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# Prescribed physical activity. A health economic analysis.

Åsa Romé



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DOCTORAL DISSERTATION

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<p>Abstract: The overall aim of this thesis was to estimate health economic consequences of the 4-month primary care "Physical Activity on Prescription" (PAP) program. Inactivity is an independent risk factor and an economic burden to society. Evidence for cost effective interventions aiming at increasing physical activity (PA) level among inactive individuals is limited. The Swedish FaR® concept aims at improving PA to meet public health guidelines for a sufficient level of PA. Specifically, the aims of the different studies were to analyze costs and consequences of changed PA from the 4-month PAP-program [paper I], to estimate and analyze the willingness to pay (WTP) and examine WTP and predictors for WTP for health effects of PA [paper II], to analyze the cost offset of changed PA, motivation and attitudes after one year [paper III], and to analyze the benefits in terms of QoL and cost per QALY, respectively [paper IV]. The study was a randomized clinical trial with 528 inactive individuals randomized to either a high-dose or a low-dose group. The high-dose group consisted in supervised exercise sessions twice a week, education in PA, and a motivational counselling. The low-dose group received written information on the possibility to participate in supervised exercise groups once a week on a moderate-intense level in local fitness centres. <i>Results:</i> For the 4-month assessment 242 individuals returned. A cost-consequences analysis [paper I] showed intention-to-treat average program costs per individual of SEK 6475 for the high-dose group and SEK 3038 for the low-dose group, with the largest share of the costs being the individual's. PA level improved significantly, with no differences between the groups. The WTP-analysis in paper II (n=128) showed that WTP for health effects of PA is influenced by a higher education level, income and BMI. An analysis of cost-minimization [paper III] (n=178, 66% drop-out rate) confirms a significantly improved PA level after 1 year. The cost offset consisted in reduced health care costs and value of lost production thanks to reduced inactivity, and was equal to 22%. The cost-utility analysis in paper IV (n=178) at a 1 year follow-up showed that the PAP-program is cost-effective, and the cost per QALY, 323,750 SEK and 101,267 SEK for the high- and low-dose group, is considered moderate according to Swedish reference values. The low-dose group showed significant improvements in QoL. Completers of the program had a significant higher age and a better health status at baseline. <i>Conclusions:</i> The PAP-program increased PA level (both groups) and QoL (low-dose group) significantly after 1 year. The best adherence for the PAP-program was found for elderly and those with relatively good baseline health. Identifying the target population is necessary for adherence, effectiveness and cost-effectiveness of the program. The PAP-program was cost-effective, most for a low-dose group, and makes it worthwhile for society. An increased availability of exercise would reduce the individual's costs.</p>			
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# Prescribed physical activity. A health economic analysis.

Åsa Romé



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Orden ser ut som moln,  
plötsligt står de med glans  
eller fattigt grå  
på sin pappershimmel.  
När de kommer, vet vi inte,  
de kan vara ljusa, lätta, pärlemor-  
skimrande,  
de kan vara lysande  
som nattmoln,  
ord som vi skriver i väntan  
på Ordet,  
som genombryter allt  
och skingrar alla tvivel  
på en blå himmel.

Bo Setterlind





# Contents

List of publications	1
Descriptions of contributions	2
Abstract	3
Summary in Swedish	6
Thesis at a glance	8
Abbreviations	9
Rationale	10
1. Introduction	11
1.1 Inactivity	11
1.1.1 Definition and prevalence	11
1.1.2 Inactivity related disease and its disease burden	13
1.1.3 Cost of illness of inactivity	14
1.2 Physical Activity	15
1.2.1 The importance of health promotion	15
1.2.2 Prescribed physical activity	17
1.2.3 Physical Activity Referral (FaR®) and Physical Activity in the Prevention and Treatment of Disease (FYSS): the Swedish model	19
1.2.4 Measuring physical activity	20
1.3 Motivation for physical activity	21
1.4 Health Economics	23
1.4.1 Methodology	23
1.4.2 Demand for health	26
1.4.3 Costs	26
1.4.4 Priorities and subsidies	27
1.4.5 Economic perspectives	28
1.5 Economic concepts	29
1.5.1 Willingness to pay	29
1.5.2 Cost-consequences	30
1.5.3 Cost-utility	30
1.5.4 QALYs vs. DALYs	32

1.6	Economic evaluation of physical activity interventions	32
1.7	Economic evaluation of prescribed physical activity	34
2.	Aims	37
3.	Material and Methods	38
3.1	Study population	38
3.2	Study design and intervention	39
3.3	Statistical analyses	41
3.4	Cost-consequences approach and Cost-minimization approach (Paper I,III)	43
3.5	The WTP approach (Paper II)	45
3.6	Cost-minimization and Motivation (Paper III)	47
3.7	The cost-utility approach (Paper IV)	48
4.	Results of paper I-IV: a summary	49
4.1	Cost-consequences	49
4.2	WTP	50
4.3	Cost-minimization and motivation	51
4.4	Cost-utility	52
5.	General discussion	54
6.	Conclusions	70
7.	Acknowledgements	71
8.	References	72

# List of publications

This thesis is based on the following papers, which are referred to throughout the thesis by their Roman numerals. The papers are reprinted with the permission of the publishers.

- I            Romé Å, Persson U, Ekdahl C, Gard G. Physical activity on prescription (PAP): costs and consequences of a randomized, controlled trial in primary health care. *Scand J Prim Health care*. 2009;27(4):216-22. doi: 10.3109/02813430903438734.
- II           Romé Å, Persson U, Ekdahl C, Gard G. Willingness to pay for health improvements of physical activity on prescription. *Scand J Public Health*. 2010 Mar; 38(2):151-9. doi: 10.1177/1403494809357099. Epub 2010 Jan 11.
- III          Romé Å, Persson U, Ekdahl C, Gard G. Costs and outcomes of an exercise referral programme – A 1-year follow-up study. *European Journal of Physiotherapy*. Posted online on March 10, 2014. doi:10.3109/21679169.2014.886291.
- IV          Romé Å, Persson U, Gard G. Prescribed Physical Activity in primary care: one year cost-utility and quality of life outcomes. Submitted to *Scandinavian Journal of Primary Health Care*.

# Descriptions of contributions

<b>Study design</b>	Ulf Persson, Gunvor Gard, Åsa Romé, Region Skåne
<b>Data collection</b>	Physiotherapists in primary health care in Sjöbo, Simrishamn, Skurup, Tomelilla and Ystad. Åsa Romé
<b>Data analysis</b>	Vibeke Horstmann, Åsa Romé
<b>Manuscript writing</b>	Åsa Romé
<b>Manuscript revision</b>	Ulf Persson, Gunvor Gard, Charlotte Ekdahl, Vibeke Horstmann, Åsa Romé

# Abstract

The overall aim of this thesis was to estimate health economic consequences of the four-month primary care program "Physical Activity on Prescription (PAP)". Inactivity means a highly increased independent risk factor for public health diseases and morbidity, and is an economic burden to society. Evidence for cost effective interventions aiming at increasing physical activity (PA) level among inactive individuals is limited, why health economic evaluations are an important tool when arranging priorities in health care sector.

Promoting PA among inactive individuals within primary health care with a prescription of exercise has shown to be effective in terms of significantly increasing physical activity levels. The Swedish FaR® concept can be seen as a concept for improving physical activity behaviour to meet public health guidelines for a sufficient level of physical activity. The program has been implemented as a concept in Swedish health care, but without a common model nationwide. The present concept of the PAP-program in the south-east health care district of Region Skåne, Sweden was based on an existing program with treatment perspective.

Specifically, the aims of the different studies were to analyze costs and consequences of changing PA behaviour from the 4-month PAP-program [paper I], to analyze the willingness to pay (WTP) for health effects of physical activity due to the PAP-program, and examine predictors for the WTP [paper II], to analyze the cost offset of changing the PA behavior and motivation after 1 year [paper III], and to analyze the benefits in terms of quality of life and cost per QALY, respectively [paper IV].

The study was a randomized clinical trial with a 4-month intervention. In all, 528 inactive individuals were randomized to either a high-dose or a low-dose group. The high-dose group consisted in supervised group exercise sessions twice a week during 4 months on a moderate-intense level, education in physical activity, and a motivational counselling. The low-dose group received written information on the possibility to participate in supervised exercise groups once a week on a moderate-intense level in local fitness centres.

*Results:* A cost-consequences analysis (n=242) showed intention-to-treat program average programme costs per participant for the 4 month PAP-program being SEK 6475 for the high-dose group and SEK 3038 for the low-dose group [paper 1]. The largest cost was the individuals' time cost. PA level improved significantly, with no differences between the groups. In paper II, a WTP-analysis (n=128) showed no significant differences for different health improvements between a high- and a low-dose group, and that WTP for health improvements of physical activity is influenced by a higher education level, income and BMI. Paper III examined cost-minimization and motivation of the programme at a 1 year follow-up (n=178, 95 in the high-dose group and 83 in the low-dose group), with a drop-out rate of 66% in both groups together. The results of a significantly improved PA level in paper II were confirmed in this study. There were no differences in motivation among completers and non-completers of the PAP-program. The cost offset consisted in reduced health care costs and value of lost production due to reduced inactivity, and was equal to 22%. The cost-utility analysis in paper IV of the 178 individuals that returned for the 1-year follow-up showed that the PAP-program is cost-effective, and the cost per QALY, 323,750 SEK and 101,267 SEK for the high- and low-dose group, is considered moderate according to Swedish reference values. A low-dose group was more cost-effective and had larger improvements in QoL than a high-dose group. QoL improved significantly in the low-dose group and in both groups together.

*Conclusions:* The PAP-program showed that it was possible to make inactive individuals more physically active through intervention. Significant improvements in PA behaviour were shown in a one-year follow-up analysis. The results of this program of prescribed exercise showed significant increased QoL one year after intervention in a low-dose group. The best adherence for the PAP-program was found for elderly and those with relatively good baseline health. These individuals constitute the target population for this prescription based exercise program. Identifying the target population for participation in health promoting activity groups like the PAP-program is necessary for adherence, effectiveness and cost-effectiveness of a program. The PAP-program is cost-effective as shown in a cost-utility analysis conducted in the study. The costs per QALY estimates were considered moderate regarding to Swedish comparative values. This makes the program a method worthwhile for society. The program was most cost-effective for a low-dose group. This was showed with lower costs associated with the low-dose group, and larger improvements in QoL. An increased availability of exercise would reduce

the individual's time cost for travelling, and cost for travel. The inactive individual's preferences for improved health through exercise were influenced by a higher education level, income and BMI. The PAP-program can reduce the society's costs for inactivity by 22% per individual, every year the individual stays active.

# Summary in Swedish

Det finns övertygande evidens för att fysisk inaktivitet ökar såväl mortalitet som morbiditet i flertalet av våra vanligaste folksjukdomar. Inaktivitet är den globalt sett fjärde största riskfaktorn och orsak till förtida död, efter högt blodtryck, tobak och högt blodsocker. Enligt WHO:s beräkningar uppgår antalet dödsfall i världen orsakat av inaktivitet till minst 3,2 miljoner per år. Regelbunden fysisk aktivitet har en odiskutabelt positiv effekt på vår fysiska och mentala hälsa. Inaktivitet innebär en ökad ekonomisk börda för samhället: i Sverige år 2002 uppgick samhällets kostnader för den del av befolkningen som var otillräckligt fysiskt aktiv och inaktiv till ca sex miljarder kronor, vilket inkluderar kostnader för hälso- och sjukvården samt s.k. indirekta kostnader för produktionsbortfall p.g.a långtidssjukfrånvaro och förtida död. Evidensen för kostnadseffektiva program med syfte att öka den fysiska aktivitetsnivån bland inaktiva individer är begränsad, och därför är ekonomiska utvärderingar ett viktigt redskap då t ex prioriteringar inom hälso- och sjukvården ska genomföras.

Fysisk aktivitet på recept (FaR®) är en etablerad metod i Sverige för att förskriva fysisk aktivitet. Det är ett koncept med syfte att öka den fysiska aktiviteten hos inaktiva så att den motsvarar de nivåer av fysisk aktivitet som rekommenderas i ett hälsofrämjande perspektiv. Det 4-månaders primärvårds-program ("Fysisk aktivitet på recept / Physical activity on prescription, PAP") som låg till grund för denna avhandling genomfördes i sydöstra Skåne under åren 2006-2008, och har sedan utvärderats med främst hälsoekonomiska analysmetoder. Interventionen baserades på ett existerande behandlingsprogram.

Det övergripande syftet med avhandlingen var att analysera de hälsoekonomiska konsekvenserna av programmet "Fysisk aktivitet på recept". Mer specifikt var syftena med de olika studierna att analysera kostnader och konsekvenser av förändrad fysisk aktivitet genom FaR-programmet [delstudie I], att beräkna och analysera betalningsviljan för olika hälsoeffekter av fysisk aktivitet på recept och undersöka faktorer associerade till betalningsviljan [delstudie II], att analysera kostnadseffekter som kan relateras till en förändrad fysisk aktivitetsnivå och analysera motivation och attityder i en ett-års uppföljning [delstudie III] samt att analysera nyttan kopplat till livskvalitet och kostnader per QALY [delstudie IV]. Studien var en randomiserad klinisk studie med en fyra månaders intervention. Sammanlagt inkluderades 528 individer, som randomiserades att tillhöra antingen en hög-dos eller låg-dos grupp. Hög-dos gruppen bestod av gruppträning två gånger per vecka, undervisning om nyttan av fysisk aktivitet samt ett motiverande



samtal. Låg-dos gruppen erhöll skriftlig information om möjligheten att delta i gruppträning en gång per vecka.

Resultaten av en kostnads-konsekvens analys [delstudie I] visade att vid en fyra-månaders uppföljning (n=242) var intention-to-treat- och genomsnittlig kostnad per deltagare för programmet SEK 6475 för en hög-dos grupp, och SEK 3038 för en låg-dos grupp, och att den största delen av kostnaderna bars av individen själv. Den fysiska aktiviteten ökade signifikant, men utan skillnader mellan grupperna. Studien av betalningsviljan [delstudie II], som genomfördes på de 128 första deltagarna som fullföljde 4-månaders programmet, visade ingen signifikant skillnad i betalningsvilja för olika hälsoförbättringar av FaR mellan de båda grupperna, men att betalningsviljan var associerad till en högre utbildningsnivå, inkomst och BMI. En kostnadsanalys i delstudie III (n=178, bortfall 66%) visar att samhällets kostnader pga minskad inaktivitet minskar med 22%, pga minskade kostnader för hälso- och sjukvården och minskade kostnader för produktionsbortfall. Den signifikanta ökningen av fysisk aktivitetsnivå som sågs vid 4 månader kunde bekräftas i 1-års uppföljningen. Kostnads-nyttö analysen i delstudie IV av de 178 individer som kom till 1-års uppföljningen visade att FaR-programmet är kostnadseffektivt, och att kostnaden per QALY, SEK 323 750 (hög-dos gruppen) och SEK 101 267 (låg-dos gruppen) anses moderat i förhållande till svenska referensvärden. En låg-dos grupp var mer kostnadseffektiv och hade större livskvalitetsförbättringar än en hög-dos grupp.

Konklusioner: FaR-programmet kunde öka den fysiska aktivitetsnivån signifikant efter ett år- Livskvaliteten ökade signifikant vid en ett-års uppföljning i en låg-dos grupp och för båda grupper tillsammans. Bäst följsamhet för programmet fanns hos äldre och hos de individer som skattade sin hälsa till relativt god när de startade i programmet. Dessa individer utgör målgruppen för FaR-programmet. Att identifiera rätt målgrupp är nödvändigt för att uppnå följsamhet, effektivitet och kostnadseffektivitet för ett program som detta. FaR-programmet var kostnadseffektivt, visat i en kostnadsnyttoanalys, och gör programmet lönsamt i ett samhällsperspektiv. Programmet var mest kostnadseffektivt för en låg-dos grupp. En ökad tillgänglighet när det gäller träning hade kunnat öka marginalnyttan genom en ökad följsamhet i programmet.

# Thesis at a glance

Paper	Economic approach	Question	Answer
<b>I</b>	Cost-consequences	How much did the Physical Activity on Prescription (PAP)-program cost from a health care perspective?  Did the PAP-program change physical activity (PA) level?	The cost per patient for the four-month intervention was 6,475 SEK (high-dose) and 3,038 SEK (low-dose).  Yes, it significantly improved PA level in high- and low-dose groups, without differences between groups.
<b>II</b>	Willingness to pay	Were there any significant differences in WTP for different health improvements between a high- and a low-dose group?  Were there any predictors for the WTP for health improvements of physical activity?	No.  Yes, WTP for improved health through physical activity was influenced by a higher education level, income and BMI.
<b>III</b>	Cost-minimization	Was there a cost-offset from a societal perspective due to reduced inactivity one year after intervention?  Were there significant differences in PA level between the high- and low-dose groups after one year?  Were there differences in motivation among completers and non-completers of the PAP-program?	Yes, the PAP-program reduced the costs for inactivity by 22% per individual every year.  Both groups increased PA level significantly, but without differences between high- and low-dose groups.  We could not identify any differences neither regarding level of motivation nor change in motivation at no points of measurement.
<b>IV</b>	Cost-utility	Was the PAP-program cost-effective?  How much was the cost per QALY (ICER)?  Was there a change in QoL one year after intervention?	Yes, and a low-dose group was more cost-effective and had larger improvements in QoL.  The cost per QALY was 323,750 SEK and 101,267 SEK for the high- and low-dose group, respectively.  Yes, in the low-dose group and in both groups together the QALY-weights improved significantly.

# Abbreviations

**PA** Physical Activity

**PAR** Physical Activity Referral / **ER** Exercise referral / **EoP** Exercise on Prescription / **PAP** Physical Activity on Prescription: a written advice to the patient to exercise. It is the reference to a third party service for example leisure facilities or community resources where the exercise is performed. There is internationally different naming of similar concepts of a written prescription aiming at increasing physical activity level.

**Exercise referral scheme / program / intervention:** the program that is referred to, containing health promoting physical activities.

**FaR®** (Fysisk aktivitet på Recept ) / **Physical Activity on Prescription / Physical Activity Referral** is a written advice and the Swedish model for prescribed exercise, and aims at promoting physical activity through health care services.

**FYSS** (Fysisk aktivitet i Sjukdomsprevention och Sjukdomsbehandling/ Physical Activity in the Prevention and Treatment of Disease): the Swedish knowledge bank, which should be used as the basis for the prescription.

**ER** Exercise referral/ written prescription of physical activity

**ERS** Exercise Referral Scheme: the exercise program / intervention

**Prescription=Referral**

**QoL** Quality of life

**HRQoL** Health related quality of life

**QALY** Quality-adjusted life years

**DALY** Disability-adjusted life years

**WTP** Willingness to pay

**CUA** Cost utility analysis

**CEA** Cost effectiveness analysis

**CBA** Cost benefit analysis

**ICER** Incremental Cost Effectiveness Ratio

# Rationale

Fysisk aktivitet och träning har alltid varit en självklar del av mitt liv – ända sedan barnsben då våra föräldrar tog oss med ut i naturen för att betrakta växter och djur. Fysisk aktivitet har varit ett ledord på olika sätt, såväl professionellt som på den egna tiden. Inom sjukgymnastiken är fysisk aktivitet det kanske mest centrala begreppet. I mötet med patienten handlar det ofta om uppmuntran till och motivation för rörelse. Jag slutar aldrig att förvånas över de stora förändringar och förbättringar som uppstår hos människan när hon ges möjlighet och vägledning till fysisk aktivitet, såväl psykologiskt som fysiologiskt. Det är en stor förmån att få uppleva den glädje människor erfar när de uppnår en ökad aktivitet eller förbättrad fysisk funktion, att få dela deras framgång och ta del av deras stolthet över att ha klarat ett uppsatt mål. Fysisk aktivitet ger inte bara en förbättrad livskvalitet i vardagen, det ger också ett ökat självförtroende och ett välmående.

Det var därför utan tvekan jag tackade ja när frågan kom från Region Skåne om att arbeta med fysisk aktivitet på ett vetenskapligt plan. Den ursprungliga frågan gällde om det kanske till och med är så att det kan löna sig ur ett samhällsekonomiskt perspektiv att röra på sig regelbundet. Jag tyckte att frågeställningen lät mycket spännande och det har varit med stort intresse jag följt deltagarna i studien och analyserat data. Resultatet har utmynnat i denna avhandling som jag hoppas ska kunna utgöra ett bidrag i debatten kring fysisk aktivitet och hur vi ska prioritera frågan på olika nivåer. Att inaktivitet i dagens samhälle är ett stort problem nationellt och globalt är ställt utom alla tvivel. Men det gäller för oss som arbetar med hälsofrämjande frågor att använda oss av metoder som verkligen fungerar. Det är sannolikt så att ”one size doesn’t fit all” – det finns ingen universalmetod att tillgå. Vi är alla olika individer med olika förutsättningar, förmågor och behov.

Traditionellt har sjukgymnaster inte utvärderat sina metoder med hjälp av hälsoekonomiska verktyg. Personligen anser jag att detta är en brist eftersom det är ett sätt att få ett samhällsekonomiskt perspektiv på hur vi arbetar, och att på ett vetenskapligt sätt visa att våra metoder och sätt att arbeta på faktiskt kan gynna inte bara individen utan även bidra till att använda sjukvårdens resurser på ett meningsfullt och kostnadseffektivt sätt.

*Författaren*

# 1. Introduction

## 1.1 Inactivity

### 1.1.1 Definition and prevalence

Through new and effective technologies, people's lifestyles have substantially changed, particularly in the levels of physical activity that we see today within the general population. As novel communication technologies and ways of transportation have changed possibilities, they have altered leisure-time activity patterns. Physical labour has been replaced by machines and new methods, resulting in decreased physical activity levels.

Physical activity (PA) has extensive benefits worldwide for health. Inversely inactivity means a highly increased independent risk factor for public health diseases and mortality (1-7). In 2008, 63 % of the deaths occurred in the world were due to non communicable diseases (NCDs), like coronary heart disease, type 2-diabetes, breast and colon cancer (1). Of these, 6-10% were attributable to physical inactivity (6). It has even been suggested that physical inactivity may be the most important public health problem of the 21st century (8). Inactivity also influences morbidity. More than three million deaths annually can be attributed to an insufficient physical activity level, and is according to the World Health Organization (WHO) the 4th of the top five risk factors of death in the world after high blood pressure, tobacco use and high blood glucose (2). A more recent review shows an even larger risk of death due to inactivity, and reports an estimation of 5.3 million deaths per year worldwide (7). A global improvement in physical activity behaviour would improve public health substantially.

The WHO defines physical inactivity as less than 2.5 hours of moderate-intensity physical activity per week (9). This definition coincides with that of The Centers for Disease Control and Prevention (CDC) that defines a sufficient level of PA as 30 minutes per day on at least five days per week on a moderate-intensity level or vigorous-intensity activities at least 20 minutes per day at least three times per week (10). In the United States National Health Survey, adults were classified physically inactive when performing no light, moderate or vigorous leisure-time PA of at least 10 minutes per day (11). Defining physical inactivity in steps per day, a report suggests that an individual that performs less than 5000 steps per day is sedentary or inactive (12). Globally, 30% of adults and 80% of adolescents are physically inactive, and have less than 150 minutes of moderate PA per week or equivalent (1). There are large differences in activity level between countries; between 5 and 72% of the population are inactive among the 105-122 countries which are part of WHO measures. Women are overall more inactive than men; 34% compared to 28%, and inactivity increases with age. Worldwide, less developed countries show lower prevalence of inactivity, and in the most developed countries inactivity is substantially more prevalent (1,13). When measuring physical activity with focus on leisure-time exercise, inactivity is more common among individuals with low income. When including unpaid work in total physical activity (i.e. housework and occupational physical activity), however, individuals with low income have lower inactivity (14).

In Sweden, the WHO (2010) reports that the prevalence of insufficiently active adults was 47.1% of the population older than 15 years (among women it is 48.1%, which is slightly higher than 46.0% among men) (1). Similarly, the Public Health Agency of Sweden (former National Institute of Public Health) (Folkhälsomyndigheten) found from its nationally representative National Survey on Public Health (Nationella Folkhälsoenkäten), taken in 2011, that 13% reported a sedentary leisure-time, meaning that they spent less than two hours per week on physical activities like walking or cycling (15). The result shows no change since 2004. A sedentary lifestyle was most common among women aged 65 to 84 years. Socio-economic differences were also reported: working individuals with a longer education and good economy report in general a higher level of PA (15). Looking at another Swedish survey, the ULF-survey (Undersökningarna av levnadsförhållanden) from 2010, 15% of the Swedish population report that they are never physically active 30 minutes without a break (16). Men from the study reported a slightly higher inactivity than

women in all categories of age, and among men and women an increased inactivity with a higher age.

The above studies provide information of the state of physical inactivity in Sweden but it is difficult to estimate with precision the level of inactivity on a population-wide level and/or over time. Some of the main reasons are due to different outcome measures for inactivity and also to differences in the methods of analysing physical activity patterns. (17). While in some of the surveys, questions relate to the time spent in PA, others focus on number of exercise occasions. The authors of the Swedish guidelines of 'FaR' of the the Public Health Agency of Sweden summarize that about half of the Swedish population is insufficiently physically active (17). The authors summarize the results of four different national surveys made between 2000 and 2010 among Swedish adults, showing that 10% are totally inactive, and that 40% of the population has a high-risk level of low PA (17).

In research, interest has not only been in time spent on physical activity but also in the amount of time spent in inactivity (i.e. time spent sitting) as it represents a crucial factor for the substantial increase in risk for decreased health independent of physical activity (18). An example of this research focus is a report by Hallal et al. where it was found that about 40% of the adult population worldwide spend four or more hours per day sitting (14). It has been shown in other studies that prolonged sitting time is a risk factor for all-cause mortality, and time spent in sitting is independently associated with total mortality, aside from physical activity level (19-21).

### **1.1.2 Inactivity related disease and its disease burden**

Inactivity as a non communicable disease (NCD) has a global spread of an epidemical feature, and has great impact on individuals' health. Having an insufficient physical activity level means a greater risk of illness and an increase in both mortality and morbidity (2,5,8,10,22-25). The risk of developing non communicable diseases like cardiovascular disease, colon and breast cancers, Type 2 diabetes and osteoporosis is increased, and the evidence for a sufficient physical activity level is compelling. For insufficient physically active individuals with lifestyle related diseases it is an urgent issue to improve physical activity behaviour (5-8,10,22-25). Physical inactivity is a strong behavioural risk factor for NCDs, and can lead to physiological changes like raised blood pressure, overweight/obesity, hyperglycemia and hyperlipidemia (1). The disability-adjusted life year (DALY) is a measure of overall disease burden,

expressed as the number of years lost due to ill-health, disability or early death (26). Physical inactivity is reported to be attributed to 2.1% of DALY's worldwide, which is equal to 32.1 million DALYs each year (2).

### **1.1.3 Cost of illness of inactivity**

The costs of illness include direct and indirect costs (27). Direct costs are costs for prevention, detection, treatment, rehabilitation and long-term care due to the existence of a disease. Indirect costs reflect the value of goods and services that could have been produced if no illness had occurred. The character of these costs should be distinguished; direct costs are the value of resources shifted from one sector of economy to the health care sector because of illness and do not reflect lost resources. Indirect costs reflect the value of productivity loss and an opportunity foregone forever. These costs together represent the cost of illness (27). In two independent studies, the direct and indirect costs of inactivity in Sweden have been estimated to about SEK 6000 Millions in 2002 (28,29). The costs include costs for individuals that are physically inactive and insufficiently physically active. These costs are the economic burden that the Swedish society has to carry every year due to physical inactivity among the population. This can be compared with the costs for obesity in Sweden, where the estimated costs for obesity in 2011 were SEK 15,600 Millions, with an estimated prevalence of 10% (30). In the US, the direct and indirect costs of inactivity were 2.4 % of the national health care costs with an estimated inactivity share of 28.2% of the population, which is lower compared to Sweden (31). There are Canadian estimations showing that a reduction of inactivity of 10% would decrease direct health care costs with \$150 million (SEK 951 million) per year (32,33). Estimations show that 2.6 % of the total direct health care costs in 2001 in Canada were estimated to be attributable to physical inactivity.

The calculation of the inactivity related costs in Sweden is a description of the costs on society. The cost analysis does not show if the money spent on inactivity has any consequences. This type of health economic studies which describe the aggregate costs of a disease or a risk factor to a society fall into the category 'cost of illness' (34). Studies of cost-of-illness usually separate direct and indirect costs. The opportunity cost of illness are the direct and indirect costs taken together, and is the value of all resources that possibly had been realised in other sectors than health care when illness had



not appeared (34). The direct costs are costs of prevention, detection, treatment, rehabilitation and long-term care due to the disease. The indirect costs are the value of time lost from work (or leisure) and decreased productivity due to disease, disability or death (34). In the Swedish study of Moutakis et al. the included diseases were ischaemic heart disease, type 2 diabetes, stroke, femur fractures due to osteoporosis, colon cancer and hypertension (28). With data on the relative risk (RR) and prevalence of physical inactivity it is possible to calculate the PAR (28,29). Based on estimations of costs of illness attributed to physical inactivity, the proportion of the costs of a certain disease caused by inactivity can then be calculated. The risk of getting one of the mentioned diseases is between 6 and 300 % higher if an individual is physically inactive (28). Between 1.5 and 2 % of the total costs for health care are caused by inactivity. The highest Population Attributed Risk (PAR) due to physical inactivity was for colon cancer, followed by ischemic heart disease. These diseases were considered as having the highest PAR, 36% and 33 %, respectively. The PAR was ranging from 3 to 22% for the diseases type 2 diabetes, stroke, osteoporosis-related femur fractures and hypertension.

## 1.2 Physical Activity

### 1.2.1 The importance of health promotion

Physical inactivity is strongly associated with most NCDs worldwide (1). Lee et al. suggest that inactivity is similar to two other major risk factors of smoking and obesity (7). Unlike other risk factors, however, it is preventable and a decrease of this unhealthy behaviour would improve health extensively. Health promotion should be seen as a process which aims to increase an individual's possibility to improve and take control over his/her own health (35). In the Ottawa Charter (1986) the process of health promotion has been manifested. The strategies for an improved health have been described there as creating conditions that can support, encourage and help the individual to a healthier life (36). Health promotion should be encouraged in all sectors of society, including jobs with sedentary work tasks. Health promotion activities can prevent diseases, and for an increased participation in health promotion programmes it is necessary to provide a setting that adapts to local conditions and to provide possibilities for individuals to achieve positive attitudes towards a healthier lifestyle.

A central aim in Swedish public health policy stated by the the Public Health Agency of Sweden is to “create social conditions that will ensure good health, on equal terms, for the entire population” (37). For an improved public health in Sweden, eleven public health objective domains have been developed, covering the most important elements and sectors in society, such as economic policy, social welfare and environment, but also physical activity. It is recommended that the implementation of these objectives should be on different levels and organisations in society; municipalities, county councils, non-government organisations and other types of organisations. In today’s society, promoting physical activity to improve health among sedentary individuals is a pressing issue for policymakers. National as well as local level health promotion initiatives should be seen as a useful component of improving public health.

Individuals benefit from health since it increases their wellbeing, healthy time, amount of productive days and length of life (38). Demand for health care is a demand for health itself. When an individual invests time for him or herself, for example through physical activity, the individual makes the investment with the aim to increase his or her earnings. Grossman’s theory of the human capital (1972) describes that the individual both consumes health for an improved wellbeing and invests in health for an improved long term health improvement by giving time and physical effort when exercising (39). Performing health promoting activities would be an investment in the individual’s human capital according to Grossman. The individual as a consumer demands inputs to produce health. Spending time on activities that improve health is a way of producing health. The same theory states that the demand for health rises with higher education and income as health is deemed to be one of the mechanisms through which investments in human capital lead to increased earnings. This theoretic model coincides with findings of previous studies showing associations between a sedentary lifestyle and socio-economic factors like low income and low education level (40,41).

The definition of health-enhancing physical activity has been expressed as “any form of physical activity that benefits health and functional capacity without undue harm or risk” (42,43). To promote and maintain a good level of health, the recommendation is moderate-intensity aerobic physical activity that lasts for at least 150 minutes each week or vigorous-intensity aerobic physical activity that lasts for at least 20 minutes three days per week (44-47). It is additionally recommended to perform strength training on two or more days per week. In the last decades there has been a fundamental change in how much time is spent on sitting, which is

sometimes referred to as ‘sedentary’ time. Research shows relations not only between lack of exercise and mortality but also between sedentary behaviour and mortality (21,48,49). Furthermore, it has been shown that there is a dose-response association between sitting-time and mortality independent of leisure time PA activities has been shown (48). For these reason, people are being encouraged in public health promotions to reduce sitting time (21,48,49).

### **1.2.2 Prescribed physical activity**

The importance of promoting an active lifestyle for an improved health is not controversial and well scientifically supported. Despite the health benefits of PA, many individuals do not follow recommendations for a sufficient amount of exercise. It is important to find a relevant framework for creating strategies and models for increasing physical activity among inactive individuals and implement this framework in health care. Promoting PA among inactive individuals within primary health care with a prescription of exercise has shown to be effective in terms of significantly increasing physical activity levels, and is recommended as part of population strategies to reduce inactivity (50-54). The Swedish Council on Technology Assessment in Health Care evaluated methods to promote physical activity, and found the strongest evidence for an increased physical activity level among adults to be counselling within health care (55). Counselling has been showed to increase physical activity level by 12-50% during six months after counselling. There is also evidence for an increase of another 15-50% in physical activity level if the counselling is combined with a prescription for PA, pedometer or exercise diary (55). The recommendation from The National Board of Health and Welfare in Sweden is to combine counselling with a written prescription, since this is more effective than oral advice only (56). A review including five randomized controlled trials (RCTs) examining the effectiveness of exercise referral schemes (ERS) found relatively small effects on the physical activity level among sedentary adults, and that 17 sedentary adults would need to be referred to an exercise program to increase one individual’s activity level to a moderate level (57). The authors suggest that this may be explained by a low uptake and adherence to ERS. Another review of 14 observational studies and five RCTs evaluated predictors for uptake and adherence of ERS (58). The results showed large variation: the share of individuals that came to the first ERS visit was between 35-100%, and share of individuals taking up ERS and completed it was between 12-

82%. There was a higher level of both uptake and adherence among older individuals. Women had higher level of uptake than men, but lower levels of adherence than men.

By contrast, there have also been conflicting results concerning the effectiveness of interventions promoting physical activity and whether prescribed physical activity interventions are more effective than other interventions. Uncertain and inconsistent results concerning the effectiveness of ERS were shown in a British review of eight RCTs, and the authors suggest to further explore the effectiveness of prescribed exercise in primary care setting (59). A study of female patients in primary health care, with a comparison between a group that received a prescription for PA and a group that received a prescription together with a referral to an activity group, did not show any differences in PA change (60). Both groups showed significant improvements in self-reported PA level. A conclusion of this study is that a prescription has an effect on PA level, but the referral intervention did not have any effect. There is also evidence that these interventions can maintain an active lifestyle for a longer period of time. A review on the long-term effectiveness of PA interventions composed of 25 RCTs with at least 12 month intervention has concluded that an additional individually-adjusted prescription of exercise may improve uptake (61). Another review composed of 15 RCTs in primary health care also showed long-term improvements at the 12-month follow-up where self-reported PA level increased significantly after promoting physical activity to inactive adults in primary health care (62). This review, however, does not clearly show that the exercise referral scheme is more effective than other possible primary care interventions acting as comparators. However, only three of the 15 analysed RCTs examined exercise referral. Context preferences have been shown to be important. Different groups of adults have specific preferences concerning the context of the exercise; where the activity is performed and with whom it is performed – information that is useful when designing physical activity interventions (63).

There have been different concepts developed around prescribing exercise globally but all touch upon some common themes. In the UK, for instance, there is the *Exercise on Prescription* programme with a primary health care setting, where a general practitioner or other members of the primary care team can refer an inactive individual to a third party service. This service then prescribes an individualized exercise programme (58). On the other hand, *The Green Prescription* (GRx) in New Zealand contains written physical activity advice, and is a nationally funded program offered in primary care settings to improve PA level among sedentary adults (64). The

patient receives individual meetings, telephone calls or group support with the prescription, and help with goal setting and motivation from a coach. In the United States similarly, the *Exercise is Medicine* program has been developed by an initiative from the American College of Sports Medicine and the American Medical Association. The program aims to establish PA and exercise as the standard disease prevention and treatment for inactivity related diseases such as diabetes, hypertension and obesity (65).

The Nordic countries (Sweden, Denmark, Norway and Finland) all have models for prescribing physical activity within health care (17). Common among them is the use of oral and written advice to encourage patients to promote an active lifestyle (66). In all Nordic countries the prescription comes from primary health care. The activity groups are either performed within primary health care in special groups; or outside primary health care in private sports associations. There are differences between the target-groups: individuals who need to increase their physical activity level become a prescription in Sweden, Norway and Finland. In Denmark there is a need for the individual to have a specific diagnosis, for example type 2-diabetes (66).

### **1.2.3 Physical Activity Referral (FaR®) and Physical Activity in the Prevention and Treatment of Disease (FYSS): the Swedish model**

The Physical Activity Referral-program (FaR®) is a Swedish health promoting programme which aims to improve public health through increasing physical activity level among inactive individuals in the population. FaR is part of the national public health task, and a policy of the Swedish National Board of Health and Welfare as a method for disease prevention. The program focuses on two important public health objectives; increased physical activity and a health promoting health care (17). Since inactive individuals have an increased risk for disease- also when not yet diagnosed - the prescription also has a preventive perspective. The Swedish FaR® concept can be seen as a concept for improving physical activity behaviour to meet public health guidelines for a sufficient level of physical activity (17). It should be seen as both a health promoting as well as a preventive approach among inactive individuals. An important element is the patient-centred dialogue, which leads to the prescription itself. The program has been implemented as a concept in Swedish health care, but without a common model nationwide. Instead there are local approaches of

the method implemented. Most county councils perform FaR® in cooperation with local sports associations and clubs, but also together with the municipality. It is most common within primary health care, but prescriptions are also increasingly written within specialist health care, particularly in psychiatry (17).

The basic model of FaR® contains a patient-centred dialogue, counselling and the written prescription of physical activity (17). The dialogue has to be strongly individualised and based on the patient's health state, symptoms, diagnosis, potential risk factors, earlier experiences, and preferences for different activities. In Sweden, all licensed healthcare professionals with knowledge of the patient's state of health, physical activity as a treatment, patient-centred counselling, the FaR® method, and the local guidelines for FaR® can write a FaR® prescription (17). The prescription is based on the recommendations in FYSS, a body of knowledge in book or digital form (23). It is recommended that a follow-up meeting with the patient is performed to evaluate change in physical behaviour and health outcome. The person who wrote the prescription is responsible for the follow-up (17). The Swedish National Institute of Public Health estimated that about 50,000 prescriptions were written in 2010, a number that can be increased through greater implementation of the concept nationally and locally. To achieve this, the recommendations given were to gain approval on all levels in society and to have necessary local and regional organisational coordination for an improved utilisation of the method.

#### **1.2.4 Measuring physical activity**

There is no standardized method for assessing PA. In order to assess inactivity and its consequences adequate methods and instruments are needed. With valid and reliable instruments we are able to measure physical activity in a broader public health perspective, including analyses of different lifestyle components that together can help us to identify risk factors. Changes in physical activity level can be measured as an indicator for and a change in behaviour, as energy expenditures or as a functional improvement. Physical activity can be assessed directly (e.g. motion detectors, direct observation, remote sensing systems) or indirectly, mostly through different self-report instruments (67). These methods are considered highly feasible, easy to administer but are also connected with low accuracy due to several forms of bias such as recall bias and over-reported PA levels (42,68).

To be able to assess PA and to facilitate measurements on population level, the standardised instrument International Physical Activity Questionnaire (IPAQ), was developed in the late 1990s (69). The global work with the IPAQ resulted in the further development of the Global Physical Questionnaire (GPAQ), and with these two instruments international comparisons are possible to perform. The IPAQ has been developed for a use in cross-national analyses of PA and has been validated in 12 countries. The short form of the IPAQ has been tested among Swedish adults, comparing self-reported PA using the short, last 7-days version of IPAQ and measurement with an accelerometer (70). The results showed acceptable specificity to correctly classify individuals attaining present PA recommendations (70). The results also showed acceptable criterion validity for use in Swedish adults. However, the authors could in the same study observe a significant overestimation of time spent in PA. The Norwegian HUNT study, comparing IPAQ and another instrument (ActiReg) which measures energy expenditure during motions in different body positions, among 108 men showed good reliability for vigorous activities and fair reliability for moderate activities (71). The criterion validity for vigorous activity and sitting was deemed acceptable.

### 1.3 Motivation for physical activity

There is a need to have a deeper knowledge of the variables influencing a person's physical activity level and of the variety in people's activity patterns to develop meaningful strategies for physical activity interventions. Inactivity is more than a measure of physical activity level, i.e. an individual's energy expenditure. Inactivity is a human pattern, based on a diversity of factors in an individual's life. Inactivity is a behaviour, affected by motivation, health status, mobility, genetic components, as well as the social and tangible environment (72). Different variables can influence an individual's choice of lifestyle; if it is an active or inactive lifestyle. When designing health programs targeting an increased physical activity level, it is important to understand the reasons for an inactive lifestyle (73). Our decision making is influenced by factors on different levels: individual, group, environmental and policy level (73,74). Behavioural change among inactive individuals needs support from health care professionals and adequate methods to influence on individual's motivation process.



Prochaska (1994) describes different “stages of change” that individuals undergo in his Transtheoretical Model of Change (TTM) (75,76). According to this theory, the individual’s stage of change can be used to form that strategy being most effective for a behaviour change, for example, changed physical activity behaviour. The behaviour change can be seen as an ongoing process over time involving a progress through the different stages of change. Five different stages of change have been described: I Pre-contemplation, II Contemplation, III Preparation, IV Action, and V Maintenance.

Depending on where in the different stages of change the individual is, different strategies to support the individual are needed. For example, in the first stage the individual is not ready for change and has no intention to change an unhealthy behaviour. A strategy for support at this stage would be to make these persons aware of decisions and provide them with information and knowledge of an unhealthy behaviour. The last stage includes a sustained action and the individual is working preventively to avoid relapse. At this stage it would be important to make these persons aware of situations that could be risky and support the healthy behaviour for example through follow-up counseling. There are also other theoretical models aiming at behaviour change, such as the theory of planned behaviour, the motive/need theory, the incentive/reward theory or the goal-setting theory (77-79).

There are findings showing associations between physical activity behaviour and social-cognitive variables. An individual’s level of self-efficacy and earlier positive experiences seem to predict change in PA (80,81). This means that a high self-efficacy may facilitate the start of a physical activity. However, starting a physical activity is moderated by an individual’s action control. With a low level of perceived action control there may be difficulties in using one’s earlier positive experiences with PA (81). The intention to act is part of a motivational process influenced by self-efficacy, and is dependent on the person’s level of self-efficacy (82). Self-efficacy is defined as an individual’s own trust and belief in one’s capability to perform, and influences how a person feels, thinks, behaves and motivates oneself (82). It is therefore a factor that is important when supporting people to improve their PA behaviour since it affects goal setting and organizational skills. Different contextual factors can also contribute to an individual’s self-efficacy belief; for example, demographic and cultural factors, external influences through an intervention and individual factors (83). They can influence the level of motivation to



achieve a certain outcome like increasing PA. Motivation can also be influenced negatively by the lack of skills.

Different barriers to participation in physical activities have been studied (84-86). In one study, women experienced an increased frequency of barriers for physical activity, as they received low scores for affective/cognitive barriers, which were significantly associated with higher odds ratios for PA engagement (85). Cost barriers are another contributing factor on participation in physical activities. Budgetary constraints were shown to be an important barrier in one study that investigated participation in physical activities among low income groups (84). Another study of perceived barriers among inactive adults showed that a primary reason for inactivity was due to the lack of time (86). A bachelor thesis within physiotherapy studied drop-out factors among participants in a physical activity referral program (87). The qualitative study showed that participants chose to finish the physical activity program due to insufficiently individualized intervention, lack of time, priorities due to life situation, and accessibility. Since the benefits of exercise are not often immediate, it can be difficult adhering to PA (88). Several studies have shown exercise self-efficacy being strongly associated with the accomplished PA, and including the theory of self-efficacy in PA interventions may be useful. A Swedish study of non-adherence to exercise referrals among 1,358 patients showed that sickness and pain were the most common reasons for not adhering among older participants, while for younger participants it was economic reasons and lack of time that were more common (89).

## 1.4 Health Economics

### 1.4.1 Methodology

Economic evaluation has large applicability in health care since priorities due to scarce resources have to be performed, and health economics has in its nature relevance to health care decision-making at all levels (27). When evaluating methods within health care, the base is always the fact that society's resources are scarce, and choices must be made when allocating them. The basic definition of an economic evaluation is a comparative analysis of two or more alternatives in terms of their costs and consequences (27). The evaluation is aiming at examining the usefulness,

efficacy and availability of a health promotion program to provide information to decision-makers about how to allocate resources (27). With limited resources, priorities and decisions concerning investments in health care must be made and economic and public health approaches should be considered in the policy process (90). The information derived from a health economic evaluation can be used for allocation in health care to different programs as well as for individual treatments. A systematic analysis of differences in costs compared with differences in consequences between two programmes, or one program and status quo is performed. The different types of economic evaluations that fulfil these conditions are cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis (27). The difference between these analyses concerns the examined consequences, while the measurement and identification of costs are broadly similar.

In an economic evaluation, it is the incremental analysis, i.e., the difference between two programmes that is of importance. The result is an incremental cost-effectiveness ratio (ICER), which can be used to compare programmes across the health and health care sector. The two components of a health economic analysis are the calculation of the *costs* and the *consequences* of an activity and the comparative analysis of alternative activities (27). In the first component, differences in costs are compared with the differences in consequences (fig. 1). Then, in the second component, the same comparison of costs and consequences are applied to alternative activities to the one being evaluated.

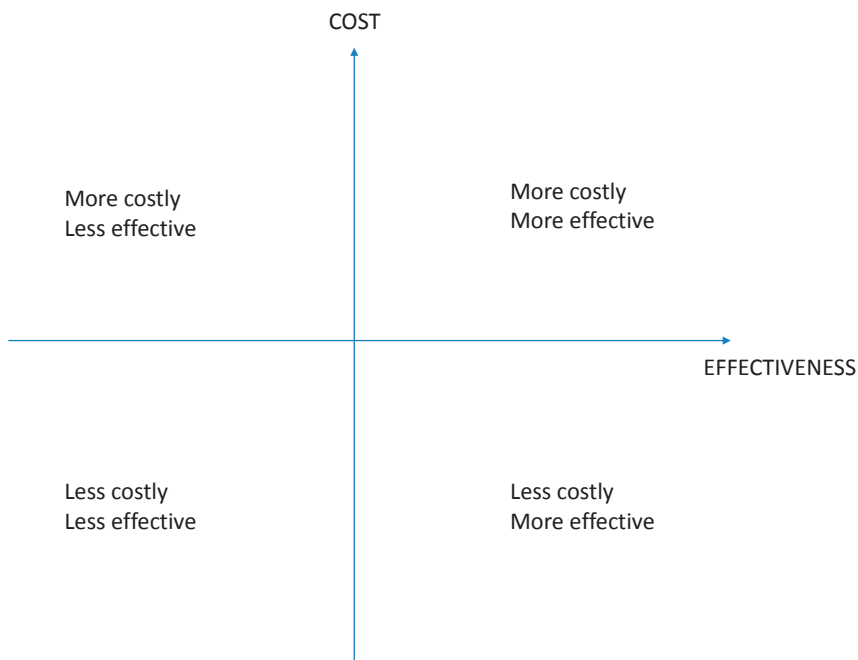
**Figure 1.** Incremental cost-effectiveness ratio

$$ICER = \frac{C_A - C_B}{E_A - E_B}$$

Essentially, health economic analysis compares the *cost-effectiveness* of competing alternative uses of health care resources. The chart in figure 2 illustrates a reference system of how costs and its associated effectiveness can be evaluated. In the figure, costs are increasing upwards while effectiveness is increasing to the right. The fourth quadrant of the co-ordinate system (lower right) contains values which are most desirable

because costs are lower while effectiveness is higher than the going alternatives. The second quadrant contains the opposite case: higher costs and lower effectiveness than the going alternatives.

**Figure 2.** Possible scenarios as a result of an incremental cost-effectiveness analysis.



With the consequences measured in ‘natural units’, the cost-effectiveness analysis (CEA) which includes both costs and consequences can be used. Natural units considered being important consequences for the patients and for health care can be chosen as general outcome measures, for example, ‘being physically active’ or ‘life years gained’. By converting patient quality of life and survival to a common unit of measure, cost-utility analysis (CUA) can be used when measuring effects of a certain program or treatment. The quality-adjusted life year (QALY) is the most frequent used outcome unit in the CUA (27). In cost-benefit analysis (CBA) costs and consequences are measured in money. Measuring both costs and benefits in the same unit, makes it possible to estimate if a program is worthwhile from a societal viewpoint. CBA also provides a possibility to compare benefits within the health care sector also with other sectors.

In the valuation of resources used in economic evaluation, market prices are available for these calculations. In the valuation of health benefits, there is no such market, and no prices. In the willingness to pay approach there is a possibility of stating an individual preference value in monetary terms for different health benefits (27). CEA and CUA cannot conclude if a health program is worthwhile, which is a limitation. It is possible to compare cost-effectiveness ratios but – compared to CBA - not possible to determine if the benefits exceed the costs (91). Another limitation of CEA and CUA is the difficulty finding an outcome measure which reflects an individual's preferences.

#### **1.4.2 Demand for health**

Having an active lifestyle is considered to be part of having good health; one must also consider other factors such as community participation, socioeconomic circumstance and a safe environment (92). People's health-related behaviour through these different factors has been explained through different health economic models (38). These models have been used to show how different components can individually influence people's health behaviour, for instance, how price or age can influence people's demand for health. They aim to explain an individual's health-related behaviour and how health demand varies between individuals and over time (90). The individual as a consumer on the health market values health in different ways, and the response to incentives will differ between individuals. Economic theory assumes that people will consume goods or services if the consequences of the benefit outweigh their cost (90). Hence, to make people participate in health promoting activities, the experienced wellbeing of these activities should be larger than the costs. Health economic evaluations may add information why individuals behave as they do regarding to their health (90).

#### **1.4.3 Costs**

Economic evaluations of health care programs classify costs in three categories: direct, indirect and intangible (27). Direct costs are costs of resources consumed or saved due to a program. These include resources in the health care sector, in particular, as well as in other sectors, patient's expenses and volunteer time. Examples of costs in health care are medical costs, such as those for health care professionals', medications, laboratory

services and/or facilities. There are also non-medical costs, for example, home help and costs for sheltered living. Indirect costs describe the cost of the participants (or relatives) time due to the program, also known as costs for productivity loss (and gains) (27). Examples of indirect costs include costs for time off work, reduced productivity at work and pre-mature death. The last category of costs, intangible costs, includes the value of an increased quality of life or an improved health which are consequences that cannot easily be measured in monetary terms (since there are generally no market prices available for them). Instead, cost-specific experiments can be performed to elicit individuals' valuation of the consequences (93).

#### **1.4.4 Priorities and subsidies**

In Sweden, health care is largely financed through taxes and not 'out of pocket' expenses borne by individuals. This system increases the incentives to demand the best health care one can get. Parallel there is a demographic change that influence and increase costs for health care through factors such as an ageing population, educated patients, improvements in technology and therapy, quality of life expectations and an unhealthy lifestyle. These are factors that all contribute to higher costs for health care. The overall productivity costs of health care are rising fast through an adaptation to a continuously improved of health care with new therapies to a higher cost (94). The aim of the economic analysis is to concern itself with choices (27). Producing all the desirable output is not possible. Developing criteria for decision-making due to scarce resources is an important issue. In a decision-making situation, health economic evaluations can provide useful information to stakeholders, which is an important task for any health economic assessment.

The Swedish National Centre for Priority Setting in Health Care has the assignment of working with strategies and tasks of priority setting. It is commissioned by the Swedish Ministry of Health and Social Affairs (Socialdepartementet) and the Swedish Federation of County Councils (Sveriges Kommuner och Landsting ). The goal of the National Centre for Priority Setting is to deepen knowledge of priority setting activities (95). The three ethical ground principals are human dignity, need and solidarity and the cost-effectiveness principle. The effects of the intervention should mainly concern the effect on quality of life, especially long-term effects. The principle of human dignity convincingly overranks the other three ethical principles (95).The recommendation is to choose the most cost-

effective method when prioritising at group level among treatments, i.e. compare methods for treatment of the same disease and prioritise between different treatments and not between for example persons. The health economic evaluation is an example of a normative analysis, and can provide recommendations for decision making based on ethical principles.

Improving physical activity level among inactive individuals has external benefits for society through a lower economic burden. Social benefits increase when an inactive individual produces health through an improved physical activity level. For individuals who are insufficiently physically active with or without diseases that could be improved by an increased physical activity level, should have a demand for health improvements of physical activity. However, the effects of physical activity on the demand for health will only represent private benefits. Since there are large benefits for society of an improved PA level, government and/or community non-profit activities are needed in cases where competitive markets fail. In this context, the question of subsidized physical activity programs should be raised, and whether such a system is justified. A failure of the competitive market would justify a subsidy from society (27).

#### **1.4.5 Economic perspectives**

Economic analyses can be performed from different perspectives. It is for example possible to have a health care system's perspective, which includes only direct costs of health care costs and not indirect costs for productivity loss, individuals' own costs or cost for municipalities, relatives, home help etc. Adopting a societal perspective in economic evaluations within health care has been recommended (27). A societal perspective should include direct as well as all other indirect costs. There are concerns when estimating productivity changes when the societal perspective has been adopted. Different types of estimates are used, most known are the human capital approach and the friction cost method (27). The human capital approach uses estimations with gross wages including employment overheads. Estimations with the human capital approach often show considerably higher costs for productivity compared with the friction cost method. Time is a resource and should be included (27). For example the individual's time spent in exercise is an indirect cost. Without an intervention aiming at improving PA, i.e. when a physically inactive individual chooses by oneself to change an inactive lifestyle to an active, the costs for the PA is solely the individual's time costs (91). It has been argued that the value of the time

that the individual spends on exercise, which is the individual's valuation of the opportunity cost, is the most important determinant for economic effectiveness (96). Another argument for adopting a societal perspective when performing a health economic evaluation is that this perspective is necessary for making optimal societal decisions (97). Beside this, other sectors of the economy also use a societal perspective, for example in the area of transport safety, why it is logical to use the same perspective in health care and make comparisons of societal investments possible.

## 1.5 Economic concepts

### 1.5.1 Willingness to pay

Cost-benefit analysis answers the question if the total willingness to pay (WTP) for a certain benefit is larger than its cost (93,98). If the WTP for the benefit is larger than its cost, then the alternative should be chosen (91). By giving a monetary value to a health benefit, the individual reveals his or her preferences. The result is an absolute value of the benefit - a monetary expression for the effect of the intervention (27). Regardless in which sector the resources are being used, the result can provide an answer how scarce resources should be used (99,100). The fact that the individuals reveal their preferences through their choices supplies information on whether an intervention is worthwhile. A cost-benefit analysis based on contingent valuation and willingness to pay (WTP) statements can be seen as an approach to replace missing markets and to quantify the consumers demand for non-market goods, for example health benefits of programs like prescribed exercise (27). There are two different approaches, revealed preferences or stated preferences of which the contingent valuation (CV) methodology is the standard method (91). A limitation of the WTP is the association with ability to pay which may make it difficult to use in for example different income groups (101). An advantage would be the possibility to value benefits of an intervention in health care for instance, where a conventional market does not exist in monetary terms. CV determines the WTP for programmes through a hypothetical scenario in surveys and aims to quantify intangible benefits to the individual, which are the monetary value of changes in health per se (27,91,93). The CV aims to reveal the maximum amount of money individuals are willing to pay for a certain benefit (consequence) of a program. An advantage with stated

preferences is its flexibility, since it can be formed for a specific situation (102). Revealed preferences on the other hand, has the aim to understand the consumer's preferences by observing behaviour with given budget constraints (93). When the individual chooses a certain good it reveals its preferences. However, revealed preference is difficult to use in health care since it is not possible to buy health care on a market. The advantage of the revealed preference is that it is based on actual decisions (102).

### **1.5.2 Cost-consequences**

An evaluation of programmes in health care should contain a valuation of all costs and consequences in monetary terms. These should be clearly described. Economically, a cost is the sacrifice made when a resource of the program is consumed (27). A cost derives from use of resources in health care sector, or other sectors, patient / family costs and costs for productivity losses. Costs consist of the quantity of a resource and prices per unit (27). The measurement of quantities is derived from the actual study, and mostly collected from case report forms, patient charts, data systems, self-reported patient data, or in a clinical trial. In an analysis of the costs of a health care program, prices should be in market prices. When valuating non-market items in health care interventions, mostly volunteer time for example of family leisure time, is made using market wage rates.

### **1.5.3 Cost-utility**

Quality of life (QoL) includes an individual's total concept of life, i.e. all aspects of the general wellbeing (6,56,92). Health is one domain of QoL, and is defined as an individual's physical and mental health and function (6, 103). The concept of the quality-adjusted life years or QALY is a measure of health related quality of life (HRQoL) that includes different aspects of QoL such as physical and mental health such as physical functioning, social activity and psychological health. People that are physically active have a better HRQoL since there are shown to be a positive association between a higher level of PA in the general population and better HRQoL (104,105).

Self-rated health has shown to be a strong measure of health, more than many other objective measurements, and can better predict mortality and morbidity (103). Different generic preference-based measures of health have been developed and are used in health economic analyses of cost-effectiveness for valuing benefits of healthcare. One possibility for



examining people's preferences for health would be to ask a person about how much he or she is willing to pay for a hypothetical benefit (93). The dominating method is to use QALYs as the measure of effectiveness. QALY measures health improvement. It is assumed that the goal of decision-makers is to allocate public resources maximizing benefits for the population, where health improvements are an important part of these benefits (106). When performing estimations with QALYs, it is also assumed that a health improvement can be measured based on how much time is spent in different health states. QALY as a measure has the advantage of capturing both length of life and quality of life in one measurement. The National Institute for Health and Clinical Excellence's (NICE) main recommendation is to use the cost-utility analysis (CUA) and outcomes reported in incremental costs per QALY (107). QALY is a Health-state utility value (HSUV) used in cost-effectiveness analyses. By assigning a value to a health state it is possible to calculate number of years in full health which is a QALY. Different health states have different values, and in the concept of QALYs, a health state that is highly preferred is more valuable (106). Methods for eliciting individual preferences for specific health states include direct instruments, such as the standard-gamble, visual analog scales, and time trade-off methods, while an indirect instrument is the preference based short form 6D (SF-6D) health survey (27,108). Responses to the SF-6D are scored occurring to an earlier valuation study where a sample of the general population values hypothetical combinations of the health states from an ex-ante perspective (108). The overall score from the responses is given an index value that is an approximation to a QALY. This can be used to analyze differences in health utility among groups. Methods of measuring QALY do differ however in their description of health as a concept, their target groups and their construction (109). Greenberg et al. found in a study of 781 interventions that changes in incremental QALY gains over time had a geometric mean (median) gain of 0.09 (0.11) QALYs (110).

To derive HSUV the SF-6D can be used which then can be further used in cost-utility analyses since it generates preference scores (109). These are estimated from the general population by use of valuation with the technique of standard gamble, and can be derived from the SF-36 scoring system. The standard gamble method includes calculating the risk; a person chooses for example to live in a specific health state for ten years with certainty, or instead receive a treatment and then to a specific chance live ten years in full health but simultaneously a risk to immediately die (108). In the SF-6D the individual values its health-state across six dimensions,

each with a number of levels (109). When rating the health status on each dimension different combinations are formed and QALY-weights are derived. By multiplying a QALY-weight with life years it is possible to calculate QALYs, since one QALY is one year in full health. The total QALY value is equal to the area (base multiplied by height divided by two) under the curve from baseline to the next point of measurement. This is calculated by multiplying the utility-value in a state of health, which is the QALY-weight, by the years lived in that state.

#### **1.5.4 QALYs vs. DALYs**

A disability-adjusted life year (DALY) is one life year in full health lost due to death and disability (26). DALYs is considered a variant of QALYs (111). A QALY is one life year gained in full health. The DALY as well as the QALY is possible to use in cost-effectiveness analyses. However, the primary use of DALYs is to measure disease burden, where loss of functioning is measured with disability weights. The most important difference between a QALY and a DALY is that the DALY includes a weighting of age - at different ages there is a different weight of life years lived. When disease starts early in life, QALYs gained is larger than DALYs saved, with disease start later in life DALYs saved is larger than QALYs gained. Also, the derivation of the disability and quality of life weights are different. The primary use of QALYs is in a cost-effectiveness analysis, aimed at evaluating improvements in quality-adjusted life expectancy achieved after a health intervention. A QALY always has the same value since it does not include an age-weighting. The weighting in QALY calculations is preference based, while in DALY calculations the weighting is based on experts' valuation.

### **1.6 Economic evaluation of physical activity interventions**

Health is an important pre-condition to economic, societal and personal development. Determining priorities to get the most out of scarce health care resources however is not clear-cut (27,38). When arranging priorities health economic evaluations are an important tool. This type of evaluations can also be used for analyses of lifestyle interventions to increase physical activity level among inactive individuals (27). When deciding how to spend

money on public health interventions aiming at increased physical activity level, stakeholders need evidence on improved PA level and its associated costs. Like other interventions in health care, physical activity interventions for an increased level of PA consume resources. Due to this fact they have an opportunity cost, and the resources consumed could otherwise be allocated to alternative activities within health care. Therefore it is important to examine whether activities like prescribed physical activity are worth their costs.

There are findings supporting cost-effectiveness of primary care based interventions (112,113). A review of cost-effectiveness analyses of PA interventions in primary health care and the community studied quality and cost per QALY as an outcome measure (112). The cost-utility was analysed in nine of the evaluated studies and showed a cost per QALY varying from €348 to €86 877. An evaluation of a lifestyle intervention with education of behavioural skills was more cost-effective than a structured, supervised exercise program (114). The study among inactive adults compared the efficiency of alternative interventions aiming at improving physical activity, and showed results of lower costs for the lifestyle intervention but without differences in effectiveness concerning energy expenditure,  $\text{VO}_2$  max, blood pressure, submaximal heart rate and body weight. However, the authors did not include the costs of the participants' time in the estimations. A study revealed that to shift an inactive individual to an active one would cost €3166 when undertaken in the primary care sector (115). The most important variable cost in the said intervention were recruitment costs. In the study, neither participants' time costs nor costs for rent of localities nor staff time were included. Therefore, it was difficult to conclude anything regarding cost-effectiveness. A cost-effectiveness analysis of prescription-based exercise estimated that the cost of shifting an inactive individual to an active one after a 12 month follow-up was €856. This figure however does not include individual time cost (116). The cost-effectiveness of physical activity promotion among persons older than 65 years was examined in a social assessment, using risk education data from observational studies (117). The authors concluded that providing twice weekly exercise classes for older adults could prevent 76 deaths every year. Through reduced in-patient days annual health care costs of €1.1 million could be avoided. The authors stated that physical activity interventions for individuals over 65 years may be more cost-effective since the time costs are lower for older persons.

Other studies have shown that there is limited evidence on the cost-effectiveness of physical activity interventions in primary health care, and

also that the results of health economic evaluations of interventions to promote PA cannot easily be generalised (58,118-122). Evidence for cost effective interventions aiming at increasing physical activity level among inactive individuals is limited. Further health economic evaluations are needed. These evaluations should also include indirect costs such as the individual's time cost to be able to analyse the cost-effectiveness of the intervention in a societal perspective.

## 1.7 Economic evaluation of prescribed physical activity

There is growing interest in examining the cost-effectiveness of public health programmes in order to derive important information on how to allocate health care resources. Health economic analysis should therefore present results of a specific evaluation method that are relevant for health care and useful when interpreting the effects versus costs. However, to apply methods for economic evaluation traditionally used for example in pharmaceutical analyses within public health interventions may be connected with methodological issues; a British study therefore recommends alternative approaches like the cost-consequence analysis (CCA) for economic evaluation of exercise referral schemes (ERS) (123). Table 1 shows an overview of primary health care based RCTs examining cost-effectiveness of prescribed physical activity interventions, published between 2004 and 2012 (51,116,124-126). The overview shows that an intervention based on exercise on prescription varies regarding type of inclusion criteria, prescription based intervention, and follow-up periods. There is also a variety of which type of economic estimation that is used; some of the studies use HRQoL analyses and preference based instruments (SF-6D and EQ-5D), and some of them the cost of shifting one person from inactivity to an 'active' category. These factors influence the economic result and costs per QALY. The included studies used the societal perspective. Three of them are Australian studies evaluating the Green Prescription national program (116,124,126). Of these are two studies based on the same intervention with counseling in general practice, and one is an enhanced Green Prescription intervention with written advice and telephone support. The other two British studies of ERS with exercise interventions (10 and 16 weeks, respectively) in leisure centres had both the inclusion criteria of also having at least one medical condition besides being low-active (51,125). All studies had a 12-month follow-up, where the cost-effectiveness was analyzed. Three of them analyzed cost-utility and

presented incremental cost-effectiveness ratios with costs per QALY ranging from €331 to €75,525. The lowest ICER was for an enhanced Green Prescription with a written prescription, brief advice, and telephone support (126). The highest ICER was for a 10-week instructor-led walking programme two to three times per week (125).

Other studies examining cost-effectiveness are based on information from research databases deriving large cohorts of participants (119,127). These have used analytic models and simulation, for example the probabilistic Markov model. The results showed limited evidence for cost-effectiveness over time. A recent population-based database study showed net health benefits of 3.2 QALYs per 1,000 participants with five years intervention of a universal strategy of promoting physical activity within primary care, and only weak evidence for cost-effectiveness (127). In another study based on a decision analytic model the authors state a mean incremental QALY of 0.008 for ERS compared to usual care in sedentary individuals without a diagnosed medical condition (119). Due to limited evidence of effectiveness and lack of trial-based design of the studies, a recent review of four different economic evaluations assessing cost-effectiveness suggests to further explore the cost-effectiveness of ERS in primary care setting and whether ERS is an efficient use of resources (58).

**Table 1.** Primary care based studies of cost-effectiveness of physical activity interventions based on a prescription.

	Design, Economic perspective	Inclusion criteria	Follow-up periods	Prescription/ERS	Control (if existing)	Economic analysis	Outcome Measure	Result
Elley et al; 2004 (116)	Cluster RCT, Societal costs	Less active primary care participants (n=878)	12 months	Green Prescription: counseling in general practice	Usual care	CEA	Cost of shifting to active category	€ 825
Dalziel et al; 2006 (124)	Cluster RCT, Markov model	Less active primary care participants (n=878)	12 months	Green Prescription: counseling in general practice	Usual care	CUA	Cost per QALY	ICER=€ 965 per QALY
Isaacs et al; 2007 (125)	RCT; three armed, Societal costs	Not currently physically active persons with at least one cardiovascular risk factor (n=943)	10 weeks, 6 months, 12 months	Exercise referral by GP: I: 10-week supervised exercise, 2-3 times/week in leisure center. II: 10-week instructor-led walking programme, 2-3 times/week. III: advice only	Tailored advice and information on PA and local exercise facilities.	CUA	Cost per QALY	I: € 23,340 II: € 56,856 III: no information (6 months)
Elley et al; 2011 (126)	RCT, Societal costs	Less active women (n=1089)	12 and 24 months	Green Prescription (enhanced): written exercise prescription, brief advice, telephone support.	Usual care	CEA	Cost per person made 'active' and sustained I: 12 months II: 24 months	ICER = I: € 331 II: € 678
Murphy et al; 2012 (51)	Pragmatic RCT, Public sector perspective	Sedentary, at least one medical condition (CHD, depression, anxiety, stress), (n=2160)	4-week telephone, 16-week consultation, 8-months telephone, 12-month review.	NERS (Wales National Exercise Referral Scheme) 16-week exercise in leisure centers, Motivational interviewing	Usual care= leaflet for information on benefits of PA, addresses of local facilities	CUA	7-day PA recall, EQ5D	ICER= £12,111 per QALY (€13,508)

## 2. Aims

General aim:

The overall aim was to estimate health economic consequences of prescribed physical activity.

Specific aims were:

- to analyze costs and consequences of changing physical activity behaviour from the 4-month PAP-program [paper I].
- to estimate and analyze the willingness to pay (WTP) for health improvements of physical activity due to the PAP-program, and examine predictors for the WTP [paper II].
- to analyze the cost offset of changing the physical activity behaviour, motivation and attitudes after one year [paper III].
- to analyze the benefits in terms of quality of life and cost per QALY, respectively [paper IV].

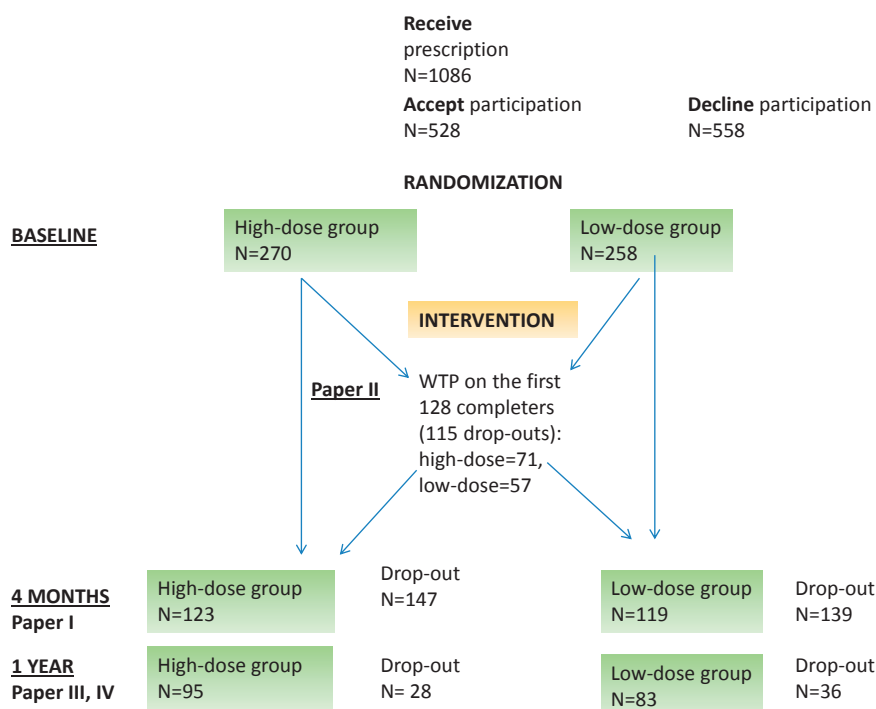
## 3. Material and Methods

### 3.1 Study population

Participants in the “Prescribed Physical Activity” program [here after referred to as the PAP-program] which will be the subjects of this study, were recruited from the south-east healthcare district of Region Skåne, Sweden. Five different primary health care centres in five different municipalities were included in this study, four of which have with a population of 6-7 000, one with 17 000 persons. Study participants who received a prescription for physical activity from these centres were recruited continuously from February 2006, until December 2007. A licensed healthcare professional with knowledge of the patient’s state of health, PA counselling and the FaR® method wrote a prescription within a regular office visit. The health care professionals were either physicians, physiotherapists, nurses, occupational therapists, welfare officers or nutritionists. Criteria for having a prescription were being at least 18 years old, having a sedentary life-style, being motivated for increased PA, and having one or several of the following diseases: cardiovascular disease, type 2-diabetes, obesity, musculoskeletal disorders, mental illness and / or respiration problems. Participants were excluded if the person who wrote the prescription estimated that the patient’s illness was not treatable with physical activity, or the person was too ill or weak to participate in the activity groups as they were organised in this setting. 1086 individuals received a prescription for physical activity. In the office visit when the prescription was written, these individuals were given short advice about PA, informed about the intervention and offered participation in the PAP-program. Of these, 558 participants chose own exercise and were not followed in the study. The other 528 accepted participation in the PAP-program, and were randomised to either a high-dose activity group or a low-dose activity group (Fig. 3). The activity groups were performed outside health care in local sports centres or leisure facilities.



**Figure 3.** Flow chart: participation in the trial.



## 3.2 Study design and intervention

The present study in five primary care districts in the south-east part of Skåne, was an approach for implementation of health promotion of physical activity in large heterogeneous groups for an increased availability for the individual and an optimized public health impact. The study was based on an existing program with treatment perspective, and was a collaboration between the different primary care districts, local sports associations and Skåneidrotten, a regional organisation representing The Swedish Sports Confederation. The design of the study had given conditions and was planned together with representatives from primary health care and Region Skåne.

This thesis was based on an exploratory study and performed in cooperation between the faculties of Medicine and Economy at Lund University and the divisions of Physiotherapy and Health Economics. The study was a randomized clinical trial with a four-month intervention. However, in the first two studies (Paper I, II) the study design was described as a randomized *controlled* trial. The design is preferably described as a randomized *clinical* trial since the low-dose group had access to the activities which did not constitute standard care. Participant outcomes were evaluated at baseline, after four months and one year after baseline. Written consent was obtained from all participants. The study was performed from a societal perspective. All costs were reported in Swedish kronor (SEK). The study protocol was approved by the Research Ethics Committee at Lund University (2006/172). The participants that accepted participation were referred to an initiation visit with the physiotherapist for randomisation and functional testing. The randomisation process, involved closed envelopes and was performed by the physiotherapists before the functional testing of participants. Participants randomised to the high-dose group were referred to supervised group exercise sessions twice a week during four months, education in physical activity, and a motivational counselling. They were also instructed to additionally exercise once a week on their own with a physical activity lasting at least 30 minutes and at least on a moderate level. The exercise sessions lasted 45 to 60 minutes, run by activity-leaders in the local sports centres. The activity-leaders were specially trained to lead the exercise groups within the PAP-program. Also present at the exercise sessions was a group-leader, supporting the participants. The activities were selected independently from an activity list, based on the participant's interest and preferences. The activities were performed in groups and were on a moderate-intense level, e.g. aerobic- and spinning classes, dynamic, light strength conditioning or Nordic Walking. The activity groups were led by activity instructors educated for this category of participants. The intensity-level of the different activities corresponded to the recommendations of FYSS given for the diseases of the participants (23). The motivational counselling lasted 20 minutes and was provided by physiotherapists in primary health care, and based on the Transtheoretical Model of Behaviour change (75). The counselling was performed with help from a prepared schedule to facilitate the process of motivation dialogue in an individually formed patient-centred approach. The education was a two-hour class twice, performed by a health educator, concerning the benefits of physical activity and exercise. This education was more generally delivered in groups. At the start of the program, the

high-dose group also had an informational meeting for one hour with their group-leader on the program itself and general conditions for participating in group-activities. The low-dose group received written information only. This was based on information about local fitness centres and about the possibility to participate in supervised exercise groups once a week on a moderate-intense level.

All subjects answered the questionnaire before participation and at follow up after four months. The participation fee for the 4-month program period was 200 SEK for the low-dose group, and 300 SEK for the high-dose group.

### 3.3 Statistical analyses

Data were analyzed using IBM SPSS Statistics 20 (Paper I-IV). The level of statistical significance was set to  $p < 0.05$ . The statistical methods used in the thesis are presented in Table 2. Descriptive statistics (means, standard deviation, and relative frequencies [%]) were used to describe the samples (Paper I-IV). Differences at baseline between high- and low-dose groups and completers and non-completers, respectively, were tested with t-tests with regards to age, BMI and income, and with Chi-Square tests with regard to sex, education and health (Paper I-IV). Due to skewed distributions non-parametric tests were used, such as the Mann Whitney's U-test for comparisons between groups with regard to MET-minutes and Six Minute Walk Test, and Wilcoxon's signed rank test for comparisons between baseline and the four month follow-up (Paper I). Chi-Square tests were used for comparisons between high- and low-dose groups with regard to physical inactivity (Paper I, III). McNemar's test was used to test changes in inactivity between baseline and the four month follow up (Paper I).

In paper II, WTP was described with mean and standard deviation as well as proportion of individuals willing to pay 0 SEK, and was presented separately for the high-dose and low-dose group and also for the combined group. Due to skewed distribution of WTP differences between the groups were tested using Mann-Whitney test. Differences in health improvements were tested using Wilcoxon's rank sum test. Spearman correlation coefficients were calculated to describe the association between the WTP and following independent variables: age, income, BMI, activity level, health status and education level. In regression analyses, carried out to

describe WTP by the independent variables simultaneously, activity level, health status and education level were transformed and used as dichotomous variables. Due to the skewed distribution of MET-minutes Mann-Whitney U-test was used for the comparisons between high-dose and low-dose groups (Paper III). Friedman's Two-Way Analysis of variance was used for comparisons between baseline, four month and one year follow-up (Paper III, IV). In paper IV an exploratory factor analysis was performed to analyze the correlations between the different motivational variables, and to distinguish underlying motivational attitudes. No power analysis was performed since the study was exploratory with unknown baseline values or effects, and with unknown distribution of the outcomes. The study also has a wide focus with several objectives. Further information on statistical analyses is presented in the different papers.

**Table 2.** Statistical analyses used in the Papers I-IV.

<b>Statistical method</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
<b>Descriptive statistics</b>				
Mean, SD	■	■	■	■
Relative frequencies (%)	■	■	■	■
<b>Analytical statistics</b>				
T-test	■	■	■	■
Chi-square	■	■	■	■
Mann-Whitney U-test	■	■	■	■
Wilcoxon's signed rank test	■	■		
McNemar's test	■			
Spearman's correlation		■		
Friedman's Two-Way Analysis of variance by ranks test			■	■
Multiple regression analysis		■		
Factor analysis			■	

### 3.4 Cost-consequences approach and Cost-minimization approach (Paper I,III)

These approaches are both based on the same calculations of physical activity level and costs of inactivity (Paper I, III).

#### *Physical Activity level*

We measured PA level subjectively in terms of self-reported physical activity level and as energy expenditure in terms of MET-minutes per week (METs), and objectively by functional testing in terms of Six Minute Walk Test. The first two methods were self-reported, self-rated physical activity with the IPAQ questionnaire short form and self-reported in a single question of present PA level (69,70). MET (Metabolic Equivalent) expresses the energy cost of PA, and is the ratio of metabolic energy consumption during a specific physical activity to the resting metabolic rate (128). One MET is equal to the resting metabolic rate, equivalent to quietly sitting, and it is also equal to the mean resting oxygen uptake in the sitting position. In other metrics one MET is equal to one kilocalorie per kilo body weight per hour or 3.5 ml oxygen per kilo body weight and minute (129). Walking slowly has a MET value of 2, running fast has a MET value of 23, i.e. MET can be considered an index of intensity of a physical activity. The IPAQ short form protocol assesses three specific types of activity, and provides separate MET scores on walking, moderate-intensity activities and vigorous activities. A calculation of the average MET values for each type of activity was performed, and the total MET-minutes (METs) for all three types of activities per week were then used in the analysis (128). Continuous scores are used in the calculation with different values of METs for walking (3.3 METs), moderate PA (4.0 METs), and vigorous PA (8.0 METs). For walking MET-minutes per week, an example of an equation to calculate total METs would thus be:  $3.3 * \text{walking minutes} * \text{walking days}$ . A corresponding calculation for the two other activity levels is performed, and then all are summarized to a total MET minutes score per week. As there are no established thresholds for presenting MET minutes, the IPAQ Research Committee propose that these data are reported as comparisons of median values and interquartile ranges for different populations.

The second method of measuring PA level subjectively is a scale asking one to rate the extent of physical activity achieved at present. This is formed as a question and is based on the Transtheoretical model and the theory of health behaviour change (75). This question itself was part of the

Transtheoretical theory in the motivational counselling sessions. However, for this analysis, the five levels related to the original theory were dichotomized into “active” and “inactive”.

The third and objective method is based on measures of functional capacity: a *functional exercise performance test* with the Six-Minute Walk Test, where the participant walked as fast as possible during six minutes, and the distance (meters) covered was measured (130). The Six-Minute Walk Test can provide a response of the physiological systems integrated in PA, which is the pulmonary and vascular systems, systemic and peripheral circulation, blood, neuromuscular units, and muscle metabolism (130). In this test, the submaximal level of functional capacity is assessed, and may therefore reflect a functional physical activity level of daily activities. The Six-Minute Walk Test is simple to administer, and easy to perform in a clinical situation within primary care; the only requirements are a hallway and a flat, hard surface to walk on. The functional testing with the Six-Minute Walk Test is an adequate evaluation beside the subjective measures with self-reported and self-rated questions.

Participants were asked to write in an exercise diary given to them which provides a measure of their compliance to the program. The participants were requested to fill in an exercise diary during the intervention period. The physiotherapists who were involved in the program delivered the questionnaires and also supervised functional testing.

### *Costs of inactivity*

Results were reported from a societal perspective, including both health care costs and costs for production losses, measured as average costs (131). In the estimation of the costs within the PAP-program, we designate the value of resources used and not expenses. All costs are reported in Swedish Kronor (SEK). The direct and indirect costs of physical inactivity in the papers I and III were calculated using the result of a Swedish study, that calculated the costs of illness attributed to physical inactivity (28). For each disease the proportion of the costs which were caused by inactivity was calculated based on analyses of the population attributed risk (PAR) (132). The PAR contains two parameters: relative risk and prevalence of inactivity in the population (132). Diseases considered attributable to physical inactivity were colon cancer, hypertension, ischemic heart disease, angina, stroke, type 2- diabetes and osteoporosis. The estimated total costs, indirect and direct, of inactivity in Sweden on price level of 2002 were between SEK 5 820 and 6 902 Million, based on three different calculation methods (28). We choose the value of the method based on self reported frequency

of exercise per week, and this method presented costs of SEK 6 343 Million. This result corresponds to results of another study of the costs of inactivity in Sweden by Bolin and Lindgren (29).

The Swedish population in 2002 consisted in 8 940 788 persons, and of these 6 999 878 persons were 18 years and older (133). The prevalence of inactivity in 2002 was according to the same method by Moutakis et al. 40% and was based on a population survey (134), which was equivalent to 2 799 951 persons. Per inactive person, this was a cost of ~SEK 2265 in the year of 2002. Transferred to 2007 price level with the Swedish consumer price index, the cost was SEK 2412 per inactive person. A sufficient physically active person does not carry this cost of society. With these estimations we can calculate the costs of inactive and active individuals, respectively, at baseline and after participation in the PAP-program.

#### *Programme costs and valuation of resources (Paper I)*

The exercise was performed in participants' leisure time. Participants' time cost were therefore calculated as leisure time costs, estimated as a mean value based on the self-reported monthly net salary and working hours. The costs of the exercise in the different sport clubs in the area included staff time for exercise instructors and normal rent of the premises for the exercise time. The number of visits at the physiotherapist was two visits for those participants who completed the 4-month program: one visit for the functional testing (for the intervention group additional 20 minutes for the motivational counselling), and one visit for the same purpose for the 4-month follow-up testing. For the drop outs only one visit was calculated: the costs for the participants who did not complete the 4-month period were based on the assumption that the majority of them dropped out within the first month. Thus, the costs in the first month for these individuals were the same as the costs in the first month for the individuals who completed the full intervention.

### 3.5 The WTP approach (Paper II)

Open-ended questions were used to elicit individuals' maximum WTP for a health improvement of physical activity on prescription. Only one version of the questionnaire was used for both the high-dose and low-dose groups. The questionnaire included open-ended questions on the amount of money the participants were willing to pay. The statements of this open WTP study

were used to measure the individuals' demand for improved health from increased physical activity. Willingness to Pay (WTP) monetary values were given in Swedish kronor (SEK), with an exchange rate in November 2007 of EUR 1 ~ SEK 9.3. The different health improvements were connected to the physical activities within the PAP-program, and the respondents made their own interpretation of the size of the health improvement. The scenarios presented to the respondents are showed in Figure 4. In the answers, the given time frame was four months, i.e. the amount of money was intended to be paid once for a four-month period.

**Figure 4.** The three WTP scenarios presented to the respondents.

1. *“There is scientific evidence that regular physical activity can be used as a therapeutic measure.*

*If you exercise 2-3 times per week with activities similar to the PAP-program, you can expect an improved health for lifestyle-related diseases, like high blood pressure, overweight and type 2 diabetes. How much would you pay to get such an improved health by exercising?”*

*(Long-term health improvement)*

2. *“There is scientific evidence that regular physical activity positively influences not only different diseases, also your wellbeing can be improved.*

*If you exercise 2-3 times per week with activities similar to the PAP-program, you can expect an improved wellbeing. How much would you pay to get such an improved wellbeing by exercising?”*

*(Short-term health improvement)*

3. *“If you exercise 2-3 times per week for 4 months with activities similar to the PAP-program, you could loose weight, 2 kg in 4 months. How much would you pay to get such a weight-loss?”*

*(Long-term health improvement)*



The explanatory variables were:

1. Income, gross income per month in Swedish kronor (SEK).
2. BMI Body Mass Index, kg / m<sup>2</sup>.
3. Activity level, self-reported scale from 1 to 5: 1= Inactive, no intention to start, 2= Inactive, but have intention to start, 3= Physically active < six months, 4= Physically active > six months, 5= Physically active > six months, and want to increase activity level. In the regression analyses we use activity level dichotomized, 0= non responders, inactive and no intention to start exercising, inactive but have intention to start exercising, and 1= physically active < six months, physically active > six months, physically active > six months and want to increase activity level.
4. Health Status, 1-5. Self-reported. 1= poor, 2= somewhat poor, 3= good, 4= very good, 5= excellent. In the regression analyses we use health status dichotomized, 0= non responders, poor, somewhat poor, and 1= good, very good, excellent.
5. Education level, 1-4. Self-reported. 1= nine-year compulsory school, 2= 2 years-upper secondary school, 3= 3-years upper secondary school, 4= university or college of higher learning. In the regression analyses we use education level dichotomized, 0= non responders, nine-year compulsory school, 2-years-upper secondary school, 3-years-upper secondary school, and 1= university or college of higher learning.

### 3.6 Cost-minimization and Motivation (Paper III)

The study was performed from the societal perspective to estimate the costs for and consequences of a method that involves the full economic impact on the participants in the intervention. The cost offset calculation is based on the measure of inactivity among the completers, using the self-reported question about present extent of physical activity. The program costs for the four month intervention period were based on intention-to-treat estimations.

The motivation questionnaire was derived from a literature review designed for individuals with a low physical activity level, and was collected by the physiotherapists together with the main questionnaire and the physical examination on physical activity. The construction of the questionnaire is relevant to the sample and has shown good reliability (135, 136). The questions are based on factors influencing a person's motivation, and

include the participant's experience with and the role of physiotherapists within the PPA-program. The questions are related to social determinants like self-efficacy and support from others, and to practical barriers like content and structure of the exercise. Responses were provided on a 100 mm scale (0= not agreeing at all, 100 mm= agree totally).

### 3.7 The cost-utility approach (Paper IV)

Preference-based QoL was measured using the SF-6D classification, which was derived using a scoring algorithm from the 36-Item Short-Form Health Survey (SF-36) (109). This index measure is based on eleven questions in the SF-36 and measures health along six dimensions (physical functioning, role limitations, social functioning, pain, mental health, vitality). Each dimension had four to six levels. The SF-36 scores were calculated using the Swedish manual, and were also used in the analysis of QoL as an outcome measure (137).

## 4. Results of paper I-IV: a summary

### 4.1 Cost-consequences

For the four month assessment 242<sup>1</sup> individuals returned, with a drop-out rate for both groups together and separately for high-dose and low-dose group of 54%. There were no significant differences between the groups in age, BMI, income, education level or self-perceived health at baseline. The program costs for the four month intervention period were based on intention-to-treat estimations. Self-reported costs of the individuals due to participation in the program included exercise equipment purchased, travel costs to and from exercise and injuries.

Of all participants 82% used a car to travel to the exercise class, 18% walked or cycled while no one used public transport. The average travel time of the participants was 22 minutes. There were three injuries in the high-dose group and four in the low-dose group due to participation in the program (knee or ankle sprains). Due to these injuries there was in total an absence from work of ten days in the high-dose group and two days in the low-dose group. The cost of a visit in primary health care at a general practitioner was SEK 845, and a visit at the physiotherapist SEK 345. The mean number of PAP-sessions for individuals completing the 4-month intervention was 31 (sd=14, range=2-48) for the high-dose group (n=91), and 12 (sd=4, range=2-23) for the low-dose group (n=79) as reported in the exercise diary.

The intention-to-treat program costs for the four month PAP-program was SEK 6475 for the high-dose group and SEK 3038 for the low-dose group. The largest cost was the individuals' time cost, which included time spent on exercise and travels to and from exercise. The costs due to participants' injuries of the PAP-program were larger in the high-dose group due to absence from work. An on-treatment analysis of the costs showed program

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<sup>1</sup> In manuscript I n=245 due to a coding error

costs for the high-dose group of SEK 10,721 per patient, and for the low-dose group SEK 4,822. The results of the on-treatment analysis were expected considering the adherence rate and time of participation of the non-completers.

All three methods of measuring PA level showed significantly improved values for both groups between baseline and the four month follow-up. Of the inactive individuals in the high-dose group, 65% reported an active level of self-perceived physical activity at four months. In the low-dose group, 53% of the inactive individuals turned active. Of the already active individuals 12% turned inactive. There were than twice as many MET-minutes estimated at the four month follow up compared with baseline. The Six Minute Walk Test showed significant improvements for both groups. As a consequence of the PAP-program the cost offset every year due to a reduced number of inactive individuals was SEK 984 per individual, based on the assumption that the individual has a maintained PA level during one year.

## 4.2 WTP

The first 128 completers of the four month programme responded to the questions about their WTP (53% response rate) for different health improvements that were connected to the physical activities within the PAP-program. The respondents made their own interpretation of the size of the health improvement in the scenarios presented to them. There were no significant differences between the groups regarding sex, age, BMI, income, education level, health status, and activity level at baseline). Compliance was self-reported in an exercise diary, which 107 of the 128 participants had filled out.

In general, the high-dose group stated a higher WTP than the low-dose group for all health improvements, short term as well as long term improvements, but there were no significant differences between the groups. Zero bids did not influence this result. The highest WTP-value for both groups together was for improved wellbeing, which was considered a short-term health improvement. The highest mean WTP-value for the high-dose group was for improved health (long-term health improvement), without zero bids for an improved wellbeing. The highest WTP-value for the low-dose group was with and without zero bids for improved wellbeing. The lowest mean WTP was for both groups separately and together, with

and without zero bids, for a weight loss of 2 kg due to exercise two to three times per week. BMI, income and education level correlated significantly with an improved wellbeing. A higher education level was significantly associated with the WTP for improved health and improved wellbeing. Income was significantly associated with the willingness to pay for improved wellbeing.

### 4.3 Cost-minimization and motivation

The study was performed at a one-year follow-up of 178 individuals that returned, 95 in the high-dose group and 83 in the low-dose group. In baseline analyses of sex, BMI, income, and education level there were no significant differences between high-dose and low-dose groups, or among completers and non-completers respectively except for self-perceived health and age comparing completers and non-completers (high and low-dose groups taken together). The sample consisted in individuals with high BMI value, low income level, low education level and low health status.

All three methods of measuring physical activity showed significant improvements for high-dose and low-dose groups between baseline and the one year follow-up, but without differences between the groups. The cost offset due to a decreased inactivity as a consequence of the PAP-program was for high-dose and low-dose group together SEK 94 068 (EUR 10 023) the first year. This means a cost offset of SEK 528 (EUR 56) per individual and year as long as the individual stays active.

The analyses of motivation showed neither at baseline nor at the four-month follow-up any significant differences between the high-dose and low-dose groups. There was an overall decrease in motivation for both high-dose and low-dose groups at four months and at the one year follow up, compared to baseline, without differences between the groups regarding changes in motivation. Analyses over time showed that motivation for most items significantly decreases from baseline to the one year follow-up.

A factor analysis of the different motivational components showed two factors; one factor describing social-cognitive motivation, and factor two practical-rational motivation. The practical/rational factor includes goal setting, having realistic goals, individual adjusted dose/intensity of exercise, variation of exercise and willingness to perform. The social-cognitive factor included importance of follow-up meeting with the physiotherapist,

opportunity to meet other people in the same situation, knowledge of the importance of exercise, feedback from physiotherapist about exercise, possibility to discuss exercise problems with the physiotherapist, self-efficacy and understanding and support from family and friends. Baseline scores on social-cognitive motivation were in general higher among all participants. The high-dose group showed slightly higher baseline scores for both factors. There were no significant differences in the mean values of the factor scores between the groups or between completers and non-completers at baseline.

## 4.4 Cost-utility

Of the 528 participants that started the PAP-program at baseline, 178 returned for the one-year follow-up with 95 in the high-dose group and 83 in the low-dose group. The drop-out rate was 66% in both groups together after one year. An analysis of background characteristics among completers and non-completers showed significant differences: those who were younger and had lower health status were found to be more common among the non-completers. It also reveals that at baseline participants (completers and non-completers) had a high BMI (Body Mass Index), low income level and low education level. Most participants were middle-aged females. There were no significant differences between the high-dose and low-dose groups in background characteristics.

Quality of Life measured with the SF-36, showed that the scores on the two component summaries, mental and physical did not change significantly during the one-year period in any of the groups. In total, there were no significant differences in QoL at baseline between the groups. There was a significant time effect in both groups in the dimensions of bodily pain and general health, with a significant decrease in these items at the measurement after the four-month programme. The result shows an increase of the QALY-weights between baseline and the one-year follow-up, strongly significant for the low-dose group and for both groups together. The QALY-weights also increased slightly at four months for both groups and together, though not significantly. There were no significant differences at any of the points of measurements, either between the high- and low-dose groups or the completers and non-completers. The non-completers had higher baseline values than the completers. QALY gains were 0.02 for the high-dose group, 0.03 for the low-dose group and for both

groups together 0.02. The cost per QALY for the PAP-programme was 323,750 SEK (36,509 EUR) for the high-dose group and 101,267 SEK (11,419 EUR) for the low-dose group.

## 5. General discussion

The main aims of this thesis were: to perform a full health economic evaluation of the primary care program Physical Activity on Prescription, as analyzed in papers I-IV, to evaluate if the PAP-programme can change PA level, to examine an inactive individual's preferences for health effects of prescribed PA, to assess motivational differences between individuals completing the program and non-completers, and finally to examine changes in QoL among participants. To achieve these aims, we performed a cost analysis (Paper I), an analysis of the consequences of the program (Paper I, III), a willingness to pay analysis (Paper II) and a cost-utility analysis (Paper IV).

Having a good health among individuals contributes to the economy overall. Improving an insufficient physical activity level among inactive individuals derives considerable benefits for society. The challenge is to find effective methods that attract targeted groups of inactive people. With the national concept of the Swedish FaR® as substratum, the present thesis is an attempt to emphasize health economically related questions of this setting of FaR® – the PAP-program. Which individuals constitute the target population, is the PAP-program a method to make inactive individuals more physically active, and how should it be designed? And if we are able to find an effective method for this, how much does it cost? Is it worth it for society? These are questions that become important when facing scarce resources and limited budgets.

### *Effects of the program on PA behaviour*

The aim of the PAP-program was to increase PA level. We used three measures using two different indirect instruments of self-reported PA and one direct measure, the Six Minute Walk Test. All three types of assessment together give an assembled view of the individuals' physical activity behaviour. I interpreted the measured changes in self-reported physical activity behaviour, self-estimated time spent on physical activity and functional capacity as a change in physical activity behaviour. The instruments were adequate for use in this type of study with a heterogeneous group of patients, and with different physiotherapists in five



different primary care centres involved. The PAP-program showed significant improvements in all three methods used. Increased and maintained physical activity level is an obvious goal with health promotion in general, specifically for programmes such as the PAP-program. The long term one year follow-up study confirmed the improvements of PA level after four months, and showed a maintained change in PA behaviour. There were no differences between the groups in PA improvements, with both groups improving significantly. This result is of interest when designing health promotion interventions in primary health care aimed at increasing the physical activity level among sedentary adults, since the low-dose group that has lower costs made the same improvements in PA behaviour. The findings of the present study regarding changes of PA are in agreement with earlier studies, showing improvements but not any differences between interventions and controls (138-140). The interventions in these studies were mainly counselling, but in one case also supervised exercise. The results, measured as change in  $\text{VO}_2\text{max}$  and self-reported physical activity, showed significant increased levels. Our results showed that exercise twice a week, education, and motivational counselling had same effects for an improved PA behaviour as exercise once a week. A possible explanation for this may be a pre-motivational effect of the prescription for physical activity, regardless of group belonging.

In this study we used self-reported measures of physical activity, though this is connected with overestimation which could lead to measurement error (67). To reduce bias and incorrect conclusions we chose three different measures. The first was the self-report instrument IPAQ, where time spent in recalled physical activity was measured (69). IPAQ short form has acceptable criterion validity for use in Swedish adults, and also acceptable specificity to correctly classify people achieving current physical activity guidelines corresponding to more than 30 minutes per day of moderate and vigorous PA (70). The correlation coefficient between total physical activity measured with the IPAQ-short and an accelerometer was similar to other self-reports (69,70). A Finnish study showed that unfit sedentary young men report high physical activity with the IPAQ short form (141). The authors suggest a further development of the instrument due to overreporting. Using objective measurements like accelerometry in the present study was not possible with the conditions given. Due to budget restrictions choosing a self-reported PA with the IPAQ short form was the most appropriate. Also Ekelund et al. showed in their study significant overestimations of self-reported PA compared to accelerometry. In the present thesis we used two different self-reported instruments to estimate

PA level. Self-reported PA is connected with overestimation and could become a bias. The awareness of this problem is an important factor when performing PA interventions as people tend to exaggerate their performed daily PA when measuring PA level subjectively compared to objective measurements (142). In a study of adults who do not achieve recommended PA levels, only 27% of the 60% 'overestimators' report a readiness to change PA behaviour (143). Individuals who do not recognize their inactivity are not likely to perceive a need to change and thereby not participate in health promoting programs.

The unit of measure of the IPAQ questionnaire is expressed in MET-minutes per week. According to the IPAQ scoring protocol, a low physical activity level is defined as less than 600 MET-minutes per week, a moderate between 600 and 1500 MET-minutes per week and a high level at least 1500 MET-minutes per week. The participants in the present study were included since they were considered inactive by the person who wrote the prescription. The median baseline values were around 500 MET-minutes per week and increased significantly to 1286 for the high-dose group and 990 for the low-dose group per week at the one-year follow-up. This means a general change from a low activity level to a moderate level. The guidelines of the Advisory Committee of the US Department of Health and Human Services suggest a range of 500 and 1000 MET-minutes per week due to a dose-response relationship. PA of 500 MET-minutes per week for example can reduce risk of premature death. In another instance however, to achieve prevention for breast cancer a higher level of MET-minutes is needed (3).

#### *Effects of the PAP-program on QoL*

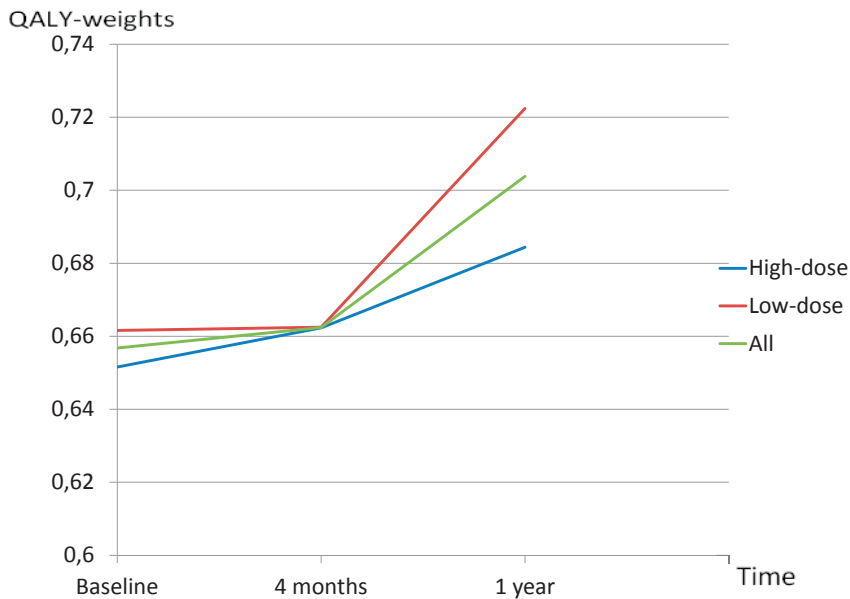
As shown in paper III, the PAP-program increased PA levels significantly in both high and low-dose groups after one year, with no differences between the groups. This implies that an improved PA level influences QoL in the long-term and contributes to the improvement of QoL between four months and one year. The results of the cost-utility analysis showed increased QoL one year after intervention, which corresponds to similar improvements seen in previous studies of prescribed exercise after six and sixteen months, respectively (52,144). There are also studies of the general population showing that people that are physically active have a better HRQoL (104,105). This association has been shown with subjective as well as with objective measurements. However, there are studies of prescription based interventions showing none or little improvement of QoL after an intervention with prescribed exercise (50,145). With limited

healthcare resources, it is important to be able to offer public health interventions in primary care with both economic effectiveness as well as improvements in PA level and QoL.

The low-dose group showed greater improvement in QoL at the one year follow up, significantly improved compared to baseline. Beside this improvement, the low-dose group also had higher baseline values of QoL. This could be interpreted as having a higher QoL from the start may be a better take-off point for an inactive individual improving physically activity level. Hence, higher values of QoL at baseline means greater improvements at four months and at one year after an exercise period at a low dose. The high-dose group had lower values at baseline, and shows in general less improvement at the one year follow up. It seems like a better health status, both mentally and physically, at baseline increases the possibility to make further improvements with help from the PAP-program. Compared with the scores of the general Swedish population, the QoL values of the SF-36 are considerably lower for all participants in the present study, completers as well as non-completers (137).

At four months there is a slight increase in QoL, however the largest improvement is between the measurements at four months and one year (fig. 4). This improvement is significant for the low-dose group and for both groups together. The observed time effect with only a very small increase in QoL at four months could be explained by an increase in bodily symptoms such as muscle soreness, resulting from participating in the exercise program. This is seen in both high- and low-dose groups. The rather low values at four months at the end of the exercise program may be a result of participating in the program which is reflected in different components in the SF-36, for example a lower score in the dimensions of bodily pain and general health due to a physiological overload on account of an increased exercise and physical activity. We would have expected a higher increase in QALY in the high-dose group, however the result is the opposite (fig. 4).

**Figure 4.** QALY-weights at baseline, 4 month- and 1-year measurements. Development over time.



### *Target population*

Our results showed that it is difficult to identify those individuals that are willing to participate and complete the programme, and with help and support from health care actually change their physical activity behaviour. About 34% of all those who received a prescription for PA and accepted participation completed the program and constitute the target group. These individuals are ready to change their physical activity behaviour: the results showed significant improvements in PA according to all three types of measurements. In the analysis of the characteristics, the result showed significant differences between completers and non-completers regarding age and self-perceived health (paper III). The completers are slightly older than those individuals who did not complete the programme and they also report a better health status at baseline. Having better health status from start ought to make participation in the different activities during the intervention period easier. A higher age can in a health economic perspective be explained with lower time costs. A higher share of older

persons in the group of completers may also be explained by having more time to spend and that they may seek opportunities for meeting other people in a social context.

The results showed that only 34% of the individuals who received a prescription had the capacity to perform regular activities on their own in the different activity groups. In the recommendations for prescribed physical activity as it is in the Swedish concept, it says that “the patient must also be able to handle physical activity outside the healthcare services”, that is for example in activity groups belonging to different sports associations (23). That means that the healthcare professionals responsible for writing the prescription also have to be able to value this very important capacity of the patient when writing the prescription. However, this is a difficult assignment to perform considering the relatively short dialogue that these professionals have with each patient – which is the most probable scenario for a normal visit with the physician in primary care. Assessing an individual’s capacity and motivational level needs longer consultations. Only a smaller part of the participants completed the program and performed the regular group activities, despite the fact that the activity groups were organised to fit particularly this target population. A specific setting with trained activity leaders could be presumed to increase the number of completers, though this was not seen in our results.

Regarding the methods of disease prevention, the guidelines of the Swedish National Board of Health and Welfare indicate that “healthcare services should offer counselling as well as written prescriptions or pedometers and special follow-ups to individuals with insufficient levels of physical activity” (146). The participants in the present setting of prescribed exercise received short advice about PA together with the prescription before programme start. During this office visit, they were considered suitable and motivated enough for participation in the group activities. The licensed health care professionals who wrote the prescriptions were experienced with this patient group. The participants in the high-dose group also received an extended motivational, patient-centred counselling, and the physiotherapists who performed these sessions were trained for counselling. However, this extended motivational boost increased neither compliance nor motivational level among the participants in the high-dose group. There are both motivational and hindering factors present in each person’s life situation. The motivational boost in the high-dose group may not have been enough or may not have addressed the necessary factors to obtain a behaviour change. The design, setting and content of the intervention itself must be considered when discussing adherence. In the present setting of

prescribed exercise there were two different groups; a low-dose and a high-dose group. The drop-out rate was the same in both groups, despite a more individualized approach in the high-dose group.

About 51% of the persons who received a prescription did not start in the programme and were not followed in the study, thus information on these individuals was not available. These individuals could be interpreted as being able to handle the advice about increasing PA themselves, and that they believe in having the capacity to increase their PA level on their own. This result coincides with the finding of a review of Pavey et al. (2011) showing considerable evidence for a variation of ERS uptake, with 35-100% of people attending the first ERS visit (58). The remaining 49% were followed in the present studies I-IV. Of these, 54% dropped out after four months, and after one year the drop-out rate reached 66%. This was a considerable drop-out rate, but is a similar rate seen in other studies of exercise on prescription. Soerensen et al. (2010) showed a drop-out rate after sixteen months being 66% in a study of exercise on prescription (144). The drop-out rate is also coinciding with the results of other studies of prescribed exercise: in a review of Pavey et al. there is evidence of large variation in adherence of exercise referral schemes, and between 12-82% of people complete the ERS programmes (58). According to the WHO, the compliance with medication is about 50%, and should also be considered in this context (147).

Our results show that screening instruments are likely needed for identifying the right target group. A suitable screening instrument should be easy to grasp for the health care professionals who work with this patient category. It should be as short and distinct as possible so that it constitutes an adequate method for use such as in primary care. An extensive investigation of each individual is not relevant for an easy every-day use in a clinical situation. When prescribing exercise, a model with different levels of interventions adjusted for the varied needs of the patient has been suggested in an attempt to meet individual diversity in motivation and self-efficacy (148).

A clear health promotion perspective concerning how to promote physical activity within primary health care is needed. A suggestion for an increased focus on PA is to routinely include information about the risks of being inactive within clinical practice, and as healthcare professionals in their unique position use the credibility and expertise in the promotion of PA (149). However, it seems like only physicians with personal PA habits gives advice for PA (150). It should be a main objective to use PA as a

first-line choice for treatment of inactivity related diseases because of the overwhelming evidence for its health benefits. We believe that a prescription for physical activity has a pre-motivational impact, and this study provides facts that it is a worthwhile tool for the health care sector to communicate the problem of inactivity to a selected target group.

#### *Cost-effectiveness of the PAP-program*

Cost-utility analysis based on the SF-6D as a measure of QoL was performed to estimate the cost-effectiveness of the PAP-program. The cost-effectiveness was calculated using QALYs, a health-related quality of life measure in health economics. The analysis found an incremental cost effective ratio (in terms of cost per QALY) for the high-dose group of 323,750 SEK for the high-dose group, which is considered to be moderate according to the Swedish National Board of Health and Welfare. On the other hand, the ICER for the low-dose group was estimated to be lower at 101,267 SEK, which is equal to 31 per cent of the incremental costs of the high-dose group.

In a review with a systematic analysis of cost-effectiveness of PA interventions in primary health care and the community, the result showed the cost per QALY varying from €311 to €75,525 (2,681-651,116 SEK) (112). The interventions with the lowest cost per QALY were mainly walking, exercise and nutrition, and brief counselling programmes. The highest cost per QALY was found in interventions with instructorled or supervised exercise sessions. In the present paper, the cost per QALY of the high-dose group, with supervised exercise, motivational counselling and education of PA, was €34,996. A QALY gain of 0.02 (0.0235) for both groups together is lower than the result of the Greenberg et al. study, where the geometric mean gain of 3240 ICERs was 0.07 (110). Another study featuring a cluster RCT with a societal perspective in primary health care showed a QALY gain of 0.0057 of a group based knee rehabilitation program with an exercise intervention (151).

The cost-utility analysis was performed with broad societal perspective since participants' time costs were included. The results of the cost-analysis of the PAP-program in paper I substantially contribute to a detailed health economic calculation when analyzing the cost-effectiveness, since it provides information not only on the distribution of the costs, but also information of the direct as well as indirect costs. The analysis with direct and indirect costs shows moderate costs per gained QALY, but in an estimation without the individual's time costs the costs per QALY are low. However, estimating cost-effectiveness excluding the individual's time



costs would not entirely reflect the societal perspective. Analysing the full societal impact requires both direct costs like costs of health care, and indirect costs like the individuals' time costs due to production losses (27,131). The value of the time that the individual spends on exercise, which is the individual's valuation of the opportunity cost, is the most important determinant for economic effectiveness (96). The cost per QALY slowly decreases if we make the assumption that the effect of an increased QoL not only remains during the first year but continuously increases also in the long term. That means, if the QoL stays the same for a longer period, the QALY-weight is stabilized and the cost per QALY will be even lower in the long term. However, this study is not able to verify cost-effectiveness of the PAP-program in the long term due to a limited follow-up time but could be evaluated in further research.

### *Marginal effects*

The results of this clinical trial may be of interest to decision-makers, since it provides information on the effectiveness of a primary care based health promoting intervention. Since we were able to calculate the total costs of the program as well as the different types of the costs paid by the participants and health care, respectively, it is possible to make an analysis of a changed effectiveness due to changed distribution of the different types of costs. In the following example, we make the premise that exercise possibilities increase, with a simultaneous decrease in participants' cost. The economy of scale is obvious; with many and smaller exercise groups the provider's costs for exercise is higher but could attract more individuals. With fewer and larger groups, the provider's cost for exercise is lower, but with lower adherence. Many and smaller groups with better availability may be more effective since participation and adherence rate probably would improve. With an improved adherence the rate of inactive individuals is expected to decrease, thus reducing the cost of inactivity for society.



**Table 3.** Exercise related costs (SEK), participants' share of total costs of the program (%), QoL-gain and cost-effectiveness of the high-dose and low-dose groups, respectively, as a consequence of the PAP-program.

	High-dose group (n=268)	Low-dose group (n=257)
Exercise costs for health care  -activity instructor, rent, introduction, groupleader	816 (14%)	415 (17%)
Exercise costs for participants  -travel and time for travel  -time for exercise, expenses for exercise equipment	4935 (86%)  2730 (47%)  2205 (38%)	2098 (83%)  1020 (40%)  1078 (43%)
Total costs for exercise in the program	5751	2513
Gained QALY	0.02	0.03
ICER (gross costs per gained QALY)	323 750	101 267

In the cost analysis (paper I) of the PAP-program we were able to present findings concerning distribution of the total program costs. Calculating exercise costs alone, the share of exercise costs of the program that the individual has to pay is even larger. Exercise related costs of the PAP-program were in total SEK 5751 for the high-dose group and SEK 2513 for the low-dose group (table 3). However, health care was only responsible for 14% of the exercise costs for the high-dose group and of the 17% of the low-dose group. The cost-utility analysis (paper IV) showed significant improvement of QoL in the low-dose-group. Due to lower costs and higher QoL after one year the low-dose group is more cost-effective. Moreover, the participants' time costs are slightly lower in the low-dose group, which

may influence the individual's preferences for PA activities. The summary of results featured in table 3 shows that the low-dose group has lower costs for participants as well as for the health care sector, higher increases in QoL, and a lower cost per QALY (ICER). These components make the low-dose exercise group a more favorable alternative from a health economic perspective. As described in table 3, the participants' costs for travel to and from exercise constitute a considerable part (40-47%) of the participants' total costs for exercise. To improve adherence to the PAP-program, a possibility would be to increase the availability of the exercise. This would increase health care costs, but it would simultaneously decrease participants' costs due to lower costs for travelling and travel time. An increase in the input of exercise would increase adherence. This would mean that if the availability of exercise would increase, for example through providing more groups, or more frequent performed exercise occasions, there would be greater adherence. Assuming adherence as a function of availability, it is expected that the effect of an increased availability of exercise on adherence would diminish in the long-term. With a flexible setting of exercise availability of exercise would increase. An example of this is organising exercise groups to a time of the day when people value their time lower, and having groups closer to people's homes or work places. This would also decrease the participants' costs for travels and costs for travel time. In the present setting of the exercise, the groups were larger but with lower cost per participant. This may lead to a lower adherence since the participant's own cost increases through higher costs for travelling and costs for travel time. Smaller groups would lead to higher costs for health care per participant when providing more groups. Smaller groups may also be more attractive for example for persons that are not used to exercise, or do not wish to feel exposed in a larger group.

A sensitivity analysis deals with the uncertainty of the results, and should include the uncertainty of central assumptions and parameters of a cost-utility analysis. Our estimations of comparing different doses of physical activity on prescription, as well as the inclusion of different perspectives (the individual's and health care provider's, respectively) of the exercise costs provides some experiences on uncertainty.

#### *The individual's preferences for health benefits of the program*

The individual's preferences for health improvements of the "Physical Activity on Prescription"-program were examined in Paper II. When designing interventions within health care the individual's own valuation of the benefits of a program is important information. When we know which

factors are associated with low and high preferences respectively, we can more efficiently design programs tailored for these individuals. When people participate in health promoting activities, the experienced wellbeing of these activities should be larger than the costs. The individual's preferences for health benefits are not captured in a cost-effectiveness analysis. In a cost-effectiveness analysis the effect is *measured*, but in the willingness to pay analysis the effect has been *valued* in monetary terms by the individual due to the stated preference approach. Willingness-to-pay analysis can be seen as a complement to an ordinary cost-effectiveness analysis, in order to elicit individuals' preferences.

Our results show that the WTP for improved health through exercise is influenced by a higher education level, income and BMI, that the highest WTP for a health outcome of physical activity is for an immediate health improvement. When designing and implementing appealing programs within primary health care for increasing PA level among inactive individuals the result may offer insights since it reflects individuals' preferences. The WTP-values cover the intangible benefits, i.e. consequences that are difficult to value such as the value of an improved health of physical activity.

#### *Change in PA influences society's costs*

With an increase in PA and a decrease in inactivity there is a cost offset for society. The cost-offset due to reduced inactivity was for both groups of SEK 94 068 (EUR 10 023) the first year, thanks to an improved physical activity level after participation in the PAP-program. The cost offset per individual of SEK 528 (EUR 56) consists in reduced health care costs and value of lost production, and is equal to 22% of the costs for an inactive individual of SEK 2412 (paper III). However, there may be an overestimation of the cost-offset since we do not have information on inactivity cost as a function of inactivity. We cannot assume a linear relationship, since we do not have the information on the relationship between inactivity and costs for inactivity looks.

#### *The physiotherapist's role in the program*

The exercise plan was not individually shaped and adjusted for each participant's demands. In the current concept of the Physical Activity on Prescription-program, the physiotherapist was responsible for the motivational counselling and the functional testing at baseline, after four months, and after one-year. The concept of the Physical Activity on Prescription-program in the south-east health care district of Region Skåne,

Sweden was the result of the collaboration between local sports associations, leisure centres, and health care sector, aiming at encouraging participants' responsibility and empowerment for health maintenance. The exercise groups were supervised by activity leaders of the local sport associations. The goal after the intervention for these inactive individuals is to have their own responsibility of a regularly performed exercise outside health care. However, not all individuals are ready for this. A high share of drop-outs after one year may indicate this. The concept of the present PAP-program may have been a step too far towards self-control for this patient category. These individuals may need more support and coaching, as well as a more individualized exercise-program. The completers of the Physical Activity on Prescription-program seem to be ready for this exercise outside health care intervention by participating in general fitness programs, often at a group level. A future study of the non-completers of the program may supply us with information on the need for more individually designed programs within primary health care. For this purpose, the physiotherapist has the needed medical knowledge and competence as well as the skills. The physiotherapist has the right competence to design an adequate individual exercise program for a certain diagnosis and disability, but also to perform motivational counselling. Physiotherapists are qualified to tailor exercise and counselling programs to improve physical activity level among sedentary individuals and to coach them in their training. Physiotherapists have an important role in health promotion within primary healthcare.

#### *Cost barriers for PA*

The participants in our study reported a low income level. The results of the WTP for health improvements of PA showed significant associations between income and the willingness to pay for health improvements of PA. These results are consistent with the predictions of the theoretical model concerning the influence of education level and income on the WTP for health effects of physical activity (39,100,102,152). A potential limitation of the WTP is the association with ability to pay (101). People with low incomes may state a lower WTP by virtue of their income level. As unhealthy behaviour (as characterised by low physical activity level) is associated with a socio-economic profile of a low education level and low income status (40), cost barriers may influence our estimations. In a study investigating economic limitations among people with low income, it was found that cost barriers influence the level of participation in physical activities (84).

### *Which economic approach?*

Theoretically, a cost-benefit analysis with the willingness to pay (WTP) approach may be the preferred method in economic evaluation since it quantifies individuals' preferences; which in this study is the preferences for improved health of prescribed physical activity. By giving a monetary value to the health benefits achieved through exercise the individual reveals his or her preferences. In WTP analyses using a contingent valuation methodology, there is a trade-off between income and how much time the individual wants to spend to achieve a certain health effect. The result is an absolute value of the benefit - a monetary expression for the effect of the intervention. The cost-utility analysis cannot provide us with an absolute value: the value of a cost per QALY can only be used as a ranking, and be compared with other cost per QALY values (153). Another advantage of the WTP is that it captures a valuation of 'everything', including intangible benefits. With the estimation of the value of the benefits, it can be compared to the costs and give decision makers broader and better information concerning resource allocation.

### *SF-36 vs. EQ-5D*

All preference-based index measures, such as the EQ-5D or SF-6D, have the advantage of calculating a single index score for an individual to be used in QALY-estimations. The dominated method today used in cost-utility analyses however is the EQ-5D. We did not use the EQ-5D since the conditions to use the SF-36 were given from the start of this research project. The SF-6D was then derived from the SF-36 using a scoring algorithm. The EQ-5D has the distinct advantage compared to the SF-6D in that it has considerably less data to administer.

### *FaR as a generalisable method*

Primary health care in Sweden has undergone large organizational changes in the last five years, primarily through the implementation of the possibility to freely choose a health care provider ("Vårdval") (154). This change has resulted in new organizational systems and economic conditions for primary care centers. Through new economic management control measures there are for example economic incentives for the health care provider writing a prescription for physical activity. This should be seen as part of a health promoting focus. However, this may result in a new selection of the target-population, since it has become more interesting to identify a larger number of individuals for a prescription. In real life, such conditions and policies may influence prescription writing, and persons

who were not included in a first selection are then selected in a second round. Beside this, the population in general has become unhealthier (30,155). In these perspectives, the promotion of FaR (Prescribed Physical Activity) now is even more important than when we performed the present study. The promotion should include knowledge about the method as well as identification of the right target group, with motivated persons willing to change their physical activity behaviour.

A suggestion for identifying motivated persons is a brief dialog of three questions, modified from Tinker et al. (156):

- How could your own capability, and motivation enhance your participation in the Physical Activity on Prescription-programme?
- What factors are barriers for you in participating in the program?
- How could these barriers be removed?

This could make impediments and motivation clearer for the individual as well as for the prescriber and thus enhancing adherence. The first question is based on the results of Paper III, where a factor analysis showed that social-cognitive factors seem important when changing PA behaviour. Other studies of motivation for PA also show the importance of self-efficacy and that it seems to predict change of physical activity (80,81). The second and third questions are related to barriers to PA. Several studies show that different types of barriers seem to influence motivation for participation in physical activities (84-86). Making the patient more aware of that barriers to PA exist and that a certain amount of planning and goal setting to remove these barriers are needed, would facilitate decisiveness, goal setting and planning of action course (82).

Based on my clinical experience from work in primary health care with inactive individuals, it is my personal opinion that planning of how to reduce practical barriers in everyday life schedule plays a central role in changing PA behaviour. Reducing the barrier to PA to a practical issue solely would be inconclusive. However, it should not be underestimated that the maintenance of a sufficient level of PA is connected with a time factor which needs daily planning and clear goal setting. This may also facilitate motivational strategies for starting and keeping the recommended, daily dose of PA.

*PA – behaviour or a unit?*

Traditionally, physical activity is measured as an individual's energy expenditure (CDC) (10). Physical activity can be defined as “any bodily movement produced by skeletal muscles that results in energy expenditure” (157). To be able to perform different activities we need extent range of different abilities like strength, flexibility or endurance. There are many different measurements and instruments for analysing these variables, and also different subjective and objective methods and technologies to measure PA level in general such as in a given population (67). For persons who are already motivated for PA it is easy to relate to a change / increase one's PA level, and to consider this as a simple change in units – minutes, meters, or calories. For persons who are not motivated and are less experienced with PA is starting an activity at all a huge barrier. It may then be difficult to look at physical activity as anything else than a very large change in life style. A person's behaviour is strongly associated with the level of motivation. Motivation is a complex concept, containing many important determinants like attitude, self-efficacy, beliefs, and intentions (80). PA may be considered a behaviour more than a measurement of units – a behaviour that is multifaceted.

## 6. Conclusions

The PAP-program showed that it was possible to make inactive individuals more physically active through intervention. Significant improvements in physical activity behaviour were shown in a one-year follow-up analysis.

The results of this program of prescribed exercise showed significant increased QoL one year after intervention in a low-dose group.

The best adherence for the PAP-program was found for elderly and those with relatively good baseline health. These individuals constitute the target population for this prescription based exercise program. Identifying the target population for participation in health promoting activity groups like the PAP-program is necessary for adherence, effectiveness and cost-effectiveness of a program.

The PAP-program is cost-effective as shown in a cost-utility analysis conducted in the study. The costs per QALY estimates were considered moderate regarding to Swedish comparative values. This makes the program a method worthwhile for society.

The program is most cost-effective for a low-dose group. This can be showed with lower costs associated with the low-dose group, and that individuals having a better QoL at baseline make larger improvements.

An increased availability of exercise would reduce the individual's time cost for travelling, and cost for travel.

The inactive individual's preferences for improved health through exercise were influenced by a higher education level, income and BMI.

The PAP-program can reduce the society's costs for inactivity by 22% per individual, every year the individual stays active.



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ORIGINAL ARTICLE

## Physical activity on prescription (PAP): Costs and consequences of a randomized, controlled trial in primary healthcare

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### Abstract

**Objectives.** To analyse costs and consequences of changing physical activity behaviour due to the “Physical Activity on Prescription” (PAP) programme. **Design.** A randomized controlled trial with a four-month intervention, with comparison between intervention and control group. **Intervention.** The PAP programme, with exercise twice a week, education, and motivational counselling. **Subjects.** 525 sedentary individuals, 20–80 years (intervention group  $n = 268$ , control group  $n = 257$ ), with lifestyle-related health problems. A total of 245 returned for the four-month assessment. **Main outcome measure.** Programme costs based on intention-to-treat estimations, direct and indirect costs of inactivity, and physical activity behaviour analysed with IPAQ (International Physical Activity Questionnaire), self-reported physical activity, and measures of functional capacity. **Results.** The intention-to-treat programme costs for the four-month programme period was SEK (Swedish Kronor) 6475 (€ [Euro] 684) for the intervention group and SEK 3038 (€ 321) for the control group. Of this, healthcare providers’ costs were 24% in the intervention group, and 31% in the control group. The physical activity behaviour was significantly improved in both groups, but no differences were found between the groups. **Implications.** The largest share of the PAP programme costs was the participants’ costs. Significant improvements were shown in physical activity behaviour in both groups, but no differences were found between the intervention and control groups. Due to many non-completers, the potential for improvements of the motivating assignment with sedentary individuals in primary healthcare is obvious. Long-term follow-up can determine the sustainability of the results, and can be used in a future cost-effectiveness analysis.

**Key Words:** Costs, primary healthcare, Physical Activity on Prescription, RCT study

Almost 40% of the Swedish population was in 2006 insufficiently physically active, implying a substantial individual and societal health burden [1–7]. The estimated costs of inactivity were SEK 6000 million in 2002 in Sweden, including costs for production loss and healthcare [8]. Scientific evidence supports physical activity as a preventive and therapeutic measure of inactivity-related chronic conditions [1,2,9–12]. The “Physical Activity on Prescription” (PAP) programme aims to increase the physical activity level among sedentary adults, and has not been evaluated from a health-economic perspective looking at costs and consequences [11,13–16]. Several studies have estimated the cost-effectiveness of physical activity interventions, but the evidence for this is limited [17–20].

The aim of this paper was to analyse the costs and consequences of changing physical activity behaviour through the four-month PAP programme by comparing a high-intensity group (intervention) and low-intensity group (control).

### Material and methods

The study was a randomized controlled trial with a four-month intervention with comparison between an intervention and a control group. Participant outcomes were evaluated before intervention and after four months. Written consent was obtained from all participants. The study protocol was approved by the Ethical Committee of Research at the University of Lund.

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Costs and consequences of changing physical activity through the "Physical activity on Prescription" programme were studied in this RCT.

- Healthcare providers were responsible for 28% of the costs. Participants' contribution – leisure time and travelling – was the largest share.
- The cost offset due to decreased inactivity is for both groups SEK 241 200 (€ 25 497) every year.
- Both intervention and control group showed significantly improved physical activity behaviour, but no differences were found between the groups.

### Sample

Participants were recruited in primary healthcare from five municipalities in the South-East Healthcare District of Skåne Region, Sweden. Starting in February 2006 participants were recruited continuously until December 2007 as all those who received a prescription for physical activity from a physician, nurse, physiotherapist, occupational therapist, welfare officer, or nutritionist. Criteria for having a prescription were: being at least 18 years old, having a sedentary lifestyle and one or more of the following diseases: cardiovascular disease, type 2 diabetes, obesity, musculoskeletal pain and disorders, mental illness, or respiratory problems.

### Intervention

The randomization process, using closed envelopes, was performed by the physiotherapists before the functional testing of the participants. Of the 525 participants randomised to either intervention or control group, 245 returned for the four-month assessment (Figure 1). The share of dropouts was for both groups 53%. Participants randomized to the intervention group had two supervised exercise sessions (45 to 60 minutes) in local sport clubs twice a week, two hours' education in physical activity and individual motivational counselling performed by physiotherapists [21]. They were also instructed to exercise additionally once a week on their own with an activity lasting at least 30 minutes and at least on a moderate level. The control group obtained written information about the possibility to participate in supervised exercise once a week on a moderately intense level. Results were reported from a societal perspective [22].

### Direct and indirect costs of physical inactivity

The estimated total costs of inactivity in Sweden on at the 2002 price level were between SEK 5820 and 6902 million [23]. In 2002 the Swedish population comprised 8 940 788 persons, and 6 999 878 were aged 18 years and older [24]. A prevalence of inactivity of 40% is equal to 2 799 951 persons, and means a cost of ~SEK 2265 per inactive person in the year of 2002. Transferred to the 2007 price level with the Swedish consumer price index, the cost is SEK 2412 per inactive person, and is a cost to society which a sufficient physically active person does not carry. Based on this calculation, we can estimate the indirect and direct costs of the inactive and active individuals respectively before and after participation in the PAP programme.

### Main outcome measures

Three different methods were used to classify inactive vs active physical activity behaviour: *self-rated physical activity* with the IPAQ (International Physical Activity Questionnaire) short form, *self-reported physical activity level*, and a *functional test* with the Six-Minute Walk Test [25–27]. The IPAQ short form protocol assesses MET values of walking, moderate-intensity activities, and vigorous activities, and the average MET minutes was used in the analysis [28,29]. The second method, a single question of present extent of physical activity level, is based on the Transtheoretical Model, and the five levels were

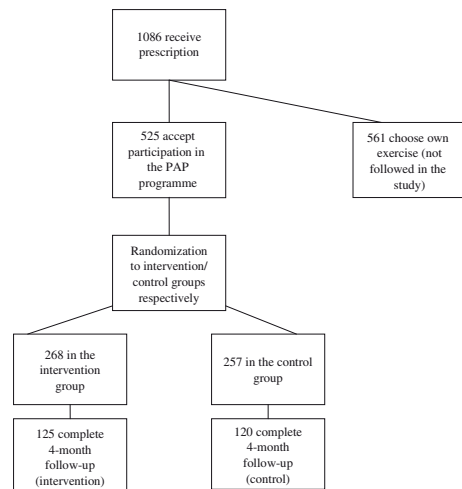


Figure 1. Flow chart showing the prescription, randomization, and participation rates of the participants.

dichotomized into “active” and “inactive” for the further analysis [30]. The third method was the Six-Minute Walk Test; the participant walked as fast as possible during six minutes, and the distance (metres) covered was measured [31]. The outcomes also included an exercise diary to measure compliance.

Self-reported costs of the individual associated with the programme included exercise equipment purchased, travelling and travel time costs to and from exercise, and injuries due to the programme. Participants’ exercise and travel time cost is a mean value, calculated on the basis of the self-reported monthly gross salary and working hours. The exercise was performed in participants’ leisure time. The costs of the exercise in the different sport clubs in the area include staff time for exercise instructors and rent of facilities. Each participant visited the physiotherapist twice (for the intervention group an additional 20 minutes’ time for the motivational counselling), at baseline and at four months. For the non-completers the costs were based on the assumption that the majority of them dropped out within the first month, implying that the first month’s costs were same for both completers and non-completers.

### Statistical analyses

Means and standard deviations as well as relative frequencies (%) were used to describe the sample. Differences at baseline between intervention and control groups were tested with t-tests with regard to age, BMI, and income, and with chi-squared tests with regard to sex, education, and health. Due to skew distributions the Mann-Whitney U-test was used for comparisons between intervention and control groups with regard to MET minutes and the Six-Minute Walk Test, while Wilcoxon’s signed rank test was used for comparisons between baseline and the four-month follow-up. Chi-squared tests were used for comparisons between intervention and control groups with regard to physical inactivity. McNemar’s test was used to test change in inactivity between baseline and four-month follow up. Statistical significance was set at  $p < 0.05$ .

### Resource utilization and costs

In the following estimation of the costs within the PAP programme, we designated the value of resources

Table I. Baseline characteristics of the completers and non-completers (baseline only): Differences between intervention and control groups are tested.

	Completers (n = 245)			Non-completers (n = 280)		
	Intervention n = 125 <sup>1</sup>	Control n = 120 <sup>2</sup>	p-value	Intervention n = 143 <sup>3</sup>	Control n = 137 <sup>4</sup>	p-value
Sex (%)			0.394 <sup>5</sup>			0.123 <sup>5</sup>
Women	70.4	66.7		63.6	72.3	
Men	29.6	33.3		36.4	27.7	
Age (years)			0.591 <sup>6</sup>			0.679 <sup>6</sup>
Mean (SD)	55.2 (12.5)	54.4 (13.2)		49.7 (13.9)	49.0 (13.5)	
Range	20–80	22–79		19–81	18–84	
BMI (kg/m <sup>2</sup> )			0.635 <sup>6</sup>			0.273 <sup>6</sup>
Mean (SD)	31.5 (5.8)	31.8 (6.7)		32.4 (6.2)	33.3 (7.0)	
Range	18.0–50.0	19.8–55.0		19.4–60.7	19.7–55.6	
Income (SKr)			0.538 <sup>6</sup>			
Mean (SD)	15 440 (7 027) <sup>1</sup>	14 805 (6 811) <sup>2</sup>		n.a. <sup>7</sup>	n.a. <sup>7</sup>	
Range	0–40 300	0–37 500				
Education level (%)			0.852 <sup>5</sup>			0.720 <sup>5</sup>
Nine-year compulsory school	36.8	33.3		30.5	34.1	
2 years upper secondary school	20.0	25.0		21.3	18.5	
3 years upper secondary school	24.8	22.5		27.0	26.7	
University or college	18.4	19.2		21.3	20.7	
Health (%)			0.858 <sup>5</sup>			0.299 <sup>5</sup>
Poor	8.9	9.2		18.3	19.7	
Somewhat poor	50.0	50.8		51.4	51.8	
Good	31.5	30.0		21.8	25.5	
Very good	8.1	9.2		7.0	2.9	
Excellent	1.6	0.8		1.4	0	

Notes: <sup>1</sup>Due to missing values n varies between 90 and 125; <sup>2</sup>due to missing values n varies between 91 and 120; <sup>3</sup>due to missing values n varies between 139 and 143; <sup>4</sup>due to missing values n varies between 134 and 137; <sup>5</sup>chi-squared test, linear-by-linear association; <sup>6</sup>t-test 1: n = 84, 2: n = 86; <sup>7</sup>not available.

Table II. Intention-to-treat programme average costs (SEK) per patient for the four-month programme period for intervention group and control group.

Type of cost		Intervention n = 268	Control n = 257
Medical staff time	Physiotherapist	SEK 586	SEK 506
	Health educator	73	0
Exercise	Activity instructor	560	288
	Rent	80	41
	Introduction	8	0
	Group leader	168	86
Participants' costs	Exercise time	1722	652
	Travel time costs	1310	449
	Exercise equipment	483	426
	Travel costs	1420	571
Costs of programme due to participants' injuries	Visits to hospital	0	0
	Visits to primary healthcare	7	7
	Costs of absence from work due to injury	58	12
		6475	3038
Total costs			

Note: The table shows the value of each cost component.

used rather than expenses. All costs are reported in Swedish Kronor (SEK).

#### *Programme costs and quantities*

Baseline analyses showed no significant differences between the groups in age, BMI, income, education level, or self-perceived health (Table I). The programme costs for the four-month intervention period were based on intention-to-treat estimations and are presented in Table II.

Among the participants, 82% used a car to travel to the exercise class, 18% walked or cycled, and 0 % used public transport. The average travel time of the participants was 22 minutes.

Three minor injuries due to participation in the programme were reported in the intervention group and four in the control group, respectively, and comprised knee or ankle sprains. They resulted in one visit to primary healthcare and absence from work for 10 and two days respectively. Due to the exercise diary, the mean number of exercise sessions for individuals who completed the four-month intervention was 31 (SD = 14, range = 2–48) for the intervention group (n = 91), and 12 (SD = 4, range = 2–23) for the control group (n = 79).

#### *Costs of the PAP programme*

The results show intention-to-treat programme costs for the four-month programme period of SEK 6475 for the intervention group and SEK 3038 for

the control group (see Table II). The largest share of the costs was the participant's cost, which included time spent on exercise, travel, and travel time to and from exercise. An on-treatment analysis shows programme costs for the intervention group of SEK 10 721 per patient and for the control group SEK 4822, which is an expected result considering the adherence rate and time of participation of the non-completers.

Table III shows the average change in physical activity of completers in intervention and control group. All three measures of physical activity were significantly improved in both groups at the four-month follow-up. After four months, 65% of the intervention group reported an active level of self-perceived physical activity, among the controls this was 53%. For both groups together, 12% of the already active individuals became inactive. The self-rated estimation of MET minutes per week showed more than twice as many MET minutes at the four-month follow-up compared with baseline in both groups. The Six-Minute Walk Test showed significant improvements for both groups. The improvements from baseline to four-month follow-up showed no significant differences between the two groups.

Table IV shows the costs for the share of inactive individuals, and as a consequence of the programme the cost offset every year due to reduced inactivity.

## **Discussion**

The cost offset due to decreased inactivity as a consequence of participation in the PAP programme was for

Table III. Physical activity behaviour for intervention and control group at baseline and at four-month follow-up for participants who have completed the four-month programme: Differences between intervention and control group.

		Baseline	Four-month follow-up	p-values <sup>1</sup>
Intervention n = 125				
	MET minutes per week <sup>2</sup> median (q1–q3)	480 (6–1737)	1020 (264–2493)	0.003 <sup>3</sup>
	Inactivity (%)	76	28.8	< 0.001 <sup>4</sup>
	Six-Minute Walk Test <sup>2</sup> (metres) median (q1–q3)	510 (457–550)	525 (489–580)	< 0.001 <sup>3</sup>
Control n = 120				
	MET minutes per week <sup>2</sup> median (q1–q3)	524 (7–1382)	1200 (268–2940)	0.001 <sup>3</sup>
	Inactivity (%)	71.8	37.4	< 0.001 <sup>4</sup>
	Six-Minute Walk Test <sup>2</sup> (metres) median (q1–q3)	500 (442–552)	521 (468–573)	< 0.001 <sup>3</sup>
p-values <sup>5</sup>				Differences between the groups regarding changes from baseline to four-month follow up (p-values <sup>6</sup> )
	MET minutes	0.733 <sup>6</sup>	0.936 <sup>6</sup>	0.681
	Inactivity	0.231 <sup>7</sup>	0.249 <sup>7</sup>	0.053
	Six-Minute Walk Test	0.444 <sup>6</sup>	0.344 <sup>6</sup>	0.180

Notes: <sup>1</sup>Comparisons between baseline and four-month follow-up; <sup>2</sup>due to missing values n varies between 183 and 225; <sup>3</sup>Wilcoxon's test; <sup>4</sup>McNemar's test; <sup>5</sup>comparisons between intervention and control group; <sup>6</sup>Mann-Whitney U-test; <sup>7</sup>chi-squared test.

both groups SEK 241 200 (€ 25 497) every year, and is a cost offset of SEK 984 (€ 104) for healthcare costs and value of lost production per individual and year based on the assumption that the individual maintains the physical activity level during a period of one year.

The healthcare provider was responsible for only a minor part of the total programme costs: 24% (intervention group) and 31% (control group), respectively. The main part of the programme costs was the participants' own costs – leisure time and travelling, together 76% for the intervention group and 69% for the control group. However, the programme costs do not cover the intangible benefits, i.e. consequences that are difficult to value such as the value of improved health.

The individuals' own cost should be considered when planning physical activity interventions for sedentary individuals with lifestyle-related diseases and the question of a subsidy from society must be raised. The individual's own contribution may also influence the motivation for participation, and be a reason for the number of non-completers.

The main strength of the present study is that it is a randomized controlled trial. We chose three different ways of measuring physical activity. The IPAQ short form has relevant questions and acceptable criterion validity and specificity to correctly classify people achieving current physical activity guidelines, and has measurement properties as good as other self-reports [25,26]. A low physical activity

Table IV. Costs of inactivity for intervention and control group at baseline and at four-month follow-up.

	Intervention n = 125 <sup>1</sup>		Control n = 120 <sup>2</sup>		Total n = 245 <sup>3</sup>	
	Baseline	Four-month Follow-up	Baseline	Four-month follow-up	Baseline	Four-month follow-up
Inactivity, n (%)	95 (76)	36 (28.8)	84 (71.8)	43 (37.4)	179 (80.5)	79 (33.8)
Costs of inactivity every year (SEK)	229 140	86 832	202 608	103 716	431 748	190 548
Estimated cost offset every year (SEK)		142 308		98 892		241 200

Notes: Inactivity was assessed using the self-reported question about present extent of physical activity. Estimated cost offset every year with a retained activity level. <sup>1</sup>Due to missing values n varies between 119 and 125; <sup>2</sup>due to missing values n varies between 115 and 120; <sup>3</sup>due to missing values n varies between 234 and 245.

level is defined as less than 600 MET minutes, a moderate level at least 600 MET minutes, and a high level at least 1500 MET minutes [29]. The participants in the present study show baseline values of around 500 MET minutes and at four months 1000–1200 MET minutes. Research shows different suggestions for significant improvements in the Six-Minute Walk Test: depending on intervention, gender, and patient category, reported mean changes of improvements in different studies have been between 33 and 170 metres [27,32]. In our results, the median increase was 15 and 21 metres respectively (both  $p$ -values  $< 0.001$ ). The changes in physical activity are in agreement with earlier studies, showing improvements but no differences between intervention group and controls [33–35]. Our study showed that exercise twice a week, motivational counselling, and education compared with exercise only once a week does not make any difference in improving physical activity, and may be of note when designing programmes in primary healthcare. The completers may have stronger motivation for physical activity and exercise, and could have influenced the results of physical activity. The number of non-completers shows substantial potential for improvements in the implementation of the PAP programme with special regard to recruitment, motivational tasks, and environmental background.

A follow-up study should analyse the net resource utilization and costs vs net benefits of quality of life per se and cost per QALY respectively. Long-term follow-up of the results can be transformed into cost-effectiveness analyses, and should contain analyses of the cost offset in a long-term perspective and the sustainability of the improved physical activity level, and should consider quality of life.

The cost offset due to decreased inactivity is SEK 984 (€ 104) per individual and year, assuming a maintained physical activity level during one year. Both intervention and control group showed significantly improved physical activity behaviour, but no differences between the groups, a result that is of interest when planning health-promotion interventions in primary healthcare and for a future cost-effectiveness study.

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## Paper II





ORIGINAL ARTICLE

## Willingness to pay for health improvements of physical activity on prescription

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### Abstract

**Aims:** To estimate the willingness to pay for health improvements among participants in the programme “Physical Activity on Prescription”. The objective was also to examine predictors such as income, education level, health status, activity level and BMI, differences for long- and short-term health effects of physical activity and differences between a high- and low-intensity activity group. **Methods:** Willingness to pay (WTP) data were collected alongside a randomized, controlled trial in Sweden 2007, and 128 sedentary individuals, 20–80 years old (intervention/high-intensity group  $n = 71$ , control/low-intensity group  $n = 57$ ), with lifestyle-related health problems answered open-ended questions in this contingent valuation study. **Results:** The highest mean WTP (€59/SEK 552) was stated for an immediate health improvement, but no significant differences compared with long-term health improvements. The high-intensity group showed higher WTP-values for all health improvements, but without significant differences compared with a low-intensity group. Regression analyses show strong associations between a higher level of education and the WTP for improved well-being and improved health, and also between income and the WTP for improved well-being. There are significant correlations between the WTP and the variables BMI, income and education level, as expected from economic theories. **Conclusions: The willingness to pay for the health improvements of exercise is influenced by a higher education level, income and BMI. The highest WTP for a health outcome of physical activity is for an immediate health improvement. The results of this randomized controlled trial in primary health care may be of interest to decision makers when evaluating different approaches to promoting physical activity among people who are sedentary.**

**Key Words:** Health promotion, inactivity, physical activity on prescription, randomized controlled trial, willingness to pay

### Background

Lifestyle-related decrease in physical activity is a well-known health problem in today's society, and represents serious consequences for public health due to an increased risk for developing several chronic diseases such as hypertension, type 2 diabetes, colon cancer, osteoporosis and cardiovascular disease [1–3]. More than 40% of the population in Sweden were not sufficiently physically active (at least two and a half hours per week) in 2006, resulting in not only an increase in mortality and morbidity, but also an increase in productivity-loss in society [3–7]. The estimated costs for production-loss and health care in Sweden were Swedish crowns (SEK) 6,000

million in 2002 [4]. Hence, from a health and an economic point of view, enhancing physical activity among the sedentary may well derive considerable benefits for the individual as well as for society. There is strong medical evidence supporting the use of exercise as a preventive and therapeutic measure [8,9]. As a result, economic evaluations of different interventions to promote physical activity have been carried out, but many of the health-economic studies show limited generalizability of the results of methods to promote physical activity [10–13].

Health can be regarded as part of the human capital, where the individual's time investment and

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health-related behaviour are determined by preferences and circumstances [14]. How do individuals value health benefits, and to which incentives do consumers on the health market respond? To oppose growing costs, society requires well-evaluated health programmes that provide adequate information to policy makers to enable them to choose the best alternative treatment [15,16].

Willingness to pay (WTP) is a measure to quantify the strength of individuals' preferences, in this case for the "Physical Activity on Prescription" (PAP) programme, which is a subsidized project that aims to increase the physical activity level among sedentary individuals. In the economic evaluation of healthcare programmes, the contingent valuation methodology determines the WTP for programme consequences through a hypothetical scenario and aims to quantify intangible benefits to the individual, which are the money value of changes in health per se [17]. The contingent valuation aims at bringing the respondents to reveal the maximum amount of money they are willing to pay for a certain benefit (consequence) of a programme, and to think about the contingency of a market where the programme occurs.

The willingness to pay for health improvements of the PAP programme reflects the individual's preferences [17]. If the inactive individual does not have any preferences for health benefits of physical activity, there will be a low demand for health promoting activities like the PAP programme. A subsidy from society is justified when the competitive market fails; a perfect market requires a high demand for long-term health improvements [15].

A sedentary lifestyle is associated with socio-economic factors like low income and low education level [18,19]. According to economic theory, willingness to pay should increase with income, and this relationship could be considered as a test of the contingent valuation method's validity [20]. Our hypothesis is that the WTP for health improvements of physical activity on prescription will decrease with a low income and education level [21]. Body mass index (BMI) is also likely to be important; the higher the BMI, the higher the WTP for weight-loss effects of physical activity on prescription, due to the possibility of losing weight [22,23]. An individual's age may affect the WTP. Previous studies show a decrease in WTP with age: individual evaluation complies with an inverted-u curve of a life cycle, peaking at an age just over 40 [24–27]. The WTP for long- and short-term health improvements of physical activity on prescription may be of different value, with regard to Grossman's theory of health as consumption and investment [14,20,28]. It is presumed that individuals valuing health effects have time preferences,

and are therefore influenced by discounting: they are more likely to highly value an immediate effect of physical activity rather than a future effect. The experience of well-being is emphasized more in a high-intensity group and may increase the preferences for well-being, which is why a comparison between a high and low intensity group is of interest [29].

## Aims

The aim of this study was to estimate the WTP for different health improvements and weight loss of physical activity on prescription among a selected group of individuals within the PAP programme. The aim was also to examine predictors for the WTP for different health improvements and weight loss of physical activity on prescription, such as income, education level, health status, activity level and BMI. We also wished to examine if there is a difference in the WTP for long- and short-term health improvements of physical activity on prescription, and differences between a high- and low-intensity activity group.

## Methods

In the economic evaluation of healthcare programmes, the contingent valuation methodology determines the WTP for programme consequences through a hypothetical scenario and aims to quantify intangible benefits to the individual, which are the money value of changes in health per se [17,30]. The approach to determining WTP used in this study was elucidation of individuals' maximum WTP for a certain health improvement or weight loss of physical activity on prescription, using open-ended questions.

Preference-oriented instrumental value is important in economic evaluation: the measure of the benefit is that cost which, in the preferences of the individual who benefits, would exactly offset it [20,21,31].

When defining the private WTP for a health change, it is possible to look at this mechanism as a utility function of the individual [32]. The function depends on the consumption of (private) goods, the individual's health, and time spent on physical activity. From the individual's point of view, there is a trade off between income and how much time the individual wants to offer to achieve better health. Because money is the only good for trading in this situation, it is the measurement of utility. Hence, there is a trade off between income (money) and health, and we measure how much the individual is prepared to offer for improved health.

*The PAP intervention as a method to obtain improved health*

The material for this WTP study was collected alongside the randomized controlled trial Physical Activity on Prescription, which is a primary-care-based programme in the South-East Health Care District of Region Skåne, Sweden, and aims to promote change in physical activity behaviour among sedentary adults. Criteria for having a prescription were: being at least 18 years old, having a sedentary lifestyle and one or more of the following diseases: cardiovascular disease, type 2 diabetes, obesity, musculoskeletal pain and disorders, mental illness or respiratory problems.

Study participants were randomized to either an intervention (high-intensity) or control (low-intensity) group. Using an ex-post (user-based) approach the respondents in both groups were asked what they were willing to pay for different health benefits of the PAP programme after participation. The material also included an exercise diary to measure compliance. Written consent was obtained from all participants and the paper has been approved by the Regional Ethical Review Board, Lund University.

Participants randomized to the intervention (high-intensity) group had two exercise sessions a week in a group on a moderate-intensity level, education about physical activity and motivational counselling and additionally exercised once a week on their own. The control group (low-intensity) exercised once a week in a group on a moderate-intensity level. Thus, both intervention and control group had experience with the PAP programme. The participation fee for the four-month programme period was SEK 200 for the control (low-intensity) group, and SEK 300 for the intervention (high-intensity) group. Of the 243 participants 128 returned for the four-month assessment and responded to the questions about their WTP (53% response rate).

Means and standard deviations as well as relative frequencies (%) were used to describe the sample. Differences between intervention and control groups were tested with a *t*-test and Chi-square-test. WTP is described with mean and standard deviation as well as the proportion of individuals willing to pay SEK 0, and is presented separately for the intervention and control group and also for the combined group. Due to skewed distribution of the WTP values differences between the groups were tested using the Mann-Whitney test. Differences between health improvements were tested using Wilcoxon's rank sum test. Spearman correlation coefficients were calculated to describe the association between the WTP and

following independent variables: age, income, BMI, activity level, health status and education level. In further regression analyses, carried out to describe WTP by all independent variables simultaneously, activity level, health status and education level were transformed and used as dichotomous variables. A *p*-value <0.05 was considered significant.

Willingness to pay monetary values for health improvements and weight loss were given in Swedish crowns, with an exchange rate in November 2007 of €1=SEK 9.3. The different health improvements were connected to the physical activities within the PAP programme, and the respondents made their own interpretation of the size of the health improvement. The scenarios presented to the respondents are shown in Figure 1. In the answers, the time frame was four months, i.e. the amount of money was intended to be paid once and for a four-month period.

The explanatory variables were:

- (1) Income, gross income per month in Swedish crowns (SEK).
- (2) Body mass index, kg/m<sup>2</sup>.
- (3) Activity level (self-reported): 1 = Inactive, no intention to start, 2 = Inactive, but have intention to start, 3 = Physically active < 6 months, 4 = Physically active > 6 months, 5 = Physically active > 6 months, and want to increase activity level. In the regression analyses we used activity level dichotomized, 0 = non responders, inactive and no intention to start exercising, inactive but have intention to start exercising, and 1 = physically active < 6 months, physically active > 6 months, physically active > 6 months and want to increase activity level.
- (4) Health status (self-reported): 1 = poor, 2 = somewhat poor, 3 = good, 4 = very good, 5 = excellent. In the regression analyses we used health status dichotomized, 0 = non responders, poor, somewhat poor, and 1 = good, very good, excellent.
- (5) Education level (self-reported): 1 = nine-year compulsory school, 2 = 2 years-upper secondary school, 3 = 3-years upper secondary school, 4 = university or college of higher learning. In the regression analyses we use education level dichotomized, 0 = non responders, nine-year compulsory school, 2-years-upper secondary school, 3-years-upper secondary school, and 1 = university or college of higher learning.

## Results

### *Sample characteristics*

The characteristics of the participants are shown in Table I. Baseline analyses show no significant

1. "There is scientific evidence that regular physical activity can be used as a therapeutic measure. If you exercise 2–3 times per week with activities similar to the PAP programme, you can expect improved health for lifestyle-related diseases, like high blood pressure, overweight and type 2 diabetes. How much would you pay to get such an <b>improved health</b> by exercising?" (Long-term health improvement)
2. "There is scientific evidence that regular physical activity positively influences not only different diseases, but also your well-being can be improved. If you exercise 2–3 times per week with activities similar to the PAP programme, you can expect improved well-being. How much would you pay to get such an <b>improved well-being</b> by exercising?" (Short-term health improvement)
3. "If you exercise 2–3 times per week for four months with activities similar to the PAP programme, you could lose weight, 2 kg in four months. How much would you pay to get such a <b>weight-loss</b> ?"

Figure 1. Willingness to pay scenarios presented to the respondents.

Table I. Baseline characteristics of the participants. Differences between intervention and control groups are tested.

		Intervention n = 71	Control n = 57	Total n = 128	p-value
Sex (%)					0.403 <sup>a</sup>
	Women	71.8	64.9	68.8	
	Men	28.2	35.1	31.2	
Age (years)					0.861 <sup>b</sup>
	Mean (SD)	54.2 (13.5)	54.6 (12.3)	54.3 (12.9)	
	Range	20–80	22–76	20–80	
BMI (kg/m <sup>2</sup> )					0.984 <sup>b</sup>
	Mean (SD)	31.5 (5.2)	31.3 (5.7)	31.4 (5.4)	
	Range	19.0–48.0	21.6–49.0	19.0–49.0	
Income (SEK)					0.464 <sup>b</sup>
	Mean (SD)	13,973 (7,426)	15,067 (7,636)	14,468 (7,505)	
	Range	0–30,000	0–37,500	0–37,500	
Education level 1–4 (%)					0.899 <sup>a</sup>
	Nine-year compulsory school	30.6	32.9	31.7	
	2 years' upper secondary school	22.0	18.7	20.4	
	3 years' upper secondary school	27.7	29.0	28.4	
	University or college	19.7	19.4	19.5	
Health 1–5 (%)					0.381 <sup>a</sup>
	Poor	15.1	12.3	13.8	
	Somewhat poor	52.9	49.7	51.4	
	Good	25.0	31.0	27.8	
	Very good	5.2	6.5	5.8	
	Excellent	1.7	0.6	1.2	
Activity level 1–5 (%)					0.687 <sup>a</sup>
	Inactive, no intention to start	4.1	1.3	2.8	
	Inactive, but have intention to start	75.6	78.1	76.8	
	Physically active <6 months	2.9	3.9	3.4	
	Physically active >6 months	4.7	3.9	4.3	
	Physically active >6 months, and want to increase activity-level	11.0	11.6	11.3	
	Non responders	1.7	1.3	1.5	

<sup>a</sup>Chi-square-test, linear-by-linear association. <sup>b</sup>t-test.

differences between the groups regarding sex, age, BMI, income, education level, health status or activity level. Compliance was measured by an exercise diary (self-reported), which 107 of the 128 participants had filled out. The mean number of exercise times during the four-month prescription period was 32 times for the intervention group (SD = 13.5) and 12 times for the control group (SD = 6.8).

*Willingness to pay for health improvements and weight loss of the PAP programme with and without zero bids*

The intervention group stated in general a higher WTP than the control group for all health improvements, for short- as well as for long-term improvements, but there were no significant differences between intervention and control groups (Table II). This result was the same without zero bids. The highest WTP-value for both groups together was for improved well-being (short-term health improvement), which was SEK 552 with zero bids, and SEK 656 without. The highest mean WTP-value for the intervention group was for improved health (long-term health improvement), and was SEK 601. Without zero bids the highest mean WTP for the intervention group was for improved well-being (SEK 681). The highest WTP-value for the control group was with and without zero bids for improved well-being, SEK 493 and SEK 616, respectively. The lowest mean WTP was for both groups separately and together, with and without zero bids, for a weight loss of 2 kg due to exercise two to three times per week. The control group had a higher percentage share willing to pay SEK 0 than the intervention group regarding both health improvements and weight loss.

A comparison between the WTP (both groups) for the different health improvements showed significant differences with and without zero bids between wellbeing vs weight loss effects ( $p$ -value = <0.000 and 0.001) and long-term health improvement vs. weight loss effects ( $p$ -value = <0.000 and 0.030) (Table III). A significant difference between short- and long-term health improvements was found in the comparison without zero bids ( $p$  = 0.030).

*Relations between the WTP for different health improvements and the independent variables*

The BMI, income and education level correlated significantly with an improved well-being (Table IV).

*Associations between the WTP for different health improvements and the independent variables*

The multiple regression analysis was carried out to determine the impact of age, income, BMI and other factors of the simultaneous influence on the WTP.

Table III. Differences between the mean willingness to pay (both groups) for the different health improvements with and without zero bids.

Health improvement	$p$ -value <sup>a</sup> with zero-bids	$p$ -value <sup>a</sup> without zero-bids
Improved wellbeing vs. improved health	0.348	0.035
Improved wellbeing vs. weight-loss effect	<0.001	0.001
Improved health vs. weight-loss effect	<0.001	0.030

<sup>a</sup>Wilcoxon's rank sum test.

Table II. Willingness to pay (SEK) for health improvements of physical activity. Both mean values and standard deviations as well as proportion willing to pay SEK 0 are presented. Differences between intervention and control groups are tested.

	Responders with zero bids				Responders without zero bids			
	Intervention <sup>a</sup> Mean (SD) % WTP = 0	Control <sup>b</sup> Mean (SD) % WTP = 0	Total <sup>c</sup> Mean (SD) % WTP = 0	$p$ -value <sup>f</sup>	Intervention <sup>d</sup> Mean (SD)	Control <sup>e</sup> Mean (SD)	Total <sup>f</sup> Mean (SD)	$p$ -value <sup>g</sup>
Health improvement								
Improved well-being by exercise four months	596 (653)	493 (394)	552 (557)	0.600	681 (666)	616 (368)	656 (566)	0.879
2-3 times per week	10.7%	16.7%	13.3%					
Improved health by exercise four months	601 (599)	423 (286)	524 (495)	0.117	668 (604)	472 (273)	586 (502)	0.082
2-3 times per week	8.5%	8.9%	8.7%					
Weight-loss 2 kg by exercise four months	445 (389)	317 (259)	387 (341)	0.134	567 (360)	439 (209)	512 (310)	0.186
2-3 times per week	20.0%	26.1%	22.8%					

Due to non responders and zero bids: <sup>a</sup> $n$  = 54-60, <sup>b</sup> $n$  = 42-50, <sup>c</sup> $n$  = 99-106, <sup>d</sup> $n$  = 42-52, <sup>e</sup> $n$  = 31-37, <sup>f</sup> $n$  = 73-89. <sup>g</sup>Mann-Whitney test.

From a scatter plot where the residuals were plotted against expected values, it was seen that heteroskedasticity was no major problem. The result of the multiple regression analysis for different health improvements and the independent variables is presented in Table V. A higher university or college level education is significantly associated with the willingness to pay for improved health and improved well-being. Income is significantly associated with the willingness to pay for improved well-being. The variables explained 18.1% and 14.7% of the variance in WTP.

## Discussion

To our knowledge this is the first study that has examined the willingness to pay for health improvements of physical activity on prescription. It is important to provide policy makers with a quantification of sedentary individuals' preferences for improved health associated with a prescribed physical activity programme. Physical Activity on Prescription can be seen as a health promoting intervention within public health and the method is well implemented. In primary health care it is important to promote

physical activity as a therapeutic measure and evaluate different outcomes.

Our empiric results are consistent with the predictions of the theoretical model concerning the influence of education level and income on the WTP for health effects of physical activity [14,20,21,32]. A potential limitation of the WTP is the association with ability to pay [33]. People with low incomes may state a lower WTP, which could have influenced the result. An unhealthy behaviour containing a low physical activity level is associated with a socioeconomic profile of a low education level and low income status [18]. A non-responder analysis of socioeconomic status of the participants in our study shows no indication of differences regarding education level between non-responders and responders.

Assuming that "wellbeing" is a short-term and "health" a long-term health effect, the interpretation of the results would be that the WTP for a short-term health improvement is higher than for a long-term health improvement. This result becomes clearer in the analysis without zero bids, and could be a result of discounting. With this exception, the analysis without zero bids confirms the general results. If there is less preference for long-term health improvements

Table IV. Relations between the willingness to pay for different health improvements and the independent variables (Spearman Correlation Coefficients).

Health improvement	Age	BMI	Income	Education level	Health	Activity level
Improved well-being by exercise four months 2–3 times per week	−0.091	0.243*	0.238*	0.203*	−0.123	0.041
Improved health by exercise four months 2–3 times per week	−0.138	0.019	0.132	0.146	0.001	0.098
Weight-loss 2 kg by exercise four months 2–3 times per week	−0.062	0.107	0.163	0.048	0.013	−0.015

\*Correlation is significant at the 0.05 level (two-tailed).

Table V. Regression models explaining the willingness to pay for different health improvements by the independent variables (regression coefficient  $\beta$ , standard deviation).

Health improvement	Age	BMI	Income <sup>a</sup>	University or college education	Health	Activity level	R <sup>2</sup>
Improved well-being by exercise four months 2–3 times per week	2.7 (5.1)	20.4 (14.5)	18.0* (9.0)	386.2* (168.1)	−155.1 (145.5)	199.4 (145.7)	0.181
<i>p</i> -value	0.602	0.164	0.043	0.025	0.290	0.176	
Improved health by exercise four months 2–3 times per week	−0.7 (4.8)	−0.4 (12.8)	8.5 (8.5)	417.1* (158.4)	−1.8 (129.4)	230.9 (133.0)	0.147
<i>p</i> -value	0.878	0.978	0.321	0.010	0.989	0.087	
Weight-loss 2 kg by exercise four months 2–3 times per week	3.7 (3.2)	0.2 (8.6)	6.5 (5.6)	48.6 (102.6)	1.1 (88.9)	15.8 (90.6)	0.044
<i>p</i> -value	0.247	0.984	0.251	0.637	0.990	0.862	

\*Regression coefficient is significant at the 0.05 level. <sup>a</sup>Income is multiplied by 1,000.



achieved from physical activity, this will influence the external benefits that society gets from a sufficient physical activity level.

There is no significant difference in WTP between a high- and low-intensity group, a result that is confirmed in the analysis without zero bids. The results appear to indicate that a high dose activity group has no influence on the preferences for health improvements. Another study with longer follow-up, a larger number of participants and larger differences in exercise regime might have produced significant differences, and can be recommended for future studies.

Body mass index is significantly correlated with a high WTP, and is a predictor for the willingness to pay for weight-loss effects of physical activity on prescription. These results are equivalent to a previous study that showed that a high weight was associated with a high WTP for effective obesity treatment [22]. Another study shows strong preferences for primary care programmes with weight-loss goals among patients with type 2 diabetes [23]. In our study, the WTP for weight-loss effects has the largest share of individuals willing to pay SEK 0 and has the lowest WTP value.

There is no standard approach to the design of a contingent valuation survey, but established guidelines recommend a number of points to elevate the quality of contingent valuation (CV)-studies [34]. It is important to give the respondent an understandable scenario with well described expected effects of a concrete and realistic situation. Before the programme started, all participants received information about the expected health improvements of physical activity when they met the physician, physiotherapist or other person for a prescription of physical activity. Thus, all participants were well informed and should have had an understanding of the health improvements of the PAP programme. The participants were informed that a marginal improvement of, for example, blood pressure and blood glucose could be expected with an increased physical activity level. Due to the extended verbal presentation, the scenario presented in the WTP questionnaire was simpler. The participants were also informed that the health effects of the PAP programme aim at improving health, and not avoiding illness. This is why WTA (willingness to accept) questions are not adequate [30].

In-person interviews are recommended for their superior reliability [30]. However, because of limited research resources our choice of methodology was self-administered surveys with open-ended questions. The agreement to participate in the PAP programme was for four months. This is why the

time frame of the amount of WTP was also set to four months.

The order of the questions may have influenced the results. An order effect can be avoided in future studies by conducting a pre-testing of the questionnaire in a small group of respondents for a better understanding of what the instrument means to people. It seems that the part of the programme costs the participants had to pay themselves influenced the answers and was used as a value for the WTP for the health improvements and weight loss. This raises the question of whether the WTP is indeed the true estimated maximum for the health improvements, or if it is a bias towards the self-cost. In general, open-ended questions also suffer from non-response, likely because of responder difficulty with understanding the meaning of the question. The share of dropouts between baseline and the four-month follow-up was large, 53%. The individuals that returned for the follow-up measurements and completed the WTP questions may be those who have stronger preferences and hold higher values for the PAP programme and its health effects. The WTP values among the sedentary non-participants are not known, and they may hold lower WTP values for the different health improvements and weight loss. This may be an explanation for a low participation rate. The WTP estimation can supply us with information on whether the PAP programme is worthwhile given the social opportunity costs of all the resources consumed. This is why a future study using the results of this contingent valuation within a cost-benefit framework with a comparison between costs and benefits would be of interest, and provide decision makers with useful information concerning resource allocation. The advantage of the WTP analysis compared to a cost-effectiveness analysis is the individual's own valuation of health improvement, i.e. the individual's preferences. These are not captured in a cost-effectiveness analysis. In a cost-effectiveness analysis a measure of the effect has been carried out, but in the WTP the effect has been rated by the individual due to the stated preference approach. The WTP analysis can be seen as a complement to an ordinary cost-effectiveness analysis in order to elicit the individual's preferences. The disadvantage is that "health improvement" may be a hypothetical scenario for the respondent and difficult to understand.

## Conclusions

Our conclusions are that the WTP for improved health and weight loss through exercise is influenced

by a higher education level, income, and BMI, and that the highest WTP for a health outcome of physical activity is for an immediate health improvement. The results of this clinical trial in primary health care may be of interest to decision makers when evaluating different approaches to promoting physical activity among sedentary individuals. The results may also offer insights into designing and implementing appealing programmes within primary health care for increasing the physical activity level among sedentary people. The WTP examined in this study may be of interest because of the fact that the PAP program is an existing and well implemented programme in Swedish primary health care in collaboration with local sports associations.

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## Paper III



ORIGINAL ARTICLE

## Costs and outcomes of an exercise referral programme – A 1-year follow-up study

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### Abstract

**Aims:** To analyse, at a 1-year follow-up, cost offset and outcomes of changing the physical activity behaviour due to a primary care intervention. **Methodology:** Participants were 528 inactive individuals with lifestyle-related health problems, 18–84 years, and randomized into a high-dose intervention group ( $n = 270$ ) or a low-dose intervention group ( $n = 257$ ). The 4-month lasting intervention “Physical Activity on Prescription” (PAP) contained exercise, education and motivational counselling. At the 1-year follow-up, 178 individuals (95 in the high-dose group, 83 in the low-dose group) were assessed with the IPAQ (International Physical Activity Questionnaire) short form, perceived physical activity and functional ability (Six Minute Walk Test). Motivation and attitudes towards physical activity were assessed with a questionnaire, and analysed based on factor analysis. **Major findings:** physical activity increased significantly, but without differences between high-dose and low-dose groups. The rate of inactive individuals decreased from 75% to 53%. Analysis of motivation showed no differences between the groups. **Principal conclusion:** The PAP-program significantly improved physical activity behaviour at the 1-year follow-up, and reduced costs for inactivity by 22%. Economic incentives, i.e. expenditures and individuals’ own valuation of leisure time, seem to influence preferences for participation in the PAP-program. Social-cognitive factors seem important when changing physical activity behaviour. Prescribed exercise may work pre-motivational for changed physical activity behaviour.

**Key words:** Health promotion, inactivity, life style, motivation, physical activity

### Introduction

To maintain good health, physical activity is essential for the individual (1–6). Moreover, general physical activity level affects society and its economic development. Inactivity as a non-communicable disease has a global spread of an epidemical feature, and has major impact on individuals’ and society’s productivity (7–9). About 3.2 million deaths worldwide every year can be attributed to an insufficient physical activity level; therefore, effective lifestyle interventions at individual and population level to prevent a sedentary behaviour are needed (1,2). With scarce resources, priorities have to be made within health-care concerning which method to use for the best

effectiveness (9,10). Health economic analyses are an important tool for making priorities and for evaluating lifestyle interventions to increase physical activity level among inactive individuals (10). Recent studies suggest further exploration of the cost-effectiveness of Exercise Referral Schemes (ERS), i.e. prescribed exercise, in primary care setting and whether ERS is an efficient use of resources, as there is an uncertainty concerning long-term effects and cost-effectiveness (11–14). Other studies show cost-effective primary care based interventions aiming at increasing the physical activity level (15,16).

Different variables influence an individual’s choice between an active and inactive lifestyle. When

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designing health programmes targeting an increased physical activity level, it is important to understand the reasons for an inactive lifestyle (17). Determinants that contribute to our choices are on all levels: individual, social, environmental and policy level (17,18). Behavioural change among inactive individuals needs support from healthcare professionals and adequate methods to influence the individual's motivation process. Different theoretical models for behaviour change have been suggested, all developed over time (19–21). There are findings showing associations between physically active behaviour and social–cognitive variables, and particularly the importance of self-efficacy and positive experience seem to predict change of physical activity (22,23).

The Physical Activity on Prescription Program (PAP-program) is a national programme of prescribed exercise in Sweden aiming at increasing the physical activity level among inactive individuals (24). The effectiveness of prescribed exercise within primary care showed in a recent meta-analysis inconsistent evidence of physical activity and different health outcomes (11). Other studies of exercise referral schemes show significant increased physical activity level (25–28). Deciding how to spend money on public health interventions aiming at increasing physical activity level, stakeholders need evidence on economic effectiveness.

When developing programmes in primary healthcare aiming at improving physical activity level, it is important to understand the individual's incentives, economic and motivational. This knowledge is important to be able to attract the target group of inactive individuals.

The aim of this paper was to analyse the cost offset of changing the physical activity behaviour associated with a high-dose group and a low-dose group within a primary care-based intervention. The aim was also to analyse motivation and attitudes among the completers of the programme after 1 year. To gain understanding for motivational factors' influence on completing the programme and change the physical activity behaviour over time, we focused on analysing physical activity motivating factors in this study.

## Methodology

### *Design*

The project was a randomized clinical trial with a 4-month intervention, with a comparison between a high-dose and a low-dose group, within a multi-professional, explorative study. The study was performed in collaboration between the faculties of Medicine and Economy and the divisions of

Physiotherapy and Health Economics. Participant outcomes were evaluated at baseline, after 4 months and after 1 year. The intervention "Physical Activity on Prescription" has been described in earlier studies (29). The study protocol was approved by the Research Ethics Committee at Lund University.

Participants in the study were recruited continuously between February 2006 and December 2007, as all those who received a prescription for physical activity from a physician, nurse, physiotherapist, occupational therapist, welfare officer or nutritionist. The participants were from five different primary care centres in the South-East Healthcare District of Region Skåne, Sweden, and included five municipalities, four of them with a population of 6–7000, and one with 17,000 inhabitants. Criteria for receiving a prescription were being at least 18 years old, having an inactive lifestyle with physical activity at a moderate intensity less than 150 min per week and one or more of the following disorders: cardiovascular disease, type 2 diabetes, obesity, musculoskeletal symptoms, mild mental illness or respiration problems (30). The participants' inactivity level was ascertained by the person who wrote the prescription, at the first meeting with the participant. Participants were excluded if the person who wrote the prescription estimated that the patient's illness was not treatable with physical activity, or the person was too ill or weak to be able to participate.

### *Intervention*

The randomization process, using closed envelopes, was performed by the physiotherapists after agreement to participation. The participants were randomized to either a high-dose or a low-dose group (Figure 1).

The 4-month intervention for the high-dose group consisted of two exercise sessions on a moderate-intensity level, education and motivating conversation. The participants in the high-dose group were also instructed additionally to exercise once a week on their own with an activity lasting at least 30 min and at least on a moderate level, which is equivalent to a brisk walk. The exercise was performed on group level with sessions lasting 45–60 min, performed by local fitness organizations. The participants chose from an activity list in which activity they wanted to take part. The education was performed twice with 2-h classes given by a health educator, aiming at providing information about prevention and benefits of exercise. The individual motivating conversation was conducted by a primary care physiotherapist and based on the Transtheoretical Model of Behaviour change (TTM) (20).



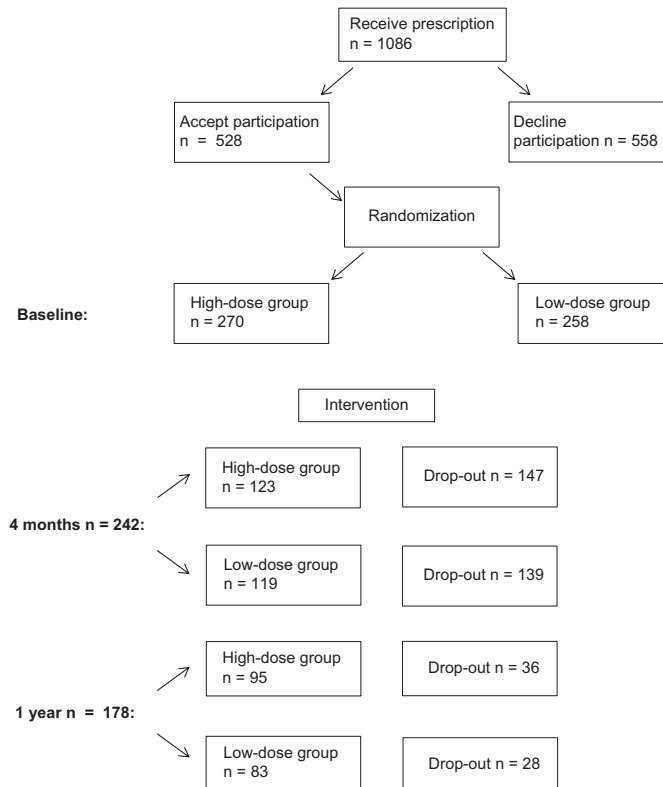


Figure 1. Flowchart of participants.

The low-dose group only received written information about local fitness centres and about the possibility of participating in supervised exercise groups once a week on a moderate-intense level.

Of the 528 participants randomized to either high-dose or low-dose group, 242 returned for the 4-month assessment, and 178 returned for the 1-year follow-up (Figure 1). At 4 months, the rate of drop-outs was 54% in both groups together, and after 1 year 66%.

#### *Analytic health economic perspective*

The study was performed from the societal perspective to estimate the costs for and consequences of a method that involves the full economic impact on the participants in the intervention (31). Healthcare programme costs include direct and indirect costs. Direct costs are costs of resources consumed or saved

due to the programme, and include resources in the healthcare sector like medical and non-medical costs, as well as in other sectors, patient's expenses and volunteer time. Indirect costs describe the costs of the time of the participants due to the programme, also called costs for productivity loss, for example cost for time off work.

#### *Assessment of motivation*

The motivation questionnaire was derived from a literature review designed for individuals with a low physical activity level, and was collected by the physiotherapists together with the main questionnaire and the physical examination on physical activity. The construction of the questionnaire is relevant to the sample and has shown good reliability (32,33). The questions are based on factors influencing a person's motivation, and include the participant's

experience with and the role of physiotherapists within the PAP-program. The questions are related to social determinants like self-efficacy and support from others, and to practical barriers like content and structure of the exercise. Responses were provided on a 100-mm scale (0 = not agreeing at all, 100 mm = agree totally).

#### *Assessment of physical activity level*

Physical activity was measured with three different methods: self-rated physical activity with the International Physical Activity Questionnaire (IPAQ) short form, which calculates MET-minutes (Metabolic Equivalent of Task) per week, with self-reported physical activity level, and with functional testing using the Six-Minute Walk Test (34,35). The first method of measuring physical activity with IPAQ short form protocol assesses MET-values of walking, moderate-intensity activities and vigorous activities, and the average MET-minutes were used in the analysis. The metabolic equivalent (MET) is a measure expressing the energy cost of physical activities. The second method, a single question of present extent of physical activity level, is based on the Transtheoretical model, and the five levels were dichotomized into "active" and "inactive" for the further analysis (20). The third method was the Six-Minute Walk Test; the participant walked as fast as possible during 6 min, and the distance (meters) covered was measured. The outcomes also included an exercise-diary to measure the compliance.

#### *Assessment of cost offset*

The estimated total costs of inactivity in Sweden on price level of 2002 were between SEK 5820 and 6902 Millions, based on a prevalence of inactivity of 40% (36,37). The proportion of the costs of a certain disease caused by inactivity was based on calculations of the population-attributable fraction (PAF) for each disease, and contained two parameters: relative risk and prevalence of inactivity. In 2002 the Swedish population consisted of 8,940,788 people, and 6,999,878 were 18 years and older (38). An inactivity of 40% is equal to 2,799,951 people, and means a cost of ~SEK 2265 per inactive person in the year of 2002. Transferred to 2007 price level with the Swedish consumer price index, the cost is SEK 2412 per inactive person, and is a cost for society that a sufficiently physically active person does not carry. Based on this calculation, we estimated the indirect and direct costs of the inactive and active individuals respectively before and after participation in the PAP-program. Hence, the cost every year an

individual stays inactive is in a societal perspective in Sweden SEK ~2412 (€257). The cost offset calculation is based on the measure of inactivity among the completers, using the self-reported question about present extent of physical activity. The costs of the PAP-program were evaluated in a previous report, and were SEK 6475 for the high-dose group and SEK 3038 for the low-dose group (26). The programme costs for the 4-month intervention period were based on intention-to-treat estimations.

#### *Statistical analysis*

Data were analysed with IBM SPSS Statistics 20. Means and standard deviations as well as relative frequencies (%) were used to describe the sample. Differences between intervention and control groups were tested with *t*-test and chi-square tests. Due to skewed distribution of the MET-minutes, non-parametric tests were used in comparisons between high-dose and low-dose group using the Mann-Whitney *U*-test. Friedman's Two-Way Analysis of variance by ranks test was used for comparisons between baseline, 4-month and 1-year follow-up. Chi-square tests were used for comparisons between high-dose and low-dose groups with regards to physical inactivity. Mann-Whitney *U*-test was used for comparison between intervention and control group for differences between baseline, 4-month and 1-year follow-up. Statistical significance was set at  $p < 0.05$ . An exploratory factor analysis was performed to analyse the correlation between the different motivational variables, and to distinguish underlying motivational attitudes.

## **Results**

Baseline analyses showed no significant differences between high-dose and low-dose groups in sex, age, BMI, income, education level or self-perceived health, among completers and non-completers respectively. The groups consisted of individuals with high BMI value, low income level, low education level and low health status. Most participants were middle-aged women (Table I). With high-dose and low-dose groups taken together, there were no significant differences between completers and non-completers for these background characteristics except for age and health. Completers are defined as those individuals who came to the 1-year follow-up measure, non-completers dropped out at 4 months or at the 1-year follow-up.

Table II shows the different physical activity behaviour variables for high-dose and low-dose

Table I. Baseline characteristics of the completers and non-completers at the 1-year follow-up.

	Completers ( <i>n</i> = 178)		Non-completers ( <i>n</i> = 350)		Differences between completers and non-completers	
	High-dose, <i>n</i> = 95 <sup>a</sup>	Low-dose, <i>n</i> = 83 <sup>b</sup>	<i>p</i> -value	High-dose, <i>n</i> = 175 <sup>c</sup>	Low-dose, <i>n</i> = 175 <sup>d</sup>	<i>p</i> -value
Sex (%)			0.321 <sup>e</sup>			0.468 <sup>e</sup>
Women	75	68		63	71	
Men	25	32		37	29	
Age (years)			0.547 <sup>f</sup>			0.601 <sup>f</sup>
Mean (SD)	57 (12)	56 (12)		50 (13)	50 (14)	
Range	27–77	23–79		19–81	18–84	
BMI (kg/m <sup>2</sup> )			0.275 <sup>f</sup>			0.491 <sup>f</sup>
Mean (SD)	31 (5.3)	32 (7.0)		32 (6.3)	32 (6.8)	
Range	18.0–45.0	21.0–55.0		19–61	20–56	
Income (SEK)			0.997 <sup>f</sup>			n.a.
Mean (SD)	10,869 (8886) <sup>1</sup>	11,860 (9392) <sup>2</sup>		n.a.	n.a.	
Range	0–30 000	0–55 000				
Education level (%)			0.303 <sup>e</sup>			0.146 <sup>e</sup>
Nine-year compulsory school	35	42		33	30	
2-years upper secondary school	22	20		21	22	
3 years upper secondary school	23	22		27	26	
University or college	20	16		19	21	
Health (%)			0.888 <sup>e</sup>			0.468 <sup>e</sup>
Poor	11	10		16	17	
Somewhat poor	46	49		54	52	
Good	33	33		23	26	
Very good	10	8		6	5	
Excellent	0	0		1	0	

Differences between high-dose and low-dose groups are tested. <sup>1</sup>*n* = 84; <sup>2</sup>*n* = 86. <sup>a</sup>Due to missing values *n* varies between 87 and 95. <sup>b</sup>Due to missing values *n* varies between 78 and 83. <sup>c</sup>Due to missing values *n* varies between 139 and 143. <sup>d</sup>Due to missing values *n* varies between 134 and 137. <sup>e</sup>Chi-square-test, Linear-by-Linear association. <sup>f</sup>*t*-test. <sup>g</sup>Mann-Whitney *U*-test. n.a., not available.

groups at the different times of measurements. Only individuals participating in the 1-year follow-up were measured. All three methods of measuring physical activity showed significantly improved values for high-dose and low-dose groups separately, as well as for both groups together between baseline and the

1-year follow-up. Inactivity decreased from baseline to 4 months and then later increased at 1 year. There were no differences in change from baseline to the 1-year follow-up between the groups.

Table III shows the costs for inactive individuals, and as a consequence of the programme the cost

Table II. Physical activity behaviour for completers in the high-dose and low-dose groups at baseline, 4 months and 1-year follow-up.

	Baseline	4-month	1 year	<i>p</i> -values <sup>d</sup>
High-dose, <i>n</i> = 95				
MET-minutes per week <sup>a</sup> , median (q1–q3)	592 (26–1790)	837 (246–2303)	1286 (84–3406)	< 0.001 <sup>g</sup>
Inactivity (%) <sup>b</sup>	75	28	53	< 0.001 <sup>g</sup>
Six Minute Walk Test <sup>a</sup> (meters), median (q1–q3)	508 (476–550)	520 (494–572)	526 (479–588)	< 0.001 <sup>g</sup>
Low-dose, <i>n</i> = 83				
MET-minutes per week <sup>a</sup> , median (q1–q3)	490 (442–552)	1386 (470–3234)	990 (0–2150)	0.002 <sup>g</sup>
Inactivity (%)	74	32	52	< 0.001 <sup>g</sup>
Six Minute Walk Test <sup>a</sup> (meters), median (q1–q3)	490 (443–554)	519 (460–580)	516 (443–584)	< 0.001 <sup>g</sup>
<i>p</i> -values <sup>c</sup>				Differences between the groups regarding changes from baseline to 1-year follow-up ( <i>p</i> -values)
MET-minutes	0.257 <sup>f</sup>	0.261 <sup>f</sup>	0.258 <sup>f</sup>	0.666 <sup>f</sup>
Inactivity	1.000 <sup>e</sup>	0.599 <sup>e</sup>	1.000 <sup>e</sup>	0.646 <sup>f</sup>
Six Minute Walk Test	0.245 <sup>f</sup>	0.341 <sup>f</sup>	0.375 <sup>f</sup>	0.830 <sup>f</sup>

<sup>a</sup>Due to missing values, *n* varies between 125 and 176 (both groups). <sup>b</sup>*n* = 94 due to missing value. <sup>c</sup>Comparisons between high-dose and low-dose groups. <sup>d</sup>Comparisons between baseline and 1-year follow-up. <sup>e</sup>Chi-square test <sup>f</sup>Mann Whitney *U*-test <sup>g</sup>Friedman's Two-Way Analysis of variance by ranks test.

Table III. Costs of inactivity (SEK) for high-dose and low-dose groups at baseline, 4 month and 1-year follow-ups.

	High-dose, <i>n</i> = 95 <sup>a</sup>			Low-dose, <i>n</i> = 83 <sup>b</sup>			All, <i>n</i> = 178 <sup>c</sup>		
	Baseline	4-month	1-year	Baseline	4-month	1-year	Baseline	4-month	1-year
Inactivity, <i>n</i> (%)	68 (75)	23 (28)	48 (53)	60 (74)	23 (32)	41 (52)	128 (74)	46 (30)	89 (53)
Costs of inactivity every year (SEK)	164,016	55,476	115,776	144,720	55,476	98,892	308,736	110,952	214,668
Estimated cost offset (SEK)		108,540	48,240		89,244	45,828		197,784	94,068

Inactivity was assessed using the self-reported question about present extent of physical activity. Estimated cost offset the first year. <sup>a</sup>Due to missing values *n* varies between 82 and 90. <sup>b</sup>Due to missing values *n* varies between 71 and 81. <sup>c</sup>Due to missing values *n* varies between 153 and 171.

offset due to a reduced number of inactive individuals. The cost offset due to a decreased inactivity as a consequence of participation in the PAP-program is for high-dose and low-dose group together SEK 94,068 (€10,023) the first year. This means a cost offset of SEK 528 (€56) per individual every year the individual stays active.

Table IV shows mean values (0–100) of the 12-item motivation questionnaire at 4 months among those participants who came to both 4-month and 1-year follow-ups (“completers”) and those who only came to the 4-month follow-up (“non-completers”). The different items are translated from Swedish for the purpose of publication in English. The analyses showed at the 4-month follow-up no significant differences between high-dose and low-dose groups. Between completers and non-completers were no significant differences comparing the groups except

for the item “Understanding and support from family and friends”.

Further analyses (not shown in table) among the completers only showed an overall decrease in motivation for all 12 questions for both high-dose and low-dose groups at 4 months and at the 1-year follow-up, compared with baseline. Analyses over time showed that motivation for most items significantly decreases from baseline to the 1-year follow-up, except for very small changes in both high-dose and low-dose groups between 4 months and the 1-year follow-up for three questions (knowledge of exercise, self-efficacy and feedback from the physiotherapist). There were no differences between the high-dose and low-dose groups regarding changes (decreases) in motivation from baseline to the 1-year follow-up. Baseline analyses of motivation showed no differences between the groups.

Table IV. Motivation: mean values and differences between high-dose and low-dose among completers and non-completers at 4 months, *n* = 242.

Motivational questions, range 0–100	Completers ( <i>n</i> = 160) <sup>a</sup>			Non-completers ( <i>n</i> = 82) <sup>a</sup>			Differences between completers and non-completers
	High-dose, <i>n</i> = 86	Low-dose, <i>n</i> = 74	<i>p</i> -value <sup>b</sup>	High-dose, <i>n</i> = 37	Low-dose, <i>n</i> = 45	<i>p</i> -value <sup>b</sup>	<i>p</i> -value <sup>c</sup>
Goal setting	74	67	0.131	71	70	0.950	0.481
Realistic goals	78	72	0.185	73	75	0.777	0.765
Individual adjusted dose/intensity of exercise	79	74	0.188	74	76	0.714	0.821
Variation of exercise	72	67	0.234	73	64	0.214	0.517
Importance of follow-up meeting with the physiotherapist	66	68	0.713	64	68	0.630	0.333
Meet other people in the same situation	77	69	0.104	69	68	0.900	0.641
Knowledge of the importance of exercise	73	66	0.174	72	73	0.860	0.724
Feedback from physiotherapist about exercise results	70	69	0.900	64	72	0.259	0.523
Possibility to discuss exercise problems with the physiotherapist	70	69	0.774	63	68	0.531	0.323
Self-efficacy/believing in own capability	80	78	0.570	71	80	0.161	0.745
Understanding and support from family and friends	76	73	0.429	76	78	0.700	0.024
Willingness to perform	71	73	0.652	68	71	0.612	0.820

<sup>a</sup>18 of the completers did not come to the 4-month follow-up. <sup>b</sup>Differences between high-dose and low-dose groups are tested by *t*-test.

<sup>c</sup>Differences between completers and non-completers are tested by *t*-test. High-dose and low-dose groups are taken together.

Table V. Factor analysis of the Motivation Questionnaire, baseline values.<sup>a</sup>

Items in the Motivational Questionnaire	Factors			
	Social-cognitive		Practical-rational	
Feedback from physiotherapist about exercise results	0.867			
Possibility to discuss exercise problems with the physiotherapist	0.851			
Importance of follow-up meeting with the physiotherapist	0.828			
Self-efficacy/believing in own capability	0.761			
Knowledge of the importance of exercise	0.716			
Meet other people in the same situation	0.675			
Understanding and support from family and friends	0.589			
Realistic goals			0.873	
Individually adjusted dose/intensity of exercise			0.871	
Goal setting			0.823	
Variation of exercise			0.796	
Willingness to perform			0.442	
Cronbach's alpha	0.892		0.864	
	High-dose	Low-dose	High-dose	Low-dose
Factor scores <sup>b</sup> for completers, mean	84.2	82.1	81.8	77.3
<i>p</i> -value <sup>c</sup>	0.382		0.105	
Factor scores <sup>b</sup> for non-completers, mean	83.0	81.2	81.5	79.4
<i>p</i> -value <sup>c</sup>	0.337		0.313	
<i>p</i> -values <sup>c</sup> completers vs non-completers	0.558	0.693	0.886	0.417

Extraction method: principal component analysis. Variance explained: 65%. Rotation method: varimax with Kaiser normalization. <sup>a</sup>Due to missing values *n* varies between 505 and 513. <sup>b</sup>Score varies between 0 and 100. <sup>c</sup>Differences between high-dose and low-dose groups, and between completers and non-completers were tested with *t*-test.

To examine further the motivational attitudes towards physical activity, a factor analysis of the different motivational components was performed. The analysis presented in Table V showed two yielded factors; factor one described social-cognitive motivation (seven items), factor two practical-rational motivation (five items). The practical-rational factor includes goal setting, having realistic goals, individual adjusted dose/intensity of exercise, variation of exercise and willingness to perform. The social-cognitive factor includes importance of follow-up meeting with the physiotherapist, meet other people in the same situation, knowledge of the importance of exercise, feedback from physiotherapist about exercise, possibility to discuss exercise problems with the physiotherapist, self-efficacy/believing in own capability and understanding and support from family and friends.

The baseline scores on social-cognitive motivation were in general higher among all participants; among completers and non-completers, and among high-dose and low-dose groups. The high-dose group showed slightly higher baseline scores for both factors, compared with the low-dose group. However, there were no significant differences in the mean values of motivation (factor scores) between the high-dose and low-dose groups, neither among the completers nor non-completers at baseline, and there were no differences between high-dose and low-dose groups concerning both factors.

## Discussion

### *Economic perspectives*

The results showed highly significant increased physical activity level and no differences between a high-dose and low-dose group after 1 year. All three methods of measuring changed physical activity behaviour showed for groups separately and for both groups together significant increases at the 1-year follow-up compared with baseline. These are findings that correspond with similar studies of exercise on prescription (28,39,40).

The decreased inactivity means a cost offset for both groups of SEK 94,068 (€10,023) the first year, thanks to an improved physical activity behaviour after participation in the PAP-program. This means a cost offset of SEK 528 (€56) for healthcare costs and value of lost production per individual and year, and is equal to 22% of the costs for an inactive individual of SEK 2412. However, the difference in average MET-minutes between inactive and active individuals is 2100 MET-minutes per week according a previous study of Persson & Moutakis (36). The results in the present study show an increase in MET-min from baseline to the 1-year follow-up of about 700 MET-minutes. Assuming linear relationship between MET-minutes and costs for inactivity, there is an overestimation of the cost offset. However, we do not have the inactivity cost as a function of MET-min and cannot assume a linear relationship.

In a previous health economic evaluation we have shown that the individual's preferences for participating in the PAP-program is influenced by economic incentives, i.e. expenditures but also the individual's own valuation of leisure time (41). Due to this, an increase in subsidies for exercise would increase participation rate. The results of this study confirm these findings, showing that the participation rate decreases when exercise is no longer subsidized. Only the first 4-month period, i.e. the intervention time, was subsidized from healthcare, and after that participation rate decreases further from 47% to 33% (both groups together). This may be explained in the change of inactivity level, which decreases from 38% at baseline (both groups) to 14% at the 4-month follow-up. The inactivity level then increases again, to 26% at the 1-year follow-up. So, as long as there is a cost-free possibility for the individual to exercise, as during the 4-month intervention period, the activity level is higher and may reflect the individual's preferences for physical activity.

The increase in inactivity between 4 months and 1 year also shows that the result from the 4-month follow-up is overestimated, which influences the benefits. This is why a longer follow-up at 1 year is important to achieve more robust results of effectiveness.

There may also be an influence of time preferences concerning discounting when the individual is valuing health benefits of a health programme. A result of this could be a discounting effect on long-term health improvements, with a high discount rate for future health benefits reflecting low preferences.

The participants' compliance may also be influenced by the costs the individual has to carry, in a former study shown as on average 72% of the PAP-program costs (26). As seen in this long-term follow-up, the share of completers has decreased further. This may be explained by the fact that the costs per person for exercising after the PAP-intervention all have to be carried by the individual alone, without any subsidies from healthcare.

Physical activity level was measured with three different methods, two of them based on self-reported instruments. Due to budget restrictions choosing a self-reported tool like IPAQ short form was the most appropriate because it has shown acceptable criterion validity and specificity to correctly classify people achieving current physical activity guidelines (42,43).

### *Motivation*

Perspectives of motivation for physical activity in this study are the *characteristics* of the completers and

non-completers, the *quantitative extent* of motivation in relation to inactivity and the completers' *attitudes* towards physical activity in the factor analysis. With the results of this study, we want to contribute to the understanding of inactive individuals' preferences for physical activity.

The analysis of the characteristics of included individuals in our study does not show any significant differences between non-completers compared with completers, except in age and self-perceived health (Table I). The significant difference in age between completers and non-completers is due to a higher share of persons older than 65 years in the groups of completers (19% among non-completers, 26% among completers). An explanation for a higher share of older persons in the group of completers is that these individuals have a lower time cost, more time to spend and that they may seek opportunities for meeting other people in a social context. The non-completers reported a lower self-perceived health status. A lower health status may be an explanation of not completing the programme since a participation in physical activities is not possible.

The average participant in the programme is a middle-aged, obese woman, with low income (this information only available for completers), low education level and a poor self-perceived health, factors that are similar with earlier studies, which show that an inactive lifestyle is associated with socio-economic factors like low income and low education level (44).

To examine the motivational effects of the intervention we chose to perform the analysis at the 4-month follow-up (Table IV). At 4 months, the participants in the high-dose group all had experience with the PAP-program. The high-dose group had more exercise; they also had an individually based motivating conversation performed by a physiotherapist and two group sessions with education about the importance of exercising. The effect of this motivation boost is not seen in the results of the analysis with this questionnaire. The motivational level measured at 4 months showed no significant differences neither between high-dose and low-dose group nor between the individuals that later came to the 1-year follow-up (completers) and non-completers (except "Understanding and support from family and friends").

We expected an increase in rating of the different motivational questions among the participants in the high-dose intervention group, and higher rating overall among the completers since they have an extended experience with physical activity and motivational input. Instead, it seems like the prescription itself has a greater influence on participation since all participants in general put high scores of motivation at baseline.

The 12-item questionnaire also did not show any differences regarding changes in motivation from baseline to the 1-year follow-up between the high-dose and low-dose group. However there was a significant decrease in the mean values of motivation among the completers between baseline and the 1-year follow-up, a decrease that was the same in both high-dose and low-dose groups. This would mean that with this instrument we are not able to show any effects on motivation for physical activity. However, there may be other factors influencing participation, not investigated in this study, such as practical barriers (travelling, family etc.). Responsiveness for change of the motivational questionnaire has to be further tested.

#### *Attitudes towards physical activity*

We chose to perform the factor analysis at baseline to be able to include all participants, i.e. become a sample that is as big as possible and attain a clearer expression of attitudes. The analysis of attitudes towards physical activity generated two different factors, one interpreted as social-cognitive, and the second as practical-rational. The first factor, interpreted as social-cognitive motivation, showed in general higher scores among all participants. The expression of this factor shows a covariation between items that included the interaction with and support from others, for example the physiotherapist or family, and own ability. The result shows the important motivating role of the physiotherapist within healthcare when designing methods for changing the physical activity level. Social-cognitive factors like attitude, subjective norm and self-efficacy influence behaviour, for example physical activity behaviour and self-efficacy is seen as a determinant for physical activity change (22). Factor two expresses a more rational attitude towards exercise, with components that are practical and objective. Dose and variation of exercise coincide with a structured exercise and goal setting. A Norwegian study of perceived barriers to engagement in physical activity among adults showed in a factor analysis similar factors with groups of practical and affective/cognitive barriers, but also health and priority barriers (45).

#### *Group belonging's influence on participation*

The initial motivational counselling session and education class in the high-dose group did not influence the change of physical activity level in the long term. The support and help from the exercise group members and leaders was not available after the intervention. During the follow-up year, the conditions were the same for both groups, which may

be reflected in the results of this study, i.e. no difference between the groups according to the physical activity level. To receive a prescription from healthcare professionals for exercise appears to be the most important factor for achieving an effect of changed physical activity behaviour, rather than belonging to a high- or low-intensity group. The prescription itself may work as a pre-motivating tool. Also the meeting with and the attention from the physiotherapist may work pre-motivating for the participants. Beside this, the process of the functional testing with the Six Minute Walk Test might work as a mini-intervention itself and may influence participation and the results at the 4-month and 1-year follow-up. With the prescription, healthcare communicates the problem of inactivity. Paying attention to inactivity, the prescription becomes an apparent advice to the individual that a sedentary lifestyle is a serious health issue (46). When planning lifestyle programmes within primary healthcare, this may be a finding to take into consideration.

The number of non-completers is for both groups together 66% (no differences between the groups). This may be considered a high drop-out rate, but the sedentary individuals who significantly increased their physical activity and actually changed their lifestyle in the observed time are not few. For these persons the change in physical activity level implies considerable health benefits. A suggestion for the incentives of the non-completers would be a low valuation of an improved health of physical activity. However, the drop-out rate may implicate the need for tailoring of programmes addressed to inactive individuals. The PAP-program in this study was performed on group basis – with a more individually adjusted programme, we would expect a higher participation rate. The share of individuals completing the programme is consistent with the results in the review of Pavey et al. (12) showing an evidence of variation in adherence of exercise referral schemes between 12% and 82%.

The non-completers were the largest part of those individuals that were recruited to the programme. We believe that these individuals have a need for an increased support and help from healthcare. They need more individualized interventions than the PAP-program and they do not seem to be the target population for this setting of prescribed exercise. They are most likely to need stronger support and coaching from medically educated and competent professionals. Physiotherapists have the appropriate medical background and experience of exercise therapy, and are used to motivational and supportive work among individuals with different physiological and psychological conditions. In addition to this, physiotherapists are qualified to



tailor exercise and coach inactive individuals in their training.

For ethical reasons, a low-dose group was chosen instead of a control group containing standard care. With this choice, all participants had access to the activities; however, to a different extent – with a control group, the result would have been more robust evidence. An advantage of this design is that the PAP method was not constructed for scientific reasons, to perform a study – instead, an analysis of an existing and well functioning primary care programme could be implemented.

A power analysis was not performed since the study was an explorative study with unknown baseline values or effects, and with unknown distribution of the outcomes. The study also has a wide focus with several objectives, which is why it is difficult to choose a certain outcome for a power analysis. There are also practical reasons for not having performed a power analysis, one of which is the time aspect: the given conditions at the start of the study were a limited time for collecting data and data analysis.

## Conclusions

At a 1-year follow-up, the physical activity behaviour significantly increased after a primary care intervention of exercise on prescription, compared with baseline. There were no differences between high-dose and low-dose groups. The PAP-program can reduce the society's costs for inactivity by 22% per individual every year.

Discounting future health effects, absence of subsidies from healthcare and pre-motivational consequences of the prescription itself may be a health economic explanation of an increase in inactivity after 1 year compared with the 4-month follow-up.

There were no differences either between the high-dose and low-dose groups, or between completers and non-completers regarding motivation or changes in motivation at 4 months and from baseline to the 1-year follow-up, respectively.

A factor analysis showed two different attitudes concerning motivational factors for physical activity: social-cognitive and practical-rational. These two different attitudes show covariance between interaction with others and self-efficacy, and between exercise framing and more rational exercise planning. The social-cognitive factor seems most important to physically inactive individuals and the results show the important supporting role of the physiotherapist within healthcare when designing methods for changing the physical activity level.

Background characteristics, for example socio-economic factors, do not seem to influence inactive individuals' preferences for participation in the

PAP-program. One exception is age; a higher age seems to increase participation.

The prescription itself has a pre-motivational impact, and is with this study shown to be a worthwhile tool for healthcare to communicate the problem of inactivity.

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## Paper IV



## **Prescribed Physical Activity in primary care: one year cost-utility and quality of life outcomes**

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## Key Points

**The primary care “Prescribed Physical Activity” programme can increase quality of Life and shows economic effectiveness in a societal perspective.**

- A low-dose group is more cost-effective, with lower costs and larger improvements in QoL.
- The PPA-programme is most effective for inactive individuals with moderate health status at baseline.
- A drop-out rate of 66% shows a need for identifying the right target group for this type of primary care programme.

## Abstract

*Objective:* Physical activity can reduce the risk of serious lifestyle-related health conditions. Decision-makers need further information on public health interventions' impact on physical activity level and economic effectiveness. The aim was to analyse the benefits of quality of life (QoL) per se and cost per QALY (Quality-adjusted Life Years) in a societal perspective.

*Design:* Change in QoL was measured with the SF-36 and the SF-6D. A cost-utility analysis aiming at analysing gained QALY was performed in this randomised clinical trial within a multi-professional study.

*Subjects:* Participants were 528 inactive individuals with lifestyle-related health problems, aged 18–84 years, randomly assigned to either a high-dose group (n=270) or a low-dose group (n=258). At the one-year assessment 178 individuals (95 in the high-dose group, 83 in the low-dose group) were analysed.

*Setting:* The four-month intervention "Prescribed Physical Activity" (PPA) was performed in Swedish primary care and comprised exercise, education and motivational counselling.

*Main outcome measures:* QALY gained was 0.02 for the high-dose group, for the low-dose group 0.03. Costs per gained QALY, including participants' time costs, were 323,750 SEK for the high-dose group (36,256 EUR) and are considered moderate according to Swedish reference values. For the low-dose group, costs per QALY were 101,267 SEK (11,339 EUR).

*Conclusions:* The "Prescribed Physical Activity" primary care programme is cost-effective and has a moderate cost per QALY compared with other methods in health care. A low-dose group is more cost-effective and shows significant improvements in QoL. For inactive individuals with moderate health status at baseline the PPA-programme is more effective.

**Keywords:** Quality of life, QALY, costs, exercise referral scheme, primary health care

## Background

Physical activity can reduce the risk of serious health conditions such as diabetes, hypertension, coronary heart disease, cancers, and stroke [1-6]. Promoting physical activity (PA) within a primary care setting with prescribed exercise for inactive individuals has shown to be effective in terms of significantly increasing physical activity levels [7-9], although a recent review concluded uncertainty concerning the effectiveness of prescribed exercise aiming at increasing PA level and fitness [10]. Another review of RCT:s found significant increased PA levels at 12 months when promoting PA in primary care, though insufficient evidence to recommend Exercise Referral Schemes (ERS) over counselling or advice [11]. The Swedish Council on Technology Assessment in Health Care evaluated methods to promote physical activity, and found the strongest evidence for an increased physical activity level among adults to be counselling within health care [12]. A Swedish study of prescribed PA in primary health care showed significant increased self-reported PA level and quality of life in a six month follow up [8]. However, this study did not examine the health economic consequences of physical activity on prescription. Due to limited evidence of effectiveness and a lack of trial-based designs of the studies, a recent review suggests further exploration of the cost-effectiveness of ERS in a primary care setting and whether ERS is an efficient use of resources [13,14].

Health-Related Quality of Life (HRQoL) includes those aspects of quality of life (QoL) that influence physical and mental health such as physical functioning, social activity and psychological health. People that are physically active have a better HRQoL, and there are positive associations between a higher level of PA in the general population and better HRQoL [15,16].

**Using QALY** (Quality-adjusted Life Years) as the measure of the benefit of QoL is the dominating method **in health economic evaluations**. The recommendation of the National Institute for Health and Clinical Excellence (NICE) is to use the cost-utility analysis and outcomes reported in incremental costs per QALY (incremental cost-effectiveness ratio, ICER) [17].

The Prescribed Physical Activity (PPA) is a national programme in Sweden aimed at increasing the physical activity level among inactive individuals. An earlier study of the PPA programme showed improvements in PA levels and decreased inactivity among inactive individuals, but also a cost offset due to reduced inactivity [9].

This paper aims to analyse the benefits in terms of quality of life per se and cost per QALY, respectively. We wanted to examine the change in QALY, costs and time in full health due to participation in the PPA programme after one year comparing a high and low-dose group.



## Methods

### Design

Criteria for having a prescription were being at least 18 years old, having an inactive life-style and one or several of the following diseases: cardiovascular disease, type 2-diabetes, obesity, musculoskeletal disorders, mental illness and / or respiration problems. If the person who wrote the prescription estimated that the patient's illness was not treatable with physical activity, or the person was too ill or weak to participate participants were excluded. The number of individuals receiving a prescription for physical activity was 1086, and they were offered participation in the Prescribed Physical Activity (PPA) program. Of these, 558 chose own exercise and were not followed in the study. The other 528 accepted participation in the program, and were randomised to either a high-dose group (n=270) or a low-dose group (n=258).

The study was a randomised clinical trial with a four-month intervention, with a comparison between a high-dose and low-dose group in a multi-professional study with collaboration between the faculties of Medicine and Economy and the divisions of Physiotherapy and Health Economics. Participants were recruited continuously between February 2006 and December 2007 as all those who received a prescription for physical activity from a physician, nurse, physiotherapist, occupational therapist, welfare officer or nutritionist. Participants were recruited from five different primary care centres in Skåne, Sweden, in five municipalities. Inclusion criteria for receiving a prescription were being at least 18 years old and inactive with a physical activity level corresponding to less than 150 minutes per week with moderate intensity activities, and having one or more of the following disorders: cardiovascular disease, type 2 diabetes, obesity, musculoskeletal symptoms, mild mental illness, or respiration problems. The person who wrote the prescription ascertained the participant's activity level at the first meeting. Participant outcomes were evaluated at baseline, after four months and after one year.

The randomisation process, using closed envelopes, was performed by the physiotherapists distributing the questionnaires to the participants after agreement to participation. Participants randomised to the high-dose group had two supervised group exercise sessions twice a week, each session lasting 45 to 60 minutes and performed in local leisure centres with activities on a moderate-intense level. The high-dose group also consisted in education, which was a 2-hour class twice, performed by a health educator, concerning the benefits of physical activity and exercise, and a motivational counselling lasting 20 minutes provided by physiotherapists in primary health care based on the Transtheoretical Model of Behaviour change. The participants in the high-dose group were also instructed to additionally exercise once a week on their own with a physical activity lasting at least 30 minutes and at least on a moderate level. At start of the exercise program, the high-dose group also had an informational meeting for one hour performed by the group-leader.

The low-dose group received written information about local fitness centres and about the possibility to participate in supervised exercise groups once a week on a moderate-intense level.

Preference-based QoL was measured with the SF-6D classification, which was derived using a scoring algorithm from the 36-Item Short-Form Health Survey (SF-36) [18]. This index measure is based on 11 of the questions in the SF-36 and measures health in six dimensions (physical functioning, role limitations, social functioning, pain, mental health, vitality), each of them with four to six levels. The SF-36 scores were calculated with the Swedish manual, and were also used in the analysis of QoL as an outcome measure [19].

Data were analyzed with IBM SPSS Statistics 20. Means and standard deviations as well as relative frequencies (%) were used to describe the sample. Differences between groups were tested with t-test and Chi-square test. To analyse changes between different points of measurements t-test and Friedman's Two-Way Analysis of variance, respectively, were used. Statistical significance was set at  $P < 0.05$ .

The study protocol was approved by the Research Ethics Committee at Lund University.

## Results

Of the 528 participants randomised to the high-dose or low-dose group, 242 returned for the four-month assessment, and 178 returned for the one-year follow-up. At four months the rate of dropouts was 54% in the high-dose and low-dose groups together, and after one year 66 %. Table I shows the background characteristics of 'completers' and 'non-completers' of the intervention. Completers are defined as those individuals who came to the 1-year follow up measure, non-completers dropped out at four months or at the one year follow up. There were significant differences in the two different variables, showing a significant lower age and lower health status among the non-completers. In general, the background characteristics at baseline showed participants (completers and non-completers) with a high BMI (Body Mass Index), low income level and low education level. Most participants were middle-aged females. There were no significant differences between the high-dose and low-dose groups in background characteristics (not shown in table).

Table II shows the scores of and changes in QoL at baseline, the four-month and the one one-year follow-up measured with the SF-36 for both the high- and low-dose groups. The SF-36 scores for the two component summaries, mental and physical, did not change significantly during the one-year period in any of the groups. For most components of the SF-36 there were no significant differences in the high-dose group between baseline and one year, except for the physical role limitation, which increased, and general health, which

decreased. In the low-dose group, there were some components that changed significantly: at the one-year follow-up there was a significant increase in physical functioning, and a significant decrease in bodily pain and general health. There was a significant time effect in both groups in the dimensions of bodily pain and general health, with a significant decrease in these items at the measurement after the four-month programme. There were no significant differences in QoL at baseline between the high-dose and low-dose groups (not shown in table).

Table III shows the outcome of the QoL analysis with the SF-6D, and the result of the estimation of QALY-weights at the different points of measurement. There was a general increase in the QALY-weights between baseline and the one-year follow-up, strongly significant for the low-dose group and for both groups together. The QALY-weights also increased slightly at four months for both groups and together – however, not significantly (Fig. 1). There were no significant differences at any of the points of measurements, either between the high- and low-dose groups or the completers and non-completers. The non-completers had higher baseline values than the completers, but lower scores at four months, though not significantly.

QALY gained is shown in Table IV. QALY gained is the area under the curve from baseline to one year, and is calculated by multiplying the time in a health state by the QALY-weight. In this analysis the time spent in a health state was one year, and generated a QALY of 0.02 for the high-dose group, 0.03 for the low-dose group and for both groups together 0.02. The cost per QALY for the PPA-programme was 323,750 SEK (36,256 EUR) for the high-dose group and 101,267 SEK (11,339 EUR) for the low-dose group. The programme costs for the PPA-programme were based on a cost analysis in an intention-to-treat estimation and were 6475 SEK (694 EUR) per patient for the high-dose group and 3038 SEK (326 EUR) per patient for the low-dose group [9]. The estimations included participants' time costs and were equal to leisure time costs.

## Discussion

The results of this primary care lifestyle intervention of prescribed exercise showed increased QoL one year after intervention. Previous studies of this intervention aimed at changing an inactive lifestyle also show significant improvements in PA levels [9]. With limited health-care resources, it is important to be able to offer public health interventions in primary care with both economic effectiveness as well as improvements in PA levels and QoL.

There is no official threshold value per QALY in Sweden, though there are different suggestions for reference values depending on different societal sectors [20]. The value of a

QALY used in Sweden – which uses a societal perspective for these estimations – is based on estimations of the Value of Statistical Life (VSL) and people's preferences for safety. The VSL in 2006 was 21 million SEK, and corresponds to a cost of 845,000 SEK (90,554 EUR) per QALY. Other reference values are £30,000 (33,851 EUR) per QALY, or the American value of 50,000 US\$ (33,449 EUR) [21, 22]. The result of this study, with a cost per QALY of 323,750 SEK (36,509 EUR) for the high-dose group, is considered moderate according to the Swedish National Board of Health and Welfare, where a cost per QALY between 100,000 SEK (10,672 EUR) and 499,999 SEK (53,361 EUR) is considered moderate. The estimated cost per QALY for the low-dose group was 101,267 SEK (11,419 EUR) and is 31% of the cost per QALY of the high-dose group. The increase in QoL of 0.02 for the high-dose group achieved after one year means a gain in healthy time, and is equal to seven days per year in full health or a value of 16,900 SEK (1905 EUR) per year, assuming a value of a QALY of 845,000 SEK (95,291 EUR). For the low-dose group the increase in QoL of 0.03 means a value of 25,350 SEK (2859 EUR), equal to 11 days.

The low-dose group showed a larger increase of QoL, measured with the SF-6D, and better economic effectiveness than the high-dose group (Table III). The low-dose group had higher QoL values at baseline, four months and one year, which is reflected in the result of the QALY-weights. It seems like the PPA programme was more effective for individuals having a better QoL from baseline. Having a better QoL already at the start may be a more favourable starting position, both mentally and physically, for participation as well as for further improvements through the intervention. This corresponds with the results from the analysis of the background characteristics (Table I), which shows that the non-completers scored a significant lower health than the completers. A better self-perceived health from the start may increase the effects of the programme and improve the possibility of completing it.

The overall increase in QoL one year after intervention corresponds with previous studies of prescribed exercise examining PA level and QoL showing improvements in self-reported QoL after six and 16 months, respectively [8, 23]. However, the low-dose group showed greater improvement in QoL at the one year follow up than the high-dose group, significantly improved compared to baseline. We believe that the prescription itself has a pre-motivational impact, which is reflected in the increases in QoL in both groups. Due to lower costs and higher QoL after one year the low-dose group is more cost-effective, and therefore has a lower cost per QALY (ICER). These components make the low-dose exercise group a more favorable alternative in a health economic aspect.

The result of a gain in QALY of 0.02 for the high-dose group and both groups together is lower than the result of Greenberg et al, where the geometric mean gain of 3240 ICERs was 0.07 [24]. The QALY gain after one year in the low-dose group was higher, 0.03. At four months there was a slight increase in QoL, however the largest improvement was between the measurements at four months and one year. This improvement was significant for the low-dose group and for both groups together. This observed time effect with only a very

small increase in QoL at four months could be explained by an increase in bodily symptoms due to participation in the programme. This is seen in both high- and low-dose groups. The rather low values at four months at the end of the intervention may be a result of participating in the programme, which is reflected in different components in the SF-36: for example, a lower score in the dimensions of bodily pain and general health due to a physiological overload on account of increased exercise and physical activity.

As shown in an earlier study, the PPA programme can increase PA levels significantly in both high and low-dose groups, with no differences between the groups [9]. Our interpretation is that an improved PA level influences the QoL in the long-term and contributes to the improvement of QoL between four months and one year. These findings correspond with previous studies showing a better HRQoL among physically active individuals [15,16]. Compared with the scores of the general Swedish population, the QoL values of the SF-36 are considerably lower for all participants in the present study, completers as well as non-completers [19]. Results of other studies of prescribed exercise in primary care show uncertainties concerning the effect on QoL. Using different methods, included participants and follow-up periods, the result of PA on QoL after intervention shows none or little improvement [25,26].

The non-completers were the major part (66%) of all those individuals recruited to the present programme and identified as individuals with a need for an improved physical activity level. These individuals' need for an increased PA level requires more individualised interventions than the PPA programme and they do not seem to be the target population of the PPA programme as it is designed in the current setting.

An earlier review reports limited knowledge of non-completers and patients declining prescribed exercise [27]. To prevent drop-outs for a future programme our suggestion is more frequent follow-up meetings, extended support and a more individualized setting which may be, for example, smaller groups. It also seems as if there is a need for a screening of the target group before the programme starts, to identify persons with better or less appropriate baseline characteristics for a certain setting. A future study could include regression models for identifying the right target population.

Our results show that it is difficult to identify those individuals that are willing to participate and complete the programme, and with help and support actually change their physical activity behaviour. About 34% of all those who received a prescription for PA and accepted participation are obviously the right target group. These individuals are ready to change their physical activity behaviour: the results showed significant improvements in PA according to all three types of measurements. In the analysis of the characteristics, these persons are slightly older than those who did not complete the programme and they also report a better health status at baseline. Having better health status from start ought to make participation in the different activities during the intervention period easier. A higher age can in a health economic perspective be explained with lower time costs, because of lower income.

No power analysis was performed since the study was an explorative study with unknown baseline values or effects, and with unknown distribution of the outcomes. The study also has a wide focus with several objectives.

Due to ethical reasons a low-dose group was chosen instead of a control group receiving standard care. With a control group the results would have been of more robust evidence of effectiveness. However, the PPA method was not constructed – instead, the study has been performed with an existing primary care programme, and has not only an analytic perspective but also a treatment perspective.

The cost-effectiveness was calculated with the effect on QALY i.e. a health-related estimation of the benefits of quality of life which is a patient-focused approach for a health economic analysis. In addition, the SF-6D is an established instrument for deriving health state utility values.

The cost-utility analysis was performed with full societal impact since participants' time costs were included. With the exclusion of the participants' time costs the indirect costs due to production loss are not calculated [28, 29]. A cost-analysis of the PPA-programme showed that participants' costs make up the largest part of the intervention costs [9]. This result contributes substantially to a detailed health economic conclusion in the present analysis.

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Table I. Participants background characteristics at baseline. Completers and non-completers.

	Completers	Non-completers	All participants	Differences between completers and non-completers
	n=178	n=350	n=528	p-value
Sex(%)				.326 <sup>a</sup>
Women	71	67	71	
Men	29	33	29	
Age (years)				<.001 <sup>b</sup>
mean (sd)	57 (13)	56 (12)	56 (12)	
range	19-84	23-79	23-79	
BMI (kg/m <sup>2</sup> )				.081 <sup>b</sup>
mean (sd)	32 (6.3)	32 (7.0)	31 (5.7)	
range	18-55	19-61	19-61	
Income (SEK)				
mean (sd)	11,870 (11,100)	n.a. <sup>Δ</sup>	n.a. <sup>Δ</sup>	n.a. <sup>Δ</sup>
range	0-30,000			
Education level (%)				.181 <sup>a</sup>
Nine years compulsory school	33	34	34	
2 years upper-secondary school	17	24	21	
3 yearsupper-secondary school	26	25	25	
University or college	24	17	20	
Health (%)				.002 <sup>a</sup>
Poor	11	17	14	
Somewhat poor	47	53	51	
Good	33	25	28	
Very good	9	5	7	
Excellent	0	0	0	

<sup>a</sup> Chi-square-test, Linear-by-Linear association <sup>b</sup> t-test <sup>Δ</sup> data not available

Table II. Quality of life. Completers. SF-36 Short-Form instrument dimensions. Changes between baseline, 4 months and 1 year follow-up.

SF-36 dimension scores												
mean (sd)	High-dose						Low-dose					
	Baseline	4 months	1 year	p-values			Baseline	4 months	1 year	p-values		
				a	b	c				a	b	c
Physical functioning	71.9 (18.7)	74.2 (21.2)	70.6 (23.1)	.269	.104	.094	71.0 (22.8)	77.5 (21.8)	73.6 (25.0)	.006	.072	.008
Role limitation, physical	56.1 (40.4)	68.7 (38.1)	64.5 (39.9)	.039	.239	.017	60.2 (41.8)	65.0 (42.5)	61.2 (44.3)	.392	.283	.343
Bodily pain	51.4 (23.0)	38.1 (24.6)	52.8 (25.5)	.005	.013	.395	61.8 (28.2)	34.1 (29.5)	58.4 (27.5)	<.001	<.001	<.001
General health	63.5 (10.9)	60.1 (10.8)	59.9 (11.2)	.021	.875	.024	62.8 (13.3)	58.4 (14.5)	56.8 (13.8)	<.001	.482	<.001
Vitality	51.3 (12.3)	56.1 (12.5)	51.5 (14.1)	.020	.019	.060	52.8 (15.1)	58.1 (14.7)	55.3 (14.9)	.050	.703	.556
Social functioning	51.9 (10.2)	50.3 (12.0)	49.4 (13.9)	.427	.941	.926	51.1 (11.7)	51.2 (11.3)	49.6 (15.1)	.780	.343	.462
Role limitation, emotional	66.3 (40.7)	78.2 (36.5)	65.9 (40.6)	.068	.012	.064	67.2 (42.8)	75.7 (37.6)	79.0 (37.8)	.150	.297	.056
Mental health	66.0 (11.7)	66.5 (10.7)	64.2 (10.6)	.915	.258	.949	65.4 (11.8)	65.7 (9.9)	66.2 (11.0)	.876	.598	.293
Physical component summary	41.6 (8.8)	40.8 (5.0)	42.3 (9.2)	.198	.130	.185	43.1 (9.2)	40.6 (6.4)	41.9 (10.5)	.001	.273	.096
Mental component summary	40.2 (7.8)	42.2 (6.5)	39.2 (6.7)	.070	.002	.057	39.8 (8.1)	42.0 (6.6)	41.7 (8.0)	.054	.991	.274

a: Differences between baseline and 4-month follow-up are tested with t-test b: differences between 4 months and 1 year follow-up are tested with t-test c: differences between baseline, 4 months and 1 year are tested by Friedman's Two-Way Analysis of Variance by Ranks Test

Table III. SF-6D. QALY-weights. Means at baseline, 4 months and 1 year.

		Baseline	4 months	p-value <sup>Δ</sup>	1 year	p-value <sup>ΔΔ</sup>	p-value <sup>ΔΔΔ</sup>
Completers							
High-dose	n=95 <sup>a</sup>	0.6516 (0.38-0.93)	0.6623 (0.51-0.83)	.986	0.6844 (0.39-1.00)	.093	.708
Low-dose	n=83 <sup>b</sup>	0.6616 (0.40-0.91)	0.6625 (0.33-0.90)	.730	0.7224 (0.39-0.97)	.001	<.000
All	n=178 <sup>c</sup>	0.6568 (0.38-1.00)	0.6624 (0.33-0.90)	.228	0.7038 (0.39-1.00)	<.000	.007
p-value <sup>α</sup>		.610	.989		.079		
Non-completers	n=350 <sup>d</sup>	0.6710 (0.30-0.97)	0.6510 (0.51-0.85)	.423			
p-value <sup>β</sup>		.234	.271				

<sup>a</sup>n varies between 85-93 due to missing values; <sup>b</sup>n varies between 71-81 due to missing values; <sup>c</sup>n varies between 156-174 due to missing values; <sup>d</sup>n varies between 343 and 350 due to missing values. <sup>Δ</sup>Differences between baseline and 4 months are tested by t-test <sup>ΔΔ</sup>Differences between baseline and 1year are tested by t-test <sup>ΔΔΔ</sup>Differences between baseline, 4 months and 1 year are tested by Friedman's Two-Way Analysis of Variance by Ranks Test <sup>α</sup>Differences between high- and low-dose groups are tested by t-test. <sup>β</sup>Differences between completers and non-completers are tested by t-test

Table IV. QALY, ICER and costs (SEK) per QALY for high- and low-dose groups.

	High-dose group (n=95 <sup>a</sup> )	Low-dose group (n=83 <sup>b</sup> )	Both groups together (n=178 <sup>c</sup> )
Gained QALY (SF-6D)	0.02	0.03	0.02
Intention-to-treat programme costs			
-including participants' time costs	6475	3038	4756
-excluding participants' time costs	1554	729	1332
ICER (gross costs per gained QALY)	323 750	101 267	237 800
Health-care providers' costs per QALY (excluding participants' time costs)	77 700	24 300	66 600

<sup>a</sup>n varies between 85-93 due to missing values; <sup>b</sup>n varies between 71-81 due to missing values; <sup>c</sup>n varies between 156-174 due to missing values

Figure 1. Changes QALY-weights at baseline, 4 month- and 1-year measurements.

