The Karolinska Institutet, Department of Medicine
Cardiology Unit, Karolinska University Hospital
Stockholm, Sweden

Effects of a Structured Lifestyle Program for Individuals with High Cardiovascular Risk

by

Matthias Lidin

Karolinska Institutet

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To my Mother –Till min Mamma

"If the person you are talking to doesn't appear to be listening, be patient.
It may simply be that he has a small piece of fluff in his ear"
Winnie the Pooh (A. A. Milne)

An ounce of prevention is
worth a pound of cure
Benjamin Franklin

From Karolinska Institutet, Department of Medicine
Cardiology Unit, Stockholm, Sweden

Effects of a Structured Lifestyle Program for Individuals with High Cardiovascular Risk

by
Matthias Lidin

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Huvudhandledare: Professor Mai-Lis Hellénius Institutionen för medicin Solna, Karolinska Institutet, Stockholm *Bihandledare:* Med Dr Monica Rydell-Karlsson Institutionen för kliniska vetenskaper, Danderyds Sjukhus, Karolinska Institutet, Stockholm Med Dr Elin Ekblom-Bak Gymnasik och Idrottshögskolan, Stockholm	*Fakultetsopponent:* Docent Patrik Wennberg Institutionen för folkhälsa och klinisk medicin, Umeå Universitet, Umeå *Betygsnämnd:* Docent Margareta Norberg Institutitionen för folkhälsa och klinisk medicin, Umeå Universitet, Umeå Professor Unn-Britt Johansson Institutionen för klinisk forskning och utbildning Södersjukhuset, Karolinska Institutet, Stockholm Professor Tomas Jernberg Institutionen för kliniska vetenskaper, Danderyds Sjukhus, Karolinska Institutet, Stockholm

CONTENTS

ABSTRACT

Cardiovascular disease (CVD) is the leading cause of death in Sweden as well as in the rest of the world. CVD is mainly caused by unhealthy lifestyle habits and lifestyle-related risk factors. National and international guidelines for the prevention and treatment of CVD highlight the importance of implementing preventive programs, with focus on lifestyle changes, in clinical practice. However, scientific evaluations of such programs are still sparse.

Aims

To evaluate a structured lifestyle program in individuals with high cardiovascular risk by investigating:

- effects on lifestyle habits and quality of life
- effects on cardiovascular risk factors and cardiovascular risk
- participants' experiences
- the influence of educational level based on university degree or not and living in different socio-economic areas

Methods

The lifestyle intervention program was launched at a department of cardiology. Patients with increased cardiovascular risk, with or without pre-existing CVD, were referred to the program by physicians in primary health care or at hospitals. The program had a multidisciplinary approach with three individual visits to a nurse at baseline, after six months and one year, for a health check-up (physical examination and blood sampling) and person-centred lifestyle counselling. The program also comprised five group educational sessions with a physician and a nurse covering: nicotine, alcohol, physical activity, food habits, stress, sleeping habits, and behavioural change. Lifestyle habits and quality of life were assessed by questionnaires, the changes in cardiovascular risk factors and cardiovascular risk were measured at each of the three health check-ups, and participants' experiences were investigated through structured interviews.

Results

One hundred participants (64 women, age 58±11 years) were enrolled between 2008 and 2014. Significant and favourable changes in lifestyle habits were observed after one year. Exercise levels increased, and sedentary time decreased. The participants' food habits improved and the number with a high consumption of alcohol decreased. Significant improvements in quality of life were noted after one year. Favourable changes in cardiovascular risk factors, such as waist circumference, systolic and diastolic blood pressure and total cholesterol were noted. In parallel, cardiovascular risk, according to the cardiovascular risk profile based on the Framingham 10-year risk prediction model, decreased by 15%. The risk reduction was seen in both men and women, and in participants with or without previous cardiovascular disease. Educational level based on univeristy degree or not and the socioeconomic area of residence, were not barriers for the capability to change lifestyle habits and decrease cardiovascular risk over one year.

From interviews with fifteen participants (13 women, age 58±9 years), three categories of experiences were noted: *"How to know*" - based on both individual counselling and group sessions, with focus on health-related tools to strengthen self-care, an individual visit with shared goal setting, group educational sessions with interactive discussions ;*"Staff who know how*" - the meeting and the importance of competent, well-educated and respectful health professionals who give continuous feedback, and *"Why feedback is essential"* - the participants' views on, and effects of, feedback to support self-care at home between visits.

Conclusion

It was possible to launch a structured, multidisciplinary lifestyle program at a cardiology unit for individuals at high cardiovascular risk. Improvements in several lifestyle habits, quality of life, multiple CVD risk factors, reduced cardiovascular risk in both men and women as well as in participants with or without CVD, were observed after one year. Educational level and living in different socioeconomic areas did not seem to have any major influence on the capability to change lifestyle habits and decrease cardiovascular risk. Also, they did not influence the changes in quality of life following the lifestyle intervention program. Three different categories about the structure, staff and feed-back based on experiences of the lifestyle program were noted among the participants.

SAMMANFATTNING

Hjärt- och kärlsjukdomar är den främsta dödsorsaken i Sverige och i övriga världen. Dessa sjukdomar orsakas främst av ohälsosamma levnadsvanor och livsstilsrelaterade riskfaktorer. Nationella och internationella riktlinjer för förebyggande och behandling av hjärt- och kärlsjukdomar lyfter fram vikten av förebyggande program med inriktning på livsstilsförändringar i hälso- och sjukvården. Vetenskapliga utvärderingar av sådana program är fortfarande få och efterlyses.

Syfte

Att utvärdera ett strukturerat livsstilsprogram hos personer med hög kardiovaskulär risk genom att undersöka

• effekter på levnadsvanor och livskvalitet

• effekter på kardiovaskulära riskfaktorer och kardiovaskulär risk

• deltagarens erfarenheter av det strukturerade programmet efter 1 år

• betydelsen av utbildningsnivå och boende i olika socioekonomiska områden

Metod

Programmet startades på en kardiologisk enhet år 2008 med inriktning för personer med ökad hjärt- och kärlrisk. Deltagarna remitterades till programmet av läkare från både primärvård och slutenvård.

Programmet karakteriserades av ett multiprofessionellt arbetssätt med tre individuella besök hos en sjuksköterska vid start, efter sex månader och ett år för hälsokontroll och ett samtal baserat på personcentrerad livsstilsrådgivning. Hälsokontrollen innefattade ifyllande av ett frågeformulär, kontroll av puls och blodtryck, midjemått, vikt och längd samt blodprover. Programmet innefattade också fem strukturerade gruppundervisningstillfällen tillsammans med en läkare och en sjuksköterska. I fokus var nikotin, alkohol, fysisk aktivitet, matvanor, stress, sömnvanor och beteendeförändringar.

Förändringar i levnadsvanor och livskvalitet utvärderades från validerade frågeformulär. Förändringar i kardiovaskulära riskfaktorer utvärderades utifrån vikt, midjemått, BMI (body mass index), blodtryck samt blodprover. Hjärt- och kärlrisk utvärderades med Framingham risk score. Förändringar i levnadsvanor, riskfaktorer, hjärt- och kärlrisk och livskvalitet studerades i relation till utbildningsnivå (baserat på universitetsutbildning eller ej) och socioekonomiskt boendeområde. Deltagarens egna erfarenheter av programmet undersöktes genom semistrukturerade intervjuer och analyserades med kvalitativ innehållsanalys.

Resultat

Ett hundra deltagare (64 kvinnor) med medelålder 58 år (± 11 år) inkluderades mellan 2008 och 2014. Positiva förändringar i levnadsvanor observerades efter ett år. Antalet rökare, alkoholintaget, och stillasittande tid minskade och motionerandet ökade. Deltagarnas matvanor förbättrades med ett ökat intag av grönsaker och frukt, en bättre fettkvalitet och mera fiberrikt bröd samt ett minskat intag av kött och extra kalorier. Livskvaliteten förbättrades.

Midjemåttet minskade, både systoliskt och diastoliskt blodtryck sjönk och total kolesterol minskade. Parallellt minskade den kardiovaskulära risken enligt den kardiovaskulära riskprofilen baserad på Framingham risk score med totalt 15 %.

Riskreduktionen sågs hos både män och kvinnor och hos deltagare med eller utan tidigare hjärt-kärlsjukdom.

Utbildningsnivå och att bo i socioekonomiskt utsatt bostadsområde var inget hinder för förmågan att förändra levnadsvanor och reducera kardiovaskulära riskfaktorer. I vissa avseenden sågs mer uttalade förbättringar hos individer med icke universitetsutbildning (minskat midjemått) samt hos dem som bodde i mer utsatta socioekonomiska områden (ökad fysisk aktivitet).

Från intervjuer med femton deltagare noterades tre kategorier gällande deltagarnas erfarenheter av programmet; "*Hur man vet"* - baserat på både individuell rådgivning och undervisning i gruppsessioner med fokus på livsstil. Hälsorelaterade verktyg var viktiga för deltagarna för att stärka förmågan till förbättrad egenvård mellan besöken, Deltagarna uppfattade ett individuellt besök possitivt med en sjuksköterska med individuell målsättning samt efterlyste fler interaktiva diskussioner i gruppundervisningen. Andra kategorin *"Personal som vet hur"* - mötet med och vikten av kompetent, välutbildad, påläst och respektfull sjukvårdspersonal som ger kontinuerlig feedback. Tredje kategorin *"Varför feedback är viktigt"* - deltagarnas syn på hur viktigt det var med kontinuerlig feedback för att få stöd hemma mellan besöken.

Slutsats

Det var möjligt att introducera ett strukturerat multiprofessionellt livsstilsprogram på en kardiologisk enhet för personer med hög kardiovaskulär risk. Positiva förändringar av levnadsvanor, livskvalitet, riskfaktorer och hjärt- och kärl risk sågs hos både män och kvinnor samt hos deltagare med eller utan tidigare hjärt- och kärlsjukdom efter ett år. Utbildningsnivå och att bo i olika utsatta socioekonomiska områden påverkade inte förmågan att förändra levnadsvanor och att minska hjärt- och kärlrisken. Det påverkade inte heller förändringarna i livskvalitet. Tre olika kategorier av erfarenheter av livsstilsprogrammet noterades bland deltagarna och ett individanpassat individuellt besök hos kompetent, respektfull sjukvårdspersonal som ger kontinuerlig feedback ansågs vara viktigt.

LIST OF ORIGINAL PAPERS

This thesis is based on the following articles, which will referred to by their roman numerals I-IV

I. Lidin M, Ekblom-Bak E, Rydell Karlsson M, Hellenius ML.

Long-term effects of a Swedish lifestyle intervention program on lifestyle habits and quality of life in people with increased cardiovascular risk.

Scandinavian journal of public health. 2018 aug,46(6)613-622. Eprint 2017dec 11.

II. Lidin M, Hellenius ML, Rydell Karlsson M, Ekblom-Bak E.

Long-term effects on cardiovascular risk of a structured multidisciplinary lifestyle program in clinical practice.

BMC cardiovascular disorders. 2018 apr 18 (1):59.

III. Lidin M, Hellénius M-L, Ekblom-Bak E, Rydell Karlsson M.

Experience of a lifestyle program in participants with high cardiovascular risk – a qualitative interview study.

Submitted manuscript

IV. Lidin M, Hellénius M-L, Rydell Karlsson M, Ekblom-Bak E.

Are educational level and socioeconomic area of residence associated with effects of a structured program on lifestyle habits, cardiovascular risk and quality of life among individuals with increased cardiovascular risk?

In manuscript

LIST OF ABBREVIATIONS

APO-A	Apolipoprotein A
APO- B	Apolipoprotein B
BMI	Body mass index
BP	Blood pressure
CI	Confidence interval
CVD	Cardiovascular disease
CV	Cardiovascular
DALYs	Disability-adjusted life year
DM	Diabetes mellitus
FYSS	Fysisk aktivitet i sjukdoms prevention och sjukdoms behandling eng: Physical activity in the prevention and treatment of disease
GBD	Global burden of disease
GQoL	Gothenburg quality of life
HADS	Hospital anxiety and depression scale
HDL	High density lipoprotein
HRQoL	Health-related quality of life
IPAQ	International physical activity questionnaire
ITT	Intention to treat
LDL	Low density lipoprotein
MetS	Metabolic syndrome
METs	Metabolic equivalent
MI	Myocardial infarction
NCD	Non-communicable disease
NEPA	Non-exercise physical activity
NNR	Nordic nutrition recommendations
PA	Physical activity
PAP	Physical activity on prescription
US	United States
Q	Quartile
QoL	Quality of life
RCT	Randomized controlled trial
SAD	Sagittal abdominal diameter
SCB	Statistiska centralbyrån
SD	Standard deviation
SEA	Socioeconomic area
WHO	World health organization
VIP	Västerbotten intervention program

BACKGROUND

Non-communicable diseases, such as cardiovascular disease (CVD), type 2 diabetes, and cancer, are leading causes of death worldwide (1, 2). Modifiable lifestyle habits, such as physical activity (PA), diet and smoking, are central in the aetiology of these diseases, and hence the first choice of treatment in cardiovascular prevention. In 2017, the main attributable risk factors for burden of disease in Sweden were almost all related to unhealthy lifestyle habits: unhealthy food habits, high BMI, tobacco and alcohol use, physical inactivity, high cholesterol and high fasting blood sugar (3-5). To counteract the increasing prevalence of non-communicable diseases internationally, a more aggressive approach against unhealthy lifestyle has to be applied. According to the World Health Organization (WHO), healthy lifestyle habits, combined with optimal medical treatment, could prevent 75% of all CVD in the world (6). Healthy food patterns, moderate physical activity, non-smoking lifestyle and a moderate consumption of alcohol can probably also prevent 30% of common cancers and increase life expectancy by approximately 15 years (7). Life expectancy in the world has increased by a mean of 5 years between 2000-2015, with the lifespan of women in Japan (mean: 86, 6 years) and men in Switzerland (mean: 81.3 years) topping the list. Still, there are large differences in life expectancy, with men and women from Sierra Leone having the shortest (mean: men 49.3 years and women: 50.8 years) (8).

There is still large socioeconomic diversity in many countries due to large inequalities in socioeconomic factors, such as education level, income, living in different residential areas (9).

According to WHO, the most important risk factors for heart disease and stroke are behavioural: unhealthy diet, physical inactivity, tobacco use and harmful use of alcohol. These factors may in turn lead to high blood pressure, raised blood glucose levels, raised blood lipids, and incraese the risk for overweight and obesity. WHO recommends that healthcare professionals should measure these types of risk factor, and support individuals with unhealthy lifestyle habits to lifestyle changes.WHO also emphasise the importance of every country having health policies that create environments conducive to making affordable, healthy choices, thus motivating people to adopt and sustain healthy behaviour (10).

There is strong evidence for the role of lifestyle changes in prevention and treatment of these diseases (11, 12), and guidelines emphasise the importance of lifestyle interventions as a first treatment (12). However, there is still a large discrepancy between the evidence for, and the implementation of, lifestyle interventions in disease prevention.

Repeated cross-sectional studies between 1995 and 2007, in large cohorts from 22 European countries (EUROASPIRE I, II and III), still demonstrate high levels of cardiovascular risk factors and increasing prevalence of obesity, abdominal obesity and type 2 diabetes (13). These results call for more effective lifestyle management in patients with CVD, as well as in individuals at risk for CVD (14, 15).

Lifestyle and disease prevention

Health is defined by WHO as, “a state of complete physical, mental and social well-being and

not merely the absence of disease or infirmity"(16). The English word *lifestyle* is defined by the Cambridge Dictionary as "someone's way of living; the things that a person or particular group of people usually do". In Sweden, lifestyle habits (in Swedish "levnadsvanor") refer to specific behaviours in everyday activities that individuals can influence (17, 18).

According to GBD 2016, ischemic heart disease is the leading cause of death in Sweden - see Fig.1.

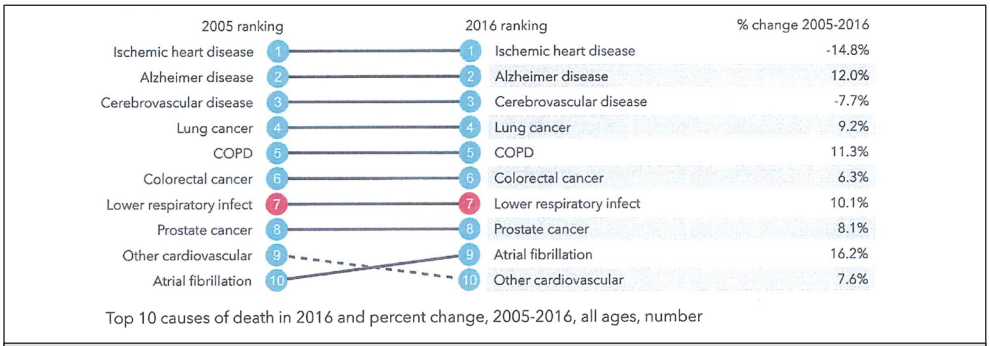


Figure 1. Top ten causes of death in Sweden 2016. From the Institute for Health Metrics and Evaluation (5).

Risk factors causing death and disability are often lifestyle related. Contributing risks for Sweden 2016 are shown in Fig 2 Contributing risks to DALYs. DALYS- Disability-Adjusted Life Year.

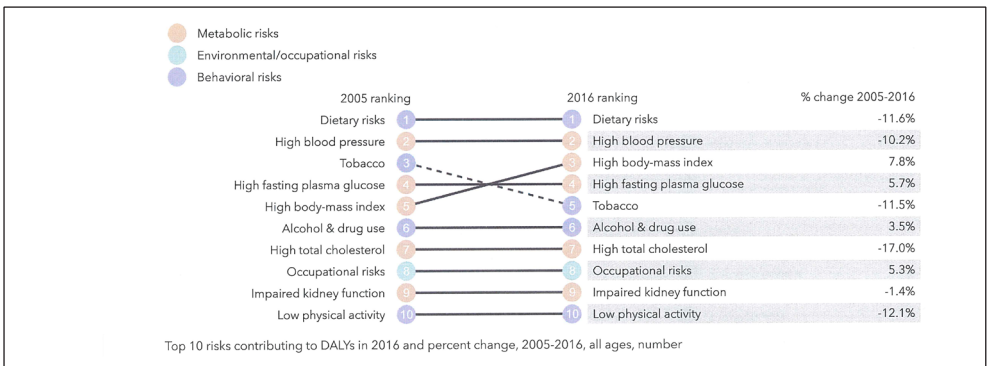


Figure 2. Top ten risks contributing to DALYs in Sweden 2016. From the Institute for Health Metrics and Evaluation (5).

In 2016, a Swedish survey (Health on Equal Terms) reported that two out of three men, and every other women, between 16-84 years reported an unhealthy lifestyle (19). Eleven percent of participants with low education, compared to 5% of participants with higher education, were daily smokers. Fourteen percent of the participants with high education had a high consumption of alcohol compared to 11-14% of the participants in the low education group. In the high education group, 43% reported moderate physical activity more than 300 min /week compared to 27-33% in the low education group. Approximately 25% consumed vegetables 3 times a day in the low education group compared to 36% in the high education

group (19). A study from Sweden, investigating whether there is any connection between lifestyle advice given by healthcare professionals and lifestyle changes, based on age gender and education level, showed that issues about lifestyle habits were raised with 32% of those who attended health care, more often among men, younger patients and those with a high education level (20). When raised, the advice contributed to 39% of individuals making a lifestyle change, to a higher extent among men, older individuals and those with a low education level. Regarding gender difference, women rated their health lower and older men were harder to persuade to change their habits.

In a study comparing the importance of lifestyle counselling with primary care health professionals in Sweden and in the US (New York upstate county), several important aspects were identified. In Sweden, for example, focusing upon risk consumption of alcohol was more important. Men and women also wanted health care counselling to focus more on eating and physical activity (PA) habits and generally expected more lifestyle counselling. In the US, food habits and weight were regarded as the most important lifestyle habits. One interesting observation was that Swedish men rated eating habits low in all categories. This important finding suggests that primary care needs to focus more on health care counselling regarding food, alcohol and PA habits. A multidisciplinary lifestyle clinic, with a variety of health professionals, could be a solution to this gap between expectations and demand (21).

Cardiovascular disease

Arteriosclerosis is a progressive inflammatory disorder in the arterial wall (22). Damage to the endothelium and the endothelial function leads to instable plaque development, involving oxidized low-density lipoprotein in the sub-endothelial matrix. If that plaque ruptures, a lesion in the vessel will develop causing platelet aggregation and a thrombus will appears occluding the artery (22). CVD affects 36.5% of Swedish men and women and is the most common cause of death in both Sweden and the rest of the world (2, 23, 24). Register data show that 1.4 million individuals living in Sweden are suffering from cardiovascular disease (24). More men develop myocardial infarction (MI) than women, but a decreasing trend is observed in both genders (24). Despite a decreasing trend in MI in Sweden, there is an inequality in cardiovascular health related to social demographic factors, such as education, economy and social status. i.e. individuals with low education, worse financial situation and/or lower social status are more prone to develop CVD (23).

The total CVD risk of atherosclerosis is usually the product of a number of risk factors. Preventive interventions of CVD should be based on the individual's total CV risk: the higher the risk, the more priority action should be given (12).
Cardiometabolic risk is a complex condition (figure 3), were obesity is one of the predominant contributing risk factor for cardiovascular disease and diabetes type 2 (25). Studies are now suggesting that other risk factors are equally involved, such as the location of the fat (abdominal visceral fat) and cardiorespiratory fitness, sedentary behaviour and nutrition habits for developing these diseases (26-29).

The INTERHEART study showed that 90% of all MI events were related to nine contributing factors, with high Apolipoprotein A (APO-A) and Apolipoprotein B (APO-B) levels as number one, followed by smoking, psychosocial risk factors, hypertension, diabetes, abdominal obesity, unhealthy food habits, physical inactivity, and alcohol risk consumption

(30). Guidelines regarding CVD are now focusing more on the causes of the diseases and prevention. Lifestyle intervention forms the basis for prevention as well as treatment of CVD (11, 12).

Lifestyle habits

In 2011, national guidelines for methods of preventing disease were published in Sweden (17, 18). The guidelines focus upon four lifestyle habits; smoking, risk consumption of alcohol, physical inactivity and unhealthy food habits. Various evidence-based methods for supporting individuals to change unhealthy lifestyle habits are presented and recommended (17, 18).

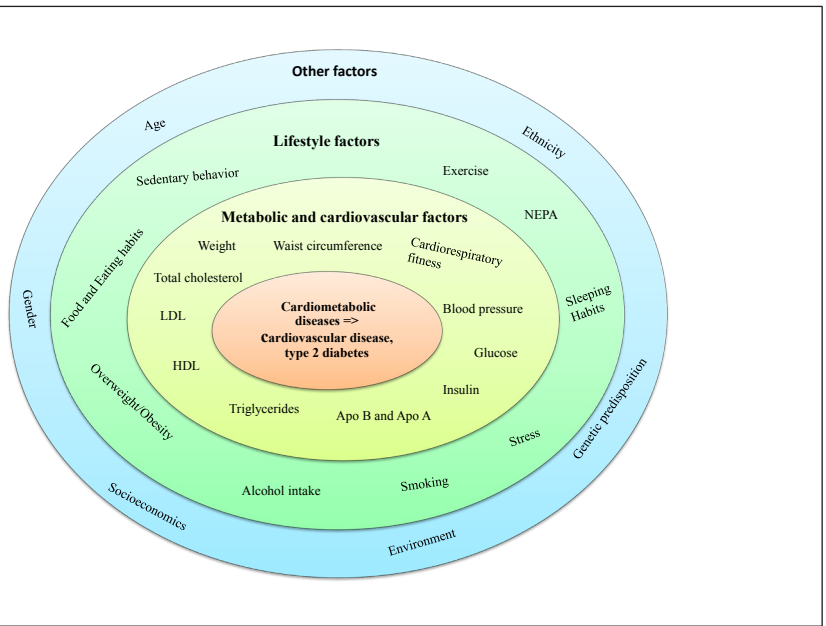


Figure 3. Cardiometabolic risk.

Smoking

The definition of smoking is daily tobacco use (17, 18). A cigarette contains over 8 000 toxic substances, and smoking is strongly associated with diseases, such as chronic obstructive lung disease, CVD and some common cancers, e.g. lung cancer (31). Studies have shown that daily smoking shortens life expectancy by 10 years on average and increases the risk of dying due to smoking 50% (32). The Nurses' Health study was the first to show that even light smoking doubles the risk of heart disease. One to 4, or 5 to 14, cigarettes per day were associated with a two- to threefold increase in the risk of fatal coronary heart disease or non-fatal infarction among women (33).

There is strong evidence that smoking cessation reduces cardiovascular risk. In a large observational study of 18 809 patients from 41 countries, hospitalized for MI, for the partcipants that stopped smoking after 6 months after their MI a 43% risk reduction of CV events were observed (34).

In the INTERHEART study, a case-control study of 15 152 individuals with first time myocardial infarction and 14 820 healthy controls (median age 56 years) in 52 countries, demonstrated that smoking was the strongest risk factor for first time myocardial infarction in younger individuals (30).

In 2014, the prevalence of smoking in Sweden was 9% in women and 10% in men. However, the prevalence was higher in younger women and individuals with low education (35). The urgency for individuals with increased cardiovascular risk to quit smoking to prevent CVD or cancer is indeed great (12). Guidelines emphasise the importance of helping individuals to stop smoking, and provide different techniques and education for health professionals (17, 18). There are a variety of drugs, both to help individuals to quit and to overcome withdrawal symptoms (12).

Alcohol consumption

Risk consumption of alcohol is defined by how many times per week alcohol is consumed and how many units per occasion (36). For men >14 glasses (or units) per week and/or >4 units at one occasion is considered as risk consumption, and for women, >9 glasses per week and/or >3 units per occasion (17, 18). There are many studies demonstrating a strong association between moderate to high consumption of alcohol and an increased risk of diseases, such as liver disease and several common cancers (breast, colon and liver) (37). In cardiovascular prevention, a low to moderate consumption of alcohol, compared to non-drinkers, has been shown to have cardiovascular preventive effects (12). The INTERHEART study showed that a moderate intake of alcohol was associated with a decreased risk of myocardial infraction (30, 37). However, there is no consistent evidence for a preventive effect of alcohol on total mortality (12, 38). A Norwegian study investigating the relationships between alcohol drinking patterns and CVD mortality, showed differences according to life course (based on household conditions, household income, and education) (39). It was found that weekly binge drinkers had a higher risk of dying from cardiovascular disease. Moderately frequent alcohol consumers had a lower risk of dying from cardiovascular disease (more prone in high positions) and frequent consumption was associated with increased risk of CVD mortality, but only among individuals with a low socioeconomic position.

A combined analysis, based on 83 prospective studies in 19 high-income countries, investigated the threshold of alcohol association with the lowest risk for all-cause mortality and CVD. The study was based on current drinkers (n=599912) without CVD. Results indicated that 100g of alcohol per week was associated with the lowest risk for all-cause mortality, regarding CVD and no clear association was observed with lower threshold alcohol consumption (40).

Physical activity

Physical activity is defined as any movement produced by skeletal muscles that results in energy expenditure (41). PA is a complex and multidimensional behaviour often described as

the energy expenditure associated with a given activity (42). Three main factors for defining PA are: frequency, duration and intensity (43, 44).
PA can be divided into (Figure 4):

- **Exercise -** PA that is planned, structured and repetitive and has the objective of improving or maintaining physical fitness (44).
- **Non-exercise physical activity (NEPA) -** light intensity activity which is not intended to constitute planned and structured exercise (45). Often embedded in daily life.
- **Sedentary behaviour** - defined as any activity in seated or reclined position that is characterized by an energy expenditure ≤1.5 METs (46).

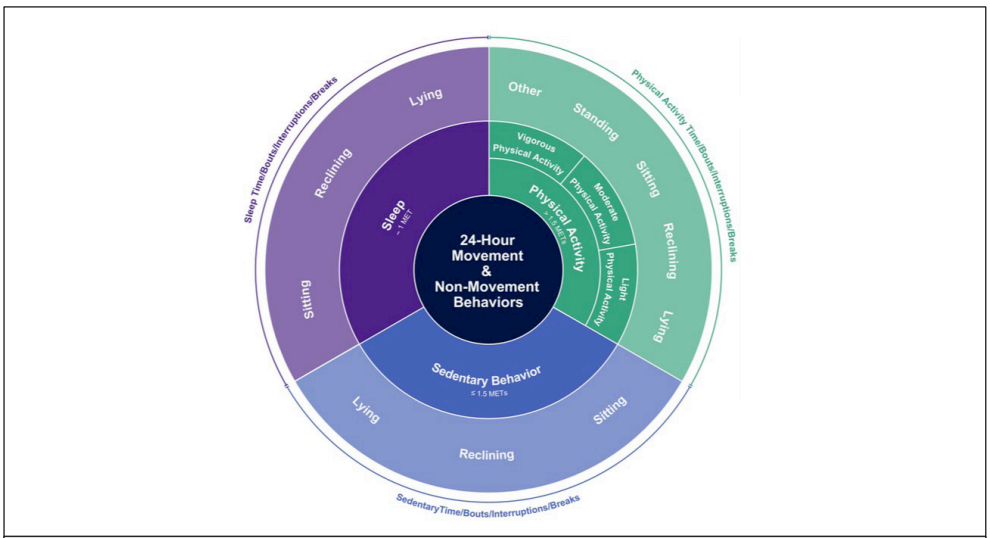


Figure 4. Definition of physical activity behaviour focusing on sedentary behaviour. International society of behaviour, nutrition and physical activity, ISBNPA(59).

National and international guidelines urge individuals to engage in 150 minutes of moderate intensity PA per week (43, 44, 47). In a survey by the Public Health Agency of Sweden, 65 percent reported that they were physically active according to the guidelines (48).

In the Eurobarometer, a survey of Europeans' PA habits, 70 percent of the Swedish participants reported adhering to the guidelines 1-2 /week (49).

Clinical health care has traditionally focused mainly upon exercise habits, with little attention paid to NEPA and sedentary time. One reason for this is the attention now being paid to the adverse health effects of prolonged sitting. The main way of counteracting this is light-intensity activity in daily life. Another reason is the challenge of recalling PA and time spent in a sedentary position. In this context, the most frequently asked question is, "How often do you exercise?"

A well-designed questionnaire about PA levels will give a more accurate self-rated measurement of all factors (exercise, NEPA and sedentary behaviour) (17, 18, 50, 51).

Additional use of step counters or activity monitors (accelerometers) gives a wider and more objective aspect of the PA span.

In a Swedish Cardio Pulmonary Bio Image Study (SCAPIS) studying the daily PA patterns, among 948 middle-aged (50-64 years old) healthy individuals, their PA and sedentary time were measured with accelerometers. Data showed that 61% of the participants time were spent in sedentary activities, 35% engaged in light physical activity and 4% in moderate to vigorous PA. Only 7% of the participants met the national guidelines regarding PA (52).

Physical inactivity is one of the four leading causes of premature mortality worldwide (53, 54). There is strong evidence that moderate physical activity has positive effects in the prevention and treatment in different diseases (43).

In 2018, the US Department of Health and Human Services presented their new PA guidelines. Previous guidelines had been revised: 150-300 min of moderate PA per week, time specifications were removed and all time spent in moderate PA was found to be beneficial to health. Breaks in sedentary behaviour and measuring PA during the day are also to be encouraged (55).

Physical activity on prescription

It is well known that Hippocrates, the father of Western medicine, prescribed physical activity to his patients in the belief that increased physical activity could lead to better physical and mental health. Physical activity on prescription (PaP) is an evidence-based method for increasing PA levels and reducing sedentary behaviour. The Swedish National Board of Health and Welfare recommends this method together with person-centred counselling (17, 18). When prescribing PaP, several factors need to be considered (Figure 5).

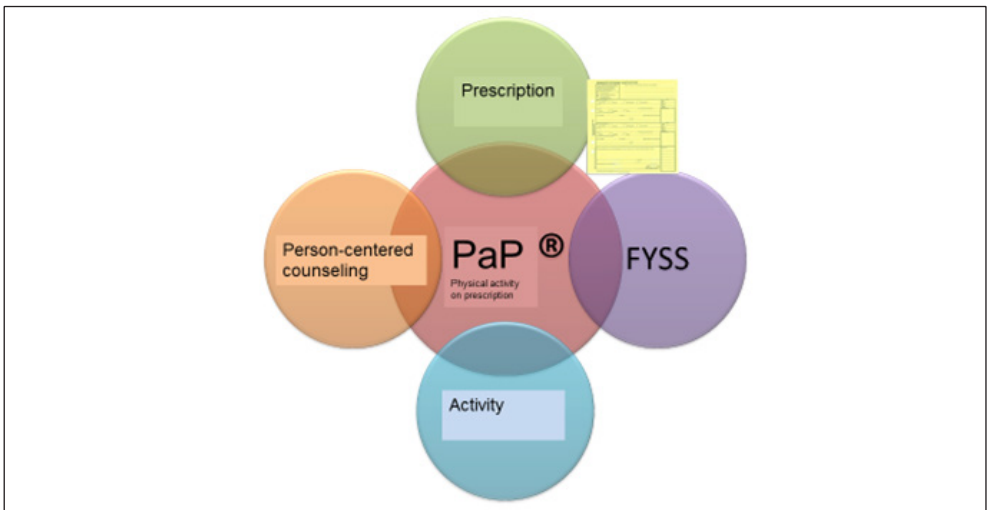


Figure 5. 1. Person-centered counselling 2. The prescription 3. FYSS- Fysisk aktivitet i sjukdomsprevention och sjukdomsbehandling (Physical activity in prevention and treatment of desease) (56) 4. Activity.

A Swedish study, focusing on the prescriber in health care, concluded that there were no differences between health professionals and what they prescribed. The most important factors were that the health professionals were licensed practitioners and that they had appropriate knowledge (57).

In a RCT, Kalling and colleagues showzed PaP effects on PA levels and sedentary behaviour in participants (n=101 age 68: mean years old) with cardiometabolic risk. After 6 months, there was an increase in PA levels and a reduction in sedentary time in the intervention group. Several cardiometbolic risk factors also showed improvement (58).

Sedentary behaviour

The definition of sedentary behaviour, according to the sedentary behaviour network 2017 is characterized by an energy expenditure ≤1.5 METs. A sedentary behaviour pattern is defined by the way in which sedentary behaviour accumulates during the day or week. This can be divided into: sitting, cycling and lying down. There is a debate among researchers whether sedentary behaviour should be defined as physical inactivity or as an independent behaviour (59). Evidence also indicates that there is a large difference in total mortality according to type of sedentary behaviour; sitting in front of a TV or screen seems to be the most dangerous (59, 60). In some epidemiological studies, sedentary behaviours are described as being independently associated with increased risk of overweight, metabolic syndrome, CVD, cancer and total mortality (61).

Modern workplaces often involve more sedentary behaviour, and work intensity has changed from moderate to a more sedentary level (62).

When not working, the amount of time spent watching TV, playing video games, using a computer (screen time) has increased. According to an observational study from Australia, participants spending more than 4 hours/day watching TV compared to individuals that spent 1 hour/day, ran an 80% higher risk of developing CVD (60). The same study also showed that time spent in a sitting position shortens life expectancy by 22 minutes per sedentary hour (60, 63). However, there are studies showing that short breaks in sedentary behaviour can substantially reduce cardiovascular risk factors, such as blood glucose, insulin levels, fibrinogen and blood pressure (64, 65).

A large systematic review, based on eight databases and 14 studies, with the aim to investigate the risk of sedentary behaviour in different diagnoses, concluded that prolonged sedentary time was independently associated with health outcomes regardless of physical activity level (61).
One prospective study investigated changes in the amount of sedentary behaviour amongst 130 participants, 3 months after participating in an exercise-based cardiac rehabilitation program. It was concluded that such an intervention did not reduce sedentary time. Behaviour-specific reduction strategies, targeting sedentary behaviour, were suggested (66).
In a qualitative paper, investigating barriers to reducing sedentary behaviours for participants and health professionals in an exercise-based cardiac rehabilitation program, several factors were presented: patients placed little importance on reducing sedentary behaviour, they were unconvinced of the benefits of breaks from sedentary behaviour and did not see themselves as a sedentary individual. The health professionals regarded sedentary behaviour as a risk but not as critical as other risk behaviours (67).

Guidelines in many countries now emphasise the importance of limiting prolonged sitting and introducing breaks. More research is needed to arrive at the optimal frequency and duration of breaks.

Food habits

In Sweden, healthy food habits are defined by the Nordic Nutrition Recommendation 2012 (NNR)5, based on available scientific evidence (68). A good, and often used, model for a healthy food pattern, as described by the NNR, is the Mediterranean diet or a Mediterranean food pattern (69).

In Sweden, this healthy food pattern means increased intake of vegetables and fruit, increased weekly consumption of fish, increased intake of polyunsaturated and monounsaturated fats and decreased intake of saturated fat and meat, as well as decreased consumption of salt and alcohol (68).

A questionnaire score from The Board of Nutrition and Health is used to calculate the daily consumption of vegetables, fruits, fish, fibres as well as breakfast habits and are recommended by The National Board of Health of Welfare (17, 18).

The Seven-Country study was one of the first studies to highlight the positive effects of Mediterranean food on mortality. This international, observational study of coronary heart disease teams, examined 12 770 men, 40 to 59 years old, in Finland, Greece, Italy, Japan, the Netherlands, the United States and former-Yugoslavia, with a 5-year follow-up. The results showed that the Mediterranean pattern (from Greece), with a high consumption of vegetables and olive oil, and the high consumption of vegetables and fish in Japan, seem to be cardiovascular risk protective (70). At a long-term follow-up, 15 years later, coronary heart disease death rates and all-cause mortality were found to be low in cohorts with olive oil as the main fat. No causal relationships were claimed but is a reminder of the importance of focussing on individualised food patterns (71).

Observational studies consistently demonstrate an association between a Mediterranean food pattern and a reduced risk of CVD, type 2 diabetes, dementia, cancer and total mortality (69, 72, 73).

In addition, many intervention studies demonstrate positive effects of this healthy food pattern on cardiovascular risk factors, such as overweight, abdominal obesity, lipids, blood pressure and insulin resistance (73).

Several primary and secondary prevention trials with incidence and mortality in CVD, as well as total mortality as endpoints, have also demonstrated positive effects of a healthy diet. A recently published, large (n 7 447), randomized controlled trial, among persons at high cardiovascular risk, demonstrated that a Mediterranean diet, supplemented with extra-virgin olive oil or nuts, reduced the incidence of major cardiovascular events (29).

In the randomized controlled Lyon Diet Heart Trial, among 605 patients with a first myocardial infarction, advice on a Mediterranean diet significantly reduced cardiovascular risk as well as

cardiovascular and total mortality. After a mean follow-up of 27 months there were 3 cardiac deaths in the intervention group compared to 16 in the control group (80% risk reduction). Moreover, there were 8 deaths in the intervention group compared to 20 in the control group (60% risk reduction) (28, 72). In the PREDIMED intervention study, the participants with high CV-risk were randomized to three different groups. Two of the groups were prompt in changing their food pattern to be more Mediterranean-based, with different fats (one group was given extra virgin olive oil 1 liter per family and week, the other group was given nuts, walnuts, hazelnuts and almonds, 27 grams per day) and one group was the control group (29). The two Mediterranean groups with different fats show similar reduction of risk for CVD and type 2 diabetes and no change in the control group. The PREDIMED study has shown that the Mediterranean diet, with the right type of fat has multifactorial effects on different diseases but not on total mortality (74, 75).

Still, Mediterranean food patterns are now being implemented in different countries using local food. In a Swedish, randomized controlled trial, amongst 88 healthy individuals with increased cardiovascular risk, i.e. increased blood lipids (the NORDIET study), the participants were given food from local farms that was similar to that in the Mediterranean food pattern (76). The intervention was shown to reduce blood lipids and several other important cardiovascular risk factors after six weeks.

However, there are still many barriers to adapting the Mediterranean diet for individuals living in the Nordic countries. In a qualitative focus group study, investigating these barriers, 67 adults (mean age: 64±10 years old) with a high CV risk from Northern Ireland were included (77). The results were presented as eight barriers: perception of expense, concern over availability, expectation of time commitment, limited knowledge, lack of cooking skills, amount and conflicting nature of media information on diets, changing established eating habits and resistance to dietary change.

Stress

It is difficult to define stress due to its complexity. However, one definition is the combination of high demands and low control, or the combination of a high work rate with poor reward for good work efforts (78). Stress is often divided into work-related stress and stress during leisure time. Work-related stress is increasing in Sweden in both gender – but mostly in women (79). One of the risk factors identified in this study was psychosocial risk, such as stress, depression and isolation (78). Almost 90% of the first-time myocardial infarction cases could be explained by unhealthy lifestyle habits according to the INTERHEART study (30). The latter found that stress at work and home, financial stress, major life events and depression were associated with a significantly increased risk of myocardial infarction in both men and women (30). Interventions focussing on stress management after myocardial infarction are often based on various behaviour change methods (12, 80). In a randomized intervention trial, amongst individuals with a coronary heart disease event within the past 12 months, the intervention group was offered stress management with cognitive behaviour therapy over one year. This resulted in a 41% reduced risk for the intervention group in fatal and non-fatal CVD events compared to the control group (80).

Sleeping habits

The global prevalence of individuals reporting disturbed sleeping pattern is 20-30 %, and

this prevalence is higher in women (81). Disturbed sleeping habits increase the risk of several conditions including CVD, diabetes and mental disorders (82). In a Swedish, 12-year prospective study, of 1 870 subjects aged 45-65 years, an association between difficulties falling asleep and CVD was observed in males (83).

Quality of life

WHO defines Quality of Life (QoL) as an individual's perception of their position in life, in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns (84). Quality of life is both subjective and multidimensional. The subjective QoL is measured from the patient's perspective. It is multidimensional, and examines a range of areas of the patient's life, including physical well-being, functional ability, emotional well-being, and social well-being (85). Each health domain has multiple factors that need to be measured (for example, symptoms, ability to function, and disability).

Health-related quality of life (HRQoL) refers to the physical, psychological, and social domains of health, seen as distinct areas influenced by a person's experiences, beliefs, expectations, and perceptions. Self-rated QoL is a predictor of morbidity, hospitalization and mortality in individuals with cardio metabolic diseases (86-88). Socioeconomic and demographic characteristics, such as lower educational level and low social economic status (SES) have been associated with a lower HRQoL (89-91).

The Gothenburg QoL instrument is a validated questionnaire divided into three domains: physical, mental and social well-being. This instrument has been validated and used with individuals with CVD (92). It has been used to measure QoL, after gastroplasty in individuals with eating problems and abnormal obesity, health-related quality of life in asthmatics, and in secondary preventive management after a coronary event (93-95).

Cardiovascular risk factors

Abdominal obesity

In clinical practice, abdominal obesity is defined by a high waist circumference (girth); ≥ 88 cm in women and ≥102 cm in men, as measured in a standing position, midway between the lower rib margin and the iliac crest. Accumulating data suggest that sagittal abdominal diameter (SAD) or abdominal height may be a better marker of intra-abdominal adiposity and cardiometabolic risk (96). SAD is measured using a ruler and a water level or a calliper. SAD or "abdominal height" is the distance between the examination point and the horizontal level.

SAD (anteroposterior) or "abdominal height" was measured, after a normal expiration, to the nearest 0.1 cm, in a supine position with slightly bent knees on a firm examination table, without clothes in the measurement area. At the level of the umbilical, SAD was measured using an instrument, (named BK-bukhöjdsmätare), with the SAD being the distance between the examination table and the horizontal level. The optimal cut-offs for SAD indicate increased cardiovascular risk of >22 cm in men and >20 cm in women (96).

In several epidemiological studies, both cross-sectional and longitudinal studies, abdominal obesity has, been shown to be associated with an increased risk for CVD and type 2 diabetes (26, 97), as well as dementia and common cancers.

Studies have shown that it is important to focus on both improving healthy eating habits as well as increasing physical activity to reduce abdominal fat (26). In an RCT, including overweight individuals with increased cardiometabolic risk, the reduction in abdominal fat mass was greatest in the combined group focusing on both PA and healthy food habits (98). Furthermore, in a Swedish RCT on PaP as an intervention, among sedentary 68-year old, overweight individuals, an increased level of PA and a reduction of sedentary time led to a reduction in sagittal abdominal height and waist circumference after 6 months (58). Several other cardiovascular risk factors were reduced and quality of life was improved (99).

Glucose abnormalities

Insulin resistance is defined as insulin levels being higher than expected, relative to the level of glucose, or as the inability of a known quantity of exogenous or endogenous insulin to increase glucose uptake and utilization in an individual, as much as it does in a normal population (100). It is a strong predictor of many common diseases, such as type 2 diabetes and cardiovascular disease, and an important component in the metabolic syndrome (100).

Impaired glucose tolerance (IGT) is defined as elevated postprandial glucose after an oral glucose test (fasting glucose after 2 hours >=7.8 <11.1 mmol/l). Individuals with IGT have a higher risk of developing type 2 diabetes (101). IGT is common in patients with acute myocardial infarction (102). In a study of patients with myocardial infarction, it was demonstrated that 2/3 of all patients had an abnormal glucose intolerance and that 1/3 of these had IGT (103).

Several RCTs examine lifestyle interventions (diet and exercise) demonstrate a potent effect on the risk of developing type 2 diabetes in risk individuals with IGT. The large Finnish Diabetes Prevention Study, found a reduction of 58 % for developing type 2 diabetes in individuals with IGT due to an increased level of PA (between 1-4 hours / week) and adoption of a more healthy dietary pattern with less calories, less saturated fat and more vegetables, fruit and fibres (101). Sedentary behaviour is associated with insulin resistance, but breaks in sedentary time with light to moderate activity can reduce postprandial-glucose and insulin levels (104).

Type 2 diabetes is a chronic disease defined as elevated levels of blood glucose due to insulin resistance or decreased production of insulin. Type 2 diabetes is diagnosed when fasting blood glucose level are over 7.0 mmol/l, or after an oral glucose tolerance test (OGTT) with a 2-hour level over 11.1 mmol/l.

The prevalence of type 2 diabetes is increasing globally and, according to the International Diabetes Federation (IDF), 640 million people will have the disease by 2040 (105). One in eleven persons has type 2 diabetes, and one in two with type 2 diabetes are undiagnosed (106).

There is consistent evidence that the incidence, prevalence and mortality rates for type 2 diabetes are negatively related to low education and living in a low socioeconomic area (SEA) especially among women (107, 108). Individuals with type 2 diabetes and CVD should have more intensive treatment regarding risk factors to prevent recurrent cardiovascular events and complications of type 2 diabetes (12). Lifestyle interventions are the first choice of treatment according to guidelines for individuals with newly-detected type 2 diabetes. Regular PA, both aerobic and strength training, have positive effects on glucose levels (43). A food pattern rich in vegetables and fibres also has positive effects on glucose levels. The Mediterranean food pattern is associated with lower risk of type 2 diabetes (69).

Hypertension

Hypertension is the leading cause of disease risk in the world according to GBD (2). A prevalence of hypertension in individuals over 18 years old is 30-45% and increases with age (109). Blood pressure over 115/75 mmHg is strongly and directly related to vascular mortality (109). Hypertension is defined as elevated systolic blood pressure over 140 mmHg and a diastolic blood pressure over 90 mmHg (12). Individuals with CVD, diabetes- type 2 or renal disease are at higher risk for CV-events and blood pressure goals should be lower than individuals without chronic disease (12). The golden standard for measuring blood-pressure is over 24 hours or repeated measurements at rest in a hospital setting (office blood pressure). Blood pressure cut-offs differ depending on the way it is measured (12).

For mild to moderate hypertension, physical activity/aerobic training has a reducing effect on systolic blood pressure by 7 to 5 mmHg on average (43). According to Dietary Approaches to Stop Hypertension (DASH), a diet, reduced in salt and rich in vegetables and fruit, can reduce systolic blood pressure with an average of 5.5 mmHg and diastolic blood pressure with an average of 3.3 mmHg (110).

Dyslipidemia

Dyslipidaemia is defined as elevated total or LDL cholesterol levels or as a high ratio between low density lipoprotein (LDL) and high density lipoprotein (HDL).

There is a causal relationship between elevated LDL levels and CVD (12). According to guidelines, treatment of dyslipidemia should always include lifestyle changes with a focus on a healthy diet (12). Triglycerides is also an independent risk factor for CVD, but not as strong as LDL.

The INTERHEART study demonstrated that the most common factor for developing first time myocardial infarction is high blood lipids (measured with APO-A and APO- B) (30).

In a population-based study the Västerbotten intervention program (VIP) in Sweden, screening of lipids followed by a dialogue with a nurse and dietician about healthy lifestyle and food habits showed a reduction in cardiovascular events. One of the explanations for this reduction was a decrease in total cholesterol (111).

The first-hand choice of treating dyslipidaemia with lifestyle changes should be dietary advice according to the guidelines for prevention of CVD in clinical practice or according to NNR5. This entails more vegetables, legumes, fibres, less saturated fats and trans fats, and more polyunsaturated and monounsaturated fat, less salt and red meat (68).

Metabolic syndrome

The Metabolic Syndrome (MetS) is a cluster of metabolic risk factors, such as abdominal obesity, dyslipidaemia, hyperglycaemia and hypertension. There are several definitions of MetS (97) and most include abdominal obesity, insulin resistance, impaired glucose tolerance, hypertension and dyslipidaemia (high triglycerides, low-density lipoprotein cholesterol-LDL and decreased levels of high-density lipoprotein cholesterol-HDL). The MetS increases the risk of cardiovascular disease, type 2 diabetes, dementia, and certain forms of cancer (26, 112). In a cross-sectional survey of men and women from Stockholm in Sweden (n=4228) the prevalence of MetS was 30% in men and 15% in women (113).

Cardiovascular risk

To estimate cardiovascular risk, different score-based, multivariable risk algorithms calculated the risk of developing CVD. Two commonly used algorithms are the Framingham 10-year CV-risk prediction model (114) and HeartSCORE (Systematic COronary Risk Evaluation) (115).

Framingham CV risk algorithm

This algorithm can be used for individuals with previous and non-previous CVD. It is based on age, smoking, systolic BP and treatment or not, total cholesterol, HDL-cholesterol and occurrence of diabetes type 2. These factors are entered into the sex-specific multivariable risk factor algorithms, where a 10-year probability of developing a CVD is calculated (114).

HeartScore

This algorithm is commonly used in clinical practice to assess risk of fatal CVD for individuals with previous CVD. It based on smoking/ non-smoking, systolic blood pressure, total cholesterol level, entered in an age and sex-specific multivariable risk factor scale in pedagogic colours (green=decreased risk and red= increased risk) with a 10-year probability of fatal CVD (115).

Prevention

Prevention includes a wide range of activities described as interventions aimed at reducing risk and improving health. CVD prevention is defined as a set of actions, at the population level or targeted at an individual, that are aimed at eliminating or minimizing the impact of CVDs and their related disabilities (12). Prevention can be divided into different levels that are often linked together.

Primary prevention is designed to prohibit or prevent the development of disease by treating the contributory factors or habits. Examples are: smoking cessation, increased physical activity and dietary interventions, such as an increased intake of vegetables and fruit. Lifestyle interventions have multifactorial effects and are therefore effective in both prevention and treatment of cardiovascular diseases (30).

Secondary prevention is designed to reduce the impact of an already occurring disease, to prevent a new event and premature mortality. For example, in the Lyon Diet Heart Trial, a randomized controlled trial in participants with newly-developed MI, the intervention

group was advised to follow a more prudent and healthier Mediterranean-like diet. The result showed a significant risk reduction of CV events and CVD deaths in the intervention group (28).

The focus in cardiovascular, or cardiometabolic prevention, is to reduce the risk of developing cardiovascular diseases and type 2 diabetes and also to prevent new events to emerge. In CVD, the focus should be on lifestyle habits affecting CV-risk factors (11, 12, 97). If unhealthy lifestyle habits are prevented or treated at an early stage, the risk of developing a CVD will decrease. Prevention of CVD and type 2 diabetes can also be achieved by treating, for example, abdominal obesity and borderline high blood glucose with education and information about physical activity and healthy food habits (101).

Cardiovascular prevention

CV prevention is defined as coordinated actions targeting individuals in the population to minimize the impact of CVD and their related disabilities and co-morbidities (12) .

Primary cardiovascular prevention. The North Karelia Project was started in 1972 as a national pilot and demonstration program for CVD prevention. Reduction in population levels of established risk factors, such as smoking, elevated cholesterol and elevated blood pressure was the main objective in order to prevent CVD. A comprehensive community-based intervention involving health services, non-governmental organizations , industry, media and public policy was used.

After the initial period (1972-77), the project was extended to a comprehensive national heart health program (116). Evaluations, involving population surveys and disease registers, have shown that population risk factor levels have been significantly reduced. Consequently, the CHD mortality rate among for example, 30-64-year old male population, has been reduced from 1970 to 1995, by 73% in North Karelia and 65% in the whole of Finland. Favourable changes in cancer and all-cause mortality, as well as the general health of the population, have also occurred (117).

In Sweden, several cardiovascular programs have been launched. In Västerbotten, a systematic long-term cardiovascular prevention program, the VIP model, combining individual and population strategies is running. For several decades, all 45, 50 and 60-year old men and women are invited to the primary health care for a health check-up and a dialogue about their health. Recently, a long-term follow-up study compared participants in the program with the general Swedish population, and demonstrated a significantly reduced all-cause mortality in both sexes, and a significantly reduced CVD mortality in women in the intervention group (118, 119). In a long-term follow-up study between 1990 and 2006 of the VIP model and its community preventive efforts showed that it had led to a reduction in all-cause mortality and CVD deaths (119).

Similar results were shown in a community based study from Habo, Sweden. The prevention program consisted of a intervention based screening of men aged 33 to 42 years, including nurse-led interviews and health counselling in primary health care (120). After

one year, improvements in eating habits, alcohol consumption and smoking were shown, and cardiovascular risk factors such as lower waist circumference, reduced blood pressure and lower blood lipids were noted (121). During the time period 1984-96, the decrease in CVD mortality was more prominent in Habo compared to other Swedish communities with similar demographics (122). In an RCT in 1993, Hellénius and co-workers showed that low to medium intensive lifestyle interventions in primary health care (one session with a physician and a dietician and/or physical activity on prescription) can improve lifestyle habits and significantly decrease several cardiovascular risk factors, and hence reduce cardiovascular risk (98).The primary preventive lifestyle program in Sollentuna primary care showed a significant reduction in cardiovascular risk factors; hypercholesterolemia, hypertriglyceridemia and high blood pressure at the 4-year follow-up (123).

In a long-term follow-up of the Sollentuna primary care program, investigating time trends in incidence, mortality and acute myocardial infarction as well as all-cause mortality in this cohort (124), a significant trend was observed toward a greater decline in acute myocardial infarction in women compared to the rest of Stockholm County. A trend of declining CV mortality and all-cause mortality was also seen for participants as favourable effects of the prevention program.

Secondary cardiovascular prevention. The EUROACTION study, a secondary preventive cluster randomized control intervention trial, investigated whether a nurse-coordinated multidisciplinary, family-based preventive cardiology program could improve standards of preventive care in routine clinical practice (125). The results showed an improvement in lifestyle habits and CV- risk management, reaching guideline targets and an optimized CV medical treatment.

In a secondary preventive study of individuals in the United Kingdom, at increased cardiovascular risk (n= 1 173), nurse-led clinics in primary care resulted in improvements in both compliance of medication and lifestyle habits (physical activity and diet) after one year (126). Most individuals in the study improved in one or more components of secondary prevention, which led to reduced cardiovascular events and mortality.

In 1998, Ornish et al.in their secondary preventive RCT amongst individuals with severe CVD, showed that intensive lifestyle changes, such as smoking cessation, vegan diet, exercise and anti-stress management training led to regression of coronary atherosclerosis after 5 years (127).

The GOSPEL-study (Global Secondary Prevention Strategies to Limits Event Recurrent After AMI), a multicentre RCT, with 3 141 participants randomized to an intensive multi-factorial intervention with focus on medication and lifestyle changes, showed that the intervention group decreased their cardiovascular risk by 33% and risk of non-fatal myocardial infarction by 36 % three years after the intervention (128). The intervention group improved several lifestyle factors, such as physical activity and diet, and cholesterol levels were lower than those of the control-group (128).

Socioeconomic inequalities and health

Low socioeconomic status has previously been identified as a predictor for an unhealthy lifestyle, increased cardiovascular risk and CVD development (129, 130). Unhealthy lifestyle habits are related to the increased rates of cardiovascular disease, type 2 diabetes and cancer in these groups (131).

Studies have shown that people with a higher socioeconomic position often tend to be early adopters of new behaviours. It takes longer for those with a lower social position (132).

Major differences in life-expectancy have been shown depending on where you live in Stockholm county (35, 131). Life-expectancy in men in Stockholm is 10-12 years shorter for individuals with low education compared to individuals with high education. These findings are correlated with differences in lifestyle factors and education level (131).

Low socioeconomic status is a major risk factor for obesity (133). In all countries, where data are available, people from disadvantaged social backgrounds have a higher rate of early mortality and are more likely to be affected by adverse health than individuals with higher socioeconomic positions (134).

Lifestyle habits and education level

In today's world, poor health is strongly associated with lower educational levels and lower socioeconomic area (SEA) of residence (89, 90, 135, 136). This is attributed to an unhealthier lifestyle and a higher prevalence of risk factors that increase the risk of non-communicable diseases (90, 129, 137). In a study based on cohorts from the United Kingdom (UK), Finland, and Japan, examining social class differences in smoking over 5-7 years, found differences in the UK and Finland, but not in Japan (138).

A Norwegian study, of the relationships between alcohol drinking patterns and CVD mortality in midlife, showed differences according to life course (based on household conditions, household income, and education) (39). It was found that weekly binge drinkers had a higher risk of dying from cardiovascular disease. Moderately frequent alcohol consumers had a lower risk of dying from cardiovascular disease (more prone in high positions) and frequent consumption was associated with increased risk of CVD mortality, but only among individuals with a low socioeconomic position. Regarding daily physical activity (reaching 150 min moderate PA/week), 73 percent reached this goal in the high education group and 60 percent in the low education group. Fifty-two percent in the high education group reached the goal for healthy food habits, based on vegetables and fruit intake /day, and fifty percent in the low education group (19). However, surveys indicate that health policies have been effective regarding inequities in promoting physical inactivity in low socioeconomic areas between years 2010 to 2014 in Sweden (139).

Lifestyle habits and socioeconomic area

According to the Swedish Public Health Agency, two in three men, and every other women, between 16 and 84 years old reported unhealthy lifestyle in a 2016 national survey of lifestyle and health (19). The prevalence of lifestyle habits, such as smoking, high consumption of alcohol and an unhealthy food intake are higher in these areas (35). Unhealthy lifestyle habits

are related to increased rates of cardiovascular disease, type 2 diabetes and cancer in these socioeconomic groups (131). In an observation study, from a large city in Sweden (Malmo), social inequalities were found when comparing low with high socioeconomic areas. Almost 35 % of the residents in the low SEA were overweight and 24% were smokers compared to the residents in a high SEA where 11% were overweight and 8 % were smokers (137).

Health behaviour, learning, teamwork and self-care

Engagement in self-management behaviours is seen as the proximal outcome influencing the long-term outcome of improved cardiovascular health (140).

A multidisciplinary person-centred approach should be used in a lifestyle intervention with a common goal of increasing the individual's knowledge and beliefs, self-care, self-regulation skills and abilities, and social facilitation (141).

The most effective lifestyle interventions in preventive care are those that focus on a total risk management approach, with both focus on lifestyle habits and quality of life using behavioural counselling with goal-setting approaches and individual treatment plans supported by follow-up visits (141, 142).

Person-centred approach and shared decision making

Person-centred care can be defined as listening to the patient's narrative, and identifying resources and possibilities that could be the basis of forming a 'shared' (shared decision making) health plan, in a partnership between the patient and health professional. In this meeting, the patient's wishes and needs will be met with respect. Any education and support regarding health and outcomes should be based on this person-centred approach (143), with focus on:

- addressing the person's specific and holistic properties
- addressing the person's difficulties in everyday life
- the person as an expert, with participation and empowerment in focus
- respect the person 'behind' the impairment or the disease (144)

In most programs, where the focus is on lifestyle, a tradition in education is to inform the participant and not allow involvement in the planning of change. However, there is now a trend towards involving patients more in their own care (145, 146).

This should be based on *shared decision-making* in health communication, i.e. in a two-way dialogue between the health professional and the patient (147, 148). This dialogue is an interaction whereby the patient is given the opportunity to be involved in his/her own care. Important factors in this dialogue are: active listening, ability to have a conversation, understanding, comfort and trust, development of coping strategies, person and patient-centred, equality, respect for the patients autonomy, and supporting wellness (149). This has been shown to have a positive effect on helping patients with CVD and/or diabetes type 2 diabetes reach their goals (150). One other important concept, when working with health promotion, is *Empowerment*. WHO defines empowerment as, "a process through which people gain greater control over decisions and actions affecting their health" and should

be seen on both an individual and a community level (151). This begins with the health provider acknowledging the patient's needs, and then aiming to increase his/her ability and capacity to, in an autonomous way, make decisions about his/her own health. This is based on shared decision-making, with the patient and caregiver jointly discussing options, potential benefits and harm, preferences and the patient's own values. Strengthening a person's empowerment through shared decision making has positive effects on their self-efficacy and leads to improved medication adherence, disease awareness, and self-management of chronic diseases (147, 152).

Health communication

Healthy lifestyle initiatives have proven to be highly effective in providing programs, education and support to reduce the risk associated with non-communicable diseases, and improve different disease outcomes. These programs are often built on information presented to the participants, whereby the health professional selects the topic of instruction, and obligates a response from individual. The health professional then evaluates the responses and provides reinforcement for correct responses and feedback for incorrect ones.

According to the US Dept. of Health and Human Services - Healthy People 2010 (153), health communication can be defined as," the art and technique of informing, influencing, and motivating individual, institutional, and public audiences about important health issues". A two-way dialogue about health is essential. Important factors in this dialogue are:

- active listening
- ability to have a conversation
- understanding
- comfort and trust
- development of coping strategies
- patient centred approach
- equality
- respect for the patient's autonomy
- positive attitude (154)

Health literacy

Health literacy is defined as the cognitive and social skills, which determine the motivation and ability for a person to gain access and understand how to use information in ways that maintain and promote good health.

Health literacy means more than being able to read pamphlets and keep appointments. By improving the individual's ability to access health information and capacity to use it, health literacy is important for a person's empowerment. One study investigated the role of health literacy in 653 individuals (age 65 years or older) with various chronic diseases (diabetes, heart failure and hypertension). Twenty-four percent of the patients had inadequate health literacy skills, and 12 % had marginal skills. Patients with inadequate health literacy knew less about their diagnoses than patients with adequate literacy, and health literacy was independently related to disease knowledge (155). A study of individuals with CVD, and health literacy, i.e. the ability to understand information about lifestyle and cardiovascular risk management, found no differences between high or low health literacy (89, 156). Both groups were able to understand the information given to them in this forum.

Motivational interviewing

Motivational interviewing can be described as a directive, therapeutic style to enhance readiness for change by helping clients explore and resolve ambivalence (157). Because of its focus on preparing people for behaviour change, motivational interviewing could play an important role in health behaviour settings and interventions (158). It is recommended by the National Board of Health and Welfare as one of the techniques helping health professionals and patients in their health communication about changing unhealthy lifestyle habits (17). There is evidence supporting motivational interviewing as tool in a variety of behaviours, such as smoking alcohol abuse and diabetes care (159).

Multidisciplinary vs interdisciplinary team approach

Two approaches often used in lifestyle management are the multidisciplinary and the interdisciplinary approaches.

Multidisciplinary

Can be explained in terms of the skills and experience of health professionals with different competencies and occupations. Each professional tends to approach the patient from his/her own professional perspective in separate consultations (160). These teams often meet regularly to discuss the care in place around the patient, often without the patient being present. This type of multidisciplinary approach with different health professionals often provides a broader expertise then working alone.

This type of approach is often recommended in cardiovascular care, resulting in positive outcomes in lifestyle habit management, CV risk management and mortality (141).

Interdisciplinary

Can be explained in terms of the person is offered a single consultation, whereby she/he meets various health professionals together (160). The patient, together with the team, is actively involved in his/her own care, including patient-history, assessment, diagnosis, intervention and short- and long-term management goals. These are addressed by the team at one appointment. This approach is known to strengthen the person-centred approach, and to enhance patient empowerment in the decision-making process, including the setting of long and short-term goals together with health care professionals.

The nurse's role as a coordinator in CV care has proven to be effective, especially in an interdisciplinary context with other health professionals, such as physicians, dieticians and physiotherapists, who provide equally important expertise in supporting holistic care (141).

Self-care

Self-care is defined as being fundamental to prevent and manage diseases, as well as to maintain health. Elements, such as self-care maintenance, self-care monitoring and self-management are important factors (140).

An important factor in the self-care process is self-care decision making. This helps the health care professional to understand how to plan together with the help of the patient and also understand the person's strengths (education level) and limitations (low health literacy) (140).

Self-care behaviour

This is a factor/ behaviour that influences the person's ability to achieve good health and prevent disease. On an individual level, this may be based on understanding self-care and the person's self-responsibility. Today, when most health care systems are based on the care provider taking responsibility for the patient's health, these two behaviours may be overlooked and the person's autonomy may be violated (140, 147).

Self-care/self-management is often thought of as only involving the individual but it also includes family and community levels (Figure 6).

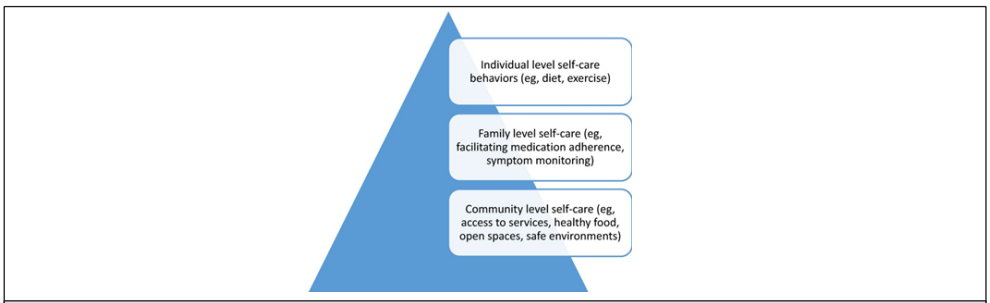


Figure 6. Self-care behaviour involvement. Reigel B et al Journal of the American Heart Association 2017 (140).

Individual level

There is a current trend in healthcare towards involving patients more in their own care (145). This should be based on shared decision-making, and a dialogue between the health professional and the patient (147, 148). This interaction increases the patient's involvement.

Family level

Involvement of family members in supporting in the person's self-care is very important. Lack of support can have a negative effect. A qualitative, interview study of individuals with heart failure, found that the males in the study were more able to interpret their symptoms than the females. These differences were associated with differences in social support (family), and mood and self-confidence (161).

Community level

There are many different environmental factors that influence health. WHO has identified 12 healthy components that are important for a healthy city including: access to services, healthy food, open spaces, safe environments, healthy air, physical activity, and social cohesion (162). Factors, such as walkability and the community food environment are important to the individual's ability to self-care. For example, studies have shown that barriers to physical activity and healthy food alternatives in the community can lead to increased BMI and obesity (163).

Self –management

Interventions to enhance self–care should be based on education and strategies focusing on increasing the patient's knowledge about disease management. *Self-care technology* as support: in today's environment, with individuals struggling to attain and maintain a healthy lifestyle, many turn to the Internet for advice. It is important for health care to provide evidence-based websites to cater for this need (164, 165).

AIMS

General Aim

To describe and evaluate the effects of a structured lifestyle program in individuals with high cardiovascular risk at a cardiology unit.

Specific Aims

- To evaluate the effects of a structured lifestyle intervention program focusing on lifestyle habits and quality of life after six months and one year in individuals with increased cardiovascular risk (**Paper I**).

- To evaluate the effects on cardiovascular risk factors and cardiovascular risk after six months and one year, in individuals with increased cardiovascular risk enrolled in the structured lifestyle program (**Paper II**).

- To describe the participants' experiences in the structured lifestyle program after one year (**Paper III**).

- To evaluate how the effects of the one-year structured lifestyle program on changes in lifestyle habits, cardiovascular risk and quality of life are associated with the participant's educational level and socioeconomic area (SEA) of residence (**Paper IV**).

MATERIAL AND METHODS

Summary of Papers I to IV is shown in Table 1.

Table 1. Summary of Papers I to IV.

Paper	I	II	III	IV
Participants	Individuals with high cardiovascular risk participating in a structured lifestyle program n= 100 mean age: 58±11 years	Individuals with high cardiovascular risk participating in a structured lifestyle program n= 100 mean age: 58±11 years	Individuals with high cardiovascular risk participating in a structured lifestyle program n=15 mean age:58± 9 years	Individuals with high cardiovascular risk participating in a structured lifestyle program n= 100 mean age: 58±11 years
Design	Longitudinal descriptive non-randomized, uncontrolled structured lifestyle intervention study	Longitudinal descriptive non-randomized, uncontrolled structured lifestyle intervention study	Qualitative interview study	Longitudinal descriptive non-randomized, uncontrolled structured lifestyle intervention study
Aim	Evaluate the effects of a structured intervention program on lifestyle habits and quality of life after six months and one year	Investigate the effects on cardiovascular risk factors and cardiovascular risk after six months and one year	To describe the participants' experiences of a lifestyle program	Investigate the change in unhealthy lifestyle habits and cardiovascular risk, in participants of different educational levels and socio-economic areas of residence, after participating in a structured lifestyle program
Data collected	Between January 2008 to January 2014	Between January 2008 to January 2014	Between November 2016 and March 2017	Between January 2008 to January 2014
Main variable	• lifestyle habits* • symptoms of anxiety and depression • HRQoL	• weight, waist circumference, BMI • blood pressure • heart-rate • blood samples • Framingham risk score	semi-structured interviews	• educational level • socioeconomic area (SEA) • lifestyle habits* • HRQoL • waist circumference • Framingham risk score

*smoking, risk consumption of alcohol, physical activity, sedentary behaviour, food habits, stress, sleep pattern.

A summary of statistical analyses and method for Paper I to IV are presented in Table 2.

Table 2. Statistical analyses and method in Paper I-IV.

Method	Paper I	Paper II	Paper III	Paper IV
Shapiro-Wilk distribution test	X	X		X
Chi-Square test Fisher exact test	X			X
Mann-Whitney U test		X		X
Wilcoxon signed-rank test		X		X
ANOVA –Freidman's	X			
ANOVA with Greenhouse-Geisser		X		
Bonferroni correction	X	X		
Confidence interval 99%	X			
Confidence interval 95%		X		X
Confidence interval compared				X
Linear Regressions		X		
Correlations Pearson / Spearman		X		
Content analysis			X	

The structured lifestyle program

The structured lifestyle program started in 2008, at an outpatient clinic at the Department of Cardiology at Karolinska University Hospital, Sweden. Recruitment to the program continued until December 2014. Individuals with increased cardiovascular risk were referred by their physicians at primary health care or hospitals. The referring physician was still the main care provider and was updated by letter from the program's physician regarding the participant's progress in changing an unhealthy lifestyle, and CV risk management. The referral was reviewed in a lifestyle round by the program's physician and a specialist nurse. They considered whether or not the patient met the inclusion criteria. This kind of round was convened twice a month.

The **inclusion criteria** for enrollment on the program were men and women >18 years, presenting at least three or more of the following risk factors for CVD; current CVD, diabetes type 2, insulin resistance, overweight, abdominal obesity, dyslipidaemia, high blood pressure, smoking, risk consumption of alcohol, physical inactivity, unhealthy food habits and stress. The **exclusion criteria** were: inability to understand the Swedish language, unable to attend the entire program, alcohol addiction, and psychiatric diagnoses (unable to attend the group sessions).

The program consisted of three individual visits to a specialist nurse (baseline, six-month and one-year follow-up) and five group education sessions with the physician and a specialist nurse.

Figure 7. Lifestyle program flow chart

Individual visit

Before the individual visit, a questionnaire including questions on lifestyle habits, living conditions and perceived health, was sent by post and completed by the participant at home. The program started with an individual visit to a nurse, who adopted a person-centred approach. The participant collaborated in creating a plan for changing their habits, based on the answers from the questionnaires.

The lifestyle counselling was based on the latest guidelines, both regarding lifestyle habits and risk factors (12, 17, 18, 56, 68) (shown in table 3).

Motivational interviewing strategies were used to strengthen the participant`s empowerment and ability to identify and change unhealthy lifestyle habits (147, 152, 166). At this visit, goals for changing an unhealthy lifestyle and reducing cardiovascular risk were formulated. This was carried out in a dialogue between the specialist nurse and the participant, i.e. shared-decision making in a collaboration between the participant and the nurse (147). The individual visits lasted one hour.

At the clinic, anthropometrics, blood pressure and fasting blood samples were obtained. Weight and height were measured. The waist circumference was measured in a standing position, midway between the lower rib margin and the iliac crest. Blood pressure was measured in a standardized way; seated position after ten minutes rest (12). Fasting blood-samples were taken: total S-cholesterol (mmol/l), S-low density lipoprotein cholesterol (mmol/l), S-high density lipoprotein cholesterol (mmol/l), S-triglycerides (mmol/l), P-glucose (mmol/l) and HbA1c (%). These were analysed according to local routines at Karolinska University Hospital. All participants were offered individualized PaP at the baseline visit (167). To prescribe the activity and dose, the handbook, Physical Activity in the Prevention and Treatment of Disease (FYSS) was used (43). After each visit, the participants received a letter from the physician with the results of their anthropometrics and blood samples. The letter included encouragement as well as advice on how to maintain lifestyle changes.

Table 3. Lifestyle, risk factors and goals according to European Guidelines on cardiovascular disease prevention in clinical practice (12).

Lifestyle Habits	**Counselling /Goals**
Smoking	Smoking Cessation
Alcohol consumption	Moderate intake Men: 1-2 glass /day Women: 1/2 -1 glass /day
Daily physical activity	30 min / day or 150 min week moderate intensity
Exercise	1-3 times /week both aerobic and strength training
Sedentary behaviour	Decrease sedentary behaviour and replace it with breaks of physical activity
Vegetable and fruit intake	>500 gram /day
Meat intake	<500 grams /week
Extra calories	decrease intake
Risk Factors	**Target**
BMI kg/m2	<25 kg/m2
Waist circumference (man, woman) cm Individuals with risk* (man, woman) cm	<102cm <88cm <94 cm <80 cm
Blood pressure mmHg Individuals with risk*	<140/90 <140/85
Total cholesterol mmol/L LDL cholesterol mmol/L Individuals with risk* LDL cholesterol mmol/L	<5.0 mmol/L <3.0 mmol/L <1.8 mmol/L

*Diagnosed CVD and DM type 2

Group education sessions

The group education consisted of five weekly sessions led by a physician and the same specialist nurses as at the individual visit. The group sessions took place in the afternoon (duration ≈ 2 hours), with 10 to 18 participants, at the hospital outpatient clinic. The first part of the session consisted of a lecture on one of the topics shown below, followed by open discussions in which participants were encouraged to share their experiences with the rest of the group. Hand-outs were distributed during each group session. From 2008 to 2014 a total of 15 groups completed the program.

Topics addressed in the group education sessions:

1) Overall lifestyle and health – focus on unhealthy lifestyle and reason for this, with practical advice on how to change patterns and replace them with more healthy choices. At this session participants were given a book, *Smart Choices,* written by health care professionals and based on experiences in making healthy choices when changing an unhealthy lifestyle.

The participants were also encouraged to visit a web-based lifestyle course, *Sundkurs (*www.sundkurs.se) (168) between visits about lifestyle and health.

2) **Physical activity and sedentary behaviour** – the focus was on defining PA and sedentary behaviour as well as their health benefits. The practical session was based on smart choices for avoiding sedentary behaviour and increasing PA. All the participants were given a pedometer (Yamax LS2000) to promote motivation, as well as to maintain and increase PA (56).

3) **Food habits and use of alcohol -** focus was on the effects of a Mediterranean food pattern on preventing diseases, and benefitting lifestyle habits and CV risk factors. The practical advice on healthy food patterns was based on guidelines from the National Food Agency (68).

4) **Smoking, stress and sleeping habits** – the focus was on helping the participant to stop smoking, good advice/choices and encouraging contact with www.slutarökalinjen.se for more help. Regarding stress, the participants were introduced to various anti-stress methods and their effects on CV risk (Medi-Yoga, mindfulness and anti-stress). Sleep disorders, and their negative impact on health, were addressed. Advice was given to help participants improve their sleep (169).

5) **Behavioural change** -with focus on behaviour change and based on practical advice regarding change, motivation and failure. Practical elements, such as eating healthy food and how to shop for healthy food with help of a dietician were also included.

The participants were encouraged to bring a relative or friend to the sessions as support. This was encouraged for all five sessions.

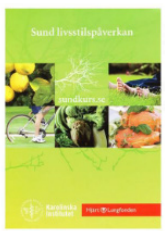
Health-related tools

Throughout the program the participants were given tools to help and support them in changing their lifestyle and to maintain changes between visits (Figure 8);

Sundkurs: www.sundkurs.se a web-based lifestyle course, including education regarding healthy lifestyle, based on recorded lectures on evidence-based lifestyle medicine. These were followed by lifestyle-related advice regarding various lifestyle habits (168).

Smart Choices: a book written by health care professionals based on experiences of making healthy choices (183).

Pedometer: a step counter (Yamax LS2000 from Keep on walking Scandinavia) to promote motivation and to obtain and maintain physical activity (PA) (56).



Sundkurs

Smart Choices

Pedometer Yamax

Figure 8. Health related tools (168, 183).

Enrollment in the program

Patients were referred from primary health care and hospitals from all over Stockholm County. In total, 140 patients were referred to the outpatient clinic between 2008 and 2014. Twenty-four of these did not meet the inclusion criteria. The remaining 116 patients were sent a letter explaining the aim of the study together with a patient consent form approved by the local ethics committee of the Karolinska Institutet. The letter explained the aim of evaluating the structured lifestyle program and asked their permission to use their data for this investigation and evaluation. Sixteen patients declined participation, which resulted in a total of 100 patients being included in the study (see flowchart in Figure 9).

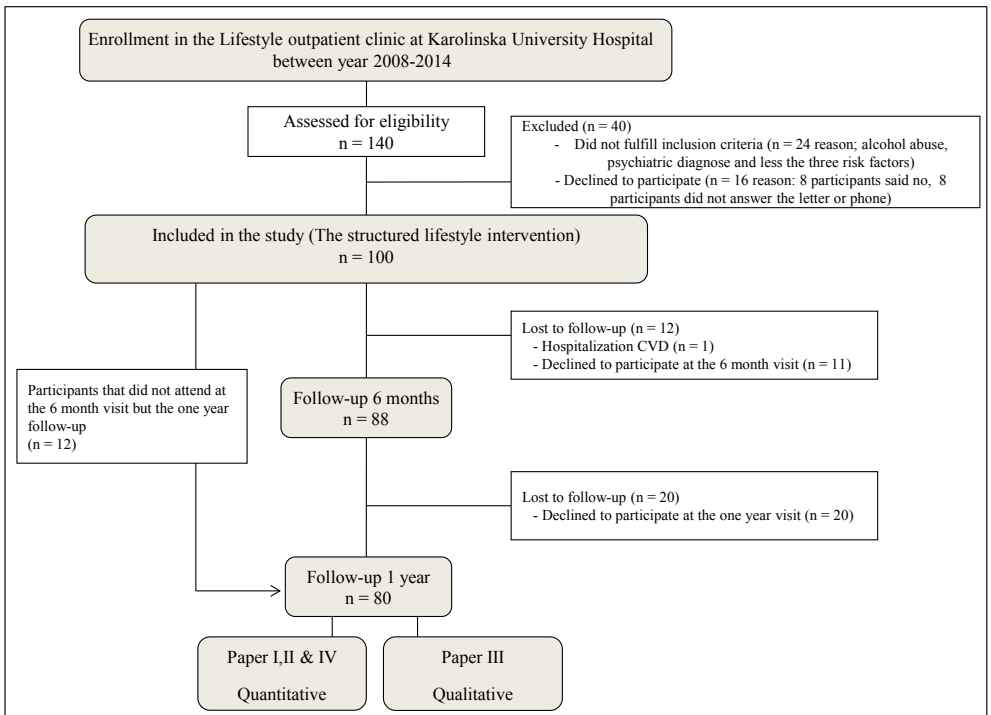


Figure 9. Flowchart of program attendance.

Study participants

The study population for Papers I, II and IV is presented in Table 4.

Between 2008 and 2014, a total of 100 individuals (64 females, 36 males, mean age 58±11 years) with ≥18 years with inreased cardiovascular risk, were enrolled in the lifestyle program. 53% of the participants reported that they did not have a university degree and this was equally distributed across genders. 39% of the participants lived alone, and 59% worked (data not shown). 36% were diagnosed with cardiovascular disease (women 31%, men 44%) and the prevalence of type 2 diabetes was 21%, higher in men. The prevalence of obesity was higher among women (36% vs. 22%), as well as abdominal obesity based on waist circumference (89% vs. 83%). 50% of the participants had hypertension at baseline; no gender difference. 35% of the women and 15% of the men were identified as having hypercholesterolemia.

The participants antiplatelet, hypertensive and lipidlowering medication is presented in Table 5. 23% of the participants were receiving antiplatelet treatment, 66% were on hypertensive treatment and 36% were on statin treatment. According to medical records and self-reports, the participants' medication did not change during the intervention.

The study population in Paper III is presented in Table 6. Fifteen participants at high cardiovascular risk were enrolled in the study.

Table 4. Demographic data of the study population at baseline.

	Total (n=100)	***Women (n=64)***	***Men (n=36)***
Age (years)	58 (±11)	58 (±12)	58 (±10)
Living alone	39 (39%)	28 (44%)	11 (31%)
No university degree	53 (53%)	30 (47%)	23 (64%)
Working	55 (55%)	33 (52%)	22 (61%)
Cardiovascular disease	36 (36%)	20 (31%)	16 (44%)
Type 2 diabetes	21 (21%)	11 (17%)	10 (28%)
Overweight	58 (58%)	36 (56%)	21 (58%)
Abdominal obesity	87 (87%)	57 (89%)*	30 (83%)
High systolic blood pressure	49 (49%)	32 (50%)	17 (47%)
High S-cholesterol	50 (50%)	35 (55%)	15 (42%)

Data is presented as mean (±SD) or n (%). Definitions: Obesity = BMI ≥30, Abdominal obesity = men ≥102 cm and women ≥88 cm, High systolic blood pressure ≥140 mmHg, Hypercholesterolemia = S-cholesterol ≥5.0 mmol/l, Differences between men and women were tested for with Fischer´s Exact test *= $p<0.05$

Table 5. Participants anti platelet, hypertensive and lipidlower medication.

Medication	***Total (n=100)***	***Women (n=64)***	***Men (n=36)***
Antiplatelet	23	13	10
Beta-blockers	38	13	25
Ace-inhibitors	41	14	27
Angiotensin-receptor blockers	11	5	6
Diuretics	18	6	12
Calcium-channel blockers	21	13	8
Statins	36	15	21

Table 6. Demographic data of the participants in Paper III.

Total n=15	
Females	13 (80%)
Age (years)	58 (±9)
Social status (single)	3 (20%)
Working	7 (47%)
No university degree	7 (47%)

Data are presented as mean for age (SD) and in numbers of individuals (%)

Design, measurements and statistical analysis

Paper I

Paper I is based on a descriptive study describing the lifestyle program's structure and evaluating its effect on lifestyle habits and quality of life.

Measurements: Information on lifestyle habits, living conditions and quality of life were obtained by validated questionnaires.

Tobacco habits were assessed by two questions: *Do you smoke? If yes, how many cigarettes a day?* and *Do you use snuff ? If yes, how many boxes of snuff a day?*

Alcohol consumption was assessed with two validated questions used in healthcare to detect alcohol risk consumption and addiction (36). One question captured how often the individual used alcohol: *How often do you drink alcohol?* The other question assessed the amount of alcohol consumed on each occasion: *How many glasses do you drink per occasion?* The individuals were shown a standard drinks scale to use in their estimates (a standard drink was 12 gram/alcohol: i.e. beer 50 cl, strong alcohol beer 30 cl, wine 12-15 cl, fortified wine 8 cl or spirits 4 cl.) (17, 18).

Physical activity and sedentary habits were assessed by three questions used in the validated instrument International Physical Activity Questionnaire (IPAQ) (50). Leisure-time non-exercise physical activity (NEPA by the question: *How much of your leisure time do you spend in physical activity that gets you slightly out of breath?* Exercise habits by the question: *How often do you exercise?* Time spent in a sedentary position was assessed by the question: *Consider the time you spend sitting in association with work, studies, transportation, at home, and during your leisure time. For example, time at a desk, visiting friends, or watching TV. During the past seven days, how much time have you spent sitting?* The participants reported sedentary time in hours and minutes per day (50).

Food habits were assessed by fourteen questions focusing on participants' intake of different food groups, a validated instrument often used in health care (170). The fourteen questions covered the frequency of intake of vegetables, fruit, fat, bread, meat, processed meat products, and extra calories from snacks.

Stress-level was defined by four graded responses to the statement: *I get easily stressed,* with the given alternatives: *Almost never, sometimes, often,* and *almost always* (171).

Sleeping habits were assessed with the question: *During the past month, have you experienced difficulty falling asleep?* and answered by one of four graded responses: *Never, rarely, sometimes,* and *often* (172).

The **Hospital Anxiety and Depression Scale** (HADS) was used to assess anxiety and depression symptoms (173). This consists of seven questions about anxiety and seven questions about depression symptoms, graded from 0–3. Each sub-scale resulted in a total score ranging from 0-21. HADS is a validated instrument used in patients with a high cardiovascular risk (174). A cut off: 8 was used for each sub-scales.

Quality of life was assessed though the Gothenburg Quality of Life (GQL), a validated instrument used in individuals with cardiovascular risk (92). It consists of 16 self-rated questions answered on a Likert scale (from 1 = *very bad* to 7 = *excellent, could not be better*), organized in three different domains of well-being: *social well-being* (including questions regarding housing, home-situation, work, economy and leisure time), *mental well-being* (including questions regarding self-esteem, mood, patience, energy and sleep), and *physical well-being* (including questions regarding health, vision, and hearing, fitness, appetite and memory) (92). A mean score was obtained for each subdomain by multiplying the Likert scale items to obtain sub-scores.

Risk-related, unhealthy lifestyle habits were dichotomized into, daily smoking or not, and risk consumption of alcohol on six-specific evaluations of frequency and quantity of alcohol intake (36). Daily activity was dichotomized into ≥ 30 minutes per day or less, and exercise habits into ≥1 hour per week or less. Sedentary behaviour (time/day) was reported in hours and minutes using the IPAQ short questionnaire (50). Dietary habits were assessed by questions regarding daily intake of vegetables and extra calories from snacks. Stress was dichotomized into easily becoming stressed (often/almost always or not).

Statistical analyses: Questionnaire data from baseline, six months and one-year were analysed. Fisher`s exact-test was used to test for gender differences at baseline. Mean values and standard deviation were calculated on continuous data to facilitate the interpretation of the results. For trend-analyses and comparisons between the three points of time, non-parametric testing was applied. Friedman's non-parametric ANOVA was used for trend analyses of continuous data over time. The Wilcoxon matched pair test was used to identify differences between the three-measurement time-points, and a Bonferroni adjustment was used to correct for multiple testing. Each participant's continuous data was dichotomized into having an unhealthy lifestyle habit or not, for each specific lifestyle variable. To compare the prevalence of an individual's lifestyle habits between each time point over one year, the raw difference and a 99% confidence interval (CI) were calculated between each occasion. The 99% CI was used to adjust for multiple testing. Existing data from the current visit (baseline or 6-month follow-up) were used and carried forward for missing data as an intention to treat (ITT) analysis. Statistical analyses were performed using SPSS (version 22) and Confidence Interval Analysis (version 2.0.0).

Paper II

This is a descriptive study of the lifestyle programs structure, and evaluates its effect on cardiovascular risk factors and cardiovascular risk according to Framingham risk scores.

Measurements: Cardiovascular disease and diabetes type 2 diagnoses were identified from the patient's medical journal. Current medication information was obtained from both, medical records and the participant at the initial visit. Anthropometrics and blood samples were collected at baseline, six months and after one year. Height was measured in light-weight clothes without shoes, with a stadiometer to the nearest 1.0 cm, and weight to the nearest 0-1 kg. Body Mass Index (BMI) was calculated. Waist circumference was measured in a standing position, midway between the lower rib margin and the iliac crest. Blood pressure was measured in a standardized way; seated position after ten minutes rest (12). Fasting blood-samples were taken; total S-cholesterol (mmol/l) , S-low density lipoprotein

cholesterol (mmol/l), S-high density lipoprotein cholesterol (mmol/l), S-triglycerides (mmol/l), P-glucose (mmol/l) and HbA1c (%); these were analysed according to local routines at Karolinska University Hospital.

Cardiovascular risk was estimated using the general cardiovascular risk profile based on the Framingham 10-year risk prediction model (114).

Statistical analyses: Normality was checked by using the Shapiro-Wilk test. Variables differed between the three time points (baseline, six months and one year) and were measured with a repeated measures ANOVA with Greenhouse-Geisser correction and subsequent post-hoc analyses with a Bonferroni correction. Skewed variables (BMI, systolic and diastolic blood pressure, heart rate, LDL cholesterol, HDL cholesterol, triglycerides and cardiovascular risk according to the Framingham CV-risk predicting model) were presented as medians with the interquartile range (Q1 to Q3). Friedman´s 2-way ANOVA by ranks and post-hoc analyses with a Bonferroni correction were used. If this was done the variables differed between the three time points changed. For missing data for all variables, an intention to treat approach was used, and the last observation (from baseline or six month) was carried forward. Further, CVD risk factors variables were dichotomized according to conventional cut-off points for increased CVD risk. The prevalence of participants with risk factor values above these cut-offs were compared over one year and a 99% confidence interval (CI) was calculated. The 99% CI was used to adjust for multiple testing. Statistical analyses were performed using SPSS (version 24).

Paper III

A descriptive qualitative interview study.

Method and Measurements: The focus in the interview was to highlight the participant's experience of the program's structure over one year: the individual and group meeting, the appointment with the health professionals, health-related tools that were distributed, feedback at follow-up, structure, and experience of bringing a relative or friend to the group sessions. Fifteen individuals, participating in the structured lifestyle program, were included in the study. The participants were asked about enrolment in the study at the programs final visit. The main author was not involved in the participants' care program to avoid bias; this was carried out by two other health-professional with a similar education. Fourteen interviews were conducted by (M.L) the main author and one interview was conducted by (M.R) the last author, for credibility reasons.

The interviews were individual, semi-structured and face-to face. All the interviews were conducted between November 2016 and March 2017 at the lifestyle clinic at a cardiology department. The interviews were conducted within a time-window of one year after the program's one-year follow-up visit.

The duration of interviews varied between 30-45 minutes. They started with (M.L) asking the participant to give a short history of attempts to change his/her lifestyle, as well as their reason for enrolling at the lifestyle clinic. All the questions were open-ended. All interviews were recorded and transcribed verbatim.

Analyse: The analysis began with the authors (ML and MR-C) reading the transcribed data and identifying emerging patterns. These were then compared. Sentences with relevant patterns were extracted and put in a matrix.

The transcribed interview data were analysed using qualitative manifest content analysis with an inductive approach, which is a method that provides a systematic way of making valid inferences from verbal or written data in order to explore a specific phenomenon (175-177). The aim of the content analysis was to highlight the experience of participating in the program. Each sentence was coded by both main authors and last author and compared. A third person, an expert in content analysis, also read five of the interviews and examined the text and the codes. The next step in the analysis was to divide the patterns into meaning units and subsequently into subcategories to search for patterns and categories.

Paper IV

A descriptive study to evaluate how education level according to university degree or non-university degree and socio economic area of residence are associated with change in unhealthy lifestyle habits, cardiovascular risk factors, cardiovascular risk and quality of life over one year.

Measurements: Educational level was self-reported and categorized in to university degree or non-university degree. The participants' demographic data including addresses were obtained from medical journals. Classification into low or high SEA was based on calculation of median income in Sweden by official statistics from Statistics Sweden (SCB) (178). Low SEA was defined as areas with median income ≤29.300 Swedish crowns, and high SEA as areas with a median income of more than 29.300 Swedish crowns. Each participant were then identified as residents of either a low or high SEA according to the mean income in the postcode area of residence (179). Information about lifestyle habits, living conditions and quality of life were obtained through questionnaires; CVD and type 2 diabetes diagnoses were obtained from medical records.

Statistical: Data were checked for normality using a Shapiro-Wilk test. The majority of the variables were found to be skewed. Data are presented as medians (quartile 1 and 3). An intention to treat approach was used, and hence the last observation carried both forward or backwards was used for missing data. Differences in proportion of unhealthy lifestyle habits a) at baseline between university and non-university degree participants, and participants living in low and high SEA of residence, respectively, b) delta change of proportions within each group and c) comparisons of delta change between groups, were tested by calculating the raw difference and a 95% confidence interval for the difference. For the skewed continuous data (Framingham risk score and quality of life), differences at baseline between groups as well as comparisons of delta change over one year between groups were calculated using Mann-Whitney U test. To test for significant delta change within each group over one year, Wilcoxon matched test was used. Significance level was set to $p<0.05$. Statistical analyses were performed using SPSS (version 24) and Confidence Interval Analysis (version 2.0.0).

Ethical considerations

To change unhealthy lifestyle habits can be a very sensitive issue. It is important that health care professionals show respect for the individual's autonomy and his/her ability to be involved in his/her own treatment. We strived to adopt a respectful and person-centred approach and to be aware of the participant's autonomy, own decisions and integrity.

The study (**Papers I, II, II & IV**) was approved by the local ethics committee in Stockholm DNR 2015/494-31/2.

The study is based on Good Clinical Practice Guidelines according to the Declaration of Helsinki.

Prior to the study: All participants received a written statement of the study plan, and written approval was obtained from participants before the start of the study.
The participants were identified by study number, thus ensuring the privacy of their data.

During the study: Ethical issues regarding lifestyle changes are a complex topic and we strove to work in a person-centred manner and to have the patient's autonomy and integrity in mind. Our approach was that the participants should not be exposed to any risks that might violate their integrity and autonomy.

Analysis: Collected data have been managed in accordance with ethical guidelines and the participants were informed that they could withdraw from the study at any time according to Good Clinical Practice Guidelines.

RESULTS

Summary of results

- It was possible to launch a structured multidisciplinary lifestyle program, with individual and group sessions, in a clinical setting at a cardiology unit.
- Participating in a structured lifestyle program over one year, led to significantly increased exercise levels, decreased sedentary time, consumption of less red meat, more healthy choices regarding fat quality, and improved quality of life for individuals with high cardiovascular risk.
- Significant improvements in the cardiovascular risk profile, with a 15 % reduction of 10 year cardiovascular risk general according to the Framingham risk score in the total study population.
- The participants found several factors to be important regarding the program's structure: competency and respectful attitude of the caregiver. The program should include individual and group education, and discussions between the participants. Health-related tools are important and should be integrated in the sessions. Feedback from caregivers should be given on a continuous basis, preferably written as a "prescription", with a positive tone.
- Educational level based on university education or not and different socioeconomic areas (SEA) of residence can imply a higher burden of unhealthy lifestyle habits and higher CVD risk. The results of the present study have clinical relevance, as suggesting that such factors are no barriers for changing unhealthy lifestyle habits and decreasing cardiovascular risk after participation in a lifestyle program.

Changes in lifestyle habits and quality of life

Results from baseline, six months and the 1-year follow-up form **Paper I** are presented in Table 7. At baseline, the mean alcohol consumption was 1-2 glasses, 2-4 times a month. The overall physical activity level, for most individuals, consisted of exercising less than 60 minutes per week and a NEPA level of 30 minutes or lower per day. The self-reported sedentary mean time was 7.4 hours per day. Regarding food habits, the intake of vegetables and fruit was low, and the consumption of meat and processed meat products high according to current guidelines. The participants reported medium levels of stress. Difficulty in falling asleep was mostly reported as rare or sometimes. In general, favourable changes in lifestyle habits were observed between baseline, 6-months and one-year follow-up. Frequency of alcohol intake per month or week was reduced after 6 months and over one year (p for trend =0.001). There was an overall improvement in dietary habits, with a significant increase in the intake of vegetables (p for trend =0.041), more healthy types of fat (p for trend=0.001) and more fibre-rich bread were chosen (p for trend =0.003). The intake of sausages and bacon was reduced (p for trend =0.001). In GQL at baseline, the mean social well-being score was 25.63, and for mental well-being 21.97. The physical well-being score was 26.55. The HADS scores for depression symptoms were higher than anxiety symptoms at baseline. Both mental and physical scores from the GQoL improved significantly (mental, p for trend =0.002, physical, p for trend =0.012), while there were no changes in social well-being, stress or sleeping habits. The HADS' scores on symptoms of depression and anxiety decreased significantly over one year (p for trend=0.016 and p for trend =0.012 respectively).

Table 7. Self-reported lifestyle habits at baseline, six months and one year.

	Baseline	***6 months***	***1 year***	***p-value trend***
Risk consumption of alcohol (n=97)				
Number of standard drinks	1.47 (±0.71)	1.45 (±0.71)	1.40 (±0.70)	0.280
Frequency	3.08 (±1.17)	2.90 [a] (±1.16)	2.95 (±1.15)	0.003
Physical activity				
NEPA (n=99)	2.65 (±0.87)	2.73 (±0.77)	2.77 (±0.82)	0.540
Exercise (n=98)	2.05 (±1.19)	2.19 (±1.14)	2.33 [a] (±1.24)	0.012
Sedentary time, hours/day (n=93)	7.38 (±3.21)	6.33[a] (±2.92)	6.31[a] (±2.84)	0.001
Eating habits (n= 100)				
Vegetables	1.83 (±0.70)	1.89 (±0.72)	1.98 (±0.73)	0.041
Fruit	2.38 (±0.74)	2.49 (±0.63)	2.46 (±0.68)	0.087
Fat preferences	2.35 (±1.16)	2.60 (±1.04)	2.60 (±1.03)	0.001
Bread	2.59 (±0.57)	2.02 (±0.51)	2.75[a] (±0.44)	0.003
Meat	2.01 (±0.81)	2.16 (±0.87)	2.07 (±0.86)	0.050
Processed meat products	2.83 (±1.07)	3.10 (±0.86)	3.07[a] (±1.00)	0.001
Dairy products	2.82 (±0.78)	2.91 (±0.75)	2.08 (±0.76)	0.083
Extra calories	2.48 (±0.70)	2.62 (±0.54)	2.63 (±0.59)	0.093
Stress (n=98)				
I get easily stressed	2.05 (±0.83)	1.96 (±0.81)	1.90 (±0.79)	0.240
Sleeping habits (n=97)				
Difficulty falling asleep	2.53 (±0.97)	2.58 (±0.90)	2.57 (±0.98)	0.240
Quality of life				
Total Social well-being (n=72)	25.63 (±5.66)	26.06 (±5.09)	26.35 (±5.07)	0.510
Total Mental well-being (n=97)	21.97 (±6.41)	22.41 (±6.33)	23.98[a,b] (±5.88)	0.002
Total Physical well-being (n=98)	26.55 (±6.05)	27.38 (±6.03)	28.14[a] (±5.92)	0.012
HADS				
Anxiety symptoms score (n= 94)	3.24 (±3.23)	2.72 (±2.26)	2.87 (±2.46)	0.012
Depression symptoms score (n=97)	5.61 (±3.71)	5.24 (±4.18)	4.80 [a] (±3.55)	0.016

All values presented as means (±SD).
[a] Significantly different from baseline, p<0.017 after adjustment for multiple testing
[b] Significantly different from 6 months, p<0.017 after adjustment for multiple testing
NEPA, Non-exercise physical activity
HADS, Hospital Anxiety and Depression Scale

Definitions to Table 7
Alcohol, Amount (glass per occasion): 1=1-2 glasses, 2=3-4, 4=5-6, 5=7 or more**.**
Frequency: 1=never**,** 2=once a month**,** 3=2-4 times a month**,** 4=2-3 times a week, 5=4 times or more a week.
Physical activity, NEPA: 1= none, 2= <30 minutes per day, 3=30-60 minutes per day, 4= >60 minutes per day.
Exercise: 1=none, 2=<60 minutes per week, 3=1-2 hours per week, 4= 2-4 hours per week, 5= > 4 hours per week. Sedentary time: Hours per day
Food intake, Vegetables: 1=seldom, 2=every day, 3=more than once a day.
Fruit: 1= rarely or never, 2=a few times a week, 3=every week.
Fat preferences: 1= saturated fat, 2= mono and polyunsaturated fat 3= mono and polyunsaturated fat, 4=no fat.
Bread: 1=whole wheat bread, 2=both whole wheat bread and whole grain bread, 3=whole grain bread and crisp bread.
Meat: 1=almost daily, 2=a few times a week, 3=once a week, 4=rarely or never.
Processed meat products: 1=twice a week of more, 2=once a week, 3= a few times a month, 4=rarely or never.
Dairy products: 1=mostly standard (3% fat), 2=both standard and low-fat (0.1–1.5%), 3= mostly low-fat, 4= rarely use.
Extra calories 1=everyday, 2=a few times a week, 3=once a week or never.
Stress, I get easily stressed 1= almost never, 2= sometimes, 3= often, 4= almost always
Sleeping habits, Difficulty falling asleep 1=never, 2=rarely, 3=sometimes, 4=often
Quality of life, Social, Mental and Physical Well-being scale ranging 1 (very bad) to 7 (excellent). Social and Mental Well-being consist of 5 items, and Physical Well-being of 6 items.
HADS, Anxiety symptoms total score 0-21. Depression symptoms total score 0-21

Quality of life

All the items in the GQoL score were analysed separately based on a seven-point interval scales ranging from "poor" (=1) to "excellent, could not be better" (=7) shown in table 8.

Table 8. Goteborg Quality of Life single item score.

Parameter	Baseline	6 months	1 year
Home and family n=94	5.20 (±1.55)	5.38 (±1.41)	5.51 (±1.29)[a]
Work n=74	5.06 (±1.45)	4.99 (±1.57)	4.97 (±1.55)
Leisure time n= 95	4.53 (±1.58)	4.60 (±1.55)	4.87 (±1.39)[a.b]
Mood n= 96	4.68 (±1.52)	4.75 (±1.44)	5.07 (±1.29)[ab]
Energy n=95	3.73 (±1.77)	3.97 (±1.57)	4.38 (±1.37)[a.b]
Patients n=97	4.57 (±1.45)	4.57 (±1.50)	4.84 (±1.41)
Sleep n=97	4.30 (±1.68)	4.37 (±1.32)	4.75 (±1.70)[a.b]
Health n=97	3.65 (±1.51)	3.90 (±1.61)	4.26 (±1.52)[ab]
Confidence n= 97	4.71 (±1.51)	4.83 (±1.61)	5.00 (±1.44)[a]
Memory n= 96	4.51 (±1.51)	4.64 (±1.46)	4.64 (±1.37)
Vison n= 97	4.90 (±1.29)	4.99 (±1.37)	4.97 (±1.30)
Hearing n= 97	5.07 (±1.56)	5.19 (±1.48)	5.20 (±1.40)
Fitness	3.08 (±1.57)	3.25 (±1.54)	3.58 (±1.52)[a.b]
Appetite n=99	5.44 (±1.45)	5.57 (±1.29)	5.62 (±1.14)

Data presented as means
From base line [a] Significantly different from baseline, $p<0.017$
From the 6 months [b] Significantly different from 6 months, $p<0.017$
Both related-samples Wilcoxon sign-rank test (Bonferroni adjusted for multiple comparision)

Changes in lifestyle habits in relation to gender

Changes in lifestyle habits, in relation to gender over one year, are shown in Table 9. In total 54 women and 36 men were included. A significant p-trend for alcohol consumption frequency was observed after one year in the female group. Significant positive results regarding sedentary behaviour were observed over one year in men. Women's food patterns showed improvements, significantly positive results were observed in fat quality, bread quality, meat quality and reducing extra calories after one year in the women. The women rated daily stress was lower and they had a significantly higher mental well-being score regarding quality of life after one year.

Table 9. Changes in lifestyle habits in relation to gender at baseline, 6 months and 1 year.

Lifestyle habit	Baseline Man n=36	Baseline Woman n=64	6 months Man n=36	6 months Woman n=64	1 year Man n=36	1 year Woman n=64	Man P-value Trend	Woman P-value Trend
Risk consumption of alcohol (n=87)								
No of standard drinks	1.66(±0.83)	1.36(±0.62)	1.69(±0.82)	1.36(±0.60)	1.62(± 0.92)	1.27(±0.52)	0.651	0.280
Frequency	3.03(±1.14)	3.08(±1.13)	2.77(±1.11)	2.92(±1.15)a	2.82(±1.15)	2.97(±1.15)	0.100	0.021
Physical activity								
NEPA (n=97)	2.38(±0.83)	2.78(±0.87)	2.44(±0.69)	2.90(±0.76)	2.63(±0.76)	2.85(±0.85)	0.088	0.630
Exercise (n=96)	1.89(±1.07)	2.16(±1.25)	1.94(±1.05)	2.36(±1.17)	2.43(±1.26)	2.36(±1.21)	0.054	0.151
Sedentary time, hours/day (n=91)	7.92(±3.43)	7.09(±3.12)	7.31(±3.13)	6.22(±2.76)a	6.60(±2.94)a	6.06(±2.85)a	0.002	0.041
Eating habits (n= 98)								
Vegetables	1.61(±0.60)	1.95(±0.71)	1.55(±0.61)	2.06(±0.70)	1.66(±0.63)	2.15(±0.72)a	0.754	0.025
Fruit	2.30(±0.82)	2.40(±0.69)	2.36(±0.68)	2.54(±0.59)	2.30(±0.71)	2.53(±0.64)	0.767	0.035
Fat preferences	2.47(±1.18)	2.32(±1.16)	2.61(±1.05)	2.64(±1.03)a	2.69(±1.01)	2.59(±1.04)	0.264	0.006
Bread	2.57(±0.56)	2.58(±0.59)	2.63(±0.55)	2.72(±0.49)	2.71(±0.46)	2.77(±0.43)a	0.257	0.007
Meat	2.11(±0.75)	1.97(±0.84)	2.08(±0.87)	2.23(±0.86)a	2.20(±0.72)a	2.18(±0.94)	0.717	0.011
Processed meat products	2.66(±1.09)	2.95(±1.05)	2.79(±0.91)	3.20(±0.83)	2.94(±0.86)	3.16(±0.92)	0.063	0.021
Dairy products	2.77(±0.85)	2.90 ±0.66)	2.97(±0.72)	2.90(±0.69)a	2.91(±0.87)	3.03(±0.64)a	0.215	0.260
Extra calories	2.48(±0.57)	2.30(±0.58)	2.70(±0.56)	2.60(±0.58)	2.70 (±0.55)	2.70(±0.60)	0.268	0.001
Stress (n=96)								
I get easily stressed	1.74(±0.56)	2.24(±0.92)	1.80(±0.75)	2.16(±0.92)	1.71(±0.62)	2.12(±0.86)	0.829	0.036
Sleeping habits (n=97)								
Difficulty falling asleep	2.30(±1.00)	2.70(±0.91)	2.44(±1.00)	2.70(±0.81)	2.41(±0.97)	2.70(±0.97)	0.440	0.923
Quality of life								
Total Social well-being (n=72)	27.36(±4.04)	24.52(±6.28)	26.71(±3.47)	25.64(±5.90)	26.71(±2.54)	26.11(±6.18)a	0.813	0.277
Total Mental well-being (n=97)	24.22(±5.03)	20.64(±6.81)	23.58(±5.34)	21.72(±6.80)	24.64(±5.34)	23.59(±6.19a,b	0.413	0.001
Total Physical well-being (n=98)	27.33(±5.48)	26.10(±5.36)	28.28(±5.31)	26.85(±5.41)	28.97(±5.39)a	27.66(±6.20)	0.085	0.119

All values presented as means (±SD).

[a] Significantly different from baseline, p<0.017 after adjustment for multiple testing

[b] Significantly different from 6 months, p<0.017 after adjustment for multiple testing

Changes in unhealthy lifestyle habits

The results regarding proportions of individuals with unhealthy lifestyle habits are presented in **Paper I** (figure 10a) and proportion of participants with stress-related symptoms at baseline, 6-month and one year (figure 10b) reveal overall positive trends over one year. At baseline, ten individuals reported smoking and six individuals reported snuff use. Three participants stopped smoking and remained nicotine free at the one-year visit. The proportion of individuals with low levels of exercise decreased significantly from 67% to 46%. A significant reduction of individuals with sedentary behaviour was observed, from 43% at baseline to 24%, after one year. Participants' eating habits improved, with a significant

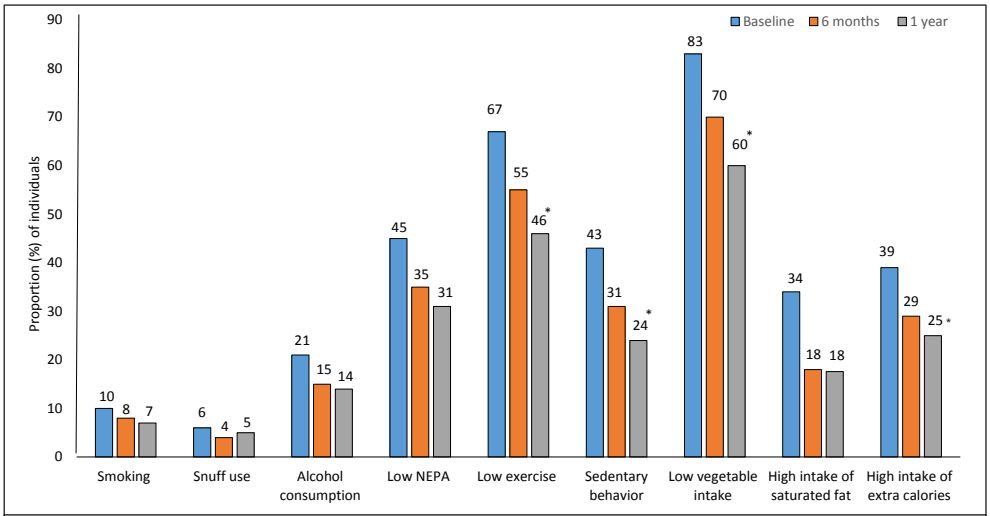


Figure 10a. Proportion of participants at risk in physically-related unhealthy lifestyle habits at baseline, 6 months and one year.*=p<0.05 compared to baseline. NEPA; non-exercise physical activity.

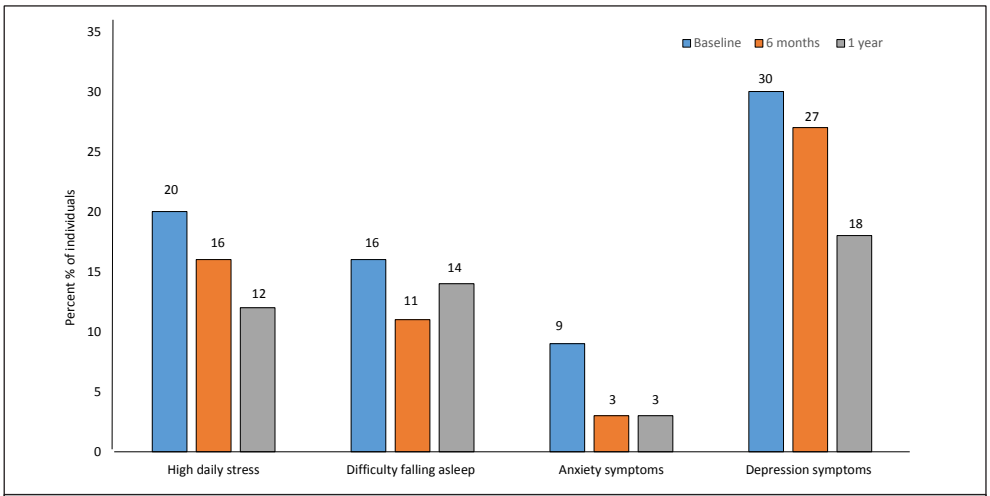


Figure 10b. Proportion of participants with stress-related symptoms at baseline, 6-month and one year. *=p<0.05 compared to baseline.

decrease in the number of individuals with a low intake of vegetables from 83% at baseline to 60% after one year. The proportion of individuals eating butter fat spread also decreased from 34% to 18% after one year. The number of individuals with a high daily intake of extra calories was significantly reduced, from 39% to 25%, over one year. The proportion of individuals who experienced high levels of daily stress was reduced from 20% to 12% after one year. There was no change in the number of individuals having difficulty falling asleep. The number of individuals with symptoms of anxiety decreased from 9% at baseline to 3%, and the number of individuals with symptoms of depression was reduced from 30% to 18% after one year.

The proportion of individuals at risk because of low PA habits decreased significantly from 67% to 46% ($p<0.05$). In parallel, a significant reduction in individuals at risk because of sedentary behaviour was observed, from 43% at baseline to 24%, after one year ($p<0.05$). Participants' food patterns improved, with a significant decrease ($p<0.05$) in the number of individuals with a low intake of vegetables 83% at baseline vs. 60% after one year. The number of individuals with a high daily intake of extra calories was also significantly reduced, from 39% to 25%, after one year. The proportion of individuals who experienced high levels of daily stress was reduced from 20% to 12% (non-significant) after one year. There was no change in the number of participants having difficulty falling asleep. The number of individuals with symptoms of anxiety decreased, from 9 % at baseline to 3%, after one year, and the number of individuals with symptoms of depression was reduced from 30% to 18%.

Changes in unhealthy lifestyle habits in relation to education level and socioeconomic areas of residence

In **Paper IV** the proportion of participants with unhealthy lifestyle habits in relation to different educational level based on university degree or not and socioeconomic area of residence was investigated. Data are presented in Table 10.

There was no difference in gender distribution between groups. However, a significantly higher prevalence of type 2 diabetes in non-university (30%) compared to university (11%) degree participants was noted (Table 10). Except for exercise habits, the baseline differences in prevalence of unhealthy lifestyle factors varied marginally between the non-university and university degree participants. While sedentary risk behaviour decreased significantly in the non-university degree participants, the decreases for the other lifestyle variables seemed to be more pronounced in university degree participants (non-significant). There were no significant difference in changes over one year between the two groups.

Prevalence of type 2 diabetes and previous CVD were similar between the low and high SEA group at baseline (Table 11). Significantly fewer individuals from the low SEA group exercised regularly at baseline, with lower daily activity but also lower intake of extra calories compared to the high SEA individuals. Although sedentary risk behaviour was prevalent to a similar extent at baseline, the proportion decreased significantly only in the low SEA group. Similar trends were seen for risk behaviour of low levels of regular exercise. Comparing change over one year, participants in the low SEA group improved daily activity habits significantly more compared to high SEA group, and a trend towards positive change of exercise habits was noted.

Table 10. Proportions of participants with unhealthy lifestyle habits, cardiovascular risk and quality of life at baseline and one year, and changes over one year, in non-university (n=53) and university (n=47) degree participants, respectively.

		Non-university degree				University degree			
		Baseline	**One year**	**Change over one year**		**Baseline**	**One year**	**Change over one year**	**Difference in change over one year between groups**
Women		62%				66%			
Diabetes type 2	n=53	30% (16)*	30% (16)		n=47	11% (5/47)	11% (5)		
Previous CVD	n=53	43% (23)	43% (23)		n=47	28% (13/47)	28% (13)		
Unhealthy lifestyle habits				**Proportion difference (95% CI)**				**Proportion difference (95% CI)**	**Proportion difference (95% CI)**
High sedentary time	n=45	47% (21)	31% (14)	-16% (-28 to -3)	n=45	44% (20)	33% (15)	-11% (-26 to 5)	-4% (-19 to 10)
Low daily activity	n=52	46% (24)	44% (23)	-2% (-15 to 11)	n=47	45% (21)	36% (17)	-9% (-23 to 6)	7% (-3 to 18)
Low exercise	n=43	86% (37)	77% (33)	-9% (-24 to 6)	n=38	71% (27)	58% (22)	-13% (-29 to 4)	4% (-11 to 19)
Smoking	n=51	12% (6)	12% (6)	0% (-8 to 8)	n=47	9% (4)	6% (3)	-2% (-11 to 6)	2% (-5 to 11)
Alcohol risk consumption	n=50	22% (11)	22% (11)	0% (-11 to 11)	n=45	22% (10)	18% (8)	-4% (-17 to 7)	4% (-3 to 15)
Low intake vegetables	n=52	87% (45)	81% (42)	-6% (-16 to 4)	n=47	81% (38)	70% (33)	-11% (-24 to 2)	5% (-7 to 17)
High intake extra calories	n=49	37% (18)	33% (16)	-4% (-19 to 11)	n=47	38% (15)	28% (11)	-10% (-22 to 3)	6% (-6 to 19)
Abdominal obesity									
High waist circumference (>100 cm)	n=53	89% (47)*	72% (38)	-17% (-29 to -6)	n=47	60% (28)	55% (26)	-4% (-16 to 8)	-13 % (-25 to -0.1)
Cardiovascular risk				**Median difference**				**Median difference**	**p-value for median difference between group**
Framingham 10-year risk, all (%)	n=53	15.9 (10.9-26.4)*	15.6 (8.0-20.0)	-2.0#	n=47	11.7 (4.5-21.6)	10.0 (4.5-21.5)	-0.6#	p=0.13
Framingham 10-year risk, previous CVD (%)	n=23	25.3 (15.9-30.0)	18.5 (13.7-29.4)	-1.7#	n=13	15.6 (9.9-29.7)	18.4 (7.0-28.5)	0.0	p=0.30
Framingham 10-year risk, non-previous CVD (%)	n=30	15.6 (9.2-19.3)	10.9 (6.3-15.9)	-2.2#	n=34	8.6 (3.9-19.3)	7.7 (3.8-15.7)	-0.9#	p=0.26
Quality of Life									
Physical well-being	n=50	27.0 (21.0-30.5)	26.5 (23.0-33.0)	1.0	n=46	26.5 (21.8-31.3)	28.0 (24.0-33.3)	1.0#	p=0.24
Mental well-being	n=49	21.0 (16.0-27.0)	25.0 (19.0-28.0)	1.0#	n=46	22.5 (17.0-27.0)	24.0 (20.0-29.0)	1.0#	p=0.97
Social well-being	n=30	25.0 (20.8-29.3)	27.0 (23.0-31.3)	1.5	n=40	27.5 (23.0-29.0)	26.5 (23.0-30.0)	0.5	p=0.33

Data presented as % (n) or median (Q1 to Q3).

*Significant group difference at baseline, p<0.05

#Significant delta change over 1 year within group, p<0.05

CVD, cardiovascular disease

Table 11. Proportions of participants with unhealthy lifestyle habits, cardiovascular risk and quality of life at baseline and one year, and changes over one year, in low (n=59) vs. high (n=41) socioeconomic area of residence, respectively.

		Low socio-economic area				High socio-economic area			
		Baseline	**One year**	**Change over one year**		**Baseline**	**One year**	**Change over one year**	**Difference in change over one year between groups**
Women	n=59	56% (33)			n=41	66% (27)			
Diabetes type 2	n=59	20% (12)	20% (12)		n=41	22% (9)	22% (9)		
Previous CVD	n=59	39% (23)	39% (23)		n=41	32% (13)	32% (13)		
Unhealthy lifestyle habits				**Proportion difference (95% CI)**				**Proportion difference (95% CI)**	**Proportion difference (95% CI)**
High sedentary time	n=52	47% (24)	29% (15)	-17% (-29 to -5)	n=38	45% (17)	37% (14)	-8% (-25 to 9)	-9% (-23 to 6)
Low daily activity	n=58	50% (29)	40% (23)	-10% (-23 to 3)	n=41	39% (16)	42% (17)	2% (-11 to 15)	-12% (-23 to -2)
Low exercise	n=49	88% (43)*	71% (35)	-16% (-30 to -2)	n=32	66% (21)	63% (20)	-3% (-22 to 16)	-13% (-26 to 2)
Smoking	n=57	12% (7)	12% (7)	0% (-8 to 8)	n=41	7% (3)	5% (2)	-2% (-13 to 7)	2% (-4 to 13)
Alcohol risk consumption	n=56	23% (13)	23% (13)	0% (-11 to 11)	n=39	20% (8)	15% (6)	-5% (-17 to 7)	5% (-2 to 17)
Low intake vegetables	n=59	83% (49)	76% (45)	-7% (-17 to 3)	n=40	85% (34)	73% (30)	-10% (-23 to 3)	3% (-8 to 17)
High intake extra calories	n=56	34% (19)	30% (17)	-4% (-17 to 10)	n=33	42% (14)	30% (10)	-12% (-26 to 3)	9% (-3 to 24)
Abdominal obesity									
High waist circumference (>100 cm)	n=59	83% (50)*	69% (41)	-15% (-26 to -4)	n=41	61% (25)	56% (23)	-5% (-17 to 7)	-10% (-22 to 3)
Cardiovascular risk				**Median difference**				**Median difference**	**p-value for median difference between group**
Framingham 10-year risk, all (%)	n=59	15.9 (8.6-25.3)	15.6 (6.3-24.8)	0.0#	n=41	13.7 (6.3-13.7)	11.2 (5.5-18.4)	-2.0#	p=0.17
Framingham 10-year risk, previous CVD (%)	n=23	25.3 (15.9-30.0)	21.6 (15.9-30.0)	0.0	n=13	15.9 (11.5-30.0)	15.9 (8.4-20.0)	-2.9	p=0.62
Framingham 10-year risk, non-previous CVD (%)	n=36	13.7 (6.6-18.5)	10.0 (5.3-15.9)	-1.1#	n=28	12.5 (4.3-24.4)	9.0 (3.9-15.6)	-1.3#	p=0.15
Quality of Life									
Physical well-being	n=58	26.0 (21.0-29.0)*	26.5 (23.0-32.3)	2.0#	n=38	29.0 (22.8-33.3)	29.0 (25.0-34.3)	1.0	p=0.61
Mental well-being	n=58	21.0 (17.0-25.0)	24.0 (19.0-28.0)	1.0#	n=37	25.0 (16.0-29.0)	25.0 (20.5-30.0)	0.0	p=0.25
Social well-being	n=37	25.0 (20.0-28.0)*	25.0 (22.5-28.5)	0.0	n=33	29.0 (23.0-31.0)	29.0 (24.0-32.0)	1.0	p=0.70

Data presented as % (n) or median (Q1 to Q3).
*Significant group difference at baseline, p<0.05
#Significant delta change over 1 year within group, p<0.05
CVD, cardiovascular disease

Quality of life in relation to education level according to university degree or not and socioeconomic areas of residence

In Paper IV Quality of life were analysed based on education level and socio-economic areas of residence presented in table 10 and table 11.

All quality of life sub-scores of well-being were similar in both groups at baseline (Table 10). Physical well-being increased significantly in the university degree group over one year, with no such change in the non-university degree group. Mental well-being increased in both groups, with no significant change of social well-being.

Physical and social well-being score were lower in low SEA group at baseline, with significant improvements in physical and mental well-being score only in the low SEA group (Table 11).

Changes in unhealthy lifestyle habits on an individual level

All the previous results are shown at group level. In Figure 11 The participants' changes on an individual level, expressed as the proportion of unhealthy lifestyle habits over one year, was measured and is presented divided in to: a/ Change in physical lifestyle-related risk habits, including smoking, use of snuff, NEPA, exercise, vegetable intake, saturated fat and extra calories and, b/ Change in physiological lifestyle risk habits and symptoms including high stress level, sleeping problems, anxiety symptoms and depression symptoms.

These changes were observed on an individual level over one year. Data are presented as medians with the interquartile range (Q1 to Q3). There was a median -1 (range 0–minus 6) positive change among the physically-related lifestyle risk habits, with 58 individuals improving one or more habits and 27 participants maintaining their habits.

For the physiological lifestyle habits, lifestyle risk habits and symptoms, the median change was 0 (range 0–4), with 35 participants improving one habit or more and 39 participants maintaining their score. For both sets of risk habits, there were also participants with no changes and those who had added risk habits over one year.

Changes in cardiovascular risk factors over one year

The changes in cardiovascular risk factors (**Paper II**) over one year are described and presented in Table 12. A significant trend was seen in weight reduction after six months but not after one year. Weight was significantly reduced after 6 months, while no significant change was noted after one year. Regarding BMI, a significant trend was observed after six months, with a mean change of 0.5 $kg^{2.}$ over one year. Mean waist circumference decreased over one year, from 108.4 cm at baseline to 105.9 cm at the one-year follow-up ($p<0.001$), a mean decrease of -2.5 cm. Men had a greater waist circumference at baseline and a mean decrease, corresponding to -1.8cm, over one year. Women started at 105.5cm with a mean decrease of - 2.9 cm over one year (men $p<0.099$ and women $p<0.001$). Both mean systolic and diastolic BP decreased over one year, from 135 to 130 mmHg ($p<0.001$) and from 85 to 80 mmHg ($p<0.001$), respectively. Comparing participants with and without BP lowering medication, revealed a decreasing trend in systolic and diastolic BP in both subgroups. There was no change in heart rate after one year. Total cholesterol decreased from baseline to six months (5.1 mmol/l to 4.9 mmol/l, $p<0.019$), with no further decrease at the one-year follow-up. Similar trends were seen for LDL-cholesterol.

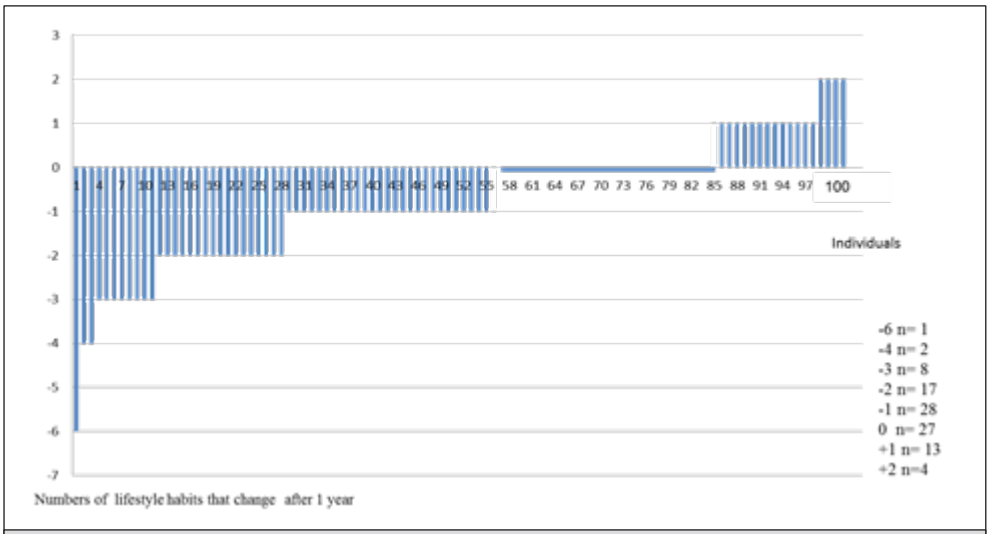


Figure 11a. Individual changes over one year in physical lifestyle-related risk habits including smoking, use of snuff, NEPA, exercise, vegetable intake, saturated fat and extra calories

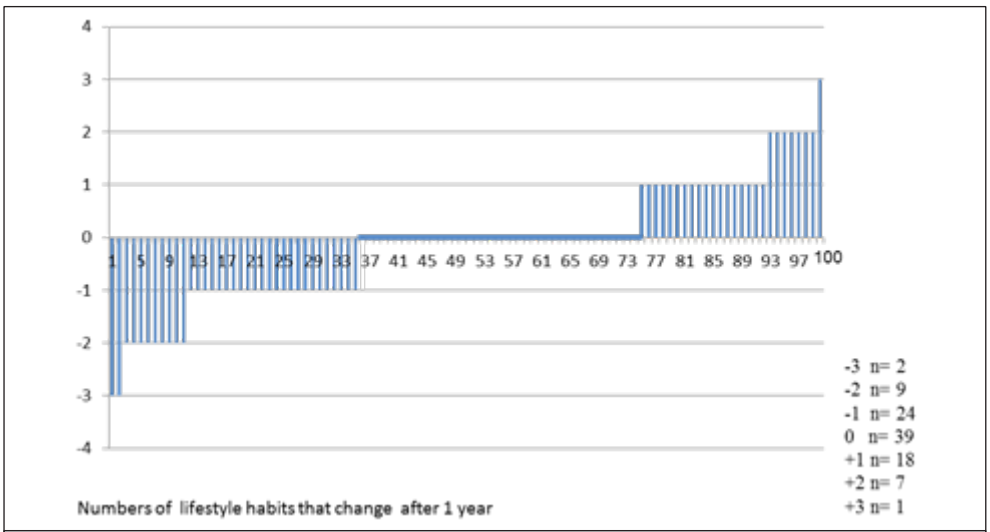


Figure 11b. Individual changes over one year in psychological lifestyle risk habits and symptoms including high stress level, sleeping problems, anxiety symptoms and depression symptoms

Changes in proportions of participants with adverse risk factors for CVD

In **Paper II,** the change in proportion (%) of participants at increased risk in each risk factor is presented in Figure 12. There was an overall trend of decreased proportions of risk for the majority of the CVD risk factors, with significant differences in high systolic and diastolic blood pressure at one year. A decreased trend was observed in total cholesterol,

Table 12. Cardiovascular risk factors at baseline, 6 months and 1 year.

Parameter	Baseline n=100	6 months n=88	1 year n=80	p-value
Weight (kg)	93.4 (19.2)	92.5 (19.5)[a]	92.6 (19.8)	0.056
BMI (kg/m^2)	31.6 (28.3 to 35.5)	31.4 (28.1 to 35.3)[a]	31.1 (28.0 to34.9)	<0.001
Waist Circumference (cm)	108.4 (15.0)	106.8 (15.3)[a]	105.9 (15.1)[a, b]	<0.001
Men (cm)	113.5 (14.6)	112.4 (14.3)	111.7 (13.2)[a]	0.099
Women (cm)	105.5 (14.6)	103.7[a](15.1)	102.6[a,b](15.1)	0.001
Systolic BP (mmHg)	135 (120 to 149)	130 (120 to 140)[a]	130 (120 to 140)[a]	<0.001
With BP lowering medication (n=66)	140 (125 to 150)	130 (120 to 140)	130 (120 to 140)[a]	0.002
No medication (n=34)	130 (120 to 140)	120 (119 to 140)	130 (118 to 136)	0.027
Diastolic BP (mmHg)	85 (80 to 90)	80 (75 to 90)[a]	80 (75to 85)[a]	<0.001
With BP lowering medication (n=66)	85 (80 to 90)	80 (75 to 90)	80 (79 to 85)[a]	0.006
No medication (n=34)	80 (80 to 90)	80 (80 to 85)	80 (70 to 90)	0.018
Heart rate (beats/min)	66 (60 to 76)	68 (62 to 80)	64 (60 to 76)	0.087
Total Cholesterol (mmol/l)	5.1 (1.1)	4.9 (1.1)[a]	4.9 (1.0)	0.019
With Statins (n=36)	4.5 (0.9)	4.3 (0.8)	4.4 (0.9)	0.151
No statins (n=64)	5.4 (1.1)	5.2 (1.1)	5.1 (1.0)	0.081
LDL (mmol/l)	3.1 (2.4 to 3.9)	2.8 (2.3 to 3.9)	2.8 (2.2 to 3.7)	0.065
With Statins (n=36)	2.6 (2.1 to 3.1)	2.4 (2.1 to 2.7)	2.4 (2.0 to 2.7)	0.342
No statins (n=64)	3.6 (2.8 to 4.2)	3.2 (2.6 to 4.1)	3.2 (2.6 to 4.0)	0.181
HDL (mmol/l)	1.3 (1.0 to 1.5)	1.2 (1.0 to 1.5)	1.4 (1.0 to 1.6)	0.227
Men (n=36)	1.1 (0.4)	1.1 (0.5)	1.2 (0.6)	0.260
Women (n=64)	1.4 (0.4)	1.4 (0.4)	1.4 (0.4)	0.633
Triglycerides (mmol/l)	1.2 (0.9 to 1.6)	1.3 (0.9 to 1.6)	1.2 (0.8 to 1.8)	0.376

Values are presented as means (SD) or medians (Q1 to Q3).

[a] Significantly different from baseline, p<0.017 after adjustment for multiple testing

[b] Significantly different from 6 months, p<0.017 after adjustment for multiple testing

BMI; Body Mass Index, BP; Blood pressure, LDL; Low density lipoprotein, HDL; High density lipoprotein.

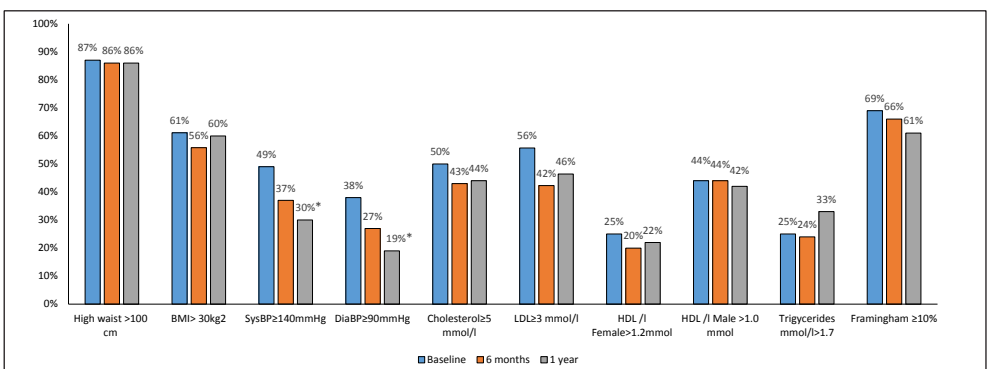


Figure 12. Proportion of participants at risk for each individual CVD risk factor at baseline and after six months and one year. *Significant <0.017 from baseline with Bonferroni correction for multiple testing.

LDL and low HDL-cholesterol one year. The proportions of participants with cardiovascular risk, according to the Framingham cardiovascular risk score, decreased somewhat, while the proportion of participants with high waist circumference and BMI was unchanged. The proportion of hypertriglyceridemia increased at the one-year visit.

Changes in cardiovascular risk

In Paper II, cardiovascular risk was calculated based on Framingham 10-year heart risk scores and was significantly reduced from baseline, 15.6%, to the one-year visit, 13.3%, in the total study population. There was a mean change of -15% over one year (Table 13). Men had a significantly higher risk at baseline compared with women, 23.5% and 10.8 % respectively, with a significant risk reduction in both sexes over one year. When comparing participants with previous CVD with those with non-previous CVD, the mean score decreased by 21% over one year, while for participants with non-previous CVD, the mean score decreased by 28% over the same time period.

Cardiovascular risk in relation to educational level and socioeconomic areas of residence

In **Paper IV** cardiovascular risk and quality of life were investigated based university degree or not and SEA. At baseline, the prevalence of abdominal obesity based on waist circumference was significantly higher in non-university degree participants compared to university degree participants (89% vs 60%) (Table 10). A significantly greater decrease (-17%) was noted in the participants with non-university degree over one year, compared to participants with university degree (-4%). Non-university degree participants had a significantly higher 10-year cardiovascular risk at baseline. The 10-year cardiovascular risk decreased significantly in both non-university and university degree groups after one year. When divided into previous or non-previous CVD, decreases were seen in both previous and non-previous CVD participants with non-university degree, but only in non-previous CVD participants with university degree.

The participants in low SEA group had a significantly higher proportion with abdominal obesity based on waist circumference at baseline compared to the high SEA group (83% vs 61%) (Table 11), with a significant decrease in the number of individuals with high waist circumference over one year (-15%) in the low SEA group. Total Framingham risk were significant reduced in both groups. Divided into subgroups of previous CVD or non-previous CVD, significant improvements were only present in non-previous CVD participants.

Table 13. Changes in Cardiovascular risk according to the Framingham heart risk score.

	Baseline	6 months	1 year	p-value
Total Framingham risk	15.6 (8.0 to 25.3)	13.7 (6.3 to 21.6)[a]	13.3 (6.3 to 20.8)[a]	<0.001
Men (n=36)	23.5 (15.6 to 30)	21.6 (15.6 to 29.4)	18.4 (13.3 to 29.4)	0.007
Women (n=64)	10.8 (4.7 to 18.5)	10.0(3.9 to 15.9)[a]	8.6 (4.5 to 15.9)[a]	<0.001
CVD (n=36)	23.5 (14.2 to 30)	21.5 (13.7 to 27.5)	18.5 (11.3 to 28.9)	0.033
Without CVD (n=64)	13.5 (5.6 to 18.5)	10 (4.1 to 18.4)[a]	9.7 (4.7 to 15.9)[a]	<0.001

All values presented as median (Q1 to Q3). [a] Significantly different from baseline, p<0.017

Association between change in sedentary behaviour and changes in cardiovascular risk factors

Associations between changes in waist circumference and cardiovascular risk factors are shown in figure 13 and 14. Pearson correlation coefficient showed significant correlations between sedentary behaviour and waist circumference (r=0.228) (p= 0.029) as well as between sedentary behaviour (r=0.245) (p=0.019) and systolic blood pressure. For correlations between lifestyle habits (categorical variables) and cardiovascular risk factors, a Spearman correlation coefficient-test was used. No correlations were observed between these variables.

Experiences from the structured lifestyle program

Overall, **Paper I-IV** showed that components, such as multidisciplinary teamwork, with focus on lifestyle rather than the disease, combining individual and group education, and using tools to increase compliance seem to have a positive outcome for the structure of the program.

The result of **Paper III** emerged in three different categories: *How to know?* – based on the individual and group sessions, and tools that strengthen self-care, *Staff who know how?* – Illuminates the meeting between health-care professional and participant, and the importance of competent health care professionals, and *Why feedback is essential?* – highlighting the views on, and effect of, the feedback between the participant and the health professional.

"How to know"-This category highlighted the participants' experiences and views on the structured program, and health-related tools being used to strengthen self-care and improve their ability to change unhealthy lifestyle habits. The individual sessions were described as valuable, and a person-centred approach in which the health professional treated a person with an unhealthy lifestyle rather than a patient with a disease, was considered important; one participant said, "…to feel seen is important". Participants also highlighted the importance of being included in the decision process regarding treatment goals. The participants saw the

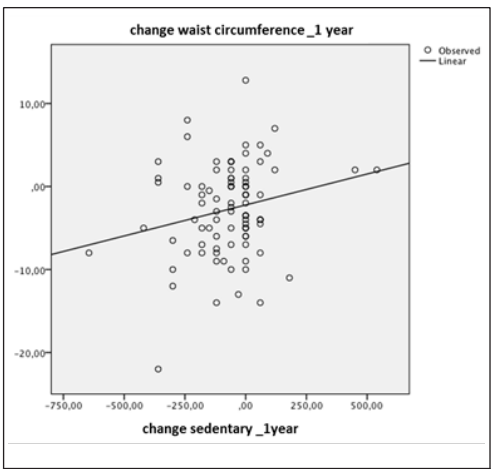


Figure 13. Correlations between change in sedentary time and waist circumference.

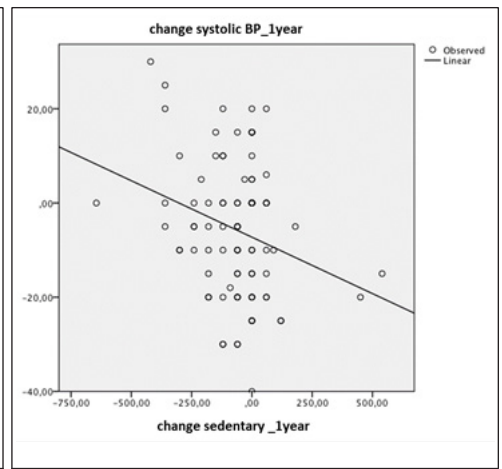


Figure 14. Correlations between change in sedentary time and systolic BP .

program as a way of confirming what they already knew and needed to be updated on. One participant compared it to an everyday activity:

"Even if you have had a driving license for 30 years it does not mean that you would pass the theory part of the driving test, if you know what I mean."

The participants experienced the group sessions as very positive, giving useful information and practical advice about, "What to change and how". That the sessions were held at a cardiology unit increased their credibility according to the participants, as did the staff's knowledge and experience in risk management and risk prevention. The health-related tools that were offered during the individual and group sessions were positively received. Participants liked the idea of having a book and an internet program for repetition between the visits. They also thought that the pedometer was a good reminder about daily physical activity. Some suggested improvements that could be made to the pedometer. It was deemed important that it should be easy to handle and access.

"**Staff who know how"**– the meeting with, and the importance of, competent health professionals
In this category, the participants described the importance of the health care professionals being competent and respectful. The participants expected a health care professional to be able to give individual, evidence-based advice about a healthy lifestyle. Lifestyle counselling should be based on current guidelines and transformed into practical advice. They also pointed out the importance of shared decision-making with the health professional in order to realise a personalized plan for changing their unhealthy lifestyle habits. One participant said:

"She was very thorough in finding out about what I would be able to do and my current situation"

The message should be positive and be respectful. Participants also pointed out the importance of multidisciplinary team work, with all health professionals involved meeting the participant face to face; one said:

"...just to be able to put a face to the person writing the letter I received".

One participant said that health professionals with a genuine interest in a healthy lifestyle, as well as carrying out research, are perceived as more enthusiastic and proactive due to their personal interested in the topic.

"Why feedback is essential" – the participants' views on and effect of feedback.
In this category, the participants found value in repeated feedback about their progress. To receive data on the lifestyle changes, such as waist circumference and body-composition measurements from each visit, was appreciated, and almost all the participants found this encouraging. They found feedback important; "*like a prescription for lifestyle change*". One participant saw feedback as "*an eye opener*" in the behaviour change process. The participants wanted individual feedback to be given continuously and preferably in writing. They expected the tone of the feedback to be positive, with concrete advice about how to make changes - smart choices in everyday life, described by one participant as:

"It was presented nicely and there were all the results and a little reminder about certain things I should be aware of, and pay attention to, and it felt good"

It was also important that information, both verbal and written, should be based on a person-centred approach and individualized. A few of the participants thought the time between the visits was too long and suggested an extra phone call or e-mail between the visits to increase motivation and compliance.

DISCUSSION

Cardiovascular disease is the leading cause of morbidity and all-cause mortality in the world, often caused by unhealthy lifestyle habits or lifestyle-related risk factors. Guidelines in prevention and treatment of CVD highlight the importance of preventive cardiology programs, with focus on lifestyle changes, in clinical practice. However, scientific evaluations of changing unhealthy lifestyle habits, CV risk factor management and participants' experiences of these programs are limited.

The present thesis is an evaluation of a structured lifestyle program for individuals with high CV risk. It focusses on describing the program, participants' experiences of the program, changes in unhealthy lifestyle habits, quality of life, CV risk over one year and associations of the effects with educational level and socioeconomic areas.

The lifestyle program

There is strong evidence showing that multidisciplinary and nurse-led interventions with both primary and secondary prevention of unhealthy lifestyle, CV risk factor management and CVD have positive effects on CV-outcomes (12, 125, 126, 180).

However, these types of interventions, to our knowledge, do not focus on both primary and secondary prevention, and risk reduction. Also, they are not located in hospital day care settings. Our program's focus was not primarily on the disease, but on the unhealthy lifestyle habits that contribute to risk factors in developing diseases or exacerbating already existing diseases. Studies of various diseases have shown that involving the patient may have positive effects on outcome (150).

The goal of the program was to educate the participants in evidence-based, healthy lifestyle habits, to support them in the behaviour change of their unhealthy lifestyle habits, and to give them the appropriate health-related tools to support the change to a healthier lifestyle.

The program consisted of both individual nurse-led visits and group education sessions.
In the individual meeting, the participants were involved in their own care and self-care process through a person-centred approach and shared-decision making to strengthen their empowerment. This approach in cardiovascular risk factor management has demonstrated positive effects on cardiovascular endpoints (140, 147, 150).

The group sessions were based on five educational meetings, once a week, with a focus on lifestyle habits, practical advice and behaviour change. They were led by a physician and a nurse. The physician's role was to enhance the participants' knowledge about the latest evidence in lifestyle research, and the nurse's role was to transform this evidence into every day practical advice.

Group sessions in lifestyle program have shown positive effects on strengthening participants' empowerment and increasing their knowledge about self-care, risk factors and an unhealthy lifestyle (147).

Our program is based on a multidisciplinary approach (160), but the ultimate approach should be an interdisciplinary approach giving the patient the opportunity to be an active participant in the planning of their own care, in partnership with the health professionals (150, 181).
The location of the program at the cardiology department's outpatient unit increased its credibility with participants, as did the health professionals' knowledge and experience in CV risk management and risk prevention.

To our knowledge, this is one of the first lifestyle program in a hospital setting to being scientifically evaluated. It is not therefore possible to compare the structure of our program with other lifestyle program.

Health-related tools

Throughout the whole program, health-related tools were used to increase motivation, compliance and the ability to search for information. One of the tools provided during the individual visits was Sundkurs (168). This evidence based internet-based course on lifestyle habits and change was perceived as an information bank **(shown in Paper III**). Sundkurs was used as a tool to increase the participant's knowledge, both in and between group sessions. To our knowledge, few studies based on a lifestyle program have used evidence-based lifestyle advice courses on the Internet as a supplement. Existing studies suggest that there is still a gap in knowledge, and more research is needed on internet-based behaviour change (182). During the groups sessions, the participants were given both the book "Smart Choices"(183) and the pedometer (Yamax). The latter was given out during the group session about PA and how to increase the level of steps /day (17).

The pedometer and "Smart Choices" were the most appreciated (**Paper III**) of all the tools. "Smart Choices" was perceived as a source of information and advice about replacing unhealthy lifestyle habits with more healthy ones; a way to make the "healthy choices". The pedometer was appreciated for the effect it had on the participants' awareness of steps per day. This could result in a positive or negative message at the end of each day as referred to in **paper III**. Including a pedometer in attempts to increase PA, for individuals with low PA, has been shown to have positive effects on PA patterns (58). This piece of equipment is therefore intended as a supplement to guidelines when treating physical inactivity (17).

The participants

The participants in **Papers I II and IV** consisted of 36 men and 64 women, with three or more risk factors for CVD or previous CVD. Their mean age was 58 years (±11) ranging from 35 to 78 years old. The program combined individuals with only CV risk and patients with severe CVD. In **Papers III,** the question of mixing different diagnoses was raised and the participants did not regard it as a problem. They took the same view with regard to a history of CVD and whether or not other participants had CVD. The patients with CVD had longer experience of behaviour change and shared their experiences in the group sessions.

Regarding gender distribution in **Papers I, II and IV,** 64 % of the participants were women. When investigating the referral reasons to our program, in **Paper III** and non-published

data, we observed that women had a tendency to refer themselves to the program, wheras the men often were referred because their physician thought it was best for them to change their habits or risk factors. However, a Swedish survey reported that two out of three men and every other women between 16-84 years, reported an unhealthy lifestyle, thus indicating a low proportion of men in our program (19). This could be due to the program focussing upon both primary and secondary prevention. The gender distribution may have been different if the focus been only on secondary prevention. Such proportions were seen in the secondary preventive EUROACTION study, with total of 5 405 participants enrolled from hospital and primary care settings. Seventy percent of the participants from the hospital sites were men compared to 50% at the primary care sites (125).

Fifty-three percent of the participants reported no university education and 59% were living in low SEAs, as shown **in Paper IV**. A large proportion of individuals in these groups have an unhealthy lifestyle, a higher prevalence of hypertension, obesity, diabetes type 2 and increased risk for CVD (5-10).

Twenty-one percent of the participants had diagnosed type 2 diabetes. The prevalence of diagnosed type 2 diabetes is 4-7 % in Sweden (106).

The prevalence of type 2 diabetes was higher in men living in a low SEA, and significantly higher among individuals with a low education (43 % vs 28 % at base line) compared to those with high education. This is in anccordance with various surveys and studies globally (107). Improving accessibility of physical activity and healthy food habits, as well as access to health services, are key components in achieving a reduction of socio-economic-related diabetes' inequalities worldwide (107).

The proportion of participants in the program with CVD was 36 % at baseline (women 31%, men 44%), as shown in **Paper II**. In Sweden, the prevalence of CVD means: 296 newly-diagnosed myocardial infarction /100 000 individuals in 2015, with a gender distribution of 200 women and 400 men newly-diagnosed myocardial infarction /100000 individuals (137). In 2015, there were just under 11.3 million new cases of CVD in Europe (184). More women than men die from their CVD, both in Sweden and Europe, and CVD mortality rates for women are 49% and men 40%, due to large geographic inequalities between countries (185). In **Paper II,** after categorizing by gender, the CV risk, according to the Framingham risk score, showed a significant reduction in both women and men. This suggests that the program has no gender differences in outcome regarding change in CV risk. In **Paper IV,** participants were subcategorized according to education level based on university degree or not and SEA, with a higher proportion of CVD being observed in both these subgroups. Both no university degree and living in a low SEA have been shown as predictors of CVD (137, 186).

The program showed significant reductions in CV risk all groups both in the eduction groups and SEA groups at the one-year follow-up program. This could be explained by the structure of the, with an individual meeting with a health professional characterised by a person-centred approach, letting the participant's education level be central and focusing upon adapting healthy lifestyle habits by using the resources in the SEA. For example, prescribing PAP, using relevant options of PA in nearby areas and focusing upon healthy food shopping in nearby grocery stores.

Changes in unhealthy lifestyle habits and quality of life

Non-communicable diseases (NCD) are the leading cause of mortality globally, and unhealthy lifestyle habits, such as physical inactivity, unhealthy diet and smoking are central to the aetiology of these diseases. Lifestyle change is the first choice of treatment in almost all NCD, according to guidelines (5, 187) (12). There is call for action to help individuals change unhealthy lifestyle in order to avert dramatic consequences on the global burden of disease (12). Our goal with this program was (**Paper I)** to increase the awareness and knowledge of the importance of a healthy lifestyle, and to give individuals the appropriate tools and support to make healthy lifestyle changes. The uniqueness of our approach was to treat unhealthy lifestyle habits with the aim of beneficial, secondary effects on CV risk factors. Previous studies, from both primary and secondary prevention, at population and individual levels, show reductions in several unhealthy lifestyle habits (98, 180, 188, 189).

In the EURASPIRE surveys, between 1994-2016, the investigators highlight the poor lifestyle risk factor management all over Europe, and state that a new approach for CV prevention is needed both in primary and secondary prevention programs. The latter should focus upon lifestyle changes for individuals with previous CVD and non-previous CVD (142). Our program's approach was to combine individual consultations and group sessions to optimize and strengthen participants' own self-care and knowledge about lifestyle habits. The program targeted individuals with high CV risk defined by 3 risk factors. This meant that participants could have a diagnosed CVD or CV risk.

The results from **Paper I** show significant effects on the frequency of alcohol intake, exercise, time spent in a sedentary position, intake of vegetables, choosing a better quality of bread, consumption of fat and dairy products and less extra calories after one year for those participating in the structured lifestyle program. In **Paper I**, the participants (women) decreased their frequency of alcohol intake. This could be due to an awareness of the relationship between alcohol and calories. In **Papers I** and **IV,** participants significantly increased their exercise level and decreased sedentary time after one year. In a Swedish, randomized controlled, 4-arm study, middle-age men, with slightly to moderately raised cardiovascular risk factors, were allocated to different arms. Those in one arm were given an individual PaP written by a physician and in another arm there was a combination of a PaP and personalized advice about food from a dietician (98). The results, from these two arms, showed significantly increased physical activity regarding frequency, duration and intensity compared to the other two arms (food advice only and control arms).

Similar results were presented in an RCT, based on participants with high sedentary behaviour and overweight, where the intervention group received PaP and a pedometer (58). This resulted in significantly increased physical activity levels and less sedentary time after six months, together with an increased number of steps/ day. In the secondary preventive program, MyAction, enrolling participants with increased CV-risk, there were significantly increased levels of PA (>30 min/5day/week) after one year on the program, and increased amounts of step/day (180).

In our program, the participants received an individualized PaP and a pedometer, and this may have led to increased motivation to increase their PA pattern and a reduction in sedentary time.

A more favourable food pattern was observed after one year among our participants (68). Healthy "Mediterranean like" food patterns, according to international and national dietary guidelines, are associated with a reduced risk of CVD (28, 29). Our approach was to highlight a "food pattern" instead of diets, and different food groups. The education session about food and alcohol produced the most questions, and discussions between the participants.

There remain many obstacles to adopting a healthy food pattern for individuals living in Nordic countries. These were described in a study pinpointing 8 different barriers making it difficult to comply with food guidelines (77). One was the media's influence regarding healthy food advice and various diets. This was a very common topic in the program and highlighted in **Paper III**, with questions from the participants: Who to believe? and Why? It is important that all advice about healthy food is given by health professionals and comes from the latest evidence based on guidelines (68). This will engender trust in patients. Females showed a greater tendency to focus on food and drinking habits and significant improvements were observed after one year. Males were keener to improve their PA pattern with more exercise and less sedentary time.

We calculated the proportion of frequency in change of unhealthy lifestyle habits over one year. Knowing that the CV risk increases for every unhealthy lifestyle habit, the opposite effect will be a CV risk reduction for every unhealthy lifestyle habit replaced with a "healthy" one, as shown in the INTERHEART and OASIS studies (30, 34). Our aim was to evaluate the program's effects on more than one unhealthy lifestyle habit. We found that more participants changed their habits to a more favourable pattern, with a mean change of -1 unhealthy lifestyle (median range 0–minus 6). It is well known that changing more than one unhealthy habit at a time is difficult, as has been shown in both primary and secondary preventive studies (34, 98).

Quality of life

When investigating the participants' quality of life in **Papers I and IV,** we used the Gothenburg Quality of Life instrument which is based on three well-being scores (physical, mental and social). These scores have been used before in similar populations with CVD (92, 95). As shown in **Paper I**, the participants' self-rated mental and physical quality of life improved significantly after one year. The highest rated single items in the score, in the physical well-being score, were self rated health, energy and fitness, which were separately significantly higher after one year. One explanation could be the increase in level of fitness PA. The latter should always be included in a program focussing on lifestyle and which has been shown to increase QoL positively and be strongly correlated with decreased mortality (190, 191). QoL should therefore be targeted in lifestyle related interventions (192, 193). Several studies have demonstrated the impact of NCD, such as CVD, type 2 diabetes and lung cancer, as well as the association between socioeconomic inequalities, risk factors for NCDs and QoL (90, 129, 192, 194).

Participants self-rating scores regarding confidence, patients, mood and sleep showed a significant change in the mental well-being score after one year.

After categorizing the participants according to education level based university degree or not and living in different socio-economic areas in **Paper IV,** we found that physical well-

being scores increased in both the university degree group and the low SEA group. This was probably due to the parallel increase in the PA level of these groups. In the mental well-being score, a significant increase in the university degree and no university degree groups was noted, and even observed in the low SEA group. This could be an effect of participating in a program and receiving help. One participant in **Paper III** explained that the experience of the individual session in the program, of being 'seen' as a person and receiving personalized advice was very important. This could be one of many reasons for the increase in the mental well-being score in the total cohort.

Changes in cardiovascular risk factors

At baseline, demographic data showed (**Paper II)** a high proportion of risk regarding obesity (58%) and abdominal obesity (measured by waist circumference) (87%). In **Paper IV** the participants were divided into sub-groups of university degree and no university degree, and SEA. A significantly higher baseline value for both no university degree and low SEA was observed and a significant positive change in the no university group compared to the university group were observed after one year. The association between obesity and education has been found in several earlier surveys and studies, and it is important to highlight this issue in in both groups (133, 137).

Another observation, at baseline, was that almost half of the participants had high systolic blood pressure, despite 66% receiving hypertensive treatment. In our program, 50% of the participants had high s-cholesterol over 5.0 mmol/L at baseline, and 36% were on statin treatment. Those taking statins had a lower s-cholesterol of 4.5 mmol/l.

High cholesterol is the most common risk factor for CVD (30) and, according to EUROASPIRE studies, there is a gap between reaching treatment targets and compliance. This discrepancy is high on the cardiovascular risk management agenda all over Europe (142, 195).

After one year on our program, there was a risk reduction of -19 % in individuals with high systolic BP and -6 % among those with high cholesterol. A significant reduction was recorded at the 6-month follow-up with a mean total cholesterol of 4.9 mmol/ l for the whole group after one year. The reduction of the CV risk profile in **Paper II** could be explained by the changes in lifestyle habits (**Paper I)** but not so easy to prove due to the multiple lifestyle changes on an individual level. In **Paper II** we used regression analyses to calculate correlations between lifestyle-related risk factors and lifestyle habits after one year. A modest correlation was found between reduction of sedentary time and a reduction in waist circumference (r-squer=0.228, p=0.029), also a modest reduction of sedentary time and systolic BP (r=0.245,p=0.019) were observed. Studies have shown that reducing sedentary time, and replacing 2 hours of daily sitting with stepping, has been associated with a reduction in waist circumference of -7.5 cm and a 11% lower BMI (196). In their 6-month RCT using individualized prescribed PAP, Kallings and co-workers showed beneficial effects on body composition, and significant effects on BP, after increasing daily PA with more exercise and less sitting(58).

The participants' food patterns also improved with and increased intake of vegetables and fruit, a reduction of meat and more healthy choices regarding bread with whole grains, such as in the DASH diet pattern (110). This may have contributed to a reduction of systolic and

diastolic BP. The favourable food patterns may also explain the reduced s-cholesterol (197). The positive effects on cholesterol levels, regardless of statin treatment, indicates that this program could be used in both primary and secondary prevention settings.

Overall, we found (**Paper II)** significantly lower waist circumference, BMI, systolic BP, diastolic BP and total cholesterol over one year for participants enrolled on the lifestyle program. Similar effects on BP, lipids and waist circumference were seen in both MyAction and EUROACTION (125, 180), where the focus was secondary prevention in participants with coronary events. Our program had both a primary and a secondary preventive focus, and included a more heterogeneous study population with different diagnoses and risk profiles. According to EUROASPIRE I-V, there is a large discrepancy between identifying and reaching treatment targets. There is general call for action amongst health professionals seeking a type of CV-prevention approach integrating primary and secondary prevention with a preventive cardiovascular program. The latter should focus upon lifestyle habits and CV-risk factor management as well as on improving quality of life for both patients with CVD and those at high risk of developing it (142). We suggest that our program has the potential to fulfil the need described above.

Changes in cardiovascular risk

In **Paper II** we observed a significant reduction of 15% in the Framingham 10-year risk score for the whole group at the one-year follow-up. This reduction is perhaps modest compared to other studies, for example, the GOSPEL- study with a total reduction of 33% of cardiovascular risk three years after the intervention (128). This could be explained by our participants being a mixture of previous and non- previous CVD individuals. However, in a primary preventive study, Hellénius and co-workers showed, at a 6-month follow-up of participants with high cardiovascular risk, that lifestyle counselling reduced cardiovascular risk by 12-14% according to Framingham 10-year risk scores (98).

The Framingham score decreased by 21% over one year for participants with CVD, while for those with non-CVD, it decreased by 28% over the same time period. This may indicate that our program can be used both in primary care with individuals with high CV risk as primary prevention as well as with individuals with previous CVD in secondary prevention hospital settings.

We observed (**Paper II)** that men and participants with a history of CVD had a significantly higher Framingham risk score at baseline compared to women. However, importantly, a significant reduction was seen in both men and women, thus it seems that the program has no gender difference regarding change in CV risk.

Paper IV showed that participants with no university degree had a significantly higher Framingham score compared to participants with university degree at baseline. The no university degree group also showed the greatest risk reduction after one year. Level of educational is a predictor of unhealthy lifestyle habits, unfavourable risk factors and CVD (198, 199). In **Paper IV**, participants with previous CVD and no university degree had the highest CV risk at baseline compared to the university degree group. The EUROSPIRE IV, showed that significant differences regarding reaching treatment targets were due to the

patient's educational level. In cardiovascular secondary prevention, participants with no university degree had significantly worsened lifestyle habit patterns after treatment (200). However, our results agree with previous studies concluding that educational levels are no obstacle to achieving changes in cardiovascular risk when participating in a lifestyle intervention program (119).

Regarding SEA, a significant reduction in the Framingham risk score was observed in both low and high groups.

Significant results were observed after one year for low and high SEA groups with no previous CVD. Similar results have been found in previous studies, where the largest changes were seen in participants with no university degree and living in low social economic areas. For example, both the North Karelia Program & the Västerbotten-program reported greater changes in the higher socioeconomic groups, shown by higher absolute numbers of prevented deaths among the groups with low education (119, 201). Our program showed positive effects on the Framingham CV-risk score amongst participants with CVD and without previous CVD, with individualized CV risk management for individuals with both university degree and regardless of which socioeconomic area they lived in. This suggests that our type of program could be suitable for implementation in low SEA area primary care.

Participants' experience of the program

In **Paper III** we aimed to investigate the participants' experience of the program's structure. Participants highlighted the importance of the individual visit, with shared goal setting and of being involved in the own care together with the health professional. Being treated as an "individual with feelings" was also appreciated. Studies on strengthening participants' empowerment and self-awareness in cardiovascular risk factor management have demonstrated that shared-decision making has positive effects on cardiovascular endpoints (147). To increase patients' empowerment has been shown to have a positive effect on cardiovascular risk management and diabetes care, by improving their self-care and strengthening their ability to change unhealthy lifestyle habits (147, 152, 202). One of the key components in our lifestyle education program was self-management and self-efficacy (203). The aim was to help the participants take control of their own health and lifestyle habits and start a behaviour change journey that will lead to healthier lifestyle habits, risk reduction in CV risk management and improved quality of life.

The participants thought that the group sessions were important and educational, and highlighted the need for more time for discussions with other participants. Open discussions in lifestyle-related programs have shown positive effects on strengthening empowerment and increasing knowledge about health, risk factors and unhealthy lifestyles (147). The second important category was that the health professionals should be competent, educated and respectful as well as providing continuous feedback. Guidelines for CVD highlight the importance of cardiovascular risk management programs focussing on unhealthy lifestyle and CV risk factors in clinical practice, with well-educated health professionals (12, 204-206).

The participants emphasised the importance of well-educated health professionals who are updated regarding evidence-based treatment of unhealthy lifestyle habits. In today's environment, where society often promotes an unhealthy lifestyle that may increase cardiovascular risk, many "players" in the market claim to be experts. It is important that education and evidence-based advice are promoted in health care by all health care professionals according to guidelines (12, 17, 207).

Continuous feed-back, both written and verbal, given in a respectful tone was the third category in **Paper III**. Working with a person-centred approach means involving the participants in their own treatment plan as well as continuously updating the person about their self-care management progress (140, 143, 150). The participants received a letter from the physician after each visit with individual advice regarding their lifestyle changes and risk factor parameters. This made it possible to compare and monitor change over time. This was appreciated and the participant's referred to it as a "prescription" for health change, as highlighted in **Paper III**. To receive a written note or care plan is shown to have positive outcomes (143, 208).

METHODOLOGICAL CONSIDERATIONS

Papers I-IV are registered at www.clinicaltrials.gov (ClinicalTrial.gov ID: NCT02744157).

Papers I, II and IV are a 1-year follow-up of a non-randomized, uncontrolled and structured lifestyle intervention. **Papers I-IV** are based on evaluations of an ongoing, structured lifestyle program located at a cardiology out-patient unit.

Although we did not have a control group, we could possibly have created a reference group from registers. However, our aim was not to compare participants' outcomes with other interventions, but rather to evaluate the program's effects on changes in lifestyle habits, the structure of the program, and the participants' own experience of the program. Studies on the implementation of evidence-based lifestyle intervention program for cardiovascular prevention in clinical practice are increasingly requested. In this respect, a randomized controlled study may have high internal validity, whereas our study has a high external validity. Individuals who participated in our program may be more motivated, which may limit generalizability. The causal relationship between program participation and effects on cardiovascular risk, as well as the effect of regression towards the mean on the results must be taken into account.

To measure and evaluate multiple lifestyle habits in intervention programs presents many methodological challenges.

In **Paper I** and **IV**, validated self-reported questionnaires were used to evaluate changes in lifestyle habits and quality of life. The problem with misreporting has to be taken into consideration (209).

In **Paper II,** the participants' CV risk over time was evaluated using the Framingham score. If our participants had been only a homogenous group of individuals with CVD, heart scores would have been an excellent tool for calculating risk over time. However, our participants were a heterogeneous group, a mix of both participants with, and without previous CVD. The Framingham scores were thus deemed to be a more suitable method for predicting CV risk (114).

Due to loss of participants at follow-up, an intention to treat (ITT) approach was used in **Papers I, II & IV,** where existing data from the prior visit (baseline or 6-month follow-up) were carried forward for missing data on all variables. The advantages of using an ITT analysis are that it reflects the practical clinical scenario in admitting noncompliance, maintains prognostic balance and preserves the sample size (210).

In the risk analyses, in **Papers I, II** and **IV,** participants were dichotomized into risk, or no risk, regarding different lifestyle habits and risk factors according to guidelines. The strength of this analysis is that it shows the program's effect on these variables, and facilitates interpreting them in terms of clinical reality. A limitation may be the proportion of individuals who made a positive change within the risk group. It would be interesting to investigate this in future studies.

One limitation in **Paper II** is the difficulty to prove the correlation between changes in lifestyle habits and risk factors. Studies indicate that changing more than one unhealthy lifestyle habits one at a time is harder (34, 98). We found a modest correlation between sedentary time and waist circumference, as well as systolic blood-pressure and total-cholesterol.

One statistical strength, in both **Papers I & II,** was that risk factor values above these cut-offs were compared over one year, and a 99% confidence interval (CI) was calculated. The 99% CI was used to adjust for multiple testing.

In **Paper III** we used qualitative content analysis with a manifest and inductive approach when transcribing data from the interviews (175-177). Content analysis is used to code transcript verbal material into more manageable data from which researchers identify patterns and gain insight(176).

We chose a content analysis model to enable us to analyse direct communication via texts or transcripts, and hence identify the central aspects of the participants' experience of the program's structure.

A manifest approach means that the text deals with the content aspect, and describes the visible, obvious components. Using an inductive approach, we created various categories, based on the participants' experience. In **Paper III,** we describe the analysis process in as much detail as possible to contribute to the study's it is credibility (176, 177).

STRENGTHS AND LIMITATIONS

One of the program's strengths was the high **compliance and attendance rate;** 88 % of the participants attended the 6-month follow-up and 80 % the one-year follow-up. These rates are higher than in other lifestyle program, for example, one-year rates from 56% to 65% (180, 188). The participants not attending the follow-up were contacted by phone or email regarding their reason for dropping out; the most common reason being disappointment at not achieving their goals.

Papers I-IVthis is a descriptive non-randomised intervention study with no control group. We are aware of the lack of a control arm. This is not an RCT, and the fact that regressions towards the mean could affect the results has been to be taken into account. This could indicate that internal validation was low, but the opposite of this is a high external validation for the program. The structure of the program could be implemented both in primary or hospital care settings.

The subcategorized analysis of both gender and CVD yielded important findings although the small sample size potentially influenced the power of the analyses.

One other strength, illuminated in **Paper III,** was that the program allocated more time for the visits. Time is at a premium in today's health care, where stress due to lack of time is a problem for both patients and caregivers in clinical settings. There is also a statistical power problem to be considered regarding the cohort and a skew distribution of gender. However, as this study is a pilot we find it important to call attention to these findings. Regarding gender distribution, only three (20%) of the participants interviewed in **Paper III** were male. This mirrors the gender distribution in **Papers I, II** and **IV**.

Evaluating the implementation of the program was an important part of the study. Implementation can be measured by determining whether the innovation corresponds to the originally intentions of the program in terms of structure, compliance and uniqueness (211). The program's structure was maintained throughout **Paper III** providing feedback about the participants' experience of the structure, and compliance was confirmed by the high attendance rates in **Paper I**.

Another strength of the program is making the primary focus that of encouraging the participants to change their unhealthy lifestyle habits so as to have a positive effect on CV risk factors and CV risk.

The program's effects on lifestyle habits, risk factors, CV risk and quality of life, coupled with the location and the primary and secondary preventive treatment approach, define the uniqueness of this new approach.

The health-related tools were appreciated by the participants, as highlighted in **Paper III** when they worked. The pedometer frequently malfunctioned for various reasons, such as being put in a washing machine, dropped or lost. In some cases the participants bought a new pedometer or used their smart phone for the same purpose. Regarding compliance and the internet course, Sundkurs, some participants experienced difficulties in locating it or logging in.

Another strength of this program is measuring the effects of the program on quality of life, and the positive results. It is important to adopt a holistic approach and to consider many parameters when planning to evaluate such a program, and measure physical, mental and social outcomes.
As we measured lifestyle habits by validated questionnaires, addressing lifestyle habits, the problem of misreporting has to be taken into consideration (209). Ideally, a more objective measurement would have been a better approach, for example, accelerometers for measuring PA level, and dietary diaries. However, questionnaires are a common and useful method to collect information on lifestyle habits in large groups in a clinical setting.

One strength of **Paper III** is its qualitative approach and that it illuminates the participants' experiences in their own words. It is important, when conducting a study about a new method and structure, to have a broad evaluation that includes both quantitative and qualitative measurements. One limitation was the delay of the execution of the interviews, some of the participants had forgotten detail information of the programs structure.

CLINICAL IMPLICATIONS

Today, there is extensive knowledge about, and sound evidence for, lifestyle interventions in the prevention and treatment of cardiovascular disease. However, there is a lack of clinical structures focusing on lifestyle behaviours in everyday clinical practice. We need to focus more on implementing research to increase our knowledge about suitable structures that can be used in everyday clinical practice, in both primary care and hospital settings.

If this can be achieved, it would enhance and facilitate lifestyle interventions to counteract unhealthy lifestyle habits and cardiovascular disease. It might even be that inequalities in health could be reduced. There is a need for more evaluated lifestyle preventive programs in our everyday work, with both a primary and secondary focus, for individuals at cardiovascular risk.

The aim should be to treat unhealthy lifestyle habits in multidisciplinary or interdisciplinary teams, and to involve the participants in their own behaviour change using shared decision -making and a person-centred approach.

It is of great importance that these individuals receive personalized education, in a combination of individual and group sessions focussing upon changing their unhealthy lifestyle habits. Is also important to focus upon follow-ups using validated methods to evaluate the changes in the various lifestyle habits. We hope that our experiences and results can add to the current knowledge for both health professionals working with lifestyle programs and individuals participating in such programs in everyday clinical practice.

FUTURE PERSPECTIVES

I hope to continue working in the same field as this thesis. I have some ideas for further investigations regarding this program and also for expanding the programs structure to reach primary care and hospital settings.

Further investigations:

- A long-term follow-up study of the participants from Papers I, II and IV with changes in lifestyle, cardiovascular risk and quality of life
- To investigate the participants' individual changes with regards to level of risk reduction
- To investigate patterns in changes in unhealthy lifestyle habits, QoL, CV risk factors and CV risk with cluster-analysis
- To include a health economic study based on unhealthy lifestyle habit risk reduction, CV risk factors improvement, CV risk reduction and improvement of quality of life for the participants in the program
- To help implement lifestyle programs similar to our program in different setting both in primary care and hospital settings regardless of age, disease, gender, education level or residence in low SEA

CONCLUSION

It was possible to launch a structured multidisciplinary lifestyle program with individual- and groups sessions in a clinical setting at a cardiology unit.

Participating in a structured lifestyle program for a year:

- improved several lifestyle habits and quality of life
- led to improvements in multiple, individual CVD risk factors
- reduced CV risk in both men and women, as well as in both participants with CVD and non-CVD regardless education level (based on universitydegree or not) and SEA of residence

Individuals participating in a structured lifestyle program experienced and described several factors as important:

- an individual visit with shared goal setting and group education session with interactive discussion
- competent, educated and respectful health care professionals who gives continuous feedback
- appropriate health-related tools to support self-care at home between visits

Low educational level (based on university degree or not) and living in low SEA can imply a higher burden of unhealthy lifestyle habits and higher CVD risk. The results of the present study have clinical relevance, as suggesting that such factors are no barriers for changing unhealthy lifestyle habits, decreasing cardiovascular risk and improvement in QoL after participation in a lifestyle program.

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