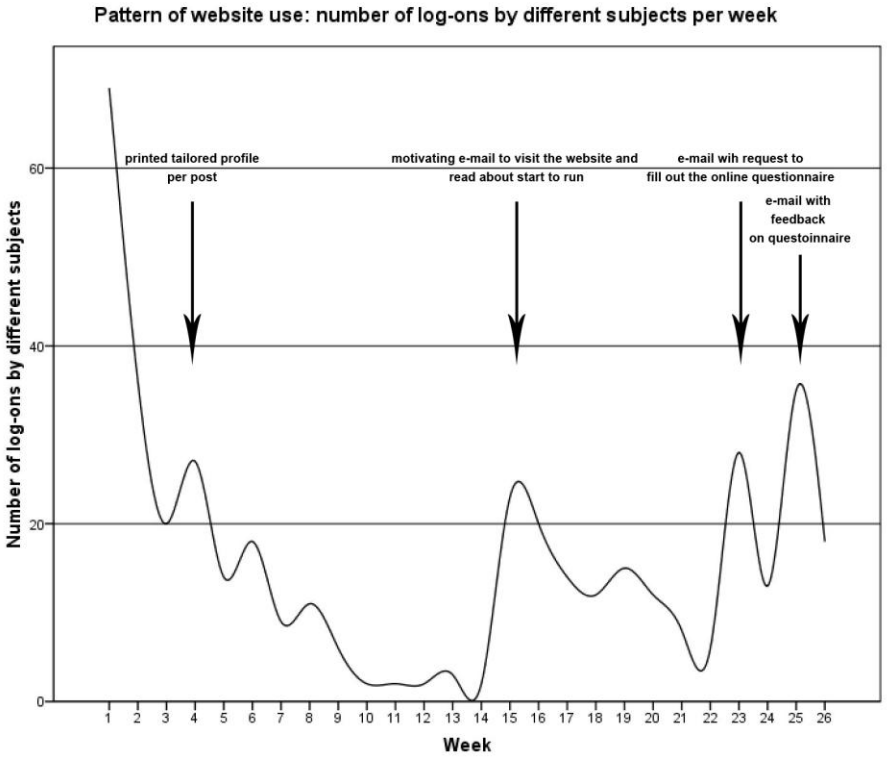

Figure 2: pattern of website use: number of log-ons by different subjects per week and reinstating interventions

TABLES

Table I: Visits to the website subsections, page view duration, number of hits and surfing depth per website subsection

	Website subsection						
	Homepage	**Cardiology**	**Physical activity**	**Physical activity feedback**	**Nutrition**	**Fat intake feedback**	**Smoking**
Variable							
Visits (at least once)	156 (75,0%)	58 (37%)	93 (60%)	80 (51%)	102 (65,4%)	88 (56%)	37 (24%)
Page view duration (in seconds) (mean±SD)	26.52 (±34)	18.34 (±11)	16.47 (±15)	151.95 (±151)	22.39 (±15)	159.98 (±131)	10 (±8)
Page view duration (in seconds) (median)	20	15	13	123	19	110	7
Hits (mean±SD)	6.66 (±10)	2.30 (±4)	7.18 (±10)	1.29 (±1)	9.12 (±22)	1.23 (±1)	2.81 (±2)
Hits (median)	4	1	3	1	2	1	2
Surfing depth (mean±SD)	0.63 (±0.48)	1.32 (±0.47)	2.54 (±0.90)	1.00 (±0.00)	2.31 (±0.69)	1.03 (±0.30)	2.02 (±0.61)
Surfing depth (median)	1	1	2	1	2	1	2

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Chapter 6

Chapter 6

Effect of a tailored behaviour change programme on a composite lifestyle change score: a randomised controlled trial

Based on:
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ABSTRACT
Objective: To evaluate the effect of a tailored behaviour change programme on a composite lifestyle change score.
Methods: A randomised controlled trial conducted in Belgium in 2007-2008 with 314 participants allocated to a control and an intervention condition. The intervention was a tailored behaviour change programme (web-based and individual coaching). The dose of the coaching was chosen by the participants and registered. Outcome measures were weight, saturated fat intake, fruit- and vegetable intake, physical activity, smoking status and a composite lifestyle change score. Mann Whitney U tests, Kruskal-Wallis tests, T-tests, and One-way analyses of variance were used to compare the study conditions and three intervention dose groups (no/low, medium, and high intervention dose).
Results: There were no significant differences between the study conditions or between the intervention dose groups for the individual lifestyle factors. The composite lifestyle change score was significantly higher in the high intervention dose group compared to the no/low intervention dose group ($p=0.009$).
Conclusions: The composite lifestyle change score was positively related to the intervention dose while the individual lifestyle factors were not. Behaviour change programmes that target multiple lifestyle factors could be evaluated by using a composite lifestyle change score taking into account the intervention dose.

INTRODUCTION
Chronic diseases such as cardiovascular disease (CVD) are caused by multiple biomedical and lifestyle factors (1). The European guidelines on cardiovascular prevention emphasise the importance of smoking cessation, taking sufficient exercise and adhering to a balanced diet and exercise. Overweight and obesity are associated with a raised blood pressure and dyslipidemia and ultimately with an increased CVD risk (1). Studies showed that dietary lifestyle factors such as fat, fruit- and vegetable intake are related to cardiovascular disease or risk factors such as elevated blood pressure and lipid levels (1, 2). Low levels of physical activity are associated with an increased cardiovascular risk and mortality (3). Finally, smoking is the only lifestyle factor that directly is included in the determination of the 10-year risk of cardiovascular death using the SCORE model (4). The factors taken into account in this algorithm are age, sex, smoking status, cholesterol level, and blood pressure level. Based on this model, people can be classified to have a low, average or high risk. Guidelines recommend to target interventions at people at low, average and high risk (mixed population) and this is considered to be cost-effective (1, 5).

The INTERHEART study showed that lifestyle factors contribute for 55% to the risk of myocardial infarction (6). The lifestyle factors considered in that study were eating fruit and vegetables on a daily basis, taking regular exercise, and avoiding smoking, and abdominal obesity. The association of 6 core protective lifestyle factors with a lower prevalence of hypertension and a raised cholesterol was confirmed in a recent cross-sectional study (7). The core protective lifestyle factors were having a normal Body Mass Index (BMI), having a waist-hip-ratio below the current threshold for central obesity, never smoking, low alcohol consumption, a healthy diet, and adequate levels of physical activity. Behaviour change programmes targeting more than one lifestyle factor simultaneously are warranted and were found to be effective in provoking positive lifestyle changes (8). It is important for multiple behaviour change interventions to find a way of communicating the complete behaviour change effect (9). They can be evaluated accordingly using a composite lifestyle score. Nevertheless, consensus on how to report changes in multibehavioural interventions is lacking. Several methods to calculate a composite lifestyle score such as combined change scores or an index can be used. A number of cohort studies with large population samples included a composite lifestyle score (10-12). However, no randomised controlled trial of a behaviour change intervention programme for mixed populations has used a composite lifestyle score as outcome measure yet. One randomised trial in patients with established coronary heart disease used a composite lifestyle score as an outcome measure of an intensive lifestyle programme (13).
The present study tested the effect of a tailored behaviour change programme targeted at multiple lifestyle factors using a randomised controlled study design with a composite lifestyle change score as an outcome measure. Moreover, the received intervention dose was considered because it is related to the effect size of behaviour change interventions (14).

METHOD

Participants and study design

Study recruitment began in Belgium in February 2007 and ended in April 2007 (15). Requests for study participation were sent to customers from an insurance company that insures self-employed professionals (e.g., lawyers) against loss of income due to sickness (n= 737) (Figure 1). Eligible participants were 25 to 75 years old with Internet access. Informed consent was obtained from 314 overall healthy and highly educated adults (Master's degree in Law).
They were randomised using to a control and an intervention condition using a non-stratified randomization technique with a 1/3 versus 2/3 ratio in order to keep enough power to study dose-response effects (15). The randomisation was performed by hand by an independent person. The

participants were blinded to group assignment. The informed consent form stated that participation meant that the participant would be offered a cardiovascular prevention programme. Participants in both conditions received a medical assessment to determine the cardiovascular risk using the SCORE algorithm and a profile with a risk summary (4). Two hundred and eighty-seven participants completed a questionnaire in April 2007. Next, participants in the intervention condition received access to a tailored behaviour change program (web-based and individual coaching) aimed at reducing overweight, reducing saturated fat intake, increasing fruit- and vegetable intake, increasing physical activity, and quitting smoking. After 6 and 12 months, the participants completed the questionnaire again. The 6-month results are published elsewhere (16). The present study examines the 12-month year results. The study was approved by the Hasselt University Ethics Committee (ISRCTN23940498).

Intervention

The behaviour change programme was based on leading behaviour change and motivational theories such as the Theory of Planned Behaviour (TPB) and Self-Determination Theory (SDT) (17-19). TPB is a theory that describes and predicts behaviour using theoretical constructs such as attitudes, subjective norms, perceived behavioural control, and intentions (17). SDT complements TPB because it distinguishes between qualities of motives that regulate behaviour and influence TPB constructs (19). One of the recommendations from SDT is to offer choice to increase motivation (19). Hence, the participants could freely compose their own individual coaching with regard to the targeted lifestyle factors, the dose, and the delivery mode (e-mail; regular mail; telephone; face-to-face). A health psychologist telephoned the participants before the intervention to ask them how they wanted their coaching to look like. This information was used to individually tailor the coaching to the needs of the participants. The coaching was given by a health psychologist who used behaviour change techniques (e.g., set graded tasks; provide instruction) and an autonomy-supportive inter-personal style (e.g., avoiding a controlling language, taking the perspective of the individual) to stimulate lifestyle change (18). The autonomy-supportive inter-personal style is an example of an SDT recommendation that was followed in this intervention. The participants in the intervention condition that preferred no coaching received no intervention dose. The participants in the intervention condition could also make use of web-based coaching. The participants could log in to a tailored website including a cardiology section by default. Participants were free to subscribe to sections with information on individual lifestyle factors (e.g., fat intake, fruit- and vegetable intake, physical activity, and quitting smoking), behaviour change techniques (e.g. self-monitoring), self-tests and tailored advice.

Intervention dose registration

The intervention dose registration for individual coaching consisted of a prospective registration of the targeted lifestyle factor, the delivery mode, and the duration of each contact (in minutes) by the study personnel alongside the trial. This registration can be considered to be reliable since this information was used for the determination of intervention costs in a cost-utility study of this cardiovascular prevention programme (20). The total duration of all contacts to promote a healthy lifestyle per participant was calculated and was used as a measure for the intervention dose in this study. Tailored website traffic was also registered but the effect of the web-based coaching was not included in the present study because website use naturally declines over time and an exploration of website use was described elsewhere (21). Participants in the intervention condition were divided in three intervention dose groups using the 50th and 75th percentiles of the total duration of all contacts of one year. These percentiles were chosen because about half of the participants underused the program (no or a low dose) and in the present study the aim was to gain more insight into actual intervention exposure and its effects individual lifestyle factors and a composite lifestyle change score. Hence, there were three groups: no or a low intervention dose (less than 5 hours), a medium intervention dose (between 5 and 7 hours) and a high intervention dose (more than 7 hours). The no or low dose group received a mean of 227.81 minutes of intervention (S. D. 4.23), the medium dose group received a mean of 343.74 minutes of intervention (S. D. 5.20), and the high dose group received a mean of 727.03 minutes of intervention (S. D. 58.01). The dose-response effects were only examined for the intervention condition.

Lifestyle factors

The questionnaire included self-reported weight, height and questions on the smoking status. Weight was reported in kilograms (kg), height in centimeters (cm). Saturated fat intake was assessed in grams of fat per day with a validated food frequency questionnaire (22). Fruit- and vegetable intake was assessed using a short food frequency questionnaire (23). The latter questionnaire was validated in a sample of children but was chosen because of its brevity only consisting of 6 items: 1) How often do you eat fresh fruits?; 2) How often do u usually eat salads?; 3) How often do u usually eat raw vegetables?; 4) How often do u usually eat potatoes?; 5) How often do u usually eat boiled vegetables?; and How often do you drink fresh orange juice? (answer categories: Never, less than one day a week, one day a week, 2-4 days a week, 5-6 days a week, every day (1x), every day (2x), every day (>2x)). A summed score of daily portions of fruit and vegetables was calculated. Total physical activity in minutes per week was assessed using a validated questionnaire, the International Physical Activity Questionnaire (IPAQ) (long version, usual week) (24). The IPAQ has been used to monitor changes in physical activity computer-tailored and whole-

community interventions before (25, 26). Proportional differences were calculated for each lifestyle factor (weight, saturated fat intake, fruit- and vegetable intake, and physical activity) by subtracting the baseline score from the 12 month follow-up score and multiplying it by 100. For all these factors and for smoking, net effects were calculated by subtracting the change in the control condition from the change in the intervention condition and dividing it by the mean baseline score in the control condition.

Composite Lifestyle Change Score

A score ranging from -2 to +2 was calculated using the quintiles of the proportional differences of each lifestyle factor. This method was used before to recode individual lifestyle factors into categorical variables to determine a composite lifestyle score (12, 10). For weight, the 20% of the participants that gained most weight received a score of -2. The next 20% received a score of -1 and so on. The 20% participants that improved this lifestyle factor most, received a score of +2. The same procedure was followed for saturated fat intake, fruit- and vegetable intake, and physical activity. For smoking, a score of -2 was given to participants that started smoking, a score of zero was given to participants that never smoked, kept smoking or stayed abstinent and a score of +2 was given to participants that quitted smoking. For smoking, the scores of -1 and +1 were not used to account for the greater importance of this lifestyle factor for cardiovascular prevention. A composite lifestyle score was calculated by summing up the scores for each lifestyle factor. The composite lifestyle change score ranges from -10 (lifestyle worsened the most) to +10 (lifestyle improved the most).

Sample size

A two group t-test with a 0.05 two-sided significance level had 80% power to detect a difference of 12.00 grams of fat (common standard deviation=34.50 grams/day) and 86% power to detect a difference of 122.00 minutes of total physical activity (common standard deviation=323 minutes/week) (total sample size=300) (Nquery Advisor 4.0®).

Statistical analyses

Mann Whitney U and Kruskal-Wallis tests were used to compare the mean proportional differences between the two study conditions and the intervention dose groups (SPSS 16.0). These analyses were conducted separately for specific subgroups that were not in line with the recommendation for that particular lifestyle factor at baseline (BMI□25 kg/m²; saturated fat intake□10% total energy intake per day; 4 portions of fruit and vegetables per day; sports 3 times/week□20 minutes or moderate activity□6 days/week; smoking abstinence) (4, 27-29, 1). T-tests and One-way analyses of variance with a post hoc Tukey test were used to compare the mean composite lifestyle change scores of the two study conditions and the intervention dose groups. These analyses were also conducted separately for people who smoked and/or were not in line with at least two other lifestyle recommendations. For individuals missing information on any

lifestyle factor, the last observation was carried forward (intention-to-treat) ($\alpha = 0.05$). The net effects were calculated for the individual lifestyle factors by subtracting the mean one-year change in the control condition from the mean one-year change in the intervention condition and dividing this by the mean baseline score for that lifestyle factor in the control condition.

RESULTS

At baseline the participants that filled out the questionnaire in April 2007 (n= 287) consisted mainly of men (67%) and the mean age was 40.49 years (standard deviation; S.D. 10.55) (Table 1). The response percentage was 39% (287/737). The drop-out rate was 32% (34/106) for the control condition and 29% (61/208) for the intervention condition. Drop-out analysis showed no significant differences for gender, age, study condition, cardiovascular risk, Body Mass Index (BMI), saturated fat intake, fruit- and vegetable intake, physical activity and smoking. The control condition and intervention condition were also comparable with regard to these factors at baseline.

The composite lifestyle change score was significantly different for the intervention dose groups ($F=5.89;df=2;p<.01$). The lifestyle change score was higher in the high intervention dose group (n= 48) compared to the no/low intervention dose group (n= 97) ($p<.01$).

The medium dose group was not significantly different from the other intervention dose groups. Table 2 shows the composite lifestyle change score and individual lifestyle factor changes for the total sample and for subgroups that were not in line with lifestyle recommendations at baseline. The composite lifestyle change score was not significantly different for both study conditions ($t=-0.95;df=285;p=.34$). There were no differences for the individual lifestyle factors between both study conditions or between the intervention dose groups. The results for the subgroups that were not in line with the recommendations were comparable to those for the total sample (Table 2). The net effect of the intervention was -0.01 for weight, -0.04 for saturated fat intake, 0.004 for fruit- and vegetable intake, 0.02 for physical activity and -0.33 for smoking.

DISCUSSION

Significant differences between the intervention dose groups were found for the composite lifestyle change score. A high intervention dose led to a significantly higher composite lifestyle change score compared to no or a low intervention dose. No differences, however, were found between the study conditions for the composite lifestyle score or the individual lifestyle factors. No differences were found between the intervention dose groups for the individual lifestyle factors either.

Previous studies including a composite lifestyle score differed with regard to the number and nature of the included factors and the formula for the

composite score (10-12). Except for the absence of alcohol consumption, the lifestyle factors included in the present study are comparable to those described in the literature. Like in other studies the composite score was determined by summing up the scores on separate lifestyle factors. These studies calculated a binary score (compliance vs. non-compliance) for each lifestyle factor. In the present study, however, a categorical score with three to five categories was determined for each lifestyle factor. In this way, small behavioural changes can better be grasped. Composite lifestyle scores are determined in a pragmatic way and it is advised in the literature to apply different methods to come to a universal composite score (11, 9). In other studies, the predictive value of the composite score for the risk of stroke and CVD was investigated and confirmed (10-12). In spite of these findings, only one randomised study considered the direct effect of an intervention on a composite lifestyle score (13). In the latter study there was a significant difference between the study conditions for the composite score but not for each separate lifestyle factor. This is in line with the findings from the present study. The study of Ornish et al. (1998), however, included patients with moderate to severe coronary heart disease whereas the present study included a mixed population as recommended by the guidelines on CVD prevention (1). The question is not whether cardiovascular prevention programmes should be reserved for high-risk individuals, but how the content and costs of these programmes should be adapted to the risk. A different ceiling of investment can be determined for healthy individuals, high-risk individuals and coronary patients.

The most important strengths of this study were the use of a randomised design and the analysis of the dose-response effects. A higher intervention dose was associated with significant lifestyle improvement. The fact that a higher intervention dose leads to greater interventions effects is generally accepted (14). One could, however, be concerned that the difference between the intervention dose groups was caused by a selection bias (i.e., more motivated participants select a higher intervention dose and make more positive lifestyle changes). Randomisation of the dose is the optimal strategy to examine dose-response effects (30). However, the aim of the present study was to examine the effect of a self-selected intervention dose. As suggested by McGowan et al. (2010) we explored pre-treatment confounding variables for the three groups and found no differences for the behavioural outcomes used in the composite lifestyle change score at baseline (weight, saturated fat intake, fruit and vegetable intake, physical activity) and motivation to change physical activity, diet or smoking ($p>.05$) (30). Participants' BMI at baseline, however, was higher in the high intervention dose group versus the no/low intervention dose group ($F=8.17;df=2;p<.01$). The high intervention dose group included two participants suffering from morbid obesity (BMI ≥ 40). There was no improvement for the individual lifestyle factors due to a higher intervention

dose. Perhaps an intervention designed to alter multiple behaviours at the same time is more likely to generate smaller changes in each behaviour than a single-behaviour intervention would provoke in one behaviour. Regrettably, a large gap remains in our knowledge about the basic principles of multiple behaviour change and efficacy of multiple behaviour interventions (31, 32). The literature holds information on the co-occurrence of behaviour (i.e., clusters of behaviour) but little is known about the co-variation of behaviours (33, 34). Co-variation exists when taking effective action in one behaviour increases the odds of taking effective action in a second behaviour. There are several hypotheses on the underlying principles of multiple behaviour change (35). One example is the Global health/behavioural category approach. This approach suggests that there may be higher order constructs such as global health attitudes or global self-efficacy that predict attitudes or self-efficacy toward behavioural categories (physical activity attitudes, dietary attitudes, and smoking attitudes). These attitudes toward behavioural categories, on their turn, predict attitudes toward specific behaviours (e.g., attitudes toward walking) and ultimately the latter attitudes predict actual behaviour (e.g., walking behaviour) (35). This approach suggests interventions that, for instance, promote a healthy lifestyle as a route to multiple behavioural changes. In the present study contacts with the participants were often targeted improving a healthy lifestyle, targeting multiple behaviours at the same time. For example, telephone calls were made wherein the health psychologist reviewed a subject's goals for physical activity as well as for diet. For all that, an improved composite score is relevant for cardiovascular prevention since the effect of each individual lifestyle factor can strengthen the effect of another lifestyle factor, the composite score holds more information than separate factors.

There are limitations to our study. Firstly, the participants were motivated volunteers and all highly educated, limiting the generalisability of our findings. Nevertheless, it is generally known that lifestyle interventions are more effective in patient samples than in overall healthy or mixed samples (36). Implementing the present intervention in the less healthy or lower educated may further improve its effectiveness. Secondly, the use of self-reported questionnaires could have led to over or under reporting. A lack of sensitivity of these questionnaires to measure individual behaviour change could have led to an underestimation of the intervention effect on the composite lifestyle change score. Furthermore, the short fruit and vegetable questionnaire used in this study was only tested in a children's sample and might not be valid in an adult sample but was chosen because of practical reasons. Nevertheless, Kim et al. (2003) stated that, despite validity issues, brief instruments can be used to monitor consumption trends over time (37). Thirdly, the difference between the intervention dose groups might partially be attributed to a regression towards the mean effect. Fourthly, the small

sample size could be a limitation of the study and might have caused an underestimation of the intervention effect. Lastly, a negative score was given to gaining weight by default. One could argue that this is disadvantageous to people without overweight. Therefore, the composite lifestyle change score was determined separately for people who did not meet the recommendation for BMI at baseline. In this respect, it can be argued that weight should not even be included because it is highly connected with physical activity and diet. However, weight is a mediator or the effect of the latter behavioural risk factors on CVD, it is not included in the SCORE algorithm, and was include in a composite lifestyle score before (10).

The present study showed that the composite lifestyle change score only increased in the high intervention dose group compared to lower dose groups. This makes one think that there is a certain intervention dose that is crucial to alter the composite change score whereas a lower dose fails to do this. However, clear-cut, causal inferences cannot be made without dose-randomisation. Nevertheless, studies targeted at multiple lifestyle factors would benefit from evaluating them accordingly, using a composite lifestyle score while taking into account the received intervention dose. Researchers in behavioural medicine should agree on a composite score that concurs with the scores that are used in cardiology to investigate the contribution of lifestyle to the risk of cardiovascular disease. Moreover, future studies on composite scores might be beneficial with regard to other chronic diseases as well. Danaei et al. (2009) described in their manuscript that cardiovascular diseases, cancers, and diabetes mellitus can be attributed to dietary risk factors, physical inactivity, smoking and overweight (38). Consequently, one can assume that the intervention and composite lifestyle change score from the present study might be of use in the context of other chronic diseases that can be attributed to unhealthy behaviours.

FIGURES

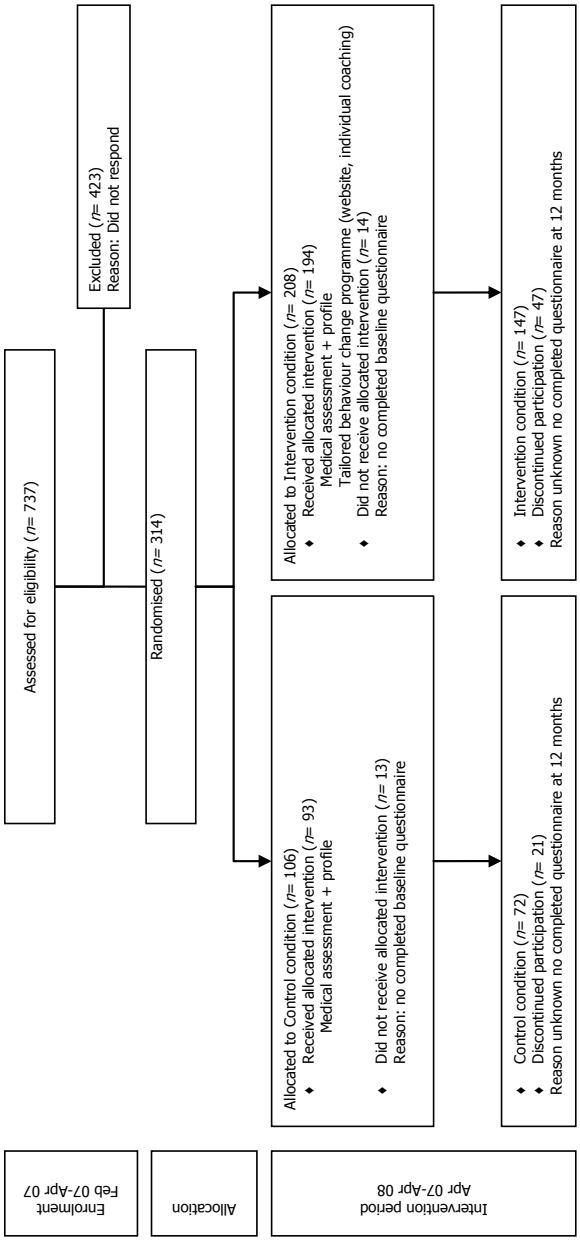

Figure 1: study flow

TABLES

Table 1: Baseline characteristics (% or mean ± S.D.) of the total study sample, the two study conditions and the three intervention dose groups

	Study sample (*n*= 287)	Control condition (*n*= 93)	Intervention condition (*n*= 194)	No/low dose group (*n*=97)	Medium dose group (*n*=49)	High dose group (*n*=48)
Gender (male)	66.60	67.70	66.00	63.90	67.3	68.8
Age	40.49 (10.55)	39.60 (10.50)	40.91 (10.57)	39.73 (10.29)	40.98 (10.22)	43.23 (11.30)
BMI in kg/m²	25.12 (4.14)	24.79 (3.37)	25.28 (4.47)	24.68 (3.57)	24.35 (3.24)	27.45 (6.23)
Cardiovascular risk						
Low	69.69	70.97	69.07	74.23	63.27	64.58
Average	10.80	8.60	11.86	6.19	12.24	22.92
High	8.36	12.90	6.19	5.15	6.12	8.33
Unknown	11.15	7.53	12.89	14.43	18.37	4.17
Saturated fat intake in grams/day	40.94 (16.74)	40.06 (14.74)	41.37 (17.53)	42.18 (20.58)	38.41 (13.71)	42.76 (13.90)
Fruit and vegetable intake in portions/day	1.49 (1.11)	1.46 (1.08)	1.51 (1.13)	1.65 (1.24)	1.44 (1.07)	1.27 (0.88)
Physical activity in min/week	237.73 (178.12)	235.73 (161.79)	238.69 (185.83)	245.58 (207.51)	253.92 (167.12)	209.23 (155.26)
Smokers	21.30	16.10	23.70	21.65	26.53	25.00

Table 2: Composite Lifestyle Change Score and individual lifestyle factor changes (%) for the total sample and subgroups that were not in line with lifestyle recommendations at baseline

Composite Lifestyle Change Score	**Control condition *n*=93**	**Intervention condition *n*=194**	***t***	***p*-value**	**No/low dose group *n*=97**	**Medium dose group *n*=49**	**High dose group *n*=48**	***F***	***p*-value**
	mean (S.D.)	mean (S.D.)			mean (S.D.)	mean (S.D.)	mean (S.D.)		
Composite Lifestyle Change Score (total sample)	-0.09 (3.05)	0.26 (2.76)	-0.95	.34	-0.28 (2.69)	0.24 (2.61)	1.35 (2.79)	5.89	.003[a]
Composite Lifestyle Change Score (smokers and/or not in line with at least two other individual lifestyle recommendations)	-0.18 (3.02)	0.43 (2.85)	-1.49	.14	-0.14 (2.81)	0.45 (2.75)	1.43 (2.79)	4.45	.013[a]
Individual Lifestyle Factors			***Z***					***Chi²***	
Weight (% change)	-0.01 (4.65)	-0.63 (3.97)	-1.48	.14	-0.57 (4.40)	-0.05 (3.64)	-1.37 (3.28)	2.84	.24

Weight – not in line with the recommendation (% change)	-0.64 (3.69)	-1.06 (3.91)	-0.99	.32	-1.39 (4.67)	-0.20 (2.62)	-1.15 (3.40)	2.67	.26
Saturated fat intake (% change)	0.32 (27.18)	-0.54 (34.25)	-0.65	.51	1.10 (30.76)	-2.57 (30.26)	-1.78 (44.04)	2.46	.29
Saturated fat intake – not in line with the recommendation (% change)	-2.89 (25.47)	-6.03 (31.56)	-1.06	.29	-4.29 (26.64)	-9.02 (25.96)	-6.34 (42.72)	2.18	.34
Fruit and vegetable intake (% change)	16.62 (95.50)	23.93 (105.62)	-0.25	.81	10.58 (95.47)	30.89 (102.94)	43.78 (124.68)	4.15	.13
Fruit and vegetable intake – not in line with the recommendation (% change)	22.30 (103.46)	33.62 (113.21)	-0.59	.56	19.48 (106.39)	40.37 (108.76)	51.12 (127.17)	3.36	.19
Physical activity (% change)	76.16 (200.87)	83.25 (213.60)	-0.78	.44	60.74 (193.93)	78.03 (203.83)	134.06 (253.75)	4.33	.12
Physical activity – not in line with the recommendation (% change)	90.45 (229.02)	99.39 (228.42)	-0.03	.98	83.24 (217.18)	93.88 (230.83)	137.47 (249.63)	2.10	.35

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Chapter 7

Chapter 7

Testing an integrated model of the Theory of Planned Behaviour and Self-Determination Theory for different energy-balance related behaviours and intervention intensities

Based on:
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ABSTRACT
Objectives: The aim of the study was to test the relations between constructs from the Self-Determination Theory (autonomous and controlled motivation), the Theory of Planned Behaviour (attitudes, self-efficacy, and intentions), and behaviour change within a theoretically-integrated model. Additionally, the aim was to test if these relations vary by behaviour (physical activity or dietary behaviour) or intervention intensity (frequency).
Design: It was a randomised controlled trial with a 'usual care' condition (medical screening only) and an intervention condition (medical screening + access to a website and coaching). Participants in the latter condition could freely determine their own intervention intensity.
Methods: Participants (N = 287) completed measures of the theoretical constructs and behaviour at baseline and after the first intervention year (N = 236). Partial Least Squares (PLS) path modelling was used.
Results: Changes in autonomous motivation positively predicted changes in self-efficacy and intentions towards a healthy diet. Changes in controlled motivation positively predicted changes in attitudes towards physical activity, changes in self-efficacy, and changes in behavioural intentions. The intervention intensity moderated the effect of self-efficacy on intentions towards physical activity and the relationship between attitude and physical activity. Changes in physical activity were positively predicted by changes in intentions whereas desired changes in fat intake were negatively predicted by the intervention intensity.
Conclusions: Important relations within the theoretically-integrated model were confirmed but others were not. Moderation effects were found for behaviour and intervention intensity.

INTRODUCTION
Cardiovascular disease can be prevented by an active lifestyle and a healthy diet (1, 2). Although vigorous-intensity physical activity leads to greater improvements than moderate-intensity physical activity, both types should be promoted (3). As most people are sedentary they are more likely to view physical activity of moderate intensity as appealing in order to change their inactive lifestyle. A healthy diet can further lower this risk by reducing or modifying dietary fat intake and increasing fruit and vegetable consumption (4, 5).
Despite the benefits of making positive lifestyle changes, people generally fail to meet the recommendations for physical activity and dietary behaviour. Consequently, the literature reports the psychosocial determinants that promote or thwart lifestyle changes (2). Physical activity and dietary behaviour are thought to be associated and cluster analyses have shown that such energy-balance related behaviours tend to co-occur (6).
Research on the psychosocial determinants of these energy-balance related behaviours has been performed before adopting theoretically-integrated

models of health behaviour incorporating the Theory of Planned Behaviour (TPB) (7) and Self-Determination Theory (SDT) (8, 9).

The primary postulate of the TPB is that an individual's intention is the most proximal predictor of his/her behaviour and mediates the effect of three sets of belief-based perceptions on behaviour: attitudes, subjective norms, and perceived behavioural control (PBC) (7). Attitudes reflect beliefs as to whether the behaviour (e.g., physical activity and dietary behaviour) will lead to desirable outcomes. Subjective norms summarise beliefs about whether salient others want an individual to participate in the behaviour. The concept of PBC is similar to Bandura's concept of self-efficacy (10, 11) and reflects whether a person believes he/she has the resources or capacity to engage in the behaviour. Cumulative quantitative reviews of research across a wide variety of behaviours (12), including physical activity (13) and dietary behaviours (14) have identified attitudes and PBC as having medium effects on intention with subjective norm demonstrating a substantially weaker effect (12, 14).

In contrast, SDT is a theory of human motivation that distinguishes between the quality of the reasons or *motives* (i.e. autonomous vs. controlled) that regulate behaviour (8). At the centre of the theory is the distinction between self-determined or *autonomous* forms of motivation and non-self-determined or *controlled* forms of motivation. Autonomous motivation reflects engaging in behaviours and activities that are perceived to originate from the self and fulfil personally-relevant goals. Controlled motivation reflects engaging in behaviours for reasons perceived to emanate outside the self. The driving force behind the forms of motivation that people adopt is basic psychological needs. People have the tendency to be attracted to autonomously-motivated activities in order to satisfy three innate psychological needs: the needs for autonomy, competence, and relatedness. The need for autonomy refers to the need to experience oneself as an initiator and regulator of one's actions. The need for competence refers to the need to master one's environment. The need for relatedness refers to people's innate need to seek close and intimate relationships with others. Autonomous motivation is associated with increased psychological well-being and persistence with health-related behaviours. Controlled motivation is associated with negative psychological outcomes and desistance or avoidance of tasks (15, 16). Autonomous motivation can also be supported or thwarted by environmental contingencies (2). Autonomy-supportive environments offer a rationale for the proposed health behaviour, offer choice, take the perspective of the individual, and acknowledge difficulties associated with changing behaviour (8). SDT is often adopted for tailored behaviour-change intervention programmes as autonomous motives positively affect behavioural engagement (17, 18).

Theoretically-integrated models of TPB and SDT have been effective in explaining physical activity and dietary behaviour (e.g., 2, 9, 14). In these

models, a motivational sequence is proposed such that the effects of autonomous versus controlled motivation on intentions and behaviour are mediated by the proximal determinants of intentions: attitudes and self-efficacy (14). Although the motivational sequence has been confirmed in several correlational studies, few intervention or experimental studies have tested this sequence (19-22) and only one study focusing on physical activity adopted a true intervention or experimental design using randomisation (20). No study to date has adopted a theoretically-integrated model to evaluate behaviour change in the context of dietary behaviour (Hagger, 2009). There is also very little research that has identified the components of interventions that would target the key psychosocial and motivational constructs that influence behaviour in the context of this integrated model. This is necessary in order fully realise the importance and contribution of formative theoretical research integrating these theories in the development, and design, of interventions to change behaviour (23). Research is needed to identify these components and the extent to which participants engage with these components i.e. their self-selected intervention *intensity* affects the behavioural outcomes.

The Present Study and Hypotheses

The present study is the first randomised controlled trial testing the relations between constructs from the SDT, the TPB, and behaviour change within a theoretically-integrated model for different behaviours and intervention intensities. Figure 1 shows the study flow and Figure 2 shows the theoretically-integrated model. Autonomous and controlled motivation were hypothesised to be distal predictors of attitudes and self-efficacy (e.g., 9, 14). Attitudes and self-efficacy were hypothesised to be proximal predictors of intentions in accordance with the TPB. We hypothesised indirect relations between autonomous and controlled motivation and intentions and between attitudes and self-efficacy (or PBC) and behaviour (7, 14). The theoretically-integrated model additionally included intervention intensity (or intervention 'dose') as a moderator of all the relations within the model.

METHODS

Participants

Participants (*N* = 287, 191 male, 96 female, *M* age = 40.48 years, *SD* = 10.55) completed the measures at baseline after randomisation. Seventy percent (*N* = 202) had a low risk to die of a cardiovascular event in the next 10 years. All participants were highly educated (Master degree). Participants engaged in an average of 237.31 minutes (*SD* = 178.66) of physical activity per month and their daily fat intake was 106.31 grams (*SD* = 38.46) per day. These data suggest that participants in this sample were already quite active. With regard to fat intake, however, they had worse scores compared to the general population (24).

Study Design

E-mails requesting study participation were sent to clients (N = 737) of an insurer (De Onderlinge Ziekenkas). Three hundred and fourteen adults signed an informed consent form and were randomised to intervention conditions using a 1/3 (receiving 'usual care') versus 2/3 (receiving the intervention) procedure in order to study the dose-response effects of the intervention (25). The randomisation was blind and performed by an independent person. The names of the participants were written on papers that were put in sealed envelopes. Next, the envelopes were randomly assigned by hand to baskets for the 'usual care' and intervention conditions.

A power calculation using Nquery Advisor 4.0 showed that 300 participants were required to detect a clinically-significant difference of 12 grams daily fat intake (common SD = 34.50 grams) and a difference of 40 minutes of weekly physical activity (common SD = 323.00 minutes) between the 'usual care' and intervention conditions, with levels of statistical power of 80% and 86%, respectively (2-tailed; $p < .05$). The Hasselt University Ethics Committee approved this study and it was registered (ISRCTN23940498).

After blind randomisation, 287 adults completed the baseline measures (t = 0) and were asked to complete the measures again at the end of the first intervention year (t = 1). To examine the intervention effect, however, it is insufficient to merely compare both study conditions because the participants in the intervention could freely determine their own intervention intensity. This freedom enabled participants who were allocated to the intervention condition to choose for an intervention intensity that was comparable to 'usual care'. A focus on the intervention intensity rather than on the original randomisation to 'usual care' and intervention conditions is supported by previous results after 6 months of the intervention (26). The latter manuscript dealt with the effects and the dose-response effects of the intervention. No behavioural differences were found between the original study conditions (usual care and intervention condition). The hypothesis was that this was due to people selecting an intervention intensity that was not of a sufficiently high intervention 'dose' to gain health benefits. This hypothesis was confirmed: a higher intervention dose led to better outcomes, independent of the baseline motivation. The present study includes a path analysis of the data after one year of intervention, again, taking into account the intervention intensity (or intervention dose).

Intervention

The intervention consisted of an educational website and one-on-one or group coaching sessions in addition to usual care (i.e. medical screening and follow-up). In the present study, we focus on the impact of the coaching aspect of the intervention. The coaching sessions consisted of several techniques to change the psychosocial determinants from TPB and SDT, physical activity and dietary behaviour. The participants were encouraged to increase their level of physical activity by conforming to one of the following

recommendations: performing sports at least 3 days a week for 20 minutes or adopting moderately-active pastimes for at least 6 days a week (1, 27). For dietary behaviour, participants were encouraged to consume less than 30% of their dietary energy from fat and eat at least four portions of fruit and vegetables per day (28, 29). The participants thus could choose to work on multiple behaviours simultaneously.

The intervention comprised behaviour change techniques adopted from a recent taxonomy (30). The techniques used were: provide information on the behaviour-health link; provide information on the consequences of not changing; provide information on others' approval; prompt intention formation; prompt barrier identification; provide general encouragement; set graded tasks; provide instruction; model/demonstrate the behaviour; prompt specific goal setting; prompt review of behavioural goals; prompt self-monitoring of behaviour; provide feedback on performance; teach to use prompts/cues; prompt practice; use of follow up prompts; provide opportunities for social comparison; plan social support; relapse prevention; and motivational interviewing.

An autonomy-supportive inter-personal style was used to change SDT constructs. This was done by providing positive feedback, providing a rationale, avoiding a controlling language, taking the perspective of the individual, acknowledging difficulties associated with changing health behaviours and enhancing a sense of choice (22, 31). The sense of choice was enhanced by letting the participants in the study freely determine their own intervention intensity and delivery mode and the target behaviour they wanted to work on. Before the intervention (i.e. coaching) started, participants were telephoned by a health psychologist and asked which intervention style they preferred. Participants could determine the delivery mode and intervention intensity of the coaching. Several delivery modes were possible for the coaching: e-mail, regular mail, telephone, and face-to-face. The intervention components adopted to target the constructs from SDT are described in detail elsewhere (18). The coaching was conducted by a health psychologist with the assistance of undergraduate students and all activities were measured using an online registration system.

Measures

Motivation. Autonomous and controlled motivation in the physical activity and dietary behavioural contexts were measured using four items selected from the Behavioural Regulation Exercise Questionnaire II (BREQII) (32, 33) and the Treatment Self-Regulation Questionnaire (TSRQ) (34), respectively. The items for autonomous motivation were "A reason to be physically active every day or to do sports 3 times per week is: (i) because it is fun, and (ii) because I find being physically active a pleasurable activity". The items for controlled motivation for physical activity were "A reason to be physically active every day or to do sports 3 times per week is: (i) because I feel ashamed when I miss a physical activity session, and (ii) because others will

not be pleased with me if I don't. Responses to these items were measured on 5-point Likert scales (1 = *not true for me* and 5 = *very true for me*). The items for autonomous motivation for changing dietary behaviours were "A reason to eat a healthy (=low-fat) diet and 5 portions of fruit and vegetables every day (a portion = 80 grams) is: (i) because I have carefully thought about it and believe it is very important for many aspects in my life and (ii) because it is an important choice I really want to make". The items for controlled motivation for changing dietary behaviours were "A reason to eat a healthy (=low-fat) diet and 5 portions of fruit and vegetables every day (a portion = 80 grams) is (i) because I feel pressure from others to do so and (ii) because I want others to approve of me". Responses to these items were measured on 7-point Likert scales (1 = *strongly disagree* and 7 = *strongly agree*).

Attitudes. General-affective attitudes towards physical activity (two items) and dietary behaviours (two items) were assessed using bipolar adjectives on 7-point Likert scales. For physical activity, participants were asked whether being active every day for 30 minutes or do sports 3 times per week is 'bad-good' and 'stressing-relaxing'. For dietary behaviours, participants were asked whether eating a low-fat diet every day is 'not pleasant-pleasant' and 'stressing-relaxing'.

Self-efficacy. Self-efficacy was measured by two items for each behaviour on 7-point Likert scales ranging (1 = *strongly disagree* and 7 = *strongly agree*). For physical activity, the following two items were used: "I am sure that, when it's up to me, I am capable to be physically active every day or to do sports 3 times per week, also on days when I'm very busy or family and friends ask time from me" and "I have the feeling that being physically active every day for 30 minutes or doing sports 3 times per week is completely under my control in the coming month". For dietary behaviours, the following two items were used: "I am sure that, when it's up to me, I am capable to eat 5 portions (1 portion = 80 grams) of fruit and vegetables every day, also on days when I'm very busy or family and friends ask time from me" and "I have the feeling that eating healthy is completely under my control in the coming month".

Intention. Intentions were measured by one item for each behaviour on 7-point Likert scales (1 = *strongly disagree* and 7 = *strongly agree*): "I plan to be active every day or do sports 3 times per week in the coming month" and "I plan to eat a healthy, low-fat diet and eat at least 5 daily portions of fruit and vegetables in the coming month". The use of more than one item to measure a construct is desirable but this was unfeasible in the present study due to time constraints and questionnaire length (35).

Behaviour. Physical activity was measured in minutes per week with the International Physical Activity Questionnaire (IPAQ) (long version-usual week) which has been found to be a reliable and valid physical activity assessment tool for the general Belgian adult population (36, 37). To correct

for over reporting, the household activities (in and outside the house) were left out of the analyses and the scores were multiplied by 0.80 (38). Fat intake was measured in grams per day with a computerised fat intake questionnaire with a good reliability and adequate validity (24).

Intervention intensity. The intervention intensity measure consisted of a registration of the delivery mode, the target behaviour, and the frequency of coaching sessions. The intervention intensity was operationalised as the total frequency of the coaching sessions to promote physical activity or dietary behaviour, respectively. The total frequency was accurately measured using an online registration system to gather data for a cost-utility study (39).

Statistical Analyses

Preliminary analyses consisted of descriptive statistics, correlation analyses, and an assessment of the psychometric properties of the measures. Residualised change scores have been proposed as a solution to the problem of autocorrelation (regression to the mean) when one wants to measure change (40, 41). Hence, residualised change scores were created by regressing the post-test measures onto the baseline measures and subtracting the predicted value from the post-test value. Next, we standardized the residualised change scores. Standardized residualised change scores were calculated for all the independent and dependent variables in the theoretically-integrated model. The standardised residualised change scores for behaviour were then compared for the participants of the original intervention conditions ('usual care' versus intervention).

The aim of the analyses was to assess the hypothesised relations within the theoretically-integrated model depicted in Figure 2. The theoretically-integrated health behaviour model should be rejected if the major hypotheses of the model are non-significant. Furthermore, the confirmation of the main effects (e.g. autonomous motivation on TPB constructs, TPB constructs on intention, intention on behaviour) are considered to be more important than the confirmation of the moderation effects because the latter effects were added to the model for the purpose of this specific study including an intervention with a variable, self-selected intensity.

To test these hypotheses we used PLS path modelling. PLS path modelling is a variance based structural equation modelling (SEM) technique that does not rely on distributional assumptions. There are a number of reasons why PLS path modelling was chosen. First, our data exhibited significant deviations from normality (see below and descriptive statistics). Second, the analysis of continuous moderator variables is extremely problematic using covariance-based SEM (e.g., 42, 43). All analyses were conducted with SmartPLS. Based on the empirical work of Andrews and Buchinsky (44) and MacKinnon, Lockwood, and Williams (45), the significance of the parameter estimates is assessed by constructing 95% bias-corrected percentile confidence intervals based on a bootstrap procedure with 7,000 replications.

To model the hypothesized moderator effects we used the PLS approach suggested by Goodhue, Lewis, and Thompson (46). According to this approach, the moderator effect is modelled as a latent variable with a single indicator that is the product of the summed indicators of the constructs underlying the hypothesized moderator effect. Goodness-of-fit measures evaluate the performance of the entire model with all dependent relationships considered simultaneously. Significance level was set at a=.05.

RESULTS

Preliminary Analysis

Tables 1 and 2 depict the descriptive statistics and correlation matrices for the relevant variables for physical activity and dietary behaviour respectively. In both tables the lower triangle of the correlation matrix contains the coefficients between the variables measured at t = 0 and the upper triangle contains the coefficients between the variables measured at t = 1. There were no differences between the original study conditions for standardized residualised changes in physical activity (t = -.024;df = 234;P = .98) or fat intake (t = 1.17;df = 234; P = .24). The mean total frequency of coaching sessions to promote physical activity was 15.52 (SD = 10.75) and the mean total frequency of coaching sessions to promote dietary behaviours was 13.71 (SD = 9.03).

Running the measurement models with all the available items for each construct revealed inconsistent results for the multiple-item controlled motivation factor. Consequently, in the remainder of this study the controlled motivation construct was modelled as a single item variable. The estimation results concerning physical activity and dietary behaviour for both measurement periods are presented in Table 3. The relative goodness-of-fit statistic was .93 for physical activity .94 for dietary behaviours. A relative goodness-of-fit statistic of .90 or higher is indicative of good model performance (47).

Main Analysis

Table 4 provides an overview of the estimates for the different model parameters for the PLS models in both behavioural contexts.

Physical activity

For the physical activity context, changes in autonomous motivation significantly and negatively predicted changes in attitudes towards physical activity (β = -.38; P < .05) and changes in controlled motivation positively predicted changes in attitudes towards physical activity (β = .23; P < .05). Concerning an individual's changes in self-efficacy to be physically active results revealed that variance in this construct was significantly explained by changes in autonomous motivation alone (β = .30; P > .05). Changes in autonomous motivation and self-efficacy significantly and positively predicted changes in intentions towards physical activity (β = .17; p < .05; β = .44; P < .05). Furthermore, the impact of changes in self-efficacy on

changes in behavioural intentions was significantly moderated by intervention intensity (β = .37; P < .05). More specifically, a higher intervention intensity resulted in a higher positive influence of changes in self-efficacy on changes in behavioural intentions. Finally, changes in behavioural intentions towards physical activity significantly predicted increases in physical activity (β = .24; P < .05). The intervention intensity significantly and negatively moderated the relationship between changes in attitudes towards physical activity and physical activity behaviour (β = -.20; P < .05). For physical activity, the hypothesized relationships explained 22% of the variance in attitudes, 10% of the variance in self-efficacy, 30% of the variance in behavioural intentions, and 9% of the variance in changes in physical activity.

Dietary behaviour

For the dietary behaviour context, changes in attitudes towards changing dietary behaviours were significantly and negatively predicted by changes in autonomous motivation (β = -.20; P < .05). Changes in self-efficacy regarding dietary behaviours were significantly and positively related to changes in autonomous motivation (β = .32; P < .05) and intervention intensity (β = .14; P < .05). Changes in behavioural intentions towards changing dietary behaviours were significantly and positively predicted by changes in autonomous motivation (β = .15; P < .05) and self-efficacy (β = .48; P < .05). Finally, desired changes in fat intake (negative sign = reduction of fat intake) were significantly and negatively predicted by the intervention intensity alone (β = -.14; P < .05). Regarding dietary behaviour the hypothesized relationships explained 13% of the variance in self-efficacy, 32% of the variance in behavioural intentions, and 6% of the changes in fat intake.

DISCUSSION

The purpose of the present study was to test relations within a theoretically-integrated health behaviour model of TPB and SDT and to compare the results in two health behaviour contexts related to 'energy balance': physical activity and dietary behaviours. Another aim of the study was to test whether the relations varied due to the intervention intensity. Findings from well-fitting PLS path-analytic models indicated that there were some clear congruences in the variables that predicted changes in the antecedents of both health-related behaviours, namely, the effect of autonomous motivation on attitudes, self-efficacy, and intentions, in both behavioural contexts. Specifically, autonomous motivation was a significant predictor of changes in attitude, self-efficacy, and intentions in both contexts. Self-efficacy was also a significant predictor of changes in intentions in both samples. However, when it came to the prediction of behaviour, there were marked differences in the direct predictors. In the dietary behaviour context, intervention intensity was a significant predictor of behaviour, while changes in

behavioural intentions were a significant predictor of behaviour in the physical activity context. There were also some important moderation effects. Findings indicated that the effect of self-efficacy on intentions and the effect of attitude on behaviour were moderated by intervention intensity in the physical activity behaviour context. There were no interaction effects in the dietary behaviour context. Instead, intervention intensity had a direct effect on changes in fat intake suggesting that more frequent interventions were effective in changing fat intake.

It is important to note that there were a number of consistent patterns of effects that were in accordance with the expected patterns from integrated models adopting the TPB and SDT. Specifically, it seems that, for both behavioural contexts, increases in autonomous forms of motivation led to changes in attitudes and self-efficacy. This is consistent with previous research that has shown significant relations between the immediate antecedents of behavioural intentions from TPB, namely attitudes and PBC, and autonomous forms of motivation from SDT (2). Such research indicates that people are likely to form future beliefs about outcomes and control over health-related behaviours if their motives are self-determined. A likely mechanism for this is that people with autonomous motives are more likely to pursue personally-relevant outcomes and feel competent in pursuing those outcomes. Such outcomes and perceptions of competence are motivationally adaptive, which means it is unsurprising that these variables are likely to be related to intentions to act in the future. An important contribution of the present study is that these patterns of effects are corroborated in terms of change scores, which means that these effects are apparent when controlling for previous perceptions and enables us to better infer causal links between the component theory constructs.

Another set of relations that were consistent across the behavioural contexts in the present study and were consistent with previous research was the effect of changes in self-efficacy and autonomous motivation on changes in intentions. These relations indicate that it is self-efficacy (PBC) from the TPB and autonomous motivation from SDT that are most effective in predicting changes in intentions across the course of the intervention. The effect of increases in self-efficacy on intention change is consistent with previous studies that have shown PBC to have a strong, significant, and consistent effect on intentions in health behaviour (12, 13). The direct effect of autonomous motive change on increases in intentions has been found in some studies (2, 48, 49). A recent meta-analysis of this integrated model, however, has demonstrated that the direct effects of autonomous motivation on intentions independent of attitudes and PBC are relatively unsubstantial (2). This means that the direct effect in the present study is contrary to trends in previous research. It must be noted that regardless of whether autonomous motives predict intentions directly or indirectly via attitudes and PBC, these motives are directly implicated in the formation of intentions.

This is unsurprising, as research has demonstrated this link consistently (50) and it represents that motives reflecting the pursuit of behaviours that are personally-valued, are consistent with a person's sense of self, and satisfy psychological needs are likely to lead to the formation of intentions to pursue that behaviour again in the future.

There were relations in the present models that were specific to each behavioural context. Many of these differences related to the moderation of the effects in the model by intervention intensity. Specifically, there was an interaction between self-efficacy and intervention intensity on intention for the physical activity behavioural context only. This indicated that more frequent interventions increased the positive effect of self-efficacy on intentions. This demonstrates the value of engaging participants in more intensive forms of the intervention to maximise effects of motivationally relevant outcomes. In addition, controlled motivation predicted attitudes in the physical activity context only.

There were also incongruent patterns of effects of the proximal antecedents of behaviour change on actual dietary and physical activity behaviour change. For the dietary behaviour context, the link between changes in intentions and changes in fat intake was not confirmed. Many authors have identified an "intention-behaviour gap" in cross-sectional and prospective studies adopting the theory of planned behaviour (51). However, the link between intentions and behaviour is seldom zero, and in most studies a significant intention-behaviour link has been documented (2, 9, 22, 52) and has been corroborated by meta-analyses (12, 13). The problem with the intention-behaviour relationship usually lies in the scale inconsistency. This is likely to result in a modest effect size and a relatively large proportion of the variance in behaviour left unexplained by intentions. The lack of a significant relationship for fat intake in the present study may have been due to a lack of correspondence between the measures. In the present study, participants reported their intentions to change their diet through the adoption of a healthy low-fat diet including five portions of fruits or vegetables per day. Although an explicit reference to fat intake was made, participants also considered the adoption of an alternative behaviour, namely their fruit and vegetable intake. This might have caused the lack of prediction of fat intake by intention due to a lack of scale correspondence.

There was, however, a significant intention-behaviour relationship in the physical activity context. Given the lack of conclusive evidence that intra-individual changes in intention are predictive of behavioural changes the latter finding is very important (53). Our findings also corroborate previous findings that the intention-behaviour link is usually weaker for dietary behaviour than for physical activity (9). However, it is important to note the caveat regarding the intention and behaviour measurement correspondence which was far greater in the physical activity measures than in the dietary measures (9).

Intervention intensity had no moderating effect on the intention-behaviour relation in the present study. Maybe the present intervention would have benefitted from techniques designed to convert intentions into behaviour such as implementation intentions and action planning to achieve a moderation effect (54-58). However, there is evidence that questions the effectiveness of implementation intentions as moderators of the intention-behaviour relationship (59). Perhaps the moderation effect of the intervention on some relations within the model was thwarted by the large number of choice options. SDT recommendations include advice to enhance a feeling of choice. However, letting participants determine their own intervention intensity and delivery mode might undermine the effectiveness of the intervention because participants can opt to be unexposed to the intervention materials and therefore the options would have not been met with sufficient information. Ryan and Deci (60) stated that "one can have many options and not feel autonomy, but instead feel overwhelmed and resentful at the effort entailed in the decision making" (p. 1577). The number of options is not, in itself, enough to stimulate a feeling of autonomy, they need to be meaningful and informed (60). The comparison of the original study conditions pointed out that there was no intervention effect when the actual exposure to the intervention (intervention intensity) was not considered. Exposure to the intervention had a direct effect on dietary behaviour by decreasing the fat intake. The actual intervention intensity that the participants received plays a fundamental role in interpreting the effects of the present intervention.

Overall, the original contribution of this study is threefold. First, it corroborates prior research that showed TPB and SDT to be complementary (9). The important relationships between TPB and SDT constructs were supported (e.g., between autonomous motivation and self-efficacy for dietary behaviour). Second, the most important contribution of this study is the fact that it is the first of its kind to include a measure of intervention exposure. Intervention intensity (frequency) was included as a moderator in the theoretically integrated model but influenced different paths in different behavioural contexts. This is important as it indicates that the intervention can be effective in influencing components from both theories. Not only the 'offered' intervention but the 'used' intervention should be included in future modelling of intervention effects as it is the way interventions are interpreted and utilized 'on the ground' rather than in 'theory' that is important (61). The findings of the present study support this point of view. Third, the present study is the first to adopt the theoretically-integrated model to evaluate actual behaviour change in the context of dietary behaviour using an experimental design with a long-range evaluation. The study is therefore consistent with calls to adopt experimental and intervention designs to test the model and in behavioural contexts other than physical activity such as dietary behaviour (e.g., 2, 19).

Of course it would be remiss for us not to identify the limitations of the present study and recommendations for future research. Our data are limited because the intervention was conducted on a sample of highly educated adults who were motivated to change their behaviour. The results might not, therefore, be generalisable to the population. Our model may also omit a number of potentially valuable constructs (e.g., perceived autonomy support and psychological need satisfaction). Measures for these constructs could have given more insight into the experience of the participants with the many choice options available and the extent to which this might have stimulated or thwarted feelings of autonomy or competence. Other interventions made use of manipulation checks or included measures to gain more information on SDT-related constructs that might have been influenced by an intervention (19, 22). Despite these limitations, present results support the important relations embedded in a theoretically-integrated model of TPB and SDT. The theoretically-integrated model is useful as it provides a rationale behind the origins of the social cognitive variables of intention, attitude, and self-efficacy within the TPB. The present study showed that this, however, may depend on the type of behaviour and the level of intervention. Future research should focus on the following issues arising from the current study: increasing the number of options and the actual intervention intensity given to participants. The intervention intensity was found to be a moderator of important relations within the theoretically-integrated model for physical activity and a direct predictor of a decrease in fat intake. In terms of practical recommendations arising from this research, health promotion interventions should be aimed at increasing autonomous motivation to influence the distal and proximal determinants of behaviour. In doing so, they can follow the SDT recommendation of enhancing choice. The health care professional should explain the options available, guide the decision-making process but not leave the participant alone risking him or her to get overwhelmed by the options available.

FIGURES

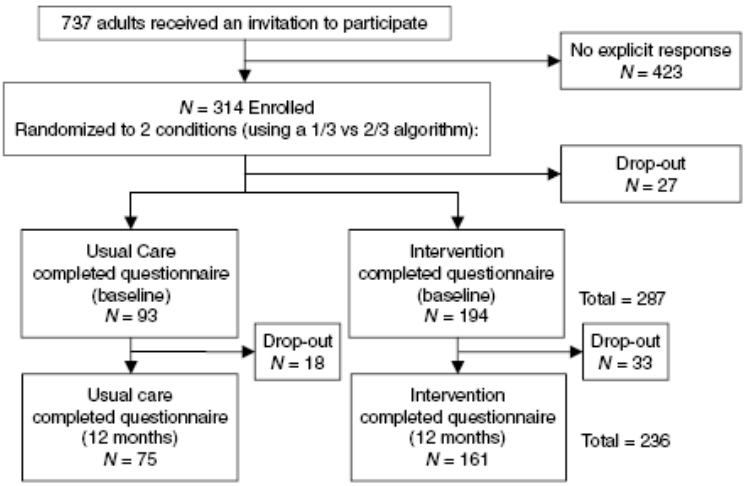

Figure 1. Participants flow diagram

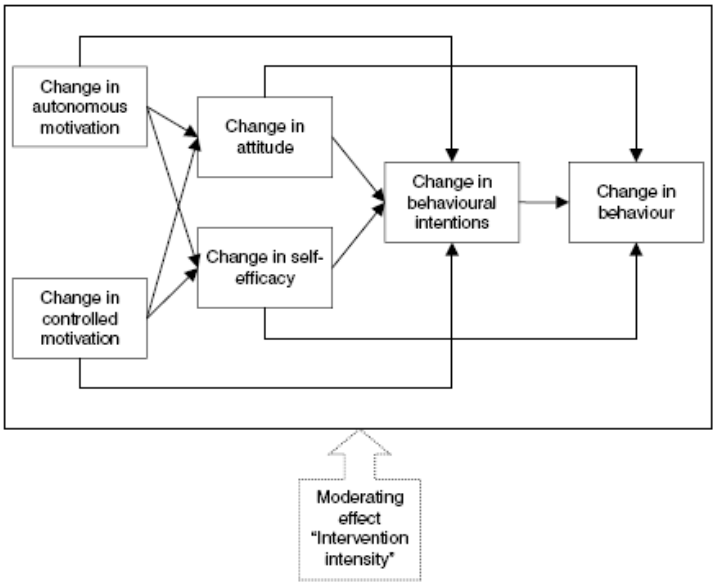

Figure 2. Theoretically-integrated health behaviour model

TABLES

Table 1

Descriptive statistics and correlations for dietary behaviour

	M t=0	SD t=0	SK t=0	KU t=0	M t=1	SD t=1	SK t=1	KU t=1	1	2	3	4	5	6	7	8	9	10
AM (item 1)	5.25	1.36	-0.61*	-0.24	4.95	1.49	-0.41*	-0.53	**1.00**	0.69*	0.06	0.11	0.35*	0.32*	0.18*	0.31*	0.35*	-0.19*
AM (item 2)	5.21	1.40	-0.53*	-0.17	4.80	1.48	-0.38*	-0.42	0.70*	**1.00**	0.16*	0.18*	0.41*	0.41*	0.34*	0.45*	0.37*	-0.16*
CM (item 1)	2.86	1.63	0.44*	-0.89*	2.56	1.58	0.86*	-0.17	0.06	0.06	**1.00**	0.58*	0.07	0.01	0.08	0.06	0.12	0.11
CM (item 2)	2.44	1.45	0.74*	-0.33	2.32	1.52	1.01*	0.47	0.12	0.10	0.56*	**1.00**	0.02	0.02	0.09	0.13	0.14	0.10
Attitude (item 1)	3.95	1.56	0.04	-0.50	3.78	1.79	0.05	-0.81*	0.29*	0.39*	-0.01	-0.04	**1.00**	0.78*	0.33*	0.46*	0.31*	-0.36*
Attitude (item 2)	4.14	1.32	0.07	0.20	4.00	1.49	0.05	-0.03	0.32*	0.40*	-0.03	0.00	0.75*	**1.00**	0.30*	0.45*	0.24*	-0.22*
SE (item 1)	4.67	1.78	-0.42*	-0.94*	4.61	1.82	-0.42*	-0.83*	0.28*	0.44*	0.06	0.11	0.29*	0.27*	**1.00**	0.68*	0.64*	-0.09
SE (item 2)	4.80	1.43	-0.43*	-0.52	4.67	1.39	-0.31*	-0.27	0.27*	0.42*	-0.08	-0.02	0.34*	0.40*	0.59*	**1.00**	0.48*	-0.15*
Intention	5.30	1.47	-0.82*	0.31	4.99	1.8	-0.50*	-0.61*	0.39*	0.52*	-0.02	0.04	0.32*	0.32*	0.56*	0.44*	**1.00**	-0.07
FI (grams/day)	107	39	0.95*	1.19*	102	42	2.04*	9.41*	-0.12	-0.15	0.21*	0.17*	-0.20*	-0.15*	-0.07	-0.09	-0.12	**1.00**

Note. *p < .05; M = mean; SD = standard deviation; SK = skewness; KU = kurtosis; AM = autonomous motivation; CM = controlled motivation; SE = self-efficacy; FI = fat intake

ıble 2

escriptive statistics and correlations for physical activity

	M t=0	SD t=0	SK t=0	KU t=0	M t=1	SD t=1	SK t=1	KU t=1	1	2	3	4	5	6	7	8	9	10
ʎ (item 1)	3.82	1.01	-0.96*	0.39	2.98	0.77	-0.26	-0.62*	**1.00**	0.80*	0.08	-0.04	0.31*	0.55*	0.41*	0.51*	0.49*	0.33*
ʎ (item 2)	3.84	0.94	-0.96*	0.64*	2.98	0.76	-0.26	-0.49	0.81*	**1.00**	0.08	0.05	0.36*	0.64*	0.37*	0.48*	0.56*	0.30*
ʎ (item 1)	1.78	0.93	1.24*	1.20*	1.58	0.70	1.18*	1.41*	0.06	0.05	**1.00**	0.58*	-0.08	-0.05	0.08	0.09	0.13*	0.03
ʎ (item 2)	1.69	0.88	1.23*	1.12*	1.46	0.62	1.35*	2.21*	-0.08	-0.07	0.56*	**1.00**	-0.17*	-0.16*	0.01	0.02	-0.01	-0.05
titude (item	6.36	0.87	-1.32*	1.13*	6.24	1.04	-1.95*	5.42*	0.40*	0.37*	0.01	-0.09	**1.00**	0.69*	0.22*	0.25*	0.24*	0.16*
titude (item	5.94	1.17	-1.05*	0.60	5.82	1.36	-1.26*	1.48*	0.66*	0.65*	0.06	-0.05	0.59*	**1.00**	0.40*	0.48*	0.40*	0.25*
ɛ (item 1)	4.52	1.72	-0.27	-1.07*	4.56	1.81	-0.36*	-0.97*	0.40*	0.40*	-0.04	-0.08	0.23*	0.40*	**1.00**	0.77*	0.57*	0.23*
ɛ (item 2)	4.69	1.78	-0.32*	-1.06*	4.47	1.84	-0.27	-1.08*	0.36*	0.37*	0.00	-0.07	0.35*	0.43*	0.76*	**1.00**	0.57*	0.25*
tention	5.29	1.42	-0.49*	-0.61	5.11	1.69	-0.53*	-0.85*	0.46*	0.44*	-0.03	-0.12	0.34*	0.43*	0.62*	0.67*	**1.00**	0.30*
ʌ inutes/week)	242	175	0.92*	0.72*	302	235	2.92*	17.06*	0.33*	0.36*	0.10	0.01	0.23*	0.32*	0.28*	0.32*	0.28*	**1.00**

Note. *p < .05; M = mean; SD = standard deviation; SK = skewness; KU = kurtosis; AM = autonomous motivation; CM = controlled motivation; SE = self-efficacy; PA = physical activity

Table 3
Psychometric properties

Behaviour	Construct	Construct level statistics t=0*	Construct level statistics t=1*	Items	Description	CI t=0*	CI t=1*
Dietary behaviour	Autonomous motivation	λ_1 = 1.70; λ_2 = 0.30 ρ = 0.92 AVE = 0.85	λ_1 = 1.69; λ_2 = 0.31 ρ = 0.91 AVE = 0.84	1 2		[0.83;0.83] [0.93;0.96]	[0.85;0.93] [0.91;0.95]
Dietary behaviour	Attitude	λ_1 = 1.75; λ_2 = 0.25 ρ = 0.93 AVE = 0.88	λ_1 = 1.78; λ_2 = 0.22 ρ = 0.91 AVE = 0.84	1 2		[0.90;0.95] [0.91;0.96]	[0.93;0.96] [0.91;0.96]
Dietary behaviour	Self-efficacy	λ_1 = 1.59; λ_2 = 0.41 ρ = 0.88 AVE = 0.79	λ_1 = 1.68; λ_2 = 0.32 ρ = 0.91 AVE = 0.84	1 2		[0.87;0.93] [0.80;0.92]	[0.90;0.94] [0.87;0.94]
Physical activity	Autonomous motivation	λ_1 = 1.81; λ_2 = 0.20 ρ = 0.95 AVE = 0.90	λ_1 = 1.80; λ_2 = 0.20 ρ = 0.95 AVE = 0.90	1 2		[0.93;0.97] [0.92;0.97]	[0.92;0.96] [0.92;0.97]
Physical activity	Attitude	λ_1 = 1.59; λ_2 = 0.42 ρ = 0.88 AVE = 0.79	λ_1 = 1.77; λ_2 = 0.23 ρ = 0.91 AVE = 0.83	1 2		[0.73;0.90] [0.91;0.95]	[0.78;0.92] [0.94;0.97]
Physical activity	Self-efficacy	λ_1 = 1.76; λ_2 = 0.24 ρ = 0.94 AVE = 0.88	λ_1 = 1.69; λ_2 = 0.32 ρ = 0.94 AVE = 0.89	1 2		[0.91;0.96] [0.92;0.96]	[0.91;0.96] [0.92;0.96]

Note. λ_i = i-th eigenvalue of the item correlation matrix; ρ = composite reliability; AVE = average variance extracted; CI= confidence interval

Table 4 (residual change scores)

Structural model parameter estimates

			Dietary behaviour		
Dependent variable	Independent variables	Mean estimate	Bootstrap t-value	Bootstrap *P*-value	CI
Attitude	Autonomous motivation	-0.20	**-2.45**	0.02	[-0.34;-0.03]
	Controlled motivation	-0.03	-0.29	0.77	[-0.19;0.19]
	Intervention intensity	0.02	0.33	0.74	[-0.12;0.15]
	Autonomous motivation * Intervention intensity	-0.10	-1.31	0.19	[-0.23;0.05]
	Controlled motivation * Intervention intensity	-0.02	-0.36	0.76	[-0.15;0.11]
Self-efficacy	Autonomous motivation	0.32	**4.91**	0.00	[0.18;0.44]
	Controlled motivation	0.04	0.52	0.60	[-0.13;0.17]
	Intervention intensity	0.14	**2.34**	0.02	[0.02;0.26]
	Autonomous motivation * Intervention intensity	-0.05	-0.82	0.41	[-0.18;0.08]
	Controlled motivation * Intervention intensity	-0.05	-0.69	0.49	[-0.20;0.10]
Behavioural intentions	Autonomous motivation	0.15	**2.25**	0.03	[0.02;0.28]
	Controlled motivation	0.04	0.75	0.45	[-0.07;0.14]
	Attitude	-0.09	-1.48	0.14	[-0.03;0.22]
	Self-efficacy	0.48	**7.82**	0.00	[0.36;0.60]
	Intervention intensity	0.07	1.02	0.31	[-0.06;0.20]
	Autonomous motivation * Intervention intensity	-0.06	-0.93	0.35	[-0.20;0.07]
	Controlled motivation * Intervention intensity	-0.01	-0.21	0.83	[-0.10;0.08]
	Attitude * Intervention intensity	-0.07	-0.96	0.34	[-0.21;0.07]
	Self-efficacy * Intervention intensity	-0.08	-1.35	0.18	[-0.20;0.04]
Behaviour	Attitude	0.12	1.96	0.05	[0.01;0.24]
	Self-Efficacy	-0.08	-1.18	0.24	[-0.22;0.05]
	Behavioural intentions	0.00	0.01	0.99	[-0.13;0.15]
	Intervention intensity	-0.14	**-2.22**	0.03	[-0.26;-0.01]
	Attitude * Intervention intensitv	0.01	0.07	0.94	[-0.15;0.16]
	Self-Efficacy * Intervention intensity	-0.02	-0.30	0.76	[-0.14;0.11]
	Behavioural intentions * Intervention intensity	-0.10	-1.28	0.20	[-0.26;0.04]

Note. Statistics in bold font are significant at $p < .05$; CI=confidence interval

Table 4 (residual change scores) (continued)

Structural model parameter estimates

			Physical activity		
Dependent variable	Independent variables	Mean estimate	Bootstrap t-value	Bootstrap *P*-value	CI
Attitude	Autonomous motivation	-0.38	**-4.47**	0.00	[-0.53;-0.21]
	Controlled motivation	0.23	**2.30**	0.02	[0.05;0.43]
	Intervention intensity	-0.06	-0.50	0.62	[-0.17;0.05]
	Autonomous motivation * Intervention intensity	0.14	2.00	0.05	[0.01;0.28]
	Controlled motivation * Intervention intensity	-0.18	2.01	0.05	[0.01;0.34]
Self-efficacy	Autonomous motivation	0.30	**5.00**	0.00	[0.17;0.41]
	Controlled motivation	0.02	0.25	0.80	[-0.12;0.16]
	Intervention intensity	0.07	1.21	0.23	[-0.05;0.19]
	Autonomous motivation * Intervention intensity	0.02	0.32	0.75	[-0.10;0.12]
	Controlled motivation * Intervention intensity	0.03	0.39	0.70	[-0.11;0.16]
Behavioural intentions	Autonomous motivation	0.17	**2.64**	0.01	[0.05;0.30]
	Controlled motivation	-0.01	-0.17	0.87	[-0.13;0.11]
	Attitude	-0.06	-0.87	0.39	[-0.21;0.06]
	Self-efficacy	0.44	**6.57**	0.00	[0.30;0.56]
	Intervention intensity	0.00	0.02	0.98	[-0.11;0.11]
	Autonomous motivation * Intervention intensity	-0.07	-1.23	0.22	[-0.18;0.04]
	Controlled motivation * Intervention intensity	-0.02	-0.30	0.76	[-0.14;0.10]
	Attitude * Intervention intensitv	0.12	1.68	0.09	[-0.01;0.27]
	Self-efficacy * Intervention intensity	0.21	**2.72**	0.01	[0.05;0.35]
Behaviour	Attitude	-0.08	-1.46	0.15	[-0.18;0.03]
	Self-Efficacy	0.01	0.05	0.96	[-0.18;0.21]
	Behavioural intentions	0.24	**3.50**	0.00	[0.09;0.37]
	Intervention intensity	0.04	0.47	0.64	[-0.13;0.19]
	Attitude * Intervention intensitv	-0.20	**-2.43**	0.02	[-0.35;-0.03]
	Self-Efficacy * Intervention intensity	-0.14	-1.40	0.16	[-0.32;0.08]
	Behavioural intentions * Intervention intensity	0.07	0.71	0.48	[-0.13;0.24]

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Chapter 8

Chapter 8

Evaluation of a two-year tailored behaviour change programme for cardiovascular disease prevention: a randomised controlled trial

Based on:
Jacobs N, De Bourdeaudhuij I, Dendale P, Thijs H, Claes N. Evaluation of a two-year tailored behaviour change program for cardiovascular disease prevention: a randomized controlled trial (submitted)

ABSTRACT
Objective: Evaluate the effect of a two-year tailored behaviour change programme for cardiovascular disease (CVD) prevention.
Methods: Three hundred fourteen highly educated participants were randomised to a control condition (risk assessment & communication) or an intervention condition (risk assessment & communication + a tailored behaviour change program). The behaviour change programme consisted of two stages: (1) tailored website and individual coaching with a self-selected intervention dose/delivery mode; and (2) tailored website and 10 tailored messages delivered by e-mail and regular mail. The aim was to reduce the saturated fat intake, increase physical activity and promote smoking cessation. The main outcome measures were saturated fat intake (grams/day), moderate and vigorous physical activity (minutes/week) and smoking behaviour. Pre- and post-assessments were performed using online questionnaires and repeated measures analyses of variance (ANOVAs) were used for the effect evaluation.
Results: No significant difference was found between the two conditions for the main outcome measures ($P > .05$). Physical activity of vigorous intensity increased in both conditions ($P < .01$).
Conclusion: The two-year tailored behaviour change programme was not effective in improving behaviour. Practice implications: Risk assessment and communication may be sufficient to increase physical activity of vigorous intensity in highly educated adults.

1. INTRODUCTION

Cardiovascular disease (CVD) is an important cause of death and disability in Europe and leads to a significant personal and societal burden (1). The guidelines for CVD prevention recommend a systematic risk assessment and management. Presently, however, these guidelines are not strictly followed by practitioners in spite of the availability of valuable tools and risk charts to determine the total CVD risk (2, 3). The SCORE algorithm is an example of a risk chart that can be used to assess the 10-year risk of dying from a cardiovascular event (4). Next to the assessment of this risk, the communication of this risk between the general practitioner and the individual patient is equally important (5). In this respect, innovative electronic tools can aid the general practitioner by automatically calculating the risk and generating advice for risk factor communication and management (6).
Risk factor management could help people with an increased CVD risk to reduce it and people with a low risk to maintain it (3). The risk factors for CVD include medical risk factors and risk behaviours (unhealthy diet, insufficient levels of physical activity, smoking) (7). These behaviours can simultaneously be improved by tailored health promotion messages (8-10). Tailoring can be defined as any combination of information or change

strategies intended to reach one specific person, based on specific characteristics of that person that have been measured in a formal assessment (11). The literature is inconclusive about the most beneficial delivery mode for tailored messages (12-14). Since each mode has its advantages, the use of multiple modes can improve intervention efficacy (15-17).
The present study aimed to evaluate the effect of a two-year tailored behaviour change programme with multiple delivery modes to reduce saturated fat intake, increase physical activity and promote smoking cessation compared to risk assessment and communication.

2. METHODS

2.1. Recruitment and design

Participant enrolment took place from February 2007 to April 2007 and eligible participants were 25 to 75 years old with Internet access (18). Three hundred and fourteen highly educated adults singed an informed consent form and were randomised to a control and an intervention condition using a non-stratified randomisation technique with a 1/3 versus 2/3 ratio in order to keep enough power to study dose-response effects (Figure 1) (18). The power calculation showed that the study would have 80-86% power to detect clinically significant changes in fat intake and physical activity with a total sample size of 300 (18). The present intervention has been evaluated after 6 and 12 months (19).

2.2. Intervention

Participants of both study conditions received a baseline CVD risk assessment by a general practitioner using the SCORE algorithm (4). Patients younger than 30 years were categorised as having a low risk unless they had an exuberant risk factor, diabetes or suffered from a personal ischemic event. Next, participants received a printed profile summarising their total risk and individual risk factors by regular mail.
The behaviour change programme ran from April 2007 to April 2009 and consisted of two stages. During the first stage, from April 2007 to April 2008, the participants received access to a tailored website and individual coaching. The dose and the delivery mode (e-mail, regular mail, telephone, face-to-face) of the individual coaching were self-selected. Participants' preferences were explored and registered by a health psychologist by telephone and the individual coaching was adapted to these preferences. The website content and the individual coaching were based on the Theory of Planned Behaviour and the Self-Determination Theory (20-22). The coaching was given by a health psychologist who used behaviour change techniques (e.g., set graded tasks) and an autonomy-supportive inter-personal style (e.g., avoiding a controlling language). The effect evaluations after 6 and 12 months showed significant dose-response effects and showed that some participants selected an insufficient intervention dose, undermining the

intervention effectiveness (19). Therefore, in the second stage, from April 2008 to April 2009, the tailored website was supplemented with individual coaching delivered by e-mail and regular mail by default and the dose was fixed to 10 messages of which participants received one every three weeks. These messages were tailored to the total CVD risk, behaviour and determinants of behaviour.

2.3. Measurements and statistical analysis

Measurements were performed using online questionnaires (pre-assessment April 2007; post-assessment April 2009). Saturated fat intake was assessed with a validated online food frequency questionnaire (23). Physical activity (moderate + vigorous, moderate, vigorous) was assessed using a validated online version of the International Physical Activity Questionnaire (IPAQ) (long version, usual week) (24). Smoking behaviour was assessed using a short questionnaire (25).

To explore equality between the study conditions at baseline and for the drop-out analysis, chi-square tests and one-way analyses of variance (ANOVAs) were used. To evaluate the effect of the tailored behaviour change programme repeated measures ANOVAs with time (within) and study conditions (between) as factors were used. The analyses were performed with SPSS 16.0 and $\alpha = .05$.

3. RESULTS

3.1. Participants

A total of 196 participants (68% response rate) completed post-assessment in April 2009, 61 in the control condition and 135 in the intervention condition. No significant baseline differences were found between the study conditions but differences were present in smoking and total CVD risk (Table 1). The drop-out analysis showed that people that were less physically active at baseline were more likely to have dropped out at post-assessment ($P < .05$).

3.2. Effects on behaviour

There were no differences between the participants in the intervention and the control condition for saturated fat intake ($P > .05$) (Table 2). Furthermore, there were no differences between these conditions for moderate physical activity, vigorous physical activity or the sum of both ($P > .05$) (Table 2). Nevertheless, physical activity of vigorous intensity increased in both study conditions ($P < .01$). An equal number of smokers, namely 5, quitted smoking in both study conditions ($P > .05$).

4. DISCUSSION AND CONCLUSION

4.1. Discussion

In the present study, no difference between both study conditions was found after two years of intervention. However, self-reported physical activity of vigorous intensity increased in both groups. These findings are inconsistent

with the conclusion of a recent review that tailoring can be effective to promote health behaviour change (13). However, not all tailored interventions were effective (13). For instance, computer-tailored physical activity interventions that were effective in a laboratory setting were found to be ineffective when implemented in a real-life setting (26, 27). A one-year tailored programme aimed at improving physical activity and dietary behaviours in male retirees was not effective compared to a control group (28). The findings from the present study corroborate these results. However, our study was different because of the use of multiple delivery modes and its strong focus on total CVD risk assessment, communication and management. Furthermore, the intervention from the present study was embedded in the primary care context as advised by the literature (6, 27). The fact that both study conditions included CVD risk assessment and communication may explain the lack of difference between the control and intervention condition. In other randomised trials, a nurse practitioner performed a face-to-face risk assessment and this nullified the intervention effect (29, 30). The conclusion may be that face-to-face risk assessment and communication can lead to similar results than a more intensive intervention, at least for vigorous physical activity. This is an important result since the latter type of physical activity can increase physical fitness, a protecting factor for CVD (31). This conclusion has important implications for the ongoing debate about the cost-effectiveness of health promotion interventions. For the moment, however, only a limited number of cost and cost-effectiveness studies alongside randomised trials were performed (32-34).

Other explanations for the lack of difference between both conditions can be given. Firstly, the sample size might have been too small. Next, the specific sample of highly educated adults who are in general more motivated for behaviour change might have reduced the added value of the programme. Furthermore, the participants could have been disappointed that the stage 2 approach did no longer include coaching by telephone or face-to-face, resulting in a decreased motivation. The lack of effect might be due to ineffective tailored materials. However, some of the materials were effective in prior trials (35). Lastly, the effect size of tailored interventions decreases on the long-term and this was a two-year intervention (13).

The present study was a two-year randomised trial with a focus on both medical and behavioural risk factors for CVD following the guidelines on CVD prevention (3). Weaknesses of the study were the relatively small sample, the use of self-reported. The findings can only be generalised to a highly educated adult population.

4.2. Conclusion

In the present study, CVD risk assessment and communication alone was as effective as a tailored behaviour change programme to increase physical activity of vigorous intensity.

4.3. Practice implications

Practitioners can focus on risk assessment and communication to promote physical activity of vigorous intensity in highly educated adults. The additional value and cost-effectiveness of more intensive approaches should be confirmed before implementation.

FIGURES

Figure 1: study flow

TABLES

Table 1: baseline population characteristics (mean±SD) of the control condition and the intervention condition

	Total sample (n=287)	**Control (n=93)**	**Intervention (n=194)**
Gender (%male)	66.60	67.70	66.00
Age (y) (SD)	40.49 (10.55)	39.60 (10.50)	40.91 (10.57)
Cardiovascular risk			
Unknown (%)	30 (11%)	7 (7%)	23 (12%)
Low (%)	202 (70%)	66 (71%)	136 (70%)
Average (%)	31 (11%)	8 (9%)	23 (12%)
High (%)	24 (8%)	12 (13%)	12 (6%)
Smokers (%)	46 (16%)	10 (11%)	36 (19%)
Saturated fat intake (grams /day) (SD)	40.95 (16.67)	40.06 (14.74)	41.37 (17.53)
Physical activity			
Moderate + vigorous (SD)	283.50 (201.03)	277.95 (174.70)	286.15 (212.87)
Moderate physical activity (SD)	219.61 (170.07)	214.52 (148.49)	222.05 (179.81)
Vigorous physical activity (SD)	63.89 (77.61)	63.43 (77.07)	64.10 (78.07)
Body Mass Index (SD)	25.12 (4.14)	24.79 (3.37)	25.28 (4.47)

SD indicates standard deviation

Table 2: Mean saturated fat intake, physical activity and number of quitters for the control condition and the intervention condition

	Control condition (*n*=61)	**Intervention condition (*n*=135)**	***F* time**	***P*-value**	***F* Time X Study Condition**	***P*-value**
Saturated fat intake (grams/day)						
Mean ± SD (pre)	42.51 ± 15.30	40.48 ± 14.58	0.94	.33	0.06	.81
Mean ± SD (post)	44.20 ± 17.52	41.50 ± 22.58				
Change ± SD	+1.68 ± 13.73	+1.02 ± 19.73				
Physical activity (minutes/week)						
Moderate + vigorous						
Mean ± SD (pre)	294.07 ± 178.28	307.36 ± 208.61	0.75	.39	0.00	.97
Mean ± SD (post)	315.34 ± 291.36	327.04 ± 331.08				
Change ± SD	+21.27 ± 305.38	+19.68 ± 305.96				
Moderate						
Mean ± SD (pre)	220.72 ± 148.98	238.07 ± 175.87	0.74	.39	0.32	.57
Mean ± SD (post)	214.93 ± 237.38	210.30 ± 259.23				
Change ± SD	-5.79 ± 231.91	-27.77 ± 262.19				
Vigorous						
Mean ± SD (pre)	73.35 ± 83.71	69.30 ± 83.00	8.39**	. 00	0.63	.43
Mean ± SD (post)	100.41 ± 134.71	116.75 ± 170.59				
Change ± SD	+27.06 ± 152.38	+47.45 ± 172.81				
Quitters (#)	5	5				

SD indicates standard deviation

* *P* <.05; ** *P* <.01; *** *P* <.001

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Chapter 9

Chapter 9

The Implementation Costs of an Electronic Prevention Programme in Belgian General Practice

Based on:
Claes N, Jacobs N, Van Mierlo J. The Implementation Costs of an Electronic Prevention Program in General Practice. The European Journal of General Practice 2010; 16(1): 12-7

ABSTRACT
Introduction: Guidelines to prevent cardiovascular (CV) disease are widely available. To implement these guidelines an electronic prevention programme (EPP) with a risk calculator for general practitioners (GPs) was developed. The aim of the present study was to calculate the implementation cost per installation. Methods: This cost study is part of a larger clinical trial, studying the effects of interventions in GP-practice on the management of CV risk factors. Participating GPs were asked to install the EPP. They could take part in a group education session or receive education by e-mail, telephone or at home. After a prospective cost registration, the cost per installation and a sensitivity analysis were calculated. Results: 185 GPs participated in the study. The total implementation cost of the EPP was €83,939. As the EPP was successfully installed by 102 GPs, the mean cost equals €823 per GP. Sensitivity analyses showed a decrease in costs due to a decrease of the costs of group education and/or an increase of installations.
Conclusion: This study showed that it is possible to implement an EPP for cardiovascular prevention with an acceptable cost.

INTRODUCTION
Cardiovascular (CV) diseases are the leading cause of death and the third cause of disability in Europe (1). Guidelines to prevent CV diseases are available (2). To implement these guidelines in general practice, an implementation plan has to be worked out taking into account the bottle-necks in actual care (3). After studying the needs of the Belgian general practitioners (GPs), we developed an electronic prevention programme (EPP) with a risk calculator based on the European guidelines for CV prevention (4). The EPP calculates the risk and generates standardised therapeutic goals depending on the risk profile and stage of behaviour change. The development of the EPP is one intervention mode to support GPs and will be evaluated in a three-year clinical trial. In the latter trial the effects of multidisciplinary interventions in GP-practice on the management of CV risk factors will be studied. The GPs participating in this trial could install the EPP. After installation, the EPP is automatically linked to the existing electronic medical files (EMF) of the GP's. The need for information and communication technology (ICT) in health care grows and the Belgian government stimulates GPs since 2000 to use an EMF. Although 76% of the Belgian GPs use an EMF, little is known about the implementation costs of ICT tools in general practice. An economical evaluation of the implementation of ICT tools in companies shows an underestimation of these costs (5). The aim of this study was to determine the cost for installation.

METHODS

Study design

This cost study is part of a registered clinical trial approved by the Hasselt University Ethics Committee (ISRCTN23940498) (4) in which 314 patients are randomised in an intervention and a control group. Both groups receive several prevention consultations by their GP using an EPP. Only the patients of the intervention group receive a follow-up with intensive support of health behaviour change via different delivery modes (i.e. a tailored website and personal advice of a multidisciplinary team) (6). The primary outcome measures will be cardiovascular risk factors. The GPs situated in the region of the included study patients were invited to participate in the study (n = 792). They received a written invitation by the GPs' president and a telephone and e-mail from a study collaborator to participate in the randomised clinical trial. An informed consent was signed by 185 GPs (23%). Figure 1 shows a screen print of the EPP. Medical risk factors and stage of behaviour change (healthy food, physical activity, not smoking) have to be filled in per patient via the input screen. The EPP calculates the cardiovascular risk and generates medical and behavioural advice with therapeutic goals (output screen) (2). The cardiovascular risk calculation is based on the patient's cardiovascular history, glycaemia, systolic blood pressure, total cholesterol, age, gender and smoking habit using the SCORE algorithm. If a person has diabetes or has suffered from a personal ischemic event or has a SCORE risk ≥ 5 he is classified as a patient with a high risk to die within 10 years from a cardiovascular event. A patient is also considered to have a high risk if he has one exuberant medical risk factor: cholesterol level ≥ 320 mg/dl; blood pressure $\geq 180/110$ mm/Hg; LDL cholesterol ≥ 240 mg/dl. A SCORE risk 2–4 is classified as medium risk and < 2 as low risk. Based on the input, the EPP generates an individual advice with therapeutic goals. This advice can be printed for the patient to take home. The risk calculator also includes a function to send each consultation and the patient's calculated risk to other physicians using secured data transport (Figure 2). SIX (Secure Information eXchange) is a web service based platform that ensures authentication, confidentiality and message integrity through PKI (Public Key Infrastructure). To implement the EPP, the participating GPs were invited to a group education session that consisted of a theoretical course on cardiovascular prevention and a computer training session. Afterwards, they received an e-mail with a hyperlink to download the EPP. If a GP successfully installed the EPP, the study collaborator automatically received a confirmation message. If this message was not received, the study collaborator contacted the GP and offered assistance by telephone or by e-mail. If this intervention was not successful, the study collaborator suggested technical assistance at home by an assistant. GPs were free to accept this extra service.

Definition of costs

A societal perspective was chosen. All costs to implement the EPP were progressively registered from the 1 January to 31 December 2007. Following costs are included: programme costs (e.g. personnel, overhead, transport, education material) and costs to participants (e.g. time, transport). Overhead costs are costs for resources that are shared by different departments (e.g. power, heating). Since university rooms are for rent to others, this price, for a total of €800 is assumed to cover for the overhead cost. For each cost type a distinction in fixed and variable costs is made. Fixed costs of a programme are those that do not vary with the level of activity (number of GPs included) (7). Variable costs are those that change as the level of activity changes (level of education, number of GPs included). The variable costs will be determined by multiplying the quantity with the unit cost (Table I). The quantities to determine the personnel costs were electronically registered. Each employee involved in the study could log on to a website to register an activity towards a GP. The duration of the activities in minutes was used as a quantity for the calculation of the costs for personnel input. These quantities were multiplied with the unit costs (i.e. wages per hour) (Table I). The unit cost for GPs was calculated based on the proportion of patient visits performed at home (30%) and at the office (70%), their duration as reported in literature and the present tariffs for GPs (€31.2 for home visit and €18.1 for consult in GP-practice) (8).

The mean costs for different education methods are determined as follows: the total costs for individual education per e-mail are divided by the number of e-mails sent, the total costs for individual education per telephone are divided by the number of telephone calls, the total costs for individual education at home are divided by the number of home visits and the total costs for the group education sessions are divided by the number of those present. The total cost of the implementation is calculated by summing all the costs incurred. The mean cost for an installation is calculated by division of the total cost by the total number of installations.

Statistics

Microsoft Excel and SPSS version 14.0 for Windows were used. To find possible differences between participants and non-participants we performed chi square tests. To examine the influence of uncertainties in the variables, a one-way sensitivity analysis was performed varying different variables along a plausible range of values while holding all other variables constant. Owing to the prospective registration of costs, the margins for error are chosen arbitrary to fall within a range of 10%. The influences of uncertainties are examined for individual education per telephone, per e-mail, at home and for group sessions as follows costs base case –10% and 110%. The range of installations goes from half of the installations (n = 50) to a doubled number of installations (n = 200). The costs that vary with the number of participating GPs are the variable programme costs and the variable costs to

participants. Both costs are divided by two (half of the base case installations), multiplied by two (doubled base case) or multiplied by 10 (1.000 successful installations). The fixed programme costs do not vary with the number of participating GPs.

RESULTS

Study population

A total of 185 GPs enrolled in the study (148 males and 37 females). On average the GPs graduated 25 years ago (SD 610 years). Of this group, 99 were solo practitioners and 86 were working in a group practice. Participants and non-participants were similar with respect to graduation year (P = 0.567), solo/group practice (P = 0.119), but not with respect to gender (P = 0.001). The proportion female in the non-responders was larger than the proportion female in the study population.

Cost per installation

Individual education per e-mail included different cost types: personnel costs and participants' time to read an e-mail. One hundred and five e-mails were sent. Consequently, the mean cost for this education method was €10. Individual education per telephone included different cost types: personnel costs, participants' time, and telephone costs. Forty-nine telephone calls were made. The mean cost per for this education method was €13. Individual education at home included the following cost types: personnel costs, transportation costs, and participants' time. Fourteen education sessions were given at home. The mean cost for this education method was €53. Group education consisted of the following cost types: personnel costs for preparation of the group education, personnel costs (lectures, etc.), education material, participants' time, participants' transportation costs and catering. 96 GPs attended these sessions. The mean cost for this education method was €247. The total costs for the implementation of the EPP were €83,939 (Figure 3). The EPP was successfully installed by 102 GPs. The calculated cost per installation equalled €823. The cost types that contributed most to total costs were the personnel costs. Personnel costs contributed 93% to programme costs. The costs to participants mainly consisted of the time of the GPs taking part in the group education session (82%).

Sensitivity analysis

Table II shows the results of the one-way sensitivity analysis. A 10% decrease in the costs for the group education changed the cost for installation from €823 (base case) to €800. A doubled number of installations would change the cost for installation from €823 to €610. A tenfold number of installations would change the cost for installation from €823 to €426. If the number of installations would decrease from 102 to 50, the cost for installation would increase from €823 to €1,299.

DISCUSSION

An electronic prevention programme (EPP) with risk calculator and linked to the electronic medical files (EMF) was installed on the GPs' computer (2,4). In this study we calculated the different costs for installation. Hundred and two of the 185 GPs in the study successfully installed the EPP. The mean cost per installation was €823. A decrease of the costs of the group education or an increase in the number of installations can lead to the lowest possible cost per installation.

The prospective electronic registration of all costs is an advantage of this study. Another strength of the study is the fact that we based our EPP on issues found by Terry et al. These authors concluded after different focus groups that four issues have to be studied before implementing an EPP in GP-practice (9). First, 'GPs' expectations of the EPP and their needs to use software' have to be studied. In our study the expectations and needs were discussed with several GPs before programming the EPP. A second issue, 'the level of commitment of all parties to the implementation and adoption of electronic tools' was foreseen by different levels of support by the study team. The third issue, 'the leadership of the construction and of the implementation of the EPP', was performed by the study coordinator. Finally, the fourth issue, 'the knowledge of computers potential of the EPP users' was anticipated by an education session with practical workshop for the installation and the use of the EPP.

This study, however, has several limitations. First, the individual education at home was only given on GPs' demand. A more proactive offer to install the EPP at home could have been more successful. Furthermore, this self-selecting mechanism resulted probably in the fact that only highly motivated GPs demanded individual education at home. A second limitation is the absence of data on the use of the programme in daily practice of the GP. A third limitation is the absence of a systematic registration of the reason why 83 out of 185 GPs did not successfully install the ICT-tool. Systematic registration of obstructions could give information on the implementation or the ICT-tool itself and has to be considered in a following study. A fourth limitation is the fact that these GPs participated in a larger clinical trial, studying the effect of multidisciplinary interventions on the follow-up of CV risk factors within their patients. This could give an inclusion bias, for example, GPs were motivated to accept new tools to support their prevention management in daily practice.

The total cost of the implementation of the EPP was €83,939 with a mean cost per installation of €823. Our cost for group education, i.e. €247, was low in comparison with literature, where amounts ranging from €505–€702 were reported (8,10). The difference in costs in these studies could be explained by the higher number of education sessions. Group education is more expensive than individual education at home, mean cost of €53. This difference could be explained by the limited time during education at home

(10–15 min) instead of (2 h 30 min) during the group education. The group education session, however, gives the opportunity to convince GPs of the importance of using an EPP.

It has been reported that the most cost-effective implementation method for alcohol screening in general practice was practice-based training and a support telephone call every two weeks (in comparison to practice-based training only) (11). In our study on cardiovascular prevention we did not find any benefit of assistance by telephone. In comparison to the cited study, we have not called systematically every two weeks. A more intensive support could have been beneficial.

The sensitivity analysis demonstrated that a doubled number of installations would decrease the cost per installation to €610. If the programme could be implemented in 1000 GP practices the cost per installation would drop to €426. This decrease of costs is due to a decrease of fixed costs like the development of the EPD.

The costs for GPs' transport and contact time amounts to €20,171 for 185 GPs. However, the GPs in our study were not paid. When implementing the EPD on a larger scale the question will arise 'who will pay these costs?' One possibility is that the public health care organization pays. The literature reported a return on investment of $86,400 (€55,616) on five years per GP from using an electronic medical file to the health care organization due to an improved utilization of test (12). Health information technology increases the efficiency of health care (13). Another possibility is that GPs invest. Their return on investment is estimated at $14,055 (€9,047) annually, mainly due to a reduction in chart pulls (63%) (14).

FIGURES

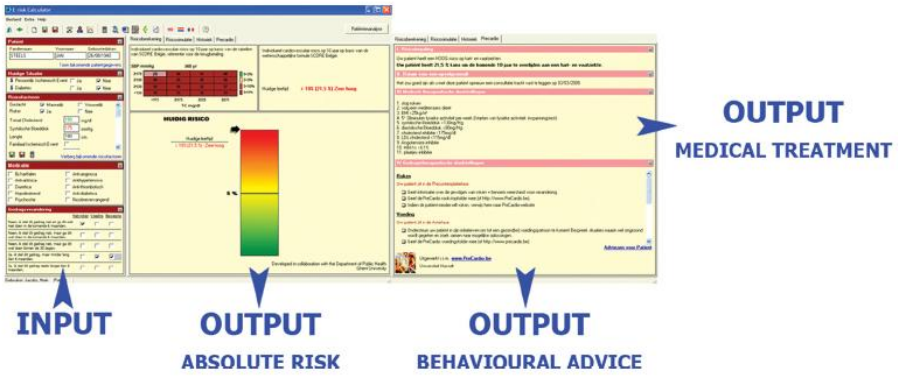

Figure 1: Electronic Prevention Program (EPP) with risk calculator

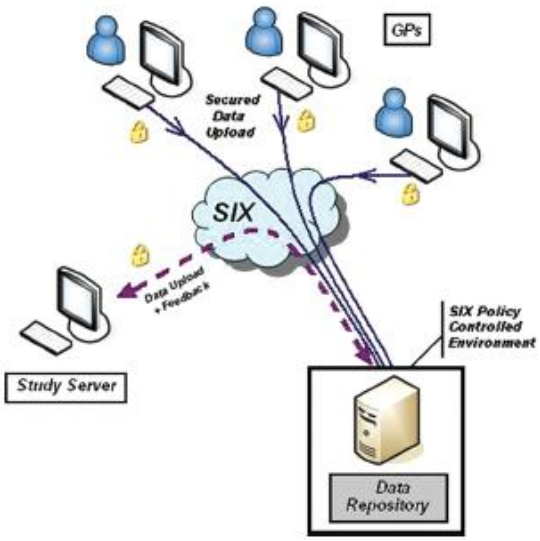

Figure 2: data transport

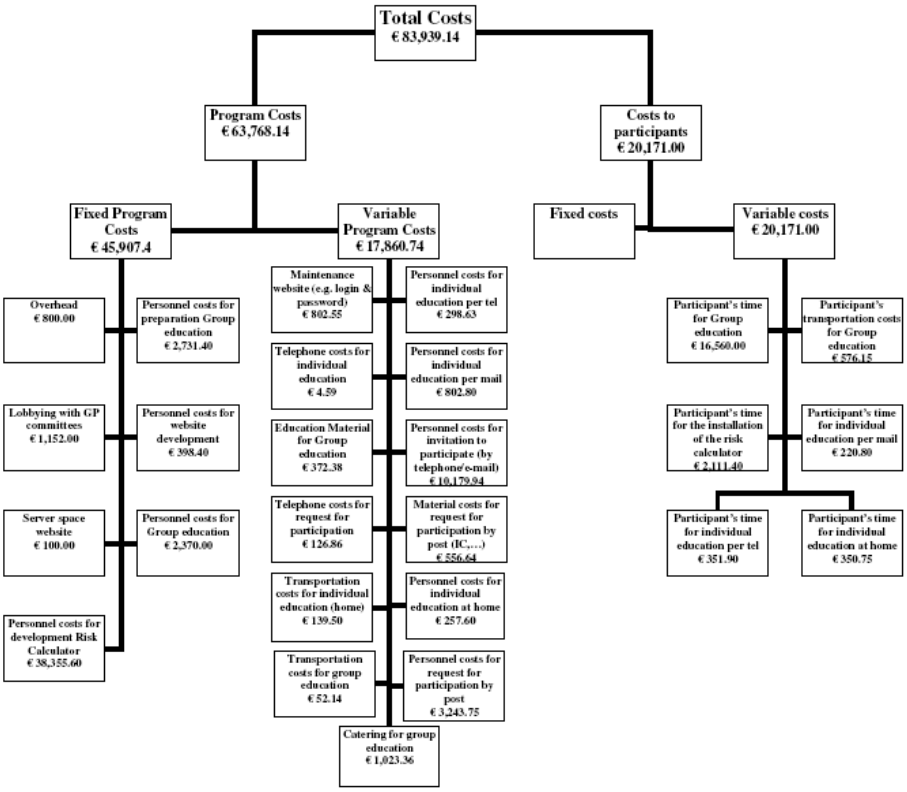

Figure 3: Different cost types

TABLES

Table I. Unit costs for material and personnel input.

Material input	
Resource	Value (€/unit)
Transport	0.15 [16]
Printed colour page	0.92
Printed Page, black and white	0.03
Collate	1
Coloured paper	0.02
Stamped envelope	1
Personnel input	
Resource	Value (€/h)
Psychologist	50
Consultant	150 [8]
Programmer	50
Administrative employee	27
External assistant technical support	40
General practitioner	74 [8]

Table II: One way sensitivity analysis.

Variables	Base case cost	Cost for installation underestimation of costs overestimation of installations	Cost for installation overestimation of costs underestimation of installations
Costs for telephone education	655	824	821
Costs for mail education	1023	823	822
Costs for education at home	747	823	822
Costs for group education	23,685	846	800
Number of installations	102	1,299	610

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Chapter 10

Chapter 10

Cost-Utility of a Cardiovascular Prevention Programme in Highly Educated Adults: Intermediate Results of a Randomised Controlled Trial

Based on:
Jacobs N, Evers S, Ament N, Claes N. Cost-Utility of a Cardiovascular Prevention Programme in Highly Educated Adults: Intermediate Results of a Randomised Controlled Trial. Int J Technology Assessment in Health Care 2010; 26(1): 11-19

ABSTRACT
Objectives. Little is known about the costs and the effects of cardiovascular prevention programmes targeted at medical and behavioural risk factors. The aim was to evaluate the cost-utility of a cardiovascular prevention programme in a general sample of highly educated adults after one year of intervention.
Methods: The participants were randomly assigned to intervention (n=208) and usual care conditions (n=106). The intervention consisted of medical interventions and optional behaviour change interventions (e.g. a tailored website). Cost data were registered from a health care perspective and questionnaires were used to determine effectiveness (e.g. quality adjusted life years (QALYs)). A cost-utility analysis and sensitivity analyses using bootstrapping were performed.
Results: When adjusting for baseline utility differences, the incremental cost was €433 and the incremental effectiveness was 0.016 QALYs. The incremental cost-effectiveness ratio (ICER) was €26,910 per QALY.
Conclusions. The intervention was cost-effective compared to usual care in this sample of highly educated adults after one year of intervention. Increased participation would make this intervention highly cost-effective.

INTRODUCTION
Unhealthy behaviour is an important independent risk factor for several diseases such as cardiovascular disease. Next to the personal burden of cardiovascular disease, the associated costs are a burden on society as cardiovascular disease consumes 12% of total healthcare expenditure in the European Union (15). Guidelines on the prevention of cardiovascular disease include advices targeted at medical and behavioural risk factors (8). Consequently, cardiovascular prevention programmes should be targeted at these risk factors.
In the current health economic climate it is important to report both on the effectiveness and on the cost-effectiveness of such programs. A recent review was positive about the cost-effectiveness of behaviour change interventions targeted at high risk groups (9). The behaviour change programmes that were analysed were intensive and did not make use of cheaper alternatives such as computer-tailoring interventions (9, 14). Nevertheless, computer-tailoring interventions have a number of merits: they are cheaper than face-to-face interventions; they were found to be effective and participants can consult the intervention whenever they feel like. One can expect this intervention type to be cost-effective but this has not been investigated yet. Cost-utility analyses using Markov modelling have been performed previously with positive results (3, 10). However, modelling techniques have several disadvantages. Firstly, they do not make use of real time observations. Secondly, the connection between costs and effects is often unclear. Several cardiovascular prevention programmes can be found

in literature but do not report on a trial based cost-utility analysis yet (6, 18, 21). The reasons for this lacuna are, amongst other things, the need for a randomised trial, the need for a detailed monitoring of the personnel and material input and the need to be in line with the guidelines for economic evaluation.
The aim of the current study is to assess the cost-utility of an intervention versus usual care using data from a randomised controlled trial (PreCardio) (6). The main research question was whether a tailored intervention targeting medical and behavioural cardiovascular risk factors was cost-effective compared to a usual care intervention only targeting medical risk factors. The trial complies with the Declaration of Helsinki, was approved by the Hasselt University Ethics Committee and was registered (ISRCTN23940498).

METHODS

Study design

Seven hundred and thirty-seven potential participants, insured by De Onderlinge Ziekenkas (a company that offers income protection insurance in case of illness or an accident) received an invitation to take part in the study. Figure 1 shows the flow-chart of the participants throughout the trial. They were highly educated (Master degree in Law – 5 years of education) and lived in Belgium. Eligible participants were between 25 and 75 years with internet access and a signed informed consent. Three hundred and fourteen participants (43%) enrolled in the programme and signed an informed consent. The participants were randomised to usual care and intervention conditions using a 1/2 ratio to keep enough power to study the dose-response effects of the intervention. The nonstratified randomisation was performed by an independent person. The names of the participants were written on papers that were put in sealed envelopes. Next, the envelopes were randomly assigned by hand to two baskets. The participants were blinded to group assignment. The intervention started in April 2007 and will end in April 2010. This study includes intermediate results after one year of intervention.

Sample size

The power calculation was performed with Nquery Advisor 4.0® and it was based on the literature on sample size calculations for health related quality of life data (24). A two group t-test with a .05 two-sided significance level will have 92% power to detect an effect size of 0.420 and a difference in means of 0.05, assuming that the common standard deviation is 0.12, when the sample sizes in the two conditions are 200 and 100, respectively (a total sample size of 300) (24).

Study conditions

Participants in the **usual care** condition were invited to Hasselt University for a medical intervention. This condition was comparable to a preventive

consultation in general practice following the guidelines. The risk of dying from cardiovascular disease within 10 years using the SCORE algorithm was determined (8). The participants in the usual care condition received a general risk profile after the medical intervention. Depending on their cardiovascular risk, the participants were referred to their general practitioner for follow-up treatment (e.g. medication for hypertension).
The **intervention** condition additionally provided a tailored risk profile based on the medical intervention, access to a tailored website, individual coaching and group sessions. The conceptual framework underpinning the tailored website, the individual coaching and the group sessions was based on the Theory of Planned Behaviour and the Self-Determination Theory (2, 13, 20). The tailored website included several behaviour change techniques for nutrition, physical activity and smoking cessation (e.g. self-monitoring), self-tests and tailored advice. The individual coaching was conducted by an experienced psychologist assisted by undergraduate students Sports and Nutrition. The individual coaching was based on a needs assessment that was performed by the psychologist at baseline. The participants could determine the target behaviour(s) they wanted to change, the dose of the coaching (frequency and duration) and the delivery mode (e-mail, face-to-face and/or telephone).

Costs

A prospective cost registration was carried out alongside this trial. The cost analysis was performed using data from all the participants that enrolled in the study (n=314). The **cost data** included personnel, material costs and transportation costs. To determine personnel costs, each activity provided to a participant was electronically registered. The duration of the activities in minutes was used as a quantity for the calculation of the costs for personnel input. These quantities were multiplied with the unit costs (i.e. wages per hour) (Supplementary Table 1). For the personnel costs for health professionals that delivered medical interventions after referral, the duration of a consultation was based on the literature (7).
The intervention costs included fixed and variable program costs. The fixed program costs included developmental costs, a fixed cost and overhead costs. The developmental costs consisted of website development personnel costs, personnel costs for preparation of medical content and content for dietary behaviour, physical activity and smoking behaviour interventions. The fixed cost was the cost for website server space. The overhead costs (e.g. rent, heat, electricity) equalled 17% and were calculated using a standard formula [(cost*0.17)/(1-0.17)]. The variable program costs are presented in Figure 2.
The usual care costs only included variable program costs. The variable program costs included personnel, material, transportation and overhead costs. The personnel costs included costs for medical interventions at Hasselt University and costs for medical interventions by a GP or cardiologist after

referral. The material costs included material costs for medical interventions and telephone costs.
The costs for participants for drug treatment were not included in the analysis because these were considered to be comparable in both conditions. The unit costs are expressed in Euros at 2008 prices and the costs were not discounted.

Cost-utility analysis and cost-effectiveness analyses

The cost-utility analysis and the cost-effectiveness analyses were performed using data of the participants that filled out the questionnaires at baseline, 6 and 12 months (n=219). These questionnaires were used to gather the **effect data**. A health care perspective was chosen and on-treatment analysis was performed. Baseline differences for demographic, cost and effect data between the study conditions were examined with student T-Tests and Chi squared tests. The same methods were used for a drop-out analysis for which only the non-completers who filled out the questionnaire at baseline were selected (n=68). Between group changes since baseline were analysed using repeated measures ANOVAs. Because of the electronic questionnaires and prospective cost registration, there were no missing data. If standard errors of skewness were less than -2 or higher than 2, the data were not considered to be normally distributed.
For a **cost-utility analysis (CUA)**, the effect data are quality adjusted life years (QALYs). The Short Form 36 (SF-36)© was used to measure health related quality of life (Chronbach's alpha 0.81-0.91) (1). SF-36 data were converted into health state utility values for the calculation of QALYs (5). The QALYs for the intervention and usual care conditions were calculated using the area under the curve method:

QALY=(0.5*(baseline utility value +6 months utility value)*6+0.5*(6 months utility value + one year utility value)*6)/12

These QALYs per participant were adjusted for baseline utility differences using the DELTA QALY method:(16)

DELTA QALY=QALY + (Mean baseline utility (total sample)-Mean baseline utility of Usual Care/Intervention)

The DELTA QALY per participant is calculated by adding the difference between the mean baseline utility of the total sample and the mean baseline utility for the study group to the QALY. For the CUA, the incremental cost effectiveness ratios (ICER) for the intervention were calculated by dividing the incremental cost by the incremental (DELTA) QALY.

$$\text{ICER} = \frac{\text{Cost intervention} - \text{Cost usual care}}{\text{(DELTA) QALY intervention} - \text{(DELTA) QALY usual care}}$$

For a **cost-effectiveness analysis (CEA)**, the effect data depend on the intervention. In the present study, behavioural effects were measured using computerized versions of the International Physical Activity Questionnaire

(IPAQ) and a validated fat intake questionnaire.(23, 22) The outcome measure for **physical activity** was the change in weekly physical activity of vigorous intensity in minutes. To control for over reporting, the household activities were left out of the analysis and the final result was multiplied with .80. Physical activity of vigorous intensity was chosen because guidelines on cardiovascular prevention advise sports. The outcome measure for **fat intake** was the change in daily fat intake (in grams per day) (one gram=.035 ounces). For the CEAs, the ICERs were the cost per incremental change in weekly physical activity of vigorous intensity in minutes or the cost per incremental change in fat intake (in grams).

To report the uncertainty due to sampling variation a non-parametric bootstrapping technique was used. Bootstrap estimation is based on random sampling (1,000 replications) with replacement of several of the patients in the trial, using the original data. ICERs were calculated for each bootstrap replicate. The bootstrapped cost-effect pairs were graphically represented on cost-effectiveness planes. The planes were determined for the outcomes in DELTA QALYs and for the behavioural outcomes.

SPSS 16.0 was used to perform the statistical analyses. The bootstrapping was performed using a macro in Excel for Microsoft Windows 2007 and the significance level was set at $p<.05$.

Sensitivity analyses

Since decision making in health care is undertaken in a context of uncertainty concerning the effectiveness and costs of an intervention a sensitivity analysis has to be included and the uncertainty can be represented by a cost-effectiveness acceptability curve (CEAC). This curve gives information on the probability that the intervention is optimal, given a certain limit for the money the government is willing to spend per quality adjusted life year (QALY). In Belgium, there is no official threshold. In neighbouring countries, the thresholds range from £20,000-£30,000 per QALY (United Kingdom) to a maximum threshold of €80,000 (The Netherlands) (19). The latter cut off value is high for a cardiovascular prevention program (mostly healthy individuals with no current burden of disease). The potential burden of disease, however, can be significant since ischemic heart disease is considered as one of the leading disabling conditions by the World Health Organization (25). Therefore, the cut off score was set at €30,000. The sensitivity analyses were performed using the same data as used in the CEA/CUA. Three sensitivity analyses were performed using the total costs and DELTA QALYs. Since computer-tailored interventions are supposed to be implemented on the large scale, the first analysis examined the effect of changes in the number of participants. Two scenarios were used: 3x more participants and 48x more participants (total of 10,000). In the latter scenario, the developmental costs become almost negligible. For this sensitivity analyses CEACs were plotted. The second analysis examined the variations due to changes in the effectiveness of the

intervention using the upper limit of the confidence interval of the mean incremental DELTA QALY. The third analysis explored the possible effect of a different intervention effectiveness, namely that in an unhealthy population. To examine this effect, the mean incremental QALY from another CUA of a walking programme in a group of moderately depressed elderly women was used (12). The incremental effectiveness in the latter study was 0.132 QALY. After 3 years of intervention, all participants will undergo a medical intervention to determine their cardiovascular risk and gather data on (adherence to) the medication regimens prescribed by their general practitioner after referral. Adherence to the behaviour change interventions will be described elsewhere. Data on adherence were not included in the sensitivity analyses.

RESULTS

Patients

Seventy percent (219/314) of the participants at baseline completed questionnaires after 6 and 12 months. The baseline characteristics and the results of the drop-out analysis are presented in Table 1. No significant differences were found for both study groups at baseline or after one year of intervention. The drop-out analysis showed there were no significant baseline differences between completers and non-completers.

Costs

Figure 2 shows the results of the cost analysis. The costs of the intervention equalled €114,782. Without the developmental costs, these costs equalled €48,271. The costs of usual care were €12,576. For the 147 participants in the intervention condition, the mean cost was €568. For the 72 participants in the usual care condition this was €136. The mean incremental cost was €433. There was a significant difference between these costs (t=-24.661,df=217,p=.000). The cost data were normally distributed.

Effects

The QALYs gained by the intervention and usual care were 0.770 and 0.765, respectively (t=-0.431,df=217,p=.667). The mean incremental effectiveness of the intervention was 0.005. The effect data were normally distributed. If the QALYs were adjusted for baseline utility differences, the DELTA QALYs gained by the intervention and usual care were 0.774 and 0.758, respectively (t=-1.287,df=217,p=.200). Supplementary Table 2 shows the utility values, the QALYs and the DELTA QALYs. The mean incremental effectiveness of the intervention was 0.016. For physical activity, the mean incremental effectiveness equalled 11.20 minutes and for fat intake, the mean incremental effectiveness was -4.40 grams of fat per day.

Cost-utility analysis and cost-effectiveness analyses

If the unadjusted QALYs were used, the ICER was €80,421 per QALY. If the ceiling of investment is €30,000 per QALY, the probability that the intervention is cost-effective is 23%. If the DELTA QALYs were used, the

ICER was €26,910 per QALY. If the ceiling of investment is €30,000 per QALY, the probability that the intervention is cost-effective is 55%. The ICER for increasing physical activity was €39 per minute. The ICER for decreasing fat intake was €98 per gram of fat. Supplementary Figure 1 shows the cost-effectiveness planes for the outcomes in DELTA QALYs (a) and the behavioural outcomes (b, c). For the outcomes in DELTA QALYs, the majority (90%) of the cost-effect pairs after bootstrap analysis were located in the northeast quadrant, suggesting more effect but at higher costs. Nevertheless, 10% of the cost-effect pairs were located in the northwest quadrant, suggesting higher costs without additional effect. For changes in physical activity (b) and fat intake (c) 83% and 89% and of the cost-effect pairs were located in the northeast quadrant.

Sensitivity analyses

The results of the CUA were very dependent on the number of participants and the effectiveness of the intervention in this specific and overall healthy study group. Figure 3 shows the CEACs for the outcomes in DELTA QALYs for the present sample, for 3x more participants and for 10,000 participants. The CEAC with 3x more participants showed a 81% probability that the intervention is an acceptable strategy if the ceiling of inversion is €30,000 per QALY. The mean incremental cost of the intervention would drop from €433 to €219. In this scenario, the ICER changed from €26,910 per QALY to €13,610 per QALY. If 10,000 participants would receive the intervention, the mean incremental cost would drop to €119. The ICER would change from €26,910 per QALY to €7,402 per QALY. The CEAC with 48x more participants showed a 88% probability that the intervention is an acceptable strategy if the ceiling of inversion is €30,000 per QALY. Using the higher limit of the confidence interval of the mean incremental DELTA QALY, the original ICER changed from €26,910 per QALY to €25,335 per QALY and 91% of the cost-effect pairs were located in the northeast quadrant. The CEAC showed a 58% probability that the intervention is an acceptable strategy if the ceiling of inversion is €30,000 per QALY. If one assumes that the intervention from the present study can lead to an incremental effectiveness of 0.132 QALYs in an unhealthy sample, then the ICER would drop from €26,910 per QALY to €3,349 per QALY. In this analysis, all the cost-effect pairs were located in the northeast quadrant.

DISCUSSION

In this trial-based cost-utility analysis a cardiovascular prevention program was compared to usual care in a general sample of highly educated adults after one year of intervention. The study pointed out that the intervention was cost-effective. The incremental cost-effectiveness ratio (ICER) was €26,910. The cost-effectiveness of an intervention, of course, depends on the ceiling of inversion used. The cut off value was set at €30,000 per QALY. In case of a large scale implementation the ICER would drop to €7,402 per

QALY making it highly cost-effective. In the United Kingdom, this ICER would result in a recommendation to provide the intervention, taking into account the sensitivity analyses. In the present study, the decision was made to include the developmental costs. This is not a commonly used practice because it results in a high ICER. Nevertheless, this way complete information on the costs of the intervention is included in the ICER. Moreover, the intervention from the present study was cost-effective even with the inclusion of the developmental costs.

Comparable studies on behaviour change or cardiovascular prevention interventions can be found in the literature. However, there is a large variance in the ICERs that are reported. Two other trial-based cost-utility analyses, both stimulating an increase of physical activity, reported ICERs ranging from €311-€17,174 per QALY (12, 17). However, these studies both targeted specific high-risk groups: groups of elderly women, with or without a moderate depression. In these studies, only one behaviour was targeted, the developmental costs were not included; the interventions were less intensive and were not based on behavioural theories. Other studies using modelling reported comparable ICERs as well (4). However, important costs such as the cost to screen and approach participants were not included disregarding considerable implementation barriers.

The present study included a highly educated and overall healthy study group. Because of the higher education of these participants, the findings from the present study might not be generalisable to the Belgian population. It is indeed not our intention to generalise to other populations than the highly educated. Behaviour change interventions have to be tailored to a specific target group and cost-utility analyses may differ by target group as well. The differences between these target groups and its relevance for the design of prevention programmes and cost-utility issues have to be studied thoroughly. The highly educated are expected to live healthier and they might be the group that benefits least from cardiovascular prevention programs. In general, intervention effectiveness is higher people with a lower socioeconomic status but because of more barriers to deliver the intervention, the costs increase as well.

The sensitivity analysis in the present research showed that if the intervention would be given to a less healthy target group, the ICER would change from €26,910 to €3,349 per QALY. The baseline utility values in the present study sample were indeed very high when compared to other study samples in cost-utility analyses (e.g. 0.77 versus 0.69) (12). The incremental effectiveness found in the present study was low, 0.016 QALYs but remains comparable to other findings (e.g. incremental QALY gain of 0.011 after 2 years) (17).

This study has several strengths. Firstly, this is a trial-based cost utility analysis. Secondly, the costs for different medical and behavioural interventions were determined in a detailed fashion. Thirdly, three

behavioural risk factors were targeted in this prevention program. Furthermore, cost-effectiveness planes were determined for the behavioural outcomes. The cost-effectiveness planes showed that an investment of €400-€450 per person leads to different effects. More information is needed on the cost-effectiveness of different components of prevention programs for different target groups (different risk profiles,…).
This study has several weaknesses. Firstly, the present study included a small number of participants for the cost-utility analysis. Secondly, no modelling was used to extrapolate the results to a longer time horizon. The present study might depict an underestimation of the benefits on the long term. The suggestion was made in the literature to use modelling to fully grasp the effects of a prevention programme on the long-term (11).
The results from the present study can be used in policy decisions. It is cost-effective to offer this cardiovascular prevention programme to a highly educated subgroup of the population. The programme can be financed by the ones that potentially benefit from the desired health changes i.e. the government, the insurers and the users. More research is needed to test whether this programme is cost-effective in other target groups as well.

CONCLUSION

This is the first trial based cost-utility study of a cardiovascular prevention programme in a general sample of highly educated adults. The intervention was cost-effective after one year of intervention. A large scale implementation would make this intervention highly cost-effective.

FIGURES

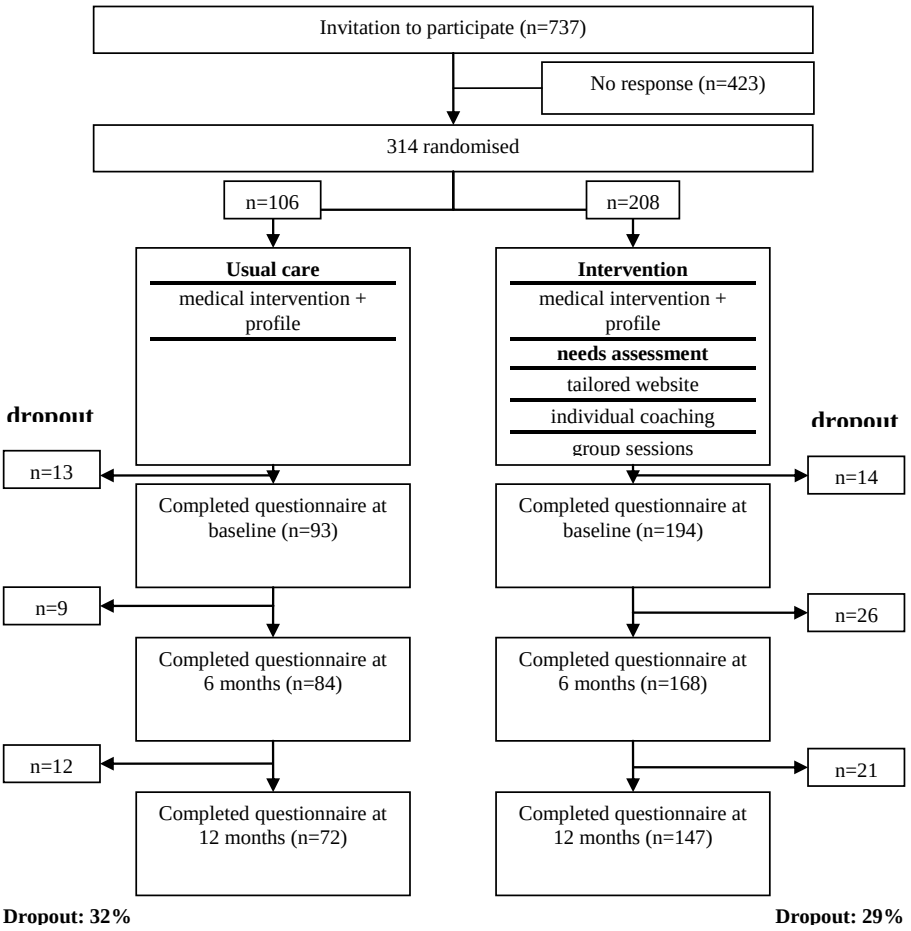


Figure 1: flow-chart of the participants throughout trial

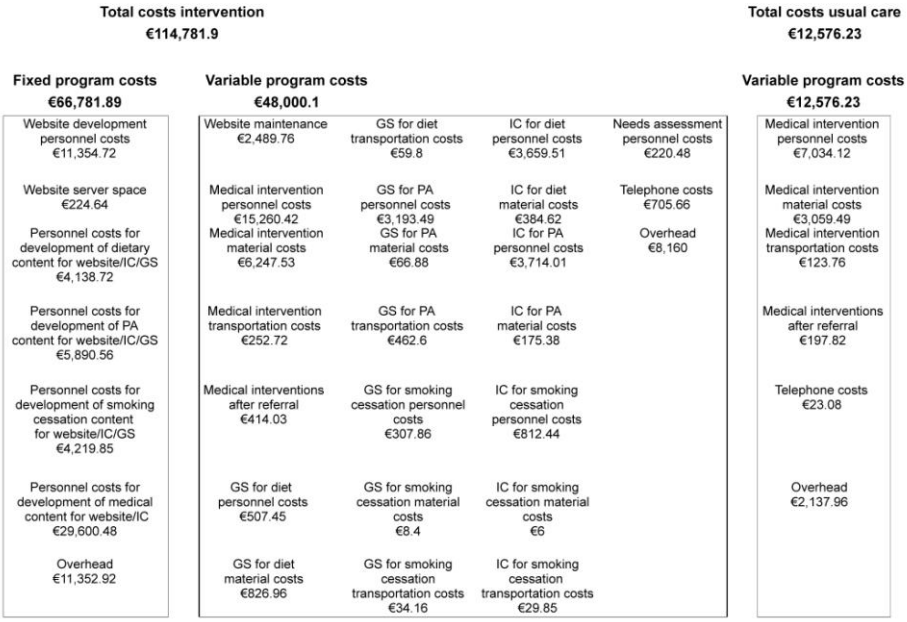


Figure 2: results cost analysis
IC, Individual Coaching; GS, Group Session; PA, Physical Activity

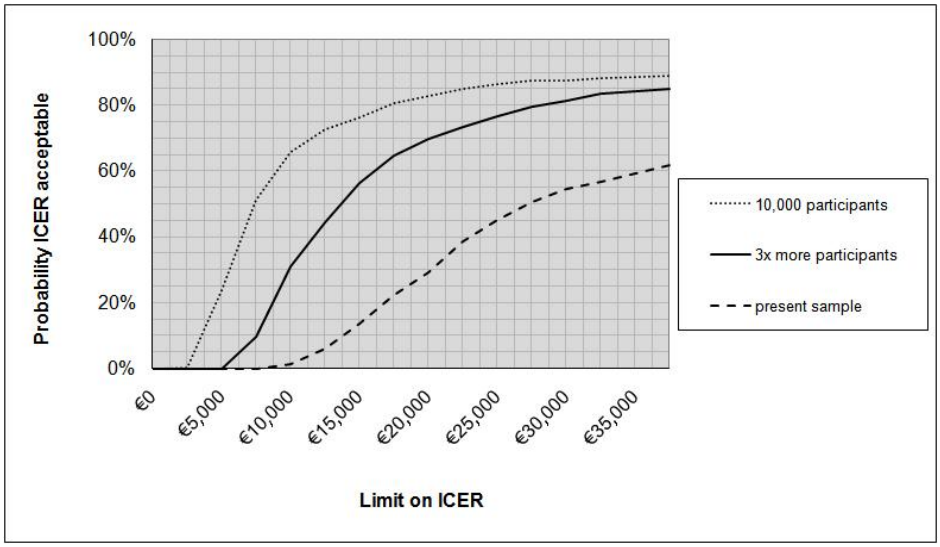
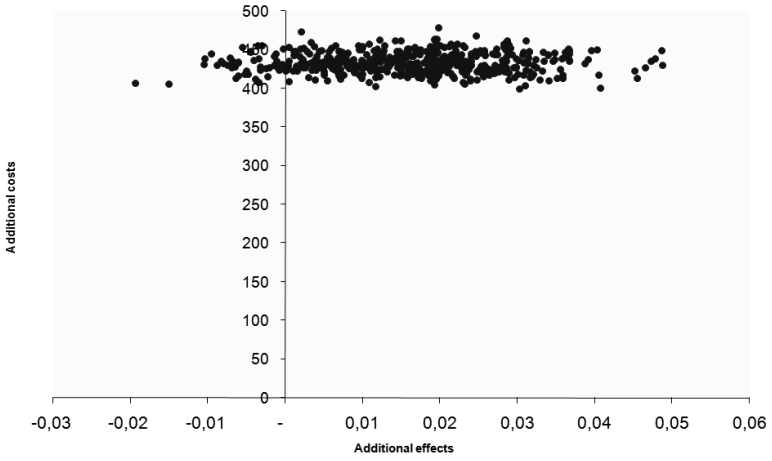
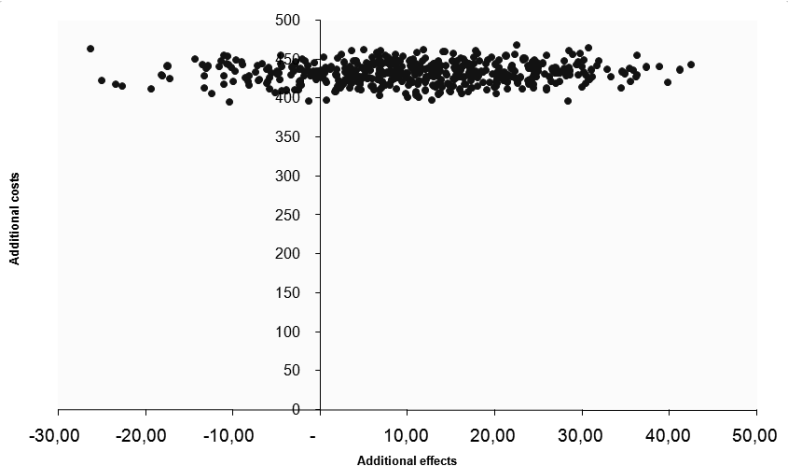


Figure 3: cost-effectiveness acceptability curves

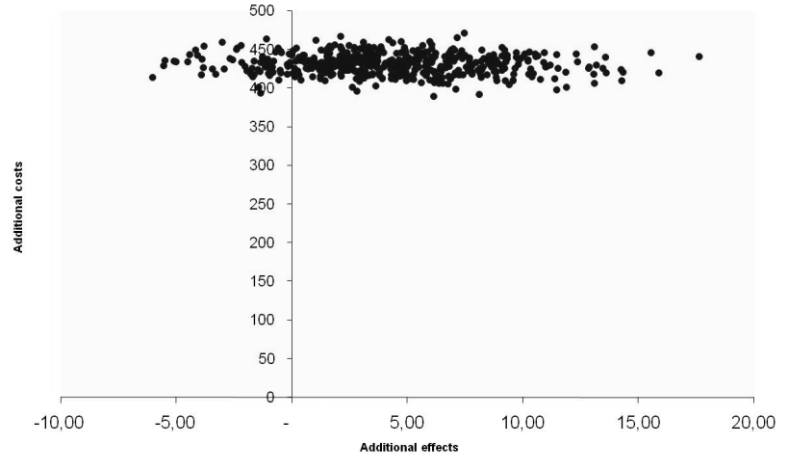
(a) outcomes in DELTA QALYs



(b) physical activity



(c) fat intake



Supplementary Figure 1: cost-effectiveness planes for the outcomes in DELTA QALYs (a), changes in physical activity (b) and changes in fat intake (c)

TABLES

Table 1: baseline characteristics, final sample results and drop-out analysis

	BASELINE CHARACTERISTICS			BASELINE STUDY CONDITION	ONE YEAR RESULTS FINAL SAMPLE			CHANGES p-values	DROP-OUT ANALYSIS p-values
	Total sample (n=287)	Usual care (n=93)	Intervention (n=194)		Total sample (n=219)	Usual care (n=72)	Intervention (n=147)		(n=68)
Age (±SD)	40 (±11)	40 (±11)	41 (±11)	.326	42 (±11)	40 (±10)	42 (±11)		.818
Gender (%male)	67%	68%	66%	.767	67%	68%	67%		.712
BMI	25 (±5)	25 (±5)	25 (±4)	.853	25 (±4)	25 (±3)	25 (±5)	.612	.760
Cardiovascular risk (SCORE)				.162					.239
Unknown (%)	30 (11%)	7 (7%)	23 (12%)						
Low (%)	202	66 (71%)	136 (70%)						
Average (%)	31 (11%)	8 (9%)	23 (12%)						
High (%)	24 (8%)	12 (13%)	12 (6%)						
Systolic blood pressure in mmHg (±SD)	132 (±19)	132 (±19)	132 (±18)	.867					.546
Smokers (%)	46 (16%)	10 (11%)	36 (19%)	.092	23 (11%)	5 (7%)	18 (12%)	.229	.427
Fat intake in g/day (±SD)	106 (±38)	105 (±36)	107 (±40)	.595	101 (±35)	106 (±37)	98 (±34)	.305	.787
Physical activity, high intensity, in min/week (±SD)	64 (±78)	63 (±77)	64 (±78)	.946	76 (±84)	74 (±71)	76 (±90)	.375	.508
Health utility value (±SD)	0.77 (±0.10)	0.77 (±0.10)	0.76 (±0.10)	.194	0.79 (±0.10)	0.78 (±0.09)	0.79 (±0.11)	.184	.828

Supplementary Table 1: unit costs material, transportation and personnel input

Material Input	
Resource	Value (€/unit)
Print costs per page	0.04-0.92*
Stamped envelope A4	1.01*
Transport	0.15 (18)
Personnel Input	
Resource	Value (€/hour)
Psychologist	25.65**
Dietician	20.73**
Physiotherapist	30.40**
General practitioner	74 (7)
Cardiologist	129***
Consultant	100*
Programmer	19**

* Hasselt University Records
** Local Hospital Records
*** National Wage Records

Supplementary Table 2: utility values, QALYs and DELTA QALYs

	Survival rate	Mean baseline utility (±SD)	Mean utility at 6 months (±SD)	Mean utility at 12 months (±SD)	QALY[1] (±SD)	DELTA QALY[2] (±SD)
Total sample (n=219)	100 %	0.7669 (±0.09790)	0.7608 (±0.10400)	0.7852 (±0.10135)	0.7684 (±0.08673)	0.7684 (±0.08702)
Usual Care (n=72)	100 %	0.7741 (±0.09503)	0.7530 (±0.09765)	0.7792 (±0.08977)	0.7648 (±0.08196)	0.7576 (±0.08196)
Intervention (n=147)	100 %	0.7634 (±0.09940)	0.7646 (±0.10710)	0.7882 (±0.10674)	0.7702 (±0.08919)	0.7737 (±0.08919)

[1] QALY=(0.5*(baseline utility value +6 months utility value)*6+0.5*(6 months utility value + one year utility value)*6)/12

[2] DELTA QALY=QALY+ (Mean baseline utility (total sample)-Mean baseline utility of Usual Care/Intervention)

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Chapter 10

Chapter 11

Willingness to pay for a cardiovascular prevention programme in highly educated adults: a randomised controlled trial

Based on:
Jacobs N, Drost R, Ament A, Evers S, Claes N. Willingness to pay for a cardiovascular prevention program in highly educated adults: a randomized controlled trial. International Journal of Technology Assessment in Health Care 2011; 27(4): 283-89

ABSTRACT
Objectives: To determine the Willingness to Pay (WTP) of the participants of two study conditions and different intervention dose groups of a randomised controlled trial on Cardiovascular Disease (CVD) prevention.
Methods: Three hundred fourteen participants were randomised to two study conditions: (1) CVD risk assessment/communication; (2) CVD risk assessment/communication + a behaviour change programme. The behaviour change programme was aimed at increasing physical activity, reducing saturated fat intake and smoking cessation. It consisted of a tailored website and individual coaching with a self-selected dose. At post-assessment, WTP and perceived autonomy support items were included. The intervention dose was registered throughout the trial and post-hoc intervention dose groups were created. Pearson Chi-Square tests, Student's T-Tests, One-way ANOVAs were used to examine WTP-differences between the study conditions and intervention dose groups.
Results: Twenty-four months post baseline, 61 and 135 participants of the control and intervention condition, respectively, completed the questionnaires. No WTP difference was found between the study conditions. However, participants that selected a higher intervention dose were willing to pay significantly more for their program ($P<.05$).
Conclusion: In general, people want to pay the same amount of money for a CVD prevention program, irrespective of the inclusion of a behaviour change programme. However, there seems to be an association between the self-selected dose of the latter program and the WTP.

INTRODUCTION
Cardiovascular disease (CVD) is a major cause of death and disability worldwide. In 2004, 29 percent of all global deaths and 148 disability-adjusted life-years were due to CVD (1). Furthermore, CVD consumes about 10% of the health care expenditures across the European Union (2). CVD and its consequences can, at least partially, be avoided by the adoption of a healthy lifestyle (3). Consequently, effective and cost-effective behaviour change programmes are needed to manage behavioural risk factors for CVD. Such programmes should be theory-based and use effective behaviour change techniques and an autonomy-supportive interpersonal interaction style to establish long-term behaviour change (4, 5). Economic evaluations of these programmes are crucial for the decision making process of health resource allocation (6).
Cost benefit analysis (CBA) is an example of an economic evaluation that is often used as a tool to compare costs with the outcome benefits (7). The major issue for CBA is the evaluation of health outcomes in monetary terms. One approach to do this is that of stated preferences or willingness to pay (WTP), also known as contingent valuation (7). In contingent valuation, individuals are directly asked what they are willing to pay for a service or

benefit (8). Different formats can be used for WTP questionnaires. Firstly, an open-ended format can be used in which scenarios are described and participants are free to fill in the amount of money they are willing to pay. Secondly, a close-ended format in which participants are asked to give a yes or no answer to a predetermined WTP amount can be used. Thirdly, a bidding game format in which participants are asked to give a yes or no answer to an alternate WTP question after a prior WTP question was answered can be used (8). Disadvantages of contingent valuation are that people receive scenario's of interventions and/or benefits but do not experience these programmes directly which may result in an hypothetical bias and an overestimation of the true WTP value (9).
The latter bias, however, can be avoided by truly exposing people to an intervention and after they have experienced it, determining their WTP. Therefore, the WTP can be determined for different study conditions of a randomised controlled trial. This method has only been used in one other study before. Romé et al. (2010) determined the WTP of chronically ill and sedentary adults for health improvements of physical activity on prescription (10). Nevertheless, this study considered a single-behaviour intervention whereas prior studies found multiple behaviour and more intensive interventions to be more effective in promoting behaviour change (11).
The main aim of the current study was to determine the WTP of the participants of the study conditions and intervention dose groups of a randomised controlled trial on CVD prevention including a multiple behaviour change programme.

METHODS

Participants and study design

The recruitment period for the study took place from February 2007 to April 2007 (Figure 1). Requests for study participation were sent to the customers of an insurance company that insures self-employed professionals (e.g., lawyers) against loss of income due to sickness (n=737). Eligibility criteria were subjects aged between 25-75 years who signed an informed consent and had Internet access.
The study population at baseline consisted of 314 highly educated participants (Master's degree in Law; five years of studying at university level in Belgium) who were randomly allocated to a control condition and an intervention condition using a 1/3 ratio to keep enough power to study dose-response effects (12). Questionnaires were completed at baseline (April 2007) and at 6, 12 and 24 months post baseline (13, 12). Two hundred and eighty-seven participants completed the questionnaire at baseline. The study was approved by the Hasselt University Ethics Committee and was registered (ISRCTN23940498).

Intervention

Both study conditions consisted of CVD risk assessment, risk communication and medical follow-up. The assessment took place at Hasselt University where general practitioners determined the 10-year risk of dying from a cardiovascular event using the Systematic COronary Risk Evaluation (SCORE) algorithm (14). The intervention condition additionally included a tailored behaviour change programme, consisting of a tailored website and individual coaching (Figure 2).

The tailored website could be visited to gain information on risk factors for CVD and to read guidelines on behaviour change and tailored advices on physical activity and fat intake (15, 16). The individual coaching was given by a health psychologist and the dose and delivery mode (e-mail, regular mail, telephone and/or face-to-face) of it were self-selected by the participants during the first intervention year (16). During the second intervention year, the individual coaching was adapted because people administered themselves an insufficient intervention dose. Therefore, the dose of the individual coaching became fixed and the number of delivery modes limited (i.e. ten messages delivered through e-mail or regular mail). The techniques of the individual coaching targeted determinants of behaviour derived from theories such as the Theory of Planned Behaviour (TPB) and Self-Determination Theory (SDT) (17, 4). These determinants included, amongst others, knowledge, skills, self-efficacy and motivation. The tailored behaviour change programme was autonomy-supportive to increase motivation and behavioural engagement on the long-term (4).

Measures

The participants were categorised according to their CVD risk: they had a low, medium or high risk of dying from CVD in the next 10 years (14). Twenty-four months post baseline, the participants completed a questionnaire that additionally contained questions about perceived autonomy support (PAS) and WTP questions. The WTP questions were: 1) a take-it-or-leave-it-question (TOL question) and 2) close-ended format questions dependent on the TOL answer (18). The TOL question was "Are you willing to pay €90 per year for the programme you received?". The received programme the participant had access to was summarised before this question was asked. The close-ended format question was dependent on the TOL answer. In case people were willing to pay €90, they were asked to choose between predetermined maximum WTP options of €182, €336, €568 or €726 per year. In case people weren't willing to pay €90, they were asked to choose between predetermined maximum WTP options of €0, €11, €23 or €45 per year. WTP amounts on the payment cards were presented in Euros and inspired by a previous WTP study related to CVD prevention (18). However, two figures (€336 and €568) were adapted to represent the average annual subscription fees at respectively simple and a more exclusive (e.g. including a personal coach) fitness centres in Belgium. Participants

were also asked for reasons of their WTP decision. In case people were willing to pay, an open-ended format was used. In case people weren't willing to pay, a close-ended format was used with the following options: (1) Out of principle; (2) Insufficient support of the programme; (3) Not the right support for me. For the assessment of PAS, the Dutch version of the short 6-item form of the Health Care Climate Questionnaire (HCCQ) was used (19).

Data analyses

Mean and median WTP were determined for both study conditions. Pearson Chi-Square and student's T tests were used for the drop-out analysis (gender, age, study condition, body mass index, smoking status, and CVD risk). Pearson Chi-Square tests were used to assess the relation between WTP and CVD risk groups. This was done by transforming WTP results in two groups: those wanting to pay less than €90 and those wanting to pay €90 or more.

Pearson Chi-Square tests, Student's T-tests, and One-way ANOVAs were used to compare study conditions and different intervention dose groups within the intervention condition. These intervention dose groups were created post hoc, using the 50th and 75th percentile of the total duration of individual coaching. This resulted in a low, a medium and a high intervention dose group, respectively. Pearson correlations were used to test the relation between continuous measures of WTP, intervention dose, and PAS. SPSS 15.0 for Windows was used and the significance level was set at α=.05.

RESULTS

Twenty-four months post baseline, a total of 196 participants (134 male, 62 female) and a mean age of 41 years (SD=11) completed the questionnaires of whom 61 were in the control condition and 135 were in the intervention condition. The drop-out analysis showed that there were no differences with regard to gender, age, study condition, BMI, smoking status, and CVD risk. Table 1 shows the baseline characteristics of the participants that completed the questionnaire at baseline for both study conditions and the intervention dose groups. For the intervention dose groups, there were baseline differences for BMI with BMI being significantly higher in the high dose group compared to the low and medium dose groups (P<.05).

The take-it-or-leave-it question (TOL question), namely to pay €90 for the received programme, was answered positively by 18 participants (30%) of the control condition and 57 participants (42%) of the intervention condition (Table 2). However, this difference was not significant ($\chi^2(1)=2,88$,P=.06). For the different intervention dose groups, the answers on the TOL question were not statistically different either (Table 2). For the different CVD risk groups no differences for the TOL question were found ($\chi^2(2)=1.06$;P=.59). Of the participants that answered the TOL question, 154 also answered the Maximum WTP question (WTPmax). The mean and median WTPmax values

can be found in Table 2. No differences were found between the study conditions for WTPmax. However, the WTPmax was significantly different for the high versus the medium/low dose groups (F=3.09;df(2);P=.04) (Figure 3). Participants with a high intervention dose were willing to pay more for the behaviour change programme. In accordance, a strong correlation was found between the continuous measure of the intervention dose and maximum WTP (r=0.25;P=.01). The low intervention dose group (n=67) had a mean intervention duration of 325 minutes and a median WTP of €45. The medium intervention dose group (n=35) had a mean intervention duration of 472 minutes and a median WTP of €34. The high intervention dose group (n=33) had a mean intervention duration of 903 minutes and a median WTP of €182. Seventy participants mentioned a reason why they didn't want to pay: out of principle (66%); the programme didn't give enough support (14%); the programme didn't give the right support (20%).
A significant, positive relation was found between continuous measures of PAS and WTP (r=0.29;P<.001). People with a higher perceived autonomy support were willing to pay more for the behaviour change programme.

DISCUSSION
There were no WTP differences between both study conditions. This means that people want to pay the same amount of money for a CVD prevention programme, irrespective of the availability of a tailored behaviour change programme. However, the self-selected intervention dose of the latter program was positively associated with WTP. There were no differences between the CVD risk groups. Furthermore, a relation between WTP and PAS was found.
The mean maximum WTP in the control condition was €75 per year and this was €107 per year for participants in the intervention condition. Our WTP values were lower than those found in the study of Romé et al. (2010) (10). In that study the mean WTP for improved health by exercise for four months was €45 in the control condition and €64 in the intervention condition. This is surprising because people with a higher education and income, as included in our study, are believed to have a higher WTP than the lower educated (20). A possible explanation for this result may be the difference in the WTP questionnaire at item level. Romé et al. (2010) asked participants what they were willing to pay for the health benefits of the program (long-term health improvements) and in the present study the participants were asked what they were willing to pay for the programme itself. In the present study, the question potentially captured three elements: the health benefits of the programme, the disutility of the programme itself; and the subjective perception of the programme effectiveness in terms of health. Furthermore, the study of Romé et al. (2010) included a patient sample whereas our study included a sample of overall healthy adults (i.e. 70% had a low CVD risk).

In a previous study, WTP and perceived risk were found to be positively related (20). In a WTP study of Johnson et al. (2006) wherein scenario's of diabetes prevention programmes were used, the participants with a low perceived risk of diabetes wanted to pay €33 per year and those with a high risk wanted to pay €1080 per year (20). Our findings do not corroborate these results since no association between WTP and CVD risk groups was found. Adler et al. (2006) determined the WTP of a representative sample of primary care patients (21). Of those participants with Internet access, 60% were willing to pay $10 or more per year and 31% were willing to pay $50 or more per year for a primary care web-portal (e.g. with e-mail possibilities with their physician). In the latter study the participants did experience the intervention in contrast to that of Johnson et al. (2006).

In the present study no WTP differences between the study conditions were found. This is in line with the findings of Romé et al. (2010). Reasons for this lack of difference may be the small sample size and the presence of risk assessment and communication in both conditions. In a previous study, a nurse practitioner determining CVD risk in both the control and intervention condition of a randomised controlled trial nullified the intervention effect (22). Consequently, risk assessment may not only influence the effect of the intervention but also the participants' WTP.

The behaviour change programme of this study was based on SDT, a theory that recommends to design interventions as autonomy-supportive contexts with choice possibilities (4, 5). This can influence the participants to become intrinsically motivated for behaviour change. Participants could choose their own intervention dose and delivery mode of the coaching during the first intervention year. This self-selected intervention dose led some participants to underuse the programme but was found to be significantly related to the programme's effectiveness (23). The present study emphasises the importance of the intervention dose and showed that the dose that participants received is associated with their WTP.

The strengths of the present study were that participants actually experienced the programme and no scenarios were used; the long duration of the programme; the use of a randomised controlled trial and the inclusion of a tailored behaviour change programme using modern technologies. Weaknesses of the study were the small sample size and the fact that the sample only included highly educated adults limits the generalisability of the results.

Nevertheless, to our knowledge, the present study is the first that examined the WTP for a CVD programme including a multiple behaviour change programme. The findings from the present study give policy makers an idea about the WTP of highly educated adults for health promotion programmes. It also indicates how much money a sponsor organization can recover from the programme's participants. For the present intervention, the mean yearly costs per participant, determined for the first intervention year, equalled

€136 and €568 for the control and intervention condition, respectively (13). Thus, participants of the control and intervention condition would be willing to pay 55% and 19% of the actual programme costs, respectively. This information is valuable for the development and implementation of future health promotion interventions, certainly for their feasibility at societal level. Future CBA studies could be performed to calculate the net benefit of health promotion programmes to aid the decision making process even further.

TABLES

Table 1 Baseline characteristics of the study sample and the intervention dose groups

	Study conditions (N=287)		Intervention dose groups[a] (N=135)		
Characteristics	Control condition (N=93)	Intervention condition (N=194)	Low dose group (N=67)	Medium dose group (N=35)	High dose group (N=33)
Age	40 (SD 11)	40.91 (SD 11)	40 (SD 10)	42 (SD 11)	43 (SD 12)
Gender	63 (68%)	128 (66%)	44 (66%)	27 (77%)	22 (67%)
BMI	25 (SD 5)	25 (SD 4)	25 (SD 4)	25 (SD 4)	27 (SD 5)
Smoking status	10 (11%)	36 (19%)	9 (13%)	6 (17%)	8 (24%)
CVD risk[b]					
Low	66 (71%)	136 (70%)	50 (75%)	25 (71%)	21 (64%)
Medium	8 (9%)	23 (12%)	5 (7%)	5 (14%)	7 (21%)
High	12 (13%)	12 (6%)	3 (4%)	2 (6%)	4 (12%)
Unknown	7 (8%)	23 (12%)	9 (13%)	3 (9%)	1 (3%)

[a] intervention dose groups: low dose = mean intervention duration of 325 minutes; medium dose = mean intervention duration of 472 minutes; high dose = mean intervention duration of 903 minutes.

[b] CVD risk = 10-year risk of dying from a cardiovascular event using SCORE

Table 2 WTP outcomes for different study conditions and intervention dose groups

	Study conditions (N=135)		Intervention dose groups[a] (N=135)		
WTP outcome	Control condition (N=61)	Intervention condition (N=135)	Low dose (N=67)	Medium dose (N=35)	High dose (N=33)
TOL question[b]	18 (30%)	57 (42%)	25 (37%)	14 (40%)	18 (55%)
Answered WTP_{max}	47 (77%)	107 (79%)	48 (72%)	32 (91%)	27 (82%)
Unwilling to pay	13 (21%)	27 (20%)	13 (19%)	11 (31%)	3 (9%)
Mean WTP_{max}	75 (100)	107 (115)	110 (134)	72 (82)	141 (103)
Median WTP_{max}	45	45	45	34	182

[a] intervention dose groups: low dose = mean intervention duration of 325 minutes; medium dose = mean intervention duration of 472 minutes; high dose = mean intervention duration of 903 minutes.

[b] TOL: take-it-or-leave-it question (pay €90 for the received programme)

FIGURES

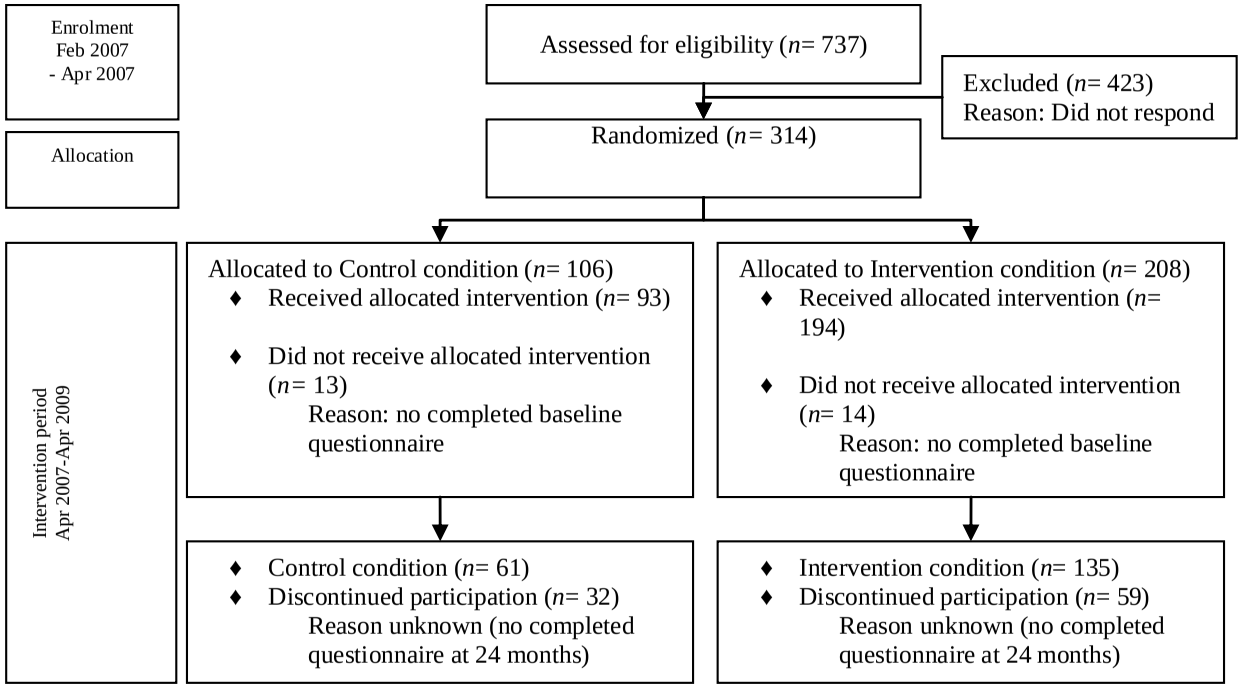

Figure 1 Study flow

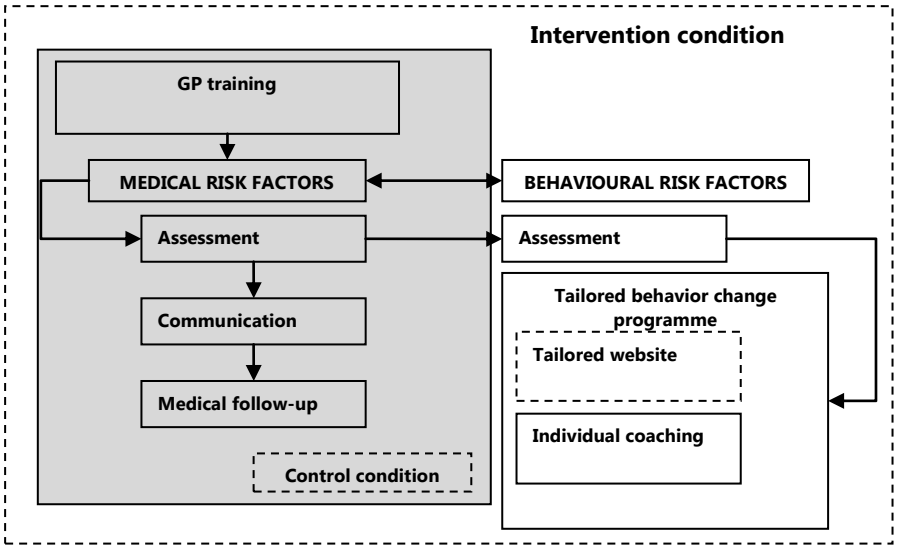

Figure 2 Graphical representation of the Intervention; the grey area symbolises the CVD risk assessment, communication, and medical follow-up present in control and intervention conditions. The Intervention condition additionally included a tailored behaviour change programme (white area).

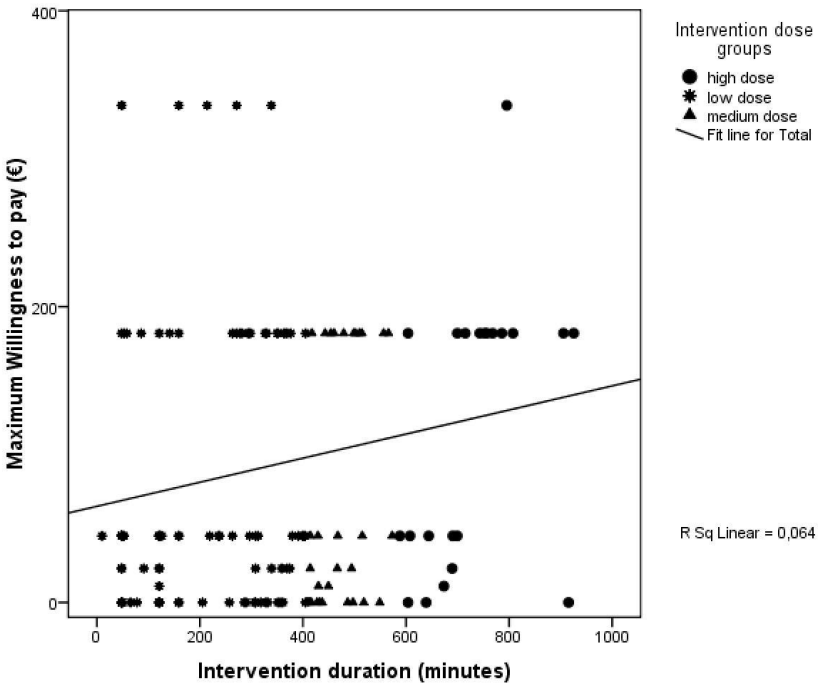

Figure 3 Intervention dose* and maximum WTP for each participant in the intervention condition.

* intervention dose groups: low dose = mean intervention duration of 325 minutes; medium dose = mean intervention duration of 472 minutes; high dose = mean intervention duration of 903 minutes.

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Chapter 12

Chapter 12: General discussion

The primary aims of this thesis were to examine the effectiveness of the individually tailored behaviour change programme on behaviour, to examine the dose-response effects, the effects on determinants of behaviour, and to perform an economic evaluation alongside the trial. The individually tailored behaviour change programme combined with medical interventions (risk assessment, communication and follow-up) formed the cardiovascular prevention programme PreCardio.
The first paragraph of this discussion consists of a description of the **behavioural goals of the tailored behaviour change programme**. In the second paragraph the **main findings** in accordance with the primary aims of the thesis are described. In the third paragraph the **secondary findings** in line with the secondary aims are discussed. Next, **strengths and limitations** are discussed. To conclude, **directions for future research** and **recommendations for practice** are given.

1. Behavioural goals of the individually tailored behaviour change programme

The goals of the individually tailored behaviour change programme were to help smokers to reach abstinence, to increase physical activity, to eat a healthy diet, and to influence determinants of behaviour. The strategies that were used to change the medical risk factors and risk behaviours were: the screening event, the individually tailored website, and the one-on-one coaching by different delivery modes. The *screening event* was organised at Hasselt University and included a total CVD **risk assessment, communication and follow-up**. After the risk assessment, this risk was communicated to the patient: immediate feedback could be given by the GP and was summarised on a printed profile per participant. Medical follow-up was given to participants with a medium or high CVD risk by their own general practitioner, irrespective of the study condition. The intervention condition additionally included an individually tailored behaviour change website and one-on-one coaching. The *individually tailored behaviour change website* consisted of various sections such as a cardiology section, a physical activity section, a nutrition section, a smoking cessation section, a section with personal messages, a forum, and contact page. Each behavioural section included a behaviour change guideline. The one-on-one coaching consisted of contacts between participants and a member of the multidisciplinary PreCardio team (health psychologist, physical therapist, cardiologist, GP or last-year students (dietician, sports coach)). During the first stage of the behaviour change programme (first year), the participants could freely determine the target behaviour(s), the intervention dose and the delivery mode (website, regular mail, e-mail, telephone, or face-to-face) of the interventions they received. During the second stage of the behaviour change programme, the dose was fixed to 10 tailored messages per year and the delivery mode was limited to regular mail and e-mail.

2. Main findings

The main aims of the present thesis were to examine the effectiveness on (determinants of) behaviour and the dose-response effects of the individually tailored behaviour change programme and to examine the cost-effectiveness and willingness to pay for the intervention. The results of the interventions on the medical parameters are briefly described below.

2.1. Effect on medical parameters

After 36 months, almost all medical risk factors improved in both study conditions, thus **significant time effects** were found (1). Firstly, there was a significant time effect for blood pressure. The systolic and diastolic blood pressure significantly decreased in both study conditions. Secondly, the total cholesterol significantly decreased in both study conditions. For objectively measured BMI, however, a positive time effect was found. The BMI increased in both study conditions over time. No time effects were found for physical fitness, and the fat percentage. One may wonder whether the positive time effects that were found in this study can be ascribed to trends in these medical risk factors in the Belgian population due to improved care and preventive action at the national level (e.g., by health care insurers). However, articles on trends in prevalence of hypertension and other risk factors in European populations show that the changes that were observed in this three-year study were larger than predicted annual changes (2, 3). Furthermore, the effect of the intervention on the medical parameters was evaluated compared to the control condition. **No time x study condition interaction effects** were found at 36 months. This means that the individually tailored behaviour change programme was no more effective in changing medical risk factors compared to the control condition with medical interventions only.

2.2. Effect on behaviour

Time effects were found in the present study. In fact, significant negative time effects were found for total fat intake and self-reported BMI after 6 months and these decreases are desirable results. This means that the participants in both study conditions decreased their total fat intake ($p<.05$) and had a lower BMI after 6 months ($p<.01$). This means that risk assessment, communication, and follow-up is as effective as the intervention with the additional behaviour change programme in changing fat intake and BMI. Furthermore, additional analyses of the results after 12 months showed significant positive time effects for physical activity ($p<.01$) and a negative time effect for self-reported BMI ($p<.05$) after 12 months of intervention. Thus, physical activity increased and self-reported BMI decreased. After 24 months, there was a significant time effect for vigorous physical activity

($p<.001$). Vigorous physical activity significantly increased in both study conditions after 24 months of intervention. Actually these findings correspond with the effects on medical parameters described above. The risk assessment, communication and follow-up is thus sufficient to change behaviour in a sample of highly educated adults.

Furthermore, significant **dose-response effects** of the intervention were found. Therefore, the results of this thesis emphasise the importance of intervention exposure or the intervention dose that participants actually received. The results after 6 months showed that a higher intervention dose of the individual coaching led to better effects for physical activity and fat intake, independent of baseline motivation (Chapter 4). After 12 months, the intervention dose was found to be a significant positive moderator or the relationship between self-efficacy and intention for physical activity. Furthermore, the intervention dose had a negative, significant and direct effect on changes of fat intake (grams per day) (Chapter 7). After 12 months, a significant dose-response effect was also found when using a composite lifestyle change score as an outcome measure (Chapter 6). Lastly, the willingness to pay (WTP) of the participants in the intervention condition was also strongly associated with the intervention dose (Chapter 11). The higher the intervention dose, the higher the willingness to pay.

Next, this thesis adds to the research on the use of different **delivery modes**. One should keep in mind that the delivery modes were freely chosen by the participants during the first intervention year. After 6 months, this led to different outcomes for physical activity and for dietary behaviours (Chapter 4). For physical activity, website use combined with coaching and intensive coaching by e-mail and telephone were effective to increase physical activity. For diet, frequent face-to-face sessions combined with frequent coaching by telephone was effective in reducing fat intake. This suggest that Internet-delivered interventions (website or e-mail) are adequate modes to stimulate physical activity in highly educated adults, more than for the promotion of a healthy eating pattern. For dietary behaviours, more intensive one-on-one coaching by more personal modes such as telephone or face-to-face consultations was more successful. A study of Krebs et al. (2010) looking at the moderating effects of delivery modes on the effectiveness of computer-tailored interventions showed that the communication channel (i.e., print, computer, telephone,…) did not influence the effect size (4). The literature is inconsistent about the effect of different delivery modes and combination of modes. In some studies it was concluded that the delivery mode does not matter with regard to the intervention effectiveness (4). Other authors, however, emphasised the advantages of different delivery modes (5-10).

The main hypothesis was that participants in the intervention condition would make more favourable lifestyle changes than the participants in the control condition. In spite of the additional behaviour change programme in

the intervention condition, this condition was no more effective than the control condition. There were **no time by study condition interaction effects** at 6 months, 12 months or 24 months. After 6 months, the effectiveness of the tailored behaviour change programme was evaluated (Chapter 4). The results of this study showed that there were no significant differences for behaviour or BMI between the participants who received the tailored behaviour change programme and those who received the total CVD risk assessment, communication, and follow-up only. The level of physical activity, however, increased more in the intervention versus the control condition but this was not significant (p=.14). After 12 months, the effectiveness of the intervention to change individual lifestyle factors was examined again (Chapter 6). At this point in time, there were no differences between the study conditions for behaviour, weight or the composite lifestyle change score. Nevertheless, participants in the intervention condition decreased more in weight than the participants in the control condition but this effect was again not significant (p=.14). After 24 months, the effect of the tailored behaviour change programme with fixed intervention dose and delivery modes was evaluated (Chapter 8). Again, no time by study condition interaction effects were found. The participants in the intervention condition increased their vigorous physical activity with 47 minutes per week versus 27 minutes in the control condition but this difference was not significant. It can be concluded that the tailored behaviour change programme is no more effective in changing behaviour than the total CVD risk assessment, communication, and follow-up in highly educated adults. Highly educated adults might have enough benefit from screening only.

Different reasons could have led to the lack of difference between the control and intervention condition in the present study. Most importantly, the **control condition** of the present study was no "no-intervention" control condition. In fact, it even cannot be seen as a "usual" care condition because the European guidelines for CVD prevention were strictly followed and this is not the case in primary care at present (11). Thus, it can be concluded that the control condition with risk assessment, communication, and follow-up was an improved quality of care condition. In an intervention where the tailored feedback from the present study was used but with a waiting-list control condition, there was a favourable effect on physical activity and fat intake (12). Furthermore, the latter study was conducted under lab conditions but when implemented in a real life setting, the effects seemed to disappear. In a study of Spittaels et al. (2006), where a control condition with generic physical activity advice was included, the same advice was no more effective in changing physical activity than the control condition (10). Nevertheless, when a "no-intervention" control condition was chosen by Spittaels et al. (2007), the intervention was effective in changing physical activity (13). In other studies, where a practice nurse performed a risk assessment in both the control and intervention condition, this shared aspect

was considered as a factor that impeded the effect of the intervention (14, 15).

Thirdly, the shared emphasis on medical and behavioural risk factors might have given the participants the inaccurate idea that when their CVD risk was low, they had no further reason to make lifestyle changes. About 70% of the participants in this trial were told that they had a low risk on CVD. Perhaps they felt relieved that they were not referred for medical treatment like some of their colleagues and were satisfied with their risk score. The **motivation to make lifestyle changes** might have decreased. Participants could have been subject to an "unrealistic optimism" with regard to risk perception. Vanderweijden et al. (2008) gave an example of a statement of an unrealistic optimist: "Well, I mean, if your cholesterol is OK it means there's no risk of cardiovascular disease, isn't that right?" (16). If a moderate or high risk was found, referral to the GP was made in the printed profile the participants received by post. Not being referred might have given the low risk participants a feeling of safety.

One may consider that the **sample size was too low** to find significant differences between the study conditions. However, a power calculation was performed and for 80% power we would need 98 participants in the control condition and 196 participants in the intervention condition to find a relevant difference for fat intake between the conditions. For physical activity, the needed sample size would be 84 in the control and 168 in the intervention condition. After 6 months, the number of participants was 84 in the control condition and 168 in the intervention condition. In this case, the power to detect a significant difference for fat intake was 73% and for physical activity this was 80%. At 12 months, drop-out led to 72 participants in the control condition and 147 participants in the intervention condition. In this case, the power to detect a significant difference for fat intake was 67% for fat intake and 74% for physical activity. At 24 months, 61 and 135 participants still took part in the study, lowering the power to detect a significant difference for fat intake to 61% and for physical activity to 68%. So, even if the drop-out in the present study was low in comparison to other studies, the sample size could have been too low to detect significant differences in the second and third year of the study.

Furthermore, the present study included a very **specific sample** consisting of highly educated and mostly male participants. In the studies of Vandelanotte et al. (2005) where the effectiveness of the tailored advice also used in the present study was confirmed, the sample had different characteristics than the sample used in this thesis (12). For instance, in our sample 67% was male compared to 36% of the participants in the sample of Vandelanotte et al. (2005) where similar feedback as ours was found to be effective (12). Wendel-Vos et al. (2009) also found no meaningful differences in a male sample after a large CVD prevention project (17). Moreover, one might think that the baseline characteristics of the sample

used in this study were already favourable because it were highly educated adults. The hypothesis could be made that a ceiling effect might have caused the lack of interaction effects on behaviour. However, comparing our baseline data gathered with the questionnaires for physical activity and fat intake they were not more favourable than population samples. For physical activity, we found a mean value of 350 minutes per week for total physical activity. This is lower than the mean values reported in other studies, for instance, Vandelanotte et al. (2005) reported a mean value of 569 minutes per week in a population sample (12). For fat intake our mean value at baseline was 106 grams of fat per day; this is comparable to the mean values in other studies (12). It is unlikely that a ceiling effect is responsible for the lack of effect on behaviour. Furthermore, the time effects described above showed that improvements for both conditions were found. This is also contradictory to the ceiling effect hypothesis. The improvement of both conditions might have been due to the medical interventions only or because of a self-selection bias. Perhaps the participants that enrolled in the study might have already been very motivated to make lifestyle changes (10).

Next, it might have been possible that the intervention had **no effect on determinants of behaviour**. There are limited numbers of variables that need to be considered in order to predict, understand, change, or reinforce a given behaviour. These major variables are intention, attitude, perceived norms, self-efficacy or perceived behavioural control, behavioural beliefs (which are often referred to as cost-benefits or outcome expectancies), normative beliefs, and control beliefs (18). The intervention may have increased perceived and objective knowledge but no other determinants of behaviour as was found in previous studies (19). Nevertheless, our findings of the theory testing study after 12 months were inconsistent with this hypothesis (Chapter 7). In this study, effects of intervention intensity on self-efficacy of dietary behaviours and interaction effects with intervention intensity on intention for physical activity were found.

Furthermore, the **computer-tailored intervention might have been unsuccessful** in changing behaviour on itself. Kroeze et al. (2006) performed a review on the effectiveness of computer-tailored education on physical activity and dietary behaviours (20). They concluded that the evidence for computer-tailored nutrition education (especially for fat intake) is quite strong but that the effect sizes are fairly small. For physical computer-tailored interventions, no conclusion was drawn. Krebs et al. (2010) confirmed that the effect sizes of computer-tailored interventions decrease over time or failed to invoke effects on behaviour as well (4, 10, 14, 21, 22).

Next, the **intervention dose or intervention exposure** might have been too low. For instance, the tailored physical activity feedback and the tailored fat intake feedback that were effective in other studies were only read by 51% and 56% of the participants in the present trial, respectively (12).

Krebs et al. (2010) mentioned that, on the long-term (13 months or more), dynamic tailoring (multiple contacts) is more effective than static tailoring (4). In this review, the effect size increased by multiple contacts. The impact of an intervention depends on the efficacy of and the exposure to the intervention materials. The self-selected intervention dose might have led some participants to under use the individually tailored behaviour change programme limiting the intervention effectiveness. This is supported by the dose-response effects that were found in the present study after 6 and 12 months. Greaves et al. (2011) performed a systematic review on the intervention components associated with increased effectiveness of dietary and physical activity interventions (23). However, the included studies involved samples at risk of type 2 diabetes, the results are valuable in the context of our study given the correspondence of risk factors for type 2 diabetes and CVD. The authors stated that greater intervention effectiveness was associated with a higher frequency of contacts or contact time. However, the amount of clinical contact in the included studies varied widely. The range of the frequency was 1-80 sessions and the duration ranged from 15-150 minutes over periods ranging from 1-2 years. After 1 year, in the present thesis, the median frequency of contacts was 39 and the total median contact time was 283 minutes. Today, the evidence does not support the recommendation of a minimal threshold (23). However, Michie et al. (2009) concluded that the target behaviour and many design characteristics such as duration and use of multiple sessions did not distinguish between effective and ineffective dietary and physical activity interventions (24).

Because of the disease and cost burden of many diseases caused by multiple health behaviours, interventions targeting multiple behaviours are seen as the future of preventive medicine (25). Nevertheless, **participants might have been overwhelmed** by the many components of the interventions and the many **choice options** (target behaviour(s), intervention dose, and delivery mode). In this study the target behaviours that could be worked on were physical activity, fat intake, and smoking. There is evidence that targeting different and multiple behaviours simultaneously increases intervention effectiveness (4, 12). However, Vandelanotte et al. (2005) also state that intervening simultaneously on three or more behaviours can create an overload of information in participants but should be further examined (12). If people feel overwhelmed they might return to their unhealthy lifestyle. Krebs et al. (2010) reported a positive trend between effectiveness and number of behaviours targeted but this trend did not continue when four behaviours were targeted. However, a limited number of studies have directly compared a single to a multiple behaviour interventions (26). Indeed, in spite of the potential benefits of multiple health behaviour interventions some obstacles exist (26). A recent meta-review on the effect of single versus multiple behaviour interventions pointed out that single behaviour interventions were more effective in promoting physical activity

and changing dietary behaviour (26). The authors from the meta-review state that multiple health behaviour interventions could result in small, non-significant improvements in health behaviours, leading to the conclusion that multiple health behaviours are not effective. However, these small improvements may lead to significant weight loss (26). Furthermore, the three behaviours targeted in the present study belong to different behavioural clusters (27). Perhaps the combination of behaviours from different clusters impedes the intervention effectiveness. Nevertheless, there are interventions wherein targeting three behaviours did not lead to a lack of effect on all behaviours. For instance, in interventions where physical activity, fat intake and smoking were targeted no effects on smoking were found but favourable effects on the other behaviours were reported (28-30). The opposite did also occur, interventions with an effect on smoking but not on physical activity or nutrition (21). Thus, the results in the literature are mixed. Despite these mixed results, we feel that the present intervention might have overwhelmed the participants causing the lack of intervention effect. This because of the many choice options presented to them with regard to the target behaviour(s), the self-selected intervention dose and delivery mode. Possible future solutions may be to use a fixed intervention dose and a limited number of fixed delivery modes that have been proven to be good combinations.

2.3. Economic evaluations: Cost-effectiveness and Willingness to pay

Next to an evaluation of the effectiveness of an intervention, an economic evaluation can be performed. In the next paragraphs the results of the cost-utility analysis of the individually tailored behaviour change programme is described followed by a description of the willingness to pay study. Information from economic evaluations is needed for evidence-based decision making.

A **cost-utility analysis** (CUA) is a specific type of cost-effectiveness analysis using quality-adjusted life years (QALYs) as consequences (31). A cost-utility analysis relates the difference in costs (cost intervention-cost control condition) over the difference in consequences (effect intervention-effect control condition). The outcome measure is the result of this ratio and is described as the incremental effectiveness ratio (ICER). According to CUA, an intervention is cost-effective if the ICER is below a pre-determined threshold. The individually tailored behaviour change programme was cost-effective compared to the control condition (Chapter 11). The costs for the participants in the control condition equalled €12,576. These costs include costs for the total CVD risk assessment, communication, and follow-up consultations for participants with an increased CVD risk. The costs for the participants in the intervention condition were €114,782. The costs of the control condition equalled €136 per person per year and of the intervention

condition these costs equalled €568 per year. The mean incremental cost of the intervention condition (tailored behaviour change programme) was €433 per participant. After 12 months, an intermediate cost-utility analysis was performed that resulted in an **ICER of €26,910**. The cost-effectiveness of an intervention, of course, depends on the ceiling of inversion used. The cut off value was set at €30,000 per QALY. In case of a large scale implementation the ICER would drop to €7,402 per QALY making it highly cost-effective. Moreover, the intervention from the present study was cost-effective even with the inclusion of the developmental costs. The results from the present study are important given the lack of economic evaluation of more innovative behaviour change interventions with or without computer-tailoring (32-37). In the study of Ronckers et al. (2007) on the cost-effectiveness of Hartslag Limburg an ICER of €12,500 per yols was found (38). This ICER was also below a predetermined threshold of €18,000. The authors concluded that a community programme for CVD prevention was cost-effective. Findings form other studies corroborate these results (34, 35). In the study of van Keulen et al. (2010) lower ICERs were found than in the present study (32). These authors compared 4 study conditions: one with tailored printed communication (TPC), one with telephone motivational interviewing (TMI), one condition with TPC and TMI and a waiting list control condition. The control condition was most cost-effective and then the TPC condition with an ICER of €2,851. This is much lower than the ICER of the present thesis. However, there were a number of costs that were included in our economic evaluation and not in that of van Keulen et al. (2010). The latter authors have only included the implementation costs while in our study also the developmental costs were included. Furthermore, the medical interventions of both conditions were included. The difference in outcomes was larger in the study of van Keulen, namely 0.02 QALY differences. In our study this was 0.016. This difference in effect might be due to the inclusion of a less healthy and lower educated sample in the study of van Keulen et al. (2010) (32). About half of their participants suffered from hypertension, were female and had a lower education (32). Also in a study of Sevick et al. (2007) a print intervention was more cost-effective than a telephone intervention (33).

One may wonder how an intervention that was no more effective than medical risk assessment only can be cost-effective. Firstly, one of the explanations is that different outcome measures are used in the effectiveness analyses and the cost-utility analyses. In the effectiveness analyses medical outcomes (e.g., blood pressure) and behavioural outcomes (e.g., physical activity, composite lifestyle change score) are evaluated. For a cost-utility analyses a ratio is used as an outcome measure, the ICER, mentioned above, consists of a difference in costs divided by a difference in effects, the latter expressed in QALYs. In our study there was a difference in QALYs in favour of the intervention condition. The QALYs that were gained

by the control condition were 0.774, and for the intervention condition this was 0.758 (t=-1.287,df=217,p=.200). This was no statistically different result between both study conditions as well. In fact, this outcome was consistent with the lack of differences for the medical risk factors, risk behaviours and composite lifestyle change score. This difference in QALYs (0,016) is low, and because of the lack of statistical significance, we are not sure that it is due to the intervention. Nevertheless, a cost-utility analysis using this difference in QALYs as a denominator was performed. Other authors with similar differences (e.g., 0.011 QALY difference) in QALYs have performed cost-utility analyses too. Furthermore, it is unlikely for people with already high QALY or utility values that these figures increased by chance. The baseline utility values were already very high compared to values in samples of other studies (e.g., 0.77 versus 0.69). When calculating the ICER using this difference the intervention is considered to be cost-effective using a ceiling of investment of €30,000 per QALY. However, this is an arbitrary ceiling of investment since in Belgium, no threshold for exists.

A **willingness to pay (WTP) analysis** is performed to determine the consequences of an intervention in monetary terms (Chapter 11) (31). The WTP analysis showed that there was no difference between the control condition and the intervention condition with regard to the WTP for the received services. In general, there is no difference between what participants in our sample are willing to spend on primary prevention interventions. Generally, they were not willing to pay extra for an individually tailored behaviour change programme. The costs of the control condition equalled €136 per person per year and of the intervention condition these costs equalled €568 per year. The median amount the participants allocated to the control condition were willing to pay was €45 per year so they are willing to cover for one third of the actual costs. The median WTP was €45 per year. However, taking into account the different dose groups, the median WTP for the highest dose group increases to €182, also being 1/3 of the actual costs of the intervention condition. This is important information for decision makers. It means that when interventions like PreCardio would be introduced on the market the out-of-pocket cost of the interventions for highly educated people could be set at one third of the cost of the health promotion programme. The other costs could be covered by public-private partnerships, insurance companies or the government (European, national and regional funding). The WTP gives information for a cost benefit analysis (CBA) and this analysis, on its turn, reveals whether a programme on itself is worthwhile. This by subtracting the costs of the interventions from the benefits of the interventions (both in monetary terms). The individually tailored behaviour change programme is not worthwhile on itself.

3. Secondary findings

3.1. Step test validation

One of the strengths of this thesis is the validation of an objective measure for physical fitness. A simple step test was used to estimate VO_{2max}, a measure for physical fitness, in healthy individuals (Chapter 3). In contrast to most validation studies this study included a representative population sample. Most previous step test validation studies were limited by small sample sizes (mostly 50 subjects or less) (39-44), inclusion of non-representative samples (college students or subjects ≥ 65 years (43-48) or patient samples (49-52)) and/or lack of data on VO_{2max} (41, 53). The conclusion of this chapter was that the step test is a valid instrument to assess physical fitness in a population sample. This can be of interest in the light of epidemiological or intervention studies using exercise on prescription programmes.

3.2. Website usage

Seventy-five percent of the participants of the intervention condition logged on to the tailored behaviour change website (Chapter 5). A decrease of the number of log ons was found in the first 26 weeks of the intervention. This is consistent with the literature were most authors reported log-on rates and percentages of continued use, showing a decline over time (54, 55). The actual reach of and exposure to Internet-delivered interventions is not in line with the expectations (10, 56, 57). Twenty-five percent of the people who logged on to the website only visited the homepage and 51% and 56% consulted the physical activity and fat intake feedback, respectively. About half of the participants were exposed to the tailored advice for physical activity and fat intake. Brouwer et al. (2008) looked at factors related to exposure to Internet-delivered behaviour change interventions (58). These factors include motivation, personal relevance, tailored feedback on the website, clear information, provision of new content and reminders. In the present thesis reminders sent by e-mail and regular mail indeed caused an increase of log on rates, even around week 23 and week 25. The median surfing depth was 2 (2 extra clicks after the home page). Less than 10% of the participants made four extra clicks or more. Surfing depth did not predict behaviour change (Chapter 5).

3.3. Costs of the Electronic Prevention Programme

The implementation costs of the Electronic Prevention Programme (EPP) in general practice were studied (Chapter 10). The EPP was successfully installed in general practice and the implementation costs were mainly driven by personnel costs (93%) for giving installation support and organising group education sessions. The costs to participants mainly consisted of the time of the general practitioners taking part in the group

education session (82%). The use of user-friendly electronic support tools in general practice can help general practitioners to overcome barriers to follow CVD prevention guidelines such as lack of time (11).

4. Strengths and limitations

The PreCardio study has a number of valuable assets that contribute to the existing literature on health promotion.

1. Firstly, it is a **randomised controlled trial** of an intervention that is completely based on the European guidelines for CVD prevention. Thus a mixed population (low, medium, and high CVD risk) was selected in line with the advice to target the general population, also including people at low CVD risk. Two paths were followed aimed at reducing medical as well as behavioural risk factors for CVD.
2. Secondly, it includes two **E-health components**. One of these components was to support the GP, namely an Electronic Prevention Programme (EPP). Support of the GP, the patient and shared decision making was put forward by the implementation model presented in Chapter 2. The E-health intervention for the participants was a tailored behaviour change website. The Internet can be a valuable delivery mode for behaviour change interventions but these interventions have small effect sizes and engagement and retention are important challenges in E-health studies (13, 59). Because of these drawbacks and the fact that Internet-delivered are not always preferred above other modes, the participants could freely opt for other additional delivery modes for the one-on-one coaching (6).
3. This is, to our knowledge, the first trial that considered the effects of **different delivery modes** in different behavioural contexts. Additional delivery modes increase the effectiveness of others; different modes can reinforce one another (59).
4. Furthermore, the present study evaluated the effects of the intervention on **multiple behaviours** on the short- and long-term (6, 12, and 24 months). Targeting multiple behaviours simultaneously was advised by prior research and is believed to be more cost-effective than single behaviour interventions but this has not been proven yet (4, 12).
5. Next, this is one of the first trials where the evaluations of behavioural effects and economic aspects such as **cost-effectiveness and willingness to pay** are studied at the same time. This was possible through prospective cost registration. However, cost-effectiveness analyses are often not performed in other studies because of additional time investments to perform an economic evaluation alongside a trial (31).

6. One of the positive aspects of the present study is the emphasis on **dose-response analyses**. This aspect was given special attention because the participants could determine their own intervention dose at the start of the study. It was thus a self-selected intervention dose in terms of frequency or duration. Direct effects of the intervention dose were found at 6 and 12 months post baseline.
7. Next to the focus on the delivery mode and the dose of the intervention most importantly we have included different **behaviour change techniques** and developed the intervention in line with the recommendations for planned health education (60). Behaviour change techniques with proven effectiveness in other trials have been applied (e.g. self-monitoring of behaviour was advised on the website in combination with goal-setting exercises) (24). The theory-based nature of the intervention is extra visible in the modelling study of the theoretically integrated TPB-SDT model on which the individually tailored behaviour change programme is based.
8. The **drop-out rates** in PreCardio are low, despite the high number of males in the study. The drop-out rates in the intervention study of this thesis were 20% after 6 months, 30% after 12 months, and 38% after 24 months. This is a good result in comparison with other studies were a drop-out rate of 34% was already reached after 6 months (13, 61). The efforts that were made to maintain collaboration with the study were significant (e.g., telephone calls or visits for people to fill in questionnaires).
9. Lastly, the literature includes advices to try out new methods such as using an **overarching measure of change**, giving information about multiple behaviours in a single measure (26). This is exactly why, at 12 months, we have developed the composite lifestyle change score as an outcome measure.

There are a number of limitations or methodological considerations that deserve some attention as well.

1. Firstly, a very **specific sample of adults** was included. It considered an overall healthy sample, mostly male and highly educated. Therefore, we do not intend to generalise to the general population, only to the highly educated. In fact, in a number of comparable studies 70-75% of the participants were also highly educated (12, 62).
2. The fact that participants could determine their own delivery mode and intervention dose may have thwarted the potential effectiveness of the intervention. The actual **exposure to the different intervention components** was beyond our control. It was a new approach, in line with SDT, to let the participants freely determine their own intervention dose at baseline. However, this led to people under using the programme. A considerable part of the study participants did not select

anything from the behaviour change programme. This limited the potential effectiveness of the intervention. Therefore, we deviated from the original protocol for the behaviour change programme in the second intervention year. In this second stage, the dose of the individual coaching was fixed to 10 messages that were sent by regular mail or e-mail. Of course, this deviation from the original protocol further complicates the interpretation of the findings with regard to behaviour change after 24 months.

3. Next, it was a **complex behaviour change intervention** with many different components. This limits the interpretation of the findings for we do not know what the most important components of the intervention are. Furthermore, the more complex the intervention, the lower the reproducibility of the findings although this can be solved by a careful description of the intervention. Michie et al. (2009) provided a framework for describing important elements of an intervention (63). One should clearly describe the following: the content or elements of the intervention (techniques), characteristics of those delivering the intervention, characteristics of the recipients, characteristics of the setting, the delivery mode, the intensity, the duration and the adherence to delivery protocols. Most of these aspects were described in Chapter 2, however, the last 4 aspects are problematic to depict because of the self-selection of multiple intervention aspects (delivery mode and intervention dose).
4. Most outcome measures in the present thesis were **self-report measures**. Despite the fact that only validated questionnaires were used, these instruments are prone to response biases (e.g., over reporting on the IPAQ) (64). Using objective measures can be advantageous in behaviour research. In the present thesis an effort was made to use objective measures: a step test to measure physical fitness was successfully validated and found to be a reliable measure for physical fitness.
5. Next, it might be that the intervention lacked effect because students in sports and nutrition education assisted a health psychologist in the delivery of the coaching. Perhaps the inclusion of trained and licensed dieticians and personal trainers would have increased the intervention effectiveness.
6. Lastly, the **sample size might have been too low** to find significant differences between the study conditions. The power was 80% at the start but due to drop-out this decreased to 61% for fat intake at 24 months. It was higher for physical activity at 24 months, namely 68%. Nevertheless, this amount of drop-out should have been foreseen and a larger sample should have been selected.

5. Directions for future research

There are, considering the present study and its research questions, 4 areas of research that that can be further explored.

1. Fundamental research
   Fundamental research looks in detail at intervention aspects using an experimental design. Some aspects that were interesting to look at in the present study deserve further attention in future research. The following topics could be explored by controlled designs:
   - In the present thesis a multibehavioural intervention was evaluated. It is believed that multibehavioural interventions might be more effective and cost-effective than single behaviour interventions, but this has not been proven yet. In the total CVD risk assessment, communication, and follow-up condition the medical parameters are considered and with regard to these medical risk factors all lifestyle behaviours are relevant. From the CVD prevention perspective, multibehavioural interventions seem to be more beneficial because of the potential effect on total CVD risk. To be sure of the superiority of multibehavioural interventions, a direct comparison between single and multiple behaviour interventions is needed. Furthermore, researchers should distinguish between behaviours from the same or different behavioural clusters and between simultaneously or sequentially offered interventions (26, 27, 65). This line of research could give more insight into the co-variation of behaviour instead of the co-occurrence of behaviour.
   - In the present thesis, different delivery modes could be selected by the participants. This self-selection of delivery modes led to many different combinations of modes. The study described in Chapter 4 from this thesis showed that Internet and e-mail delivered interventions had a positive effect on physical activity and that face-to-face contacts were important to change dietary behaviours. To confirm these results and to get a clearer picture of the delivery modes that reinforce each other, direct comparison of different delivery modes is necessary. For Internet-delivered interventions, behaviour change can further be supported by personal contact via email, online, or text-messages (59). The study on website use learnt that e-mail was effective in intensifying website use.
   - A strength of the present study was the self-selected intervention dose. This freedom with regard to the intervention intensity was given to the participants based on

the recommendations from SDT. The studies from the present thesis showed that a higher dose led to more effects and also to a greater willingness to pay (Chapters 4, 6, 7, 11). Nevertheless, the studies from this thesis do not give information on a minimal threshold for the intervention dose in order to change behaviour. Therefore, a direct comparison of different intervention dose conditions using a randomised design is needed (66).

- The behaviour change programme of the present study influenced determinants of behaviour (Chapter 7). Nevertheless, we do not know which component of the intervention provoked this change. We need more information about the exact components of interventions that change behaviour and behavioural determinants. Behaviour change theories do not tell us how we can change or reinforce the beliefs that underlie the distal predictors of behaviour (18). This is defined as the "technology problem" in the Theory of Planned Behaviour (TPB) (67).

2. Internet-delivered interventions
   The study described in Chapter 5 showed that the website use declined over time and hereby underwrites the difficulties and challenges encountered with Internet-delivered interventions. Despite the advantages (high potential reach, low costs, interactivity) of using the Internet as a delivery mode, the actual exposure to the content is low (10, 68). The future challenge for researchers is to explore those factors that improve exposure rates of Internet-delivered interventions. Brouwer et al. (2008) performed a Delphi study identifying factors that enhance these rates but more extensive and applied research is needed on this topic (58). Furthermore, Internet- or computer-delivered interventions are not preferred by everyone as an ideal delivery mode. For instance, in a study of Kroeze et al. (2008) directly comparing computer-delivered and print-delivered tailored information, people with lower and higher education levels read the print-delivered material more often than the computer-delivered material.
3. Input for policy making: outcome measures and economic evaluation
   One should be aware that if health promotion interventions need to be translated into practice, policy makers become involved and they need the necessary input for fast decision-making. The reporting of behaviour change interventions can contribute to the translation of evidence into practice.
   - In prior research, it was concluded that it is important for multiple behaviour change interventions to find a way of communicating the complete behaviour change effect (25).

Investigation of overarching change scores for multiple behaviour interventions was advised in a more recent study as well (26). In the present thesis Chapter 6 includes a composite lifestyle change score as an outcome measure. More research is needed to examine the best ways to construct these kinds of composite scores.

- Performing health economic evaluations alongside health promotion trials is the best way to provide input for policy making. In the present thesis, a cost-utility analysis was described that was performed alongside the trial (Chapter 10). The present thesis showed that it is feasible to perform an effectiveness and cost-effectiveness analyses alongside a behaviour change intervention. Hopefully this can become a standard procedure so that every study on behaviour change will be informative for policy-making. Furthermore, these economic evaluations can also include a modelling technique to capture all the costs that are saved by the intervention on the long-term. A willingness to pay study gives insight to policy makers and stakeholders of health promotion interventions, more specifically on the amount of money that can be paid out-of-pocket by the users of the intervention.

4. Implementation

The individual effectiveness of the individually tailored behaviour change programme or the complete PreCardio intervention should be examined using a mere and no-intervention control condition before it can be implemented into practice. If PreCardio would be effective when compared to a no-intervention control condition, it can be implemented for highly educated adults. The programme could be valuable to other population subgroups as well, like a comparable programme, "Hartslag Limburg", but this needs to be examined (17). When implementation comes up for discussion, the programme should be transferred to practice using an evaluation model of dissemination and diffusion such as the Diffusion of Innovation model or the RE-AIM framework (69, 70). Dissemination is considered as conscious efforts to increase awareness of the programme and spread new knowledge, policies or practices to specific target groups or to a public at large (e.g., through interpersonal communication health education of the public and education of professionals) (71). Diffusion is the direct or indirect outcome of formal dissemination strategies. The RE-AIM framework assesses the reach, effectiveness, adoption, implementation as intended, and maintenance of a project in order to estimate the public health impact (70). Examples of dissemination strategies can

be found in the literature. For instance, the whole-community project '10,000 Steps' included the following strategies: sale and loan of pedometers (via sports services), website of 10,000 steps Ghent, promotion of physical activity and distribution of folders through GPs, dieticians, physical therapists and posters in schools and public places. The former strategies were the strategies at the intrapersonal and interpersonal level; at the policy level there were partnerships between the local city and the provincial government, health insurance companies, and the local health promotion service.

6. Recommendations for practice

A number of recommendations for practice can be made based on the present thesis.

1. Organise screening events to change medical risk factors and risk behaviours for CVD (*multiple risk factor management*). From the results of the present study the tailored behaviour change programme did not change behaviour more than the control condition of CVD risk assessment, communication and follow-up. The screening event and distribution of the printed risk profile might have been sufficient to change behaviour. It seems that "less is more". This might be explained by the fact that screening on itself can increase the awareness and the risk perception of highly educated adults motivating them to change their behaviour. Organising screening events in the primary care setting might be a good alternative to reach the less educated or minority groups. This aim can hardly be reached by computer-tailored interventions that have a high reach but seem to attract mainly highly educated and female subgroups of the population.
2. From the willingness to pay analysis of the present thesis we learn that participants were willing to pay one third of the costs of the total CVD risk assessment, communication, and follow-up condition. The screening can be organised while one third of the costs can be directly refunded by subscription rates of the participants. This means that two thirds of the screening have to be paid by other stakeholders (e.g., health care insurers or companies).
3. The behaviour change programme can be offered as an extended intervention to the people at medium or high risk for CVD or people that are willing to pay for this extra service. The dose-response effects that were found in the present study showed that more use or exposure to the intervention increased the effectiveness and the willingness to pay. People that opted for a high dose of the behaviour change programme were also willing to pay one third of the total costs of the more expensive 'combined' PreCardio prevention programme. People do not want to pay for the 'combined' programme by default.

4. Future CVD prevention programmes ideally include a computer-tailored intervention since the tailored physical activity feedback had a positive effect on physical activity. When a website is used it is advocated to construct the website with a maximum of 2 layers since the median surfing depth was two. Newspaper websites are excellent examples of how this type of website can be developed in practice. Next, other delivery channels should be used to stimulate use and exposure to the website content. From this thesis it became clear that e-mail and regular mail were effective in stimulating website use.
5. A mixed population should be targeted by health promotion interventions. The meaning is not to exclude population subgroups from health promotion initiatives but to determine which intervention is effective and cost-effective for which population (or who is willing to pay extra, see recommendation 3).
6. Involve general practitioners in the follow-up of patients after the screening event. In the present thesis, an Electronic Prevention Programme was introduced that the general practitioner could use for adequate CVD risk factor management in general practice.
7. Implementation of the PreCardio 'combined' programme with screening and the individually tailored behaviour change programme shouldn't be implemented at this point. It should be compared to a no-intervention control condition and if it is effective in that case, it can be disseminated.

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