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Lifestyle counselling in primary health care for patients with high cardiovascular risk

*Aspects of a 1-year structured lifestyle programme
promoting healthier lifestyle habits to reduce future
risk of cardiovascular disease*

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Abstract

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While the effects of lifestyle habits on hypertension or type 2 diabetes mellitus (T2DM) are well established, few lifestyle programmes in primary care directed towards patients with high cardiovascular risk have been evaluated.

Aims To describe and elaborate on how participation in a 1-year lifestyle programme supported changes in lifestyle habits and altered the risk of cardiovascular disease (CVD) as well as explore patients' and community health nurses' (CHNs') experiences of lifestyle change and counselling.

Methods The 1-year lifestyle programme consisted of five appointments with a CHN for patients diagnosed with hypertension, T2DM or impaired glucose tolerance (n = 448). Focus was on lifestyle habits that were related to patients' diagnosis. Different behaviour change techniques were used to support lifestyle changes. Blood sampling and anthropometrical measurements were obtained at baseline and 1-year follow-up. The design of Studies I and II was observational and based on data that were consecutively collected between 2009 and 2014, whereas Studies III and IV had a qualitative design. Qualitative content analyses were performed based on data from individual interviews with patients (n = 16) and a focus group interview of CHNs (n = 3).

Results *Study I:* Favourable changes in physical activity, dietary habits and smoking were detected after participation in the programme. *Study II:* Significant improvements were demonstrated for all cardiovascular risk factors and the estimated 10-year CVD risk after participation in the programme. *Study III:* Patients' experiences of lifestyle changes indicated that increased knowledge of lifestyle habits, gaining trust in oneself and support from others were important elements in the adoption of lifestyle changes. *Study IV:* The informants expressed that counselling should be based on a partnership, include goal setting and repeated measurements, and incorporate long-term support after the completion of the lifestyle programme.

Conclusion This thesis adds to the knowledge on how lifestyle counselling can be designed and implemented in primary care. The findings show that patients with a new diagnosis of hypertension or T2DM are at high risk for future CVD and a structured lifestyle programme can contribute to improved lifestyle habits and a reduced 10-year CVD risk.

Keywords: primary health care, hypertension, type 2 diabetes mellitus, cardiovascular risk factors, healthy lifestyle, qualitative research

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*To my family, -
you will always
be the ones closest to my heart.*

*'Don't be ashamed to be a human being, be proud!
Inside you, one vault after another opens endlessly.
You'll never be complete, and that's as it should be.'*
Tomas Tranströmer

List of Papers

This thesis is based on the following papers, which are referred to in the text by their corresponding Roman numerals.

- I Lena Lönnberg, Elin Ekblom-Bak, Mattias Damberg. Improved unhealthy lifestyle habits in patients with high cardiovascular risk: results from a structured lifestyle programme in primary health care. *Ups J Med Sci.* 2019;124(2):94–104.
- II Lena Lönnberg, Elin Ekblom-Bak, Mattias Damberg. Reduced 10-year risk of developing cardiovascular disease after participating in a lifestyle programme in primary health care. *Ups J Med Sci.* 2020;125(3):250–6.
- III Lena Lönnberg, Mattias Damberg, Åsa Revenäs. “It’s up to me”: The experience of patients at high risk of cardiovascular disease of lifestyle change. *Scand J Prim Health Care.* 2020;38(3):340–51.
- IV Lena Lönnberg, Mattias Damberg, Åsa Revenäs. Lifestyle counselling – a long-term commitment based on partnership. *BMC Prim Care.* 2022;23(1):35.

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Abbreviations

BCT	Behavioural change technique
BMI	Body Mass Index
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
HDL	High density lipoprotein
IGT	Impaired Glucose Tolerance
LDL	Low density lipoprotein
MI	Motivational Interviewing
NCD	Noncommunicable disease
PA	Physical activity
SCT	Social cognitive theory
SCORE	Systematic Coronary Risk Estimation
SPB	Systolic blood pressure
T2DM	Type 2 diabetes mellitus
TTM	The Transtheoretical Model
WHO	World Health Organization

1. Introduction

1.1 Preface

Noncommunicable diseases (NCDs) account for > 70% of the disease burden worldwide and this proportion is even higher in Sweden (1). In 2016, the leading cause of disability-adjusted life years was cardiovascular disease (CVD) (35%) followed by cancers (26%) (2) .

Modifiable behaviours, such as the use of tobacco, an unhealthy diet, physical inactivity, and harmful use of alcohol increase the risk of NCDs and have a crucial impact on metabolic risk factors, such as high blood pressure, overweight, hyperglycaemia and hyperlipidaemia (1).

According to the Swedish act on health care, the overall goal for the health-care system is as follows: ‘a good health and healthcare on equal premises for the entire population’ (Chapter 3, §1) (3). Moreover, the Swedish act regarding patients’ states, that all patients should be provided information on their health condition and on methods to prevent further illness. (Chapter 3, §1:8) (4).

Although knowledge regarding the importance of preventive efforts has been available for decades and several guidelines on the prevention and treatment of unhealthy lifestyle habits have been published, there is a paucity of information about the implementation of methods to support patients in changing their unhealthy lifestyle habits (5, 6).

In 2009, a 1-year structured lifestyle programme was launched at a primary health-care centre in Västmanland County, Sweden, to provide adequate support to patients with high cardiovascular risk, to increase their ability and motivation for lifestyle changes, in addition to providing them with standard medical care.

The beginning of this 1-year structured lifestyle programme was also when the evaluation from which this thesis originates began.

1.2 Philosophy of science

The philosophy of science analyses what science is, how it works and the logic by which scientific knowledge is built. A researcher collects information or observations on a given phenomenon by applying structured and valid methods. This is a cumulative knowledge-building process where the present

findings systematically add to the existing knowledge (7). However, how a phenomenon is viewed could differ depending on what paradigm is predominant within a specific area or research field (8).

The philosopher Thomas Kuhn challenged the paradigm that considered research to be a steady, cumulative acquisition of knowledge and argued that any progress is relative to the present paradigm that defines a scientific discipline at that particular time (9). Such a paradigm was described as follows: 'a disciplinary matrix, a set of commitments shared by practitioners of a particular scientific field, including a special vocabulary and established experimental techniques, as well as accepted theoretical claims' (10).

The positivistic ideal of science represents a quantitative paradigm found in natural science. In brief, scientific knowledge is produced by performing experiments and collecting data that can be measured and quantified. In addition, hypotheses are confirmed or rejected to explain or prove something. Researchers are supposed to be objective and distant from the research objects, whereas data collection aims for their findings to be representative and generalisable (7).

In contrast, the hermeneutic ideal of science represents a qualitative paradigm, which is often found in human sciences. This paradigm seeks to produce knowledge by collecting data using qualitative methods in search for the unique with the intention to understand the whole by describing its unique elements. This unique knowledge cannot be generalised into other contexts; however, by using a thorough description of its aspects, such as the informants and context, other researchers can judge whether the findings can be applied or transferred to other areas, that is, transferability is possible. In the case of this ideal, the researcher is closer to the object of the study to enable a deeper understanding of the phenomenon being studied (7).

To improve the understanding of the different aspects of lifestyle counselling and lifestyle change, both a positivistic and hermeneutic standpoint will be used in this thesis (11, 12).

1.3 Health behaviour theories: theoretical framework

How people change their health behaviour has been studied for decades and a variety of theories that explain and predict health behaviour have been presented. In their review of behaviour change theories, Michie et al. identified 83 different theories or models that assessed individual outcomes of behaviour change interventions (13). The most, frequently used theories and models are the social cognitive theory (SCT), the theory of planned behaviour (14), the health belief model (15) and the transtheoretical model (TTM) (8, 16). The health belief model, planned behaviour theory and TTM focus on the individual and are based on the belief that health behaviour is a reflection of expected values (8). The theories can be used to design and evaluate behaviour change

interventions. In this thesis, the TTM will be used in the deductive part of study III, to describe which processes the participants used to perform lifestyle changes (17) and will be described in more detail under section 3.3.3.

The SCT is an interpersonal model that comprehends how behaviour, cognitive and socio-environmental factors interact and will be further elaborated in the next section (18). According to the SCT an individual's behaviour is determined by an interaction of this triad of interacting factors. It can and has been used to support people to perform healthy behaviours and reduce habits that impair health (8). The 1-year structured lifestyle programme included components that was directed to support behaviour change, included the patient's social environment, and addressed cognitive factors. This thesis will use the SCT to explain and enhance understanding of how lifestyle counseling in primary health care can be performed.

1.3.1 Social cognitive theory

In a famous experiment in the early 1960s, Albert Bandura demonstrated that some children learned violent behaviours through vicarious experiences (19). In their interpretations following the experiment, Bandura et al. offered an alternative explanation for how human behaviour develops, which departed from the theory that human behaviour is a result of positive or negative reinforcements, such as during respondent and operant learning. This theory was initially called the social cognitive learning theory, but was later developed into the SCT (18). The SCT includes that behaviour changes require both forethought and a personal sense of control, commonly known as 'agency' (20).

Within the SCT, human behaviour is explained in terms of 'reciprocal determinism' wherein behavioural, personal cognitive and socio-environmental factors interact with each other (21). (Figure 1).

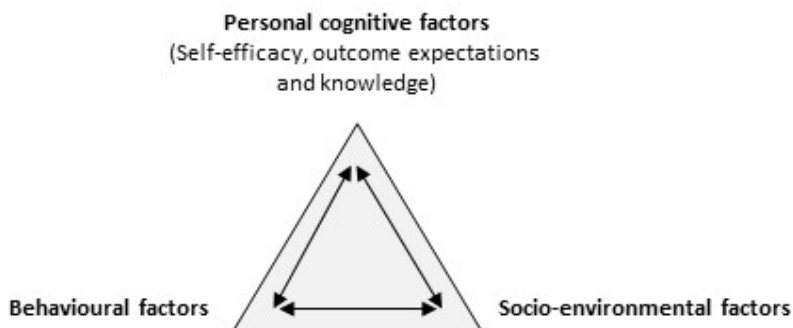


Figure 1. The three major factors involved in reciprocal determinism in Social cognitive theory, modified from Bandura, A. (17)

Personal cognitive factors

Personal cognitive factors include the following three constructs: self-efficacy, outcome expectations and knowledge.

Self-efficacy is considered the core concept of SCT and is defined as individuals' confidence in their ability to perform a behaviour e.g. performing PA or preparing a healthy meal (21). Confidence is achieved and enhanced by mastery experiences, social modelling, verbal persuasion, and practice. Self-efficacy is strongly influenced by earlier successful mastery experiences. Being successful in performing a particular task increases the likelihood that individuals will continue to perform that behaviour. However, if the outcome was interpreted as negative by the individual, then it will lower their self-efficacy and diminish the possibility for another 'attempt' at performing that particular task. Therefore, an intervention using active learning strategies should include incremental steps to develop mastery experiences and support high self-efficacy for a particular task. Other important sources of self-efficacy are vicarious experiences (e.g. observing others perform a particular task). This could be especially important if the individual is uncertain of their capability and is even more efficient if the person who models the performance of the task is a desirable role model (e.g. someone with high status, same gender, same racial group). Moreover, verbal persuasion can support self-efficacy by providing arguments for the targeted behaviour. Furthermore, emotional arousal can act as a reinforcement for the desired behaviour if it is replete with positive emotions, which will increase the likelihood of a successful performance. However, the opposite can occur wherein negative emotions may lead to poorer performance (8, 21).

Outcome expectations are the individual's judgement about the likely consequences of an action. Individuals tend to perform activities that provide

them with self-satisfaction, pride and/or joy. Conversely, people avoid actions that could lead to humiliation, shame or sadness (8, 21).

Knowledge of health behaviour, such as both the benefit when performing a healthier behaviour and the negative impact of an unhealthy habit, is described as a precondition for change. Knowledge alone is generally insufficient to change behaviour. However, when information (knowledge) is combined with actions to enhance self-efficacy or outcome expectations, it has been proven to be more successful (8, 21).

Socio-environmental factors

Socio-environmental factors include the following three factors that promote, permit and discourage engagement in a particular behaviour: that is, observational learning, normative beliefs and barriers and opportunities. The SCT distinguishes between cognitive and environmental barriers. Cognitive barriers relate to individuals' self-efficacy for performing a task as described above. Environmental barriers refer to physical prerequisites in the environment that impede healthier behaviour, such as the lack of safe bicycle paths, which hinders people from commuting to work on their bicycles (20).

Behavioural factors

Behavioural factors include individuals' existing health capabilities, their goals to add or modify a behaviour and the rewards or punishments that they receive for engaging in a health behaviour. According to the SCT, among several behaviour change techniques (BCTs), it is fundamentally important to set goals when changing behaviour. Setting goals is considered to reflect individuals' intentions and indicate their readiness to perform a specific action. When goals are specific and have short timeframes for their achievement, they become a powerful predictor of future behaviour. Furthermore, goal achievement is enhanced if individuals have high self-efficacy and positive outcome expectations (8, 20).

In summary, the SCT aims to increase the understanding of how cognitive, environmental and behavioural factors influence the way individuals can change their behaviour. The SCT has been used in a great variety of interventions and cultures to promote lifestyle changes (21).

1.3.2 Behavioural change techniques

Interventions to promote behavioural change are typically multifaceted and include several interacting elements. In this thesis the taxonomy by Michie et al (22) will be used to enhance the report of the different BCT's that was included in the 1-year structured lifestyle program. A BCT has been defined as '...an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour, that is, the

technique is proposed to be an active ingredient' (22). In any intervention a composite of different BCT's can be used. Interventions are often described in terms of *who* gives the counselling, *to whom*, *how often*, *in what context* and *with what content*. Except for 'content', this gives limited information on what ingredients that are active and irreducible to bring about behaviour change. One of the most comprehensive taxonomies is the one developed by Susan Michie et al; The Behaviour Change Technique Taxonomy (v1) of 93 hierarchically clustered techniques (22). The authors of the taxonomy have identified and defined 93 different BCT's and then grouped the different BCT's with similar content into 16 clusters. When an intervention is reported according to the taxonomy this will enable that the intervention can be scrutinised and/ or replicated with more accuracy by other researchers.

1.4 Noncommunicable diseases

One of the leading causes of death worldwide is NCDs (1). The increase in the prevalence of NCDs is mostly due to the adoption of a Western lifestyle in developing countries. The top four causes of death worldwide are CVD, cancer, respiratory diseases and diabetes mellitus (mainly, type 2) (23). Non-communicable diseases are medical conditions that develop over a long period of time, often with a slow progression and long duration. Type 2 diabetes mellitus (T2DM), impaired glucose tolerance (IGT) and hypertension are three common NCDs that all contribute to an increased cardiovascular risk (24).

There are several risk factors for the development of NCDs, which can be either modifiable (i.e. lifestyle habits, high blood pressure, obesity and high blood cholesterol) or non-modifiable (i.e. gender, genetic factors, age and ethnicity) (1).

1.4.1 Type 2 diabetes mellitus and impaired glucose tolerance

Definition and prevalence

Type 2 diabetes mellitus is a common chronic disease and its prevalence is increasing worldwide, including in Sweden (25, 26). It is characterised by hyperglycaemia, insulin resistance and impaired insulin secretion. It can be diagnosed in the following ways (27):

- Haemoglobin, type A1c (HbA1c) level ≥ 48 mmol/mol on two different occasions or one occasion together with increased plasma glucose levels (fasting or after the glucose tolerance test; see below) or
- Fasting plasma glucose level ≥ 7.0 mmol/L on two occasions, alternatively:

- Non-fasting plasma glucose level ≥ 11.1 mmol/L, including symptoms of hyperglycaemia, alternatively:
- Oral glucose tolerance test with a 2-hour plasma glucose level ≥ 11.1 mmol/L (2 hours after the intake of 75 g glucose + 250–300 mL of water).

Approximately 500 000 people have diabetes mellitus in Sweden (4.8%) according to the National Diabetes Register, with a vast majority (85%–90%) having T2DM (26).

If the 2-hour plasma glucose levels after an oral glucose tolerance test are between 7.8 mmol/L and 11.0 mmol/L, then IGT is considered to be present (27). The IGT could be regarded as a preliminary stage, which precedes the development of T2DM, although this development is not inevitable.

Aetiology and treatment

There are several known risk factors for T2DM and IGT; including family history, older age, obesity (especially with an increased percentage of body fat distributed predominantly in the abdominal region) and a sedentary lifestyle. They occur more frequently in women with prior gestational diabetes mellitus and individuals with hypertension or dyslipidaemia. Their frequency varies in different racial/ethnic subgroups (28). Type 2 diabetes mellitus occurs when the pancreas does not produce enough insulin, when the body cannot effectively use the insulin that it produces, or both. Hyperglycaemia associated with diabetes leads to angiopathy which is associated with long-term damage, dysfunction, and failure of different organs, especially the heart, blood vessels, eyes, kidneys, and nerves (27, 29).

The overall treatment goal for T2DM is to improve quality of life and prevent disease-related complications. Therefore, diabetes treatment involves adopting a healthy diet and increased physical activity (PA) along with oral blood glucose-lowering medication if/when lifestyle changes do not sufficiently lower blood glucose levels. The treatment also includes addressing other known risk factors that can damage blood vessels, such as treatment for hypertension and hyperlipidaemia in addition to lifestyle counselling, for example, counselling to promote smoking cessation. (29, 30). Treatment goals should always be individualised and tailored to patients' condition, including age, years with T2DM, coexisting morbidity, frailty and cognitive function. The recommended treatment goal for the HbA1c level is ≤ 52 mmol/mol for all patients, with a lower level for younger patients with T2DM (≤ 48 mmol/mol). For older patients or those experiencing severe side effects of drug treatment, such as hypoglycaemia, a higher HbA1c level could be acceptable. A general recommendation for blood pressure is 140/85 mmHg and at least a 50% reduction of low-density lipoprotein (LDL) cholesterol (29, 31). According to the 2020 annual report from the National Diabetes Register,

56.4% of all patients with T2DM achieved the treatment goal of HbA1c level ≤ 52 mmol/mol and 56.9% achieved the treatment goal of blood pressure $< 140/85$ mmHg (32).

1.4.2 Hypertension

Definition and prevalence

Blood pressure is the force exerted by circulating blood against the walls of the blood vessels, which is defined by systolic (SBP) and diastolic blood pressure (DBP), respectively. The definition of hypertension is an office SBP value ≥ 140 mmHg and/or DBP value ≥ 90 mmHg. The same classification is used in younger, middle-aged and older people. The definitions of hypertension grades are as follows (33,34):

Grade 1: 140–159/90–99 mmHg

Grade 2: 160–179/100–109 mmHg

Grade 3: $\geq 180/\geq 110$ mmHg

Cardiovascular diseases is the leading cause of disease burden worldwide (33). During the last three decades, the prevalence of CVD has nearly doubled. Hypertension is a serious condition and the number one risk factor for developing CVD (24). Approximately 25% of the population in Sweden over 20 years of age has high blood pressure or takes blood pressure-lowering medication. Hypertension becomes more prevalent with age and $> 60\%$ of people older than 60 years of age have this condition (34).

Hypertension is diagnosed using a sphygmomanometer. Confirmation of the diagnosis should be based on repeated measurements over time. The number of visits and the time interval between visits vary according to the severity of the disease. Three measurements with a time interval of at least 1 week are recommended for low-to-moderately elevated blood pressure (34, 35).

Aetiology and treatment

In most cases (80%–90%), no single cause of elevated blood pressure can be detected. Instead, several modifiable and non-modifiable risk factors can be identified. Age, genetic factors and coexisting diseases, such as kidney diseases, are examples of non-modifiable risk factors. Modifiable risk factors include smoking, unhealthy dietary habits, harmful use of alcohol, overweight and low PA (34, 36, 37). Moreover, a strong association exists between change in cardiorespiratory fitness and incident hypertension. In a study of 91 728 participants (normotensive at baseline), the findings from submaximal bicycle tests to estimate maximal oxygen volume demonstrated that an increase in cardiorespiratory fitness was associated with an 11% lower risk of

hypertension, and vice versa. In addition, a decrease in cardiorespiratory fitness was associated with 25% higher risk of incident hypertension (38).

When the diagnosis of hypertension is established, a CVD risk estimation, including physical examinations and blood sampling should be performed to detect other risk factors, such as hyperglycaemia and dyslipidaemia.

According to the European Society of Cardiology/European Society of Hypertension's current guidelines on atrial hypertension, the first treatment objective should be to lower blood pressure for all patients to $< 140/90$ mmHg (34). Provided that the treatment is well tolerated by patients, the target blood pressure value should be $130/80$ mmHg. In patients aged < 65 years who take blood pressure-lowering drugs, the target blood pressure should be lowered to a range of $120\text{--}129$ mmHg. The desired target range for all patients aged > 65 years who take blood pressure-lowering drugs is $130\text{--}139$ mmHg, if well tolerated. However, any blood pressure reduction towards this target range is likely to be beneficial (34). According to a pooled analysis conducted by the World Health Organisation, the control rate, which is the proportion of patients who have been diagnosed with hypertension, received treatment and have their blood pressure under control, was 23% for women and 18% for men worldwide (39). A Swedish study recently concluded that the proportion of patients with hypertension who achieved the target blood pressure of $< 140/90$ mmHg was 49.1% in 2017 (40).

The two main treatment strategies for the treatment of hypertension are as follows: lifestyle intervention (for all patients) and drug therapy for patients with grades 1, 2 or 3 hypertension. Lifestyle interventions include smoking cessation, sodium restriction, increased PA, healthier food habits and moderation of alcohol use. Changes in lifestyle habits, including single or multiple lifestyle changes, are all beneficial for lowering a high normal or hypertensive blood pressure (34). Regular PA can lower SBP with up to 9 mm Hg after a period of at least 4 weeks of PA (41). Sodium reduction by a reduction of 4.4 g salt/day was associated with a mean reduction of SBP of 5.4 mmHg in people with hypertension (42). Treatment decisions should always be based on CVD risk evaluation, comorbidities, and patient preferences (36). However, the different drug treatment alternatives are beyond the scope of this thesis.

Meta-analyses of randomised controlled trials have demonstrated that a 10-mmHg reduction in SBP or a 5-mmHg reduction in DBP is associated with significant reductions in all major cardiovascular events (by 20%), all-cause mortality (by 10%–15%), stroke (by 35%), coronary events (by 20%) and heart failure (by 40%). These relative risk reductions are consistent and irrespective of the baseline blood pressure within the hypertensive range (43).

According to both Swedish and international guidelines on hypertension, treatment should be based on a risk estimation for CVD. This risk estimation shall also be communicated with the patient to facilitate a shared treatment decision.

1.5 Estimation of cardiovascular risk

Several algorithms can be used to estimate the risk of a serious event or death in CVD. Two of the more commonly used risk assessments are the Framingham risk score (FRS) assessment (44) and Systematic Coronary Risk Estimation (SCORE) (45). The assessment of metabolic syndrome is another way to identify individuals' risk for CVD, although it does not calculate the extent of the risk. In this thesis, the definition of metabolic syndrome from the Adult Treatment Panel III (ATP-III) guidelines was used to classify the number of patients diagnosed with metabolic syndrome (46).

A risk score estimates individuals' risk to develop a CVD (fatal and/or non-fatal) within a specific period, usually 10 or 30 years. Such scores are recommended to be used for CVD prevention in clinical practice to tailor interventions on an individual level (36, 37). Using a risk score increases the probability of a more realistic estimation of risk vs benefits of treatment and thereby leads to better-informed treatment decisions. The use of risk scores can also enable shared and informed decision making by patients and their health-care professionals.

1.5.1 Framingham risk score (FRS)

In 1948, CVD was the leading cause of death and serious illness in the United States and worldwide. However, knowledge about what caused this epidemic was limited. To better understand the underlying causes of CVD, the National Heart Institute launched the Framingham Heart Study. The objective was to identify common factors that contribute to CVD. By following a cohort of 5209 men and women without overt symptoms of CVD over a long period, risk factors such as smoking, high blood pressure, high blood cholesterol and physical inactivity were identified. Since 1948, the participants have returned to the study every 2 years for a detailed medical history, physical examination and laboratory tests. To meet the need for a more diverse population, the first Omni cohort was enrolled in 1994 (47). Although the Framingham cohort is primarily Caucasian, the importance of the major CVD risk factors identified in this group was shown to apply almost universally to other racial and ethnic groups in other studies (48). The most recent version of the FRS in 2008 (44) calculates the risk of developing a cardiovascular event in ten years. The FRS was used in this thesis to evaluate changes in individual risk for CVD after participation in the 1-year structured lifestyle programme.

The prediction variables used in FRS evaluation are age, sex, total cholesterol, high-density lipoprotein (HDL) cholesterol, SBP, blood pressure treatment or not, diabetes mellitus or not and current smoking. Individuals aged 30–74 years and without CVD were targeted. Endpoints assessed in the FRS are a composite of coronary heart disease (coronary death, myocardial infarction, coronary insufficiency and angina), cerebrovascular events (including

ischaemic stroke, haemorrhagic stroke and transient ischaemic attack), peripheral artery disease (intermittent claudication) and heart failure. A calculated 10-year risk of < 5% is considered low, ≥ 5 to < 7.5% is borderline, $\geq 7.5\%$ to < 20% is intermediate and $\geq 20\%$ is high risk (44).

1.5.2 Systematic coronary risk estimation (SCORE)

The Swedish (49), European and American guidelines for the prevention of CVD recommend using SCORE in clinical practice to estimate the risk for CVD within 10 years (36, 37). The Systematic coronary risk estimation has been the most used risk estimation in Sweden for many years. The original SCORE algorithm predicts the 10-year risk of a fatal cardiovascular event (50). This leads to an underestimation of total CVD risk for younger people in whom mortality due to stroke and myocardial infarction is low because of the current optimised treatment options. To meet the limitations of over- and underestimation due to age and current treatment options, an updated version, named SCORE2, was developed by the European Society of Cardiology in 2021 (51). The SCORE2 predicts the risk of developing both fatal and non-fatal CVD and has been validated by other cohort studies conducted around Europe (51).

The prediction variables used in the SCORE2 are age, sex, smoking, SBP and non-HDL cholesterol (total cholesterol minus HDL cholesterol). It defines four risk regions in Europe according to country-specific CVD mortality. The predicted CVD risk varies across Europe and for individuals with a given risk factor, the risk estimation can be almost tripled in a very high-risk country compared with that in a low-risk. Cardiovascular disease risk categories use different risk cut-off levels for various age groups to avoid undertreatment in younger patients and overtreatment in older patients (Table 1). Certain risk factors are not included in the SCORE2, such as family history, abdominal obesity, chronic kidney failure and diabetes mellitus. For Swedish patients with diabetes mellitus, the risk calculator from the National Diabetes Register is recommended.

A limitation of the SCORE2 is that it estimates the risk up to 69 years of age. To meet this limitation, SCORE2-Older Persons (SCORE2-OP) (52) was developed. It is a separate risk score for people aged 70–89 years. The prediction variables used are the same as those for the SCORE2. However, it has a more limited base for the risk model because it was developed based on data from a low-risk region alone. Moreover, the transferability to other risk regions was hampered due to the lack of adequate data from some regions (52). However, as the population in Sweden is becoming older and more vital, SCORE2-OP can cover a gap that is clinically relevant (53). The SCORE was used in the 1-year structured lifestyle programme to evaluate the patients' risk and decide the treatment approach.

Table 1. Cardiovascular disease risk categories according to age, SCORE 2 (49)

	< 50 years	50–69 years	≥ 70 years
Low-to-moderate CVD risk: risk factor treatment generally not recommended	< 2.5%	< 5%	< 7.5%
High CVD risk: risk factor treatment should be considered	2.5%–< 7.5%	5%–< 10%	7.5%–15%
Very high CVD risk: risk factor treatment is generally recommended	≥ 7.5%	≥ 10%	≥ 15%

1.5.3 The metabolic syndrome: Adult Treatment Panel III

The metabolic syndrome is the name for a group of risk factors that, when present, increases an individual's risk for CVD (46). According to the National Cholesterol Education Programme (NCEP)/ATP-III, metabolic syndrome is present when individuals meet three or more of the following risk factors:

- Waist circumference > 88 cm for women and > 102 cm for men.
- Triglyceride level > 1.7 mmol/L.
- HDL level < 1.03 mmol for women and < 1.29 mmol for men.
- Blood pressure level ≥ 130/≥ 85 mmHg.
- Fasting plasma glucose level ≥ 5.6 mmol/L.

Metabolic syndrome has several causes, such as overweight, low PA, age and family history of CVD, which can act together. The syndrome is closely related to insulin resistance and significantly raises an individual's risk for CVD. In Sweden, approximately 20% of people younger than 65 years and approximately 30% of people older than 65 years have metabolic syndrome. Moreover, metabolic syndrome is closely related to increased risk for future CVD, cancer and dementia (41).

1.6 Lifestyle counselling in the Swedish healthcare system since the 1980's

By law, the Swedish health-care system is obliged to provide care that ensures good health for the people according to the Swedish Health and Medical Services Act (2017:30). Furthermore, the health-care system is required to provide care that prevents illness (Chapter 3, §2) (3) .

Knowledge on how to provide preventive measures has developed over the decades. In the 1950s, knowledge regarding the risk factors that contributed

to CVD was limited. Several large-scale studies were initiated that contributed to growing evidence on the impact of lifestyle habits on the risk of CVD. In 1981, the World Health Organisation initiated the 'Health for All by the Year 2000' programme and recommended governments and authorities worldwide to make efforts aimed at lowering the incidence of and mortality from NCDs, such as CVD and cancer. Several initiatives were taken in Sweden to address the concern of preventive measures.

Three of these projects, from different parts of Sweden, will be elaborated: the projects from Västerbotten, Habo and Sollentuna.

In the 1960s and 1970s, CVD mortality gradually increased in Sweden, especially in the most northern counties. In 1984, as a response to having the highest mortality rates in Sweden, the Västerbotten County Council decided to develop a population-oriented intervention for CVD and T2DM prevention. In brief, the intervention model combined a strategy to reach all middle-aged persons individually with another that was designed to reach the whole community. The individual approach was to invite every citizen aged 30, 40, 50 and 60 years to a health examination, which comprised an oral glucose tolerance test, measurements of lipids and blood pressure and other anthropometric measurements. The participants answered a comprehensive questionnaire on psychosocial conditions, self-reported health, family history of CVD and T2DM and lifestyle habits. The results of the examination and questionnaire responses were discussed with a trained nurse and offered a shared decision base for what steps that needed to be taken to decrease the participants' risk for CVD or T2DM. Studies on smoking prevalence, obesity, hypercholesterolaemia, hypertension and PA after participation in the Västerbotten project demonstrated positive effects on these variables among the participants compared with those among the non-participants (54-58). A study of the long-term impact on all-cause and CVD mortality compared the participants in the Västerbotten project ($n = 59\,629$) with a reference population comprising individuals from the whole Swedish population aged 40, 50 and 60 years. The study demonstrated a reduction in the all-cause mortality rate of 12.1% among women and 7.8% among men. In addition, the reduction in the death rate indicated that 587 premature deaths were prevented among the participants in the Västerbotten project (59).

Furthermore, in 1984, the primary health-care council in Habo decided to initiate a prevention programme to reduce cardiovascular risk. All men aged 33-42 years who lived in the community were invited to a health examination and dialogue similar to the one conducted in Västerbotten. The primary prevention programme was carried out in Habo from 1985 to 1987 (60). In 1989, the health programme 'Live for Life' was initiated in Skaraborg County, which also included the individuals from Habo. In the 'Live for Life' project, all men and women aged 30 and 35 years were invited to a health examination and proceeding health dialogue. In total, 17 988 men and women participated in the project during the first 8 years. The project also included different

community activities, such as programmes to promote PA and educational activities for staff in grocery stores. At the 1-year follow-up, unhealthy lifestyle habits, such as smoking, had decreased and healthy dietary habits had improved. Both SBP and serum cholesterol levels had decreased (61). In a follow-up study conducted 24–26 years after the Habo project, the authors compared the mortality rate between the men who participated in the health dialogue and those from a corresponding age cohort from all of Sweden. Among men who attended the health examination, the mortality rate was 55.2 ([number of deaths per person-years of observation] \times 1000) compared with 92.3 for the reference group (odds ratio, 0.57; 95% confidence interval [CI], 0.40–0.81) (62).

Finally, the Sollentuna prevention programme is another example from the same period that aimed to reduce the future risk for CVD in the inhabitants of Sollentuna. This programme was initiated in 1988 and combined an individual and population-based approach. All four primary healthcare centres in Sollentuna participated in the programme. Patients who visited the primary healthcare centre were invited to participate in the programme. Those who agreed to participate were asked to complete a self-administered questionnaire, which was used for an initial screening, followed by a physical examination by a nurse or general practitioner. Fasting blood samples and anthropometric measurements were collected. All patients received treatment and lifestyle advice in accordance with the established guidelines. In addition, all participants were offered to participate in different educational groups and lecture series to support their lifestyle changes. Physical activity on prescription was used to support increased PA and different exercise groups were made available at local sports associations. Occasionally, group appointments for cooking, weight reduction, smoking cessation and stress management were also made available. Weekly public lectures for patients and their relatives focusing on healthy lifestyles and behaviour changes were offered for a period of 17 years. At the 1-year follow-up, the levels of cardiovascular risk factors, such as DBP, serum cholesterol and triglycerides, had decreased (63). With a median follow-up of 22 years, the incidence rates of first cardiovascular event, cardiovascular death and all-cause death were reduced by 12%, 21% and 17%, respectively, in the intervention group compared with the reference group. The hazard ratios in the intervention group compared with the reference group were 0.88 (95% CI, 0.81–0.95; $p < 0.001$) for first CV event and 0.79 (95% CI, 0.70–0.89; $p < 0.001$) for cardiovascular death. The authors estimated that 175 premature deaths were prevented or delayed in the intervention group of 5761 individuals during a follow-up of approximately two decades (64).

All three projects mentioned above are examples of a combination of strategies to approach both the individual and strategies that are more population based.

Over time, there has been a discussion on to which extent healthcare professionals can or should provide health promotion and disease preventive

services. Some healthcare professionals can hesitate to discuss lifestyle habits to avoid interfering with the patients' integrity or depending on their personal views on lifestyle habits (65, 66). Other studies have demonstrated that health-care professionals consider limited time resources to discuss lifestyle as a hindrance to from addressing lifestyle habits as a part of treatment or as a preventive effort (6, 65, 67, 68). However, a majority of patients did not disapprove of being asked questions regarding their lifestyle habits. On the contrary, they assumed that it was a part of their health care. The annual national 'Health on Equal Terms' survey demonstrated that the population had a positive attitude towards the health-care professionals addressing their lifestyle habits. Moreover, they were motivated to change their unhealthy lifestyle habits and accept support for doing so. However, only approximately half of the population reported that they had discussed their lifestyle habits at their last primary health-care appointment (69).

1.7 National guidelines for disease prevention and unhealthy lifestyle habits

The increasing knowledge on how both primary and secondary preventive measures reduce the impact of NCDs led to the important step of publishing the first Swedish national guidelines on methods for disease prevention in 2011 (70). Despite the knowledge of the impact of poor lifestyle habits on processes such as the development of CVD and cancer, preventive medicine was not implemented in the Swedish health-care system, and no uniform praxis existed regarding how to address lifestyle habits. In addition, large discrepancies existed regarding how and when these questions were addressed depending on regional differences. However, other national guidelines, such as the national guidelines for CVD (71) and diabetes care (72) included recommendations on the importance of healthy lifestyle habits. Nevertheless, they did not focus on which methods had the best effects to support lifestyle changes. Instead, they mostly acknowledged the impact of healthier lifestyle habits. The development of national guidelines regarding lifestyle habits was initiated at the beginning of 2009 by the National Board of Health and Welfare. The objective was to provide evidence-based recommendations on methods to prevent illness by supporting individuals to change their lifestyle habits. The following four lifestyle habits that contribute the most to the disease burden in Sweden were focused on, namely, use of tobacco, the harmful use of alcohol, low PA and poor dietary habits. The guidelines clarified which methods the health-care providers should use to support lifestyle changes. In addition to the first objective, the guidelines were also expected to provide a basis for transparent and systematic priorities in the health-care system (70). The

guidelines for unhealthy lifestyle habits were revised in 2018 to the Swedish national guidelines for prevention and treatment of unhealthy lifestyles (5).

The basis for the treatment of unhealthy lifestyle habits according to the 2011 national guidelines was either ‘short advice’, ‘counselling’ or ‘qualified counselling’. The counselling/dialogue could also be accompanied by other tools.

Short advice refers to imparting information and standardised recommendations regarding patients’ lifestyle habits. It usually lasts < 5 minutes and does not involve inviting the patient to a dialogue. The oral advice can be accompanied by written information.

Counselling refers to a dialogue with the patient, involves tailored recommendations and might include tools to support lifestyle changes, such as PA on prescription or a food diary. The counselling can include motivational strategies and usually lasts 10–15 minutes but can sometimes extend up to 30 minutes.

Qualified counselling also refers to a dialogue with the patient and involves tailored recommendations with regard to patients’ condition, age, general health, etc. It includes tools to support lifestyle change as in ‘counselling’. However, it is more structured, based on a behaviour change theory, includes BCTs and is often performed repeatedly. The qualified counselling visit is usually longer than an ordinary counselling visit.

All three above actions postulate that the healthcare provider has sufficient knowledge of both the lifestyle habit in focus and, that it has been clarified that the patient’s lifestyle habit is considered unhealthy, and relevant for his/her condition.

The recommended actions in the 2011 national guidelines were ‘qualified counselling’ for smoking and unhealthy dietary habits respectively and counselling + tools to support increased physical activity, and counselling regarding the harmful use of alcohol (70).

1.8 Lifestyle habits

Currently, there is extensive evidence for the impact of lifestyle habits on health and quality of life.

Modifiable risk factors, such as tobacco use, physical inactivity, unhealthy diet and the harmful use of alcohol, increase the risk of NCDs. In addition, the following four metabolic risk factors add to the risk of NCDs: raised blood pressure, overweight, obesity, hyperglycaemia and hyperlipidaemia, conditions closely related to lifestyle habits (73).

1.8.1 Prevalence of unhealthy lifestyle habits

Healthy lifestyle habits are a prerequisite for good health. The proportion of people with healthy lifestyle habits differs depending on the measurements or questionnaires that are employed. The Public Health Agency of Sweden performs a survey on the living conditions and prerequisites for health and lifestyle habits every year and summarises the results in the Public Health Report. In their 2022 report, the Public Health Agency concluded that the inequality regarding health remains and in 2019, the most common causes of death were circulatory diseases and cancers. The disparity continues to exist with regard to health, both physical and mental, between different socio-economic groups (74).

Regarding specific lifestyle habits and health-related risk factors, the report stated that in 2021, harmful use of alcohol was noted in 15% of the adult population (16–84 years). This proportion was relatively stable during the last 15 years, except for a small decline in the youngest (16–29 years) and a small increase in the elderly (65–84 years) population with harmful use of alcohol. Similar findings were reported in the adult population in Västmanland County (15%). In contrast to smoking, dietary habits and physical inactivity, the harmful use of alcohol was more prominent among groups with higher education and among men born in Sweden (75).

Daily smoking decreased during the last 15 years and 6% of the adult population in Sweden reported daily smoking in 2021, although with large differences depending on socio-economic factors. Approximately 8% of people in Västmanland County reported daily smoking in the 2020 ‘Health on Equal Terms’ survey (76).

The proportion of individuals, in Sweden as well as in Västmanland County, that met the criteria of 150 minutes of moderate PA/week (self-reported data) was almost stable at 65% during the same period (74). No sex differences were reported for PA, but a slightly higher proportion of men reported sitting for > 10 hours/day. However, when objectively measured, a steady decline in mean cardiorespiratory fitness in Swedish men and women was demonstrated in a previous study (38).

According to the latest survey on dietary habits by the Swedish Food Agency, some improvements have occurred since the last survey in 1997/1998. However, the pattern of food intake still shows shortcomings with regard to the intake of fruits and vegetables, fish, full grains, low amounts of sodium and polyunsaturated fats. In general, one in five people have poor dietary habits. Young people (aged 18–30 years) have an unhealthy dietary pattern compared with other age groups, and women generally have better food patterns than men (35, 77). The prevalence of overweight (body mass index [BMI] ≥ 25 m²/kg) and obesity (BMI ≥ 30 m²/kg) has increased during the last 15 years. Presently, > 50% of the Swedish population has overweight or

obesity. In Västmanland County, almost one in five people are obese, which is an almost two-fold increase compared with that in 2000 (76).

1.8.2 Self-reported data and objective measurements of lifestyle habits

Research regarding lifestyle habits is often based on self-reported data or a combination of objective measurements and self-reports/questionnaires. Questionnaires are a convenient tool to collect data regarding various aspects, such as lifestyle habits. However, self-reported data for lifestyle habits can also be complicated because of biased reporting. People tend to report socially acceptable answers when responding to questions regarding, for example, dietary habits, PA and intake of alcohol. It is not uncommon to overestimate 'good behaviour' and underestimate less favourable behaviour (12). This issue must be considered when analysing answers from a questionnaire regarding lifestyle habits.

Physical activity

Questions regarding PA with a 4–5 item scale are often used to screen PA. For example, 'How much time have you spent performing PA of moderate intensity, which makes you feel warm and breathe heavily?' This type of question has been demonstrated to be both valid and reliable as an objective test of PA. The over- or underestimation in the answers tends to be consistent but also tends to have a poor relationship with the objective measurements of PA, such as those using pedometers or accelerometers. The questions from the National Treatment Protocol for unhealthy lifestyle habits - prevention and treatment can be used to screen PA (75). The results (total minutes spent in vigorous and/or moderate PA) indicate whether individuals reach the level of sufficient PA or not. The recommended PA level is currently >150 min of moderate intensity PA, or 75 min of vigorous-intensity PA per week or any equivalent combination of the two. In addition, muscle-strengthening PA should involve major muscle groups ≥ 2 times/ week, and for those aged ≥ 65 years, PA to enhance balance and prevent falls should be performed ≥ 3 times/ week. (78).

For an objective assessment of PA, a pedometer (step counter) or accelerometer can be used (75). A pedometer counts how many steps an individual takes and provides an easily administered, objective measurement of PA. It can also be a powerful tool to use in communication with a patient who wants to increase their PA (41). In recent years, pedometers have been incorporated into many products, such as smartphones, watches and activity bracelets.

An accelerometer does not only measure the number of steps but also the intensity at which a movement occurs. The data are obtained by measuring movement and acceleration in three different directions and can objectively measure the intensity of the activity (41). Although the use of accelerometers

has become more widespread in research in recent years, it is still not common in routine primary health care.

Several tests can be used to assess cardiorespiratory fitness. A maximal volume oxygen uptake test is the gold standard for measuring cardiorespiratory fitness. However, performing this test requires expensive equipment, expertise and time. Moreover, for patients with high cardiovascular risk, medical contra-indications could be present for a maximal volume oxygen uptake test. Therefore, submaximal tests that estimate maximal volume oxygen uptake are more common in primary health care. One example of a submaximal test is the Åstrand submaximal cycle ergometer test (79). This test estimates the maximal volume oxygen uptake based on heart rate response at a submaximal work rate. This test has been further developed in recent years and a new submaximal bicycle test, called the Ekblom-Bak cycle ergometer test, has been shown to estimate maximal volume oxygen uptake with higher precision (80).

Use of tobacco

Regarding the use of tobacco, smoking or snus, self-reported use of tobacco has been demonstrated to have a good correspondence to the objective measurements of biomarkers (81, 82). Quantity is recorded as the number of cigarettes/day or snuffboxes/week (75). Tobacco consumption is often stable over the week.

Spirometry is an example of a test that is used to assess pulmonary function by measuring lung function, specifically the amount and/or speed of air that can be inhaled and exhaled. Moreover, it can be one examination to identify conditions such as asthma and chronic obstructive pulmonary disease, which are conditions closely related to smoking. Spirometry can also be used as a tool to increase motivation for smoking cessation (83). Presently, spirometry is incorporated into primary health care.

Dietary habits

Questionnaires to assess dietary habits are the most used method in ordinary health care to assess dietary patterns. Because this method involves self-reported data, the same limitations as those for the questionnaires for PA should be considered for food questionnaires. For screening dietary habits, the so-called 'Kostindex' can be used (75). For the first four questions, each answer receives a point from 0 to 3. The sum of all points gives an indication of whether the individual has unhealthy dietary habits (0-4 points), somewhat unhealthy dietary habits (5-8 points), or healthy dietary habits (9-12 points). Several more extensive questionnaires, such as the 'Riskmaten flex' (84) or a 24-hour recall, can be applied for more in-depth counselling or research. Objective measurements in clinical practice often include measurements of parameters that can act as a proxy for dietary habits, such as body weight, BMI, waist circumference and blood lipid levels.

Alcohol use

Questionnaires are commonly used to assess how individuals habitually consume alcohol. According to the Swedish national guidelines regarding unhealthy lifestyle habits, two questions can be used to detect the harmful use of alcohol. The questions cover frequency and weekly intake, respectively, and both have five response options each (5). Another option to screen for if a person has a harmful use of alcohol is to use the shorter form of AUDIT (Adult Use Disorders Identification Test), i.e. AUDIT-C. This shorter version has been proven both valid and reliable to detect harmful use of alcohol (85). An alcohol diary can also be used as an evaluation instrument and provide information that can be useful during counselling. Objective measurements using biomarkers for liver function or carbohydrate-deficient transferrin and phosphatidylethanol can be used in addition to self-reported data.

1.9 Rationale

Although knowledge regarding the effects of lifestyle habits on hypertension or T2DM had a solid foundation in 2009 and growing evidence existed regarding the methods to be used by health-care professionals to support patients in changing their lifestyle habits, the implementation of such methods had not been realised. This is the rationale for this thesis. To our knowledge, no similar primary health-care programmes existed in Sweden till the time of initiation of the 1-year structured lifestyle programme. The prevention programmes in Västerbotten, Habo and Sollentuna were all directed towards people without known risk factors, which is opposite to the 1-year lifestyle programme that was directed towards patients with established diagnoses: that is, either hypertension, T2DM or IGT. The objectives of this thesis are to describe and elaborate on how participation in the 1-year structured lifestyle programme supported lifestyle habit changes and altered CVD risk, and to explore the elements of counselling that were considered to be important by the participating patients and community health nurses (CHNs). Thus, this thesis will contribute more knowledge on how methods to support lifestyle changes could be performed in a primary health-care setting.

2. Aims

The overall aim of this thesis was to describe and evaluate different aspects of a 1-year structured lifestyle programme in primary health care to promote healthier lifestyle habits and reduce future risk of CVD.

The specific aims of the studies included in this thesis were as follows:

Study I

To describe a 1-year structured lifestyle programme in primary health care and evaluate change in unhealthy lifestyle habits over 1 year in men and women with high cardiovascular risk, who participated in the 1-year structured lifestyle programme.

Study II

To evaluate changes in cardiovascular risk factors and 10-year risk for CVD according to the Framingham risk score in men and women with high cardiovascular risk after participation in a 1-year structured lifestyle programme in primary health care.

Study III

To explore the experiences of participants at high risk of CVD, regarding lifestyle change after participation in a 1-year structured lifestyle programme and to study how the techniques and strategies used by the participants related to the processes of change described in the TTM.

Study IV

To explore patients' and CHNs' experiences of lifestyle counselling after participation in a 1-year structured lifestyle programme in primary health care.

3. Methods

3.1 Design

This thesis originates from an evaluation of a 1-year structured lifestyle program in primary health care based on both a positivistic and hermeneutic ideal of science. The Social cognitive theory and the TTM will be used to further evaluate how lifestyle change was promoted in the 1-year structured lifestyle programme. Four studies are included in this thesis. Studies I and II were based on data that were collected consecutively for 5 years and have a quantitative design. To clarify which BCT's that were used in the 1-year lifestyle program the taxonomy by Michie et al (22) will be used. Studies III and IV were based on interviews of the participating patients and CHNs and have a qualitative design. An overview of the studies is presented in Table 2.

Table 2. Overview over included studies I-IV, design, setting, sample, data sources and analyses

<p><u>Study I</u></p> <p>Design: Observational study with before and after measurements.</p> <p>Aim: To evaluate the change in lifestyle habits after participation in a lifestyle programme.</p> <p>Setting and sample: Patients who participated in a lifestyle programme during 2009–2014 (same as Study II).</p> <p>Data sources: Consecutively collected data from a questionnaire.</p> <p>Analysis: Using Wilcoxon's rank test, McNemar test, two-tailed paired sample t-test.</p>	<p><u>Study II</u></p> <p>Design: Observational study with before and after measurements.</p> <p>Aim: To evaluate the change in CV risk factors and 10-year CVD risk after participation in a lifestyle programme.</p> <p>Setting and sample: Patients who participated in a lifestyle programme during 2009–2014 (same as Study I).</p> <p>Data sources: Consecutive collected data from blood sampling and anthropometric measurements.</p> <p>Analysis: Using unpaired t-test, McNemar test, two-tailed paired sample t-test, chi-square test.</p>
<p><u>Study III</u></p> <p>Design: Qualitative explorative.</p> <p>Aim: To explore patients' experiences of lifestyle change after participation in a lifestyle programme.</p> <p>Setting and sample: Purposive sample from patients who participated in a lifestyle programme during 2014–2015.</p> <p>Data sources: Semi-structured individual interviews with 16 participants (same as Study IV).</p> <p>Analysis: Abductive qualitative content analysis.</p>	<p><u>Study IV</u></p> <p>Design: Qualitative explorative.</p> <p>Aim: To explore patients' and CHNs' experiences of lifestyle counselling after participation in a lifestyle programme.</p> <p>Setting and sample: Purposive sample from patients who participated in a lifestyle programme during 2014–2015 + participating CHNs.</p> <p>Data sources: Semi-structured individual interviews with 16 participants (same as Study III) + one focus group interview of the participating CHNs.</p> <p>Analysis: Inductive qualitative content analysis.</p>

3.1.1 The 1-year structured lifestyle programme

Considering the growing evidence for the association of lifestyle habits with cardiovascular risk, a lifestyle programme was launched in 2009 at a primary care centre in Västmanland County. The programme involved patients who recently had been diagnosed with either hypertension, T2DM or IGT. The objective of the lifestyle programme was to address and provide counselling regarding lifestyle habits for patients with high cardiovascular risk. The lifestyle programme comprised five appointments where the patient met the same CHN.

Each appointment followed a checklist (see the Appendix), to ensure that every patient received the same basic elements regarding lifestyle counselling, although in an individualised and tailored manner. The focus in every appointment was on lifestyle habits in relation to patients' current condition. An individual risk estimation (SCORE) was performed, and antihypertensive or

cholesterol-lowering medication was prescribed when needed according to hypertension and diabetes guidelines (45, 72, 86, 87).

Fasting blood samples were obtained 1 week before the first and last appointment and a submaximal cycle ergometer test was performed the same day as the first and last appointment.

At the baseline appointment, the CHN and patient discussed the results of all measurements (blood sampling, anthropometric measurements including those for weight, height, waist circumference, blood pressure, arm/ankle index and bicycle test) as well as current lifestyle habits according to responses in the questionnaire (see Appendix). The patient's motivation for changing behaviour was assessed using a 0–10 scale and discussed together. The aim of the baseline appointment was to set both treatment and behavioural goals for the next 3 months. This included discussions on problem-solving, action planning and addressing different ways to change lifestyle habits. The results of anthropometric measurements and blood samples were noted on a 'health card' together with the set goals and provided to the patient.

If patients were insufficiently physically active (< 150 minutes/week), they received a prescription on PA in accordance with Professional Associations for Physical Activity, Physical Activity in the Prevention and Treatment of Disease, FYSS 2008 (88, 89). The prescription was accompanied by a diary for PA and a pedometer to further support PA. The counselling on PA also included information and elaboration on questions related to PA, such as those on planning, dividing a PA goal into realistic sub-goals and introducing techniques that support PA maintenance. Written and oral information on how PA was related to the patients' diagnosis and health was generally provided when suitable.

Dietary counselling was performed following the Nordic Nutrition Recommendations (90, 91). The recommended dietary pattern included a daily intake of fruits and vegetables, regular intake of fish, vegetable oils, wholegrain, low-fat alternatives of dairy products and limited intake of red and processed meat, sugar, salt, and alcohol (90, 91). The counselling for dietary habits included the same BCTs as those for PA in addition to oral and written information on food and diet related to the diagnosis.

The baseline appointment lasted between 60 and 90 minutes.

During the following appointments at 3, 6 and 9 months, the focus continued to be on lifestyle habits, including a follow-up/review of behavioural and treatment goals. blood pressure and waist circumference were measured at the 3-, 6- and 9-month appointments. For patients with T2DM, blood sugar levels for the last week were analysed. The patient's motivation for changing behaviour was assessed using a 0–10 scale and discussed together. Adjustments to set goals were made in the dialogue between the CHN and patient and documented on patients' health card. Information (oral and/or written) was distributed according to the lifestyle habits that had been in focus during the

appointment. The appointments at 3, 6 and 9 months lasted approximately 30 minutes each.

At the 1-year follow-up, the results of all measurements and the questionnaire were discussed and summarised. Goal completion was discussed and new goals for the coming period were set. An assessment of motivation for achieving these goals was performed using a 0–10 scale and discussed. Information was provided about the forthcoming follow-up in accordance with the guidelines for hypertension and T2DM, respectively. The final appointment lasted approximately 60 minutes.

When needed, the patient could be referred within the primary health-care centre for extended counselling regarding one or more lifestyle habits such as, to a physiotherapist for adjustment of PA or a CHN specialised in smoking cessation.

Before the baseline appointment and 1-year follow-up, the CHN discussed patients' condition with their family physician. An overview of the content of the lifestyle programme is shown in Table 3.

Table 3. An overview of the content and measurements of the five individual counselling appointments in the 1-year structured lifestyle programme

	Baseline appointment	Appointments at 3, 6, and 9 months	Appointment at 1-year
Counselling content	Individual counselling (This included discussion on prerequisites and motivation for lifestyle changes, setting behavioural and treatment goals, and verbal and written information on lifestyle habits in relation to diagnosis)	Individual counselling (e.g., follow-up by a discussion on the content in diaries for food or physical activity, evaluation of goal achievement, exploring barriers, setting new goals, providing information regarding lifestyle in relation to diagnosis)	Individual counselling (The same as previous appointments including summarising of experiences and results of the past 12 months, setting new goals)
Measurements	Fasting blood sample Anthropometric measurements: Weight, height, waist circumference, blood pressure, arm/ ankle index Submaximal volume oxygen test Questionnaire	Anthropometric measurements: Blood pressure Waist circumference	Fasting blood sample Anthropometric measurements: Weight, waist circumference, blood pressure, arm/ ankle index Submaximal volume oxygen test Questionnaire

The CHNs had postgraduate credits in diabetes care (minimum 7.5 credits) and metabolic syndrome care (minimum 7.5 credits) and had, at minimum, attended a 1-week full-time training programme in motivational interviewing (MI). The training focused on the basic processes within MI and combined both theoretical parts with the training of practical skills, such as those related to conversations regarding evoking change, formulating open-ended questions, goal planning and change maintenance. The training was provided by Västmanland County Council (MI - Grundutbildning (luvit.se) (92). The MI-trainer was a member of The Motivational Interviewing Network of Trainers, MINT (93). Moreover, because the CHNs also worked as diabetes care nurses, they received yearly updates on diabetes care provided by Västmanland County Council.

All patients were also invited to participate in three evening group appointments to further motivate and stimulate lifestyle changes, alone or together with a spouse or friend. The group appointments focused on the following: (I) Cardiovascular risk factors and PA; (II) healthy food, alcohol and tobacco use and (III) stress, sleeping habits and behaviour change. Every appointment lasted approximate 120 minutes. The participation rate varied over time. Approximately 15%–25% of all participants attended ≥ 1 of the group appointments (the exact numbers are not known).

3.1.2 Motivational interviewing

Motivational interviewing is a frequently used concept in Swedish health care in supporting patients to adopt and maintain lifestyle changes (75). The MI method was first described by William R. Miller in 1983 as an approach to motivate problem drinkers to reduce their alcohol consumption (94). The method was further developed by Miller and Rollnick and a detailed description of MI's content was presented in 1991 (95). Since then, the method has been elaborated and refined several times. The most current version is described by Miller and Rollnick in *Motivational interviewing: helping people to change* (3rd edition) (96). The authors described MI as:

A collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion. (96) .

This quote implies that MI involves evoking the person's own desire and motivation for change by exploring the importance that the change has for the individual. MI comprises the following four fundamental processes: engaging, focusing, evoking and planning. The MI process can go back and forth between these different processes as a part of developing discrepancy, dealing

with resistance and eventually developing a plan based on the person's own thoughts and intrinsic motivation.

Even though this method was originally developed for the treatment of alcohol overconsumption, it has been applied across a broad range of settings, populations, languages, treatment formats and presenting concerns (e.g. lifestyle habits, medication adherence, substance use, gambling, parenting, etc.) (97).

3.1.3 Behaviour change techniques: analysis of the 1-year structured lifestyle programme

To identify and categorise the different techniques that were included in the 1-year programme to support lifestyle change the author of this thesis and her co-supervisor performed an analysis according to the taxonomy presented by Michie et al (22).

The author of this thesis and co-supervisor separately identified the different BCTs that were included in the 1-year structured lifestyle programme. They then compared their findings to reduce the risk of neglecting any BCTs in the programme. Finally, the author of this thesis coded all identified BCTs according to the taxonomy presented by Michie et al. and sorted them into different groups (clusters) according to content. Twenty-two different techniques were identified in the 1-year structured lifestyle programme and could be classified as different BCT's belonging to 12 of the 16 groups presented in the taxonomy (22). (Tables 4 and 5).

Table 4. Behaviour change techniques included in the 1-year structured lifestyle programme. Index numbers refer to the taxonomy developed by Michie et al. (94)

Intervention content	Behavioural change technique
Blood sampling	Biofeedback (2.6)
Anthropometric measurements	Biofeedback (2.6)
Bicycle test	Biofeedback (2.6)
Motivation, assessment scale	--
Set treatment goal	Goal-setting outcome (1.3)
Set behavioural goal	Goal-setting behaviour (1.1) Problem-solving (1.2) Action planning (1.4) Restructuring the physical environment (12.1)
Health card	Behavioural contract (1.8)
Prescription of PA	Behavioural contract (1.8) Instruction on how to perform a behaviour (4.1) Information about antecedents (4.2) Graded task (8.7) Restructuring the physical environment (12.1)
Diary for PA	Self-monitoring of behaviour (2.3)
Use of pedometer	Feedback on behaviour (2.2) Self-monitoring of behaviour (2.3)
Diet recommendations	Problem solving (1.2) Action planning (1.4) Instruction on how to perform a behaviour (4.1) Information about antecedents (4.2) Information on health consequences (5.1) Graded task (8.7) Restructuring the physical environment (12.1)
Written information	Information on health consequences (5.1)
Oral information	Social support (unspecified) (3.1) Information on health consequences (5.1) Pros and cons (9.2) Future punishment (10.11)
Repeated measurements	Feedback on behaviour (2.2) Biofeedback (2.6) Feedback on outcome(s) of behaviour (2.7) Social reward (10.4)
Repeated motivation assessment	Goal-setting behaviour (1.1)
Adjustment of treatment goal	Review treatment goal (1.7)
Adjustment of behavioural goal	Problem-solving (1.2) Action planning (1.4) Review behavioural goal (1.5)
Questionnaire	Feedback on behaviour (2.2)
Reflection on goal achievement	Review behavioural goal (1.5) Review treatment goal (1.7)
Follow-up after lifestyle year	Feedback on behaviour (2.2) Biofeedback (2.6) Feedback on outcome(s) of behaviour (2.7) Social reward (10.4)
Group appointment	Social support (practical) (3.2) Social support (emotional) (3.3)
Involvement of people close to patient	Social support (practical) (3.2) Social support (emotional) (3.3)

Table 5. Behaviour change techniques included in the 1-year structured lifestyle programme sorted by the different groups. Index numbers refer to the taxonomy developed by Michie et al. (94)

Groups within the taxonomy	Behavioural change technique
<i>1. Goals and planning</i>	Goal-setting behaviour (1.1)
	Problem-solving (1.2)
	Goal-setting outcome (1.3)
	Action planning (1.4)
	Review behavioural goal (1.5)
	Review treatment goal (1.7)
	Behavioural contract (1.8)
<i>2. Feedback and monitoring</i>	Feedback on behaviour (2.2)
	Self-monitoring of behaviour (2.3)
	Biofeedback (2.6)
	Feedback on the outcome(s) of behaviour (2.7)
<i>3. Social support</i>	Social support (unspecified) (3.1)
	Social support (practical) (3.2)
	Social support (emotional) (3.3)
<i>4. Shaping knowledge</i>	Instruction on how to perform a behaviour (4.1)
	Information about antecedents (4.2)
<i>5. Natural consequences</i>	Information on health consequences (5.1)
<i>8. Repetition and substitution</i>	Graded task (8.7)
<i>9. Comparison of outcome</i>	Pros and cons (9.2)
<i>10. Reward and threat</i>	Social reward (10.4)
	Future punishment (10.11)
<i>12. Antecedents</i>	Restructuring the physical environment (12.1)

3.2. Population and participants

3.2.1 Study population for studies I and II

Patients aged 18–75 years and registered at Citypraktiken were enrolled from October 2009 to September 2014. When patients met the criteria for either hypertension, T2DM or IGT for the first time, they were referred to the lifestyle programme (n = 448) and invited to participate. The diagnosis criteria were:

- Hypertension: blood pressure level > 140/90 mmHg
- T2DM: fasting plasma glucose level > 7 mmol/L, or non-fasting plasma glucose level ≥ 11.1 mmol/L or 2-hour plasma glucose level ≥ 11.1 mmol/L after the oral glucose tolerance test
- IGT: 2-hour glucose level of 7.8–11.0 mmol/L after the 75-g oral glucose tolerance test

For Study I, 101 patients were lost to follow-up: 69 patients did not complete the questionnaire at baseline and 1-year follow-up, or their questionnaires were missing, 30 patients did not complete the questionnaire at baseline and declined to complete the programme, and two patients died.

For Study II, the inclusion criteria were the same as those for Study I, except that the patient had to be aged 30–74 years to be able to meet the criteria for the FRS.

The exclusion criterion for both studies was severe psychiatric disease or dementia.

Figure 2 presents a flow chart of participant inclusion in Studies I and II.

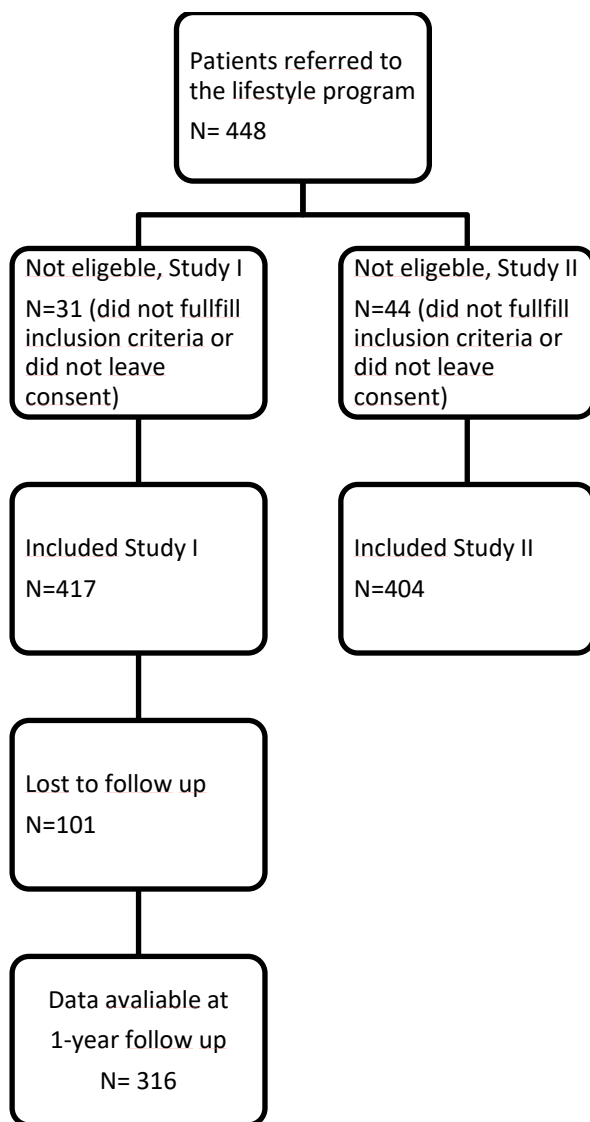


Figure 2 .Flowchart over participants in study I and II

3.2.2 Participants studies III and IV

To answer the research questions in Studies III and IV, purposive sampling was performed using the population of patients who completed the 1-year lifestyle programme in 2015. To gather as rich data as possible, participants with different diagnoses, sex, age and those who had met either of the CHNs were included. Additional inclusion criteria were being fluent in Swedish and

having participated in all five counselling appointments with the respective CHN. The CHNs contacted eligible patients in May 2018 and asked them to provide consent for an interview with the author of this thesis. To enrich the data for Study IV, a focus group interview with three of the four CHNs who had performed the counselling in 2015 was added. The fourth CHN had ended her employment at the primary health-care centre at the time of the interview.

3.3 Data collection

3.3.1 Study I

All data were collected consecutively and registered in a database by one of the CHNs, from October 2009 to September 2014. The author of this thesis has verified the data by comparing the imported data with the original data sources.

Questionnaire

Information about lifestyle habits was obtained using a self-administered questionnaire comprising 25 questions that covered PA, dietary habits, alcohol consumption, tobacco use, stress and sleeping habits (see Appendix). The questionnaire combined validated and reliability-tested questions from different questionnaires regarding lifestyle habits and other questions to capture the current lifestyle habits. The complete questionnaire was not validated and tested for reliability in its present form.

PA levels and sedentary habits were assessed via questions about leisure-time non-exercise activity, exercise and sedentary time using a 1–4 scale. Global PA was assessed using a 0–10 visual analogue scale. Similar questions have been presented in the Global Physical Activity Questionnaire, International Physical Activity Questionnaire and the 2008 National Survey of Living Conditions (98–100).

Dietary habits were assessed via eight questions about the intake of different food groups (i.e. fish, fruits and vegetables, fast food, high-calorie foods and soft drinks) using a 1–4 scale. The dietary questions were a selection of questions that have been tested and found to correlate with the objective measurements of fatty acids (101) and questions incorporated in the Diet Index, which is called ‘Kostindex’ in Swedish (102).

Alcohol consumption was assessed using two questions about frequency and quantity (103).

Smoking and snuff use were assessed using questions covering daily consumption (yes/no) and the number of cigarettes/portions of snuff.

Stress and sleep habits were evaluated with different questions, using a 1–4 scale (100). Please see the Appendix for the complete questionnaire.

Unhealthy lifestyle habit index

To further understand whether patients change more than one lifestyle habit at the same time, a lifestyle habit index was constructed. The index comprised daily smoking, hazardous use of alcohol, low daily PA, low exercise level, high level of sedentary activity, low intake of fruits and vegetables, high fast-food consumption, sleeping difficulties and high level of stress. The answers to each question in the questionnaire were dichotomised into 'healthy' or 'unhealthy' considering the lowest-ranked answers for eight of the questions as unhealthy and the two lowest-ranked answers for the question on 'fruits and vegetables' as unhealthy. Therefore, the total number of unhealthy lifestyle habits for every patient could be assessed, that is, 0–9 unhealthy lifestyle habits could be identified for every patient at the baseline and 1-year follow-up.

3.3.2 Study II

All data were collected consecutively from October 2009 to September 2014 and registered in a database by one of the CHNs. The data were verified by the author of this thesis by comparing the imported data with the original data sources.

Clinical examination

At the baseline and 1-year follow-up, all individuals were weighed to the nearest 0.1 kg using an electronic scale. Height was measured to the nearest 0.5 cm. Body mass index was calculated from the measured weight and height as kg/m². Waist circumference was measured with the participant in a standing position midway between the lower rib margin and the iliac crest to the nearest 0.5 cm. Blood pressure was measured using the standard auscultatory method with the participant in a seated position, after a 10-minute rest.

To evaluate patients' aerobic capacity, an Åstrand test was performed at the baseline and 1-year follow-up appointments. The test was performed by one of three physiotherapists. The patients were informed not to drink coffee, energy drinks, Coca Cola or use snuff 2 hours before the test. The test was performed using a mechanically braked Monark E 818 or Monark E 928 cycle ergometer (Monark Exercise AB, Vansbro, Sweden). Patients who were taking a β -blocking medication or those who had a physical impairment that hindered them from using a bicycle did not perform the test.

Laboratory measurements

A blood sample was drawn from the antecubital vein after overnight fasting, 1 week before the baseline and 1-year follow-up appointments. The levels of total cholesterol (mmol/L), LDL cholesterol (mmol/L), HDL cholesterol (mmol/L) and triglycerides (mmol/L) were analysed using the standard methods at Aleris MediLab (Stockholm, Sweden, ISO/IEC 15189 – certified).

Capillary fasting plasma glucose level was analysed at the primary health-care centre using the HemoCue® glucose 201 RT system.

Cardiovascular risk estimation

To demonstrate the prevalence of metabolic syndrome, the criteria according to the NCEP/ATP-III were used (46). The FRS was used to estimate the 10-year CVD risk (44).

3.3.3 Studies III and IV

The individual patient interviews were conducted by the author of this thesis between July 2018 and November 2018 at the primary health-care centre. The interviews were conducted following an interview guide prepared by the author of this thesis and her co-supervisor, Åsa Revenäs. (See the Appendix). The interview guide focused on the following two main research questions: (i) what was the participant's experience of lifestyle changes? and (ii) what was the participant's experience of lifestyle counselling? The interview guide was piloted twice and found to be appropriate with minor modifications.

Each interview lasted approximately 25–40 minutes. After 12 interviews, the information started becoming repetitive. After four more interviews, the information collected was considered rich enough to answer the research questions (i.e. redundancy of information was present). In total, 16 patients were interviewed.

A focus group interview with the CHNs was performed in May 2020 by one of the co-supervisors to further enrich the data material. This interview lasted for 90 minutes.

The interviews were audio-recorded and transcribed verbatim by the author of this thesis.

The transtheoretical model of behaviour change

The TTM of behaviour change has been used for the deductive part of Study III. The theory was first described by Prochaska and DiClemente in 1983 to describe and explain how people change behaviour, specifically how they stopped smoking (17). The TTM integrates different therapies to guide and support an individual to change their behaviour. The model comprehends a temporal dimension where changes are described to develop when passing through different stages: precontemplation, contemplation, preparation, action and maintenance (104). Relapses are common and can increase individuals' ability and willingness to make new attempts (17). To proceed from one stage to another, individuals must use different strategies or processes (16, 105). While the stages of change are useful in explaining *when* changes in cognition, emotion and behaviour occur, the processes of change help to explain *how* those changes occur. The 10 overt and covert processes that focus on how

change is achieved are often divided into the following two groups: behavioural and experiential (16).(Table 6) .

Table 6. The processes of change within the transtheoretical model of behaviour change (16)

Experiential	Behavioural
Consciousness raising <i>(Increasing awareness)</i>	Helping relationship <i>(Support for the healthy behaviour change)</i>
Dramatic relief <i>(Emotional arousal)</i>	Counter conditioning <i>(Substituting undesired behaviour)</i>
Self-reevaluation <i>(Self-reappraisal)</i>	Stimulus control <i>(Avoidance, environmental re-evaluation)</i>
Environmental re-evaluation <i>(Social reappraisal)</i>	Reinforcement management <i>(Overt or covert reinforcement)</i>
Social liberation <i>(Environmental opportunities)</i>	Self-liberation <i>(Committing to act)</i>

3.4 Statistics

Results are presented for the total population and subgroup analysis by sex or diagnosis (hypertension or T2DM + IGT). For questionnaire data, CV risk factors and FRS values from the baseline were carried forward for the missing data.

Continuous data were checked for normality by visual inspection of histograms for each variable. Parametric statistical methods were used for all cardiovascular risk factors and the FRS. The Wilcoxon signed-rank test was used for questionnaire data to detect changes within the group over 1 year. A two-tailed paired *t*-test was used to study within-group changes over 1 year and an unpaired *t*-test to study subgroup differences regarding cardiovascular risk factors and FRS values. Δ values, which indicate the difference between before and after measurements, are presented for all CVD risk factors and 10-year CVD risk according to the FRS. The rejection criteria for each of the individual null hypotheses were adjusted according to the Bonferroni–Holm method to counteract the problem of multiple comparisons (i.e. type I error) (106). The McNemar test was used to identify changes in the proportion of each unhealthy lifestyle habit over the year and the proportion of patients at increased risk for each CVD risk factor and 10-year CVD risk. The analyses were performed using the Statistical Package for the Social Sciences (IBM SPSS Statistics for Windows, version 24.0; IBM SPSS, Armonk, NY, USA)

3.5 Qualitative analysis

To answer the research questions in Studies III and IV, a qualitative content analysis according to the method described by Graneheim and Lundman was performed (107, 108). The processes described in the TTM were used for the deductive part of the analysis.

In Study III the analysis was abductive, which entailed a process of moving back and forth between the deductive and inductive analyses. Initially, all condensed meaning units were coded and analysed in a deductive manner according to the ten processes of change within TTM (17). The next step included sorting the codes into subcategories based on the similar manifest content in an inductive manner. As a third step, all subcategories were grouped into categories reflecting their content. Finally, a theme that interpreted the latent content was created.

In Study IV, an inductive content analysis was performed. The inductive process also included identification of meaning units, condensation and coding and sorting of codes into subcategories and categories. It uses the process of abstraction to form subcategories, categories and themes to answer a research question (107-110).

Trustworthiness

The interviews were transcribed by the author of this thesis, who checked the transcripts against the audio files on two occasions. One of the co-supervisors also checked the transcripts in the case of the two test interviews and interviewed the CHNs. In Study III, the author of this thesis performed the coding, started the analysis and discussed the findings with her co-supervisor on several occasions. In Study IV, the author of this thesis and her co-supervisor coded the first two interviews together and discussed the coding to reach coherence. Both authors scrutinised all codes, subcategories and categories and compared them with the original data material on several occasions throughout the analysis. For both studies, both authors discussed the categorisations several times to increase coherence and ensure that the subcategories and categories were independent and could be distinguished from each other. To maintain an awareness of personal biases or judgements during the process, the author of this thesis maintained reflexive memos of her discussions with her co-supervisor. To further enhance trustworthiness, the results were also scrutinised by one independent researcher for Study III and two independent researchers for Study IV. The external researchers were all experienced in qualitative research but had not previously been involved in the project. The author of this thesis used to work as a physiotherapist at the primary health-care centre but had no patient-provider relationship with any of the interviewed patients. The interview with the CHNs was performed by one of the co-supervisors because the author of this thesis had a former working

relationship with them. The co-supervisor was not involved in the lifestyle programme.

3.6 Ethical considerations

All studies were approved by the local ethics committee at Uppsala (DNR 2014/497 for Studies I and II and DNR 2014/497/1 for Studies III and IV). The studies were performed according to good research practices and the 2013 Declaration of Helsinki and included the provision of written and oral information to interested people, voluntary participation and secure data management. All participants provided their written informed consent (111-113).

The risk of negative side effects was low and could be managed at the primary health-care centre. The scientific and clinical value of the studies was considered high as the results would contribute to increase the knowledge on how lifestyle counselling could be implemented in primary health care.

4. Results

4.1 Study I

Baseline characteristics

Three hundred and sixteen patients (median age, 62 years; range, 43–74 years; women, 54%) diagnosed with either hypertension (69%), T2DM (29%) or IGT (2%) were included in the analysis. Of them, 51% met the criteria for metabolic syndrome. Patients lost to follow-up ($n = 101$) were significantly younger and received cholesterol-lowering medication to a lesser extent than the included patients. No differences in weight, waist circumference, BMI or prevalence of metabolic syndrome were observed between the patients lost to follow-up and included patients.

Main findings

The main findings from this study were significant and favourable changes in PA levels, dietary habits, feelings of stress and sleeping difficulties after participation in a 1-year structured lifestyle programme for patients with high cardiovascular risk, provided at a primary health-care centre (Table 7). This was observed in both men and women and in participants with hypertension or T2DM or IGT. Eight of the 27 patients that reported daily smoking at baseline did not smoke at 1-year follow-up.

The mean value of the unhealthy lifestyle index decreased over 1 year from 1.67 (standard deviation [SD] ± 1.40) at the baseline to 1.16 (SD ± 1.22) with a moderate effect size (Cohen's $d = 0.59$) at the 1-year follow-up (Figure 3). Men had a higher index than women at the baseline although the mean index decreased for both men and women. The subgroup analysis for diagnosis did not reveal any differences at the group level.

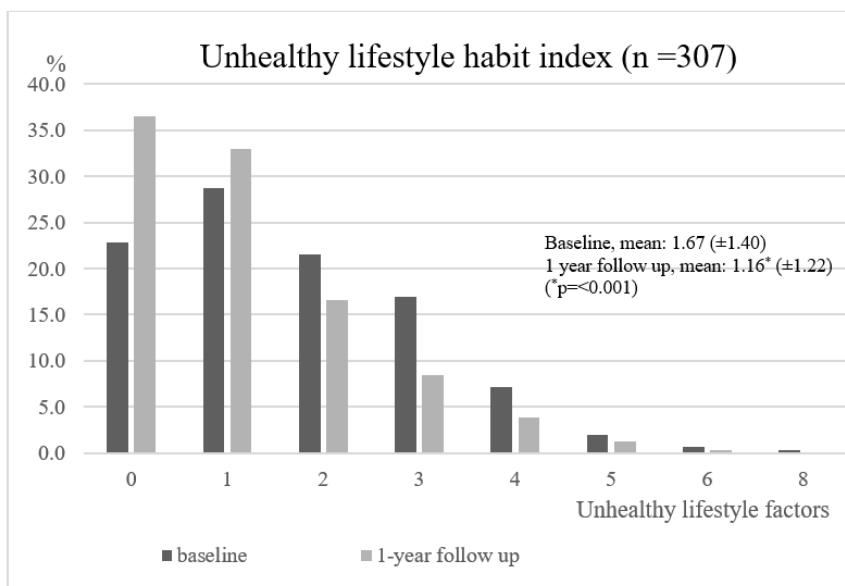


Figure 3. Proportions of individuals with 0–9 unhealthy lifestyle habits at the baseline and 1-year follow-up

Table 7. Change in lifestyle habits over 1 year (N = 312–316) * Significantly different after Bonferroni–Holm correction

Change in lifestyle habits according to the questionnaire response	Baseline mean (SD)	1-year mean (SD)	p-value over 1 year
Daily physical activity (1 = not at all physically active; 2 = < 30 min/day; 3 = 30–60 min/day; 4 = > 60 min/day). (3.13 (0.80)	3.25 (0.72)	0.001*
Exercise (1 = no activity at all; 2 = < 1 hour weekly; 3 = 1–2 hours weekly; 4 = > 2 hours weekly))	2.23 (1.10)	2.71 (1.03)	<0.001*
Overall physical activity (visual analogue scale 0 = not at all physically active and 10 = very physically active)	4.45 (1.79)	5.92 (1.70)	<0.001*
Sedentary time (1 = 0–4 hours/day; 2 = 5–8 hours/day; 3 = 9–12 hours/day; 4 = ≥ 3 hours/day)	1.86 (0.72)	1.79 (0.67)	0.015*
Fish (1 = rarely/never; 2 = a couple of times a month; 3 = once a week; 4 = a couple of times a week or more)	3.00 (0.78)	3.12 (0.76)	<0.001*
Fast food (1 = rarely/never; 2 = a couple of times a month; 3 = once a week; 4 = a couple of times a week or more)	2.27 (0.87)	2.19 (0.87)	0.036*
Fruits and vegetables (1 = a few times a month; 2 = 1–2 times a week; 3 = 3–5 times a week; 4 = daily)	3.63 (0.88)	3.80 (0.82)	<0.001*
Extra calories (1 = a few times a month; 2 = 1–2 times a week; 3 = 3–5 times a week; 4 = daily)	2.14 (0.88)	2.03 (0.82)	0.003*
Soft drinks/juice (1 = a few times a month; 2 = 1–2 times a week; 3 = 3–5 times a week; 4 = daily)	1.43 (0.60)	1.38 (0.56)	0.041*
Alcohol, frequency (1 = never; 2 = less than once a month; 3 = 2–4 times a month; 4 = 1–3 times a week; 5 = ≥ 4 times/week)	2.52 (1.05)	2.48 (1.03)	n.s.
Alcohol, intake/occasion (0 = none; 1 = 1–4 glasses; 2 = 5–9 glasses; 3 = ≥10 glasses)	0.99 (0.46)	0.97 (0.44)	n.s.
Stress (1 = never; 2 = rarely; 3 = sometimes; 4 = often)	2.82 (0.79)	2.73 (0.8)	0.009*
Sleeping difficulties (1 = never; 2 = rarely; 3 = sometimes; 4 = often)	2.59 (0.97)	2.54 (0.89)	n.s.

4.2 Study II

Baseline characteristics

Four hundred and four patients (median age, 59 years; range, 43–74 years; women, 52%) recently diagnosed with either hypertension (73%), T2DM (25%) or IGT (2%) were included in this study. The metabolic syndrome was present for 50% of all patients (46). Sixty-three patients (16%) did not complete the program.

Patients who did not complete the programme were slightly younger, more often daily smokers and more often treated with cholesterol-lowering medication. No differences were observed at baseline regarding medication and prevalence of metabolic syndrome between the included patients and those who did not complete the 1-year structured lifestyle programme.

Main findings

Significant improvements were demonstrated for all risk factors evaluated and the estimated 10-year CVD risk, with low-to-moderate effect sizes, after participation in the 1-year structured lifestyle programme in primary health care, in both men and women at high cardiovascular risk and irrespective of whether they were diagnosed with hypertension, T2DM or IGT (Table 8). This included improvements in weight, waist circumference, blood pressure, blood lipid and fasting glucose levels. The 10-year CVD risk rate decreased from 24.8% to 21.4% in the total study population, which is equivalent to an absolute mean decrease of 3.4% in the total study population ($p < 0.001$). Individual Δ -values of the 10-year CVD risk are presented in Figure 4.

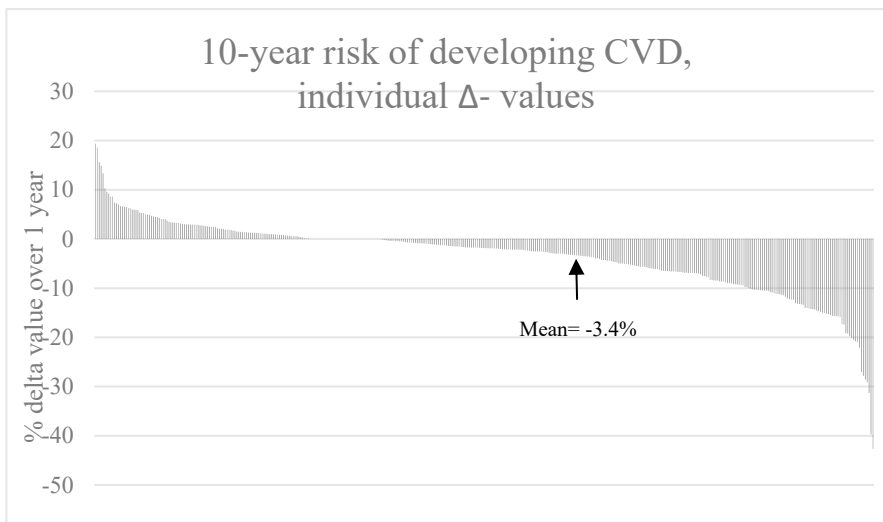


Figure 4. 10-year CVD risk, individual Δ -values

Table 8. Cardiovascular risk factors at baseline, 1 year and change over 1-year

Cardiovascular risk factor (n=404)	Baseline mean (SD)	1-year mean (SD)	Δ over 1-year mean (95% CI)	p-value	Cohen's d
Weight (kg)	86.7 (18.7)	84.5 (18.6)	-2.1 [‡] (-1.6 to -2.6)	<.001*	0.12
BMI (kg/m ²)	29.3 (5.5)	28.6 (5.5)	-.7 [‡] (-.5 to -.9)	<.001*	0.13
Waist Circumference (cm)	101.2 (13.7)	98.2 (13.5)	-2.9 (-2.5 to -3.4)	<.001*	0.22
SBP (mmHg)	149.2 (17.1)	140.5 (15.4)	-8.7 [‡] (-7.1 to -10.4)	<.001*	0.53
- Antihypertensive medication, n =268	150.3 (18.1)	139.3 (15.3)	-11.0 [‡] (-9.0 to -13.1)	<.001*	0.66
- No medication n =136	147.0 (14.8)	142.8 (15.5)	-4.2 (-1.7 to -6.8)	.001*	0.28
DBP (mmHg)	88.0 (10.5)	84.1 (8.8)	-4.0 [‡] (-3.0 to -4.9)	<.001*	0.40
- Antihypertensive medication n =268	88.4 (11.1)	83.3 (8.6)	-5.1 (-3.9 to -6.3)	<.001*	0.51
- No medication n =136	87.4 (9.3)	85.5 (9.0)	-1.8 [‡] (-.3 to -3.3)	.017*	0.21
Total cholesterol (mmol/L)	5.94 (1.18)	5.72 (1.10)	-.22 (-.13 to -.31)	<.001*	0.19
-Statin medication n =65	6.19 (1.63)	5.22 (1.36)	-.97 (-.58 to -1.37)	<.001*	0.64
-No statin medication n =339	5.89 (1.06)	5.81 (1.02)	-.08 (.00 to -0.15)	.051	0.08
LDL (mmol/L)	3.86 (.99)	3.72 (.99)	-.14 (-.06 to -.21)	<.001*	0.14
- Statin medication n =65	3.89 (1.32)	3.21 (1.19)	-.68 (-.38 to -.98)	<.001*	0.54
- No statin medication n =339	3.86 (.92)	3.82 (.91)	-.04 (-.03 to .10)	.249	0.04
HDL (mmol/L)	1.37 (.37)	1.40 (.38)	.04 [‡] (.02 to .05)	<.001*	0.08
Triglycerides (mmol/L)	1.66 (1.06)	1.51 (.82)	-.15 ^{‡,‡} (-.08 to -.23)	.001*	0.16
Fasting plasma glucose (mmol/L) n =109	8.51 (2.99)	7.15 (1.70)	- 1.36 (-0.85 to -1.88)	<.001*	0.56
- Glucose lowering medication n =42	10.17 (3.75)	7.85 (1.92)	- 2.32 (-1.19 to -3.46)	<.001*	0.78
- No medication n =67	7.48 (1.75)	6.72 (1.39)	-.76 (-.35 to -1.17)	<.001*	0.48

Values are presented as mean (SD) for baseline and 1-year measurements, and as mean (95% CI) for change (Δ) over 1 year. * Significantly different after Bonferroni–Holm correction. □ Significantly different between sexes, ‡ Significantly different between diagnoses (p < 0.05). Cohen's d effect sizes: small, 0.20; medium, 0.50; high, 0.80.

4.3 Study III

Background information on participants

A total of 16 patients were interviewed: eight women and eight men (age range, 51–75 years). Nine patients had hypertension, six patients had T2DM, and one patient had IGT.

Main findings

The deductive analysis resulted in 148 codes that related to eight of 10 processes within the TTM. Although the participants had made lifestyle changes and therefore could be in an ‘action stage’, they expressed that they had used both experiential and behavioural processes when participating in the lifestyle programme. Environmental re-evaluation and social liberation were not found to relate to any of the codes from the data. The inductive part of the analysis resulted in four categories that described the patients’ experiences of the following dimensions that assist lifestyle changes: ‘The value of knowledge’, ‘Taking control’, ‘Gaining trust in oneself’ and ‘Living with a chronic condition’. The findings highlighted the importance of increased knowledge, sense of control and self-confidence as well as support from significant others and health-care personnel when attempting lifestyle changes. The patients also stated that living with a chronic condition, such as hypertension and T2DM, was experienced as both a threat and motivational factor at the same time. The theme ‘It’s up to me’ acknowledged lifestyle change as a person-centred matter and highlighted the individuals’ own actions for healthier lifestyle habits (Figure 5).

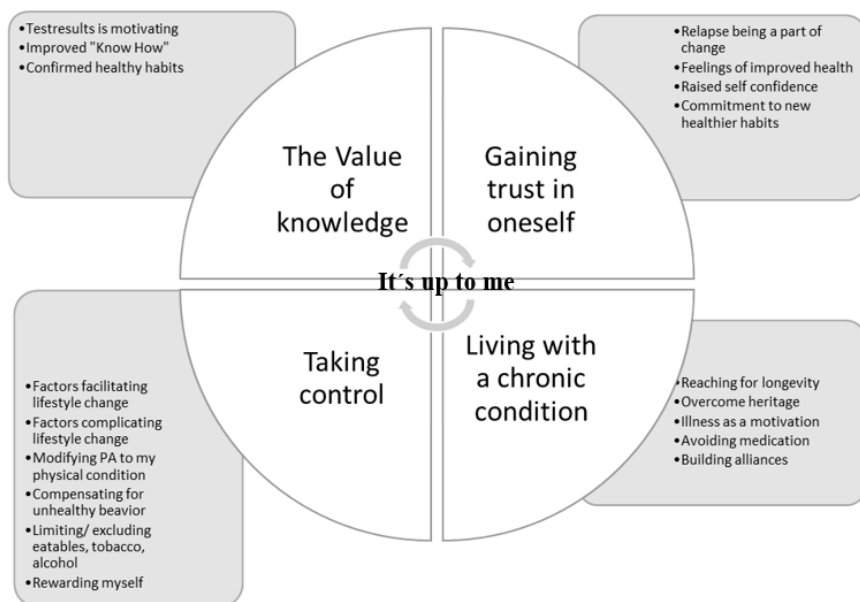


Figure 5. An overview of the result presenting the theme 'It's up to me' and the four categories and subcategories

4.4 Study IV

Background information on participants

A total of 16 patients were interviewed (the same patients as in Study III). To further enrich the data, a focus group interview was performed with three CHNs. All CHNs had > 10 years' experience in lifestyle counselling and in-depth knowledge about diabetes care, metabolic syndrome and MI.

Main findings

The inductive analysis resulted in one theme: 'Lifestyle counselling: a long-term commitment based on partnership' and five categories that described the participating patients' and CHNs' experiences of lifestyle counselling (Table 9).

The theme highlighted that the participants felt that counselling should be based on partnership. The categories described the manifest content of how the participants experienced lifestyle changes. The participants (both patients and CHNs) highlighted that their alliance and cooperation were the basis for a dialogue on a personal matter, such as lifestyle habits. Both parties recognised that meeting the same person and building a trusting relationship enabled the patient to speak about their setbacks and facilitated discussions on

behaviour changes that were easy, as well as more challenging lifestyle changes. A reciprocal interest wherein the patient was identified as the expert on their current life situation was also expressed as a key element by both patients and CHNs. Other important dimensions of lifestyle counselling that were revealed were increased knowledge, goal setting, the power of repeated measurements and long-term support for the individual to make changes in their lifestyle habits.

Table 9. Theme, categories and subcategories that described the participants' experiences of lifestyle counselling

Lifestyle counselling – a long-term commitment based on a partnership				
Collaboration should be based on respect and mutual interest	Counselling should facilitate understanding of illness and lifestyle habits	Measurements and goal setting are valuable, but knowledge is required	Long-term support after the end of the lifestyle programme is important	The care unit should support counselling for lifestyle change
A good alliance enables a trusting dialogue and an equal partnership	Counselling should provide and/or increase knowledge about lifestyle habits	Measurements increase motivation and clarify the current condition	Recurrent counselling is needed to maintain lifestyle change (P)	Different modes of delivery should be used for counselling
Dialogue provides confirmation and exploration of the patient's need for support	Counselling should provide and/or increase knowledge about illness	Goal setting is important for increasing motivation (P)	It can be burdensome to monitor illness by myself (P)	The lifestyle programme should include a structure for the delivery of counselling (CHN)
Recurrent dialogue motivates change and builds relationships	Counselling should provide/increase knowledge about how lifestyle actions can affect illness	Measurements can be difficult to interpret (P)	Support should focus on maintenance and positive changes (CHN)	Continuous education is needed for health-care professionals to maintain and improve their counselling skills (CHN)
External control by the nurse supports lifestyle changes (P)	Both patients and CHNs should be aware that medication can affect motivation (P)	Patients need support to set achievable goals (CHN)		
		Treatment goals should be consistent with the guidelines (CHN)		

CHN = subcategories expressed only by nurses, P = subcategories expressed only by patients. Subcategories without (CHN) or (P) refer to the experiences of both nurses and patients.

5. Discussion

Combining quantitative analyses and qualitative analyses i.e., positivistic, and hermeneutical research provides an opportunity to give a rich description on a heterogenous phenomenon such as lifestyle counselling. It gives a chance to describe, both to what extent lifestyle changes were performed, how cardiovascular risk factors changed after participation in the 1-year structured lifestyle programme and explore how this was experienced by the participants.

5.1 Discussion of results

5.1.1 Study I

The main findings in study I were favourable changes in lifestyle habits for patients with high cardiovascular risk, who participated in the 1-year structured lifestyle programme. This included increased PA, improved dietary habits, reduction of harmful alcohol consumption and smoking cessation. The results were consistent regardless of the diagnosis or sex. The proportion of individuals with 0–1 unhealthy lifestyle habits increased over 1 year from 51% to 69% ($p < 0.001$). This is in line with previous study findings from Sweden and Europe (114–116) as well as reports from both the US Preventive Services Task Force and the European Society of Cardiology (117–119).

Having few unhealthy habits is associated with reduced risk of CVD, T2DM and all-cause mortality (120–122). A prospective study of 20 044 participants examined how health behaviours, such as not smoking, having a moderate alcohol intake, not being physically inactive and having a healthy intake of fruits and vegetables, related to all-cause mortality. The analysis showed that the relative risk for all-cause mortality after 11 years of follow-up for men and women who had three, two, one and zero health behaviours were 1.39 (95% CI, 1.21–1.60), 1.95 (95% CI, 1.70–2.25), 2.52 (95% CI, 2.13–3.00) and 4.04 (CI, 2.95–5.54), respectively (122). Therefore, the results from Study I, wherein the proportion of individuals with 0–1 unhealthy lifestyle habits increased, are promising to consider that these were patients with high cardiovascular risk.

In Study I, 51% of the total sample, 60% of all men, 43% of all women, 77% of patients with T2DM and 39% of patients with hypertension fulfilled the criteria for having metabolic syndrome according to the ATP-III (46). This

is more than that for the general population in Sweden where metabolic syndrome is prevalent among approximately 30% of people over the age of 65 years (41). This finding was somewhat unexpected considering that the patients who participated in the lifestyle programme had a new diagnosis of either hypertension or T2DM, within a short timeframe before their participation in the lifestyle programme. In addition to the findings from Study II regarding the 10-year CVD risk, this finding highlights the importance of identifying this patient group as being at very high risk of CVD. Therefore, all efforts to reduce CVD risk factors and change lifestyle habits are of fundamental importance, as stated in both the national and international guidelines regarding hypertension, T2DM and CVD prevention (5, 29, 34, 36, 37).

5.1.2 Study II

The main findings from Study II were significant improvements regarding cardiovascular risk factors and a reduction of the 10-year CVD risk after participation in the 1-year structured lifestyle programme.

The observed reduction of SBP in Study II is in line with the results from several other studies (115, 123-125). Even modest reductions in blood pressure (2 mmHg in SPB and 1 mmHg in DBP) lead to a reduction in both CVD morbidity and mortality (124). The results in Study II demonstrated that the mean SPB and DBP almost reached the targeted 140/90 mmHg at the 1-year follow-up (mean blood pressure at the 1-year follow-up: 140.5 [SD, 15.4]/84.1 mmHg [SD, 8.8]). Despite this result, > 50% of the patients did not achieve the target blood pressure. A recent Swedish study of 392 277 patients with hypertension who were followed up for > 8 years also reported a similar finding. The proportion of patients who achieved the target blood pressure of < 140/90 mmHg was 49% at the end of the study period in 2017 (126). Other studies have reported that 20%–30% of patients who had been prescribed blood pressure-lowering medication achieved the treatment goal (87, 127). This result from Study II indicates that a structured lifestyle programme can contribute to an increased proportion of patients who achieve a blood pressure target of $\leq 140/90$ mmHg.

In Study II only patients who received statin medication, in addition to lifestyle changes, showed significantly decreased levels of LDL and cholesterol. The beneficial effect of administering statin treatment is well established and demonstrated for both patients with and without previous cardiovascular events. (128-130). Improvement in lifestyle habits is recommended for patients with dyslipidaemia and should be accompanied by drug treatment after individual risk assessment (43). This was also the intention of the 1-year structured lifestyle programme in Study II. The results from this study add to the existing knowledge on how lifestyle counselling can support patients diagnosed with dyslipidaemia together with hypertension or T2DM.

A small increase in HDL levels was detected in the whole study population and found most prominently in patients with T2DM. The HDL levels are closely associated with PA. The more physically active individuals are, the higher their HDL levels (41, 131, 132). In Study I, we found that the participants increased their time spent being physically active, both with regard to exercise and low-intensity PA, which could have contributed to the increased HDL levels found in Study II, even though it is not possible to establish a causal relationship due to the design of the study.

The decrease in the 10-year CVD risk by 14% for the whole study population in Study II is a positive finding although not sufficient. Despite this decrease, the mean 10-year CVD risk remained high (> 20%). This finding highlighted that more preventive efforts, including counselling for enhanced lifestyle habits, need to be incorporated into the care of patients with hypertension or T2DM. During the last decade, several initiatives have been taken to implement the Swedish national guidelines for the prevention and treatment of unhealthy lifestyle habits (5). The health examinations directed to identify CV risk factors for different age groups in 11 Swedish counties are one example of how lifestyle habits and present CV risk factors are identified and addressed in primary health care. Previous evaluations of the health examinations' long-term effects have demonstrated both reduced mortality and morbidity for individuals who participated in the health examinations in combination with lifestyle counselling (59, 61, 64). Different health promoting activities and web-based lifestyle counselling programmes, such as 'Act in Time' (ClinicalTrials.gov Identifier: NCT04799860), 'Prevention With the Health and Lifestyle Tool' (ClinicalTrials.gov Identifier: NCT05006508) and 'Health Integrator'(133) with the objectives of detecting early signs of elevated CVD risk factors and providing support for achieving healthier lifestyle habits are under development. The results from our study can contribute to the existing knowledge regarding the implementation of lifestyle counselling in or in collaboration with the Swedish health-care system.

5.1.3 Study III

This study aimed to explore patients' experiences of lifestyle changes. According to the patients, increased knowledge, gaining trust in oneself and support from others, including both health-care professionals and close family members or friends, were important for adopting lifestyle changes. The patients also stated that the repeated measurements increased their motivation for altering one or more lifestyle habits.

The findings correlate with several major constructs within the SCT (8, 18). For example, knowledge on risks and health benefits of lifestyle change has been described as a precondition for change, even though it is not sufficient alone to produce behaviour change. The identification of factors that facilitated or complicated lifestyle change was also experienced as helpful by the

patients. Facilitating factors highlighted by the patients included enjoyment, planning of PA, having company and encouragement from others. This finding has also been reported in other studies. For example, a Finnish study of 74 patients with high risk of T2DM reached the same conclusion regarding these facilitating factors (134). Barriers are equally important for identifying and resolving issues related to lifestyle change. In Study III, bad weather, seasonal changes, limited time and perceived incapacity to perform PA were found to be barriers to PA. The dialogues between health-care professionals and patients play a crucial role in elaborating how the patients can remove or modify such barriers. According to the SCT identifying barriers, both cognitive and environmental/ physical plays an important role for lifestyle change to be successful (8).

Although support from close family members or friends was often recognised as positive, it was also highlighted as a complicating or even obstructive factor. This finding was also reported by a Swedish interview study where 16 participants with T2DM expressed ambiguous feelings regarding how their relatives interfered with their lifestyle changes (135). The recognition of how people close to a patient affect the possibility of them adopting lifestyle changes is also stated in the SCT, wherein the socio-environmental factors are as important as personal and behavioural factors (20).

In Study III, we used the TTM for the deductive part of the qualitative content analysis. The findings showed that although all participants had adopted lifestyle changes and therefore could be assumed to be in an ‘action phase’ or ‘maintenance’, they did not use the processes that are usually associated with the action phase. They used both experiential (usually associated with the pre-contemplation, contemplation and preparation phases) and behavioural processes (usually associated with the action and/or maintenance phases) (105). This finding was also reported by other studies, such as the meta-analysis reported by Marshall et al., who concluded that the application of the TTM for PA behaviour offers a limited explanation of how change is performed, which is the opposite of behaviour change regarding tobacco, drugs and alcohol (136).

5.1.4 Study IV

This study aimed to explore patients’ and CHNs’ experiences of lifestyle counselling. Both parties emphasised that counselling should be based on a partnership wherein they both, with respect for each other’s expertise, could identify the different elements that are important for patients’ lifestyle changes. While Study III focused on how the patients experienced factors that are important for lifestyle changes *per se*, Study IV focused on experiences of counselling regarding lifestyle habits.

The main finding was that the partnership, in this case between the CHN and patient, is fundamental to the dialogue regarding lifestyle habits. The five

recurrent appointments over 1 year facilitated a process wherein the patients could share their experiences of lifestyle changes, including difficulties and setbacks. The CHNs also recognised that this partnership enabled them to tailor counselling and information based on patients' needs, rather than providing prefabricated advice following a checklist regardless of the patients' personal circumstances. This is in line with the spirit of MI, wherein the key elements are empathetic listening, elaborating of ambivalence and strengthening of self-efficacy (96, 137). The CHNs also expressed that the recurrent appointments allowed them to 'take a step back' and await patients' motivation for a lifestyle change and their experiences of the made efforts. This will also allow a process where lifestyle change is divided into smaller steps, facilitating a process of "mastery experience", a key construct within SCT, and thereby enhance self-efficacy for the performed activity (21).

Several BCTs, such as goal setting for both treatment and behavioural goals, were involved in the counselling. According to the SCT goal setting could be a way to realise an intended behaviour (21, 138). The goals were set in dialogue between CHN and patient. However, in Study IV, the CHNs noted that it was their responsibility that the treatment goals were set in line with the current guidelines regarding hypertension, T2DM and IGT. Behavioural goals were more often developed from patients' own motivation and preference for a lifestyle change. The different BCTs that were included in the 1-year structured lifestyle programme were found to strengthen motivation and self-efficacy in earlier studies. Goal achievement and positive outcome expectations are also recognised within the SCT as important factors to perform lifestyle change (8). Interventions that combine self-monitoring, such as e.g. a food diary or step counter, have been demonstrated to be significantly more effective than other interventions (139). The informants expressed that lifestyle changes were often evaluated via treatment goals and anthropometric measurements. For example, weight reduction was used as a proxy for change in dietary habits and increased maximal volume oxygen VO_2 as an indicator for increased PA. This could be an explanation for why some patients expressed that drug treatment would allow them 'to cheat' regarding dietary habits or PA. A more direct follow-up of the behaviour change might have supported lifestyle changes better than focusing on the results of laboratory or anthropometric measurements.

The informants also expressed that long-term support after completion of the programme was important. In the findings from the analysis in Study IV, we noted different opinions regarding whether this expectation was fulfilled or not. Patients with hypertension voiced that they felt that they were left alone once the lifestyle programme had ended. This contrasts with patients with T2DM who instead acknowledged that they had persistent and recurrent contact with 'their' diabetes nurses. Patients with hypertension experienced that it was up to them to follow their blood pressure and contact the primary health-

care centre once a year when a new prescription for anti-hypertensive medication was needed. This is in contrast with the existing guidelines and local recommendations regarding the treatment of hypertension, which includes a yearly follow-up of blood pressure, lifestyle habits and individual risk assessment, including an evaluation of the need for anti-hypertensive medication (34, 35). However, patients may not be aware that this is part of an evaluation performed by the physician before a new prescription is made. The findings may also indicate that more efforts should be directed to enhance patient empowerment. The concept of patient empowerment is defined by WHO as ‘a process through which people gain greater control over decisions and actions affecting their health’ (140). Patient empowerment involves patients reclaiming their responsibilities to improve and maintain their health and to take action regarding their own health status. This might contribute to overcome patients experience of being left alone regarding their condition (i.e. hypertension).

The patients with hypertension asked for a more structured follow-up, for instance, a follow-up via phone or e-mail. Earlier studies demonstrated that these types of interventions may have positive effects and provide an efficient method to meet the patients’ desire for a structured follow-up (141-143). Promoting patient empowerment together with a yearly follow-up by phone and or e-mail might help to reduce the experience of being left to manage their condition by themselves.

5.1.5 The 1-year structured lifestyle programme in relation to SCT

Within the SCT, health behaviour can be explained as a result of how three major factors (personal cognitive factors, behavioural factors and socio-environmental factors) interact. According to the analysis of which BCTs that were included in the 1-year structured lifestyle programme (see section 3.1.3), several components, related to SCT, were identified that can have contributed to the change of lifestyle habits after participation in the 1-year structured lifestyle programme:

- Information on lifestyle habits and diagnosis, use of diaries, goal-setting and different biometrical measurements are examples of elements that support personal cognitive factors.
- Graded tasks, problem solving, and action planning are examples of elements that supported behavioural factors.
- Social support – both practical and emotional, social reward and restructuring of the physical environment are examples from the BCT analysis of elements that supported socio-environmental factors.

These results in addition with the contribution of the findings in study III and IV can also provide an opportunity to further improve the counselling to promote lifestyle change included in the 1-year structured lifestyle programme..

5.2 Methodological considerations

Before the initiation of the lifestyle programme, several steps were taken to implement the programme in regular care. Information and education for the whole staff were repeated on several occasions before the initiation of the programme in 2009 and during the 5 years that followed. This ensured that patients diagnosed with either hypertension, T2DM or IGT received individualised information on lifestyle habits and a referral to the lifestyle programme. By the time the lifestyle programme started in 2009, the evidence for how lifestyle counselling should be performed was growing and manifested in different guidelines and government documents (71, 87, 88, 91). However, information on how lifestyle counselling should be implemented in everyday primary health care was more limited. A lifestyle programme similar to the programme evaluated in this thesis was launched at the Department of Cardiology, Karolinska Hospital in 2008. This programme was directed towards both patients from the hospital and those from primary health care (114, 144). To our knowledge, no other lifestyle programme directed towards patients with high cardiovascular risk was ongoing in a primary healthcare setting in Sweden at that time.

Considering this, the quantitative part of this thesis was designed to be observational to evaluate the extent to which lifestyle habits and cardiovascular risk factors changed after participating in the lifestyle programme. Although our findings are in line with those of previous randomised controlled studies regarding the effects on cardiovascular risk factors after participating in lifestyle counselling (123, 124, 145), the lack of control group in our study limits the interpretation of results.

The use of a questionnaire to collect information on the patients' lifestyle habits served dual purposes. First, it was part of the data collection for analysis of how lifestyle habits changed after participation in the lifestyle programme at Citypraktiken. Second, the CHN used the questionnaire to start a dialogue on patients' current lifestyle habits in relation to their new diagnosis of either hypertension, T2DM or IGT. The use of questionnaires is a convenient way to collect information on different topics although it has limitations, including recall bias and patients providing socially acceptable responses. However, both patients and CHNs expressed that the questionnaire contributed to the focus on lifestyle habits and their relevance regarding hypertension or T2DM, as concluded in Studies III and IV.

To enhance the patients' motivation for lifestyle changes, the CHNs used the technique of MI. This communication strategy is one of several recommended communication strategies in both the Swedish national guidelines and national care programme for the prevention and treatment of unhealthy lifestyle habits (5, 75) and the European guidelines on CVD prevention (36). The underlying spirit of MI is a collaborative process where every step in the process is performed in partnership with the patient. The CHNs used the technique of MI as a collaborative method to support lifestyle changes. They used tools as open-ended questions, affirmation, and reflective listening for evoking the patient's motivation for lifestyle change, which is in line with 'the spirit of MI'.

Even though the use of MI is widespread, different results are obtained in the evaluation of the interventions' efficiency. Common difficulties when reporting MI interventions concern the fidelity of the method and evaluation of the quality of the health-care professional's MI training. Poor reporting quality hampers the possibility of performing high-quality meta-analyses or reviews. A review of 104 reviews, including 39 meta-analyses, concluded that the evidence for the promotion of healthy behaviour was inconclusive or of low quality because of methodological flaws in the reviews and the poor quality of the included studies (97). Despite this lack of stringent reporting, MI has been demonstrated to be more effective than usual care for altering smoking habits, increasing PA, weight loss and improving SBP, DBP and depression (137, 146-151). A systematic review and meta-analysis of 9618 participants demonstrated that the use of MI showed higher efficacy than the usual treatment regarding the change in different health behaviours, with an overall modest advantage for MI (odds ratio, 1.55; 95% CI, 1.40–1.71). The findings were independent of who delivered the counselling although they indicated a preference for an individualised delivery compared with group appointments (152).

In this thesis, the taxonomy developed by Michie et al. (22) was used to enhance the reporting of the different BCTs that were included in the lifestyle programme. However, the taxonomy developed by Michie et al. did not include MI in the analysis because they considered MI to be more of an 'approach' than a specific technique. Considering that MI is a widespread technique used in different behaviour change settings, the need to accurately report an intervention that includes MI is the same as those for other behaviour change interventions. Based on the latest edition of Miller and Rollnick's *Motivational interviewing: helping people change* (96), Hardcastle et al. presented a study to identify the BCTs unique to MI and determine whether they were 'content-related' or 'relational'. A second objective was to evaluate the extent to which the techniques used in MI overlapped with the BCTs in the taxonomy developed by Michie et al. (153). According to this study, content-related techniques focus on the information and knowledge shared with and by the patient. These techniques can also be found in the taxonomy developed by Michie et al. The relational aspect refers to what is commonly known as

the MI spirit (96). The spirit of MI, as described earlier in this thesis, contains the following four basic elements that are used to evoke the individual's inner motivation for behaviour change: collaboration, evocation, autonomy and compassion. Hardcastle et al. collectively referred to these four elements as relational. These relational components are not included in the taxonomy developed by Michie et al. (22) The authors found 38 distinct MI-techniques, of which 16 were overlapping with the taxonomy by Michie et al.

Although the counselling within the 1-year structured lifestyle programme described in this thesis was performed with MI as the basis for communication on lifestyle change it was not documented in a way that would provide basis for a analysis according to Hardcastle et al (153). Therefore, the taxonomy by Michie et al was used to enhance the reporting of the BCTs that were used in the lifestyle programme.

5.3 Limitations

This thesis and the included studies originated from everyday clinical practice at a Swedish primary health-care centre. Patients and health-care professionals, such as CHNs, family physicians and physiotherapists, can be found at most primary health-care centres in Sweden. Thus, the data from this thesis represent the heterogeneity that can be found at any ordinary Swedish primary health-care centre. Studies I and II had an observational design, which limits the possibility of analysing a causal relationship between the lifestyle programme and change in lifestyle habits, cardiovascular risk factors and 10-year CVD risk. A randomised controlled study design would have provided data on the extent to which the lifestyle programme contributed to improved lifestyle habits and cardiovascular risk factors compared with standard care or no care (in the case of the waiting list control group). However, the 'real-world data' that are represented in studies I and II strengthen the external validity of our findings although the lack of a control group limits the analysis.

Other concerns regarding the design of Studies I and II are the 'regression to the mean' effect (154) and the Hawthorne effect (155), which must be taken into consideration when analysing the results. The regression to the mean effect is to some extent reduced considering that blood pressure and waist circumference were measured on all five appointments which may indicate a possible relationship with patients' lowered CVD risk and participation in the 1-year structured lifestyle programme.

The primary health-care centre had a low Care Need Index (CNI; < 1.0) indicating a lower need for care than that needed in primary health-care centres with higher CNIs (156, 157). The CNI is based on factors that influence a population's need for care. The factors included in the CNI are as follows: age > 65 years; living alone; born in Eastern Europe, Asia, Africa or South America; single parent living with a child aged < 17 years; low educational level at

age 25–64 years; and age < 5 years. This limits the transferability of the study findings to other primary health-care centres and geographic areas.

Another concern is whether the patients would perform lifestyle changes solely because of having received a diagnosis of hypertension or T2DM. A longitudinal Canadian study including 1281 persons with a new diagnosis of hypertension interviewed the participants regarding change of lifestyle habits after receiving the diagnosis. The findings from this study indicated that smoking cessation was associated with a new diagnosis of hypertension with a relative risk reduction of 18.6% and a small change was observed in the sedentary time. The findings also indicated that persons not taking antihypertensive medications were not more likely to change lifestyle in response to their recently diagnosed hypertension (158). Chong et al. demonstrated a similar pattern of responses to a diagnosis of T2DM. One aim of their study was to compare changes in lifestyle behaviours between participants who were newly diagnosed with T2DM and those who had no such diagnosis. A total of 888 patients with a new diagnosis of T2DM were included in the study, with a mean duration of time since diagnosis of 1.8 ± 1.1 years. The findings indicated positive effects of decreased sedentary time and increased incidence of smoking cessation but no changes in body weight, amount of walking, moderate-to-vigorous PA and fruit and vegetable consumption (159).

Finally, for Studies III and IV, a recall bias may be present because the patients participated in these studies 3 years after the completion of the lifestyle programme. Although impaired memory might alter views of lifestyle changes, elapsed time could simultaneously offer a different perspective of the participants' experience of lifestyle changes. To meet the objectives described in Studies III and IV, the participants were recruited from the population that had completed all five appointments with the CHNs during the lifestyle programme. Hence, we do not have information for the individuals who did not participate in the programme for the whole year. Barriers to participation in a lifestyle programme are likely to be present. In further studies, it would be interesting to explore the experiences of lifestyle changes and lifestyle counselling in individuals who did not complete the lifestyle programme.

6. Conclusion

Launched in 2009, the 1-year structured lifestyle programme was directed towards patients with a new diagnosis of either hypertension or T2DM, that is, patients with high cardiovascular risk. The programme was one of the first lifestyle programmes of its type that was implemented in primary health care and used only the regular resources available at the Swedish primary health-care centres. The results from Studies I and II add to the existing knowledge and suggest that tailored counselling that focuses on lifestyle habits, including follow-up of anthropometric measurements and CV risk factors, supports patients' ability to change their unhealthy lifestyle habits. Moreover, the findings from Study II indicate that participation in the lifestyle programme contributed to improved cardiovascular risk factors and reduced the 10-year CVD risk.

The findings from the qualitative Study III show that increased knowledge of lifestyle habits, gaining trust in oneself and support from others, including both health-care professionals and close family members or friends, were important for adopting lifestyle changes. Repeated measurements and identifying barriers and facilitating factors increased patients' motivation for altering one or more lifestyle habits. Finally, the findings from Study IV highlight that counselling should be based on a partnership wherein both patients and CHNs, with respect for each other's expertise, can identify the different elements that are important for lifestyle changes. This included goal setting for both treatment and behavioural goals and a need for long-term support after the completion of the lifestyle programme.

The findings from this thesis, which includes both quantitative and qualitative studies, add to the knowledge on how lifestyle counselling can be implemented in primary health care. The use of SCT, has provided a theory-based analysis of the behavioural content of the 1-year structured lifestyle programme and the BCT analysis have provided a more precise reporting of the BCTs included in the 1-year structured lifestyle programme.

7. Clinical implications and future studies

According to the findings from this thesis, lifestyle counselling in primary health care can be implemented using the resources available at the Swedish primary health-care centres and can contribute to improved care of patients with either hypertension or T2DM. Considering that these patients were at high risk for future fatal or non-fatal CVD, this conclusion is highly relevant. The lifestyle programme described in this thesis is one example of how structured counselling can be implemented in everyday care. The results demonstrate that issues related to lifestyle habits can be addressed and counselling to support patients in making healthier choices can be offered with rather small efforts.

The need for long-term support is another issue that was highlighted by the participants in Study IV. Perhaps this could be easily managed with the present-day technology, for example, with an automated, yearly e-mail that prompts patients with hypertension to check their blood pressure and book a follow-up appointment at their primary health-care centre with a CHN or family physician. At this follow-up appointment, the results of both blood pressure and current lifestyle habits could be in focus, which would be in adherence with the recommendations in treatment protocols for hypertension. The findings from the qualitative analyses in Studies III and IV contribute to increased knowledge regarding how lifestyle counselling can be implemented to meet the patients' need for support in adopting lifestyle changes. According to the participants, continuity, that is, meeting the same person at each appointment, was a crucial factor. Therefore, efforts must be undertaken to give both health care professionals and patients the prerequisites that this requires.

In the future it would be of interest to study the effects of the 1-year structured lifestyle programme in a randomised controlled study. This design would provide more information on the causal relationship between participation in the programme and the findings from Studies I and II. In addition, future studies could evaluate how the programme could be implemented in different socio-economic contexts.

The results of study III and IV implies that the counselling could be further enhanced and more efficient, by implementing more specific techniques to promote and evaluate behavioural change. For example, this could include a review of behavioural goals, action planning and reflexive tasks for the

participants. Another suggestion is to include Internet- or telephone-based interventions to support behaviour change.

Finally, a long-term follow-up evaluating the incidence of cardiovascular events and death due to CVD 20–25 years after participation in the programme during 2009–2014 would be of great interest. This would preferably include a matched control group with patients who had also been diagnosed with either hypertension, T2DM or IGT during 2009–2014 and underwent ‘treatment as usual’.

8. Svensk sammanfattning

Hjärt-kärlsjukdom, vissa cancerformer och psykisk sjukdom, räknas till våra folksjukdomar, alltså sjukdomstillstånd som är vanligt förekommande i befolkningen.

Det är väl känt att ohälsosamma levnadsvanor: tobaksbruk, fysisk inaktivitet, ohälsosamma matvanor och riskbruk av alkohol har stor inverkan på risken att drabbas av sjukdom, och att de, i sin tur, påverkar hur sjukdomen utvecklar sig. Dessa fyra levnadsvanor har också en avgörande påverkan på förekomsten av typ 2-diabetes, högt blodtryck, övervikt/ fetma och höga nivåer av blodfetter, vilket i sin tur leder till en förhöjd risk för hjärt-kärlsjukdom. Flertalet av dessa sjukdomar kan dock förebyggas, till exempel genom att inte röka, äta hälsosamt, vara fysiskt aktiv och att inte ha mer än ett måttligt intag av alkohol.

Målet för hälso- och sjukvården är en god hälsa och vård på lika villkor för hela befolkningen. Enligt den svenska hälso- och sjukvårdslagen ska hälso- och sjukvården även informera patienten om hens hälsotillstånd och använda metoder för att förebygga sjukdom eller skada.

Även om kunskapen om vikten av förebyggande insatser hade gott vetenskapligt stöd, så fanns det brister i införandet av metoder för att stödja patienter att förändra ohälsosamma levnadsvanor, när den här studien startade.

Som ett led i att förbättra arbetet med levnadsvanor startade en "Livsstilsmottagning" på en vårdcentral i Västmanland. Syftet med mottagningen var att ge patienter med nyupptäckt högt blodtryck, typ 2-diabetes eller ett förstadium till typ 2-diabetes en strukturerad rådgivning med fokus på levnadsvaneförändring, för att därigenom minska patienternas risk för framtida hjärt-kärlsjukdom.

På livsstilsmottagningen fick patienterna träffa en distriktssköterska med fördjupad kunskap om diabetessjukdom, hjärt-kärlsjukdom och metoder i syfte att ge stöd till förbättrade levnadsvanor. Vid varje besök, sammanlagt fem besök under ett år, gjordes olika kroppsliga mätningar och patienten gavs tillfälle att diskutera de levnadsvanor som patienten hade behov av att förändra. Som en följd av denna dialog kunde målsättning för både levnadsvanor och behandling av aktuell sjukdom fastställas. Måluppfyllelse följdes upp vid nästkommande besök och vid behov justerades målsättningen till nästa besök.

Det övergripande syftet med det här forskningsprojektet var dels att utvärdera vilken påverkan deltagande i livsstilsomläggningen hade avseende förändring av levnadsvanor och olika riskfaktorer för hjärt-kärlsjukdom dels att beskriva patienternas erfarenhet av att förändra levnadsvanor och upplevelsen av själva rådgivningen.

Syftet med studie I var tvådelat - dels att beskriva upplägget och innehållet i den Livsstilsomläggning som startades på vårdcentralen 2009, dels att beskriva i vilken utsträckning deltagarna i livsstilsomläggningen ändrade sina levnadsvanor efter deltagande i livsstilsomläggningen. Resultaten visade att patienter som deltagit i livsstilsomläggningen a) i större utsträckning var fysiskt aktiva och mindre stillasittande, b) att de hade ett mer gynnsamt kostmönster, till exempel ett dagligt intag av frukt och grönsaker, c) att en lägre andel var rökare. Resultaten var likartade oavsett kön och oavsett om patienten hade högt blodtryck eller typ 2-diabetes.

Syftet med studie II var att utvärdera hur olika riskfaktorer och en beräknad framtida risk att drabbas av hjärt-kärlsjukdom förändrades efter deltagande i livsstilsomläggningen. Deltagare i livsstilsomläggningen hade, efter avslutad rådgivning, förbättrade värden avseende blodtryck, fastande blodsocker, blodfetter och kolesterolnivåer. De hade även minskat i vikt och hade ett minskat midjeomfång. Risken att drabbas av framtida hjärt-kärlsjukdom inom 10 år minskade något, men låg fortfarande kvar på en hög risknivå vid ett-årsuppföljningen.

Syftet med studie III var att beskriva patienters erfarenheter av att förändra levnadsvanor efter deltagande i Livsstilsomläggningen och beskriva vilka tekniker och strategier deltagarna har använt sig av kopplat till den transteoretiska modellen. Analysen av intervjuer med deltagande patienter resulterade i ett tema - "Det är upp till mig" och fyra kategorier som beskrev deltagarnas erfarenheter av att förändra levnadsvanor. Patienterna beskrev att ökad kunskap, att ta kontroll, att få en ökad tilltro till den egna förmågan och att leva med en kronisk sjukdom var betydelsefulla delar vid förändring av en eller flera levnadsvanor. Patienterna beskrev också att de använde sig av både erfarenhetsmässiga strategier och beteendemässiga strategier vid förändring av levnadsvanor.

Syftet med studie IV var att beskriva deltagande patienters och distriktsköterskors erfarenheter av rådgivning med fokus på levnadsvanor. Analysen av intervjuer med deltagande patienter och distriktsköterskor resulterade i fem kategorier och ett tema som beskrev deltagarnas erfarenheter av rådgivning med fokus på förändring av levnadsvanor. Deltagarna förklarade att rådgivningen behöver vara baserad på ett partnerskap mellan patient och distriktsköterska. Enligt deltagarna behöver rådgivningen också ge en fördjupad förståelse av sjukdomen och kopplingen till levnadsvanor och det bör finnas en tydlig målsättning för behandlingen. Patienter med högt blodtryck uttryckte samtidigt att de saknade en naturlig fortsättning och återkommande kontakt med vårdcentralen efter att året på livsstilsomläggningen var slut.

Sammanfattningsvis indikerar resultaten att det är möjligt att, med de resurser som vanligtvis finns i svensk primärvård, stödja patienter till att förändra och förbättra ohälsosamma levnadsvanor och därigenom minska risken för framtida hjärt-kärlsjukdom. Framtida forskning behöver dock omfatta studier där den strukturerade rådgivningen jämförs med ordinarie behandling för att säkerställa resultaten.

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Appendix

Check list - lifestyle programme

Baseline appointment

- “Sit in” with patient’s family physician before baseline appointment
- Review of questionnaire and laboratory measurements, blood glucose
- Assessment of motivation on a scale 0-10, and overall, PA on a scale 0-10
- Goalsetting together with the patient
- Need for in-depth counselling (PA, tobacco, alcohol, diet, stress?)
- Anthropometric measurements (blood pressure, WAIST CIRCUM-FERENCE, weight, height, ankle brachial index)
- Prescription of PA, distribution of pedometer, water bottle, PA diary and written information
- Schedule 3-month appointment, if necessary phone call and laboratory measurements preceding the next visit. Remind patients with T2DM to bring data regarding blood glucose levels.
- Ask for patients e-mail and add to the list for group appointments

3-, 6 and 9-month appointment

- Goal achievement review, need for modification of goals
- Review of PA and need for new prescription of PA
- Review of laboratory measurements – need for medication?
- Assessment of motivation
- Measure blood pressure, WC
- Need for in-depth counselling?
- Providing information on lifestyle habit in focus – written or oral
- Schedule the next appointment, remind patients with T2DM to bring data regarding blood glucose levels

1-year appointment

- “Sit in” with patient’s family physician before 1-year appointment
- Review of questionnaire and laboratory measurements, blood glucose
- Review of goal achievement – set new goals

- Assessment of motivation on a scale 0-10 and overall, PA on a scale 0-10
- Anthropometric measurements (blood pressure, WAIST CIRCUM-FERENCE, weight, ankle brachial index)
- Prescription of PA, return of pedometer
- Give information to the patient that he/ she will be scheduled for a follow up every 6 month with CHN and once a year with family physician, patients with T2DM, and once a year with family physician for patients with hypertension as part of the regular care programme for T2DM and hypertension.

Interview guide

Interview guide with questions used to explore patients' and community health nurses' experiences of lifestyle counselling. Every question was followed up with prompts such as, 'Can you tell me more?' or 'Can you give me some more examples?'. P = question for patients, CHN = question for community health nurses, MI = motivational interviewing

Background information	<p>Previous experiences of counselling? (P, CHN)</p> <p>Are you receiving or giving counselling today? (P, CHN)</p> <p>What kind of education do you have that is relevant to providing lifestyle counselling, e.g. diabetes care, metabolic syndrome, MI? (CHN)</p>
About lifestyle habits	<p>Which habits were addressed? (P, CHN)</p> <p>Who prioritized which habits to address? (P, CHN)</p> <p>Who sets the goals? (P, CHN)</p>
About counselling	<p>What components of counselling do you find helpful? (P, CHN)</p> <p>What motivates you to change your lifestyle habits? (P)</p> <p>How do you act to enhance motivation? (CHN)</p> <p>What are the easy parts of providing counselling, and what is more difficult? (CHN)</p>
About maintenance	<p>What do you need to maintain a healthier lifestyle? (P)</p> <p>How do you prepare the patient to maintain a healthier lifestyle? (CHN)</p>
About the supervisor role	<p>How do you want the CHN to guide you? (P)</p> <p>How do you see your role as supervisor – 'carrot or stick'? (CHN)</p> <p>When the patient doesn't adhere to the advice – what do you do? (CHN)</p>
Final comments	<p>Is there something else you want to add? (P, CHN)</p>

Questionnaire

To help guide you to better health and quality of life, we ask you to complete this questionnaire and bring it with you to your next appointment.

How do you perceive your health in general?

☐ very good ☐ good ☐ not so good ☐ not at all good

How would you rate your risk of future cardiovascular illness?

☐ very low ☐ low ☐ fairly high ☐ very high

PHYSICAL ACTIVITY

How physically demanding is your occupation?

☐ very easy ☐ easy ☐ strenuous ☐ very strenuous

How do you commute to work?

☐ walking ☐ by bicycle ☐ by car ☐ by bus or train

How physically active are you during the day?

(e.g., taking a walk, bicycling, taking the dog for a walk, cleaning the house, gardening, shovelling snow, playing with your children)

☐ not at all physically active ☐ <30 min per day ☐ 30–60 min per day
☐ >60 min per day

How much exercise do you perform in a week?

(e.g., gymnastics, jogging, swimming, ball games, riding)

- ☐ no activity at all ☐ <1 hour weekly ☐ 1–2 hours weekly ☐ >2 hours weekly

Please estimate the amount of time you sit each day.

- ☐ 0–4 hours ☐ 5–8 hours ☐ 9–12 hours ☐ 13 hours or more

How would you rate your physical fitness?

- ☐ very good ☐ good ☐ not so good ☐ poor

DIET

How many days a week do you eat breakfast?

- ☐ every day ☐ 4–6 days ☐ 1–3 days ☐ never

How many days a week do you eat lunch?

- ☐ every day ☐ 4–6 days ☐ 1–3 days ☐ never

How many sandwiches do you eat daily?

- ☐ ≤2 daily ☐ 3–4 daily ☐ 5–6 daily ☐ >6 daily

How often do you eat fish?

- ☐ a couple of times a week or more ☐ once a week ☐ a couple of times a month ☐ rarely/never

How often do you eat sausages, hamburger or pizza?

- ☐ a couple of times a week or more ☐ once a week ☐ a couple of times a month ☐ rarely/never

How often do you eat fruit and vegetables?

☐ daily ☐ 3–5 times a week ☐ 1–2 times a week ☐ a few times a month or less

How often do you eat “extra” calories?

☐ daily ☐ 3–5 times a week ☐ 1–2 times a week ☐ a few times a month or less

How often do you drink sweetened soft drinks or juice?

☐ daily ☐ 3–5 times a week ☐ 1–2 times a week ☐ a few times a month or less

ALCOHOL

How often do you drink alcoholic beverages?

☐ never ☐ less than once a month ☐ 2–4 times a month ☐ 1–3 times a week ☐ ≥ 4 times a week

How many “glasses” do you typically drink when you drink alcohol?

(One glass equals 45 cl light beer, 33 cl beer, 12 cl wine, 8 cl fortified wine, 4 cl spirits)

☐ 1–2 glasses ☐ 3–4 glasses ☐ 5–6 glasses ☐ 7–9 glasses ☐ ≥ 10 glasses

Are you or your relatives worried about your current alcohol consumption?

☐ yes ☐ no

TOBACCO

Do you smoke?

☐ yes ☐ no

If yes, how many cigarettes daily? ...cigarettes

Do you use snuff?

☐ yes ☐ no

If yes, how many portions daily? ... portions

STRESS

Do you feel stressed?

☐ never ☐ rarely ☐ sometimes ☐ often

Have you experienced difficulties with sleep?

☐ never ☐ rarely ☐ sometimes ☐ often

Do you feel anxious?

☐ never ☐ rarely ☐ sometimes ☐ often

Do you feel depressed?

☐ never ☐ rarely ☐ sometimes ☐ often

Do you feel tired?

☐ never ☐ rarely ☐ sometimes ☐ often

Are you affected by any form of body pain?

☐ never ☐ rarely ☐ sometimes ☐ often

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