### Physical activity on prescription in primary care

Impact on physical activity level, metabolic health and health-related quality of life, and its cost-effectiveness - a short- and long-term perspective

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## Abstract

Non-communicable diseases (NCDs) are the leading cause of death globally and one of the major health challenges of the 21<sup>st</sup> century. In Sweden, NCDs are estimated to account for 90% of all deaths. Strong evidence indicates a relationship between regular physical activity (PA) and positive health effects, and that PA can be used to prevent and treat diseases. In Sweden, licensed healthcare professionals offer PA on prescription (PAP) as a method of supporting patients to increase their PA level. PAP treatment includes three core components: an individualized dialogue; an individually dosed PA recommendation, including a written prescription; and a structured follow-up. PAP treatment is underutilized in Swedish health care, and further studies are needed to elucidate effective PAP treatment strategies. The Gothenburg PAP study on which this thesis is based started in 2010 at 15 health care centers (HCCs) that offered PAP to 444 patients (aged 27–85 years) who were physically inactive with metabolic risk factors, between 2010 and 2014 and followed them for 5 years. The overall aim of this thesis was to evaluate the Swedish PAP treatment regarding PA level, metabolic health, and health-related quality of life (HRQOL) for patients who were physically inactive with metabolic risk factors, and to explore factors that may predict an increased PA level. Furthermore, this thesis aimed to evaluate two different PAP treatment strategies, supported by either the HCC or a physiotherapist (PT), for patients who still had not reached a sufficient PA level after a prior 6-month period of PAP treatment. The cost-effectiveness of the two PAP strategies was also evaluated in a health economics study.

A prospective observational study evaluated 6 months of PAP treatment in daily clinical care at 15 HCCs in Gothenburg. During this 6-month period, 80% of the patients received PAP support from caregivers once or twice, 73% increased their PA level and 42% moved from an inadequate PA level to sufficient according to public health recommendations. Significant improvements were seen in a majority of the metabolic risk factors and HRQOL components measured, and associations were found between changes in the PA level and health outcomes (Paper I). We also identified potential predictive factors for increased PA after a 6-month PAP intervention: positively valued self-efficacy, preparedness, and physical health, and BMI <30 kg/m<sup>2</sup>. Among patients with the lowest PA levels at baseline, 84% had increased their PA level at the 6-month follow-up. In the patient group with 1 to 3 positively valued predictive factors included, 87–95% had increased their PA level. (Paper II).

In a randomized controlled trial, 190 patients who still had not achieved sufficient PA levels after 6 months of PAP treatment, described in Papers I and II, were randomized to continued, 2-year PAP intervention supported either by a PT or the HCC. Both long-term PAP interventions increased the PA level, metabolic health, and HRQOL with no difference between groups. Results appeared to be independent of any changes in pharmacological treatment. The study suggested that the continuous support and the duration of the intervention may be most important factors for increasing PA (Paper III).

Finally, in a health economic evaluation of 3 years of PAP treatment, a costeffectiveness analysis compared the two PAP treatment strategies described in Paper III. From the societal perspective, the cost per gained quality adjusted life years (QALY) for the PT group compared to the HCC group was 147 250 SEK. The willingness to pay for a QALY needed to be >150 000 SEK for the PT strategy to be a cost-effective choice compared to the HCC strategy indicating a moderate level of costs per QALY. Due to similar results in both groups, it was not possible to draw certain conclusions about the most cost-effective strategy; none of strategies could certainly be chosen before the other (Paper IV).

In summary, this thesis shows that, in ordinary primary health care, both short- and long-term PAP treatment can be a feasible intervention to increase PA, metabolic health, and HRQOL in adult patients who are physically inactive and have at least one metabolic risk factor. These results seem to be most pronounced among patients with the lowest PA levels. Furthermore, improvement occurs in regards to metabolic risk factors, benefitting several aspects of life for the patients and reducing the cost and strain for the public health service. The identification of predictive factors for increased PA levels (positively valued self-efficacy, preparedness, and physical health, and BMI <30 kg/m<sup>2</sup>) and the benefit of long-term PAP is essential. These findings offer clinicians an opportunity to better support patients' behavioral changes and the individualization of PAP treatment. In optimizing the support for patients, we need educated, skilled healthcare professionals with knowledge about PAP, structured routines, and organizational support. The findings in this thesis may also create the opportunity for more widespread use of PAP as an important method of gaining health benefits for physically inactive patients.

**KEYWORDS** Primary health care, Physical activity, Physical activity on prescription, Metabolic syndrome, Health related quality of life, Quality of life, Health behavior, Life style, Correlates of physical activity, Predictive factor, Health economics, Cost-effectiveness, Cost-Benefit Analysis.

## Sammanfattning på svenska

Evidensen och sambandet mellan regelbunden fysisk aktivitet och positiva hälsoeffekter har under senaste decennierna klarlagts. Fysisk aktivitet kan användas både för att förebygga och behandla en rad sjukdomar. Samtidigt så är ett stort antal människor otillräckligt fysiskt aktiva och den levnadsvanerelaterade ohälsan ökar. Behovet av att finna effektiva strategier för att öka fysisk aktivitet har uppmärksammats av en rad samhällsorgan där hälso- och sjukvården är en viktig del. I Sverige så erbjuds patienter fysisk aktivitet på recept (FaR) som behandlingsmetod av legitimerad vårdpersonal som stöd för att öka sin fysiska aktivitetsnivå. FaR-behandling består av tre huvuddelar: en individbaserad dialog med patienten, en individuellt avpassad fysisk aktivitet med en skriftlig ordination samt en strukturerad uppföljning. FaR-behandling är idag otillräckligt implementerat inom Svensk hälso- och sjukvård och mer forskning behövs för att utvärdera effektiva FaR-behandlingsstrategier. FaR-studien i Göteborg, som denna avhandling baseras på, påbörjades 2010 på 15 vårdcentraler där 444 patienter i åldrarna 27–85 år, med metabola riskfaktorer och fysiskt inaktiva erbjöds FaR-behandling. Patienterna inkluderades under tidsperioden 2010–2014 och erbjöds uppföljning under sammanlagt 5 år.

Syftet med denna avhandling var att både ur kort- och långtidsperspektiv utvärdera Svensk FaR-behandling gällande fysisk aktivitetsnivå, metabol hälsa och hälsorelaterad livskvalitet hos fysiskt inaktiva patienter med metabola riskfaktorer, samt att utforska möjliga prediktiva faktorer för ökad fysisk aktivitetsnivå. Syftet har också varit att utvärdera två olika FaRbehandlingsstrategier, antingen via vårdcentral eller via fysioterapeut, för patienter som efter 6 månaders FaR-behandling fortfarande varit otillräckligt fysiskt aktiva, samt beräkna kostnadseffektiviteten ur ett hälsoekonomiskt perspektiv.

I en prospektiv observationsstudie utvärderades 444 patienter som erhållit FaR-behandling i daglig klinisk verksamhet under en 6-månadersperiod på 15 vårdcentraler i Göteborg. Under dessa 6 månader träffade 80 % av patienterna sin FaR-behandlare 1-2 gånger. Av 368 patienter som följdes upp vid 6 månader hade 73 % ökat sin fysiska aktivitetsnivå och 42 % hade nått en tillräcklig fysisk aktivitetsnivå (≥150 min/v) enligt folkhälsorekommendationen. Statistiskt signifikanta förbättringar uppmättes för flertalet metabola riskfaktorer och livskvalitetsparametrar och ett klart positivt samband mellan fysisk aktivitetsnivå och hälsoutfall kunde ses (Paper I). Fyra prediktiva faktorer för en ökad fysisk aktivitetsnivå vid 6 månader kunde också identifieras; en positivt skattad tilltro och förändringsberedskap, en positivt skattad fysisk hälsa samt ett BMI <30 kg/m<sup>2</sup>. De minst fysiskt aktiva patienterna ökade sin fysiska aktivitetsnivå mest (84% av dessa patienter) och med 1–3 positivt skattade prediktiva faktorer, så var andelen patienter med ökad fysisk aktivitetsnivå än större (87–95 %) vid 6-månadersuppföljningen (Paper II).

I nästa steg inkluderades 190 patienter, som efter 6 månaders FaR-behandling på vårdcentral var otillräckligt fysiskt aktiva (<150 min/v), i en randomiserad kontrollerad studie. Patienterna randomiserades till fortsatt FaRbehandling under två år, antingen fortsatt via vårdcentralen (VC-grupp) eller via fysioterapeut (FT-grupp). Båda långtidsinterventionerna ökade fysisk aktivitetsnivå, metabol hälsa och hälsorelaterad livskvalitet hos patienterna utan någon signifikant skillnad mellan grupperna. De uppmätta förbättringarna verkade också vara oberoende av förändringar i farmakologisk behandling. Det kontinuerliga stödet till patienten och durationen av FaR-behandlingen bedömdes vara viktiga faktorer för ökad fysisk aktivitet (Paper III). I en treårig hälsoekonomisk utvärdering så gjordes en kostnadseffektivitetsanalys av interventionen i de två FaR-behandlingsgrupperna beskrivna i Paper III. Utifrån ett samhällsperspektiv, där kostnader för intervention, sjukvårdsresurser, sjukskrivning och tidskostnad för utförande av fysisk aktivitet inkluderats, beräknades kostnaden vara 147 250 SEK för ett kvalitetsvaliderat levnadsår (QALY – kostnaden för ett friskt levnadsår) för FTgruppen jämfört med VC-gruppen. Betalningsviljan (willingness to pay) för ett kvalitetsvaliderat levnadsår beräknades till 150 000 SEK för att FTinterventionen skulle anses vara kostnadseffektiv jämfört med VC-interventionen, en summa som motsvarar en måttlig kostnadsnivå. Resultaten i båda grupperna var lika goda och gjorde slutsatsen om kostnadseffektivitet osäker (Paper IV).

Sammanfattningsvis visar denna avhandling att FaR-behandling i ordinarie primärvårdsverksamhet är möjlig för att öka fysisk aktivitetsnivå, metabol hälsa och hälsorelaterad livskvalitet hos fysiskt inaktiva patienter med metabola riskfaktorer. Resultaten verkar vara mest uttalad hos patienter med lägst fysisk aktivitetsnivå. Dessa förändringar är naturligtvis till nytta för patienterna i sig, men kan också leda till minskad belastning och minskade kostnader för hälso- och sjukvården. Identifieringen av prediktiva faktorer för ökad fysisk aktivitet och nyttan av långtidsbehandling med FaR är viktig. Dessa fynd ger medarbetare inom hälso- och sjukvården ökad möjlighet att stödja patientens förändringsprocess samt att individualisera FaR-behandlingen. För att optimera patientstödet så krävs utbildade, skickliga medarbetare med god kunskap kring FaR-behandling men även ordnade rutiner och stöd från organisation och ledning. Fynden från denna avhandling kan underlätta spridningen av FaR-behandling som en viktig metod inom hälsooch sjukvården för att uppnå positiva hälsoeffekter hos fysiskt inaktiva patienter med metabola riskfaktorer.

## List of papers

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

- Lundqvist S, Börjesson M, Larsson MEH, Hagberg L, Cider Å (2017).
   Physical Activity on Prescription (PAP), in patients with metabolic risk factors. A 6-month follow-up study in primary health care.
   PLoS ONE 12(4): e0175190. https:// doi.org/10.1371/journal.pone.0175190
- II. Lundqvist S, Börjesson M, Larsson MEH, Cider Å, Hagberg L (2019).
   Which patients benefit from physical activity on prescription (PAP)?
   A prospective observational analysis of factors that predict increased physical activity.

BMC Public Health (2019) 19:482 https://doi.org/10.1186/s12889-019-6830-1

III. Lundqvist S, Börjesson M, Cider Å, Hagberg L, Bylin Ottehall C, Sjöström J, Larsson MEH (2020).

Long-term physical activity on prescription intervention for patients with insufficient physical activity level - a randomized controlled trial. *Trials (2020) 21:793. https://doi.org/10.1186/s13063-020-04727-y* 

 IV. Ryen L, Lundqvist S, Cider Å, Börjesson M, Larsson MEH, Hagberg L (2020).
 Cost-effectiveness of physical activity on prescription in previous non-complying patients - comparing two long-term strategies.
 Manuscript

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## Abbreviations

A-L	-L	
ACSM	American College of Sports Medicine	
AHA	American Heart Association	
BMI	Body mass index	
CEA	Cost-effectiveness analysis	
CEAC	Cost-effectiveness acceptability curve	
Chol	Total cholesterol	
CVD	Cardiovascular disease	
DBP	Diastolic blood pressure	
ERS	Exercise referral scheme	
FaR	Fysisk aktivitet på recept (Swedish PAP treatment)	
FPG	Fasting plasma glucose	
FYSS	Physical activity in the prevention and treatment of diseases	
НСС	Health care center	
HDL	High density lipoprotein	
HRQOL	Health related quality of life	
ICER	Incremental cost-effectiveness ratio	
IPAQ	International Physical Activity Questionnaire	
LDL	Low density lipoprotein	
LIPA	Low-intensity physical activity	

M-W	
MCS	Mental component summary
MET	Metabolic equivalent of task - 3.5 ml $O_2 \times kg \times min$
MetS	Metabolic syndrome
MVPA	Moderate- and vigorous-intensity physical activity
NCD	Non-communicable diseases
PA	Physical activity
PAP	Physical activity on prescription
PCC	Person-centered care
РСР	Person-centered perspective
PCS	Physical component summary
РНС	Primary health care
PT	Physiotherapist
QALY	Quality adjusted life years
RCT	Randomized controlled trial
SBP	Systolic blood pressure
SF-36	Short Form 36
TG	Triglycerides
WC	Waist circumference

## Definitions in short

Physical activity	"Any bodily movement produced by the skeletal muscles that results in energy expenditure" (1).
Aerobic physical activity	Includes any activity that could be main- tained using only oxygen-supported metabolic energy pathways and could be continued for more than e few minutes (2). Includes physical activity on a low to very high-intensity level (3).
Physical inactivity	An physical activity level insufficient to meet present recommendations (4) or performing insufficient amounts of moderate- to vigorous-intensity physical activity (5).
Insufficient physical activity	Not meeting the recommendations on physical activity for health, i.e. at least 150 min of moderate-intensity, or 75 min of vigorous-intensity physical activity per week, or any equivalent combination of the two (6).

Exercise	"Physical activity that is planned, structured, repetitive, and purposive in the sense that improvement or maintenance of one or more components of physical fitness is an objective" (1).
Sedentary behavior	"Any waking behavior characterized by an energy expenditure ≤ 1.5 METs while in a sitting or reclining posture" (5).
Person-centered perspective, person-centered care	"A way of thinking and doing things that sees the people using health and social services as equal partners in planning, developing and monitoring care to make sure it meets their needs. This means putting people and their families at the centre of decisions and seeing them as experts, working alongside professionals to get the best outcome" (7).

## Introduction

Non-communicable diseases (NCDs) are the leading cause of death globally, responsible for 41 million (73%) of 57 million deaths, and are one of the major health challenges of the 21<sup>st</sup> century (8,9). The largest numbers of deaths from NCDs are estimated to be due to cardiovascular disease (CVD), and three metabolic risk factors are considered leading contributors to the global burden of disease: high systolic blood pressure (SBP), high fasting plasma glucose (FPG), and high body mass index (BMI) (10, 11).

Physical inactivity is one of the leading causes of the increase in NCDs and accounts for approximately 30 % of the ischemic heart disease burden, 27 % of the type 2 diabetes burden, and 21 % of the breast and colon cancer burden (9, 12). Globally, the prevalence of insufficient physical activity (PA; <150 min of moderate-intensity, or 75 min of vigorous-intensity PA/week, or any equivalent combination of the two) is approximately 25 %, meaning that 1.4 billion people are so scarcely physically active that it poses a health risk (6). In 2016, the prevalence was twice as high in high-income countries as in low-income countries (6, 13). However, there are differences both within and between countries due to inequities in access to PA, with women, older adults, people of low socioeconomic position, and people with disabilities and chronic diseases being less physically active (14).

## Non-communicable diseases and physical inactivity

### Swedish perspective

In Sweden NCDs are estimated to account for 90 % of all deaths (9). In 2019, the Public Health Agency of Sweden reported that 36 % of Swedish adults were insufficiently physically active (15). There were no differences between women and men, but the PA level was lowest among older adults, citizens with less education and lower socioeconomic position and people living in rural areas. Regarding sedentary time, 44% of women and 50% of men were sedentary  $\geq$ 7 hours/day. Notably, the sedentary time was higher in younger adults, in the group with a higher level of education, and among people living in urban areas.

In a 15-year follow-up study of accelerometer data in Swedish adults, Dohrn et al. (16) reported an inverse relationship between PA and all-cause, CVD, and cancer mortality. An almost 90% lower mortality risk was shown in the moderate-vigorous intensity PA (MVPA) group compared to the most sedentary, and even 30 min/day of light-intensity PA (LIPA) had a beneficial effect on both all-cause and CVD mortality in the sedentary group (16, 17). The 15-year follow-up period also revealed the importance of PA for preventing chronic disease requiring hospital care (18). Hagströmer et al. (19) investigated changes in PA and sedentary time over 6 years (2002-2008), as assessed by accelerometry, in 1172 Swedish adults. They identified an overall decrease in LIPA (mean 51 min/day) and an increase in sedentary time (mean 26 min/day), with more pronounced changes for men and the elderly (60+ years). Another accelerometer-based study of 948 urban participants (aged 50-64 years) in 2012 found that 7.1 % of the study population met the previous national PA recommendations of 30 min/day of MVPA in bouts of  $\geq 10$  minutes, 5 days/week (20). The time spent sitting and in LIPA was approximately 9 and 5.5 hours/day, respectively.

Ekblom-Bak et al. (21) highlighted the importance of cardiorespiratory fitness in a study with more than 266 000 adult Swedes followed between 1995 and 2015. They found an inverse relationship between fitness level and CVD morbidity and all-cause mortality in both men and women for all age groups. Between 1995 and 2017, Ekblom-Bak et al. (22) found a steady and pronounced decline in mean cardiorespiratory fitness in a population of more than 354 000 Swedish adults (aged 18–74 years), with the proportion of participants with low fitness increasing from 27 % to 46 %. The most pronounced deterioration was seen among participants living in a rural area, men, young people, and persons with less education. Lindgren et al. (23) found that living in an area of low socioeconomic status (SES) was associated with increased risk of cardiovascular events due to, for example, lower PA levels and lower cardiorespiratory fitness compared to people living in a high SES area. The author concluded that these social inequalities in health have to be targeted to improve public health.

### Primary health care

Primary health care (PHC) is the core of the health system and the 1978 Alma-Ata Declaration (24) proclaimed PHC the important keystone in health services including the principles of equity, social justice, and health for all. The principles also included health promotion, prevention, and rehabilitation, community participation, and appropriate use of resources to bring health care, within the national health system, as close to where people live and work as possible (24, 25). Both international and national studies have shown that PHC is associated with a more equitable distribution of health in populations (26, 27), partly depending on a greater focus on prevention and early management of health problems, which requires generic interventions rather than interventions focused on specific manifestations of ill health (28). In contrast to specialty care, PHC is associated with a more equitable distribution of health in the population and increases access to health services for relatively deprived populations (e.g., low income and education level) (26, 27, 29).

The World Health Organisation (WHO) reported that, in 2008, people were overall healthier, wealthier, and living longer than 30 years prior (30). However, the substantial progress in health over recent decades has been deeply unequal, and the international and national health systems have developed in directions that contribute little to equity and social justice and to being cost-ineffective. Health systems have focused disproportionately on offering narrow, specialized curative care focused on short-term results in

fragmented service delivery and allowing unregulated commercialization of health, completely against the PHC goals articulated in the Alma-Ata declaration (30). Business as usual for health systems is not a viable option. Fries et al. (31) proposed focusing on systematically reducing the need and demand for medical services by expanding the PHC area of health promotion, primary prevention, and preventive care, not neglecting the potential of these interventions to prevent up to 70% of the disease burden.

### Swedish primary health care

In several European countries, the average adult visits their PHC physician 5-6 times each year, which allows continuity in contact with the patient. Sweden has a lower rate of three visits to the PHC physician annually, which can be explained by the fact that different countries apply different working methods in PHC. In Swedish PHC, nurses, physiotherapists, occupational therapists, nutritionists, and psychologists perform tasks that, in other countries, are performed only by physicians (27). Compared to other European countries, Sweden has relatively limited resources, with a smaller total health care budget and limited accessibility, coordination, and continuity in primary care. From an international perspective, Sweden has larger health care centers (HCCs) with a wider range of professionals and more team work. The majority of residents in Sweden (84%) consider themselves as having access to the healthcare they need, and 59% have high or fairly high confidence in their PHC, with higher rates in the population aged >60 years and lower rates for people with multimorbidity (32). The Swedish Ministry of Health and Social Affairs (Socialdepartementet) has during the latest years prepared a new health care reform including a coordinated development of a modern, equitable, accessible and effective health care, focusing on primary care (33). The report Good quality, local health care – A reform for a sustainable health care system (SOU 2020:19) highlights the importance of person-centered care and the involvement of the local community. There is also an emphasis on interprofessional learning and a salutogenic approach as a strategy enhancing health and preventing diseases.

Primary care providers are in a unique position to affect public health through healthy lifestyle recommendations (34), and the Swedish PHC has an ideal setting for work with lifestyle behavioral changes. In 2011, the Swedish National Board of Health and Welfare (Socialstyrelsen, SoS) published

national clinical practice guidelines regarding unhealthy lifestyle habits, including tobacco use, hazardous use of alcohol, unhealthy eating habits, and insufficient PA (updated in 2018), that were to be implemented in the 21 regional health care organizations in Sweden (35, 36). At the same time, the Swedish Professional Associations for Physical Activity (Yrkesföreningar för fysisk aktivitet, YFA) released a national PA recommendation for adults (37). Despite these guidelines and a positive attitude from patients to discuss lifestyle habits with their health care provider (38), the work with changing lifestyle behaviors is still severely underutilized in Swedish PHC. The SoS concluded in a follow-up of the National Guidelines in 2014 that PHC has to develop internal working methods, including team work, increase competence among co-workers, and improve the conditions for co-workers to work with lifestyle counseling (38). In a 2-year follow-up of the SoS guideline implementation in PHC, Kardakis et al. (39) concluded that 18% of the physicians and 58 % of the nurses used the guidelines, with nurses more likely to consider them as a support in daily work. In the whole group, 41 % reported having enough knowledge of counseling skills. Johansson et al. (40) found, in focus group discussions with seven professional groups, one major theme: "If we only got a chance." The health professionals reported a positive view and a willingness to develop a health-promoting and preventive role, while simultaneously feeling limited by existing values, structures, and resources. There is a need to prioritize prevention and health promotion interventions in PHC, with educated and competent co-workers, to have more explicit leadership with a clear direction towards health-promoting health services, and with enough resources to work changing lifestyle behaviors among patients (39-42).

### Physical activity

### Physical activity definitions

PA is a complex and multidimensional behavior that is defined by Caspersen et al. as "any bodily movement produced by the skeletal muscles that results in energy expenditure" (1), and can be categorized into domains related to the routines of daily living; household, occupational, leisure, and sporting activities; and active transportation (43, 44). Exercise is a subcategory of PA that is planned, structured, and repetitive with the objective to improve or maintain physical fitness components, such as cardiorespiratory capacity, muscular strength, and body composition (1). The total amount of PA is estimated by the frequency, duration, and intensity, which is then combined with mode/type of PA to describe the dose of PA needed for a specific response (43).

### Physical activity recommendations

In order to improve health and reduce the risk of NCDs among adults there is an internationally recommended PA level of at least 150 min of moderateintensity PA, or 75 min of vigorous-intensity PA per week, or any equivalent combination of the two (45). Updated recommendations proclaim that bouts of any length of MVPA contribute to the health benefits associated with accumulated PA (2). In addition, muscle-strengthening PA should involve major muscle groups  $\geq 2$  times/week, and for those aged  $\geq 65$  years, PA to enhance balance and prevent falls should be performed  $\geq 3$  times/week. Elderly individuals and those with chronic illnesses or disabilities who cannot achieve these recommendations should be as active as their condition allows.

The Swedish PA recommendations were developed by the YFA, and the guidelines were adopted by the Swedish Medical Association in 2011 (37). These science-based national PA guidelines are important for enhancing health literacy among the population and in healthcare and health-promoting settings (46). The guidelines facilitate information about national PA policies and other public health interventions and the establishment of goals and objectives for PA promotion (45). The guidelines can also enable stakeholders to transfer policy into common action, with the allocation of appropriate resources.

### Physical activity guidelines

The Swedish National Board of Health and Welfare's National Guidelines, *Prevention and treatment of unhealthy lifestyle habits*, was updated in 2018 (36). The guidelines include the four lifestyle habits: tobacco use, hazardous use of alcohol, unhealthy eating habits, and insufficient PA. The guidelines recommend person-centered dialogue, supplemented with a written pre-

scription, a movement sensor, and structured follow-up when the patient's PA level is insufficient, and proposes PA on prescription (PAP) to be used in Swedish health care. The national guidelines support health and medical care professionals prioritizing interventions for those with the greatest need and provide a basis for making decisions on resource allocation in health care and social services.

From a regional perspective, one of the Drug and Therapeutics Committee of Region Västra Götaland therapy groups, the 'Therapy group for physical activity', has issued a *Regional medical guideline for physical activity* (47). This guideline summarizes the health effects of PA, explains concepts related to PA and behavioral changes, and provides clinical advice for the work of PA in health care. One aim of the guidelines has been to increase belief in and awareness of the importance of PA as a treatment strategy for physically inactive patients among both co-workers and management.

### Assessment of physical activity

PA is a complex and multidimensional behavior and not easily measured, and is based on the dose (frequency, duration, and intensity), the specific type of activity that is performed, the context of the activity, and location (48, 49). PA is also affected by other related constructs, such as sedentary behavior, energy expenditure, and physical fitness, and is influenced by physiological, psychological, social, and environmental factors (50). PA is optimally measured with direct or indirect measurement of energy expenditure. Another way is to measure movement behavior and, depending on how data are collected, categorize these as objective measurements or patient-reported outcome measures.

#### **Objective measurements**

The doubly labeled water method, measuring carbon dioxide production via injected isotopes, is considered to be the gold standard for direct measurement of human energy expenditure under daily living conditions (51). The method is the most valid measurement for energy expenditure, but is both complicated and expensive to use. Other objective direct methods for measuring

energy expenditure are direct calorimetry and direct observation. Objective indirect methods include physiological measures (i.e., cardio-respiratory fitness and heart rate monitoring) and movement sensors (i.e., pedometers and accelerometers) (52). Despite the advantages of using direct methods, they are often time and cost-intensive, difficult to apply to large populations, and require specially trained co-workers with specific equipment (53). Thus, these methods are not optimal for use in primary care. The most frequently used objective methods for measuring PA behavior are pedometers, which measure steps and can estimate the distance walked, and accelerometers, which have the ability to measure acceleration in body movement in one to three planes and sedentary behavior over time. The accelerometer has the advantage of capturing the PA pattern, namely the intensity, duration, and frequency of physical movement during short, predetermined, recurring periods of time (54). The accelerometer data have to be converted to meaningful PA or sedentary outcomes, for which metabolic equivalents (METs) per minute or hour are often used. The MET unit expresses PA intensity, with 1 MET representing the resting energy expenditure during sitting, defined as a body oxygen consumption of 3.5 ml/kg/min (52, 55). The use of movement sensors in health care has been linked mostly to research (56), and very little to clinical practice. However, the accelerometry data outcome has been refined in recent years, and the accelerometers are more user-friendly with decreased cost. These factors could affect the use of movement sensors in ordinary primary care practice in Sweden.

#### Patient-reported outcome measures

Patient-reported outcome measures for assessing PA comprise self-administrated questionnaires (short-term and long-term recalls), activity diaries, surveys (global or general), and interviews in which the individual records activities as they occur or recalls previous activities (53, 57). These measures, especially questionnaires, are frequently used due to their practicality, low cost, general acceptance, and ability to collect data from a large number of patients. Self-administered questionnaires range in detail. *Global PA questionnaires* include a few items that provide a quick overview of a person's PA level in order to provide a PA score or a classification. *Short recall PA questionnaires* generally include 7–12 items and provide a quick assessment of the total MVPA volume, which is used to identify changes in PA behavior in intervention studies. *Quantitative history PA questionnaires* are detailed surveys that often include PA behavior over several months or years, and are used in epidemiological studies to determine if PA in the past may be relevant to current health status (52).

Self-reported PA questionnaires have limitations in their validity and reliability and increase the risk of over- or under-estimating the PA level, with generally low-to-moderate correlation compared to PA measured by an accelerometer (53, 58). Prince et al. (53) analyzed 148 studies on PA changes among adults and reported an overall low-to-moderate correlation between self-reported and directly measured PA (mean 0.37 (SD 0.25), range -0.71 to 0.98). The self-reported measures of PA were both higher and lower than the directly measured levels of PA. One-third of the studies were of poor quality, increasing the risk of bias. In a review of 36 studies including older adults, Kowalski et al. (58) reported an overall correlation between indirect and direct measurement of PA levels of r = 0.38 (95% CI 0.36-0.40). The author requested more high-quality studies and highlighted the difficulty capturing all dimensions of a complex behavior such as PA with a single measure. Social desirability bias and difficulties recalling PA due to its complexity and memory limitations can possibly affect the outcome, and measures may not capture the primary modes of PA for a certain gender, age, occupation, income, or cultural group (59). Many questionnaires have been developed and validated according to leisure time PA or MVPA. This increases the risk of missing health-enhancing PA performed at a light level of intensity and health effects from reduced sedentary time (52).

However, questionnaires are valid to assess structured, vigorous-intensity PA, and have the possibility of ranking PA into high/low categories and identifying the dimensions (type, frequency, duration, and intensity) and domains (occupational, domestic, transportation, and leisure time) of PA. Self-reported PA questionnaires also have value for monitoring changes in PA in a population (60). However, no single most appropriate PA measure for all circumstances is known; therefore, the choice of a certain questionnaire should always start with defining the purpose of the study and evaluating the content validity of a possible questionnaire (57, 61). A questionnaire suited to a particular situation is relevant to use in both research and practice settings. The assessment of PA has to be considered a vital health measure

and should be measured regularly in health care (52). Measuring "the previous week of PA" has shown a higher correlation with accelerometer data than measuring "the usual week of PA" (r = 0.41 vs. 0.26) (61).

### Physical activity and health effects

Two influential scientific publications in the area of PA and health were published in the mid-1990s. The "Physical Activity and Health – A Report of the Surgeon General" (62) declared the relationship between PA and health and that moderate amounts of PA in daily life can substantially improve health and quality of life. The first public health recommendations on PA were published in 1995 by the Centers for Disease Control and Prevention and the American College of Sports Medicine (CDC/ACSM) (63), in which the dose-response relationship between PA and health was also established. These two publications had a major impact on the scientific approach and the continuing work with PA towards increased health, and were updated in 2007 (64) and 2018 (2).

PA improves health and, in addition to disease prevention, physically active individuals sleep better, feel better, and function better (2, 65). Strong evidence has demonstrated that regular PA has positive health effects in several areas, including the prevention and treatment of CVD, type 2 diabetes, chronic obstructive pulmonary disease, arthritis, and pain conditions, and can improve mental health, quality of life, and well-being (4, 12, 66). Regular PA also reduces the risk of several types of cancer and the risk of developing or the progression of chronic diseases (2, 67).

### Metabolic syndrome and physical activity

Metabolic syndrome (MetS) includes being overweight, abdominal obesity, insulin resistance, dyslipidemia, and hypertension in various combinations (68). PA is indicated with high priority (3). The acute physiological effects of PA include an immediate response with decreased plasma glucose, increased lipid metabolism, and decreased SBP immediately after PA (post-exercise hypotension) and in the longer term to roughly the same extent as one hypertensive medication (69). All components of the MetS are positively

affected by regular PA, with aerobic MVPA resulting in the best effect (70, 71). A linear dose-response association has been found between the amount of PA performed and the risk of developing MetS, with a 10% reduced risk for every 10 MET h/week of moderate-intensity PA compared to physical inactivity (RR 0.90, 95% CI 0.86–0.94) (72).

In a study by Halldin et al. (73) including 4228 Swedish 60-year-olds, the prevalence of MetS in men and women was 24% and 19%, respectively. Individuals reporting regular MVPA for 30 min  $\geq$ 2 times/week had approximately 70% lower incidence of MetS than physically inactive persons (OR 0.33, 95% CI 0.22–0.49). The Swedish CArdioPulmonary bioImage Study (SCAPIS) (74) of 930 middle-aged women and men used the cardiorespiratory fitness test and accelerometry to show that cardiorespiratory fitness, PA, and sedentary behavior are independently related to the prevalence of MetS. Comparing the first and third tertiles (including the lowest and highest values, respectively), high fitness reduced the prevalence of MetS by 76% (OR 0.24, 95% CI 0.12–0.48), MVPA reduced the prevalence by 67% (OR 0.33, 95% CI 0.18–0.61), and LIPA reduced it by 50% (OR 0.50, 95% CI 0.28–0.90) after adjusting for potential confounders.

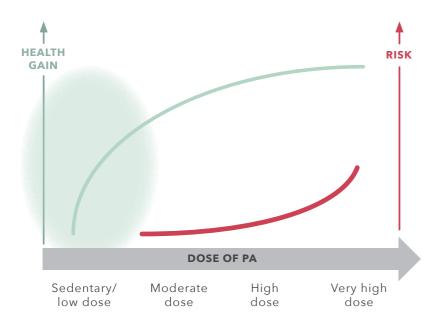
#### Health related quality of life and physical activity

A consistently positive association has been shown between PA level and health-related quality of life (HRQOL) in cross-sectional studies of the general adult population under 65 years of age, but weaker evidence has been gained from randomized controlled trials (RCTs) and cohort studies (75). In this systematic review, the most frequently used HRQOL instrument was the Short Form 36 (SF-36) questionnaire. The use of self-reported PA and HRQOL in most of the included studies complicates the analysis of outcome, as they may have conceptual overlap, augmenting the actual relationship between the physical functioning domains of HRQOL. The authors discuss the need for further studies to better understand the dose-response curve of the relationship between PA and HRQOL and the causal pathway of the association between changes in PA and HRQOL (75). Among adults aged 40–82 years with chronic illness, a meta-analysis found that patients who received PA interventions in primary care had increased HRQOL compared to baseline and the control group (76). The authors found no differences in HRQOL outcomes between the three most common types of chronic illness: type 2 diabetes, cardiac disease, and cancer. However, there was considerable heterogeneity in the design of the included studies, the measurement used, and in the magnitude of the effect, and the effect size for PA level did not predict the HRQOL effect size. The authors concluded that the explanation for changes in HRQOL is unclear, and that the interventions are designed for PA behavior, not primarily affecting HRQOL. They also discussed the possibility that even a small increase in PA, possibly not detected by the PA measure, could improve functional status, affecting HRQOL and increasing the enhanced perceived mastery over a chronic illness (76).

### The dose-response relationship

Different types of PA promote different types of physiological changes and diverse health outcomes in which aerobic PA, using large muscle groups in repetitive movements at a low to high-intensity level, is associated with the broadest range of health benefits (2). The volume of PA (duration, frequency, and intensity) is essential and closely related to the overall health outcome, expressed as the dose-response relationship (65). There is a curvilinear dose-response relationship between PA and health benefits by which the most physically inactive individuals have the greatest health gains from an increased level of PA (Figure 1). There is no lower or upper threshold of PA dose for health benefits, and a reduction of mortality risk is seen in every step of increasing PA; thus, regarding PA, something is better than nothing and more is better than something (65, 77). For the general population increasing their PA level, there is no risk of, for example, musculoskeletal injuries or other adverse events that would overtake the health benefits, as long as the increase occurs gradually.

During the last decade, several research studies have explored the value of replacing physical inactivity and sedentary time with LIPA, even if the recommended level of 150 min of moderate-intensity PA is not achieved. Replacing sedentary behavior with LIPA reduces the risk of mortality and the incidence of CVD and type 2 diabetes for those who perform no or little MVPA (2), and it seems to be helpful to interrupt prolonged sitting with repeated 1-minute bouts of LIPA to positively affect metabolic risk factors (78). Research from Ekelund et al. suggests substantial curvilinear, dose-response risk reduction in all-cause mortality from LIPA, with the public health message "sit less and move more and more often" (79, 80).



**FIGURE 1.** Dose-response – relationship between physical activity and health. Reworked graphics from *Läkartidningen*, 2015.

#### Intensity and perceived exertion

When performing and measuring PA, intensity is one of three important components to take into consideration. Intensity is the rate of energy expended during PA and can be divided into *absolute intensity* vs. *relative intensity*. Absolute intensity refers to the rate of energy expenditure required to perform specific PA without considering the physiological capacity of the individual performing the PA. Absolute intensity can be measured in METs, kilocalories, joules, or oxygen consumption and is commonly divided into four categories:

- Sedentary behavior requiring ≤1.5 METs
- Light-intensity PA requiring 1.6 to 2.9 METs, such as walking at a slow pace or cooking/food preparation (light effort)
- Moderate-intensity PA requiring 3.0 to 5.9 METs, such as walking at a normal pace or general yard work (moderate effort)
- Vigorous-intensity PA requiring ≥6.0 METs, such as climbing hills or running (81)

Relative intensity refers to the ease or difficulty with which an individual performs any given PA and is proportional to an individual's current maximal capacity. It can be described using physiological variables, such as percent of maximal oxygen uptake (VO<sub>2</sub>max) or percent of maximal heart rate (HRmax). Relative intensity can also be measured by how hard an individual perceives a PA to be using, for example, the Borg's rate of perceived exertion scale (Borg RPE-

scale) (82). The Borg RPEscale is a categorical scale based on linguistic expressions anchored in numbers from 6 to 20, where 6 means no effort at all and 20 means maximum effort. The numbers correlate with the different intensity levels as shown in Figure 2.

The Borg RPE-scale has shown good correlation with physiological variables, such as  $VO_2max$  and HRmax (82), and is suitable for use in clinical practice. The scale is widespread and frequently used by physiotherapists in Swedish health care practice, but is hardly used among other healthcare professionals.

#### Perceived exertion Intensity level

	No exertion at all	6
	Future as a built as let	7
	Extremely light	8
	Very light	9
LOW		10
	Light	11
		12
MODERATE	Somewhat hard	13
		14
	Hard	15
HIGH		16
	Very hard	17
		18
	Extremely hard	19
	Maximal exertion	20

**FIGURE 2.** Borg-RPE-skalan<sup>®</sup>. Relative intensity and perceived exertion. © G. Borg, 1970, 1998. Reworked graphics from RMR Terapigrupp fysisk aktivitet, Läkemedelskommittén VGR. FYSS - the summary of evidence for health benefits of physical activity

A digital resource or printed book for healthcare professionals in the use of PA in clinical practice is the evidence-based handbook *Physical activity in the prevention and treatment of disease* (FYSS) published by YFA (3). FYSS provides a broad background on the topic of PA and describes how PA and exercise can be used to prevent and treat a variety of medical conditions. In Sweden, FYSS is frequently used in clinical PAP-treatment and is included as course literature in a number of health care programs at university level. The FYSS is also used internationally, and has been translated into English and Vietnamese thus far.

## Physical activity as a method of prevention and treatment

Increased and regular PA has multiple positive health effects, including the prevention and treatment of a wide range of diseases. The healthcare system has an important role in developing and evaluating effective PA interventions to support physically active people in active environments and societies (2, 66). Several systematic reviews and meta-analyses of diverse PA interventions has been published during the last decade, revealing an overall positive effect on PA compared to minimal or no-treatment controls (2, 83–89).

### Methods for improving physical activity level

#### PA INTERVENTIONS IN DIFFERENT SETTINGS

In studies analyzing different PA interventions in different settings, including health care settings (83–85, 88) among healthy adults and older adults, Conn et al. (84) presented an effect size (*d*) (90) of 0.19 (95% CI 0.15–0.23, p<0.001) for intervention vs. control, consistent with a mean difference of approximately 500 steps/day. They also found that face-to-face behavioral interventions targeting individuals were the most effective approach, as the attention on the message may be higher in individually delivered interventions. Targeting older adults, Chase et al. (83) found an effect size (*d*) of 0.18 (95 % CI 0.10–0.26, p<0.001), representing a difference of 620 steps/day between the intervention vs. control group. The mean age of the population included in this meta-analysis was 75 years, with 70 % women and a mean BMI of approximately 28 kg/m<sup>2</sup>. The authors concluded that effective PA interventions may be efficiently delivered using already available resources and personnel with enhanced knowledge of behavioral PA changes and self-management interventions.

A meta-analysis by Love et al. (85) found maintained improvement in PA levels >12 months after various PA interventions in healthy adults. The evidence for effectiveness of PA immediately post-intervention was considered to have reached sufficient levels in 2007, and for long-term follow-up (at least 12 months post-baseline) in 2011, recommending a shift in the research focus to investigate the optimization, implementation, sustainability, and cost-effectiveness of interventions. Limitations possibly affecting interpretation of the results were discussed in the above studies and mainly concerned the lack of information available in study reports, the heterogeneity of the methods, measurements, and outcomes, and the widely varying quality in the included primary studies.

#### PA INTERVENTIONS IN PRIMARY CARE

Different primary care-based PA interventions have been analyzed, showing small to medium positive effects of increased PA, which should be interpreted with caution, as further research is needed (86, 87, 89). Orrow et al. (89) included 15 primary care trials (n = 8745) with a wide range of PA interventions and a minimum follow-up of 12 months revealing small to medium positive intervention effects (OR 1.42, 95% CI 1.17–1.73; standardized mean difference 0.25, 95% CI 0.11–0.38). An estimate of the number needed to treat (NNT) for one additional sedentary adult to report a sufficient PA level at 12 months was 12, which could be compared to the estimated NNT of 50–120 for smoking cessation (91). In a review of reviews, Sanchez et al. (86) reported a small to moderate positive effect of PA intervention, with an estimated NNT of 12–25. Interventions including multiple techniques for behavioral changes (e.g., establishing objectives, providing feedback, and writing PA prescriptions) that targeted insufficiently active or sedentary patients presented better results.

Gagliardi et al. (87) reviewed the evidence from PA counseling in primary care and found that counseling provided by clinicians exploring motivation increased self-reported PA among patients for at least 12 months. The authors proclaimed a need for clinicians to require training and tools to operationalize PA counseling. The limitations mentioned in the analysis of primary care-based PA interventions were the heterogeneity of PA-promoting interventions across studies, with a sometimes a poor description of the content, the use of self-reported measures of PA, and the risk of social desirability and publication bias. Most of the included studies were performed in highincome countries where most trial participants were white and socioeconomic characteristics were poorly reported, which may limit the generalizability of the available evidence.

### PAP methods used in health care an international perspective

PAP schemes were introduced during the 1990s and early 2000s in several European countries (United Kingdom, the Nordic countries, the Netherlands, Germany, Belgium, Spain, and Portugal) and the USA, Canada, New Zealand, and Australia (92). The name of the PAP schemes vary between countries (e.g., exercise referral scheme [ERS], exercise on prescription [EoP], PA referral [PAR], PAP, or green prescription) (93-96), and the designs of the schemes differ regarding the targeting of eligible groups, reasons for referral, type of PA provided, and program characteristics and evaluation (92). A model used in several countries is the ERS, in which patients are formally referred by a health professional (usually a general practitioner [GP] or practice nurse) within a primary care-based setting to an exercise professional who will, after additional health screening procedures, prescribe a program of exercises for the patient (92, 93, 97, 98). This exercise program is often delivered within a controlled, usually leisure-based setting over 10-14 weeks, during which the patient usually takes part in supervised group exercise. ERS typically focuses on physically inactive patients with one or more cardiovascular risk factors, non-clinical depression, respiratory disorders, or musculoskeletal issues. Patient follow-up often occurs mid-way through the exercise period and at the end point by the exercise professional, and there is a recommendation (99) that GPs should receive a patient progress review after the ERS period, something that is often missing (93, 100).

Several systematic reviews of ERSs indicate a small to medium increase in PA level (92, 96, 101-103). Campbell et al. (101) updated an earlier review (104) and found in eight studies with 5192 participants a higher proportion of individuals achieving 90-150 minutes/week of MVPA at 6-12 months of follow-up (relative risk 1.12, 95% CI 1.04-1.20), consistent with an increase of 55 min/week of total PA in the ERS group compared to usual care. A majority of the included interventions evaluated a 10-12 week, leisure center-based MVPA, 2×45-60 min/week with both group and individual sessions. Williams et al. (103) reported a small ERS effect (relative risk 1.20, 95% CI 1.06-1.35) on increased PA in sedentary adults with cardiac risk factors. Six RCTs were included in this systematic review, and the interventions generally consisted of gym/leisure center-based exercise or a walking program over 10-12 weeks. Although improvements have been reported in both physiological and psychological outcomes and a sustained increase in the PA level among those that completed the ERS, one-third of patients did not participate in the schemes at all, and only 12% to 42% completed the 10 to 12-week program. Another systematic review analyzing ERSs until 2009 found an adherence rate of 43 % to 49 % (105). Arsenijevic et al. (92) concluded in a systematic review of 37 studies that providing access to a physical leisure center is an important, but not sufficient, step to increasing PA. The ERS has to be implemented in home surroundings and include tailor-made programs targeting specific population groups, including the knowledge of different sociodemographic characteristic and taking into account their preferences (34, 92, 93, 102, 103, 105, 106).

A majority of the reviewed studies have been RCTs limited by a short followup period and criticized for not measuring a 'real world' intervention under real circumstances (92, 93). Longer duration with prolonged follow-up of ERSs has resulted in associations with higher levels of self-reported PA (92, 106). The analysis of ERS interventions has been complicated by high heterogeneity in the design of interventions, duration of programs, reasons for referral, patient payment, and effect size measures (92). Detailed characteristics of patients who are referred but fail to start or complete an ERS are lacking, reflecting a gap in the understanding of large subgroups of patients who cannot benefit from the ERS (106). The variability in ERS adherence rates may also reflect a less than optimal referral process with flaws in the PA consultation with the patient, a lack of individual tailoring of PA options, and inappropriate referrals (105). Further insight and knowledge has been gained concerning ERSs and the importance of behavioral change, patient facilitators, and barriers to improving and maintaining PA level, and factors of importance for health care providers to incorporate PA promotion into their practice.

### FACILITATORS AND BARRIERS TO IMPROVING AND MAINTAINING PHYSICAL ACTIVITY

Among facilitators, perceived improvements, support, and supervision from providers, including continuing professional support after the ERS, support from family and other attendees was seen as important for ERS adherence. Other facilitators mentioned were the variety and personalized nature of sessions offered and the possibility of 'making exercise a habit' after the ERS period (107). Perception of the environment (e.g., the presence of parks and green spaces in the urban environment) has been identified to be important for sustained changes in behavior (101). Barriers to participation in ERSs include concerns about worsening health problems and lack of ongoing professional support after the ERS period. Personal barriers, such as lack of self-efficacy, poor body image, poor time management, and lack of social support, have also been reported as important. Exercise scheme barriers include an intimidating gym atmosphere, a lack of confidence in operating gym equipment, inadequate supervision, and the inconvenient timing, cost, and location of sessions (103, 107). In a systematic review published in 2020, Albert et al. (108) analyzed the functionality of Physical Activity Referral schemes (PARSs) and categorized five factors as facilitators: perceived support, defined goals and motivation, professional advice and supervision during and after the PARS period, incentives, and social engagement with other participants. Six factors were reported by patients as being barriers: time constraints, psychological/perceived negative feelings, inaccessibility (transport/venue problems), unwell, inadequate support, and financial constraints.

#### HEALTH CARE PROFESSIONALS INCORPORATING PA PROMOTION INTO PRACTICE

Despite increasing awareness of the importance of enhancing PA counseling in primary healthcare, a majority of patients are still not provided PA counseling or any type of PAP intervention by primary care professionals (98, 109, 110). There could be a lot of reasons, including a feeling that PA promotion is outside their expertise and remit and is less important than other health promotion activities (111). Other reasons could be lack of time, lack of adherence and competing priorities, and lack of knowledge regarding the PA promotion processes and referral options (98, 109, 110, 112). General practitioners have been using PA promotion in their practice primarily as a disease management tool, with limited specificity and with doubts that patients are interested and motivated in changing their PA behaviors (111, 113). Campbell et al. (101) summarized factors perceived to reduce health professionals' referral to ERSs as lack of enthusiasm for the project, poor knowledge of the ERS, and poor interpersonal skills on behalf of the health professional. Workload, competing demands, and the extra time needed to manage with the ERS were also considered barriers to referral. There is a lack of education, knowledge, and skills among health care providers to assess, counsel, and support the patients in PA promotion and in using any type of PAP intervention. If PA promotion is to be incorporated into routine primary care, the health care providers' concerns regarding skills, priority setting, time constraints, and financial support need to be considered (93, 98, 111, 112).

### The Swedish physical activity on prescription

The concept of PAP (in Sweden; Fysisk aktivitet på Recept – FaR<sup>©</sup>) was introduced in 2001 as part of the national project "Sweden on the move" (114, 115). This large-scale project focused on health-promoting PA among Swedish residents and started a long-term strategy for several stakeholders and settings, one of which was the healthcare system. The Swedish Professional Association for Physical Activity (YFA) was commissioned to form a scientific expert group, which comprised the first national public PA recommendation and created the idea of PAP, producing the evidence-based handbook FYSS for healthcare professions (115, 116). Before launching PAP, a pilot study was carried out in 2003 in Swedish healthcare settings by Kallings and Leijon (115), revealing that 93% of healthcare professionals felt positive about the project and 9 out of 10 patients preferred PA over drug treatment if the outcome was the same. Important findings from this pilot study were the need for a well-defined organizational structure, including a coordinator who works within the organization, support of the management, and having a clear structure in the communication with PA organizations outside the healthcare system. Among obstacles experienced by health care professionals in implementing PAP as a treatment were lack of time, staff turnover, insufficient communication within the organization, and that change takes time: "The healthcare system must also prepare itself for behavioral change" (115).

During the last few decades, PAP has been most widespread in PHC, but is affected by the limited uptake in routine care and still severely underutilized in Swedish PHC. Although there is uncertainty about the reliability of PAP statistics, Leijon et al. (95) found in 2004–2005 that less than 1.4% of patients visiting PHC in one county received PAP. In calculating PAP statistics for the total Swedish health care system, Kallings L. (117) found a rate of 1.2 PAP/1000 visits in PHC in 2010, with a large variation in prescriptions between the 21 regions. Even if these figures should be interpreted with caution, they must be taken into consideration with the fact that at least one-third of the Swedish population are physically inactive and in need of some form of PA intervention (15).

### SWEDISH PAP TREATMENT - THE CORE ELEMENTS, STRUCTURE, AND ORGANIZATION

The aim of PAP is to increase the patient's motivation for PA and their PA level. The Swedish PAP treatment is based on an individualized methodology with a person-centered perspective (PCP) (118) and tailored for each patient as a first-line treatment for preventive and therapeutic purposes (116, 119). It can be used as a compliment or as a substitute for drug treatment and may be included as part of rehabilitation but does not replace this type of intervention. In Sweden, all licensed healthcare professionals may use PAP provided they have sufficient knowledge about the patient's health status; how PA can be used for promotion, prevention, and treatment; and knowl-edge of behavioral change processes and person-centered dialogue. Knowl-edge is also needed about the PAP treatment including the awareness of local routines and local PA organizers out in the community (120).

PAP treatment includes three core elements: individual consultation, agreed tailored PA recommendation with a written prescription, and individualized structured follow-up (Figure 3) (121).



FIGURE 3. The three core elements of Swedish PAP treatment. Reworked graphics from HFS/YFA.

The individual consultation with the patient is mostly based on the principles of motivational interviewing (MI) (122) in which the patient's previous and current PA level and preferences for different types of physical activities are elucidated. Furthermore, the patient's motivation, self-efficacy, and readiness to change their PA behavior and potential obstacles are evaluated. Physical activities that the patient is interested in and finds fun and possible to do should be highlighted and the environmental support and socio-economic situation taken into account. This information, including the patient's health status and potential risk factors, serves as the basis for further strategies to change their PA behavior and for the selection of an appropriate type of PA. Having a professional, respectful dialogue with the health care provider is crucial for the patient throughout the PAP treatment period (123, 124). The patients describe the need to conform the PAP treatment to the current situation and previous experiences with PA, and to adapt the PAP to their current physical capacity.



The agreed tailored PA with a written prescription includes the type and volume of PA. The volume of the chosen PA is determined by an appropriate relative intensity using the Borg RPE-scale (82), as well as duration and frequency. The prescription

may also contain an agreement for reduced sedentary time, replaced with everyday activity and optimally supplemented with a PA diary and/or a movement sensor. The evidence-based handbook FYSS (125) is frequently

used in clinical PAP-treatment as method support and a guideline for recommending PA and exercise to prevent and treat a variety of medical conditions. The written prescription has been shown to be essential for the patient, to serve as a reminder, take the agreed PA more seriously, and to become more motivated (123, 124, 126). All PA agreed upon in the prescription is handled by the patient outside the health care system. The majority of patients chose a PA to be carried out on their own in everyday life (e.g., walking) near their residential area or workplace (95, 127). Other patients prefer to do their PA in a more organized manner via activity organizers in the local community, such as sports associations, pensioners associations, and fitness centers. To have a community-based network is another method support and an important part of PAP in which the health professionals in some regions have access to a registry of the local supply of physical activities to support patients in choosing a suitable PA (119, 128). The prescription is documented in the patient's medical journal, including a planned follow-up.

> The individualized structured follow-up is flexible in time, and adapted to the patient's needs and wishes in order to increase motivation and provide an increased opportunity

for changes in PA behavior (36, 126). The health care provider that started the PAP process with the patient is responsible for ensuring that follow-up is done through either re-visits or telephone contact. The follow-up is used to recapitulate the previous PA period, to discuss possible adjustments to the agreed upon PA, and to reinforce the patient's motivation and self-efficacy. There is also an opportunity to follow-up on the PA diary and/or the use of the movement sensor and to measure PA level and health outcome. There is no golden rule for how long there should be between the follow-ups, as this is decided in dialogue with the patient based on the patient's wishes and needs. From the patient's point of view, the follow-up serves as an extra motivating factor with an opportunity for support in continuing or upgrading the PA level (123, 124). Including the measurement of health effects and control of risk factors contributes to a high degree of perceived safety.

3

#### THE EVIDENCE FOR SWEDISH PAP TREATMENT

The Swedish Council on Technology Assessment in Health Care (SBU) declared in a systematic review, *Methods of promoting physical activity* (126), that patient counseling in everyday clinical practice increases PA by 12–50% with an additional boost in PA from more frequent, intensive counseling. Counseling supplemented by prescribed PA, diaries, pedometers, and information materials increases PA by another 15–50%. The Swedish National Board of Health and Welfare updated their National Guidelines in 2018 regarding *Prevention and treatment of unhealthy lifestyle habits* (36) and recommended the use of person-centered dialogue, supplemented with a written prescription, a movement sensor, and structured follow-up when the patient's PA level is insufficient, and proposes PAP to be used in Swedish health care.

In 2018, Health Technology Assessment (HTA-center), Sahlgrenska University Hospital in Gothenburg published a systematic review on Swedish PAP treatment, Efficacy of the Swedish model for physical activity on prescription (129). This review included nine articles, including seven RCTs (130-136), one cohort study (127), and one case series (137) concerning PAP treatment in adult patients deemed to be in need of increased PA by a health care professional. The primary outcome was the effect on the level of PA, which was reported in seven articles (n = 642), and the result was that Swedish PAP treatment likely improves the level of PA, with little or no difference in adverse events compared to no PAP. There was a moderate certainty of evidence defined according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system (GRADE  $\oplus \oplus \oplus \odot$ ) (138), which means moderate confidence in the effect estimate; the true effect is likely close to the estimate of the effect, but there a substantial difference is possible. Notably, the GRADE system is based on drug studies in which double-blinded RCTs have the possibility of reaching the highest grade of evidence. In PA studies, however, there is no possibility for blinding, resulting in an automatic decrease in the valuation of study quality (e.g., from GRADE  $\oplus \oplus \oplus \oplus \oplus$  to GRADE  $\oplus \oplus \oplus \odot$ ). In other words, GRADE  $\oplus \oplus \oplus \odot$ is as high a PA RCT can reach. The authors concluded that Swedish PAP treatment should be implemented as part of routine healthcare. Further research is needed to quantify the effect on the level of activity and the longterm efficacy, and the cost-effectiveness of Swedish PAP treatment (121, 129).

#### SWEDISH PAP TREATMENT AND THE PERSON-CENTERED PERSPECTIVE

The PCP (person-centered care [PCC]) is known as a multidimensional concept with roots in humanistic psychology (139). There is a complexity of the concept that makes it challenging to articulate its shared meaning and describe how it can be used in practice. The PCP emphasizes the importance of knowing the person behind the patient, their context and history, their family and loved ones, and their strengths and weaknesses (118). The perspective takes into account the person's reason, will, feelings, and needs in order to strengthen their confidence and identify resources for healing. From a PCC perspective, healthcare professionals see patients as an active partner in the planning and performing of care and treatment processes (118, 140). Putting people at the center of care, respecting people's values and expressed needs, working together to ensure good communication, and making sure people are physically and mentally comfortable and safe are different aspects of PCC (7). These aspects have been found to increase the quality of healthcare, to impact health outcomes, and encourage people to embrace a healthier lifestyle (141, 142). The PCP is crucial in all parts of PAP treatment and, as a method of treatment, PAP treatment should be integrated into the concept of PCC with the patient placed in the center to avoid the PAP intervention being perceived as paternalistic (39).

#### THE PATIENT'S PERSPECTIVE

There are some evaluations regarding Swedish PAP treatment among patients in PHC. In a waiting room study between 2001 and 2003 that included 831 patients (75% women) with a variety of diagnoses and a mean age of 50 years, Kallings and Leijon (115) found that 80% of the patients felt positively about being offered lifestyle counseling and PAP by their health care provider. Among women and men, 60% and 80%, respectively, wanted to perform their PA on their own, and 36% vs. 10% wanted to participate in organized group activities. PAP treatment was considered to be an important reason for the individual to realize her/his intentions to start PA. Among barriers, the patients mentioned lack of time, "not being the sporty type", and insufficient health; 2.2% thought it was their own responsibility to change their lifestyle without involvement from health care. In 2017, Joelsson et al. (143) interviewed 12 women and 3 men (mean age 58 years) with chronic musculoskeletal non-malignant pain who participated in a 3 to 12-month PAP treatment between 2012 and 2014. The overarching theme for this study was patients with chronic pain requiring extra support when changing their PA behavior. Some patients increased their PA level and HRQOL, and reduced their perceived limitations, but expressed requiring more from the physician in regards to taking the patient's circumstances into account and requesting more support from a physiotherapist. The patients were pleased to have been offered PAP treatment but expressed the presence of multiple barriers in which the pain made it difficult to be physically active. An increase in the quality of the PCP from the physician in the PAP treatment process was also required.

Andersen et al. (123) interviewed 13 patients (9 females, mixed age groups) 1.5-2.5 years after their PAP intervention in PHC during 2013-2014. The patients expressed the importance of adapting the PA to the individual's physical and psychological capacity and taking into account previous experiences with PA, both positive and negative experiences. The opportunity to engage in PA was affected by the quality and professionalism of the health care provider in handling the PAP treatment process and the possibility of having access to a PAP counselor, a physiotherapist or nurse with expertise in PAP treatment and MI counseling techniques. The flexibility in the duration of PAP counselor support was experienced as positive by the patients and seemed to support sustained PA. The authors proclaimed that no "one-size-fits-all" program exists for PAP treatment. In a 5-year follow-up study of PAP treatment by Joelsson et al. (124), 20 patients (9 females, mean age 58 years) with metabolic risk factors were interviewed. The overarching theme was that tailored PAP and regular follow-up contribute to increasing and maintaining motivation and PA level. The quality of the person-centered MI was considered crucial, as was the adaptation of the PAP treatment to the patient's present situation and previous experiences with PA. A written prescription was seen as probably more effective than just verbal information, with PAP becoming an eye opener. The patients expressed that their own opinions, wishes, and integrity were important factors in finding a PA that felt motivating, appealing, and functional in their everyday life schedule. This was supported by a health care provider with knowledge about various PA options. Barriers to implementing PA mentioned by the patients were lack of time; limiting disease, including musculoskeletal pain; bad weather

conditions; and aversion to physically hard work. In summary, this study highlighted the positive experiences of an individually customized PAP treatment with support from skilled healthcare providers during a long time period.

#### THE HEALTH CARE PROFESSIONAL'S PERSPECTIVE

In a 2002 questionnaire survey among 200 health care professionals mostly working in PHC, 70-90% had a positive view of working with lifestyle counseling and PAP (115); 95% considered that health promotion and disease prevention was a task for the health care system as an obvious part of every treatment, and their confidence in the ability to influence the patient's lifestyle habits regarding PA was high. Education in PA and PAP treatment knowledge were considered important, as well as structure, clarity, and simplicity concerning the PAP routines. The most common obstacle to working with lifestyle counselling and PAP was the lack of time and, notably, the lack of self-performed PA. In a qualitative study published in 2013, Persson et al (144) evaluated the GPs' perspective on PAP and reported four categories: The pharmacological treatment tradition makes it hard to change attitude, Shared responsibility with the care team is necessary, PAP has low status and is regarded with distrust, and Lack of procedures and clear guidelines complicate the use of PAP. The GPs commonly talked with their patients about the importance of being physically active but had no tradition of prescribing PA. There was insight into the need for teamwork with other professionals at the clinic, but the pressure of their work situation hampered this possibility. Though solid routines and working methods had been established for handling drugs, there was a lack of routine and knowledge in non-pharmacological methods, leading to uncertainty among the GPs as to which diseases and conditions should be treated with PA and how to prescribe PAP.

The PHC nurses perspective of PAP treatment was investigated by Bohman et al. (145) in 2015. The nurses experienced PAP as an important tool and an essential part of their everyday practice in supporting patients' health and well-being. They experienced that PAP treatment had gained a more prominent position, especially after the release of the National Guidelines (36) and an increased demand for PAP from the public. Having knowledge about

the PAP treatment processes, individualizing the PAP in accordance with the patient's wishes, having well thought-out work with motivational factors, and having a plan for continuous follow-up were seen as vital parts influencing the degree of adherence to PAP. Something that had to be dealt with sensitively was the fact that not all patients could afford all types of activities, and the possibility of subsidizing high-cost activities was considered to be important. Among barriers, the nurses experienced a lack of local organizational routines in PAP in which the follow-up was the most difficult to plan. These factors, in combination with stress, lack of time, and a low interest in and knowledge about PAP treatment among colleagues, were given as the main reasons why PAP was not used more often. In 2018, Gustavsson et al. (146) published an interview study with primary healthcare staff and management with the purpose of identifying the requirements for successful implementation of Swedish PAP treatment in PHC. The overarching theme was a need for knowledge and organizational support. There was low in-depth knowledge of the content and mode of use of all the core components, for which the written prescription was seen as equivalent to the PAP treatment. Increased knowledge and an affirmative attitude, a belief in the PAP treatment, among the health care professionals were seen as essential. The participants requested more interested, clear, and supportive management with the responsibility to make policies and guidelines well known and approved in the organization and to prioritize more resources, primarily with earmarked time for the PAP treatment. Having a centralized PAP support function within the health care organization responsible for coordinating PAP routines, expanding cooperation with PA organizers in the community, and educating co-workers were perceived to be important by all participants. The need to develop locally tailored PAP routines and appointing a local PAP coordinator at each HCC, and enhancing the cooperation with physiotherapists were also emphasized.

## Physical activity and behavioral change

#### Theoretical models of behavioral change

The purpose of using a theoretical model is to illuminate the processes of health-related behavior and to provide tools for health interventions on a societal, interpersonal, and individual level (147). A behavior change theory should be able to clarify the understanding of the objective of health behavior work and the contexts in which it is performed. The theoretical model should also provide tools to increase awareness of how we can go behind our intuition, our beliefs and opinions and provide a structure for designing and evaluating the work. Several theory-based models of behavioral change have been used in PA research, and Swedish PAP treatment is mainly based on the Social Cognitive Theory (SCT) and the Transtheoretical Model (TTM) (126).

### Social Cognitive Theory

The SCT emphasizes the interaction between personal, behavioral, and environmental influences in the way we learn and modify our behaviors (148). Perceived self-efficacy, i.e. an individual's judgement of their capability to organize and execute courses of action, is a key factor (149) that, together with goals, outcome expectations, and perceived facilitators and impediments, regulates human motivation, behavior and well-being (150). The SCT is broad and addresses health behaviors to maintain or increase health, reduce the risk of disease and manage long-term illnesses. This model has frequently been used as a basis for changes in PA behaviors by incorporating a behavioral process that is described as dynamic and constantly ongoing (147, 151).

### Transtheoretical Model

In the TTM, behavior change is explained as a dynamic process involving movement through a series of stages of change (152, 153). The model explains the individual's readiness to change in five stages:

- Precontemplation Individuals are physically inactive and not considering changing PA behavior in the near future.
- Contemplation Physically inactive individuals have an intention to change their PA behavior in the near future. This stage is interconnected with ambivalence concerning the costs and benefits of the behavioral change.
- Preparation Individuals intend to take action, making a serious commitment to changing their PA behavior and taking some steps towards PA, but not regularly.
- Action Behavioral change is initiated and the individuals are physically active for less than 6 months. This stage is considered as an unstable stage with a high risk of relapse.
- Maintenance Individuals are currently physically active and have been for more than 6 months.

The stages of change are described as a steady linear progression but could probably be cyclical, with individuals making several attempts before reaching the maintenance stage. Apart from the five stages of change, the TTM also includes processes of change (cognitive/thinking processes and behavioral/doing strategies), decisional balance (weighing the pros and cons of changing), self-efficacy, and temptation (the will to engage in PA when in the midst of difficult situations) (151, 153).

### Behavioral change processes

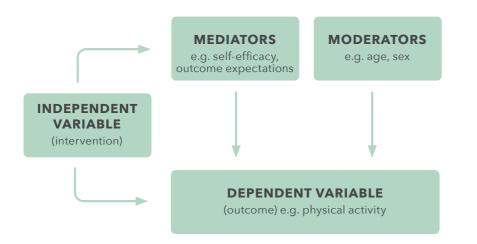
Evidence from PA promotion research has demonstrated the importance of incorporating theory-driven intervention to complete an ERS and embrace behavioral change techniques for the adoption and maintenance of a physically active lifestyle (105). The transtheoretical model of behavior change and social cognitive theory, alongside behavioral change techniques, such as motivational interviewing, are underutilized tools used in health care to support ERSs (106). In a systematic review published in 2019, Eynon et al. (97) found that intrinsic motivation, psychological need satisfaction, social support, and self-efficacy were the prominent psychosocial factors associated with ERS adherence. In addition, patients with lower expectations for change when entering the scheme had greater opportunity to adhere to the ERS.

### Correlates of physical activity change

Evaluating factors correlating with a change in PA is a way of understanding individual enablers and barriers to changing PA behavior (151, 154). More research is needed to explore the correlates affecting adherence to a PA intervention and the mechanisms essential for a change in PA behavior in experimental PA studies (155). Correlates of PA are defined as intervening causal variables creating a cause-effect pathway between an intervention and PA in which changes in the variables could lead to changes in PA (151, 154, 156). Correlates of PA that can be changed are referred to as mediators (e.g., self-efficacy, outcome expectations) and are a focus of PA intervention strategies (151, 157, 158). Some correlates of PA cannot be changed and are referred to as moderators, or effect modifiers (e.g., age, sex) (156, 159, 160). These factors affect the direction and strength of the relationship between a PA intervention and the outcome, and may be used to identify target groups (Figure 4).

In previous PA research, several possible correlates of PA have been identified but are in need of further research in experimental studies (158, 161). Factors that are interesting related to PA behavior change are listed below:

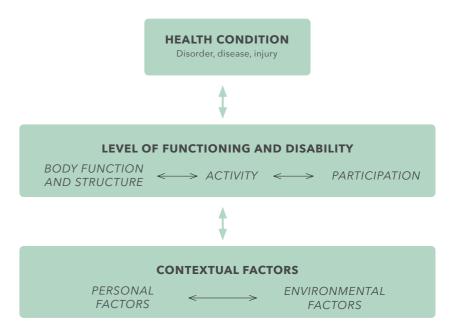
- Self-efficacy expectations Originating from SCT and are defined as the belief in the capability to perform PA (162).
- Outcome expectations Based on SCT and the self-efficacy concept and are defined as the belief that a specific PA will contribute to a desired outcome (163).
- Enjoyment From the expectancy-value theories, enjoyment can be defined as a positive affective state, reflecting feelings such as pleasure, liking, and fun (164).
- Social support Based on SCT and includes dimensions such as the structure of social relationships enhancing an individual to perform PA and moving toward a goal (165).
- Readiness to change Based on the principles of TTM in which the stages of change are an attempt to describe the readiness to change. The individual's feelings about importance (why should I change?) and confidence (how will I do it?) contribute to the state of readiness to change (166).



**FIGURE 4.**The role of correlates of physical activity behaviour change. Adapted after Baranowski et al. (157) and Biddle et al. (151).

### The physiotherapeutic perspective

Physiotherapy encompasses knowledge of the human as a physical, mental, social, and existential whole from a health perspective (167). Models and theories in physiotherapy are based on the concept of movement as both goals and means aiming at developing, maintaining, and restoring maximum movement and functional ability to individuals and populations throughout their lifespan (167–169). The physiotherapy approach is generally used within a person-centered context, and the physiotherapist is qualified to intervene in different areas of promotion, prevention, treatment/ intervention, habilitation, and rehabilitation. A generally accepted framework for the multidimensional description of functioning and disability in rehability, and Health (ICF) (169). The ICF provides a classification of health and health-related domains, including the bio-psycho-social perspective, and offers a basis for a successful rehabilitation strategy, practice, and research (170–173) (Figure 5).



**FIGURE 5.** Interactions between the different components in the ICF model of functioning and disability. Adapted after WHO ICF (169) and Geidl et al. (170).

In the ICF, functioning and disability are seen as outcomes of interactions between a *health condition* (disease, disorder, or injury) and *contextual factors*, such as *personal factors* (e.g., gender, age, social background, education, behavior pattern) and *environmental factors* (e.g., social attitudes, legal and social structures, architectural characteristics). The ICF further identifies three levels of functioning: functioning at the level of body/body part (*body functions and structure*), the whole person (*activity*), and the whole person in a social context (*participation*). Personal and environment factors interact with a health condition and determine the level and extent of disability and functioning (169, 170). Using the ICF-based concept and integrated health behavior change theories concerning personal factors, such as an individual's attitudes, skills, emotions, beliefs, and knowledge, gives the physiotherapist an enhanced possibility of promoting long-term changes in PA behaviors for patients with chronic diseases (170).

Health care systems have been criticized for the lack of action concerning non-pharmacological interventions in lifestyle-related NCDs (174), and PA is one of the cornerstones. Physiotherapists are in a pre-eminent position to work with PA, as the profession is educated in understanding the body, its movement and function, and interaction with others and the environment (167, 169, 175). As non-invasive health care practitioners, the physiotherapists are uniquely qualified to offer patients, at all health levels, support in the behavioral change process towards increased PA levels. For the 21<sup>st</sup> century, physiotherapists need to reflect and act in line with global and regional public health strategies, as we know that lifestyle modification (e.g., increased PA level) is probably the single most powerful strategy a clinician can use to maximize health (176).

### The physiotherapist's role in PAP treatment

PAP treatment is useful for physiotherapists embracing health-focused practice with every patient. The individualized parts of Swedish PAP treatment, including the individually tailored PA recommendation, requires an approach that advances health-focused physiotherapy and changes in health behaviors as a clinical competency. Although some Swedish PAP studies have involved physiotherapists (127, 131, 134, 137, 177, 178), showing evidence for increased PA, and there has been an increasing use of PAP among Swedish physiotherapists during the last few years (128), PAP is still underutilized as a treatment strategy among physiotherapists in Sweden. However, decisions have been made in recent years concerning national, regional, and local supporting structures for the implementation and use of PA and PAP in Swedish health care (36, 47, 125, 128). Physiotherapists are considered to be particularly suited for using PAP treatment for patients with complex health disorders (146, 178), but need to increase their knowledge, belief, and self-efficacy (179) in using the PAP treatment. The physiotherapists, as well as other licensed healthcare professionals, also request more resources, primarily time, earmarked for the work with PAP in daily clinical practice. Dean E. (175) proclaimed that it is a primary professional and ethical responsibility of every physiotherapist to ensure that lifestyle interventions, including PA, are being used to promote lifelong health among patients across all settings.

### Health economic analysis

## Standard methods for health economic evaluation in health care

One important reason to perform health economic evaluations is the more and more prominent role of health care in a public economy in which approximately 11 % of the Swedish gross national product (GDP) is used in the health care sector (180). The resources needed to produce health care are limited at the same time as the use and users of health care resources can be boundless (181). Economic evaluation has broad applicability in health care for examining the usefulness, efficacy, and availability of two or more health interventions in terms of their costs and consequences (182). This information gives health care decision-makers the possibility of prioritizing the use of scarce health care resources. The Swedish Health and Medical Service Act (2017, 4 kap, 1 §) states that all publicly funded health care activities must be organized so that it promotes cost-effectiveness. Health economic evaluations are used when comparing two different treatment methods to determine, for example, if one treatment is more cost-effective to use before the other treatment, or when a more expensive treatment with superior outcome is compared to a cheaper treatment with inferior outcome.

In general, four methods are used for the economic evaluation of interventions in health care, but this thesis uses a cost-utility analysis, a kind of cost-effectiveness analysis (CEA). According to the WHO's recommendations, CEAs should be used in health care when the benefit of an intervention (health improvement) results in a gain in welfare and the costs represent the welfare forgone because the resources could not be used in the next-best alternative (183). In conducting an analysis in the health sector, the concept of need instead of demand, and health instead of utility, is an especially important aspect of welfare functions (i.e., the extra-welfare framework) (184). Measurement of personal and interpersonal changes in the health care sector should be based on the health state of the individual. To optimize the comparison between two treatment options, preference-based generic outcome measures regarding patient benefits are recommended when the effect is measured in HRQOL. The most common health-related benefit measure is quality adjusted life year (QALY); in this thesis it is based on the answers to the SF-36 survey instrument, which was transformed to the Short Form 6 Dimensions (SF-6D) health state classification measuring six health dimensions: physical functioning, role limitations, social function, pain, mental health, and vitality (185). The QALY weights include the effects on life-span and HRQOL using a scale from 0 (death) to 1 (perfect health) (186).

In CEAs, both costs and patient benefits are taken into account when comparing two treatments, and the difference in costs and benefits between the treatments constitutes the incremental cost-effectiveness ratio (ICER) (Figure 6). The ICER indicates the cost per unit of patient benefit in the evaluation treatment compared to the comparative treatment.

ICER = \_\_\_

∆Cost

Patient benefit – Patient benefit

 $Cost_a - Cost_b$ 

 $\Delta$  Patient benefit

FIGURE 6. Incremental cost-effectiveness ratio.

Economic analyses can be performed from different perspectives. A health care perspective includes only direct intervention costs and costs for health care resource use. A societal perspective includes all costs wherever they occur (direct and indirect costs), including costs for health care, other public sectors, private sector, patients, and other individuals, and should be considered in the evaluation. In this thesis (Paper IV), the societal perspective includes the cost of production loss due to sick leave, individual expenses for PA, and the cost of time the patient spent in PA.

Evaluations of cost-effectiveness in health care have been recommended to be done from both a health care perspective and a societal perspective, along with an impact inventory to clarify included consequences (187). This is the most appropriate perspective for decisions about the allocation of scarce health resources. In this thesis (Paper IV), both a health care perspective and a societal perspective were used in the CEA.

### Costs of physical inactivity

There is a broad impact on societal costs due to physical inactivity that is difficult to determine because only a fraction of the costs can be estimated (188). Both direct costs (health care resources used) and indirect costs (productivity loss due to work disability and mortality) should be included, representing the cost of illness (189). Physical inactivity is responsible for a substantial economic burden, with a conservatively estimated global cost for health care systems of \$53.8 billion in 2013, and a productivity loss of \$13.7 billion (190). Physical inactivity was also responsible for 13.4 million disability adjusted life years (DALYs) worldwide when estimated for coronary heart disease, stroke, type 2 diabetes, and breast and colon cancer. In Sweden, Bolin K. (191) compared productivity losses and health care costs due to physical inactivity for the years 2002 and 2016. In this analysis, the PA habits among Swedes improved somewhat between the 2 years, and the economic costs decreased (from 6.6 billion SEK 2002 to 4.7 billion SEK 2016). At the same time, the health care costs attributable to physical inactivity as share of total healthcare expenses increased from 0.86% in 2002 to 0.91 % in 2016. The calculation of relative risks for disease included ischemic heart disease, hypertension, stroke, depression and anxiety, breast cancer, colon cancer, osteoporosis, and type 2 diabetes. The analysis did not

include the costs associated with the use of pharmaceuticals and the cost of productivity losses due to temporary illness caused by the diseases, which probably affects the outcome. The author concluded that the adverse health effects associated with physical inactivity cause large economic costs. Initiatives aiming at achieving improvements in PA habits are likely to be costeffective, or even cost-saving.

## Cost-effectiveness of physical activity interventions in health care

The evaluation of PA interventions in health care have to be prioritized within a restricted budget, competing with other medical treatment therapies. Stakeholders need evidence for improvements in PA levels and its associated costs to be able to prioritize interventions. A CEA can be used for this purpose. The result of a CEA in health care, the costs per gained QALY, has to be assessed against the willingness to pay for a gained QALY (cost-effective-ness threshold) in the country where the analysis is done. In Sweden, the National Board of Health and Welfare has categorized the cost-effectiveness according to Table 1 below (192).

**TABLE 1.** Categorization of cost-effectiveness – the National Board of Health and Welfare.

Costs per QALY	Cost in relation to health benefits
<100,000 SEK	Low
100,000-500,000 SEK	Moderate
500,000-1,000,000 SEK	High
> 1,000,000 SEK	Very high

There are some discrepancies in the cost-effectiveness findings in primary care- and community-based PA interventions.

A systematic review of nine studies by Garrett et al. (193) found a cost per QALY varying from €348 to €86,877 or, based on the higher-quality studies, between € 1,120 and € 15,860 per QALY gained. Most PA interventions in the review were considered cost-effective compared to international thresholds for acceptable levels of publicly funded interventions and compared to the cost-effectiveness in many pharmaceutical interventions. The authors highlighted some complicating factors, such as the variability of interventions, outcome measures, population groups, and different health systems, which made the comparison between studies and different countries difficult. Thus, it was difficult to conclude which type of intervention was most cost-effective. However, primary care-based Exercise on Prescription (the "green prescription" intervention in New Zealand, similar to Swedish PAP treatment) (194) was mentioned as a possible cost-effective intervention. In another systematic review, Vijay et al. (195) evaluated the cost-effectiveness of brief interventions promoting PA in primary care or community settings. The brief interventions were grouped into brief exercise advice, exercise on prescription, pedometers, and motivational interviews. In 9 of 13 included studies, the cost-utility was estimated to range from £57 to £14,002 per QALY (The National Institute for Health and Care Excellence (NICE) threshold: £20,000-£30,000/QALY) (196). In summary, brief interventions in primary care and community settings, especially pedometers used as a motivational tool or in combination with exercise advice, increased individual's PA levels at reasonable cost and were cost-effective. The authors requested more long-term interventions to improve the estimates of the longer term costs and benefits of PA.

Hagberg et al. (197) studied 26 studies concerning healthcare-based PA interventions and concluded that the promotion of PA could be cost-effective, but a lack of evidence is available for which specific method should be used for a specific population. Most of the evidence of cost-effectiveness was found for older people and individuals with manifest physical inactivity-related poor health and heart failure. It was not possible to rank the cost-effectiveness between the studies due to the short study period ( $\leq 1$  year), not evaluating both preventive and treatment effects, a concentration on one disease-specific outcome and not on additional health gains for the participants,

and not estimating savings from PA in the form of increased productivity. The authors also claimed that the cost estimates were incomplete, and the value of participants' time spent on PA was lacking.

A few studies have evaluated cost-effectiveness of PA interventions in adult patients in PHC in Sweden. Lindgren et al. (188) evaluated a combination of PA advice from GPs, the use of an activity log, and the opportunity to participate in group exercise and concluded that this was a good strategy. The ICER of the PA intervention was 180 470 SEK per life-year gained compared to no intervention, and was considered cost-effective. Romé et al. (198) randomized primary care patients to a high-dose group, including education, motivational counseling, and supervised group exercise sessions twice a week vs. a low-dose group including written information and moderate-intensity group exercise once a week. The low-dose group was more cost-effective, with a cost per QALY of  $\in$  11,339 compared to  $\in$  36,256 for the high-dose group.

In the Björknäs study, Eriksson et al. (199) targeted a population at moderate-to-high risk for CVD in ordinary PHC and showed that a 3-month PA and diet intervention with scattered follow-up meetings over 3 years was highly cost-effective relative to standard care. At a 3-year follow-up, the cost per gained QALY was between \$1,668 and \$4,813. The authors declared that the main reason for cost-effectiveness was probably the long-time contact with the patients and the sustainable increases in PA and HRQOL. The cost-effectiveness was probably underestimated in the study, where only a treatment perspective and not the preventive effects were analyzed. The control group also received more lifestyle-related promotion than is usual in standard PHC. Another primary care-based PA and diet intervention is the Kalmar metabolic syndrome program (KMSP), in which Feldman et al. (200) analyzed cost-effectiveness based on the patient's risk profile (low, middle, high). Despite heterogeneity in the cost-effectiveness over the risk groups, the program was cost-saving for middle- and high-risk men, while cost per gained QALY was € 3,500-€ 18,000 for other groups compared to do-nothing. Even in this study, the cost-effectiveness was probably underestimated due to a decrease in medication among patients with cost savings not included in the analysis. Furthermore, the analysis did not consider the preventive effects of lifestyle changes for other health problems. Cost-effectiveness of PAP interventions in health care According to the cost-effectiveness of Exercise Referral Schemes (ERSs), Campbell et al. (101) evaluated eight RCTs in a systematic review. This health technology assessment report was pooled with existing data from a previous review by Pavey et al. (201). The CEA indicated that the ICER for ERSs compared to usual care was approximately £76,000 per QALY, with considerable uncertainty in the sensitivity analysis. There were limitations with the model for the CEA, e.g., there were estimates of the impact of PA on only one selected morbidity at a time (obesity, hypertension, or depression) and an assumption that these subgroups of patients had the same efficacy of ERS as the general population. The model also excluded any long-term benefits of PA that fall outside the three morbidity groups.

Virtually no cost-effectiveness evaluations have been done for the Swedish PAP treatment. An unpublished paper in a thesis by Romé Å. (198) evaluated a 4-month prescribed physical activity (PPA) intervention for 528 physically inactive primary care patients with lifestyle-related health problems, with a 1 year follow-up. The high-dose group was offered supervised group exercise sessions twice a week and additional education and informational meetings; the cost per gained QALY was € 36,256. For the low-dose group, which received information about local fitness centers with the possibility to participate in supervised exercise groups, had a cost per gained QALY of €11,339. The cost in relation to health benefit was considered moderate for the high-dose group according to Swedish reference values, whereas the low-dose group was even more cost-effective. However, the intervention was not individualized according to the core elements of Swedish PAP treatment; thus, the study excluded from a systematic review analyzing Swedish PAP interventions (121). Notably, there was a drop-out rate of 66 % in both groups combined, with the author paying attention to the need to identify the right target group for this type of primary care program (198). Another unpublished paper in a thesis by Rödjer L (202) analyzed non-randomized lowsupport vs. high-support PAP intervention conducted by physiotherapists at a wellness center, including 144 primary care patients. The high-support intervention appeared to be very cost-effective compared to the low-support intervention, with an ICER of \$4,299. The PAP intervention in this study was individualized to the needs of each patient to a greater extent, but the amount of support makes this intervention seen as a reinforced, not an ordinary, PAP intervention.

# Aims and objectives

### Aims

The overall aim of this thesis was to evaluate the Swedish physical activity on prescription (PAP) treatment regarding physical activity (PA) level, metabolic health, and health-related quality of life (HRQOL) for physically inactive patients with metabolic risk factors, and to explore correlating factors that possibly predict increased levels of PA. The aim was also to evaluate the PA level, metabolic health, HRQOL, and cost-effectiveness of two different PAP strategies, supported by either a physiotherapist or by the health care center (HCC), for patients who had not achieved a sufficient level of PA after a prior 6-month period of PAP treatment.

### Objectives

- To explore the association between PAP treatment at the HCC and the PA level of patients with metabolic risk factors, and the relationship between changes in the PA level and changes in metabolic risk factors and HRQOL at the 6-month follow-up (Paper I).
- To explore potential predictive factors for increased PA in a 6-month period of PAP treatment at the HCC and to identify the patients in primary care most likely to benefit from a PAP intervention (Paper II).
- To evaluate two different strategies for PAP treatment, supported by either a physiotherapist or by the HCC, for patients with insufficient PA levels after a prior 6-month period of ordinary PAP treatment in a primary health care setting. In this 2-year intervention, PA level, metabolic health, and HRQOL were analyzed (Paper III).
- To evaluate the cost-effectiveness of the physiotherapist strategy compared to the HCC strategy of PAP treatment over a 3-year period. Both a societal perspective and a health care perspective was used. (Paper IV).

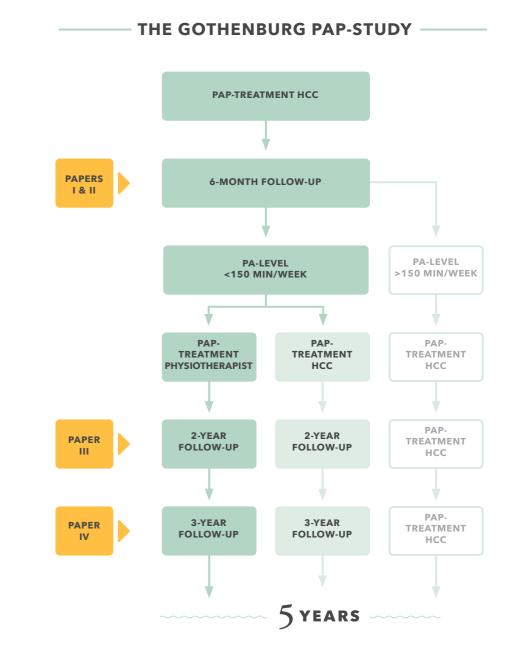
## Methods

The study included 444 adult patients who were physically inactive with metabolic risk factors and participated in PAP treatment in ordinary primary health care at one of 15 HCCs in Gothenburg. At the 6-month follow-up, changes in PA level, metabolic risk factors, and HRQOL were analyzed (Paper I). Eight baseline correlates of PA change were also evaluated in a predictor analysis against the PA level at the 6-month follow-up (Paper II).

At the 6-month follow-up, 190 patients who had not achieved a sufficient PA level were randomized to either continued PAP treatment at the HCC (n = 92) or enhanced support from a physiotherapist (PT group, n = 98) in which the PAP treatment was supplemented with more frequent scheduled follow-ups and aerobic fitness tests. After a 2-year intervention, the PA level, metabolic health, and HRQOL were evaluated (Paper III), and after a 3-year intervention a health economic analysis was performed to compare the cost-effectiveness of the physiotherapist vs. HCC intervention (Paper IV).

### Study design

The four papers were part of the ongoing *Gothenburg PAP study*, with a total 5-year follow-up of PAP treatment in primary health care. Several research studies were published under the *Gothenburg PAP study* but not included in this thesis. Papers I and II were a 6-month prospective longitudinal observational study; Paper III was a 2-year randomized controlled trial; and Paper IV was a 3-year health-economic cost-effectiveness study (Figure 7). Paper II was retrospectively registered on July 17, 2018 (Clinical Trials NCT03586011) and Paper III on December 30, 2016 (Clinical Trials NCT03012516). Papers I and IV were not deemed necessary to register.





### Ethical approval

All studies followed the World Medical Association (WMA) Declaration of Helsinki, and ethical approval was obtained from the Regional Ethical Review Board in Gothenburg, Sweden, for Papers I and II (Dnr 678–14) and Papers III and IV (Dnr 529–09). All patients received written and verbal information about the study and agreed to participate. The patients were informed about the volunteer nature of the study and the possibility of withdrawing at any time without stating a reason and that this decision would not affect any future treatment or health care for the patient.

### Study population

The study population included 444 patients, aged 27–85 years, and was selected as a convenience sample from 15 primary HCCs in Gothenburg during 2010 to 2014. The patients were physically inactive according to the recommended minimum PA level of 150 min/week (45), had at least one metabolic risk factor (203), and had accepted to commence PAP treatment. To fill in the questionnaires, the patients also had to understand the Swedish language (*Appendix*).

The patients enrolled in the study were from a population of 220,000 inhabitants in central/western parts of Gothenburg, Sweden, which have a higher socio-economic status than Gothenburg overall. The mean age of the patients was 57 years, and 56% were female. A majority had at least two metabolic risk factors, 61% were taking medications for these risk factors (Table 2), and the mean BMI was 32 kg/m<sup>2</sup>, with a waist circumference of 104 cm for women and 113 cm for men (Table 3). The self-assessed PA level was low using all four PA instruments (see measurements below); 36% of patients were sedentary according to the Saltin-Grimby Physical Activity Level Scale (SGPALS) and almost half of the patients reported <1 hour/week of moderate intensity PA according to the American College of Sports Medicine and American Heart Association (ACSM/AHA) questionnaire (Table 4).

TABLE 2. Baseline characteristics of all patients included.

Variable ª (n)		
<b>Age</b> , years (444)	57.5 (11.3)	
<b>Sex</b> (444)		
Female	251 (56.5)	
Male	193 (43.5)	
Nationality (436)		
Sweden	374 (85.8)	
Other	62 (14.2)	
Social situation (428)		
Single	170 (39.7)	
Married/ cohabit	238 (55.6)	
Other	20 (4.7)	
<b>Economy</b> , perceived (430)		
Good	249 (57.9)	
Neither nor	126 (29.3)	
Bad	55 (12.8)	
Education (432)		
Elementary grade	83 (19.2)	
Upper secondary school	167 (38.7)	
University college	182 (42.1)	

Continued below.

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Variable ª (n)	
<b>Tobacco</b> (431)	
Smokers	44 (10.2)
Non-smokers	270 (62.7)
Ex-smokers	117 (27.1)
<b>Part of metabolic syndrome</b> (436)	
Overweight/Obesity	404 (91.2)
Hyperglycaemia	174 (40.0)
Hypertension	346 (78.5)
Hyperlipidaemia	253 (57.5)
Other diagnosis	
Mental health, depression	65 (14.9)
Musculoskeletal disorders	77 (17.7)
Other	193 (44.2)
Drug treatment (436)	
Overweight/Obesity	2 (0.5)
Hyperglycaemia	59 (13.6)
Hypertension	236 (54.1)
Hyperlipidaemia	94 (21.6)
Other drug treatment	
Mental health, depression	64 (14.7)
Musculoskeletal disorders	60 (13.8)
Other	167 (38.3)

<sup>a</sup> Age data are given as mean (standard deviation) and data for other variables are given as number (percentage).

**TABLE 3.** Baseline characteristics in anthropometrics, metabolic risk factors, and health related quality of life – all patients included.

Variableª (n)	
BMI, kg/m² (439)	32.2 (5.3)
Waist circumference, cm	
Women (244)	104.2 (12.5)
Men (191)	113.0 (12.4)
Blood pressure, mmHg	
Systolic (440)	137.1 (17.7)
Diastolic (439)	82.2 (10.2)
Metabolic components, mmol/l	
Fasting plasma glucose (431)	6.3 (1.9)
Triglycerides (437)	1.7 (1.0)
Cholesterol (439)	5.6 (1.2)
HDL (440)	1.4 (0.5)
LDL (435)	3.6 (1.1)
HRQOL SF-36, score	
Physical functioning (431)	79.3 (19.8)
Role limitation, physical (424)	67.9 (38.4)
Bodily pain (430)	65.0 (27.2)
General health (429)	59.3 (20.5)
Vitality (432)	51.1 (23.4)
Social function (431)	77.2 (26.2)
Role limitation, emotional (423)	70.5 (40.4)
Mental health (432)	71.0 (20.3)
Physical component summary (418)	45.0 (10.1)
Mental component summary (418)	43.7 (13.5)

BMI, body mass index; LDL, low density lipoprotein; HDL, high density lipoprotein; HRQOL SF-36, Health Related Quality of Life 36-Item Short Form Health Survey. <sup>a</sup> Data are given as mean (standard deviation).

TABLE 4. Baseline characteristics - Physical activity level.

Variable (n)	
ACSM/AHA questionnaire, score (440) <sup>a</sup>	1.7 (1.5)
IPAQ, total MET-minutes/week (361) <sup>b</sup>	693 (297-1386)
SGPALS 1-4, score (433) <sup>c</sup>	2 (1-3)
SGPALS 1-4, category, No (%)	
• 1	158 (36.5)
• 2	268 (61.9)
• 3	7 (1.6)
• 4	0
Frändin/Grimby 1-6, score (434) <sup>c</sup>	3 (1-5)
Frändin/Grimby 1-6, category, No (%)	
• 1	31 (7.1)
• 2	75 (17.3)
• 3	243 (56.0)
• 4	81 (18.7)
• 5	4 (0.9)
• 6	0

ACSM, American College of Sports Medicine; AHA, American Heart Association; IPAQ, International Physical Activity Questionnaire; MET, metabolic equivalent; SGPALS, Saltin-Grimby Physical Activity Level Scale.

Values are given as <sup>a</sup> mean (standard deviation), <sup>b</sup> median (25-75 percentile) or <sup>c</sup> median (minimum-maximum).

### Papers I and II

The 444 patients who started the PAP intervention, 368 completed the 6-month follow-up, with a dropout rate of 17 %. An overview of the study population and drop-outs at the 6-month follow-up is presented in Figure 8. When comparing baseline characteristics between the completer's and the dropout group (n = 76), there was a higher proportion of women and patients who had musculoskeletal disorders, and a lower HRQOL in the dropout group. There were also some baseline differences between the women and men, with inferior HRQOL for women and inferior values for metabolic risk factors among men.

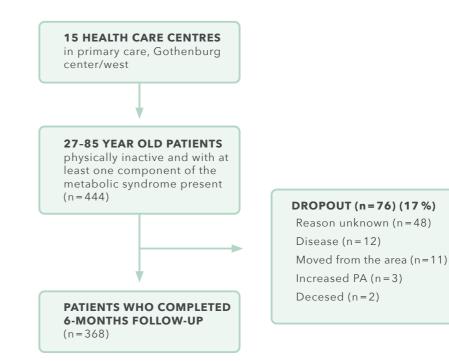


FIGURE 8. Flow of patients involved in paper I and II.

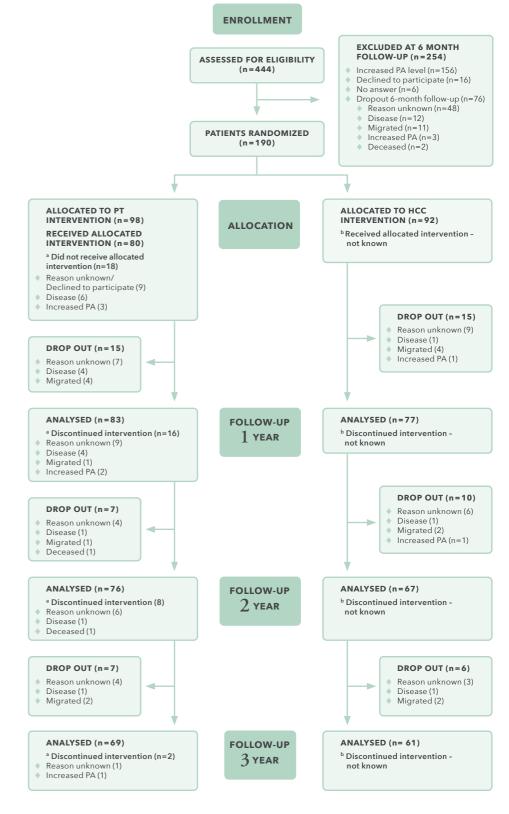
### Papers III and IV

Of the 368 patients who completed the 6-month follow-up, 190 were still insufficiently physically active (PA level <150 min/week). All of these patients were asked and agreed to participate further. They were randomized to either continued ordinary PAP treatment, the same as the previous 6-month treatment, with support from nurses at the HCC (n = 92), or enhanced PAP treatment, with support from a physiotherapist (PT group, n = 98). An overview of the study population, drop-outs, and patients not receiving allocated intervention over the 2 vs. 3-year follow-up is presented in Figure 9.

FIGURE 9. Flow of patients involved in paper III and IV.

<sup>a</sup> A majority of the patients in the PT-group not receiving allocated intervention or discontinuing intervention was attended to 1, 2 and 3 year follow-up.

<sup>b</sup> The number of patients in the HCC-group not receiving or discontinuing intervention is not known dependent on non-access to the patient's medical record with the current information.



### Intervention

### PAP treatment at the health care center

All licensed professionals were educated in the health effects of PA according to the *Physical activity in the prevention and treatment of disease* (FYSS) (3) and the concept of the Swedish PAP treatment (119). Authorized personnel, mainly nurses, at the HCCs were involved in the study and provided PAP treatment to the patients. The PAP treatment included an individualized dialogue about PA, an individually dosed PA recommendation, including a written prescription, and an individually adjusted follow-up. PAP treatment is part of person-centered care, taking into account the patient's knowledge, experiences, and needs (204, 205), and is commonly based on the principles of motivational interviewing (MI) (122).

The patient's previous and current level of PA and their preferences for various physical activities; the patient's motivation, self-efficacy, and readiness to change their PA behavior; and the patient's health status were evaluated. This information served as the basis for discussing appropriate goal setting with an increased level of PA, discussing the relevance of decreasing sedentary time and increasing low-intensity daily activity. The information also provided the opportunity to select a more vigorous-intensity PA. An individually dosed PA was agreed upon and written down at the appropriate relative intensity using the Borg's rate of perceived exertion scale (82), as well as duration and frequency. To help the patient choose a suitable PA, a registry of the local supply of PAs was presented. The acknowledged PA was performed by the patient outside the health care system, and the most frequently approved PA was moderate-intensity walking, 30–45 min/episode, 2–5 times/week, to be carried out individually in everyday life.

In the prescription, there was a possibility to fill in two different types of PA, which allowed the patient to switch between activities (e.g., walking 2 times/week and gymnastics 1 time/week). There was also a possibility for the patient to choose an outdoor PA during the warmer seasons and an indoor PA during winter, as Sweden has to deal with snow, ice, and polar bears during this period. The first meeting with the patient lasted approximately 60 minutes.

The patients were offered individually adjusted support during the PAP intervention period, either by revisits or telephone contacts. At the revisit, the patient's motivation, self-efficacy, and readiness to change their PA behavior were re-evaluated. The content of the prescription regarding goal-setting, sedentary time, and low-intensity daily activities was discussed and the choice and dose of PA possibly revised. Each revisit session lasted 30 to 45 minutes. During the first 6-month period of PAP treatment, the majority of the patients (80%) visited the PAP-providing nurse 1 to 2 times, including the 6-month follow-up visit.

### PAP treatment by physiotherapist

The physiotherapists that provided PAP treatment in Papers III and IV were educated in PAP. The PAP intervention included the same first two parts of treatment as described for the HCCs: an individualized dialogue about PA and an individually dosed PA recommendation, including a written prescription. The third part of treatment (the follow-up) differed and was arranged via a fixed follow-up schedule. Patients were followed up 6 times during the first year of the intervention (at 4 weeks, 10 weeks, 4 months, 6 months, 9 months, and 1 year), three times during the second year (at 15 months, 18 months, and 2 years), and one time at the 3-year follow-up (Table 5).

The physiotherapist also provided an added aerobic physical fitness test  $(VO_2max)$ , performed on an ergometer bicycle (3 tests in the first year; 1 test at the 2 and 3-year follow-ups; Table 5). The results from the ergometer bicycle tests provided the basis for a continuing motivating dialogue about PA and an individually dosed PA recommendation. The agreed recommendations were written in the prescription regarding the appropriate frequency, duration, and intensity of PA.

**TABLE 5.** Overview of the aerobic physical fitness tests provided by physiotherapist.

	Time	Ergometer cycle test
1	Baseline	$\checkmark$
2	4 week	
3	10 week	
4	4 months	$\checkmark$
5	6 months	
6	9 months	
7	1 year	$\checkmark$
8	15 months	
9	18 months	
10	2 year	$\checkmark$
11	3 year	$\checkmark$

### Data collection

All measurements were performed by the nurses at the HCCs at baseline and 6 months for Papers I and II. For Papers III and IV, the 6-month follow-up was the new baseline, as the subgroup of insufficiently physically active patients included in these studies were randomized from there. The measurements were then performed at the 1, 2, and 3-year follow-ups. An overview of measurements in each paper is presented in Table 6.

### **TABLE 6.** Overview of outcome measurements.

Paper I	<ul> <li>PA level - ACSM/AHA, IPAQ, SGPALS, Saltin-Grimby 6-grade</li> <li>BMI, WC, SBP, DBP, FPG, TG, Chol, HDL, and LDL</li> <li>HRQOL SF-36</li> <li>Readiness to change-VAS</li> <li>Frequency of PAP-support from caregivers</li> </ul>
Paper II	<ul> <li>PA level - ACSM/AHA</li> <li>BMI</li> <li>HRQOL SF-36</li> <li>Correlates of PA change - Self-efficacy expectations, Outcome expectations, Enjoyment, Social support, Readiness to change</li> </ul>
Paper III	<ul> <li>PA level - ACSM/AHA, IPAQ</li> <li>BMI, WC, SBP, DBP, FPG, TG, Chol, HDL, and LDL</li> <li>HRQOL SF-36</li> <li>Changes in medication, Frequency of PAP-suppor from caregivers</li> </ul>
Paper IV	<ul> <li>HRQOL SF-36, SF-6D</li> <li>Intervention costs, Health care costs, Sick leave</li> <li>Individual expenses and Time costs related to PA</li> </ul>

### Physical activity

The PA level was the primary outcome and four self-reported PA questionnaires were used: two global instruments scoring 1–4 or 1–6 levels of PA during the last year, and two 7-day recall instruments including time in MVPA, time walking, and time spent sitting during the last 7 days. Multiple questionnaires were used due to the known complexity of PA assessments.

- A questionnaire based on the American College of Sports Medicine (ACSM) and American Heart Association (AHA) public health recommendations was used (64). The questionnaire was included in the working document during the time that new indicator questions regarding PA were evaluated and validated by the Swedish National Board of Health (206). The last 7 days of PA were investigated, and the patient responded to two PA questions (ACSM/AHA questionnaire), with 30 min/day of moderate-intensity PA resulting in 1 point and 20 min/day of vigorous-intensity PA resulting in 1.7 points during each specific day of the week. A value ≥5 points indicated a sufficient PA level. The vigorous-intensity question has been used in previous studies, supporting the construct validity of the measure (207, 208).
- 2. International Physical Activity Questionnaire Short Form (IPAQ), assessing the level of PA during the last 7 days (209). The IPAQ measures three specific types of PA as separate scores (duration in minutes and frequency in days): walking, moderate-intensity activities, and vigorous-intensity activities. The scores are presented as median metabolic equivalent (MET)-min/week, and a total MET-min/week can be summarized. The IPAQ also calculates a categorical score (low-moderate-high) in which the moderate level corresponds to a PA level of at least 600 MET-min/week, a level equivalent to the international public health recommendation (45). The instrument is translated into Swedish and has acceptable test-retest reliability, concurrent validity, and criterion validity for adults (209, 210).

- 3. The Saltin-Grimby Physical Activity Level Scale (SGPALS) assesses leisure time PA during the past year at four different levels, from *seden-tary/physically inactive* to *vigorous physically active* (211). The levels have been validated against metabolic risk factors (212, 213) and the SGPALS has been published in an updated Swedish form (214).
- 4. The Saltin-Grimby six-grade PA scale includes household activities (215). The scale is divided into six categories ranging from *hardly any physical activity* to *hard or very hard exercise regularly and several times a week* (216, 217). This scale correlates with physical performance and self-assessed fitness and is used to classify PA among the elderly (218).

### Metabolic risk factors

Anthropometrics: Body weight was measured to the nearest 0.1 kg using an electronic scale with the patient wearing light clothing and without shoes. Body height was also measured in an upright position without shoes to the nearest 0.5 cm using a scale fixed to the wall and the body mass index (BMI) calculated. Waist circumference (WC) was measured to the nearest 0.5 cm in a standing exhaled position, with a measuring-tape placed on the patient's skin between the lower rib and the iliac crest.

**Blood pressure:** Systolic and diastolic blood pressure (SBP and DBP, respectively) were measured in mmHg according to guidelines (219) after 5 min rest with the patient seated using a blood pressure sphygmomanometer attached to the right upper arm at the level of the heart.

**Blood samples** were used to measure (in mmol/l) fasting plasma glucose (FPG) after overnight fast, triglycerides (TG), cholesterol (Chol), high density lipoprotein (HDL), and low density lipoprotein (LDL). Values were analyzed according to the European Accreditation system (220).

**Cut-off values for metabolic syndrome components:** The cut-off values were determined according to the National Cholesterol Education Program (NCEP) classification: WC >88 cm for women, >102 cm for men; BP  $\geq$ 130/85 mm Hg; FPG  $\geq$ 6.1 mmol/l; TG  $\geq$ 1.7 mmol/l; and HDL <1.3 mmol/l for women, <1.0 mmol/l for men (203).

### Health-related quality of life

The HRQOL was assessed using the Swedish version of the Short Form 36 (SF-36 Standard Swedish Version 1.0), which includes 36 questions (221). It generates eight health concepts: physical functioning (PF), role physical functioning (RP), bodily pain (BP), general health (GH), vitality (VT), social function (SF), role emotional functioning (RE), and mental health (MH). The health concepts were converted to 0–100 points, with higher values representing better HRQOL. The different health concepts of the SF-36 were also grouped into a physical component summary (PCS) and mental component summary (MCS). The SF-36 has shown good to excellent internal consistency and reliability and was validated in a representative sample of the Swedish population (221).

### Correlates of physical activity change

**Self-efficacy expectations** were measured using the *Self-Efficacy for Exercise Scale (SEES)* (162) focusing on the ability to exercise for 20 minutes, 3 times/ week despite barriers to exercise. The questionnaire includes nine items (e.g., The weather was bothering you, You had to exercise alone, You felt depressed) rated on an ordinal 10-point scale ranging from 1 (Not confident) to 10 (Very confident). The item scores are summarized and divided by the number of responses, indicating the strength of self-efficacy expectations (SEE). The SEE has been tested for older adults and older women post-hip fracture, presenting high internal consistency, acceptable reliability measured with squared multiple correlation coefficients, and sufficient to strong evidence for construct and criterion validity (162, 222, 223).

**Outcome expectations** were assessed with the *Outcome Expectations for Exercise-2 Scale (OEE-2)* (163), a revised version of the original OEE scale consisting of nine positively worded items (224) that was developed to identify elderly individuals with low expectations for the effects of exercise. The OEE-2 questionnaire is a 13-item measure with nine positively worded items (e.g., Helps me feel less tired) and four negatively worded items (e.g., Is something I avoid because it causes me to be short of breath) divided into two subscales: positive OEE and negative OEE. The items are rated on a 5-point Likert scale ranging from 1 (Strongly agree) to 5 (Strongly disagree). The negative OEE items are reverse scored, and the numerical ratings for each response are summarized and divided by the number of items. The OEE-2 questionnaire was revised in 2005 to include four items concerning negative expectations with exercise based on qualitative findings (225, 226) and has shown some evidence of convergent validity, internal consistency, and person-item reliability (163).

**Enjoyment** was measured using the *Physical Activity Enjoyment Scale* (*PACES*) (227) as modified by Motl et al. (164). The questionnaire consists of 16 items with 9 positively worded (e.g., I think it's fun, It gives me energy, It is very pleasant) and 7 negatively worded (e.g., I feel bored, I don't like it, It's frustrating for me). Each item is rated on a 5-point Likert scale from 1 (Does not apply at all) to 5 (Truly applies); the negatively worded items are reversed scored and the responses added to a score, ranging from 16 to 80. The PACES has been tested for 18 to 24-year-old students and adults with functional limitations, exhibiting acceptable test-retest reliability,

internal consistency, and criterion validity correlating to physical function (227, 228). The modified PACES has satisfying factorial and construct validity for adolescent girls (164) and invariance for the factor structure, factor loadings, and factor variances across time (229).

**Social support** was assessed using the *Social support for exercise scale (SSES)* (165), which comprises 13 items divided into a family and friends portion and measured on a 5-point Likert scale. Eleven items are positively worded (participation and involvement) and two items negatively (rewards and punishments) worded, describing social interactions possibly linked to exercise behavior during the previous 3 months. Responses range from 1 (none) to 5 (very often) and "not applicable" was given a score of 1. The item scores are summarized in three subgroups: *Family support – positive, Friend support – positive,* and *Family support – negative.* The Friend support – negative subgroup scores were excluded by Sallis et al. because it did not emerge in the factor analysis. The SSES has shown acceptable test-retest reliability, high internal consistency, and significant criterion validity correlated with a vigorous exercise measure (165).

The readiness to change PA level was measured at baseline by three questions estimated on a 100 mm visual analogue scale (VAS): How prepared are you? How important is it for you? How confident are you to succeed (self-efficacy)? The VAS line is anchored in each end with words describing the minimal maximal extremes of the dimension being measured. The questions are derived from MI and behavior change counseling according to Rollnick et al. (166, 230), with a higher value on the VAS indicating increased readiness to change. VAS has been used in the social and behavioral sciences as both a research and clinical tool and is considered to have acceptable reliability and validity (231).

### Sociodemographic factors

*Age* (years), *sex* (female–male), *social situation* (single–married/cohabit–other), *economy* (good–neither nor-bad), *education* (elementary grade–upper secondary school-university college) and *smoking* (yes/previously/no) were also reported.

### Supplementary questions

The PAP support from caregivers during the prior 6 months was assessed by questioning the patient about the frequency of visits to the HCC. We also measured changes in medication by asking the patient, *Have you changed your medication during the past six months?* with multiple choice options: *No, Yes increased,* or *Yes decreased.* 

### Health economics

Health benefits for the individual are measured by changes in HRQOL using the SF-6D and quality adjusted life years (QALYs) computed. Intervention costs, health care costs, individual expenses, and time costs related to PA, and sick leave were measured and calculated.

### Statistical analyses

Table 7 lists the statistical methods used in the studies. Statistical analyses in Papers I and II, except the multivariate linear regression analysis in Paper I, were calculated in SPSS version 22.0 (IBM Corp, USA). The data in the multivariate linear regression analysis were analyzed using SPSS for Windows, version 23 (IBM Corp, USA). In Papers III and IV, the data were analyzed in SPSS version 25.0 (IBM Corp, USA) except for the health-economic part of the analysis in Paper IV, which used Stata (Stata Corp. 2019. Stata Statistical Software: Release 16. College Station, TX: Stata Corp LLC) and the decision analysis software TreeAge Pro 2019, R2 (TreeAge Software, Williamstown, MA; software available at http://www.treeage.com). Statistical significance was set at  $p \leq 0.05$ .

### **TABLE 7.** Overview of the statistical methods.

Methods		- Pap	ers -	
	I.	П	Ш	IV
Analysis principle				
Per-protocol (PP)	×	×		
Intention to treat (ITT)		× <sup>a</sup>	×	×
Cost-effectiveness analysis (CEA)				×
Descriptive statistics				
Number (%)	×	×	×	×
Median (max-min or 25-75 precentiles)	×	×	×	
Mean (SD or 95% CI)	×	×	×	
Statistical methods				
Paired sample t-test	×		×	
Independent sample t-test	×	×	×	
Wilcoxon signed-rank test	×		×	
Mann Whitney U-test	×	×	×	
Cohen's d or Phi coefficient (Cohen's criteria)	×	×		
Univariate multiple linear regression	×			
Multivariate linear regression	×			
Spearman's rank correlation		×		
Mixed linear regression		×		
Univariate regression		×		
Chi-square test for independence		×	×	
Linear mixed-effects models			×	
McNemar-Bowker test			×	
Incremental cost effectiveness ratio (ICER)				×

<sup>a</sup> An additional ITT analysis was done.

### Paper I

A per-protocol analysis was used and differences between baseline and the 6-month follow-up analyzed within the group using paired sample t-test or Wilcoxon sign-rank test based on the data level. In subgroup analyses between women and men, and completers and dropouts, the independent sample t-test or Mann Whitney U-test were used. Cohen's *d* was used to calculate the effect size of the mean difference between baseline and 6-month follow-up within the group regarding metabolic risk factors and HRQOL. The effect size was considered small when d=0.2-0.3, medium when d=0.5, and large when d=0.8 (90).

Both univariate and multivariate regression methods were used to evaluate associations between changes in the PA level and changes in health outcomes when adjusting for potential confounders. The predictor of interest was the change in PA level ( $\Delta$ -value). This  $\Delta$ -value was compared to the  $\Delta$ -value outcomes of metabolic risk factors (BMI, WC, SBP, DBP, FPG, TG, Chol, HDL, LDL) and HRQOL (PF, RP, BP, GH, VT, SF, RE, MH, PCS, MCS), both individually and divided into two clusters, and were adjusted for potential confounders (PA level at baseline, age, sex, social situation, economy, education, and smoking).

Univariate multiple linear regression was used to check whether a change in PA (independent variable) significantly correlated with the 19 dependent variables, one at a time, when all the potential confounders were considered. Multivariate linear regression was then used to test if changes in PA were significantly associated with the two clusters (change in metabolic risk factors and change in self-rated health) and not just the specific variables in the clusters. The significance was tested using a regression-based MANOVA and test-statistic for Pillai's trace. Assumptions of normality, linearity, and outliers were checked using residual plots.

### Paper II

A per-protocol analysis was used, complemented with an additional intention-to-treat (ITT) analysis, revealing results that did not make any difference to our conclusions. Spearman's rank correlation was used to examine associations between correlates of PA change at baseline and PA level at the 6-month follow-up. For each significant factor, a mixed linear regression analysis was performed, followed by a univariate regression analysis, with the PA level at the 6-month follow-up as a dependent variable, the factor as an independent variable and including random baseline covariates (age, gender, social situation, economy, education, smoking, and an additional covariate; intervention of care at 6 months).

The significant correlates from the univariate regression analysis were dichotomized in order to better understand the relationship between baseline and 6-month variables from a clinical perspective, and to evaluate how the intervention could be most effective. The correlates were divided into values that were less than or greater than the median value for self-efficacy expectations (SEE), readiness to change–prepared (PREP), readiness to change– confident (CONF), and the SF-36 physical component summary (PCS). The BMI was dichotomized into <30 versus  $\geq$ 30. The PA level at baseline according to the ACSM/AHA questionnaire was dichotomized into low values (<2 points) versus high values ( $\geq$ 2 points), and then combined with the dichotomized correlates of PA in the predictive analysis.

The chi-squared test for independence was used to analyze possible predictive factors for increased PA level ( $\Delta$ -value) and achieved PA level according to the public health recommendation ( $\geq$ 150 min of moderate-intensity PA/ week) at the 6-month follow-up. The degree of association between variables was measured using the phi coefficient (phi) with Cohen's criteria of 0.10 for a small effect, 0.30 for a medium effect, and 0.50 for a large effect (90).

### Paper III

In this RCT, all analyses were performed according to ITT. Sample size was calculated to detect a difference of 20% between groups in patients achieving  $\geq$ 150 min of moderate-intensity PA/week based on a power of 87.5% and a significance level of 0.05 (30). According to this analysis, 200 patients were needed, i.e., 100 patients in each group. We randomized 190 patients for the study, with 98 patients in the PT group and 92 patients in the HCC group.

Independent sample t-test or Mann-Whitney U-test were used in baseline analyses between the 2-year completer and dropout groups. Independent sample t-test was used to analyze increases in PA level between the PT group and the HCC group at the 2-year follow-up, as well as paired samples t-test for within-group analyses. At the 2-year follow-up, we analyzed the question: *Have you changed your medication during the past six months?* with multiple choice options: *No, Yes increased,* or *Yes decreased.* The Chi-square test for independence was used for between groups and the McNemar-Bowker Test for within-group comparisons.

Linear mixed-effects models were used to analyze longitudinal changes from baseline to 1 and 2 years. The dependence between repeated measures for each individual was modeled by a random intercept, and the residuals were modeled with a diagonal covariance matrix, allowing for unequal variances at different time points. All parameters and marginal means for outcome variables were reported with point estimates and 95 % confidence intervals (CIs). Fixed effects independent variables were *time, group*, and the interaction term *time* × *group*. Dependent variables were *TotalMET*, *BMI*, *WC*, *SBP*, *DBP*, *FPG*, *TG*, *Chol*, *HDL*, *LDL*, *PCS*, and *MCS*. To achieve homogeneity of variance, we log-transformed the dependent variables TotalMET, FPG, and TG. The potential covariates (*age, sex, smoking, economic status, social situation*, and *education* at baseline) were first added individually for each model. Interaction terms and potential covariates with *p*-values >0.05 were not included in the final regression model.

### Paper IV

1

This cost-effectiveness (cost-utility) analysis included 98 patients in the PT group and 92 patients in the HCC group. QALYs were computed from the SF-6D. Intervention costs, health care costs, individual expenses and time costs related to PA, and sick leave were estimated from the patient data in the questionnaires. The result was presented as the ICER, comparing the health effects to the costs for the PT group compared to the HCC group. (Figure 10).

$$CER = \frac{Cost_{enhanced PAP} - Cost_{ordinary PAP}}{QALYs_{enhanced PAP} - QALYs_{ordinary PAP}}$$

FIGURE 10. Incremental cost-effectiveness ratio.

The ICER is interpreted as the cost of achieving one additional QALY when applying enhanced PAP (PT group) compared to ordinary PAP (HCC group). In this analysis, both a health care perspective, including intervention costs and costs for health care resource use, and a societal perspective, also including individual expenses for PA and indirect costs in terms of production loss due to sick leave and the time cost for exercise, were used.

A sensitivity analysis by bootstrapping was performed to calculate the uncertainty in both costs and effects, presented in a cost-effectiveness acceptability curve (CEAC) for both perspectives, showing the probability of each treatment being the most cost-effective choice at different willingness-to-pay thresholds (232).

# Results

# Papers I and II

Exploring the association between PAP treatment and PA level, metabolic risk factors, and HRQOL, and identifying patients most likely to benefit from PAP and the factors predictive of PA change.

A total of 368 patients (83%) completed the 6-month follow-up, and a majority of the patients (80%) answered that they received follow-up counseling with their PAP support caregiver 1–2 times during the first 6-month period of the PAP treatment (20%  $\geq$ 3 times).

### Physical activity level

Of 368 patients, 73% increased their PA level and 42% moved to a sufficient PA level of  $\geq$ 150 min of moderate-intensity PA/week. All four instruments measuring PA showed significant differences (Table 8). The most accomplished PA overall was moderate-intensity walking, 30–44 min, 2–5 times/week.

### Metabolic risk factors and HRQOL

There were significant improvements in 7 of 9 measured metabolic risk factors and 8 of 10 measured HRQOL concepts with small *d*-values, except for women's WC (medium), at the 6-month follow-up (Tables 9 and 10).

**Notes for Table 8** CI, confidence intervals; ACSM, American College of Sports Medicine; AHA, American Heart Association; IPAQ; International Physical Activity Questionnaire; SGPALS, Saltin-Grimby Physical Activity Level Scale. Values are given as <sup>a</sup> mean (standard deviation), <sup>b</sup> median (minimum-maximum). *P* values were determined by <sup>c</sup> a paired samples t-test, or by <sup>d</sup> Wilcoxon Signed Ranks Test, for the difference between baseline and 6-months follow up. **TABLE 8.** Differences for physical activity level at baseline and 6-months follow-up.

Variable (n)	Baseline	6-months follow-up	Mean diff.	p value
ACSM/AHA questionnaire, score (361)ª	1.75 (1.55)	4.57 (3.29)	2.8 (3.4) 95 % Cl 2.5;3.2	<0.001°
IPAQ 1-3, score (275) <sup>b</sup>	1 (1-2)	2 (1-2)	-	<0.001 <sup>d</sup>
IPAQ 1-3, category, No (%)				
• Low	222 (62.4)	130 (47.3)	-	
• Moderate	134 (37.6)	145 (52.7)	-	
• High	0	0	-	
SGPALS 1-4, score (343) <sup>b</sup>	2 (1-3)	2 (1-3)	-	<0.001 <sup>d</sup>
SGPALS 1-4, category, No (%)				
• 1	158 (36.5)	66 (19.2)	-	
• 2	268 (61.9)	223 (65.1)	-	
• 3	7 (1.6)	54 (15.7)	-	
• 4	0	0	-	
Frändin/Grimby 1-6, score (344) <sup>b</sup>	3 (1–5)	3 (1-6)	-	<0.001 <sup>d</sup>
Frändin/Grimby 1-6, category, No (%)				
• 1	31 (7.1)	7 (2.0)	-	
• 2	75 (17.3)	41 (12.0)	-	
• 3	243 (56.0)	169 (49.1)	-	
• 4	81 (18.7)	107 (31.1)	-	
• 5	4 (0.9)	17 (4.9)	-	
• 6	0	3 (0.9)	-	

Variable <sup>a</sup> (n)	Baseline	6-months follow-up	Mean difference	95 % CI	p value <sup>b</sup>	Cohen′s d <sup>c</sup>
BMI, kg/m <sup>2</sup> (353)	32.0 (5.2)	31.7 (5.4)	-0.3 (1.7)	-0.5;-0.1	0.001	0.25
Waist circumf., cm (352)	107.8 (13.2)	106.2 (13.9)	-1.7 (5.8)	-2.3;-1.1	<0.001	0.41
female (187)	103.4 (12.2)	101.4 (13.2)	-2.1 (5.9)	-2.9;-1.2	<0.001	0.50
male (165)	112.8 (12.6)	111.6 (12.6)	-1.3 (5.6)	-2.1;-0.4	0.005	0.32
Blood pressure, mm/Hg						
Systolic (358)	137.5 (17.3)	133.9 (16.2)	-3.6 (16.4)	-5.3;-1.9	<0.001	0.31
Diastolic (358)	82.8 (10.1)	82.5 (9.3)	-0.4 (9.9)	-1.4;0.6	0.466	0.05
Metabolic components, mmol/l:						
Fasting plasma glucose (352)	6.26 (1.92)	6.01 (1.44)	-0.3 (1.2)	-0.4;-0.1	<0.001	0.29
Triglycerides (355)	1.69 (0.99)	1.59 (0.88)	-0.1 (0.8)	-0.2;0.0	0.016	0.18
Cholesterol (358)	5.57 (1.21)	5.39 (1.16)	-0.2 (0.9)	-0.3;-0.1	<0.001	0.27
HDL (357)	1.41 (0.45)	1.43 (0.45)	0.0 (0.3)	0.0;0.1	0.196	0.10
LDL (353)	3.63 (1.06)	3.52 (1.03)	-0.1 (0.8)	-0.2;0.0	0.009	0.20
See notes on next spread						

See notes on next spread.

Variable ª (n)	Baseline	6-month follow-up	Mean difference	95 % CI	p value <sup>b</sup>	Cohen's d <sup>c</sup>
HROOL SF-36, score:						
Physical functioning (335)	81.3 (18.1)	81.8 (19.1)	0.4 (14.1)	-1.1;2.0	0.558	0.04
Role limitation, physical (323)	70.0 (37.4)	77.4 (33.3)	7.4 (39.7)	3.1;11.8	0.001	0.26
Bodily pain (334)	67.3 (26.6)	69.6 (27.2)	2.3 (22.9)	-0.2;4.7	0.069	0.14
General health (335)	60.7 (20.2)	64.2 (20.8)	3.6 (14.4)	2.0;5.1	<0.001	0.35
Vitality (333)	52.6 (23.1)	58.3 (21.6)	5.7 (19.4)	3.6;7.8	<0.001	0.42
Social function (334)	79.2 (25.2)	83.6 (21.8)	4.4 (24.6)	1.8;7.1	0.001	0.26
Role limitation, emotional (324)	73.4 (38.8)	77.8 (36.2)	4.4 (39.0)	0.2;8.7	0.042	0.16
Mental health (333)	72.2 (19.8)	74.3 (18.8)	2.2 (16.3)	0.4;3.9	0.017	0.19
Physical component summary (318)	45.8 (9.9)	46.8 (9.9)	1.0 (8.0)	0.1;1.9	0.029	0.17
Mental component summary (318)	44.6 (13.2)	46.6 (11.8)	2.0 (10.9)	0.8;3.2	0.001	0.19

**TABLE 10.** Differences for health related quality of life at

baseline and 6-month follow-up.

See notes on next spread.

# **TABLE 9.** Differences for anthropometric and metabolic characteristics at baseline and 6-month follow-up.

### Notes for Table 9 and 10 (above)

Table 9: CI, confidence intervals; BMI, body mass index; HDL, high density lipoprotein; LDL, low density lipoprotein.

Table 10: HRQOL SF-36, Health Related Quality of Life 36-Item Short Form Health Survey.

Table 9 and 10: <sup>a</sup> Values are given as mean (standard deviation).

<sup>b</sup> *P* values were determined by a paired samples *t*-test for the difference between baseline and 6-months follow up.

<sup>c</sup> Effect size in within-subjects comparisons (Cohen's d<sub>z</sub> ×  $\sqrt{2}$  = Cohen's d) was measured quantifying the degree of differentiation in values between baseline and 6-months follow-up.

Statistical significance was set at  $p \le 0.05$ .

### Dose-response physical activity level vs. health outcome

There was a dose-response association between changes in PA levels and health outcomes for metabolic risk factors and HRQOL at the 6-month follow-up, meaning that the more PA, the more health benefits (Table 11).

**TABLE 11.** Association between change in PA and metabolic risk factors and HRQOL at 6-month follow-up.<sup>a</sup>

Dependent variable	Independent variable	etaPillai's Trace	p value
$\Delta$ Metabolic risk factors	∆ Change PA	0.063	0.032
Δ HRQOL (SF-36)	∆ Change PA	0.095	<0.001

Adjusted for – PA level at baseline, age, sex, social situation, economy, education, and smoking. <sup>a</sup> The associations were analysed using multivariate regression analysis. Statistical significance was set at  $p \le 0.05$ .

### Factors associated with PA level

We found significant associations between the following six baseline values and the PA level at 6 months: SEE, readiness to change – prepared (PREP), readiness to change – confident (CONF), HRQOL-PCS, BMI, and baseline PA level (Table 12).

**TABLE 12.** Associations between correlates of PA change at baseline and PA level at 6-month follow-up.<sup>a</sup>

Correlate of PA (n)	PA le	PA level —		
	Unstandardized Coefficient B	R² (adj)	p value	
Self-efficacy expectations (325)	0.19	0.011	0.033	
Outcome expectations (312)	-0.56	0.010	0.077	
Enjoyment (314)	0.02	0.008	0.118	
Readiness to change				
Prepared (347)	0.02	0.013	0.020	
Confident (346)	0.02	0.027	0.001	
BMI (356)	-0.07	0.008	0.045	
HRQOL - physical compo- nent summary (343)	0.04	0.010	0.033	
PA level at baseline (360)	0.32	0.020	0.004	

PA level physical activity level according to ACSM/AHA questionnaire; ACSM American College of Sports Medicine; AHA American Heart Association; BMI body mass index; SF-36 36-Item Short Form Health Survey. <sup>a</sup> P values were determined by an univariate regression analysis. Statistical significance was set at  $p \le 0.05$ . In a predictor analysis, the significant correlates of changes in PA were dichotomized into positive and negative values (cut-off points seen in Table 13), and the PA level at baseline was dichotomized into low and high values (< 2 or  $\ge$  2 points).

TABLE 13	Cut-points regarding positively assessed correlate values.
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Baseline correlates	Positive value
SEE, points	≥ 4.77
PREP, mm	> 86
CONF, mm	> 68
BMI	< 30
PCS, points	> 47.06

*SEE* self-efficacy expectations, *PREP* readiness to change – prepared, *CONF* readiness to change – confident, *BMI* body max index, *PCS* physical component summary – SF-36.

### Patients primarily benefiting from PAP treatment

Patients with a low PA at baseline (<2 points, corresponding to less than 30 min brisk walk 2 times/week) increased their PA at the 6-month follow-up to a greater extent than patients with a high PA level at baseline ( $\geq 2$  points) (Table 14). Including 1 to 3 positive baseline predictors, patients with low baseline PA increased their PA even more at the 6-month follow-up (87–95%).

**TABLE 14.** Patients with increased PA-level ( $\Delta$ -value) at 6-month follow-up.

Correlate of PA (n)			ed PA-leve value)	<u>ا</u> ا
	% of pa	atients	p value ª	phi coefficient
	Low values	High values		
Baseline PA level (152/119)	84.0	66.1	<0.001	0.21

<sup>a</sup> *P* values were determined by Chi-square test for independence.

### Predictors of increased PA

With a positive value for readiness to change – CONF, a higher estimated physical health – PCS, or a BMI <30, there was a significantly higher proportion of patients with increased PA at the 6-month follow-up (79–81.5%) (Table 15). Including two positive baseline predictors simultaneously increased the proportion to 79–88.2% compared to 64–69.1% for patients with two negatively valued predictors.

**TABLE 15.** Patients with increased PA-level ( $\Delta$ -value) at 6-month follow-up.

Correlate of PA (n)	Increased PA-level (Δ value)							
	% of pat	ients	p value ª	phi coefficient				
	Positive values	Negative values						
SEE (170/155)	74.1	72.9	0.804	0.01				
PREP (183/164)	77.0	70.7	0.180	0.07				
CONF (179/167)	79.9	67.7	0.010	0.14				
PCS (181/162)	79.0	68.5	0.027	0.12				
BMI (130/226)	81.5	71.2	0.031	0.12				

<sup>a</sup> *P* values were determined by Chi-square test for independence.

Predictors for achieving the recommended PA level A positive value for readiness to change – CONF and a BMI <30 resulted in a higher proportion of patients achieving PA of ≥150 min of moderate-intensity PA/week (48.3–50.4%) (Table 16). With two positively valued baseline predictors included at the same time, the proportion increased to 47.7–54.3%, compared to 28.6–34% for the patient group with two negatively valued predictors.

**TABLE 16.** Patients with reached PA-level  $\geq$  150 min/week at 6-month follow-up.

Correlate of PA (n)	ſ			
		% atients	p value ª	phi coefficient
	Positive values	Negative values		
SEE (171/115)	44.4	38.7	0.294	0.06
PREP (183/165)	47.0	37.6	0.076	0.10
CONF (180/167)	48.3	35.9	0.019	0.12
BMI (131/226)	50.4	39.4	0.043	0.11
PCS (182/162)	46.2	37.7	0.111	0.09

<sup>a</sup> *P* values were determined by Chi-square test for independence.

### Paper III

Evaluating two different PAP strategies regarding PA level, metabolic risk factors, and HRQOL for patients with insufficient PA after a previous 6-months period of PAP treatment.

A total of 76 patients (78%) in the PT group and 67 (73%) in the HCC group attended the 2-year follow-up. We found no differences in baseline values between the groups or between the completer and dropout groups except for more "other diagnoses" in the PT group (53.1% vs. 38.2%) and a lower DBP in the dropout group (-3.6 mmHg). According to the answers in the question: *Have you changed your medication during the past six months?* there were no between- or within-group differences concerning changes in medication, measured at the 1- and 2-year follow-up. A majority of patients had not changed their medication at the 1-year (77.3%) and 2-year (70.9%) follow-up.

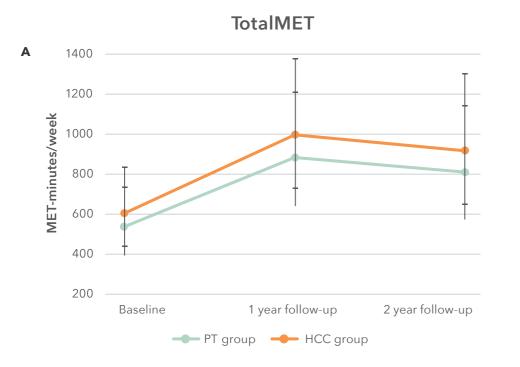
### Physical activity level

At the 2-year follow-up, 62.9% of the PT group and 50.8% of the HCC group had increased their PA level, and 31.4% vs. 38.5% achieved  $\geq$ 150 min of moderate-intensity PA/week (difference between groups n.s.). Compared to baseline levels, both the PT and HCC group had increased TotalMET over the 2-year follow-up period (*p*=0.002; Figure 11 a).

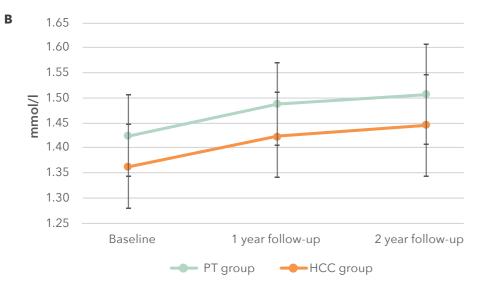
### Metabolic risk factors and HRQOL

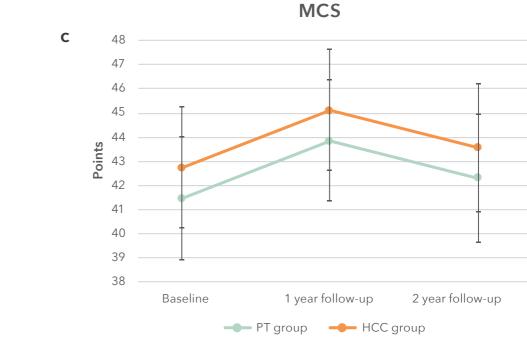
Both groups had increased HDL levels (p = 0.004) and MCS scores (p = 0.036), and a decrease in BMI (p = 0.001) over the 2-year follow-up (Figure 11 b–d).

**FIGURE 11 A-D.** Physical activity level and health outcomes over time for the PT and HCC group. Analysed with linear mixed effects models. TotalMET is presented with the estimated marginal geometric mean and 95% CI. HDL, MCS and BMI are presented with the estimated marginal arithmetic mean and 95% CI. PT physiotherapist, HCC health care centre, MET metabolic equivalent, CI confidence interval, HDL high density lipoprotein, MCS mental component summary, BMI body mass index.

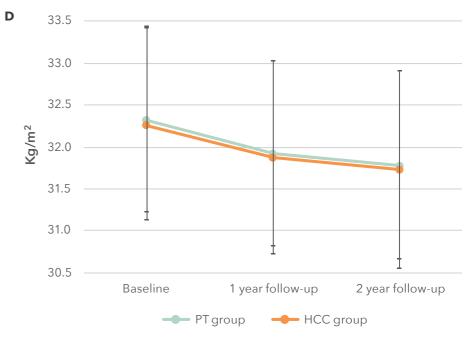


### HDL





BMI



## Paper IV

Analyzing the cost-effectiveness of two different PAP strategies for patients with insufficient PA levels after a previous 6-month period of PAP treatment.

# Cost-effectiveness analysis of two different PAP strategies

The incremental QALY gain per participant in the PT group was 0.016 compared to the HCC group, with an ICER of 147 250 SEK per additional QALY gained measured from the societal perspective and 293 688 SEK per additional QALY gained from the health care perspective. The probability of cost-effectiveness for the PT strategy compared to the HCC strategy was 0.55 and 0.57 for each perspective with a willingness to pay of 500 000 SEK, which means that if you are willing to pay 500 000 SEK for a gained QALY there is a 55% or 57% chance respectively that the PT strategy is cost-effective compared to the HCC strategy.

The results from the sensitivity analysis were presented as CEACs showing the probabilities for each strategy to be the most cost-effective choice compared to the other, depending on the willingness to pay for a gained QALY. From a societal perspective, the willingness to pay for a gained QALY needed to be >150 000 SEK for the PT strategy to be more cost-effective than the HCC strategy. From the health care perspective, the willingness to pay threshold needed to be >250 000 SEK. According to the National Board of Health and Welfare categorization of cost-effectiveness, the cost in relationship to health benefits in this analysis of two interventions were in the range 100 000–500 000 SEK considered as a moderate level.

To be able to discuss whether the interventions were cost-effective compared to doing nothing, the two strategies were compared to two previous studies with similar interventions that included a control group (199, 233). This comparison indicated that both the PT and HCC strategies had the potential to be cost-effective.

S. LUNDQVIST

# Discussion

## Main findings

This thesis contributes increased knowledge to the scientific field regarding the promotion of physical activity (PA) and health by evaluating the outcome and effects of short- and long-term PA on prescription (PAP) intervention among 444 physically inactive adults with at least one metabolic risk factor. The PAP intervention was conducted in the ordinary primary care setting, mostly by nurses at a health care center (HCC) or by physiotherapists (PTs) as part of their daily clinical work. The intervention was individualized except in the follow-up scheme for patients in the PT group. Overall, this thesis showed that PAP treatment can be used as a feasible intervention to increase the PA level, metabolic health, and health-related quality of life (HRQOL) in patients with metabolic risk factors, especially among patients with the lowest PA levels at baseline. The most prominent predictive factor for increased PA level was a positively valued self-efficacy. The 190 men and women who did not increase their PA level sufficiently after 6 months of PAP intervention were randomized to continued PAP treatment conducted either by a PT or the HCC. Similar positive increases in PA levels and health outcomes occurred, with no difference in cost-effectiveness between the two groups.

### The PAP treatment

The strength of this thesis is that it addresses one major challenge that is faced in healthcare, determining the support patients need from their health care provider to become sufficiently and regularly physically active in order to promote health. The PAP intervention was used according to Swedish PAP treatment, an evaluated method with an individualized, person-centered intervention in which the patient's views and perspectives are taken into account. Thus PAP treatment should be a natural part of the Swedish healthcare system, which has been working in recent years to implement a personcentered approach. However, Swedish Healthcare is a large, multifaceted organization with a long tradition of volume-based, invasive treatment methodology, including pharmacological treatment, with a deficient holistic approach to the patient. Increased knowledge of a person-centered approach could enable a change from the organs and disease-specific healthcare towards a healthcare system that empowers the patient's autonomy and healthenhancing resources. In the future of person-centered healthcare, PAP treatment has the potential to be a widely implemented and important part of the treatment arsenal.

Another strength is the large cohort of 444 patients with metabolic risk factors, representing a major patient group and including patients of different ages with an even distribution of women and men. The PAP intervention was also conducted at 15 different HCCs. These aspects increase the external validity of this thesis. As we know, this is the largest and longest-term PAP study conducted in Sweden. Previously, a 6-month analysis of self-reported PA, readiness to change, and HRQOL was performed in 298 of 481 primary health care (PHC) patients (127), Rödjer et al. (177) evaluated self-reported PA and HRQOL in a 2-year perspective study of 86 of 146 PHC patients, as well as Andersen et al. (178) for 400 patients in a one year follow-up. The importance of evaluating long-term PAP interventions in large populations has been emphasized for both observational studies and randomized controlled trials (RCTs) under real circumstances (92, 93, 106), and the studies included in this thesis corresponds with this need and may contribute to an increased understanding of changes in PA behavior among patients with metabolic risk factors who participate in a PAP intervention. However, more research is needed to evaluate the impact on PA level in long-term PAP interventions for different patient groups.

The PAP treatment was part of daily clinical primary care and did not require any extra resources. It was conducted by licensed professionals with knowledge concerning PA and PAP. With a majority of the patients receiving PAP support one or two times each 6-month period, the PAP treatment seems to be a low budget intervention. In light of the fact that pharmacological costs in e.g., Region Västra Götaland increase every year and were 5.8 billion SEK in 2019 (234), approximately 0.5 billion SEK of which was medications for metabolic risk factors, there is a need to expand the nondrug, non-invasive intervention strategies, such as PAP treatment. Importantly, increased PA has both a treatment effect, with multiple positive effects on several organ systems, and a preventive effect, reducing the risk of future disease. PA has virtually no adverse side effects, in contrast to drug treatment. Recently updated evidence suggest that even small increases in regular moderate-vigorous PA would appreciably reduce direct and indirect medical costs (2). To the best of our knowledge, no previous research has investigated the possibility of gradually reducing medication doses when pharmacologically treated patients increase their PA level. In the future, it would be interesting, and perhaps necessary, to evaluate possible health effects, the impact on side-effects, and medical cost effects.

During the 3.5-year PAP intervention at the HCC, a majority of the patients attended two to four follow-ups per year, approximately the same amount of nurse or PT support shown in a recently published Swedish PAP study (178). Compared to other lifestyle interventions (235), this may be seen as a low effort or low frequency intervention. The follow-up frequency was an agreement between the patient and caregiver as part of the person-centered perspective of PAP treatment and was sometimes complemented with a telephone contact. The individualized follow-up is likely essential to increase the patient's motivation and self-efficacy for changing their PA behavior and to enhance the patient's autonomy (36, 126, 236). Based on the experiences of this thesis, trying to standardize the follow-up routines via a fixed follow-up scheme for the patient seems to be a worse option (Papers III and IV) compared to an individualized approach. In an interview study from the Gothenburg PAP study (124), which was not included in this thesis, 5-years of experience with PAP treatment enhanced the importance of an individualized follow-up. The relatively low adherence to the allocated intervention in the PT group, in which an extended follow-up scheme was included, in Papers III and IV indicated that the patient group was not motivated to participate in such an extensive intervention.

The nurses and PTs, who offered PAP treatment in this thesis, were all educated on the effects of PA and the concept of the Swedish PAP treatment, and some of the co-workers had knowledge of behavioral change processes and used motivational interviewing in their consultations with the patients. However, education and knowledge are not the only important factors for co-workers to successfully manage the PAP treatment processes. Access to national and regional guidelines (36), the evidence-based handbook FYSS (125), and local support from the *Center for Physical Activity Gothenburg* (128), an organization providing education, working materials, a register of local availability of PA, and helping co-workers organize the structure of PAP routines in the PHC units, have indicated to be additional important components. The importance of national, regional, and local guidelines and support has also been highlighted in other research (144–146).

The only thing that is unchangeable is change, and this also applies to the reorganization of Swedish primary care. In 2010, health care reform was implemented in Region Västra Götaland (237) that, in various ways made work with lifestyle habits and, thus, PA and PAP treatment more difficult. Staff turnover among nurses responsible for PAP increased, and the time for working with PAP treatment decreased. As a result, the level of knowledge and skill in handling PAP decreased among co-workers, and the follow-up routines for the patients in the study were disrupted. The reform also meant that the economic conditions for working with PA and PAP treatment changed and the intervention given lower priority. Despite this, the nurses responsible for PAP managed to continue the treatment with the patients in the Gothenburg PAP study. The total impact of this health care reform in terms of the outcome of the PAP study are difficult to assess. However, our experience was that the lack of continuity among co-workers in the PAP study may have affected the patient dropout rate. Previous studies of Swedish PAP treatment have shown that a clear support and prioritization from management is required to make regional and local policies and guidelines well-known in the organization (145, 146). Based on these results and our own clinical experiences during the last decade, Johansson et al. (40) summarized the possibilities for health co-workers working with PAP treatment in a good way: "If we only got a chance." Maybe the new health care reform prepared by The Swedish Ministry of Health and Social Affairs (Socialdepartementet) (33), focusing on primary care and emphasizing person-centered care, interprofessional learning, and a salutogenic perspective, in a couple of years could lead us to say, "We got the chance."

The PAP intervention was individualized to the needs and opinions of the patients according to the Swedish PAP treatment evaluated in a systematic review (121, 238), where the authors expressed a need to further analyze each of the core elements in PAP. To our knowledge, such research has not been conducted, and this analyze was outside the scope of this thesis. However, the patient perspective of the PAP treatment has recently been highlighted in qualitative research (123, 124, 143). These results show that a professional, respectful dialogue with the health care provider was crucial for the patient throughout the treatment period, and the written prescription was essential for the patient as a reminder, for the agreed upon PA to be perceived more "seriously", and to be more motivated. Finally, the follow-up served as an extra motivating factor, with an opportunity for support in continuing or upgrading the level of PA. It seems that all three core elements are important, but the question remains: is one of the core elements more important than another? An in-depth analysis of the separate core elements of PAP treatment is needed to determine the significance of each part regarding behavioral changes in PA.

### Physical activity and the PAP treatment

The primary outcome in this thesis was PA and changes in the PA level because we know that an increased PA level has positive health effects (2, 4). Both short-term (Paper I) and long-term (Paper III) PAP intervention showed significantly increased PA, and the most commonly performed PA was taking walks at a moderate intensity level, in everyday life. During the counseling with the patient, the patient's motivation to find an interesting and suitable PA that could be carried out near their residence or workplace was encouraged, and this support from the health care provider may be an important factor in the improved PA level throughout the 2-year PAP intervention (Paper III). For the sustainability of PA in the long-term, it seems important to be supported and have the opportunity to actively choose a suitable PA. The patients primarily choosing moderate intensity walking on their own is consistent with previous Swedish PAP research (95, 115).

Analysis of international interventions similar to Swedish PAP treatment, often referred to as an exercise referral scheme (ERS), has shown small to medium increases in PA. However, these short-term (10–12 weeks), usually gym-based, partly predetermined interventions have low adherence rates (12–49%) among patients, and the lack of long-term follow-up has made it difficult to assess the effectiveness of these interventions (92, 106). The Swedish PAP treatment used in this thesis differs from most such ERS in that it is based on an individualized methodology with a person-centered perspective in which all licensed health care professionals could be included, mainly nurses and PTs in this thesis. The overall individualized parts of the PAP treatment and a professional and empathetic approach have been emphasized as factors of success in patients managing to increase their PA (123, 143), and a systematic review of Swedish PAP treatment has revealed good evidence of its efficacy in terms of increased PA (121, 238).

PA was especially increased among patients with the lowest PA levels at baseline, as illustrated by the analysis of predictive factors at the 6-month follow-up in Paper II. Of the 368 patients who were re-tested at the 6-month follow-up, 73 % increased their PA to some extent and 42 % reached the recommended PA level of 150 min/week. In the group of patients with a low PA level at baseline (equivalent to performing moderate-intensity PA for less than 30 minutes twice a week), a higher proportion (84 %) increased their PA level, compared to 66.1 % in the group of patients with a high PA level at baseline. The proportion of patients achieving the recommended level of PA was lower, though not significant, in the group of patients with a low PA level at baseline (38.7 % vs. 47.2 %).

These results are important from a clinical perspective, as they indicate that patients with the lowest PA level at baseline are primarily benefiting from the PAP treatment. These patients may have little experience with being physically active earlier in life, tried to get started with PA but failed, or experienced PA as something negative while growing up, which are all factors affecting the ability to succeed in changing PA behavior. In light of this, the health care organization must be able to provide scientifically based, professional support for patients who have the most difficulty increasing their PA, a patient group that will probably have the greatest health gain with increased PA according to the dose-response relationship between sedentary time, PA, and health (4, 79). The subgroup analysis between patients with low vs. high PA level at baseline in Paper II was performed from a 6-month perspective but was not included in the 2-year follow-up, and further subgroup analyses are needed in long-term PAP interventions. In this thesis, PA was assessed by four self-reported questionnaires, all showing significant increases in the PA level post-treatment. Multiple questionnaires were used due to the complexity of measuring PA (230), and the unambiguous result may strengthen the stability of the outcome. These results were shown, although a majority of patients were on medication and had more than one metabolic risk factor, showing higher complexity, and indicates that other patient groups may benefit from PAP treatment, which deserves more research.

### The prior 'non-responders'

To the best of our knowledge, this is the first time a 2-year RCT has been conducted with patients who were insufficiently physically active after a prior 6-month PAP treatment (Paper III), i.e., non-responders. We decided to compare two active intervention strategies conducted by PTs or nurses at the HCC, as it was considered unethical to randomize some patients to a "no PA promotion" control group. Both long-term PAP strategies resulted in similar increases in PA, metabolic health, and HRQOL, revealing a dose-response relationship between PA and health outcomes (65), which was also shown in Paper I. During the 2-year intervention, these previous nonresponding patients received a modest amount of continuous support from their PAP provider. At the 2-year follow-up, approximately 63 % of the PT group and 51 % of the HCC group had increased their level of PA. In contrast to the rather intensive, gym-based, short-term ERS used internationally (92, 105, 106), the PAP treatment in Paper III was a low-intensity intervention, indicating that continuity and duration may be two most important factors for increasing PA, something that is also supported in previous research (92, 106). Continued PAP intervention among previous non-responding patients, as shown in Papers III and IV, has not been conducted previously and the results may give an indication of how the health care organization should respond when the first intervention period does not give the desired result. A prolonged low-intensity intervention may be effective, and perhaps preferable, to an intensified intervention. Given that previous studies have shown that a large proportion of patients fail to increase their PA level during an initial period of PAP treatment, further studies are warranted to evaluate the optimal continuous PAP support for non-responding patients. Research on how to proceed is perhaps as important as research on the initiation of PAP treatment.

We hypothesized that the enhanced PAP support from PTs would increase the PA level more than support from the HCC. However, though the non-individualized follow-up routine in the PT group was scheduled as 11 follow-up sessions during the 3-year intervention, the patients only attended approximately 6 of these. The reduced compliance, unfortunately, resulted in a similar follow-up frequency in both groups, possibly affecting the hypothesized additional effect. The absence of individualized follow-up in the PT intervention may also have affected the outcome, because individualized follow-ups adapted to the patients' needs are considered important to increase motivation for regular PA among patients in Swedish health care (123). Time constraints were frequently reported by patients as a barrier to being physically active (108), and the extended follow-up schedule could possibly be perceived as too time-consuming for the patients in the PT group.

### The dropout group

An interesting finding was that, among the 76 patients in the dropout group at the 6-month follow-up, there were more women, additional musculoskeletal diagnoses, and lower self-reported HRQOL. This may indicate that a standardized PAP treatment does not fit all patients. Perhaps some patients are in need of more enhanced support, or in need of rehabilitation before or in combination with PAP treatment. There is a lack of knowledge and understanding of subgroups of patients who are less likely to benefit from PAP treatment and the possible underlying mechanisms (106). In a qualitative study including patients with chronic musculoskeletal non-malignant pain who participated in a 3 to 12-month PAP treatment, the patients expressed a need for extra support when changing their PA level due to the multiple barriers caused by the pain (143). Specific subgroup analyses of patients in the dropout group were not the focus of this thesis, and further research is needed to identify vulnerable patient groups not responding to the existing PAP treatment. Moreover, additional work is needed to better individualize the PAP intervention for these specific patients.

### Metabolic health and HRQOL

Both the short-term (Paper I) and long-term (Paper III) PAP interventions increased metabolic health and HRQOL. The 6-month follow-up including all patients showed improvements in 7 of 9 measured metabolic risk factors and 8 of 10 measured HRQOL concepts. The 2-year follow-up including only the 190 patients still insufficiently physically active after the 6-month PAP intervention showed improvements in BMI, HDL, and the mental health components (MCS) regarding HRQOL. Interestingly, we found no significant detrimental changes in the remaining seven metabolic risk factors at the 2-year follow-up. This may be seen as a positive and important result, as previous research showed that the prevalence of metabolic syndrome is higher among formerly healthy abdominally obese individuals than among healthy non-obese individuals long-term (239, 240). Thus, over the course of 2 years, we may have expected an increase in the metabolic risk factor profile, so that a non-change (non-worsening) may theoretically be a positive effect. Another interesting finding was that the health improvements appeared to be independent of any changes in pharmacological treatment. A majority of patients reported no changes in medication at the 1 and 2-year follow-up, and the most common medications were for metabolic risk factors or non-communicable diseases, such as musculoskeletal disorders, depression, anxiety, asthma, and chronic obstructive pulmonary disease. All of the mentioned conditions have the possibility of being positively affected by increased PA, where the effects could be equivalent to pharmacological treatment (69, 241-243). The increase in PA level during the 2-year PAP intervention resulted in both a treatment effect, with improved metabolic risk factors, and in a preventive effect, in which the improvements in risk factors probably reduce the incidence of future disease.

Although positive correlations were found between PA level and health effects, the effect size values measured in Paper I were generally small. The changes in PA level could only partially explain the metabolic health effects (3–5%) and health effects in HRQOL (3–12%). This could partly be explained by the dose-response relationship between PA and health outcomes, as 42% of the patients achieved a PA level of 150 min/week, usually at a moderate intensity level at the 6-month follow-up. A more extensive increase in PA or intensity level could probably increase the effect size.

The relatively low correlations must also be interpreted in light of the increased PA, which both affects and is affected by physiological, psychological, behavioral, individual, social, and genetic factors (160, 244). Increased PA has both preventive and therapeutic effects regarding metabolic syndrome, with PA-induced improvements in, for example, total and abdominal obesity, positively affecting the metabolic risk profile (245). These multifactorial effects of increased PA are difficult to capture when evaluating a clinical intervention and, thus, could affect the effect size values.

### Correlates of physical activity change

To increase understanding of the patients' individual enablers and barriers to changing PA behavior, factors (i.e., correlates) predicting changes in PA were evaluated in Paper II. More research has been requested to explore the correlates affecting increased PA and adherence to PA interventions (246); in Paper II, this was done from a 6-month perspective. We found a significant correlation between the baseline values for *self-efficacy expectations* and the PA level at 6 months, and a higher proportion of patients with increased PA were in the group who, at baseline, had confidence in their readiness to change their PA level. Confidence in readiness to change has similarities with the concept of self-efficacy, one of the most important correlates of PA in previous research (151, 160). In the dichotomized predictor analysis, we found significant values for the VAS-estimated confidence question, but not for the self-efficacy expectations outcome for which the Self-Efficacy for Exercise Scale (SEES) was used. In this questionnaire, the patients had to estimate their ability to exercise for 20 min, three times per week in light of the barriers to exercise. The reason for the non-significant values on the SEES could be the use of the word exercise instead of PA and the required predetermined level of exercise, which complicated the estimation of PA by the patient. Barriers for exercising, especially in a gym or other unfamiliar environments, have been reported in previous PAP research (108, 123, 143). In contrast, it seemed more feasible to mark confidence in readiness to change PA on a VAS. The finding that confidence in readiness to change may be a predictive factor is important and has to be studied further. The use of this measurement in an early stage of PAP treatment could give the health care provider an opportunity to individualize support for the patient in a better way, and the patient estimating a VAS score is both easy and practical to perform in clinical practice.

As in Paper I, Paper II presented small correlation values, this time between the correlates of PA and the PA level. Due to the complexity of measuring PA and PA behavior, and the wide range of correlates possibly affecting a change in PA behavior, even a well-conducted study fails to capture all of the correlating factors that may affect the outcome of changes in PA behavior (160, 247). There is also a risk of underestimating the effect of the correlates of PA at the expense of overestimating the effect of the intervention (independent variable) on the outcome (dependent variable) (159). Therefore, it is suggested that there will be small correlation values found in measured correlates of PA (157, 159), and the predicting correlates found in Paper II could be taken into consideration as potentially important components in the process of changing PA behaviors.

### Cost-effectiveness

In Paper IV, we performed a cost-utility analysis of two PAP treatment strategies conducted over 3 years by either PTs or nurses at the HCC. As in Paper III, the randomized groups consisted of patients who were insufficiently physically active after a prior 6-month PAP intervention. The costs and QALY change were similar in both groups, and it was not possible to draw certain conclusions about the most cost-effective strategy; none of strategies could certainly be chosen before the other.

The probability of cost-effectiveness for the PT strategy compared to the HCC strategy was 0.55 and 0.57 for respective perspective with a willingness to pay 500 000 SEK. Some factors may have affected the outcome. First, the two interventions were compared to each other, with the HCC intervention as the control group. Secondly, the PT intervention was intended as enhanced support with more planned follow-ups than the HCC intervention, but due to reduced compliance in the PT group, both groups received approximately the same follow-up support. The patients in the PT group may not have been motivated to participate in such an extensive intervention, and the lack of an individualized follow-up may also have affected compliance with the allocated PAP treatment strategy. In order to discuss whether these long-term interventions were cost-effective compared to doing nothing, the two strategies were compared to two previous studies with similar interventions that included a control group (199, 248). The comparison with these

studies indicated that both the PT and HCC interventions had the potential to be cost-effective. Further studies are needed to analyze the cost-effective-ness of long-term PAP intervention among sub groups of patients.

### Limitations

This thesis has some limitations. The study population was non-consecutively included during 2010 to 2014. No data were collected for non-included study-suitable patients visiting the HCCs, and it was not possible to estimate how many patients were candidates for the PAP intervention. This may increase the risk of selection bias. However, the PAP treatment is person-centered, taking into account the patient's attitude to changing their PA behavior, and PAP probably has the most potential for patients reflecting on changing their behavior (249). In Papers I and II, a per-protocol analysis was performed between baseline and the 6-month follow-up where the drop-outs were excluded. This could increase the risk of bias. The alternative would be to use an intention to treat analysis (ITT) including the drop-out group. However, the ITT analysis has been criticized for increasing the risk of a biased treatment effect when attributing characteristics to the patients in the drop-out group that they might not have had (250, 251). In Paper II, an additional ITT analysis was performed, showing that the results did not change any of the conclusions.

There was a drop-out rate of 17 % at the 6-month follow-up in Papers I and II, and 22 % and 27 % in each intervention group, respectively, at the 2-year follow-up in Paper III. This could influence the interpretation of results due to an increased risk of selection bias. However, the drop-out rate was about as expected for this type of study, and consistent with previous reports (94, 127, 134, 177, 252). Notably, the PAP intervention in this thesis was part of daily clinical practice in primary health care in which the co-workers had no extra time or other resources to manage the PAP treatment routines. In Paper III, the adherence to the allocated intervention during the 2-year study period was 57 % in the PT group, and data on adherence to the allocated intervention in the HCC group was uncertain because we did not have access to the patients' medical records. Although uncertainties about patient adherence rates could influence the interpretation of results, under these circumstances, we expect that the presented results were not overestimated.

The lack of a control group in Papers I and II complicates the interpretation of results regarding the effects of PAP treatment on PA level, health effects, and the impact on PA correlates. However, the results in Paper I are comparable to previously published studies conducted as RCTs (94, 133) or without a control group (127, 253), and no differences were found in the effect estimates when comparing effects from RCTs and effects from observational studies (254). In addition, the RCT design is criticized for its idealized and strictly controlled conditions, and for not being representative of real world patients in real world settings, something that could jeopardize the external validity (255, 256). Trial design modification has been proposed in which data generated from observational studies is integrated (255). Criticism of the RCT design can be applied to Papers III and IV in which the follow-up routine in the PT group was modified. This deviation from the real world setting is something that may have affected the outcome in the studied patients.

Another limitation of this thesis was the use of multiple measurements to assess the PA level, metabolic risk factors, and HRQOL, which may increase the risk of type I errors. The chance of finding a false 'significance' increases as the number of comparisons increases. However, the number of tests needed before doing a *p*-value adjustment has been imprecisely defined and, though a *p*-value adjustment reduces the risk of making type I errors, the chance of making type II errors increases (257). The use of *p*-value adjustment methods, such as the Bonferroni correction, has been criticized for being based on the null hypothesis, assuming that all null hypotheses are simultaneously true for all measured variables (258). If the null hypothesis is rejected in a Bonferroni test, we cannot say which, or how many, variables differ. Instead, the study's statistical significance should be illuminated based on the quality of the study, the magnitude of effect, findings from other studies, and the reason why selected tests were used (257, 258). In this thesis, multiple predefined measurements were needed to elucidate the several possible effects during the PAP intervention, and they seem to be justified without *p*-value adjustments (258).

Measuring PA by self-report may increase the risk of under- or over-estimating the components in questionnaires, and also increase the risk of recall and response bias (53, 60). Low-to-moderate correlations exist between self-reported and directly measured PA, and no single, perfect questionnaire exists (57). The PAP treatment included in this thesis was part of the daily clinical work, and there were no resources with which to incorporate a more objective measurement via accelerometer. Nevertheless, self-reported PA measures are relevant in both research and practice, suited to the specific situation, and are frequently used due to the possibility of collecting large amounts of data in a practical way and at low cost (57, 59). In this thesis, four PA questionnaires were used due to the known complexity of assessing PA and the increase in PA level was significant in all four measurements during the study period. Two of the questionnaires contained a question about 'the previous week of PA'. The use of such a 7-day recall design has been recommended, as opposed to a question about 'the usual week of PA', due to a higher correlation with accelerometer data (61).

# Conclusions and clinical applications

- Both short- and long-term PAP treatment are a feasible intervention in ordinary primary health care to increase PA, metabolic health, and HRQOL in adult patients who are physically inactive and have at least one metabolic risk factor.
- PA and the changes in PA level were positively affected in the total study group, more significant in the group of patients with the lowest PA levels at baseline, and was also affected among patients initially non-responding to a previous period of PAP treatment. The patients primary choice of moderate intensity walking, a PA carried out in everyday life, seems important for the sustainability of PA behavior.
- The improvements in metabolic health and HRQOL were related to the increase in PA level in a dose-related manner, and appeared to be independent of any changes in pharmacological treatment. Additionally, there were no increase in the metabolic risk factor profile over the course of two years.
- The PAP treatment seem to be a low budget intervention according to the rather modest amount of support in the PAP intervention conducted at the 15 different HCC during the 3.5-year study period.

- The studied population represented a large patient group of which a majority had more than two metabolic risk factors and were taking medications for a wide range of NCD's. These are factors that could increase the external validity for patients in primary care, indicating that other patient groups may benefit from PAP treatment.
- A 2-year continued PAP treatment was conducted, for the first time, among patients non-responding to a previous 6-month PAP intervention, showing increased PA level, metabolic health and HRQOL. The results in Paper III indicate that continuity and duration may be two important factors for patients to change PA behavior. The results may also provide options for the health care organization when the first PAP intervention period does not give the desired result.
- Patients with the lowest PA levels at baseline increased their PA most in a 6-month perspective, indicating that this patient group are primarily benefiting from the PAP treatment. These patients also have the greatest health gain with increased PA.
- In clinical practice, confidence in readiness to change PA, which is similar to the concept of self-efficacy, could be used to better individualize the PAP support as this was identified as a predictive factor for increased PA levels at 6-month.
- The costs and QALY change were similar in the two PAP treatment strategies conducted by either PTs or by nurses at the HCC, and it was not possible to draw certain conclusions about the most cost-effective strategy.

# Future perspectives

Although this thesis and previous research has shown that Swedish PAP treatment has positive effects on PA and health outcomes, and is feasible in ordinary primary care, further research is needed to:

- Evaluate the benefit of individualized, well-defined, long-term PAP treatment in various clinical settings to understand more about the processes and the importance of long-term follow-up.
- Analyze the factors that potentially predict changes in PA levels to improve our understanding the processes underlying patients' behavioral changes and the individualization of PAP support.
- Evaluate subgroups of patients with different diagnoses from different cultural and socioeconomic settings and patients ending their PAP treatment (dropouts) in order to improve the individualization of PAP treatment and identify patients in need of enhanced support.
- Explore if there is any effect on patients' medication use in conjunction with an increased level of PA in PAP interventions.
- Highlight health-economic aspects of the above.

In order to adequately evaluate the effects of a treatment, both health care professionals and patients need the right conditions to work with and embrace the treatment. PAP is still underutilized as a treatment strategy in Swedish health care. Some studies have been conducted concerning health care professionals' and patients' experiences with PAP treatment, their needs, and perceived barriers and opportunities, but further research is needed to:

- Explore the mechanisms and strategies for successful implementation of PAP treatment in implementation studies.
- Identify health care professionals' and managements' perceptions of what is needed for implementing, using, and engaging in PAP treatment.
- Explore and describe how physically inactive patients experience treatment with PAP.
- Highlight health-economic aspects of the above.

Well-evaluated and widely implemented, PAP treatment has the potential to become an important method and may result in major health benefits for physically inactive patients and be beneficial for the healthcare system.

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### ACSM/AHA Questionnaire



# Resultatnyckel

A dagar	<b>B</b> dagar	total poäng	A dagar	<b>B</b> dagar	total poäng
0	0	0.0	4	1	5.7
0	1	1.7	4	2	7.4
0	2	3.4	4	3	9.1
0	3	5.1	4	4	10.8
0	4	6.8	4	5	12.5
0	5	8.5	4	6	14.2
0	6	10.2	4	7	15.9
0	7	11.9	5	0	5.0
1	0	1.0	5	1	6.7
1	1	2.7	5	2	8.4
1	2	4.4	5	3	10.1
1	3	6.1	5	4	11.8
1	4	7.8	5	5	13.5
1	5	9.5	5	6	15.2
1	6	11.2	5	7	16.9
1	7	12.9	6	0	6.0
2	0	2.0	6	1	7.7
2	1	3.7	6	2	9.4
2	2	5.4	6	3	11.1
2	3	7.1	6	4	12.8
2	4	8.8	6	5	14.5
2	5	10.5	6	6	16.2
2	6	12.2	6	7	17.9
2	7	13.9	7	0	7.0
3	0	3.0	7	1	8.7
3	1	4.7	7	2	10.4
3	2	6.4	7	3	12.1
3	3	8.1	7	4	13.8
3	4	9.8	7	5	15.5
3	5	11.5	7	6	17.2
3	6	13.2	7	7	18.9
3	7	14.9	ACSM/AHA	Hackelle	
4	0	4.0	LIR, Linköp		

Hur läser jag av tabellen? Hitta patientens kombination av svar på frågorna i tabellen och avläs totalpoängen bredvid.\*

#### Vad innebär totalpoängen?

Om patienten får 5 totalpoäng eller mer (gröna fält) betyder det att den fysiska aktivitetsnivån räknas som regelbunden och motsvarar folkhälsorekommendationen.

Om patienten får under 5 totalpoäng (röda fält) betyder det att den fysiska aktivitesnivån behöver ökas.

\* Totalpoängen beräknas genom ekvationen (a x 1) + (b x 1.7) där a och b är variabler för svaren på respektive frågor.





### International Physical Activity Questionnaire - Short Form (IPAQ) Aktivitetsvanor

Följande frågor handlar om fysisk aktivitet. Vi är intresserade av att ta reda på all typ av fysisk aktivitet som utförs. Frågorna innefattar tid som du varit fysiskt aktiv de **senaste 7 dagarna**. Svara på frågorna även om du inte anser dig vara en aktiv person. Inkludera alla aktiviteter under såväl arbete, transporter, hushållsarbete, trädgårdsarbete, fritidsaktiviteter som planerad träning.

1. Tänk nu på alla de **mycket ansträngande** aktiviteter du utförde under de **senaste 7 dagarna**. Mycket ansträngande fysisk aktivitet innefattar aktiviteter som upplevs som mycket arbetsamma och får dig att andas mycket kraftigare än normalt. Tänk enbart på de aktiviteter som du utfört under minst 10 minuter i sträck.

1a. Under de <u>senaste 7 dagarna</u>, hur många av dessa dagar har du utfört arbete som är <u>mvcket ansträngande</u> såsom tunga lyft, tyngre bygg- och trädgårdsarbete, aerobics, löpning eller cykling i högre tempo?

..... dagar

☐ Ingen sådan aktivitet ➡ Hoppa över fråga 16b

1b. Hur mycket tid tillbringade du<u>, i genomsnitt under *en* sådan dag</u>, på <u>mycket</u> <u>ansträngande</u> fysisk aktivitet?

..... timmar ..... minuter

🗌 Vet ej

2. Tänk nu på alla de **måttligt ansträngande** aktiviteter du utförde under de **senaste 7 dagarna**. Måttligt ansträngande fysisk aktivitet innefattar aktiviteter som upplevs som arbetsamma och får dig att andas något kraftigare än normalt. Tänk enbart på de aktiviteter som du utfört under minst 10 minuter i sträck.

2a. Under de <u>senaste 7 dagarna</u>, hur många av dessa dagar har du utfört arbete som är <u>måttligt ansträngande</u> såsom cykling, simning, måttligt bygg- och trädgårdsarbete eller annat i måttligt tempo? Inkludera ej promenader.

..... dagar

🗌 Ingen sådan aktivitet 🗭 Hoppa över fråga 17b

2b. Hur mycket tid tillbringade du, <u>i genomsnitt under *en* sådan dag</u>, på <u>måttligt</u> <u>ansträngande</u> aktivitet?

..... timmar ..... minuter

🗌 Vet ej

3. Tänk nu på all tid du **promenerat** under de **senaste 7 dagarna.** Detta inkluderar promenader på arbetet, under transporter och under fritiden.

3a. Under de <u>senaste 7 dagarna</u>, hur många dagar har du <u>promenerat</u> i minst 10 minuter i sträck?

..... dagar

□ Inga promenader ➡ Hoppa över fråga 18b

3b. Hur mycket tid per dag tillbringade du, i genomsnitt en sådan dag, på promenader?

..... timmar ..... minuter

🗌 Vet ej

4. Tänk nu på den tid som du tillbringat **sittande** under en typisk dag, de **senaste 7 dagarna**, i samband med arbete, studier, transporter, i hemmet och på din fritid. Exempelvis tid vid skrivbordet, hemma hos vänner eller i TV-soffan.

Under de senaste 7 dagarna, hur mycket tid har du tillbringat sittande <u>under *en* sådan</u> <u>dag</u>?

..... timmar ..... minuter

🗌 Vet ej

### Saltin-Grimby Physical Activity Level Scale (SGPALS) Hur mycket rör Du Dig och anstränger Dig kroppsligt på fritiden?

Om Din aktivitet varierar mycket mellan t ex sommar och vinter, så försök att ta ett genomsnitt. Frågan gäller det senaste året. Kryssa i <u>ett</u> alternativ

### Stillasittande fritid

Du ägnar Dig mestadels åt läsning, TV, datorer, bio eller annan stillasittande sysselsättning på fritiden

### Måttlig motion på fritiden

Du promenerar, cyklar eller rör Dig på annat sätt under minst 4 timmar i veckan. I detta inräknas också gång eller cykling till och från arbetet samt söndagspromenader, trädgårdsarbete, fiske, bordtennis, bowling etc

### **Regelbunden motion och träning**

Du ägnar Dig åt t ex löpning, simning, tennis, badminton, motionsgymnastik eller liknande. Tyngre trädgårdsarbete och liknande räknas till denna grupp. Observera att det ska vara i genomsnitt minst 2-3 timmar i veckan

#### Hård träning eller tävlingsidrott

Du ägnar Dig åt hård träning och tävling i löpning, orientering, skidåkning, simning, fotboll, handboll etc. regelbundet eller flera gånger i veckan

### Saltin-Grimby six-grade PA scale Hur aktiv uppskattar du att du varit under den senaste tiden?

Du behöver inte uppfylla allt i alternativet. Om du tillexempel sköter allt hushållsarbete så motsvarar det lättare fysisk aktivitet 4 timmar/vecka. Kryssa i <u>ett</u> alternativ

<b>Knappast</b>	någon	aktivitet	alls
-----------------	-------	-----------	------

Mestadels stillasittande, ibland någon promenad, lättare trädgårdsarbete eller liknande, ibland lätt hushållsarbete, såsom uppvärmning av mat, damning och undanplockning. Har dock ej huvudansvaret för detta.

☐ Lättare fysisk ansträngning omkring 2-3 timmar per vecka, t.ex. promenader, fiske, dans, ordinärt trädgårdsarbete etc. Även promenader till och från affärer flera gånger per vecka. Har huvudansvaret för lätt hushållsarbete, typ matlagning, damning, undanplockning och bäddning och/eller hjälper till vid veckostädning.

Mer ansträngande motion 1-2 timmar per vecka, t.ex. motionslöpning, simning, motionsgymnastik, tyngre trädgårdsarbete, byggarbete eller lättare fysisk aktivitet mer än 4 timmar per vecka. Sköter allt hushållsarbete själv, lättare såväl som tyngre. Veckostädar med dammsugning, golvtorkning och fönsterputsning.

- Mer ansträngande motion minst 3 timmar per vecka, t.ex. tennis, simning, motionslöpning etc.
- Hård träning regelbundet och flera gånger i veckan, där den fysiska ansträngningen är stor, t.ex. löpning, skidåkning.

#### Self-Efficacy for Exercise Scale (SEE) Tilltro till förmåga att bedriva fysisk träning

Nedan följer nio frågor som undersöker din upplevelse av hur säker du känner dig på att kunna bedriva fysisk träning trots olika omständigheter. Med fysisk träning avses aktiviteter som upplevs något ansträngande och får dig att andas kraftigare än normalt.

Du skattar på en skala mellan ett till tio hur väl påståendet stämmer överens med din upplevelse. Markera siffran genom att kryssa i rutan under vald siffra.

### Hur säker känner du dig just nu på att du skulle kunna träna 3 gånger/vecka i 20 minuter om...

Inte säker al	ls (0)										(10) H	Helt säker
	0	1	2	3	4	5	6	7	8	9	10	
vädret besvärade dig?												
du var uttråkad av träningsprogrammet eller aktiviteten?												
du kände smärta när du tränade?												
du var tvungen att träna ensam?												
du inte tyckte det var roligt?												
du var alltför upptagen med andra aktiviteter?												
du kände dig trött?												
du kände dig stressad?												
du kände dig nedstämd?												

### Outcome Expectations for Exercise-2 Scale (OEE-2) **Förväntningar av fysisk träning**

Svara genom att ringa in det alternativ som du tycker stämmer bäst

Fysisk träning	instämmer helt	instämmer	varken instämmer eller instämmer inte	instämmer inte	instämmer inte alls
får mig att känna mig fysiskt bättre.	1	2	3	4	5
gör mitt humör bättre i allmänhet.	1	2	3	4	5
hjälper mig att känna mig mindre trött.	1	2	3	4	5
gör mina muskler starkare.	1	2	3	4	5
är något jag tycker om att göra.	1	2	3	4	5
ger mig en känsla för vad jag klarar av.	1	2	3	4	5
gör mig mer mentalt alert.	1	2	3	4	5
förbättrar min uthållighet när jag utför mina dagliga aktiviteter.	1	2	3	4	5
hjälper till att stärka mitt skelett.	1	2	3	4	5
är något jag undviker för att det gör mig andfädd	1	2	3	4	5
är något jag undviker för att det kan ge mig smärta	1	2	3	4	5
gör mig orolig för att jag skall ramla eller göra mig illa	1	2	3	4	5
är för ansträngande för mitt hjärta så jag undviker det	1	2	3	4	5

### Physical Activity Enjoyment Scale (PACES) När jag är fysiskt aktiv...

Håller inte alls	med (1)				(5) Håller	verkligen i
	1	2	3	4	5	
Jag trivs						
Jag känner mig uttråkad						
Jag tycker inte om det						
Jag tycker det är roligt						
Det är inte alls roligt						
Det ger mig energi						
Det gör mig deprimerad						
Det är mycket behagligt						
Min kropp känns bra						
Jag får ut någonting av det						
Det är väldigt spännande						
Det är frustrerande för mig						
Det är inte alls intressant						
Det ger mig en stark känsla av framgång						
Det känns bra						
Jag känner som om jag hellre skulle göra något annat						

### Social support for exercise scale (SSES) Socialt stöd

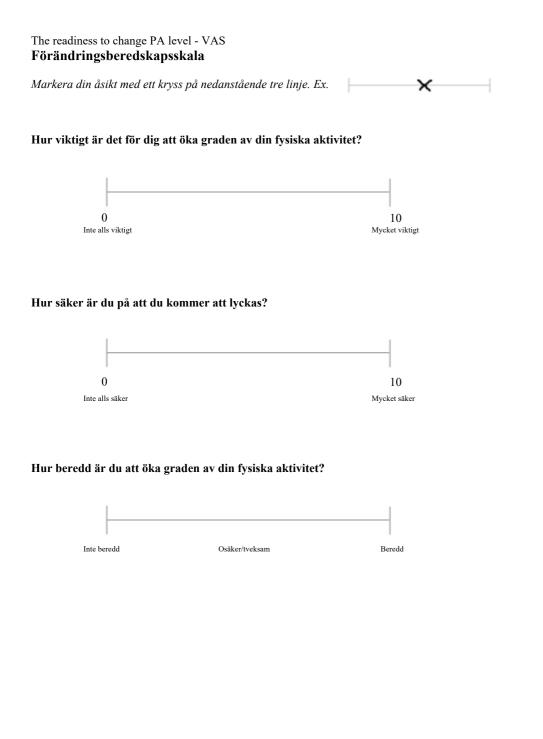
Vänligen kryssa i dina svar för var och en av följande påståenden, <u>en gång för familj</u>, och <u>en gång för vänner.</u>

Med träning menas fysisk aktivitet som du utför åtminstone 20 min i ett sträck, 3 gånger i veckan, och som är ansträngande nog att göra dig andfådd och svettig.

Under de senaste tre månaderna har min familj eller mina vänner:

		Aldrig	Sällan	Ibland	Ofta	Väldigt ofta	Inte aktuellt
	Familj						
Tränat tillsammans med mig	Vänner						
	Familj						
Erbjudit sig att träna tillsammans med mig	Vänner						
Hjälpt till att påminna mig om att träna	Familj						
(Ska du träna ikväll?)	Vänner						
	Familj						
Gett mig uppmuntran att fortsätta träna	Vänner						
Ändrat om i sin planering så att vi skall	Familj						
kunna träna tillsammans	Vänner						
	Familj						
Diskuterat träning med mig	Vänner						
	Familj						
Klagat på den tid jag ägnar åt träning	Vänner						
	Familj						
Kritiserat eller retat mig för att jag tränar	Vänner						
Gett mig belöning för att jag tränar (köpt	Familj						
något åt mig eller gett mig något som jag tycker om)	Vänner						
• /	Familj						
Planerat motion under fritidsutflykter	Vänner						
Hjälpt mig att planera aktiviteter runt min	Familj						
träning	Vänner						
Frågat mig om idéer om hur de ska kunna	Familj						
utöka sin träning	Vänner						
	Familj						
Pratat om hur mycket de tycker om att träna	Vänner						

### Hälsoenkät (SF-36)



Instruktion: Detta formulär innehåller frågor om hur Du ser på Din hälsa. Informationen skall hjälpa till att följa hur Du mår och fungerar i Ditt dagliga liv. Besvara frågorna genom att sätta ett kryss i den ruta Du tycker stämmer bäst in på Dig. Om Du är osäker, kryssa ändå i den ruta som känns riktigast.

1.	l allmänhet, skulle Du vilja säga att Din hälsa är:	Utmärkt	Mycket god	God	Någorlunda	Dålig
		Mycket bättre nu	Något bättre nu	Ungefär detsamma	Något sämre nu	Mycket sämre nu
2.	Jämfört med för ett år sedan, hur skulle Du vilja bedöma Ditt allmänna hälsotillstånd <u>nu</u> ?					

3. De följande frågorna handlar om aktiviteter som Du kan tänkas utföra under en vanlig dag. Är <u>Du på grund av ditt hälsotillstånd</u> begränsad i dessa aktiviteter <u>nu</u>? Om så är fallet, hur mycket?

		Ja, mycket begränsad	Ja, lite begränsad	Nej, inte alls begränsad
a.	Ansträngande aktiviteter, som att springa, lyfta tunga saker, delta i ansträngande sporter			
b.	Måttligt ansträngande aktiviteter, som att flytta ett bord, dammsuga, skogspromenader eller trädgårdsarbete			
c.	Lyfta eller bära matkassar			
d.	Gå uppför flera trappor			
e.	Gå uppför en trappa			
f.	Böja Dig eller gå ner på knä			
g.	Gå mer än två kilometer			
h.	Gå några hundra meter			
i.	Gå hundra meter			
j.	Bada eller klä på Dig			

4. Under de <u>senaste fyra veckorna</u>, har Du haft något av följande problem i Ditt arbete eller med andra regelbundna dagliga aktiviteter <u>som en följd av Ditt kroppsliga hälsotillstånd</u>?

		Ja	Nej
	a. Skurit ned den tid Du normalt ägnat åt arbete eller andra aktiviteter		
	b. Uträttat mindre än Du skulle önskat		
	c. Varit hindrad att utföra vissa arbetsuppgifter eller andra aktiviteter		
	<ul> <li>d. Haft svårigheter att utföra Ditt arbete eller andra aktiviteter (t ex genom att det krävde extra ansträngning)</li> </ul>		
5.	Under de <u>senaste fyra veckorna</u> , har Du haft något av följande problem i D regelbundna dagliga aktiviteter <u>som en följd av känslomässiga problem</u> (so		
		Ja	Nej

		Ja	Nej
a. Sl	kurit ned den tid Du normalt ägnat åt arbete eller andra aktiviteter		
b. U	J <b>trättat mindre</b> än Du skulle önskat		
c In	nte utfört arbete eller andra aktiviteter så <b>noggrant</b> som vanligt		

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	Under de <u>senaste fyra veckorna</u> , i vilken utsträckning hat Ditt kroppsliga hälsotillstånd eller Dina känslomässiga problem stört Ditt vanliga umgänge med anhöriga, vänne grannar eller andra?	I	nte alls	Lite	Måttligt	Mycket	Väldigt mycket
7.	Hur mycket <u>värk eller smärta</u> har Du haft under de <u>senaste fyra veckorna</u> ?	Inger	Myck n lätt	et Lätt		lig Svår	Mycket svår
8.	Under de <u>senaste fyra veckorna</u> , hur mycket har <u>värken e</u> <u>smärtan</u> stört Ditt normala arbete (innefattar både arbete utanför hemmet och hushållssysslor)?	iller I	nte alls	Lite	Måttligt	Mycket	Väldigt mycket
9.	Frågorna här handlar om hur Du känner Dig och hur Du haft det <u>under de senaste fyra veckorna</u> . Ange för varje fråga det svarsalternativ som bäst beskriver hur Du känt Dig.						
	Hur stor del av tiden under <u>de senaste fyra veckorna</u> He	ela tiden		En hel de av tiden	el En del a tiden	av Lite av tiden	Inget av tiden
	ahar Du känt Dig riktigt pigg och stark?						
	bhar Du känt Dig mycket nervös?						
	char Du känt Dig så nedstämd att ingenting kunnat muntra upp Dig?						
	dhar Du känt dig lugn och harmonisk?						
	ehar Du varit full av energi?						
	fhar Du känt Dig dyster och ledsen?						
	ghar Du känt Dig utsliten?						
	hhar Du känt Dig glad och lycklig?						
	ihar Du känt Dig trött?						
10.	Under de <u>senaste fyra veckorna</u> , hur stor del av tiden har <u>Ditt kroppsliga hälsotillstånd eller Dina känslomässiga</u> <u>problem</u> stört Dina möjligheter att umgås (t ex hälsa på släkt, vänner, etc)?	Hela t	dele iden ti	orsta en av E den	in del av tiden	Lite av tiden	Inget av tiden
11.	Välj det svarsalternativ som bäst beskriver hur mycket <u>vart och ett</u> av följande påståenden STÄMMER eller INTE STÄMMER in på Dig.						
		Stäm		mmer ska bra	i Osäker	Stämmer inte särskilt bra	Stämmer inte alls
	<ul> <li>a. Jag verkar ha lite lättare att bli sjuk än andra människor</li> </ul>						
	<ul> <li>b. Jag är lika frisk som vem som helst av dem jag känner</li> </ul>						
	c. Jag tror min hälsa kommer att bli sämre						
	d. Min hälsa är utmärkt						

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