Quality of life and cost-effectiveness of a three year trial of lifestyle intervention in primary health care

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ABSTRACT

Background: Lifestyle interventions reduce cardiovascular risk and diabetes but reports on long term effects on quality of life (QOL) and health care utilization are rare. The aim was to investigate the impact of a primary health care based lifestyle intervention program on QOL and cost-effectiveness over 3 years.
Methods: 151 men and women, age 18-65 yr, at moderate-to-high risk for cardiovascular disease, were randomly assigned to either lifestyle intervention with standard care or standard care alone. Intervention consisted of supervised exercise sessions and diet counseling for 3 months, followed by regular group meetings during 3years. Change in QOL was measured with EuroQol (EQ-5D, EQ VAS), the 36-item Short Form Health Survey (SF-36), and the SF-6D. The health economic evaluation was performed from a societal view and a treatment perspective. In a cost-utility analysis the costs, gained quality-adjusted life years (QALY) and savings in health care were considered. Cost-effectiveness was also described using the Net Monetary Benefit Method.
Results: Significant differences between groups over the 3-yr period were shown in EQ VAS, SF-6D and SF-36 physical component summary but not in EQ-5D or SF-36 mental component summary. There was a net saving of 47 USD per participant. Costs per gained QALY, savings not counted, were 1,668 – 4,813 USD. Probabilities of cost-effectiveness were 89 – 100 %, when 50 000 USD was used as stakeholder's threshold of willingness to pay for a gained QALY.
Conclusion: Lifestyle intervention in primary care improves QOL and is highly cost-effective in relation to standard care.
Trial registration: ClinicalTrials.gov identifier: NCT00486941

People who are sedentary have a higher relative risk of mortality than the physically active and unfit people have a higher risk than fit people [1-3]. Most people in developed countries do not reach recommended level of physical activity (PA) [4] thereby contributing to public health problems [5]. Extensive and intensive lifestyle intervention programs delay the onset of diabetes and reduce cardiovascular risk by increasing PA, reducing overweight and changes in dietary habits [6].

Health-related quality of life (QOL) is a patient-centered outcome and incorporates the patient's perspective of physical, mental and social well-being. Individuals with obesity, diabetes and other cardiovascular risk factors such as hypertension and hyperlipidemia report diminished well-being and QOL [7, 8], while being active is associated with a higher QOL[9, 10].

For a comprehensive assessment of an intervention program it is essential to incorporate the individual's broader perspective of well-being - not only the conventional medical outcomes[11]. One recent RCT showed a dose-response effect of PA on both physical and mental aspects of QOL[12]. Otherwise, reports on the long term effect of programs for increased PA on QOL are rare, inconsistent and very seldom carried out in primary health care[13-18].

Despite the evidence that health care can promote PA, and that it is an effective treatment method, its promotion is rarely used as standard care.

An important factor in the selection of interventions in health care should be the cost-effectiveness as compared with competing methods. A systematic review found no report concerning cost-effectiveness of PA promotion in primary health care used as a treatment method alongside standard care [19].

We recently reported a 3-yr follow-up on an RCT with lifestyle intervention carried out in a primary health care setting [20]. It involved a population at moderate-to-high risk for cardiovascular disease and favorably reduced several risk factors. Our hypothesis was that the program improved QOL and was cost-effective.

METHODS

STUDY DESIGN

A complete description of the Björknäs study has been published [20]. In brief, the study was a 3-yr RCT with a control group, which received standard care and an intervention group, which also received a lifestyle-modification program. All individuals were followed-up at 3, 12, 24 and 36 months (Figure 1).

PARTICIPANTS, RANDOMIZATION AND BLINDING

The study population was recruited from a primary care center in northern Sweden. Individuals aged 18-65 yr with hypertension, dyslipidemia, type 2-diabetes, obesity or any combination thereof was identified. Individuals with a diagnosis of coronary heart disease, stroke, severe hypertension, and severe psychiatric morbidity were excluded. The 340 eligible subjects were invited by letter, and 177 (52%) agreed to participate. Of those, 18 withdrew before randomization and a further eight met the study’s exclusion criteria. A total of 151 enrolled participants were randomly allocated to the intervention group (n=75) or the control group (n=76), using a computer-generated random numbers sequence. The allocation was concealed until after the baseline examinations were completed. There was no blinding.

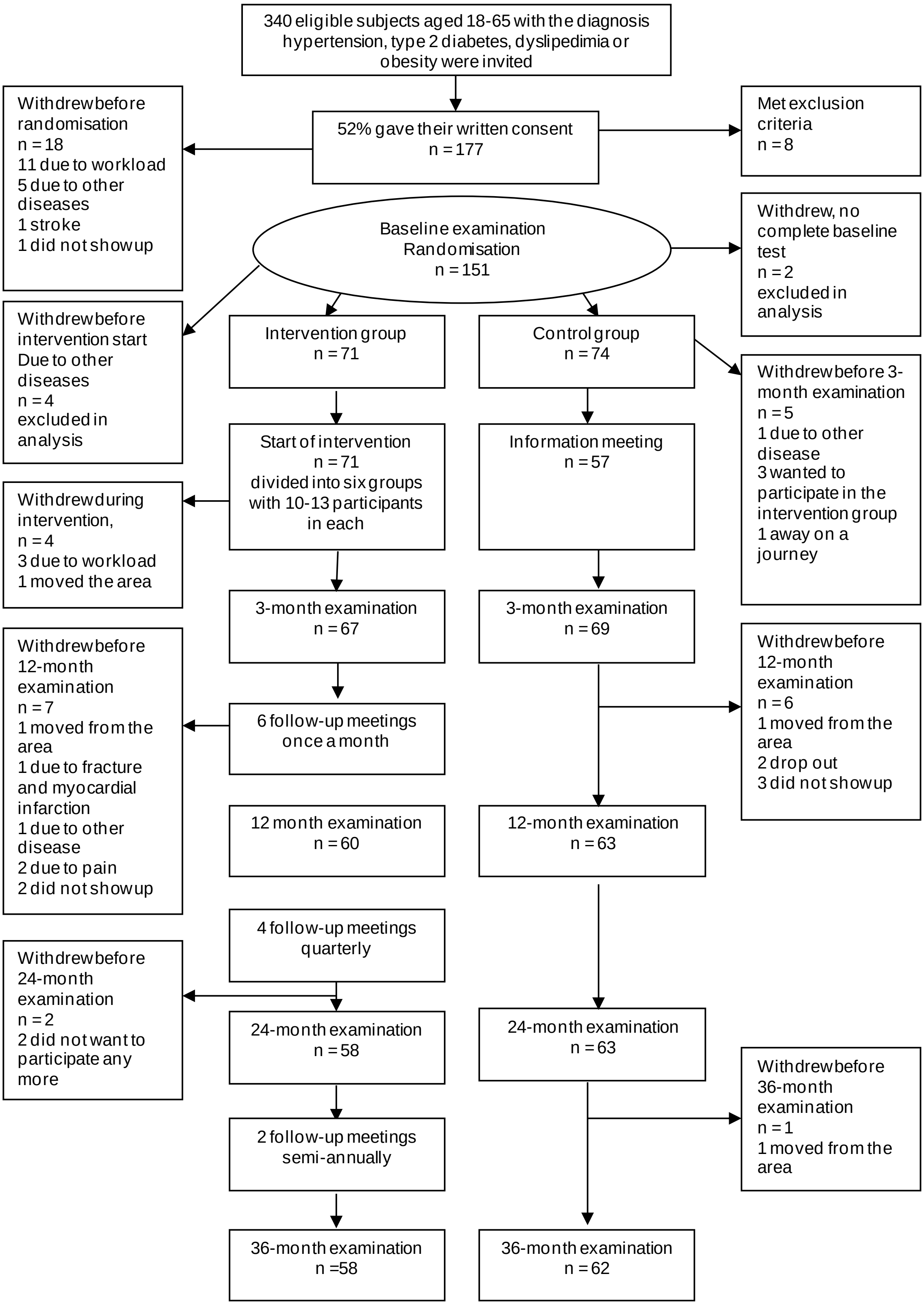

Figure 1. Participants flow Diagram

INTERVENTION

The intervention consisted of supervised progressive exercise training three times a week and diet counseling on five occasions during the first three months, followed by regular group meetings. All activities were performed in small groups (n=10-13). The exercise sessions were led by physiotherapists and consisted of Nordic walking, aqua-aerobics, and interval training on a bicycle ergometer combined with circuit-type resistance training. Each training group was offered one session of each activity every week. The diet counseling was in accordance with the Nordic nutrition recommendations and was given both verbal and written by a trained dietician.

After the 3-mo active intervention period, participants were invited to attend group meetings on six occasions during the first year, on four occasions during the second year and on two occasions during the third year. Participants were encouraged to maintain at least 30 min/day of PA. Focus was on self-regulatory strategies such as goal-setting, action planning and relapse avoidance. Participants were asked to reflect upon benefits, barriers, and costs of adherence to a healthier lifestyle.

The control group was given both verbal and written information about exercise and diet at one group meeting. Both groups were requested to complete activity logs and continued with their routine care.

OUTCOMES

Primary outcomes were change in QOL measured as EQ-5D, EQ VAS and SF-6D based on the self-administrated generic questionnaires EuroQol (EQ) and Short-Form-Health Survey (SF-36), gained quality adjusted life years (QALY) and change in resource use.

EQ includes the EQ-5D self-classifier[21], a descriptive system that measures five dimensions of health status: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. We computed a single score based on the value tariff from a British population[22]. EQ VAS records the respondent's perception of overall health status on a 20-cm line graduated between 0 (indicating worst imaginable health) and 100 (indicating best imaginable health). We transformed EQ-VAS to a 0-1 scale by dividing the actual score by 100.

SF-36 consists of 36 items grouped into eight domains: physical functioning, limitations in physical role functioning, bodily pain, general health, vitality, social functioning, limitations in emotional role functioning, and mental health [23]. Each domain is scored from 0 (worst imaginable health) to 100 (best imaginable health) obtained from the patient's raw scales. Changes ≥ 3-5 scale points may be clinically relevant[24]. The SF-36 physical component summary score and mental component summary score were calculated using the Swedish manual [23]. SF-6D is a utility score derived from responses to 11 questions in the SF-36 questionnaire and consists of six dimensions of health [25, 26].

Health economic analysis method

The analysis in this study was a cost-utility analysis with a societal perspective. Cost-effectiveness ratios were based on gained quality adjusted life years (QALY) and net costs for the intervention group as compared with the control group. In the analysis, costs for stakeholder of intervention, patients' costs, treatment effect, and savings in health care use were considered but not the cost for the participants' exercise time or changes in production.

Table 1. Measurement methods for variables in the health economic analysis

Factor	Variable	Method
Costs	Program costs for the stakeholders	Accounts of primary health care providers. Costs were calculated based on estimated time consumption, and estimated fractions of costs for care center rent, equipment, and overheads.
	Participants' expenses	Physical activity, at least 30 minutes a day, was assumed to cost 400 USD/yr, representing a yearly fee at exercise centers in Sweden, and physical activity less than 30 minutes a day was assumed to cost 67 USD/yr. Empirical data were not available. Methods used for measuring time for exercise were not validated, but frequently used by the Swedish National Institute for Public Health
Treatment effect	QOL	EQ-5D in combination with preference scores from a British population [35, 36]. EQ VAS [35]. SF-6D in combination with preference scores from a British population [25, 26]
Savings	Health care costs	Health care records regarding the last 6 months' health care use before baseline and the 3 yr use after start of the intervention. Number of visits to family physicians and nurses in primary health care, and visits and admissions in hospital care were counted. Standard production prices negotiated for trade of health care between county councils were used.

Health care utilization data were extracted from electronic patient records from all health care centers and hospitals in the county, and were followed from 6 mos before start of the intervention to 3 yr after that the intervention was started.

Measurements made at baseline and at the follow-ups that were used in the calculation are given in Table 1. All costs were transformed from Swedish currency to USD using the exchange rate 1 USD = 7.5 Skr. Costs were recalculated to the price level of 2009 using the Swedish consumer price index. Research costs and costs relating to the development of the method were not included. All changes in effect and costs were discounted 3% per yr.

The uncertainty from the underlying trial is handled with the Net Monetary Benefit method [27]. The method is based on replacing health effects (QALY) with that amount of money decision makers are willing to pay for a gained QALY. When both effects and resource use are expressed in monetary units, it is possible to calculate a confidence interval for cost-effectiveness and the probability that an intervention is cost-effective in relation to a competing intervention.

Gained QALY is calculated from the difference in QOL between intervention and control groups at the follow-up times. Differences were assumed to develop linearly between follow-up times. For instance, if QOL had increased 0.04 more at 3 mo and 0.08 more at 1 yr in the intervention group than in the control group, the mean change the first three mo would be 0.02 (0.00+0.04/2) and the following 9 mo 0.06 (0.04+0.08/2). Gained QALY for this yr would be 0.05 ((0.02x3/12)+(0.06x9/12)).

A scatter plot of 5 000 bootstrapped incremental cost-effectiveness ratios was created, by repeatedly drawing a random sample with replacement using parameters estimated from the RCT. Individual values were used for savings in health care costs and gained QALY, and mean values were used for costs in intervention and control groups. This produced estimates of the probability that the intervention was cost-effective using several thresholds of willingness to pay for a QALY. Results are presented in a cost-effectiveness acceptability curve [28]. Further, mean NMB and confidence intervals of NMB were estimated for these different threshold values.

STATISTICAL ANALYSES

Differences between groups in changes in outcome variables over 3 yr were analyzed on an Intention-to-treat (ITT) basis. If data were missing the last observation was carried forward. General linear model repeated measures of variance was used to investigate mean changes in QOL over time, overall main effects, testing also for effects of time and interaction time*group. For exploratory reasons all outcomes were also analyzed per-protocol using only available data and also adjusted for age and sex. These results did not differ substantially from the unadjusted ITT analysis which therefore is presented. T-tests, with Bonferroni correction when needed, were used for comparison at singular time points.

We calculated a statistical index of responsiveness, effect size, as standardized response mean according to Cohen [29]. A change in effect size of 0.2-0.5 should be regarded as “small”, 0.5-0.8 as “moderate” and > 0.8 as “large”.

RESULTS

A total of 151 individuals were randomized with greatest attrition during the first year Those lost to follow-up did not differ between the groups, 17 intervention and 14 control subjects. Six subjects were excluded: four did not start the intervention and two from the control group had incomplete baseline data (Figure 1). Finally, 71 intervention and 74 control subjects were included and the 3-yr follow-up was completed by 120 participants (83%).

OUTCOMES AND ESTIMATIONS

The mean age of the study population was 54.4 years and 57% were female (Table 2). Overweight or obesity was present in 86.8% and most had one or more additional risk factor. An inactive lifestyle was common; 54.5% being sedentary or minimally active and 84.2% reported none or less than 30 min of exercise per day. Smoking, diabetes and treatment with lipid-lowering drugs were more common in the intervention group, while hypertensive medication was less common. The intervention groups tended to be less physically active and reported lower mean scores in all QOL questions at baseline.

EQ-5D score and the mental dimensions of SF-36 were similar to the Swedish population [23, 30] while the EQ VAS and the physical dimensions of the SF-36 were lower (Figure 2 A-B). Problems in the dimension pain/discomfort were more common and anxiety/depression less common than in the Stockholm population [30](Figure 2 C).

Quality of life

EQ-5D did not change significantly during the 3-yr period (Table 3). However, the EQ VAS differed significantly between the groups over the 3-yr period (p=0.002) with greater improvement in the intervention group. The improvement in the SF-6D mean score was higher in the intervention group than in the control group (p=0.010).

Mean changes in scores and summaries in the SF-36 dimensions are shown in Table 3. Over three years an improved physical functioning (p=0.017) and less bodily pain (p=0.012) was found in the intervention group. The physical component summary improved to a higher degree in the intervention group (p=0.041) but not the mental component summary or its subscales.

Table 2. Patient characteristics at baseline

Variable	All participants (n=145)	Intervention group (n=71)	Control group (n=74)
Age	54.4	55.7 (6.6)	53.1 (8.2)
Sex			
Male	62 (42.8)	35 (49)	27 (36.5)
Female	83 (57.2)	36 (51)	47 (63.5)
Education			
Elementary grade	28 (19.3)	14 (20)	14 (19)
Upper secondary school	82 (56.6)	41 (58)	41 (55)
University college education	35 (24.1)	16 (22)	19 (26)
Main occupation			
Working empoyed/self-employed	77 (53.1)	38 (53)	39 (53)
Retired	52 (35.9)	26 (37)	26 (35)
Unemployed/other	16 (11)	7 (10)	9 (12)
Smoking habits			
Smokers	30 (20.7)	17 (24)	13 (18)
Presence of overweight or obesity			
Fraction with BMI ≥ 25	125 (86,8)	64 (90)	62 (84)
Fraction with BMI ≥ 30	62 (42.8)	32 (45)	30 (41)
Disease status			
Type 2 diabetes	40 (27.6)	23 (32)	17 (23)
Hypertension medication	95 (65.5)	45 (63)	50 (68)
Dyslipidemia medication	32 (22.1)	24 (34)	8 (11)
Total physical activity			
Sedentary	17 (11.7)	14 (20)	3 (4)
Minimally active	62 (42.8)	27 (38)	35 (47)
Moderateley active	47 (32.4)	22 (31)	25 (34)
Very active	19 (13.1)	8 (12)	11 (15)
Exercise			
None	80 (55.2)	43 (61)	37 (50)
<30 min/d	42 (29)	20 (28)	22 (30)
30-60 min/d	21 (14.5)	8 (11)	13 (18)
60 min/d	2 (1.4)	0 (0)	2 (3)
Quality of life score			
EQ-5D	0.81 (0.21)	0.78 (0.24)	0.83 (0.16)
EQ VAS	0.66 (0.18)	0.63 (0.20)	0.70 (0.15)
SF-6D	0.70 (0.10)	0.68 (0.10)	0.71 (0.10)
SF-36			
Physical Functioning	82.6 (17.1)	80.2 (17.6)	84.9 (16.5)
Role Limitation Physical	78.1 (34.2)	74.6 (36.7)	81.4 (31.5)
Bodily Pain	67.4 (26.)	64.0 (27.7)	70.5 (25.8)
General Health	66.6 (19.8)	64.8 (19.4)	68.4 (20.0)
Vitality	65.7 (21.4)	62.9 (22.8)	68.4 (19.7)
Social Function	89.3 (18.5)	87.0 (21.3)	91.6 (15.1)
Role Limitation Emotional	88.5 (26.5)	84.5 (29.2)	92.1 (23.1)
Mental Health	83.8 (14.6)	81.3 (16.7)	86.2 (11.8)
Physical component summary	45.8 (9.9)	44.8 (10.1)	46.7 (9.7)
Mental component summary	52.1 (8.4)	50.8 (9.7)	53.4 (6.7)

Age, SF-36 and EuroQol data are given as mean (SD); other variables are given as number and (percent)

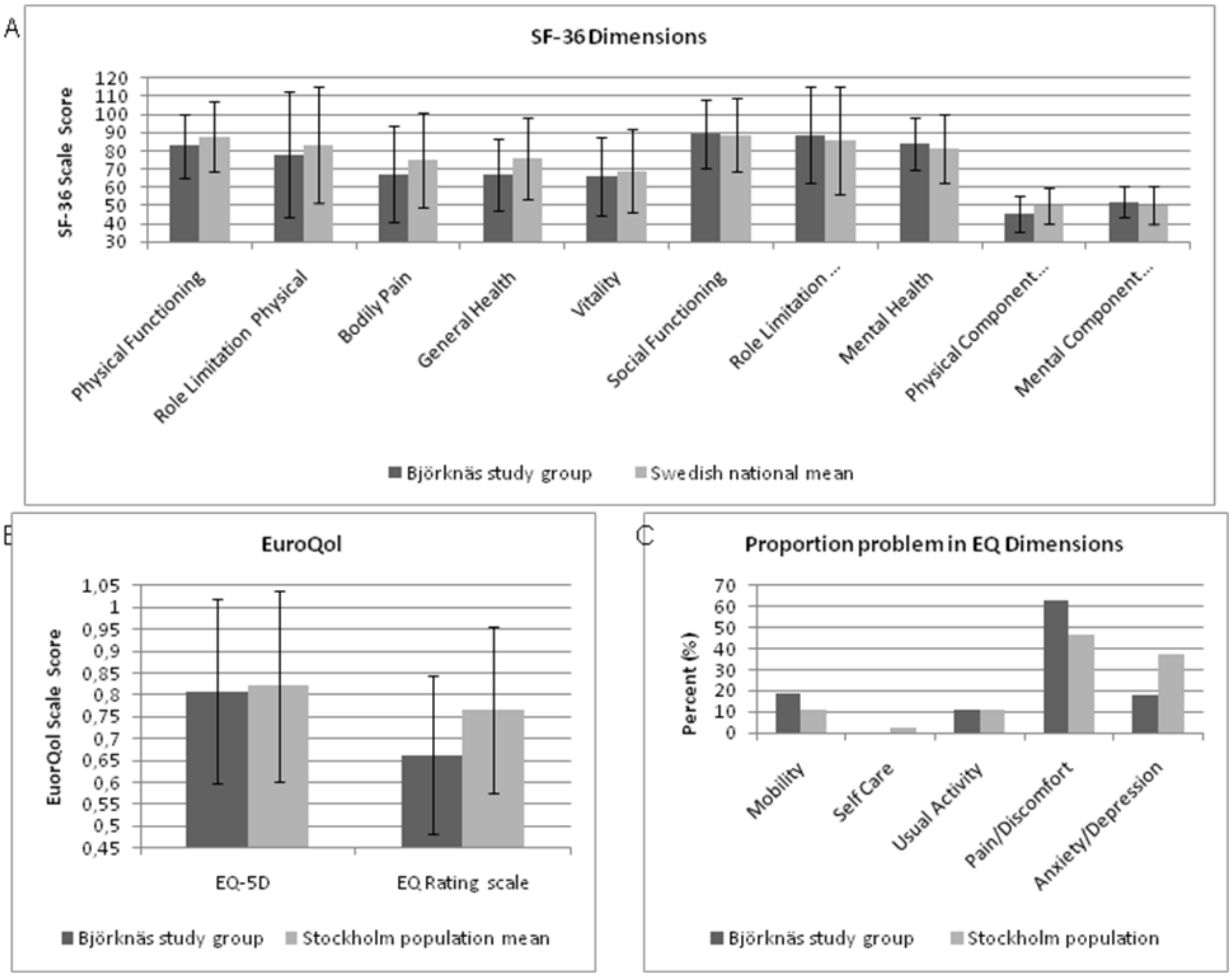

Figure 2. Baseline QOL in the Björknäs *S*tudy Group and Swedish Norm Data[23, 30]. Data are means and SDs (A-B) and the proportion (percent) reporting problem in the EQ dimensions (C).

Table 3. Mean changes in Quality of Life Scores from baseline to 3 years in the Swedish Björknäs study [a] ((Δ intervention group – control group). Effect size according to Cohen's criteria: trivial <0.20, small 0.2-0.5, moderate 0.5-0.8, large >0.8

Quality of Life Score	Study phase	Mean difference (95% Confidence Interval)	*p*-value T-test	*p*-values Repeated measures		Effect size
				Between subjects	Time*group	
EQ -5D	0-3 m	0.02 (-0.04; 0.08)	0.48			
	0-12 m	0.02 (-0.03; 0.07)	0.43			
	0-24 m	0.03 (-0.02; 0.09)	0.21			
	0-36 m	0.03 (-0.02; 0.07)	0.28	0.24	0.939	0.18
EQ VAS	0-3 m	0.08 (0.03; 0.13)	0.002			
	0-12 m	0.08 (0.02; 0.13)	0.007			
	0-24 m	0.06 (0.002;0.11)	0.043			
	0-36 m	0.09 (0.03; 0.15)	0.002	0.002	0.504	0.52
SF-6D	0-3 m	0.03 (0.01; 0.05)	0.017			
	0-12 m	0.02 (-0.01; 0.42)	0.19			
	0-24 m	0.02 (-0.01; 0.05)	0.19			
	0-36 m	0.04 (0.02; 0.07)	0.002	0.010	0.197	0.51
SF-36	0-3 m	4.7 (1.2; 8.1)	0.009			
Physical	0-12 m	3.5 (-0.04; 7.1)	0.052			
Functioning	0-24 m	1.3 (-3.3; 5.9)	0.58			
	0-36 m	5.3 (1.2; 9.4)	0.012	0.017	0.256	0.41
Role	0-3 m	-3.4 (-12; 5.3)	0.44			
Limitation	0-12 m	2.4 (-9.1; 14)	0.68			
Physical	0-24 m	-0.1 (-12; 11)	0.98			
	0-36 m	11 (-1.6; 23)	0.09	0.58	0.113	0.30
Bodily Pain	0-3 m	1.4 (-4.6; 7.5)	0.64			
	0-12 m	6.6 (0.8; 12)	0.108			
	0-24 m	6.6 (-0.5; 14)	0.07			
	0-36 m	12 (4.8; 20)	0.004	0.012	0.019	0.53
General	0-3 m	2.9 (-1.2; 6.9)	0.16			
Health	0-12 m	0.8 (-3.8; 5.3)	0.74			
	0-24 m	6.0 (1.3; 11)	0.013			
	0-36 m	3.5 (-1.2; 8.2)	0.14	0.08	0.113	0.25
Vitality	0-3 m	8.1 (3.0; 13)	0.008			
	0-12 m	0.8 (-5.0; 6.5)	0.80			
	0-24 m	0.1 (-5.3; 5.5)	0.98			
	0-36 m	3.9 (-1.8; 9.5)	0.18	0.13	0.025	0.22
Social	0-3 m	7.2 (2.6; 12)	0.012			
Functioning	0-12 m	2.3 (-3.5; 8.2)	0.43			
	0-24 m	-1.3 (-6.9; 4.4)	0.66			
	0-36 m	4.0 (-1.6; 9.6)	0.16	0.16	0.021	0.23
Role	0-3 m	2.1 (-7.4; 12)	0.66			
Limitation	0-12 m	2.8 (-7.2; 13)	0.58			
Emotional	0-24 m	3.4 (-7.4; 14)	0.54			
	0-36 m	1.5 (-10; 13)	0.80	0.58	0.979	0.04
Mental	0-3 m	4.3 (0.3; 8.3)	0.037			
Health	0-12 m	-0.3 (-4.6; 4.0)	0.91			
	0-24 m	2.0 (-2.3; 6.3)	0.36			
	0-36 m	2.4 (-2.0; 6.8)	0.28	0.23	0.168	0.18
Physical	0-3 m	0.6 (-1.5; 2.6)	0.59			
Component	0-12 m	1.7 (-0.6; 4.1)	0.14			
Summary	0-24 m	1.3 (-1.2; 3.7)	0.30			
	0-36 m	3.8 (1.4; 6.3)	0.012	0.041	0.059	0.49
Mental	0-3 m	2.8 (0.3; 5.3)	0.11			
Component	0-12 m	0.1 (-2.5; 2.7)	0.93			
Summary	0-24 m	0.6 (-2.3; 3.4)	0.69			
	0-36 m	0.4 (-2.4; 3.2)	0.78	0.37	0.147	0.05

[a] Data are given as estimated marginal means (95% confidence interval) derived from general linear model with repeated measures. *P* values for group differences at each time point were assessed by independent sample t-test using Bonferroni correction when significant time*group interaction effect.

There were no significant main time effects or time*group interaction for most QOL variables. But in the SF-36 bodily pain groups were changing in different directions over time, increasing in the intervention group and decreasing in the control group (Table 3). Also vitality and social functioning showed a significant interaction over time - the intervention group improving and the control group decreasing slightly. Main time effect was only significant for social functioning ($p=0.005$)

Calculations of effect size at 3 yr showed moderate effects on EQ VAS, SF-6D, bodily pain and physical component summary and small-to-moderate effects on physical functioning (Table 3).

Costs

Costs were 337 USD higher for the intervention group than for the control group. 197 USD of those costs were financed by health care, and the remaining 140 USD were costs imposed on the participants due to increased PA (Table 4). Costs for medical testing, such as serum lipids, glucose and HbA1c, were 185 USD per patient and yr for both intervention and control groups.

Gained QALY

Gained QALY per participant in the intervention group compared to the control group during the three yr was 0.075 ($p=0.24$) using the EQ-5D, 0.202 ($p<0.01$) using the EQ VAS, and 0.070 ($p=0.03$) using the SF-6D (discounted 3 % per yr).

Savings

The mean number of visits to the family physician in the intervention group decreased by 0.28 per half yr as compared with baseline, and increased by 0.097 in the control group ($p=0.04$). For other health care use there were no significant changes between the groups. Savings in family physician visits was 493 USD for the three-yr period, and savings for all health care use was 384 USD ($p=0.44$) (Table 4).

Cost-effectiveness

There were net savings with 47 USD per participant in the intervention group compared to the control group. Gross costs per gained QALY were 1,668 – 4,813 USD using the three different QOL-scales (Table 5). Using 50 000 USD as threshold of willingness to pay for a QALY, net monetary benefits for the intervention were significant higher than for the control using the EQ VAS and the SF-6D, but not using the EQ-5D. The probability of cost-effectiveness when stakeholders are willing to pay 50,000 USD for a QALY is 98.5 % using the SF-6D, 88.6 % using the EQ-5D and 99.9 % using the EQ VAS (Figure 3).

Table 4. Costs per participant, and changes in healthcare use 6 mo before baseline and during the three yr after start

TYPE OF COSTS AND SAVINGS	INTERVENTION GROUP	CONTROL GROUP	INTERVENTION VS. CONTROL
First year, 11 group meetings with physiotherapist and dietician. Family physician participated once.	36	0	36
Second year, 4 group meetings with physiotherapist and dietician.	12	0	12
Third year, 2 group meetings with family physician, physiotherapist and dietician.	13	0	13
First year, 1 group meeting with family physician, physiotherapist and dietician.	0	5	-5
Counseled group exercise 3 times a week during 12 weeks	103	0	103
Equipment	6	2	4
Proportion of costs for health care center rent	15	0	15
Overhead costs 11 %	20	1	19
Sum of costs for primary health care	205	8	197
Participants' costs for increased physical activity	207	67	140
Sum of costs	**412**	**75**	**337**
Family physician visits	-368	125	-493 (-24 - -960)
Nurse visits	35	37	-2 (-275 – 270)
Hospital specialist visits	113	35	78 (-600 – 756)
Hospital nurse visits	60	27	33 (-66 – 131)
Sum of savings	**-160**	**224**	**-384 (-1355 – 586)**
Net costs	**252**	**299**	**-47 (-1018 – 923)**

Prices for health care are negotiated and represent production costs. For hospital visits, costs for visits to the internal medicine clinic were used. 95 % confidence intervals are presented within brackets. All costs and savings are in USD and were discounted 3 % per yr.

Table 5. Costs per gained QALY, probability of cost-effectiveness and net monetary benefit, intervention vs. control. All costs are in USD, and discounted 3 % per yr. NMB = Net Monetary Benefit.

	EQ-5D	EQ RATING SCALE	SF-6D
Gained QALY	0.075	0.202	0.070
Program costs	197.3	197.3	197.3
Participants' out-of-pocket expenses	139.6	139.6	139.6
Sum of costs (gross costs)	336.9	336.9	336.9
Savings in health care costs	-384.3	-384.3	-384.3
Net savings	-47.4	-47.4	-47.4
Gross costs per gained QALY	4492.0	1667.8	4812.9
NMB (95 % confidence interval), 1 QALY = 50 000 USD	4,170 (-2,586–11,049)	11,865 (4,438–19,793)	3,908 (384–7,685)
NMB (95 % confidence interval), 1 QALY = 100 000 USD	8,292 (-5,039–21,953)	23,682 (8,844–39,349)	7,769 (931 – 14,929)

All costs are in USD, and discounted 3 % per yr. NMB = Net Monetary Benefit.

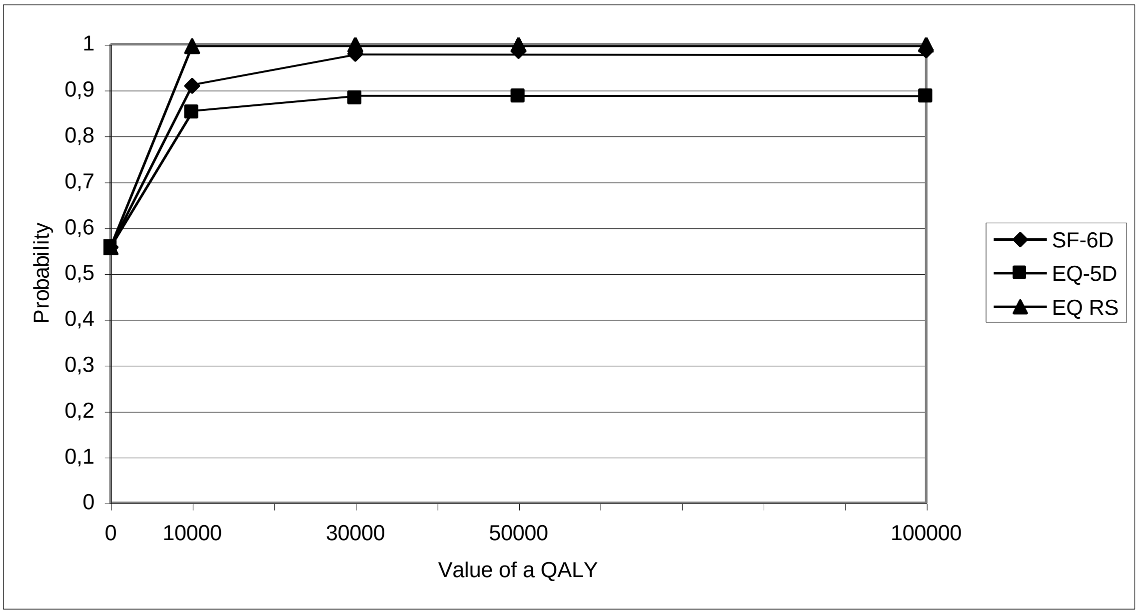

Figure 3. Probability of cost-effectiveness using EQ-5D, EQ VAS and SF-6D presented in a cost-effectiveness acceptability curve with 0, 10,000, 30,000, 50,000 and 100,000 USD as value of a QALY.

DISCUSSION

The Björknäs Study demonstrates for the first time that a lifestyle intervention over three years, targeted to a population at moderate-to-high-risk for CVD, carried out in "real life" primary healthcare, improves quality of life and is highly cost-effective. The intervention used the core features of the American Diabetes Prevention Program[13] and the Finnish Diabetes Prevention Study [31]but was delivered at a conventional primary care setting in northern Sweden, without additional resources. These results should be viewed in the context of the previously reported favorable impact on PA, fitness, waist circumference, waist-to-hip ratio, blood pressure and smoking cessation over the 3-yr period [20]. We have not been able to find any previous reports on the effect on QOL or cost-effectiveness of group-based lifestyle interventions in primary health care, focusing on physical activity with a follow-up over many years.

Physical activity and quality of life

People with obesity and other cardiovascular risk factors have lower QOL [7, 8] and obese patients have more problems regarding mobility and pain [7]in concordance with our comparison with the Swedish population. Women with higher levels of exercise reports higher QOL[32]. The causality between higher level of PA and improved QOL was recently confirmed in an RCT with sedentary postmenopausal women which demonstrated a strong and graded effect of three different doses of supervised exercise on QOL during six months [12]. Even a small increase in exercise was associated with improvements in some SF-36 dimensions. The magnitude of improvements in QOL was similar to our study with better physical and mental health after the initial supervised exercise period. We noted that the mental improvement waned over a longer period, in accordance with other lifestyle interventions[17, 18]

The effects of PA on QOL in clinical trials are inconsistent, the methods to promote it differ [13-16], some studies include only women[12]or have short follow-up. "Physical activity on prescription" involves a health professional's written advice to a patient to be more physically active. Some randomized trials in primary care, using PA on prescription, but not supervised exercise sessions, report no effect on QOL or fitness at a 6-mo follow-up [14], or some improvements in QOL after 2 yr [16].

The ProActive study targeted a sedentary population at risk of diabetes and investigated effects of a theory-based behavioral intervention [15]. The program taught behavior change and was delivered regularly during 1 year by health professionals by telephone or in participants' homes. The intervention was not more effective than written advice to promote PA or improve fitness but improved some SF-36 scales.

Physical activity and cost-effectiveness

Costs per gained QALY were low (1,668 – 4,813 USD). When also savings in health care were considered, there were 47 USD in net savings. The probability for cost-effectiveness using 50,000 USD per QALY as threshold for cost-effectiveness was between 88,8 and 99,9%. Net monetary benefits for the intervention were significantly higher than for the control using the EQ VAS and SF-6D, but not when EQ-5D was used.
There is no official level of willingness to pay for a gained QALY in the USA, but 50,000 and 100,000 USD are often used. Nor in Great Britain is there an official level, but NICE applies 32,000-50,000 USD as acceptable values, and in Sweden a threshold of 37,500 USD has been guiding decisions about subsidized medicine. Thus, cost-effectiveness of the intervention was good in relation to what western countries are willing to pay for a QALY, and the probability for cost-effectiveness was very high in this study. Most important for low cost-effectiveness ratio are patients increase in QOL. Higher QOL may also have had impact on less number of family physician visits, which enhanced good cost-effectiveness.

The main reasons for cost-effectiveness were the sustainable increases in exercise level and QOL as compared with the control group. An important aspect in the performance of the intervention method was probably the long-time contact with the participants. Another important aspect was that the group activities generated rather low costs per participant.

Strengths and weaknesses

The Björknäs study was carried out in an ordinary primary care setting, typical of Northern and Western European health care systems, with limited resources. The intervention went on for the whole 3-yr period, albeit with tapering of intensity, and attrition was rather low. More than half of those eligible were randomized, in contrast to most major intervention studies [33], which strengthens internal and external validity. The study population and the drop-outs did not differ, nor did the group who declined to participate [20]. All data were analyzed conservatively on an ITT basis.

Clinically relevant effect sizes were noted for many, but not all, outcomes and the use of two valid and reliable QOL instruments provided similar results. The study was initially powered for anthropometric measurements, not for QOL, and may thus be too small to detect significant improvements in less responsive scales.

A strength with the health economic analysis is that it is completely based on data from the trial, and only the three-year follow up time is considered in the analysis. Hence, no assumptions are needed, except for expenses for PA. The assumed costs represent a common yearly fee at exercise centres in Sweden. If the fee is doubled from 140 to 280 USD), the costs per gained QALY were still very low: 456 – 1,317 USD, instead of 47 USD in net savings. The main uncertainty is from the underlying trial. This uncertainty is managed according to recommendation from Drummond [27] when patient level data is used. The Net Monetary Benefit concept is an improvement in dealing with uncertainty as compared with using sensitive analysis, especially when insignificant changes between groups are used in the calculation of cost-effectiveness ratios.

The costs for the participants' exercise time were not considered in this analysis. It is a topic concerning loss of enjoyment when exercising. For some individuals, PA may represent a loss of enjoyment, but those who frequently perform PA do not seem to lose enjoyment when spending time on exercise [34]. Neither were savings in production considered. In a situation with full employment such savings may important, but with significant unemployment, the savings will be restricted to costs to replace a sick worker with a new one, and of restricted magnitude.

The actual program and The Diabetes Prevention Program (DPP) [13] are two of few interventions lasting for three yr. DPP was an intense lifestyle program and showed a treatment effect as compared with placebo of 0.072 QALY in three yr, very similar to the Björknäs Study. That program was very costly (2,780 USD for program holder year 2000) with mostly individual meetings. Costs were more than 10 times higher than for the actual project, which mainly used group meetings, but despite the high costs, the DPP was cost-effective.

Most important for cost-effectiveness is the effect in QALY, but there is no golden standard in method to estimate QALY. We have used tariffs based on all three standard techniques [27] (Time-Trade Off, Standard Gamble and Rating Scale), and the valuation of QOL is made by both patients and a general population. We think the result is more convincing when acceptable cost-effective ratios are achieved with different methods.

Probably the cost-effectiveness is even better. Gains in QOL may remain after the 3 yr period. The actual analysis had only a treatment perspective, but there were also preventive effects against cardiovascular diseases and type 2 diabetes [20]. Several lifestyle interventions have shown good cost-effectiveness from only a preventive perspective for similar patient groups [19]. Further, the results are likely to be an underestimate, since the control group received more promotion of healthy lifestyle than is generally common in primary health care.

Thus, high-intensity and long-lasting interventions can produce sustainable improvements in QOL and can obviously be cost-effective. Such programs may be a wise use of resources in primary health care for patients with diseases where inactivity strongly contributes.

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