Supporting healthy movement behaviours in people with metabolic risk, prediabetes, or type 2 diabetes in primary health care

KRISTINA LARSSON
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SUPPORTING HEALTHY MOVEMENT BEHAVIOURS IN PEOPLE WITH METABOLIC RISK, PREDIABETES, OR TYPE 2 DIABETES IN PRIMARY HEALTH CARE

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"Det har jag aldrig provat tidigare så det klarar jag helt säkert."
- Ur Pippi Långstrump, av Astrid Lindgren
Populärvetenskaplig sammanfattning


Resultaten från denna avhandling visar att Sophia Step Study inte hade någon effekt på det primära utfallet långtidsblodsocker (HbA1c). Däremot fann vi en statistiskt säkerställd effekt för gruppen som bara fick stegräknare; de ökade sin tid i måttlig till hög fysisk aktivitet vid sex månader jämfört med kontrollgruppen. Gruppen som dessutom fick rådgivning ökade också sin tid i måttlig till hög fysiska aktivitet över hela tvåårs perioden. Ingen effekt kunde ses för fysisk aktivitet på låg intensitet, stillasittande, antalet steg per dag eller någon av riskfaktorerna för hjärt-kärlsjukdom.
När analyserna upprepades och en metod som ser på alla rörelsevanorna i relation till varandra användes, visades en tydligare effekt för alla rörelsevanor inom båda interventionsgrupperna under tvåårsperioden. Vid ytterligare upprepade analyser såg vi att vid sex månader var det fler deltagare med lägre antal steg vid studiens start som ökade ≥500 steg per dag. Vid 24 månader var det fler män, yngre deltagare och de med högre tilltro på sin egen förmåga till fysisk aktivitet vid studiens start som ökade ≥500 steg per dag. I intervjustridien fann vi att sjuksköterskor, fysioterapeuter och läkare upplevde hindrande och möjliggörande faktorer för att stödja personer med metabola riskfaktorer kring att öka sina rörelsevanor inom fyra olika kategorier: 'Patientens beredskap för förändring', 'Stödja förändringsprocessen', 'Den professionella yrkesrollen' och 'Organisationen inom primärvården'.

Abstract

The overall aim of this thesis was to investigate if a pedometer-based intervention in the primary health care setting can support people with prediabetes or type 2 diabetes towards healthier movement behaviours. Moreover, health care professionals’ experiences of supporting people with metabolic risk factors to increase their physical activity were explored.

This thesis consists of four papers based on data from two research studies. Paper I, II, and III are based on a randomised controlled trial called the Sophia Step Study, which is a two-year, three-armed pedometer-based intervention. The three groups comprised a multi-component group that received a pedometer and extra counselling, a single-component group that received a pedometer, and a control group that received standard care.

The aim of the Sophia Step Study was to support individuals with prediabetes or type 2 diabetes in becoming regularly physically active by reporting their daily number of steps, with or without extra counselling. Paper IV is based on a qualitative interview study that explored nurses’, physicians’, and physiotherapists’ experiences in primary health care when supporting patients with metabolic risk factors to physical activity. In paper I, the effects of self-monitoring steps with or without counselling support for HbA1c, other cardiometabolic risk factors and physical activity during the two-year intervention were evaluated. In paper II, the effects of the intervention were evaluated on relative time in different movement behaviours. In paper III, predictors associated with intermediate and post intervention increases in steps were explored. Finally, in paper IV, barriers and facilitators perceived by health care professionals who work within Swedish primary care to support people with metabolic risk factors to increase their physical activity were explored.

The results show that the Sophia Step Study did not have an effect on the primary outcome HbA1c. However, a significant effect was found for the multi-component group on absolute time in moderate-to-vigorous physical activity during the entire two-year period, as well as for the single-component group at six months. No effect, however, was found for the absolute time in the other movement behaviours, the number of daily steps, any of the biomarkers or the anthropometric variables. Using relative time, instead of absolute time, when evaluating the effect showed a more pronounced effect in all movement behaviours within both intervention groups over the two-year period. At six months, lower number of steps at baseline was a significant predictor for increasing ≥500 steps per day. At 24 months, men, younger participants, and those with higher self-efficacy at baseline had significantly higher odds for increasing ≥500 steps per day. Barriers and facilitators for supporting people with metabolic risk factors in increasing their physical activity, as experienced by nurses, physiotherapists and physicians, were identified at multiple levels, represented by four generic categories: ‘Patient readiness for change’, ‘Supporting the process of change’, ‘The professional role’, and ‘The organisation of primary care’.

The overall conclusion is that the self-monitoring of steps with a pedometer seems to be an effective behaviour change technique in maintaining healthy movement.
behaviours; however, the counselling component of the intervention did not seem to improve the effect. In addition, the intervention did not find evidence for improved metabolic control or improved cardiometabolic risk factors. Moreover, barriers to and facilitators for supporting patients with metabolic risk factors can be found at several levels within primary care, from individual patients and health care professionals to the organisational level. In the primary health care setting, this should be emphasised when implementing support with the intention to increase physical activity in people with metabolic risk factors, prediabetes or type 2 diabetes.
List of scientific papers


III. Larsson K, Rossen J, Norman Å, Johansson U-B, and Hagströmer M. Predictors associated with an increase in daily steps among people with prediabetes or type 2 diabetes participating in a two-year pedometer intervention. *Manuscript.*


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<th>Full Form</th>
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<tbody>
<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>BCTs</td>
<td>Behaviour Change Techniques</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>CFIR</td>
<td>Consolidated Framework For Implementation Research</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>EQ-VAS</td>
<td>Health-related Quality of Life</td>
</tr>
<tr>
<td>GDPR</td>
<td>General Data Protection Regulation</td>
</tr>
<tr>
<td>GLP-1</td>
<td>Glucagon-Like Peptide-1</td>
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<tr>
<td>HADS</td>
<td>Hospital Anxiety and Depression Scale</td>
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<tr>
<td>HbA1c</td>
<td>Haemoglobin A1c</td>
</tr>
<tr>
<td>HDL</td>
<td>High-Density Lipoprotein</td>
</tr>
<tr>
<td>IFG</td>
<td>Impaired Fasting Glucose</td>
</tr>
<tr>
<td>IGT</td>
<td>Impaired Glucose Tolerance</td>
</tr>
<tr>
<td>ilr</td>
<td>Isometric Log-Ratio</td>
</tr>
<tr>
<td>ISPAH</td>
<td>International Society for Physical Activity and Health</td>
</tr>
<tr>
<td>LDL</td>
<td>Low-Density Lipoprotein</td>
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<tr>
<td>LIPA</td>
<td>Light-Intensity Physical Activity</td>
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<td>MET</td>
<td>Metabolic Equivalent of Task</td>
</tr>
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<td>MVPA</td>
<td>Moderate-to-Vigorous Physical Activity</td>
</tr>
<tr>
<td>NCDs</td>
<td>Noncommunicable Diseases</td>
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<tr>
<td>OGTT</td>
<td>Oral Glucose Tolerance Test</td>
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<tr>
<td>OR</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>PAP</td>
<td>Physical Activity on Prescription</td>
</tr>
<tr>
<td>PROM</td>
<td>Patient Reported Outcome Measures</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
</tr>
<tr>
<td>SB</td>
<td>Sedentary Behaviour</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>SGLT2i</td>
<td>Sodium-glucose cotransporter-2 inhibitors</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Introduction

It is well known that healthy movement behaviours (more physical activity and less time spent sedentary) can prevent non-communicable diseases (1-3). For people with metabolic risk factors, prediabetes or type 2 diabetes, healthy movement behaviours can be seen as a cornerstone in both preventing and controlling the disease (4-6). However, many people with chronic conditions are not active enough to achieve these health benefits (7).

Almost ten years ago, while working in the primary health care context, I gained insight into how preventive work regarding support for healthier movement behaviours was carried out within Swedish primary care. I identified gaps between the clinical reality compared to what I learned when becoming a health educator, mostly regarding the lack of follow-up and systematic ways of transferring patients to professions which are experts on how to support healthier movement behaviours. This was a starting point for my curiosity regarding how the support for healthier movement behaviour can be improved within the primary health care.

It is known that supporting people in the self-management of healthy movement behaviours is a major challenge for the health care system (8). However, since most of the adult population visits primary health care at least once a year, it is clearly an important arena in the prevention of non-communicable diseases through support for healthy movement behaviours (9, 10). To be able to improve the supportive work, easy-to-use evidence-based methods are requested. Moreover, to be able to implement methods that improve the support, more knowledge about barriers and facilitators within primary health care are needed.
1 Literature review

1.1 NONCOMMUNICABLE DISEASES
Noncommunicable diseases (NCDs) such as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, are among the leading causes of death worldwide (11). NCDs depend on a combination of genetic, physiological, behavioural, and environmental factors. Behavioural factors associated with NCDs include unhealthy lifestyle habits such as physical inactivity, unhealthy diet, tobacco use and harmful use of alcohol. Such unhealthy lifestyle habits can lead to metabolic risk factors, which in turn contribute to four key metabolic changes: overweight or obesity, raised blood pressure, hyperglycaemia (high blood glucose levels), and hyperlipidaemia (high levels of fat in the blood), and these increase the risk of NCDs (11).

1.1.1 Metabolic syndrome
Metabolic syndrome is defined as having abdominal obesity plus any two of the following metabolic risk factors: raised levels of triglycerides, reduced high-density lipoprotein (HDL) cholesterol levels, raised blood pressure, and raised fasting plasma glucose (FPG) levels (12, 13). Globally, around 20-25% of the adult population have metabolic syndrome (12, 14), and having metabolic syndrome generates a fivefold higher risk of developing type 2 diabetes (15, 16).

1.1.2 Prediabetes and type 2 diabetes
Diabetes is one of the fastest growing public health issues worldwide (17). Prediabetes is a condition with blood glucose levels above the normal range, but below the threshold for type 2 diabetes (18). Prediabetes can be diagnosed by having impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) (17). IGT or IFG can be identified based on plasma glucose criteria with either the FPG value, the two-hour plasma glucose concentrations during an oral glucose tolerance test (OGTT) and/or haemoglobin A1c (HbA1c) concentrations (18). HbA1c is a haemoglobin to which glucose is bound, and a test determines the average level of blood glucose over the past two to three months (17).

Type 2 diabetes develops when insulin-sensitive tissues fail to respond adequately to insulin (called insulin resistance) in combination with impaired or insufficient insulin secretion, resulting in increased levels of glucose in the blood (called hyperglycaemia) (19). To diagnose type 2 diabetes, IGT, IFG and/or Hba1c can be used. Table 1 displays the diagnostic criteria for both prediabetes and type 2 diabetes as developed by the American Diabetes Association (ADA) (20) and the World Health Organization (WHO) (21, 22).

The global prevalence of type 2 diabetes is estimated to escalate from 537 million people in 2021 (corresponding to 6.8% of the total population) to 783 million in 2045. The global prevalence of prediabetes was 541 million in 2021 (which corresponds to 6.9% of the total population) (17). The prevalence of prediabetes differs depending on whether IGT or IFG is used to identify the disease; therefore, it
Table 1. Diagnostic criteria for diabetes and prediabetes.

<table>
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<th></th>
<th>ADA (20)</th>
<th>WHO (21, 22)</th>
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<tbody>
<tr>
<td></td>
<td>HbA1c (mmol/mol)</td>
<td>FPG (mmol/L)</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>≥48</td>
<td>≥7.0</td>
</tr>
<tr>
<td><strong>Prediabetes</strong></td>
<td>7.8-11.0</td>
<td>&lt;7.0</td>
</tr>
<tr>
<td><strong>Prediabetes</strong></td>
<td>39-47</td>
<td>5.6-6.9</td>
</tr>
</tbody>
</table>


is challenging to estimate the prevalence with certainty (18). In Sweden, around 500 000 people have diabetes (6.8% of the adult population) (17). Around 90% of all people with diabetes have type 2 diabetes (17).

1.1.2.1 RISK FACTORS

The risk of developing type 2 diabetes increases with older age, tobacco use, low physical activity, overweight (especially BMI >40), larger waist circumference, and a family history of type 2 diabetes and/or gestational diabetes (17, 23). Having type 2 diabetes is moreover a risk factor for cardiovascular disease (4, 24). Healthier lifestyle habits (eating healthier, increased physical activity, reduced tobacco and alcohol use) can have a positive effect on both the prevention and treatment of metabolic syndrome, prediabetes, and type 2 diabetes (4). Healthy movement behaviours (increased physical activity and decreased sedentary behaviour) will be in focus in this thesis and described further in the following sections.

1.1.2.2 DIABETES TREATMENT AND SELF-MANAGEMENT

Type 2 diabetes is a complex disease, and treatment requires multifactorial behavioural (e.g., nutrition and physical activity) and pharmacological treatments to prevent or delay complications and maintain quality of life. This includes controlling blood sugar levels, body weight, cardiovascular risk factors, comorbidities, and complications (25). Metformin is recommended as a first-line glucose-lowering therapy for the management of type 2 diabetes due to its high efficacy in lowering HbA1c. Insulin or other glucose lowering pharmacological treatment options, like sodium-glucose cotransporter-2 inhibitors (SGLT2i) and glucagon-like peptide-1 receptor agonists (GLP-1) can be offered as monotherapy or in combination with metformin if the glucose level targets are not achieved with metformin alone (25, 26). For people with prediabetes, behavioural treatment with or without metformin decreases the incidence of developing type 2 diabetes (27).

Diabetes self-management addresses the comprehensive combination of educational, clinical, behavioural, and psychosocial aspects required for everyday self-management.
and provides the foundation to help people with diabetes handle their daily self-care and improve health outcomes (28). Self-management is mainly accomplished by patients and families and includes the process of actively engaging in self-care activities with the goal of improving healthy behaviours and well-being. Self-management includes planned physical activity, meal planning, taking diabetes medicines, blood glucose monitoring, and managing episodes of illness and low and high blood glucose (29).

1.2 SUPPORT FOR HEALTHY LIFESTYLE HABITS IN PRIMARY HEALTH CARE

Primary health care is the first level of care that is responsible for prevention at primary (prevent disease or injury before it occurs) and secondary (reduce the impact of a disease or injury that already has occurred) levels, based on the needs of the population. Preventive work should proactively address illness at an early stage, which is highlighted in the Swedish reform for primary health care: ‘Good quality, local health care – A primary care reform’ (30). Moreover, in Sweden, the National Board of Health and Welfare has developed guidelines for the prevention and treatment of unhealthy lifestyle habits (31). These guidelines aim to be used by politicians, unit managers, and healthcare professionals. They emphasise the importance of supporting risk groups in changing unhealthy lifestyles, for example, adults at particular risk due to illness.

Most of the recommended actions, regardless of lifestyle habit, consist of counselling or qualified counselling (more comprehensive than counselling both in terms of time and methodology) (32). Studies within Swedish primary health care supports that counselling is an effective method for reducing cardiovascular risk factors as well as preventing mortality (33-35). Specific for healthy movement behaviours, the guidelines (31) recommend using counselling with an activity tracker and/or physical activity on prescription (PAP) or a web-based intervention (32, 36). PAP consists of three core parts: a person-centred dialogue; individually-tailored physical activity with a written prescription; and follow-up (37). Moreover, specific guidelines for the diabetes care and people at risk of developing type 2 diabetes have been developed, including recommendations about offering structured programmes to support healthy lifestyle habits (26).

Around 70-80% of all adults, both in Sweden (9) and other developed countries (10), visit primary health care at least once a year. Therefore, primary health care, as well as health care professionals, play a key role in the prevention of NCDs through their support for healthy lifestyle habits. An evaluation of the guidelines for the prevention and treatment of unhealthy lifestyle habits concludes that patients want to discuss their lifestyle habits with healthcare professionals and prefer changing their lifestyle habits over drug treatment (38). Also, most health care professionals would prefer to spend more time supporting patients in establishing healthy lifestyle habits. However, the evaluation concluded that major barriers to not focusing on lifestyle habits are a lack of time, a lack of competence and low prioritisation by the organisation at
workplaces (38). Moreover, large differences exist between regions in Sweden regarding support for healthier lifestyle habits for the patients (39), indicating a need for improvements in the implementation of supportive work. Even though some knowledge exists about which factors act as barriers and facilitators in terms of supporting people to healthier lifestyle habits, including healthy movement behaviour, more knowledge is needed from the context of Swedish primary health care.

1.3 MOVEMENT BEHAVIOURS
Movement behaviours include sleep, sedentary behaviour, and physical activity, often captured over 24-hour cycles (40). As sleep behaviour has not been a part of data collection in relation to the aims of this thesis, from now on sedentary behaviour and different intensity categories of physical activity are addressed as movement behaviour. Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure (41).

The intensities of movement behaviours can be expressed in the unit metabolic equivalent of task (MET). One MET corresponds to the resting metabolic rate during quiet sitting (42). Intensities of movement behaviours can be divided into different categories where sleep is below 1 MET, sedentary behaviour (SB) is between 1-1.5 METs (e.g., sitting, standing quietly), light-intensity physical activities (LIPA) are between 1.6-3.0 METs (e.g., slow walking), moderate-intensity physical activities (MPA) are between 3.0-6.0 METs (e.g., brisk walking), and vigorous-intensity physical activities (VPA) require 6 or more METs (e.g., running, performing sports) (2, 42). MPA and VPA can be summarised to moderate-to-vigorous physical activities (MVPA).

1.3.1 Recommendations for movement behaviours
A dose-response relationship exists between physical activity and health (2), see Figure 1. A physical activity dose consists of the following components: frequency (how often the activity is performed), duration (time of the activity) and intensity. The dose-response relationship between physical activity and all-cause mortality, cardiovascular disease, cancer, and type 2 diabetes is curvilinear, where the greatest benefits are at the lower end of the curve, corresponding to those who are inactive and start with some activity (43, 44). This is highlighted by the WHO in the physical activity recommendations, stating that for health benefits, all adults, including people with metabolic risk factors, prediabetes or type 2 diabetes should be physically active on at least moderate intensity for 150-300 minutes per week; alternatively, 75-150 minutes at a vigorous intensity, perform muscle-strengthening activity at least twice a week, and limit sedentary time (44, 45). The recommendations also emphasise the importance of every move counts. Moreover, breaking up prolonged periods of sedentary time with activity breaks can be beneficial (6). Around 7000-8000 steps per day can correspond to the lower end of the recommended range of the physical activity dose-response curve (46).
1.3.2 Measuring movement behaviours

When measuring movement behaviours, both subjective (e.g., questionnaires and diaries) and device-based methods (e.g., pedometers and accelerometers) can be used. Subjective methods can have a lower cost and are easier to administrate in large groups of people. However, device-based methods are to prefer when feasible, due to a higher validity than subjective methods (47). Steps can be measured using either a pedometer or an accelerometer. Accelerometers are wearable devices that, besides the number of steps, measure body movement by accelerations. ActiGraph is the most common brand of accelerometers. It processes the raw acceleration signal, and the activity data are expressed as activity counts (48). Moreover, the data need to be processed further, where choices about cut-points, non-wear-time and other criteria that will affect it need to be considered (48). To facilitate the interpretation of the processed data, it can be categorised and expressed as time spent in MVPA, LIPA and SB.

1.3.3 Relative time of movement behaviours

The movement behaviours MVPA, LIPA and SB can be seen as compositional since they are dependent on each other. For instance, if time in one behaviour increases, time in one (or several) of the other behaviours must decrease. When using movement behaviours to analyse their effect on different health outcomes, it is most common to use the absolute time in each movement behaviour as separate isolated behaviours that do not consider their compositional relation to each other. However, it has been suggested to use the relative instead of absolute time when analysing movement behaviours in order to consider their compositional relation to each other (49, 50). A few studies have evaluated effects of interventions with an outcome based on relative time including all movement behaviours (51-53). But more studies are needed that use relative time in all movement behaviours in different populations.
(e.g., type 2 diabetes) and for different health outcomes, such as the effect of physical activity on blood glucose levels (54).

1.3.4 Movement behaviours in people with metabolic syndrome, prediabetes, and type 2 diabetes

For people with metabolic syndrome, each risk factor (corresponding to central obesity, raised levels of triglycerides, reduced HDL cholesterol levels, raised blood pressure, and raised fasting plasma glucose levels) is positively affected by physical activity (55). For people with prediabetes or type 2 diabetes, regular physical activity significantly impacts cardiometabolic health (6, 45, 56-60) and can be seen as a cornerstone to both preventing and controlling the disease (4-6). For example, regular aerobic exercise improves the glycaemic control and glucose uptake in the skeletal muscle (19, 25). It is thus of importance that physical activity is performed regularly since the improved glucose uptake will be reduced up to 48 hours (19). Also, combined physical activity that includes both aerobic and resistance exercise has the greatest effect on HbA1c compared to aerobic or resistance exercise performed separately (56, 61, 62).

Even though the evidence that supports the beneficial effects of physical activity for people with metabolic syndrome, prediabetes or type 2 diabetes is clear, a large number of people do not reach the recommended levels (63-65). In addition, movement behaviours are complex and influenced by many factors on several levels, from individual to external factors within our society (66). Also, supporting the individual in the self-management of healthy movement behaviours and establishing new routines in daily life is a major challenge for the health care system (8).

1.4 THEORIES AND MODELS FOR MOVEMENT BEHAVIOURS

Theories and models can be used to support the understanding of our behaviours. Within this thesis, theories and models will be used from a movement behaviour perspective to try to understand why people do not move enough and what they need to achieve healthier movement behaviours. The use of theories can work as a framework for an entire study, from planning and designing to organising the research questions, formulating a hypothesis, and collecting data (67). A theory can be an explanation or scientific prediction for what is expected to be found in research, and can be useful to guide or frame the interpretation of results and understand behaviour (67). Models are more specific; they can help us to understand a specific problem in a particular setting and are often based on a number of theories (68).

1.4.1 Theories, models and correlates within this thesis

Movement behaviours can be seen from an ecological approach where they are influenced by multiple factors on several levels, e.g., the individual, interpersonal as well as organisational levels (69, 70).
1.4.1.1 CORRELATES OF HEALTHY MOVEMENT BEHAVIOURS
Factors associated with movement behaviours can be described as correlates (factors associated with participating in healthy movement behaviours) or determinants (factors with a causal relationship to participating in healthy movement behaviours) (71). Correlates of healthy movement behaviours can be organised into six categories: socio-demographic (e.g., age, education, socioeconomic position), biological (e.g., obesity, health status), psychological (e.g., self-efficacy, self-motivation), behavioural (e.g., physical activity history), social (e.g., social support) and environmental (e.g., accessibility to sidewalks) (72). Self-efficacy is a key psychological correlate with strong evidence for an association with participation in physical activity (71, 73). Self-efficacy is defined as “the belief in one’s capabilities to organize and execute the course of action required for producing given attainments” (74). Social support can be associated with higher levels of physical activity (72); however, some reviews have shown limited support for this (71, 73). Self-efficacy and social support are included as predictors of response to an intervention within this thesis.

1.4.1.2 INDIVIDUAL LEVEL
This thesis addresses two models at the individual level. First, the Health Belief Model, which focuses on the person’s belief about health, where health motivation is its central focus. It can be effective to raise awareness and increase motivation and a willingness to change (75). The model is useful for providing both long- and short-term strategies for behaviour change and includes the individual’s perceptions of the threat caused by a health problem (severity, and susceptibility), the advantages of avoiding the threat, and factors influencing the decision to act (self-efficacy, barriers, and cues to action) (69).

The second included model is the Stages of Change Model, which describes behaviour change as a process involving five different stages of readiness to change: precontemplation, contemplation, preparation, action, and maintenance (76). The model is circular, not linear, and individuals can relapse to earlier stages, as well as progress in their change and move on through the stages (69).

1.4.1.3 INTERPERSONAL LEVEL
At the interpersonal level, the third model included in this thesis is Social Cognitive Theory. It explains behaviour as a dynamic ongoing process involving interactions between personal, behavioural, and environmental factors. When a person changes a behaviour, that will affect both the environment and the person since behaviour is not a product of the environment and the person, and the environment is not a product of the person and behaviour (77). According to Social Cognitive Theory, there are three main factors that affect behaviour change: 1) self-efficacy, 2) goals, and 3) outcome expectancies (69).

The described models and theories were used to guide the development of the intervention on which this thesis is based. Figure 2 gives an overview of the theories and models and some of their included constructs and domains, and how they are connected to the ecological approach.
1.4.1.4 IMPLEMENTATION FRAMEWORK

The Consolidated Framework For Implementation Research (CFIR) provides guidance regarding factors of importance to consider for the successful implementation of an intervention at different levels within and around the health care organisation (78). CFIR is based on several implementation theories and frameworks and describes the implementation factors within five domains of importance that influence implementation effectiveness by interacting in deep and complex ways. These domains are intervention characteristics, outer setting (social, political, and economic context surrounding the organisation) and inner setting (the organisation in which the implementation process will occur) characteristics of the individuals involved (e.g., health care professionals) and the process of implementation. The domains resemble the levels described in Figure 2, where they have been included. Within this thesis, the domains were used to guide the development of an interview guide.

1.4.2 Behaviour change frameworks

In recent years, after the intervention study included in this thesis was designed, new frameworks for behaviour change have been developed. The Behaviour Change Wheel is a framework that combines several behaviour change frameworks into one and describes behaviour change at multiple levels: the organisational, practitioner/professional, and individual (79). To use multiple levels can be a benefit when designing behaviour change interventions. It can help in understanding the nature of the behaviour that occurs, determine the broad intervention approach that is appropriate to adapt to, and then work on the specific intervention components (72). The centre of the Behaviour Change Wheel consists of the COM-B model, which is on the individual level and suggests that Behaviour occurs as an interaction between Capability (having the necessary skills and knowledge to engage in the activity concerned), Opportunity (factors outside the individual, which make the behaviour possible), and Motivation (79).

1.4.3 Behaviour change techniques

The active ingredients of interventions aiming to change the target behaviour are called Behaviour Change Techniques (BCTs). The Behaviour Change Technique Taxonomy has been conducted to give an overview of BCTs used in behaviour change interventions (80). The CALO-RE taxonomy is a taxonomy of BCTs (81), based on the original behaviour taxonomy by Abraham and Michie (82), aiming to increase the knowledge about which BCTs are effective in behaviour change interventions.

Self-monitoring is one of the most effective BCTs in supporting individuals to healthier movement behaviours. Self-monitoring tools could be pedometers, mobile phones or wearable devices such as smart watches (2, 83, 84). To use these devices are promising techniques since they provide instant feedback and increase both awareness and adherence to individual goals, as well as to physical activity guidelines (2). Review studies conclude that for people with prediabetes or type 2 diabetes, effective key components for healthy movement behaviours are supportive
programmes, allocation of social support, support for self-efficacy, goal setting, and having a plan to maintain change (85, 86).

1.4.4 Pedometer-based interventions
Several systematic reviews and meta-analyses conclude that pedometers as a self-monitoring tool for obtaining healthier movement behaviours for people with type 2 diabetes or prediabetes have positive short-term effects (87-92). However, the effect that self-monitoring steps has on cardiovascular and metabolic risk factors is inconsistent (87, 89-91, 93). Some studies suggest that movement behaviours will be further improved with counselling support (90), while others conclude the opposite (94). Moreover, it is important not only to support behaviour change during the intervention period but also focus on maintenance support to continue healthy movement behaviours after the intervention period (95). Few studies exist on the long-term effects that self-monitoring of steps has on movement behaviours, and few physical activity interventions have been evaluated in everyday practice (96).
For health care professionals working in primary health care, it can be useful to know which individuals are most likely to benefit from pedometer-based interventions, and which will need other types of support. On a group level, pedometer-based interventions could influence daily steps and work as a motivational tool (89, 92), but little is known about individual responses. Regarding movement behaviour in general, it is known that individual factors, such as age, gender and health status can influence physical activity (71). However, more detailed knowledge is needed about which predictive factors are associated with a response to a pedometer-based intervention in people with prediabetes or type 2 diabetes.
2 Rationale

Methods to support the self-management of healthy movement behaviours are needed in primary health care to prevent the development of metabolic risk factors, prediabetes, and type 2 diabetes, as well as the progression of these diseases. Effective intervention programmes to achieve healthy movement behaviours might benefit from including well recognised BCTs, like the low-cost method self-monitoring of steps, to increase motivation (79, 85). However, evidence on the effect that self-monitoring of steps has on cardiovascular risk factors and metabolic control is inconsistent (87, 89-91, 93). It is also unclear whether self-monitoring alone, or in combination with counselling, is most effective (91, 97). Moreover, few studies exist on the long-term effects that self-monitoring of steps has on movement behaviours, as assessed with both absolute and relative time (49, 50). Also, information about which baseline predictive factors associated with a response to a pedometer-based intervention can be useful for primary health care when deciding treatment for patients with prediabetes or type 2 diabetes.

Furthermore, supporting the individual in self-management of physical activity and establishment of new routines in daily life is a major challenge for the health-care system (8). The WHO, as well as The International Society for Physical Activity and Health (ISPAH), highlight the use of health care as an arena that can support increased physical activity levels (36, 98). Healthcare professionals in Sweden would like to spend more time supporting patients in establishing healthy lifestyle habits, and the patients want to discuss their lifestyle habits (38). However, in order to achieve improvements in the support to increase physical activity for patients with metabolic risk factors, more knowledge is needed about the barriers and facilitators experienced by health care professionals.
3 Research aims

3.1 OVERALL AIM OF THE THESIS
The overall aim of this thesis is to investigate if a pedometer-based intervention in the primary health care setting can support people with prediabetes or type 2 diabetes towards healthier movement behaviours. Moreover, health care professionals’ experiences of supporting people with metabolic risk factors to increase physical activity will also be explored.

3.2 SPECIFIC AIMS OF THE INCLUDED PAPERS

Paper I To evaluate the effects of self-monitoring of steps with or without counselling support on HbA1c, other cardiometabolic risk factors and physical activity during a 24-month intervention in individuals with prediabetes or type 2 diabetes.

Paper II To examine the effects of a two-year pedometer-based intervention in people with prediabetes or type 2 diabetes on relative time in different movement behaviours.

Paper III To explore predictors associated with intermediate and post-intervention increases in steps among people with prediabetes or type 2 diabetes participating in a two-year pedometer intervention.

Paper IV To explore barriers and facilitators perceived by health care professionals within Swedish primary care in their work to support persons with metabolic risk factors to increase their physical activity.
4 Materials and methods

4.1 STUDY DESIGNS
This thesis consists of four papers based on data from two research studies. Paper I, II, and III are based on a randomised controlled trial (RCT) called the Sophia Step Study, while paper IV is based on a qualitative interview study.

The Sophia Step Study was a two-year, three-armed pedometer-based intervention developed for primary health care. The aim of the Sophia Step Study was to support individuals with prediabetes or type 2 diabetes in becoming regularly physically active by reporting their daily number of steps, with or without counselling. In paper I, the findings were reported according to CONSORT guidelines for reporting non-pharmacological treatment interventions (99) and multi-arm parallel group randomised trials (100), as well as the TIDieR checklist (101).

Paper I evaluated the effect of the intervention on primary and secondary outcomes. Paper II and III report secondary analyses of the RCT, evaluating the effect on relative time in movement behaviours and addressing the response to the Sophia Step Study.

The qualitative study, resulting in paper IV, explored nurses’, physicians’, and physiotherapists’ experiences of supporting patients with metabolic risk factors to physical activity. The qualitative design is suitable when studying peoples’ lived experiences (102). The study was reported according to the COREQ 32-item checklist (103). An overview of the included papers can be found in Table 2.

4.2 SETTINGS AND PARTICIPANTS

4.2.1 The Sophia Step Study
The Sophia Step Study was carried out within Swedish primary health care, and the participants were recruited from two urban and one rural primary health care centre by their diabetes specialist nurse. The study was prospectively registered at Clinical trials (NCT02374788). Eight rounds of recruitment were conducted during all seasons of the year, between April 2013 and January 2018. The data collection ended in January 2020. In total, 385 persons were invited to the study, both at regular visits to the primary health care centre or by mailed invitation. Before baseline measurements, a general practitioner examined if the persons were eligible to be included in the study according to the inclusion and exclusion criteria (see Table 3). Participants were randomised to one of the two intervention groups or to the control group by sealed envelopes. The envelopes were prepared by project staff and distributed to the participants by the diabetes specialist nurse, stratified by gender at a ratio of 1:1:1.
Table 2 – Overview of the studies included in the thesis.

<table>
<thead>
<tr>
<th>Paper</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Randomised controlled trial</td>
<td>Longitudinal study</td>
<td>Qualitative interview study</td>
<td></td>
</tr>
<tr>
<td>Participants (n)</td>
<td>188</td>
<td>184</td>
<td>83</td>
<td>24</td>
</tr>
<tr>
<td>Data collection</td>
<td>Blood samples, accelerometry, anthropometry, demographics, questionnaire</td>
<td>Accelerometry, anthropometry, demographics, questionnaire</td>
<td>Accelerometry, anthropometry, demographics, questionnaire</td>
<td>Digital focus group interviews, questionnaire</td>
</tr>
</tbody>
</table>
| Variables | **Primary**: HbA1c  
**Secondary**: Fasting plasma glucose, triglycerides, HDL and LDL cholesterol, ApoB/ApoA1, C-peptide, resting blood pressure, weight, body fat, waist circumference, sagittal abdominal diameter, daily steps, MVPA, LIPA, and SB | MVPA, LIPA, and SB | Response: Dichotomised based on change in daily steps  
Predictors: Gender, age, education, type 2 diabetes/prediabetes, comorbidity, HADS, BMI, EQ-VAS, randomisation group, social support, self-efficacy | Transcribed audio recorded interviews |
| Analysis | Linear mixed models | Linear mixed models | Multiple logistic regression | Qualitative content analysis according to Elo and Kyngäs |

HbA1c=Haemoglobin A1c, MVPA=moderate-to-vigorous intensity physical activity, LIPA=light-intensity physical activity and SB=sedentary behaviour, HADS=Hospital Anxiety and Depression Scale, BMI=Body Mass Index, EQ-VAS=Health-related Quality of Life.

4.2.1.1 INTERVENTION COMPONENTS
The participants were randomised to one of two intervention groups or the control group. Figure 3 shows an overview of the intervention components for the three groups, as well as the time-points of measurements included in this thesis.

In the multi-component intervention group, the participants were recommended to self-monitor their daily steps and received counselling support. To self-monitor daily steps, the participants were offered pedometers (Yamax Digiwalker SW 200: Yamax Corporation, Tokyo, Japan) and registered their daily steps on a webpage (steg.se) during the whole two-year period. On the webpage, a “healthy goal” of a minimum
Table 3 – Inclusion and exclusion criteria of the Sophia Step Study.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 40-80 years</td>
<td>- Myocardial infarction in the past six months</td>
</tr>
<tr>
<td>- Prediabetes (HbA1c &gt;39-&lt;47 mmol/mol and/or fasting glucose &gt;5.6 mmol/l) or diagnosed with type 2 diabetes with a duration of ≥1 year</td>
<td>- Serum creatinine &gt;140 mmol/l</td>
</tr>
<tr>
<td>- Ability to communicate in Swedish</td>
<td>- Diabetic foot ulcer or risk of ulcer (severe peripheral neuropathy)</td>
</tr>
<tr>
<td></td>
<td>- If prescribed insulin, ≥6 months since the first prescription</td>
</tr>
<tr>
<td></td>
<td>- Additional disease prohibiting physical activity</td>
</tr>
<tr>
<td></td>
<td>- Repeated hypoglycaemia or severe hypoglycaemia in the past 12 months</td>
</tr>
<tr>
<td></td>
<td>- Being very physically active according to the Stanford Brief Activity Survey</td>
</tr>
<tr>
<td></td>
<td>(104)</td>
</tr>
</tbody>
</table>

HbA1c=Haemoglobin A1c

of 7000 steps per day was shown as a reference line (46). The participants were asked to decide on individual goals after the first week of wearing the pedometer, and the goals could be revised at any time. Activities that could not be measured by the pedometer (e.g., swimming or biking) were translated into steps by calculating that 30 min of activity, regardless of intensity, corresponds to 3500 steps. The counselling support consisted of nine individual and 12 group consultations. The individual consultations were held face-to-face with their diabetes specialist nurse, inspired by a motivational interviewing technique (105). The group consultations, on the other hand, were led by a diabetes specialist nurse at the rural centre and project staff at the urban centres. The sessions added more intense support and included social support, behavioural capacity, and role modelling. The consultations were guided by the Health Belief Model (75), Stages of Change Model (76), and Social Cognitive Theory (77), and applied several BCTs (106).

In the single-component intervention group, the participants were recommended to self-monitor their daily steps without any counselling support. The control group received standard care, which included seeing a diabetes specialist nurse and a physician once a year, or more often if needed. Further details of the intervention can be found in a previously published study protocol (106).

4.2.2 The qualitative study

The qualitative study was carried out within the context of Swedish primary health care. A convenience sampling strategy was used to identify nurses, physicians, and physiotherapists working clinically in the primary health care setting who meet patients with metabolic risk factors in their daily work. In total, 27 primary care centres or rehab centres in five regions of Sweden were invited. An initial request was emailed to the unit managers, and after their approval another request was emailed to 282 health care professionals.
Figure 3 – Overview of measurement points and the intervention components for the three groups. PROM=Patient reported outcome measures.
4.3 DATA COLLECTION

4.3.1 Measurements in the Sophia Step Study
Participants in all three groups were measured by their diabetes nurse and project staff at baseline and at the two, three, four, six, nine, 12, 18 and 24 month follow up. These measurement points included feedback on health outcomes. Figure 3 shows the measurement points included in this thesis. Table 4 shows the measurements included in each paper of this thesis.

4.3.1.1 BIOMARKERS
For biomarker analysis, blood samples were taken after overnight fasting. The included biomarkers were HbA1c (mmol/mol), fasting plasma glucose (mmol/l), triglycerides (mmol/l), high-density lipoprotein cholesterol (HDL) (mmol/l), low-density lipoprotein cholesterol (LDL) (mmol/l), total cholesterol (mmol/l), free fatty acids (mmol/l), insulin (mU/l), IGF BP1 (μg/l), ApoB/ApoA1 (g/l) and C-peptide (nmol/l), all of which were analysed according to routine methods.

4.3.1.2 ANTHROPOMETRY AND CLINICAL DATA
The included anthropometric and clinical data were as follows: resting systolic blood pressure (mmHg), resting diastolic blood pressure (mmHg) and the anthropometric variables: weight (kg), body fat (%), height (cm), waist circumference (cm) and sagittal abdominal diameter (cm). Details regarding assays and analysis of these measurements can be found in the study protocol (106).

4.3.1.3 MOVEMENT BEHAVIOIRS
To measure movement behaviours and daily steps, the ActiGraph GT1M accelerometer (ActiGraph, Pensacola, FL) was used. The accelerometer was asked to be placed on the lower back all waking hours for seven consecutive days. During those same days, the participants noted in a diary the time they wore the accelerometer, as well as those activities when the accelerometer could not be used (e.g., swimming). The diaries were used to confirm wear time and the number of valid days. The software ActiLife v.6.13.4. was used to analyse the accelerometer data, which was sampled at 10 Hz and then summed over 60 seconds. Non-wear time was set to >90 minutes of consecutive zero counts, allowing for 2 min of nonzero counts (107). Data were included for participants with valid wear time of ≥3 days and ≥10 hours per day. Wear time was distributed into intensity-related movement behaviours based on count-based thresholds: SB <100 counts per min (cpm) (108), LIPA 100-1951 cpm and MVPA ≥1952 cpm (109).

4.3.1.4 QUESTIONNAIRES
Demographic data, data on medications and health conditions were collected at baseline by a questionnaire and from patient medical records. The questionnaires were offered in both paper and web-based format, as the participant preferred.

4.3.1.5 PATIENT REPORTED OUTCOME MEASURES (PROM)
Health-related Quality of Life was measured by one item, the EQ-VAS, from the EQ-5D 3L questionnaire (110). EQ-VAS measures overall health status on a scale ranging from 0 to 100.
Table 4 – Measurements included in paper I-III

<table>
<thead>
<tr>
<th></th>
<th>Paper I</th>
<th>Paper II</th>
<th>Paper III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic data</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Biomarkers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c (mmol/mol)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Plasma glucose (fasting) mmol/l</td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>Triglycerides (mmol/l)</td>
<td>✓</td>
<td></td>
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<tr>
<td>LDL (mmol/l)</td>
<td>✓</td>
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<tr>
<td>HDL (mmol/l)</td>
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<tr>
<td>Total Cholesterol (mmol/l)</td>
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<tr>
<td>Free fatty acids (mmol/l)</td>
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<td></td>
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<tr>
<td>Insulin (mU/l)</td>
<td>✓</td>
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<tr>
<td>IGF BP1 (μg/l)</td>
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<tr>
<td>ApoA1 (g/l)</td>
<td>✓</td>
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<td></td>
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<tr>
<td>ApoB (g/l)</td>
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<tr>
<td>C-peptid (nmol/l)</td>
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<tr>
<td><strong>Anthropometry and clinical data</strong></td>
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<td></td>
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<tr>
<td>% Body fat</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Height (cm)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
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<tr>
<td>Waist circumference (cm)</td>
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<td></td>
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<tr>
<td>Sagittal Abdominal Diameter (cm)</td>
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<td></td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Movement behaviours</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MVPA</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>LIPA</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>SB</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Daily steps</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>PROM</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health related quality of life</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social support for exercise</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-efficacy for exercise</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety and depression</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HbA1c=Haemoglobin A1c, BMI=Body Mass Index, MVPA=moderate-to-vigorous intensity physical activity, LIPA=light-intensity physical activity and SB=sedentary behaviour, PROM=Patient reported outcome measures.

Social support for exercise was measured by the Physical Activity Social Support questionnaire (111). It was based on a 4-point Likert response scale and addressed general support, as well as friends and family support.

Self-efficacy for exercise was measured with The Self-Efficacy for Exercise Scale (112). It was based on a 7-point Likert response scale and addressed one’s confidence to continue exercising when feeling tired, being in a bad mood, not having time, being on vacation and experiencing bad weather.
Anxiety and depression were measured with the Hospital Anxiety and Depression Scale (HADS), which is a useful indicator of the possibility of depression and anxiety (113). It was a 14-item questionnaire with two subscales for depression and anxiety, with seven items for each subscale. It was based on a 4-point Likert response scale. A cut-off value of ≥11 was used to identify the presence of possible anxiety disorder and/or the risk of depression (114).

4.3.2 The qualitative study
Data for the qualitative study were collected in the form of six digital focus groups, conducted from June to November 2021. Two focus groups were conducted with each profession, and the number of participants within the groups ranged from two to six. A semi-structured interview-guide was constructed. The interview guide was inspired by CFIR and the included domains’ outer- and inner setting, and characteristics of the individuals involved (78). Furthermore, the structure of the interview guide was inspired by Krueger and Casey and included introductory questions, transition questions, key questions and ending questions (115). Moreover, the questions were designed to relate to areas highlighted by the National Board of Health and Welfare, for preventive work within health care (116). The interview-guide was pilot tested with a diabetes specialist nurse resulting in some minor adjustments.

Before the focus group interviews, the participants received information about the study and answered a demographic questionnaire. The questionnaire included questions about how they perceive the importance of supporting patients in increasing their physical activity and their own confidence in providing such support.

All interviews were led by a moderator and supported by an assistant. The interviews were conducted at a digital platform and recorded with an external audio recorder. The duration of the interviews ranged between 60-90 minutes. After listening to the recorded interviews several times, they were transcribed verbatim.

4.4 ANALYSIS
The descriptive and inferential statistics used in papers I-IV are presented in Table 5. All analyses were conducted using Excel, SPSS versions 26 and 27 as well as R statistical software.

4.4.1 Paper I
An external statistician, blinded to group allocation, performed the analyses, except for the descriptive statistics. To capture possible deviations for participants with type 2 diabetes compared to the full sample, sensitivity analyses were conducted as a sub-group analysis for participants with type 2 diabetes only, excluding participants with prediabetes. The data was examined for normality, outliers, and missing data. To explore the change in all outcomes from baseline to each follow-up visit, the mean and 95% confidence intervals for the participants’ difference in follow-up value and baseline values were computed.
Table 5 – Overview of analysis methods in papers I-IV

<table>
<thead>
<tr>
<th></th>
<th>Paper I</th>
<th>Paper II</th>
<th>Paper III</th>
<th>Paper IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Descriptive statistics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Counts</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Percentage</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Confidence intervals</td>
<td>✓</td>
<td>✓</td>
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<td></td>
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<tr>
<td><strong>Quantitative</strong></td>
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</tr>
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<td>Linear mixed models</td>
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<tr>
<td>Multiple logistic regression</td>
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<td></td>
</tr>
<tr>
<td>Effect size</td>
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<tr>
<td><strong>Qualitative</strong></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Content analysis</td>
<td></td>
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</tbody>
</table>

SD=Standard deviation.

To evaluate the effect of the Sophia Step Study intervention over time, a between-group analysis with an intention-to-treat approach was performed using linear mixed models. The data deviated from the assumptions of normal distribution; therefore, a robust variant of the linear mixed model was used since it applies weighting to the observations (117). In the model, subjects were included as random effect (random intercept) and age, randomisation group, time as well as a randomisation group and time interaction as fixed factors (118).

A power calculation was performed when the Sophia Step Study was designed in year 2012 to calculate the least number needed in each group. The study was designed to have 80% power with alpha=0.05, based on the ability to detect a difference of 4 mmol/mol (0.6%) in HbA1c between the groups at 12 months. This resulted in a required sample size of at least 56 participants in each group.

4.4.2 Paper II

MVPA, LIPA, and SB are dependent on each other, due to the compositional nature of movement behaviours. If time in one behaviour increases, time in one (or several) of the other behaviours must decrease (49, 50). Therefore, to evaluate the effect of the relative time in MVPA, LIPA and SB, the compositional means of the movement behaviours were calculated by creating geometric means and summarising the behaviours to 100%. A set of two isometric log-ratio (ilr) coordinates, including all relative information about the three compositional parts, was calculated for all three movement behaviours, for each participant.

To evaluate the effect of the Sophia Step Study on the relative time in each movement behaviour, one of the two ilr variables (ilr1) was used as outcome in three separate linear mixed models. The associated 95% confidence intervals were also calculated. In the linear mixed model, subjects were included as random effect (random intercept) and age, randomisation group, time (as a categorical variable) as well as a randomisation group and time interaction as fixed factors. Based on the marginal means from the linear mixed models, point estimates were back transformed into a percentage. To evaluate within-group differences between
baseline and 24 months, contrasts were performed for the relative time in each movement behaviour.

4.4.3 Paper III
To explore predictors associated with intermediate and post intervention increases in steps, dichotomous groups were conducted to capture change based on 500 steps per day (119). These two groups were ≥500 increase in steps or <500 increase or decrease in steps at six and 24 months, respectively.

Bivariate analyses explored which baseline predictors to include in regression models. Independent t-test was used for continuous variables and chi-square for categorical variables. Predictors with a p-value <0.2 were included as covariates in the regression models (120). Multiple logistic regression models explored possible associations with predictors at baseline for intermediate (six months) and post intervention (24 months) increases or decreases in steps.

4.4.4 Paper IV
Descriptive data regarding the participants’ clinical experience and the number of regions represented in each group were performed in Excel. The transcribed data from the focus group interviews were analysed with qualitative content analysis according to Elo and Kyngäs with a manifest, inductive approach (121). To identify barriers or facilitators for supporting patients to being physically active, meaning units were highlighted in the text and categorised with an appropriate code. Higher order patterns were identified based on grouping similar codes. The next step was to describe these headings in text, and lastly, pieces of text were collapsed into sub-categories and generic categories based on similarities.
5 Ethical Considerations

The Sophia Step Study (for paper I-III) was approved by the Stockholm Regional Ethical Review Board (Dnr. 2012/1570-31/3, and 2015 2075-32) and registered at ClinicalTrials.gov (NCT02374788). The qualitative study (paper IV) was approved by the Swedish Ethical Review Authority in Stockholm (Dnr. 2021-00752). All research included in this thesis was performed in accordance with the Declaration of Helsinki (122). Ethical considerations were included during the entire research process; planning, designing, data collection and analysis, as well as reporting of the results. All participants in the two studies, both patients and health care professionals, received information about the studies and gave written informed consent prior to participating. Participation was voluntary, and the participants could resign from the studies at any time. Personal data was handled according to the General Data Protection Regulation, GDPR. The data were treated confidentially and stored anonymously at Sophiahemmet University. Data in paper format were stored in a safe locker, and digital data were stored on a server at Sophiahemmet.

According to ethical considerations, it is of importance to balance the risks versus the benefits of participating in a study. Participating in the Sophia Step Study (paper I-III) have in general low risk; however, some aspects are worth considering. If the participants were using insulin and increased their daily steps, a risk could be low glucose levels with symptoms like sweating, shaking, and feeling anxious. For participants in the multi-component group, this risk was addresses early at a group counselling session. Also, some participants had problems with reduced sight and/or reduced sensation in their feet, which may be a risk at walking. This was also addressed at the group counselling where stable shoes were recommended.

Moreover, the participants could have felt pressed to achieve behaviour change of their movement behaviours, since they were participating in a research study. This could have increased their stress levels. Also, to participate in the qualitative study (paper IV) could evoke emotional effects when taking part in the focus groups, such as a reminder of previous emotional situations.
6 Results

This section summarises the main findings of the papers included in this thesis. More detailed results can be found in each of the papers on which this thesis is based. Figure 4 gives an overview of the number of participants in paper I-III. Table 6 presents an overview of the baseline characteristics of the participants included in the Sophia Step study.

Figure 4 – Flow chart of included participants in paper I-III, all of which are based on the Sophia Step Study. Number of participants (n) are based on the primary outcome in each paper (paper I=HbA1c, paper II=intensities of movement behaviours, paper III=number of daily steps).

6.1 THE EFFECT OF THE SOPHIA STEP STUDY

Paper I evaluated the effect of the Sophia Step Study on biomarkers, anthropometrics, number of daily steps and movement behaviours in absolute time, and paper II evaluated the effect on movement behaviours in relative time.
Table 6 – Overview of the baseline characteristics most relevant for this thesis, based on participants included in the Sophia Step Study.

<table>
<thead>
<tr>
<th></th>
<th>Total (n=188)</th>
<th>Multi-comp. group (n=64)</th>
<th>Single-comp. group (n=59)</th>
<th>Control group (n=65)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>64.1 (7.7)</td>
<td>64.2 (6.9)</td>
<td>65.1 (7.3)</td>
<td>63.1 (8.7)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>76 (40.4)</td>
<td>28 (43.8)</td>
<td>24 (40.7)</td>
<td>24 (36.9)</td>
</tr>
<tr>
<td>Prediabetes, n (%)</td>
<td>40 (21.2)</td>
<td>13 (20.3)</td>
<td>10 (16.9)</td>
<td>17 (26.2)</td>
</tr>
<tr>
<td>University education, n (%)</td>
<td>87 (50.6)</td>
<td>28 (45.9)</td>
<td>25 (47.2)</td>
<td>34 (58.6)</td>
</tr>
<tr>
<td><strong>Biomarkers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c (mmol/mol), mean (SD)</td>
<td>49.9 (11.4)</td>
<td>49.4 (11.2)</td>
<td>50.5 (11.2)</td>
<td>49.9 (12.0)</td>
</tr>
<tr>
<td><strong>Anthropometry and clinical data</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body mass index (kg/m²), mean (SD)</td>
<td>30.0 (4.4)</td>
<td>30.3 (4.1)</td>
<td>29.4 (4.4)</td>
<td>30.2 (4.8)</td>
</tr>
<tr>
<td>Body fat (%), mean (SD)</td>
<td>34.7 (8.1)</td>
<td>36.0 (8.2)</td>
<td>33.7 (7.8)</td>
<td>34.1 (8.1)</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg), mean (SD)</td>
<td>134.3 (15.9)</td>
<td>131.2 (14.4)</td>
<td>138.2 (16.1)</td>
<td>133.9 (16.4)</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg), mean (SD)</td>
<td>83.8 (9.2)</td>
<td>83.1 (7.9)</td>
<td>84.8 (9.4)</td>
<td>83.5 (10.1)</td>
</tr>
<tr>
<td><strong>Waist circumference</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men (cm), mean (SD)</td>
<td>107.2 (10.6)</td>
<td>107.0 (10.8)</td>
<td>107.4 (11.5)</td>
<td>107.1 (9.7)</td>
</tr>
<tr>
<td>Women (cm), mean (SD)</td>
<td>99.3 (12.3)</td>
<td>101.9 (11.9)</td>
<td>95.3 (11.8)</td>
<td>100.1 (12.8)</td>
</tr>
<tr>
<td><strong>Movement behaviours</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accelerometer wear time (min/day), mean (SD)</td>
<td>837.9 (74.1)</td>
<td>838.8 (92.3)</td>
<td>835.7 (59.6)</td>
<td>839.1 (65.0)</td>
</tr>
<tr>
<td>MVPA (min/day), mean (SD)</td>
<td>29.3 (23.7)</td>
<td>28.9 (20.5)</td>
<td>29.6 (25.0)</td>
<td>29.6 (25.9)</td>
</tr>
<tr>
<td>LIPA (min/day), mean (SD)</td>
<td>220.0 (65.4)</td>
<td>213.3 (59.7)</td>
<td>222.5 (72.3)</td>
<td>225.2 (64.9)</td>
</tr>
<tr>
<td>SB (min/day), mean (SD)</td>
<td>588.5 (84.9)</td>
<td>596.6 (89.6)</td>
<td>583.5 (91.1)</td>
<td>584.3 (73.3)</td>
</tr>
<tr>
<td>Step per day, mean (SD)</td>
<td>6570 (3090)</td>
<td>6613 (3305)</td>
<td>6559 (3125)</td>
<td>6540 (2887)</td>
</tr>
<tr>
<td>Met current recommendation of &gt;150 min MVPA/week, n (%)</td>
<td>94 (53.7)</td>
<td>39 (61.9)</td>
<td>29 (52.7)</td>
<td>26 (45.6)</td>
</tr>
<tr>
<td><strong>PROM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS anxiety, mean (SD)</td>
<td>3.5 (3.3)</td>
<td>3.7 (3.1)</td>
<td>3.2 (2.9)</td>
<td>3.7 (3.8)</td>
</tr>
<tr>
<td>HADS depression, mean (SD)</td>
<td>3.4 (2.9)</td>
<td>3.4 (3.0)</td>
<td>3.3 (2.9)</td>
<td>3.5 (2.7)</td>
</tr>
<tr>
<td>EQ-VAS, mean (SD)</td>
<td>72.6 (17.0)</td>
<td>71.6 (18.2)</td>
<td>73.5 (18.2)</td>
<td>73.4 (14.4)</td>
</tr>
<tr>
<td>Social support for exercise, mean (SD)</td>
<td>3.3 (1.4)</td>
<td>3.3 (1.3)</td>
<td>3.5 (1.4)</td>
<td>3.3 (1.4)</td>
</tr>
<tr>
<td>Self-efficacy for exercise, mean (SD)</td>
<td>21.0 (7.2)</td>
<td>20.0 (7.3)</td>
<td>22.0 (7.4)</td>
<td>21.7 (6.8)</td>
</tr>
</tbody>
</table>

HbA1c=Haemoglobin A1c, MVPA=moderate-to-vigorous intensity physical activity, LIPA=light-intensity physical activity and SB=sedentary behaviour, PROM=Patient Reported Outcome Measures, HADS=Hospital Anxiety and Depression Scale, BMI=Body Mass Index, EQ-VAS=Health-related Quality of Life.
In paper I, 188 participants were included with 64 in the multi-component group, 59 in the single-component group and 65 in the control group (see Figure 4). For all participants, the mean (SD) age was 64 (7.7) years, 40% were female and 21% had prediabetes. Moreover, mean (SD) HbA1c was 49.9 (11.4) mmol/mol and mean (SD) BMI was 30.0 (4.4). For the movement behaviours, mean (SD) MVPA was 29.3 (23.7) min/day, and daily steps had a mean (SD) of 6570 (3090) per day (see Table 6).

There was no significant intervention effect for the primary outcome HbA1c or any of the other biomarkers or anthropometric variables, for any of the two intervention groups compared to the control group at any of the timepoints. For the movement behaviours, the intervention had a significant effect for the multi-component group compared to the control group regarding MVPA at all timepoints with an effect size (CI) of 9.4 min/day (1.6 to 17.2) at six months, 8.0 min/day (0.4 to 15.7) at 12 months, 11.1 min/day (3.3 to 19.0) at 18 months and 8.5 min/day (0.8 to 16.2) at 24 months. For the single-component group compared to the control group, the intervention had a significant effect at six months with an effect size (CI) of 9.4 min/day (1.4 to 17.4). No effect was found for LIPA, SB, or the number of daily steps for either the multi or single-component groups. Table 7 describes the mean difference in movement behaviours and number of steps for each group at each measurement point, compared to baseline. Figure 5 describes the difference in the number of daily steps between baseline and six months and baseline and 24 months for each participant, coloured by their intervention group. Figure 6 shows values for the self-efficacy summa score and social support summa score in each intervention group over time.

In paper II, 184 participants were included, with 64 in the multi-component group, 57 in the single-component group and 63 in the control group. For all participants, the mean (SD) age was 64.3 (7.6) years, 41% were female and 22% had prediabetes. The movement behaviours at baseline had mean (SD) MVPA 29.3 (23.7) min/day, LIPA 220 (65.4) min/day, and SB 558.5 (84.9) min/day.

A significant intervention effect was found for the multi-component group compared to the control group at six months for relative time in MVPA with an effect size (CI) of ilr1 with 0.35 (0.07 to 0.63), LIPA -0.16 (-0.32 to -0.01) and SB -0.19 (-0.35 to -0.03). A significant intervention effect was also found at 18 months for relative time in MVPA with an effect size (CI) of ilr1 with 0.44 (0.15 to 0.72), LIPA -0.19 (-0.35 to -0.04) and SB -0.24 (-0.41 to -0.08). Also, a significant intervention effect was found at 24 months for relative time in MVPA with an effect size (CI) of ilr1 with 0.37 (0.09 to 0.65) and LIPA -0.21 (-0.37 to -0.06).

For the single-component group compared to the control group, the intervention had a significant effect at six months for relative time in MVPA with an effect size (CI) of ilr1 with 0.32 (0.04 to 0.61) and SB -0.20 (-0.37 to -0.04). A significant intervention effect was also found at 24 months for relative time in MVPA with an effect size (CI) of ilr1 with 0.37 (0.07 to 0.66) and LIPA -0.21 (-0.37 to -0.06).
Table 7 – Mean differences in movement behaviours and number of daily steps between baseline and six, 12, 18 and 24 months, per intervention group.

<table>
<thead>
<tr>
<th></th>
<th>MVPA</th>
<th>LIPA</th>
<th>SB</th>
<th>Daily steps</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Multi-component group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline to six months (95% CI)</td>
<td>5.5 (0.3 to 10.7)</td>
<td>10.8 (-1.7 to 23.3)</td>
<td>-2.6 (-26.7 to 21.5)</td>
<td>876 (155 to 1597)</td>
</tr>
<tr>
<td>Baseline to 12 months (95% CI)</td>
<td>0.2 (-4.3 to 4.6)</td>
<td>4.3 (-6.2 to 14.8)</td>
<td>-16.2 (-35.1 to 2.8)</td>
<td>89 (-446 to 625)</td>
</tr>
<tr>
<td>Baseline to 18 months (95% CI)</td>
<td>4.1 (-0.7 to 8.8)</td>
<td>20.0 (3.6 to 36.5)</td>
<td>-21.4 (-44.9 to 2.1)</td>
<td>959 (306 to 1610)</td>
</tr>
<tr>
<td>Baseline to 24 months (95% CI)</td>
<td>-1.5 (-6.2 to 3.3)</td>
<td>1.5 (-14.8 to 17.8)</td>
<td>1.0 (-30.2 to 32.2)</td>
<td>-208 (-875 to 459)</td>
</tr>
<tr>
<td><strong>Single-component group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline to six months (95% CI)</td>
<td>5.5 (-1.7 to 12.6)</td>
<td>17.5 (3.8 to 31.1)</td>
<td>4.0 (-4.2 to 12.3)</td>
<td>0.8 (-5.2 to 6.8)</td>
</tr>
<tr>
<td>Baseline to 12 months (95% CI)</td>
<td>2.8 (-2.5 to 8.0)</td>
<td>3.0 (-11.2 to 17.3)</td>
<td>18.7 (0.2 to 37.2)</td>
<td>-15.6 (-30.0 to -1.2)</td>
</tr>
<tr>
<td>Baseline to 18 months (95% CI)</td>
<td>4.0 (-4.2 to 12.3)</td>
<td>-6.4 (-27.2 to 14.4)</td>
<td>-13.4 (-38.9 to 12.2)</td>
<td>12.7 (-7.1 to 32.4)</td>
</tr>
<tr>
<td>Baseline to 24 months (95% CI)</td>
<td>0.8 (-5.2 to 6.8)</td>
<td>272 (-396 to 939)</td>
<td>830 (26 to 1634)</td>
<td>-295 (-950 to 360)</td>
</tr>
<tr>
<td><strong>Control group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline to six months (95% CI)</td>
<td>-6.4 (-11.0 to -1.8)</td>
<td>11.3 (-2.6 to 25.1)</td>
<td>5.1 (-20.2 to 30.5)</td>
<td>-503 (-1116 to 110)</td>
</tr>
<tr>
<td>Baseline to 12 months (95% CI)</td>
<td>-7.1 (-11.3 to -2.8)</td>
<td>-5.5 (-19.4 to 8.3)</td>
<td>37.5 (0.7 to 74.3)</td>
<td>-948 (-1535 to -361)</td>
</tr>
<tr>
<td>Baseline to 18 months (95% CI)</td>
<td>-8.6 (-16.2 to -1.0)</td>
<td>14.4 (0.1 to 28.8)</td>
<td>18.4 (-14.6 to 51.5)</td>
<td>-440 (-1372 to 492)</td>
</tr>
<tr>
<td>Baseline to 24 months (95% CI)</td>
<td>-9.9 (-14.8 to -4.9)</td>
<td>-5.9 (-20.3 to 8.6)</td>
<td>14.1 (-12.8 to 41.1)</td>
<td>-1295 (-1940 to -650)</td>
</tr>
</tbody>
</table>

MVPA=moderate-to-vigorous intensity physical activity, LIPA=light-intensity physical activity and SB=sedentary behaviour.
Figure 5 – Difference in the number of steps between baseline and six months and baseline and 24 months.
The within-group mean difference between baseline and 24 months reached a significant decrease in relative time in MVPA and an increase in relative time in LIPA and SB for the control group. For the multi- and single-component groups, no significant within-group difference over time was found. Figure 7 shows changes in movement behaviours over the two-year period with absolute time (left column) and relative time (right column).

6.2 THE RESPONSE TO THE SOPHIA STEP STUDY

In total, 83 participants were included in the analysis. Figure 8 shows the number of participants in each response-group at six and 24 months. For the total sample at baseline, 16% of the participants had prediabetes, mean (± SD) age was 65.2 ± 6.8 years, 33% were female and 41% had a university education. The bivariate analyses at six months resulted in a p-value <0.2 for diagnosis (type 2 diabetes or prediabetes), comorbidity, steps at baselines and social support, and at 24 months for gender, age, EQ-VAS and self-efficacy. These variables were included in the multiple logistic regression.

The results showed that, at six months, participants with lower number of daily steps at baseline had higher odds for increasing the number of daily steps; every 1000 increase in number of steps the odds of increasing ≥500 steps per day decreased by
Figure 7 – Left column shows changes in movement behaviours over the two-year period with absolute time, and the right column changes in relative time. Values are based on estimated marginal means from the linear mixed models. MVPA=moderate-to-vigorous intensity physical activity, LIPA=light-intensity physical activity and SB=sedentary behaviour.

18% (OR=0.82, 95% CI 0.69-0.98). At 24 months, women had 79% lower odds of increasing ≥500 steps per day (OR=0.21, 95% CI 0.05-0.88) compared to men. Younger participants had higher odds for increasing the number of daily steps; for every year increase in age, the odds of increasing ≥500 steps per day at 24 months decreased by 13% (OR=0.87, 95% CI 0.78-0.97). For every step increase in self-efficacy, the odds of increasing ≥500 steps per day at 24 months increased by 14% (OR=1.14, 95% CI 1.02-1.27).
6.3 EXPERIENCES OF SUPPORTING PATIENTS TO INCREASED PHYSICAL ACTIVITY

In total, 24 health care professionals participated in the qualitative study. Of these, 14 had worked clinically for <5 years, and 10 had worked clinically for >5 years. Figure 9 shows a flow chart with included participants and details of the number of participants in each focus group. Figure 10 shows how the participants rated their perceptions about the importance of supporting people with metabolic risk factors to increase their physical activity, and how they rated their own confidence in supporting these patients.

In the qualitative content analysis, barriers and facilitators, as perceived by health care professional for supporting persons with metabolic risk factors to increase physical activity, were found within four generic categories: ‘Patient readiness for change’, ‘Supporting the process of change’, ‘The professional role’, and ‘The organisation of primary care’. A total of 12 sub-categories were connected to these generic categories. Figure 11 gives an overview of all categories.

6.3.1 Patient readiness for change

This generic category described barriers and facilitators regarding the patient’s attitude to increase physical activity and the patients’ insights regarding their own diagnosis, which affected how the participants promoted increased physical activity in patients with metabolic risk factors.

Patients with a positive attitude, e.g., were self-aware and had knowledge about physical activity, were perceived as facilitators, while patients with a negative attitude, e.g., low self-awareness and self-reported unrealistic activity levels, were perceived as barriers. The patients’ insight into their own disease was seen as a barrier when they
felt guilt and shame for their unhealthy lifestyle, which caused their disease. However, as a facilitator, patients with more developed diseases (e.g., type 2 diabetes) were easier to motivate compared to those at an earlier state, since the positive effects of physical activity were more visible to them.

6.3.2 Supporting the process of change

This generic category included barriers and facilitators connected to the conversation the participants had with their patients when they are trying to improve motivation and achieve behaviour change. Also, the more practical tools they used were included.

The conversation was acting both as a barrier and facilitator. To create a positive climate of change was a key facilitator, as well as individualising the support to patients. However, some patients were described as harder to reach due to a lack of motivation, which was perceived as a barrier. Tools were acting as useful facilitators, e.g., step-counters and physical activity on prescription, but also as barriers, e.g., counselling when an interpreter was needed, or parts of physical activity on prescription, such as a lack of economic compensation, resulting in fewer prescriptions.
Figure 10 – Results from the demographic questionnaire for participants’ perceived importance of supporting patients to increased physical activity (upper figure), and perceived confidence for supporting patients to increased physical activity (lower figure).

6.3.3 The professional role
This generic category described barriers and facilitators connected to the participants own professional role, including their view of knowledge and competence, the professionals' responsibilities as well as collaboration.
The importance of supporting patients towards increased physical activity, as well as seeing a patient reaching their goal, was rewarding and acted as a facilitator. However, patients with metabolic risk factors had often progressed in their disease over a long period of time, making behaviour change more challenging. As a facilitator, all participants (nurses, physicians, and physiotherapists) perceived that their own profession was responsible for supporting the patients’ to increased physical activity. However, they all agreed that patients take the physicians words more seriously, compared to other professions. The participants own knowledge and competence could act as both a barrier and facilitator, while collaboration between professions was mostly seen as a facilitator.

Figure 11 – Overview of generic categories (bold) and sub-categories connected to barriers and facilitators perceived by health care professionals for supporting persons with metabolic risk factors to increased physical activity.
6.3.4 The organisation of primary care
This generic category included barriers and facilitators related to how the organisation of primary care affected the support the participants gave to the patients. It included factors like support from management, time and resources and a connection to economic consequences, as well as collaboration with actors outside the health care.

Support from management could be both a barrier and a facilitator, depending on the managers own interest regarding support for increased physical activity. One major barrier perceived by the participants was a lack of time and resources, which had a big impact on their daily work as well as strong connections to economic consequences. All participants agreed on the importance of preventive work in primary care; however, as a facilitator, they think that primary care centres are doing their best, but the low priority the preventive work has today in primary care was seen as a barrier. Also, for primary care to refer patients and collaborate with actors outside the health care was seen as a barrier, since no such system exists today. However, collaborations with other actors were requested from the participants since it could function as a facilitator for the supportive work.
7 Discussion

The overall aim of this thesis was to investigate if a pedometer-based intervention in the primary health care setting can support people with prediabetes or type 2 diabetes towards healthier movement behaviours. This was explored by evaluating the effect of the Sophia Steps Study and assessing the response to the intervention. Moreover, health care professionals’ experiences of supporting people with metabolic risk factors to increase physical activity was explored by a focus group interview study.

7.1 MAIN FINDINGS

- The pedometer-based intervention Sophia Step Study did not have an effect on the primary outcome HbA1c. However, an effect was found for the multi-component group (receiving a pedometer and extra counselling) on absolute time in MVPA over the entire two-year period, as well as for the single-component group (receiving a pedometer) at six months. No effect was found for the absolute time in the other movement behaviours, the number of daily steps, any of the biomarkers or the anthropometric variables.
- When relative time in movement behaviours was used as outcome, the Sophia Step Study had a more pronounced effect for the multi-component group for all three movement behaviours at six and 18 months and for MVPA and SB at 24 months. For the single-component group, an effect was found in MVPA and SB at six months, and for MVPA and LIPA at 24 months.
- Participants with lower number of daily steps at baseline had higher odds for increasing their daily steps with 500 or more at six months follow up. At 24 months, men, younger participants, and those with higher self-efficacy at baseline had higher odds for increasing their daily steps with 500 or more.
- Barriers and facilitators for supporting people with metabolic risk factors to increase their physical activity, experienced by nurses, physiotherapists and physicians were identified at multiple levels by four generic categories: ‘Patient readiness for change’, ‘Supporting the process of change’, ‘The professional role’, and ‘The organisation of primary care’.

7.2 A Pedometer-Based Intervention

7.2.1 The effect of a pedometer-based intervention

The results from paper I showed that the pedometer-based intervention Sophia Step Study did not have any effect on the primary outcome HbA1c, or any other cardiometabolic risk factors. These results add to the conflicting body of evidence regarding the effect of pedometer-based interventions on cardiometabolic risk factors, including HbA1c. A meta-analysis including nine pedometer-based studies in type 2 diabetes populations observed an increase in physical activity, but no
significant differences were found in HbA1c, blood pressure, BMI, or lipid profile (89). Other reviews support the findings of no effects (87, 123) or small effects (88) on glycaemic control. Studies only including walking, without the use of pedometers as motivational tools, conclude that walking may improve glucose control in people with type 2 diabetes. However, most of the included studies within the reviews had short intervention periods (124, 125).

It is known that resistance training alone, or when combined with aerobic exercise, has a lowering effect on HbA1c (4, 56, 126, 127). Within the Sophia Step Study, participants in the multi-component group had the opportunity to try resistance training at a gym as part of the group sessions, but it was not included as an intervention component. Other physical activity aspects can also be important for glycaemic control in people with type 2 diabetes, such as the total exercise volume (128) and physical activity at intensities higher than MVPA (129-134).

However, although no effects have been shown for cardiometabolic risk factors, pedometers may be effective to achieve healthier movement behaviours. In paper I, an effect was found for absolute time in MVPA in the multi-component group. Paper II, which used relative time as outcomes, showed an overall more pronounced effect for all movement behaviours over the two-year period, thus with some variations. The effect size for absolute time in MVPA was between eight to eleven minutes per day for the multi-component group compared to the control group, over the two-year period. The single-component group reached a statistically significant effect only at six months; however, the pattern was similar for the multi-component group (eight to nine minutes per day over the two-year period). The effect size in paper II is somewhat hard to interpret due to a lack of possibility to back transform the ilr, or percentage variables into minutes. However, Figure 7 indicates that the trendlines for MVPA are comparable to the results from paper I. An effect size between eight to eleven minutes in daily MVPA could be clinically relevant for health benefits. Five minutes more MVPA for people with low activity levels corresponds to a risk reduction for all-cause mortality of about 40% (43). The recommended level of MVPA for health benefits are 150 to 300 minutes per week (44). The effect size of eight to eleven minutes per day corresponds to 56 to 77 minutes per week, which could be helpful for people with low activity levels to reach the recommended level. According to the curvilinear shape of the dose-response curve (see Figure 1), those who are inactive and start with some activity are getting the greatest health benefits (44). A dose-response relationship has also been observed for the incidence of developing type 2 diabetes and time in MVPA. Achieving 150 minutes of MVPA per week reduced the risk of developing type 2 diabetes (135, 136). The risk was also reduced after adjusting for genetic aspects (137). However, the participants in the Sophia Steps Study already had high activity levels at baseline (group mean of 29 minutes MVPA per day) and are not representable for the lower end of the dose-response curve.

The largest mean change in MVPA from baseline was at six months for both the multi-component group and the single-component group with increases of 5.5 minutes. For 12, 18 and 24 months, the change compared to baseline ranged from a
decrease of 1.5 minutes to an increase of up to 4.0 minutes for both the multi- and single-component groups. The results are similar to another pedometer-based intervention study, which saw a change of 3.5 minutes MVPA at 12 months, but the effect was not maintained for 48 months (138). Other studies did not see any effect on MVPA at six, 12, 24 or 36 months (139, 140).

The results from paper I showed that daily steps have a similar pattern as MVPA, even though it was not a significant effect. The mean change in the number of daily steps from baseline to six months for the multi-component group was 876 steps, while for the single-component group the number was 1009 steps. Other comparable pedometer-based intervention studies at six months found somewhat higher increases for intervention groups compared to control groups, ranging from 1281 to 2744 steps (139, 141, 142). At 12 months, the change from baseline was lower for both the multi-component group with 89 steps and the single-component group with 272 steps. Other comparable studies at 12 months ranged from 59 to 1872 steps (138-141, 143-145). Only a few studies have conducted follow-up periods longer than 12 months, while none of them found any effect at 24, 36 or 48 months (138, 140). A systematic review also concludes that interventions only are effective during the intervention period (92). More recently published physical activity self-monitoring interventions within the type 2 diabetes population have often used more modern techniques to monitor steps like apps in phones or digital devices. These often include additional functions like instant feedback, graphs presenting their HbA1c levels over time, and connections to diabetes-specific digital platforms (146-148). Therefore, they are not totally comparable with the Sophia Step Study.

A clinically meaningful reduction in cardiovascular morbidity and mortality in inactive individuals can be achieved by an increase of 500 steps per day or an increase of five to six minutes of walking per day (119). It has been suggested that around 7,000 to 8,000 steps per day correspond to the physical activity recommendation for MVPA (46). A dose-response association exist between daily number of steps and mortality were increasing 2000 steps can reduce the mortality risk of about 50-60% (149, 150). Moreover, taking up to 10,000 steps per day may be associated with decreased risks of mortality, cardiovascular disease, and cancer (151). However, the results are conflicting regarding whether the intensity of the steps impacted the risk of all-cause mortality (149, 151).

Within paper I, the control group reduced MVPA by around 10 minutes per day and the number of daily steps by around 1000 steps per day (see Figure 7 and Table 7) during the two-year period. These are the main reasons for finding an effect in the intervention groups compared to the control group, since the intervention groups generally maintained their movement behaviours when comparing baseline values with 24 months. Moreover, it is common that people reduce their activity levels as getting older (152, 153). Counteracting this reduction of unhealthy movement behaviours could be seen as a benefit of the Sophia Step Study.
7.2.2 Components of a pedometer-based intervention

To use pedometers as self-monitoring tools seems to be the intervention component of greatest importance in the Sophia Step Study due to the similar trendlines in the multi- and single-component groups (both of which received pedometers) for HbA1c, daily steps and movement behaviours. This is supported by the literature showing that, in interventions aiming to increase healthy movement behaviours, self-monitoring is one of the most common BCTs, which has an effect on healthy movement behaviours (94, 154-157). Evidence also supports long term-effects for self-monitoring from 12 months up to four years in a general adult population (158).

The participants in the Sophia Step Study also registered their self-monitored steps on a webpage where they could set individual step goals, which was visualised by a line in their individual step line plot. A process evaluation of the Sophia Step Study for the first 12 months of the intervention found that 73% of the participants in the multi-component group, and 65% in the single-component group, had an individual step goal (159). Goal setting is a common BCT in web-based physical activity interventions (160), and it seems to be an important predictor for increasing physical activity in pedometer-based interventions (87, 156). However, goal setting did not have an influence in reducing BMI and weight in people with type 2 diabetes (93).

Both intervention groups received the pedometer component; the difference was the counselling component (both individual and group sessions). Since the trendline for movement behaviours and daily steps were similar for both intervention groups, the counselling component might not be of major importance. Like our results, the PACE-UP trial, with a population of less-active 45 to 75-year-olds, did not find any difference between two intervention groups at 12 months regarding the number of daily steps. One intervention group received a pedometer and nursing counselling, whereas the other intervention group only received the pedometer (144). Meta-analyses have shown conflicting results regarding the effect of complementing self-monitoring with counselling (91, 97, 155). In the Sophia Step Study, participants in both the single-component group and the control group met their diabetes nurse and/or project staff shortly during the study assessments. This may be considered as brief counselling, which can influence the participants motivation for achieving a healthier lifestyle. A previously published qualitative interview study that explored the participants’ experiences of participating in the Sophia Step Study found that participants in all three groups appreciated the study assessments since they gave feedback on health outcomes, were encouraging, gave a sense of taken care of and were adequately inspirational (161). This may have influenced motivation for self-management among participants in both the single-component group and the control group, even though the assessments were short in time (10 to 15 minutes) and did not include consultations.

7.2.3 Predictors for response to a pedometer-based intervention

As discussed above, the effect on group levels was only significant for absolute time in MVPA and relative time in movement behaviours. Therefore, additional analysis was performed with participants from the two intervention groups, aiming to evaluate if any baseline predictors could be associated with a response to the
intervention at six months and two years. The results showed that number of steps at baseline, gender, age, and self-efficacy were of importance. Younger participants had higher odds for increasing 500 steps or more after two years, compared to older participants. Similar results were found in a review study concluding that age was a negative predictor for participating in physical activity (73), which is supported by studies finding that physical activity levels reduce as we are getting older (152, 153).

Participants with higher self-efficacy at baseline had higher odds for increasing steps by 500 or more during the two-year period. However, at six months, self-efficacy was not a significant predictor for being a responder. This may be related to higher motivation to change a behaviour in the beginning of an intervention, and self-efficacy is strongly related to motivation and capability, both to initiate and maintain healthy choices, and a strong factor for participation in physical activity (73, 162). Within the Sophia Step Study, the counselling component (both individual and group) had the intention to improve self-efficacy (for participants in the multi-component group). As seen in Figure 6, the counselling does not seem to have an impact on self-efficacy over time; however, an increase was observed for up to three months, and then the level was stable for up to 12 months, and then it decreased. Nevertheless, the trendline was similar for self-efficacy in the single-component and multi-component groups; therefore, the initial increase in the multi-component group may not be due to the counselling. Based on a qualitative interview study exploring the participants’ experiences of participating in the Sophia Step Study (161), an additional analysis compared the results with the intended BCTs, where self-efficacy was an intended BCT (163). However, the additional analysis concluded that participants within all three groups did not explicitly express self-efficacy as a BCT they perceived as included. A brief walking intervention for eight weeks, with adults with type 2 diabetes, showed short-term increases in MVPA and self-efficacy during the intervention period. The effects were partly maintained at six-months follow up (164). In the MOVEdiabetes trial, which included both counselling and pedometers, self-efficacy increased after the intervention period of 12 months (165). However, it is not possible to conclude whether the increase was due to the counselling or pedometer component, or both, since they did not distinguish them. Also, self-efficacy seems to be an important mediator for increasing physical activity levels in people with type 2 diabetes (166, 167).

7.3 SUPPORTING HEALTHY MOVEMENT BEHAVIOURS IN PRIMARY HEALTH CARE

As previously discussed, self-monitoring of steps in the Sophia Step study appears to be a BCT that improves participants’ healthier movement behaviour. In order to implement this method, as well as other BCTs to support healthier movement behaviours on a larger scale within primary health care in Sweden, knowledge about barriers and facilitator from health care professionals can be of importance. Such knowledge can be useful based on a population with prediabetes and type 2 diabetes (as in the Sophia Step Study), but also for people with metabolic risk factors. The results from paper IV showed that barriers and facilitators for supporting people
with metabolic risk factors existed at several levels. This included personal factors such as patients’ attitudes towards physical activity and health care professionals’ own perceptions of the supportive work, as well as their knowledge and collaboration with other professions and actors outside health care. Another level includes organisational factors such as support from management, lack of time, and economic constraints. These results can be connected to the theoretical framework for this thesis (see Figure 2), where the implementation framework CFIR is included (78).

One domain within CFIR is characteristics of the individuals involved, which in paper IV are the health care professionals. This domain includes individual knowledge and beliefs toward changing behaviour, as well as the level of self-efficacy (168). In paper IV, one of the generic categories was ‘The professional role’, where one sub-category was ‘The own knowledge and competence’, which described that some health care professionals’ broad knowledge of how to support the patients, which acted as a facilitator. On the other hand, lack of specific knowledge about support for increased physical activity led to lack of self-efficacy in providing support when discussing with patients. Results from other studies are contrary. One study concluded that professionals in general report that they have knowledge for support (169), while a systematic review concluded that professionals had some knowledge but needed more training (170). Another sub-category within the same generic category was ‘The health care professional’s own view’, which described self-efficacy as a facilitator when being able to support the patients to increase physical activity in a way that was manageable and successful for the patients. Within this thesis, additional quantitative analysis was included based on a questionnaire the health care professionals answered before the focus group interviews. One question aimed to assess their self-efficacy for supporting to increased physical activity. The question was phrased as follows: “How confident are you in your own ability to motivate people with metabolic syndrome (metabolic risk factors) to increase their physical activity level?” Of the nurses, 60% had very high or high confidence, and for physiotherapists the number was 78%, while 90% of the physicians rated their confidence as neither high nor low. The physicians as a group stand out, and these findings were supported by discussions where physicians mentioned that they did not dare to raise the question about physical activity with their patients, due to an insecurity connected to their own knowledge and low self-efficacy. However, all three professions perceived that their own profession was responsible for supporting the patients’ increased physical activity.

Another question in the questionnaire asked, “How important is it for you to support people with metabolic syndrome (metabolic risk factors) to increase their physical activity level?” The majority within all professions thought it was very important or important (80% of the nurses, 90% of the physicians, and 89% of the physiotherapists). This was also found to be an important area within the subcategory ‘The health care professional’s own view’. Another study found associations between the enthusiasm for physical activity promotion by health care professionals’, perceived self-efficacy for promotion, and belief in the benefits of physical activity (171).
The CFIR domain inner setting takes place at the organisational level (see Figure 2) and includes structural, political, and cultural contexts (172). However, sometimes the line between the inner and outer setting is dynamic and not always clear (78). The results from paper IV have one generic category named ‘The organisation of primary care’. Several barriers for supporting people with metabolic risk factors to increase physical activity was found in this category. Lack of time and lack of resources was frequently described as barriers that also affected how the question was prioritised within the organisation. Similar obstacles have been found in other studies (170, 173-176) and within a national report on preventive work in Sweden (31, 38, 177), highlighting that more time and resources are needed if the support to increased physical activity within the primary health care is to be improved.

7.4 METHODOLOGICAL CONSIDERATIONS

7.4.1 Internal validity
Internal validity concerns methodological errors within the study and to what extent the observed results represent the truth in the population being studied (178). Within Sophia Steps Study (papers I-III), some methodological considerations need to be addressed since they can lead to an over or underestimation of the true results.

The accelerometer used to measure movement behaviours was an ActiGraph GT1M. A study validating GT1M with energy expenditure, measured by indirect calorimetry as the criterion method, found that the GT1M highly correlated with energy expenditure during walking (179). GT1M measures ambulatory movements based on vertical accelerations. The accelerometer generates a raw acceleration signal that is being processed, and the activity data are expressed as activity counts (48). Moreover, the data were processed further, where choices about cut-points, non-wear-time and other criteria were completed. The choice of cut-points can affect the data, and one study comparing different cut-points concludes that the choice affects the prevalence of meeting the guidelines for physical activity with variations ranging from 8 to 96% (180). Therefore, it of importance to try to use the most accurate cut-point possible for the current population (48). Within the Sophia Step Study, established cut-points for the current population, according to Freedson and Matthews, were used (108, 109). However, another limitation with the accelerometer is that it cannot capture activities such as swimming, cycling and strength training. Therefore, the participants’ activity levels could have been underestimated.

The variables from the questionnaire included in this thesis have good validity for anxiety and depression, as assessed by HADS (181); quality of life, as assessed by EQ-VAS; social support for exercise (182); and self-efficacy for exercise (112).

The biomarkers included in this thesis were all analysed according to routine methods that have high validity. However, the participants in all three groups had HbA1c levels around 50 mmol/mol at baseline, which can be considered as well controlled by medications, and one factor which might influence the lack of effect on the primary outcome. Moreover, changes in medication were registered as brief notes.
by the nurses at each measurement point. These notes were summarised for each intervention group. When comparing the changes in medication between groups, no difference was observed. However, since there was no systematically collected data for this, these conclusions should be made with caution. Moreover, the diabetes care is continuously being improved. Changes in the National Diabetes Registry data between 2015 to 2020 show that mean HbA1c in the general type 2 diabetes population in Sweden decreased from 54.1 mmol/mol to 52.8 mmol/mol (183).

Also, the Sophia Step Study included participants with both prediabetes and type 2 diabetes. The incentive for this was to mirror the population, which usually visits primary health care, since both groups could benefit from an intervention that aims to obtain healthier movement behaviours. However, to distinguish whether the inclusion of both people with prediabetes and type 2 diabetes could wash out an effect on the included biomarkers, a sensitivity analysis was conducted with only type 2 diabetes participants, and this analysis had the same results as the main analysis.

It was not possible to blind participants in the Sophia Step Study since they were being measured several times over a two-year period. According to the Hawthorne effect (184), being measured can affect the participants’ actions in obtaining healthier movement behaviours during measurement days compared to normal days. However, the RCT design of the Sophia Step Study should eliminate this effect between the groups. Moreover, the participants in the control group could have perceived that they received a brief intervention due to the regular measurement points. These can be seen as extra health check-ups, which may increase motivation to achieve healthier behaviours.

To reduce bias according to typing error, 10% of the data was double checked. Where there seem to be systematic typing errors within the dataset, the full data for that variable were checked.

### 7.4.2 External validity

Factors affecting the internal validity also affect how the findings of this thesis can be generalised to a broader population, expressed as the external validity (178).

Within the Sophia Step Study, recruitment bias cannot be excluded. The participants can be considered as having a high socioeconomic position. Since most of the participants were recruited from urban centres, every second participant had a university education, and some people were excluded due to their inability to communicate in Swedish or lack of access to the internet. Therefore, the results from the current study may not be the same in a sample comprised of participants with a lower socioeconomic position.

Moreover, the participants were already active at baseline (daily mean MVPA was 29 minutes). One exclusion criterion was “Being very physically active according to the Stanford Brief Activity Survey”. The scale has reasonably validity in easily assessing physical activity levels in large scale populations (104). However, in our sample it may not have been suitable to exclude those who were already active. Having this active sample in our study reflects that we might not have recruited a sample that is representative of the general population with prediabetes or type 2 diabetes.
Moreover, behavioural interventions often reach people who already have healthy lifestyles and high disease engagement, while the people who might need the intervention are the most difficult to reach.

7.4.3 Trustworthiness

Trustworthiness addresses the quality of the qualitative content analysis within all phases (preparation, organisation, and reporting) of the process (185). Trustworthiness includes credibility (whether the data and processing of data address the intended focus), dependability (the stability of data over time and conditions), conformability (objectivity), and transferability (how the findings can be generalised and transferred to different settings) (186).

In paper IV, the transferability can be affected since the participants included might not be considered a representative sample of the general health care professionals who work in primary health care. Due to the Covid-19 pandemic, which took place during the same period as the recruitment and data collection for paper IV, the recruitment was very challenging. Many possible participants who were contacted and wanted to participate did not have the opportunity due to the then high workload at health care centres. Moreover, health care professionals who accept participation in an interview study regarding support for physical activity are probably those who are more engaged from the beginning. The intention was to try to recruit participants working in areas with different socioeconomic positions, and a more equal gender distribution was also wanted. Thus, the homogeneity of the included participants could have affected the transferability of the results (185). Also, one of the focus groups only included two participants, which could have affected the richness and depth of the data.

Due to the Covid-19 pandemic, the interviews were conducted digitally, which made it possible to include participants from several different regions in Sweden. All participants had experience of clinical work within primary health care, which involved supporting patients with metabolic risk factors to increase their physical activity. This is important for the study’s credibility. Credibility was also ensured by two of the authors independently completing the selection of meaning units and matching them. To ensure the dependability of the results, a close collaboration, including discussions of codes and categories, took place between the authors.
8 Conclusions

For people with prediabetes or type 2 diabetes, the Sophia Step Study intervention concludes that self-monitoring of steps with a pedometer seems to be an effective behaviour change technique for maintaining healthy movement behaviours. The counselling component of the intervention did not seem to improve the effect. Moreover, the intervention did not find evidence for improved metabolic control or improved cardiometabolic risk factors. Using relative time, instead of absolute time, when evaluating the effect of the Sophia Step Study showed a more pronounced effect in all movement behaviours within both intervention groups over the two-year period. The control group had a negative trend in change over time, indicating that Sophia Step Study can prevent decreases in unhealthy movement behaviours.

The intervention components in the Sophia Step Study may be most effective for men, younger participants, those with lower number of steps and higher self-efficacy at baseline, since these factors were associated with higher odds of increasing daily steps by 500 or more during the two-year period. However, from a dose-response perspective, it is well known that inactive individuals have large health benefits when starting with some physical activity. The participants within this thesis were already active at baseline; therefore, we cannot rule out possible health effects of the Sophia Step study for people with prediabetes or type 2 diabetes who were less active than those in our sample.

Primary health care professions such as nurses, physicians and physiotherapists are important in the promotion of physical activity for people with metabolic risk factors. To enhance their supportive work, barriers and facilitators at several levels, from individual patients and health care professionals to the organisational level, need to be addressed. This includes prioritisation, responsibility, and the complexity of behaviour change regarding physical activity, but also factors such as time and resources. These multi-level factors should be addressed when implementing support to increase physical activity in people with metabolic risk factors.
9 Future research

The research field about support for healthier movement behaviours in primary health care has improved since the Sophia Step Study was designed in 2012. At that time point, digital tools, like smart watches and mobile phone applications, were unusual. The development of digital tools to support healthier lifestyles, including movement behaviours, is an expanding research field. Digital tools may be advantageous regarding the aspects of using time and resources more efficiently, compared to traditional counselling within primary health care. Moreover, this thesis highlights a lack of time and resources as major barriers to being able to support patients’ physical activity. Hence, finding the optimal digital support for people with metabolic risk factors, prediabetes or type 2 diabetes should be addressed in future research.

An additional aspect of improving the support for healthier movement behaviours, regardless of whether it is delivered through physical meetings with a health care professional, a digital tool, or a combination of both, is that the implementation process needs to be evaluated. More knowledge is needed regarding methods for effective implementation at multiple levels, from the individual to the organisational, within primary health care.

At last, it is well known that people with low activity levels are those who receive the greatest health benefits by starting with some activity. These people are often hard to reach and can be challenging to include in research studies. However, their participation is needed to be able to gain more knowledge about how to adapt support for this group.
10 Clinical implications

Health care professionals within primary health care get in contact with the majority of the adult population in Sweden every year, making them key actors in terms of support for healthier movement behaviours (9). Self-monitoring of steps seems to be effective in obtaining healthier movement behaviours and can be an easy-to-use method for health care professionals who encounter people with metabolic risk factors, prediabetes, or type 2 diabetes in their clinical practice. To facilitate their job, and best utilise their support, barriers at several levels need to be addressed. At the individual level, the health care professional’s knowledge and competence must be ensured to make them comfortable and feel secure about raising these, sometimes, hard questions with their patients. At an organisational level within each primary health care centre, engaging managers are needed, as well as clear routines and guidelines for how collaboration between professions should be performed. Also, a system for collaborating with actors in society, outside health care, is needed. However, the major barrier highlighted within this thesis concerning support for healthier movement behaviours was a lack of time and resources. To be able to address these barriers, preventive work in terms of supporting healthier lifestyle habits must be prioritised from a higher political level.

As part of referring patients from the health care to, in the long term, independently maintained healthy movement behaviours, a link could be needed to bridge the gap between the health care and wellness sectors. This link could preferably be a health educator, which is an underutilised profession today in connection to the primary health care. Health educators are specialised in how to achieve and maintain healthier lifestyle habits and could have more of an overall helicopter perspective.

Supporting healthier movement behaviour is a challenge for health care. Moreover, movement behaviours are complex and affected by many factors on several levels, from individual to external factors within our society (66). To capture this multilevel complexity, I will end this thesis with a quote from the Ottawa charter, stated as early as year 1986, but still relevant, where the WHO defined the term health promotion as follows: “Health promotion is not just the responsibility of the health sector, but goes beyond healthy life-styles to well-being” (187).
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