Physical activity and patient-reported outcomes during a two-year lifestyle intervention for severely obese adults

The Haugland Obesity Study

Randi Jepsen

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Author: Randi Jepsen

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Scientific environment

The research work and studies for this dissertation were supervised by Professor, RN Gerd Karin Natvig, Head of the research group on Life Phenomena and Quality of Life, Department of Global Public Health and Primary Care, University of Bergen and co-supervised by postdoc, PhD, RN John Roger Andersen, Faculty of Health Studies, Sogn og Fjordane University College and Førde Health Trust. I completed most of my PhD courses at the Faculty of Medicine and Dentistry, the Research School in Public Health and Primary Health Care, and the Graduate School of Human Interaction and Growth, University of Bergen. I have been affiliated with the Research Programme on Public Health and Obesity, Sogn og Fjordane Centre for Health Research and Haugland International R&D Centre.

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Randi Jepsen, December 2014

In grateful memory of my mother, Tove Sejersbøll Thomsen

List of abbreviations

BMI	Body mass index
CI	Confidence interval
Cm	Centimetres
CPM	Counts per minute
ES	Effect size
HUNT	Nord-Trøndelag Health Study
ICD	International Classification of Diseases
Kg	Kilograms
MCS	Mental component summary
OP	Obesity-Related Problems Scale
p	Probability (in *p*-value)
PA	Physical activity
PCS	Physical component summary
PRECEDE	Predisposing, reinforcing, and enabling constructs in educational/ ecological diagnosis and evaluation
PROCEED	Policy, regulatory, and organisational constructs in educational and environmental development
RCHRC	Red Cross Haugland Rehabilitation Centre
SD	Standard deviation
SF-36	Medical Outcomes Study Short-Form 36 Health Survey
SPSS	Statistical Package for Social Sciences
t	Student's *t*-statistics
WHO	World Health Organization

Abstract

Severe obesity is a chronic condition, which is associated with impaired quality of life and health hazards. The direct cause of obesity is an imbalance in energy intake and expenditure over time, but the underlying mechanisms include a complexity of individual, inter-relational, social, environmental, and political factors. The prevalence of severe obesity is growing in the adult Norwegian population, and the condition gives access to the specialist health services. One treatment option is multi-component lifestyle interventions, which include physical activity, change of diet, and cognitive behavioural therapy. Although physical activity is a cornerstone of such interventions, it is sparsely studied. How physical activity may be associated with subjective phenomena like psychological, predisposing factors or quality of life before and during lifestyle interventions is not known.

Therefore, the purposes of the study were 1) to examine associations between physical activity and quality of life outcomes prior to a lifestyle intervention, 2) to examine associations between change in the three psychological, predisposing factors perceived behavioural control over physical activity, self-efficacy for physical activity in the face of psychological barriers, and physical activity identity and change in physical activity during a two-year lifestyle intervention, and 3) to examine associations between change in physical activity and change in quality of life outcomes during a two-year lifestyle intervention.

The study was part of the Haugland Obesity Study, which was a two-year prospective, observational study on severely obese adults participating in a multi-component lifestyle intervention. Residential periods constituted 15 weeks in total at the Red Cross Haugland Rehabilitation Centre, Western Norway. Inclusion criteria were age between 18-60 years and body mass index (BMI) ≥ 40 kg/m^2 with or without comorbidities, or ≥ 35 kg/m^2 with comorbidities. Exclusion criteria were: referral to, or, previous obesity surgery, severe cardiovascular disease, pregnancy, alcohol or substance abuse, and mental illness or physical impairment that would compromise adherence to the intervention. Ethical approval was obtained from the Regional

Committee for Medical and Health Research Ethics for South-East Norway (registration number 2010/159a).

Multi-component lifestyle interventions were understood as health promoting activities. The socio-ecological PRECEDE-PROCEED model and its theoretical underpinnings inspired the understanding of the processes of change, the associations, and outcomes.

Physical activity was assessed using the ActiGraph GTIM accelerometer (ActiGraph, Fort Walton Beach, FL, USA). The unit counts per minute was used for level of physical activity. Psychological, predisposing factors were measured using questionnaires on perceived behavioural control over physical activity, self-efficacy for physical activity in the face of psychological barriers, and physical activity identity. Quality of life was measured using a one-item question on life satisfaction, the Medical Outcomes Study Short-Form 36 Health Survey (SF-36), and the Obesity-Related Problems Scale (OP). Anthropometric data were collected by health staff. Socio-demographic information was obtained from questionnaires. Data collection took place four times: before, during, and at the end of the intervention between February 2010 and October 2012.

A linear mixed model based on restricted maximum likelihood estimation with random intercept for subjects was used in analyses for change over time, using least significant difference from baseline. Linear regression analyses were performed to examine associations between variables. Gender, age, and (change in) BMI were used as control variables in the regression analyses.

Forty-nine individuals (37 women; 43.6 ± 9.4 years; BMI 42.1 ± 6.0 kg/m^2) consented to participate in the study. At year two, 44.9% were lost to follow-up. Attrition analyses did not reveal differences between completers and non-completers. Regression analyses revealed that 1) level of physical activity was positively and independently associated with life satisfaction and physical functioning (obtained from

SF-36) but not mental health (obtained from SF-36) prior to the intervention, 2) change in perceived behavioural control was positively and independently associated with change in physical activity during the two years, but self-efficacy and physical activity were not, and 3) change in physical activity was positively and independently associated with change in life satisfaction, the physical and mental component summary scores of SF-36, and obesity-specific quality of life.

The conclusions were that perceived behavioural control may be a valid target for increase of physical activity in multi-component lifestyle interventions, and that improvements in quality of life may have the potential to operate as a long-term motivational factor for physical activity in lifestyle interventions for severely obese adults. The findings should be further examined in larger samples and different settings, and should preferably include establishment of a control group. The impact of extra-personal factors on change of physical activity behaviour should also be examined in recognition of the complexity of factors influencing individual health-related behaviour.

List of publications

Paper I Jepsen R, Aadland E, Andersen JR, and Natvig GK. Associations between physical activity and quality of life outcomes in adults with severe obesity: a cross-sectional study prior to the beginning of a lifestyle intervention. Health and quality of life outcomes 2013;**11**(1):187.
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Paper II Jepsen R, Aadland E, Robertson L, Kristiansen M, Andersen JR, and Natvig GK. Factors and associations for physical activity in severely obese adults during a two-year lifestyle intervention. PeerJ 2014;**2**:e505.
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Paper III Jepsen R, Aadland E, Robertson L, Kolotkin RL, Andersen JR, and Natvig GK. Physical activity and quality of life in severely obese adults during a two-year lifestyle intervention programme. Journal of Obesity. Accepted 23 December 2014.

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LIST OF APPENDICES

1. Introduction

Four decades of increasing prevalence of childhood and adult obesity generate global concern. Obesity is a risk factor for longevity, health, and well-being with unfavourable consequences for populations and societies (Gortmaker et al., 2011; Swinburn et al., 2011). Alarmingly, the most severe grade of obesity, generating the highest level of suffering and representing the most serious health hazards, seems to increase the most (Midthjell et al., 2013; Sturm, 2007; Sturm & Hattori, 2013). There are surgical, pharmacological, and behavioural treatment options for severely obese adults. Multi-component lifestyle interventions, targeting physical activity and diet and including behavioural therapy, belong to the behavioural approaches (Gloy et al., 2013; Tsigos et al., 2008). Although physical activity constitutes a cornerstone in multi-component lifestyle interventions (Dalle Grave, Calugi, & El Ghoch, 2013; Kirk, Penney, McHugh, & Sharma, 2012), it is sparsely studied, and associations between objectively measured physical activity and self-reported data have not been examined in research (Aadland, 2013). Thus, this thesis studied associations between objectively assessed physical activity and quality of life outcomes in severely obese adults participating in a multi-component lifestyle intervention. It also examined associations between psychological, predisposing factors for physical activity and objectively assessed physical activity in the same group.

1.1 Classification and prevalence of obesity

The World Health Organisation (WHO) classification of human body weight uses body mass index (BMI) to define overweight and obesity (Table 1). BMI is calculated by dividing a person's weight in kilograms (kg) by the square (^{2}) of the height in metres (m). Overweight is defined as BMI $\geq$ 25 kg/m^2. Obesity class I starts at 30 kg/m^2, class II at 35 kg/m^2, and class III at 40 kg/m^2 (WHO, 2000). The concept severe obesity, which is used in this thesis, is defined as BMI $\geq$ 40 kg/m^2 with or without comorbidities or BMI $\geq$ 35 kg/m^2 with one or more obesity-related comorbidities (Mechanick et al., 2013).

Table 1 Classification of obesity in adults according to body mass index (BMI)

Classification	BMI (kg/m^2)	Risk of comorbidities
Underweight	< 18.50	Low
Normal range	18.50-24.99	Average
Overweight	≥ 25.00	
Preobese	25.00-29.99	Increased
Obese class I	30.00-34.99	Moderate
Obese class II	35.00-39.99	Severe
Obese class III	≥ 40.00	Very severe

Adapted from WHO (2000, p. 9)

For several decades, the rates of overweight and obesity have risen worldwide in children and adults. Between 1980 and 2013, the global increase was 27.5% for adults and 47.1% for children, resulting in a total of 2.1 billion overweight and obese individuals. The estimated prevalence of overweight and obesity was 36.9% in men and 38.0% in women globally in 2013 (Ng et al., 2014). The same trend has been found in the Norwegian population, including a general shift in the distribution of BMI towards the right. The Nord-Trøndelag Health Study (HUNT) has documented a continuous increase in body weight the last 30 years, leading to a prevalence of overweight and obesity of 74.5% in men and 60.8% in women in Norway in 2006-2008 (Midthjell et al., 2013). Regarding BMI ≥ 40 kg/m^2, the estimated prevalence was 0.5% for men and 1.5% for women in Norway in 2006-2008 (Midthjell et al., 2013), while estimates from the United States were 4.3% for men and 8.0% for women in 2011-2012 (An, 2014).

1.2 Measures of obesity

Different anthropometric measures are used to quantify obesity. As mentioned, BMI is one of these. The WHO classification cut-off points for weight classes are based on associations with mortality (Table 1). WHO has recommended using BMI for individual and population purposes (WHO, 2000). However, muscles are denser than fat tissue, so when dietary restrictions, leading to weight loss, is combined with

physical activity, leading to increased muscle mass, effects may be masked when using the weight-based BMI (Jebb, Johnstone, Warren, Goldberg, & Bluck, 2009).

A second anthropometric measure providing valuable information is waist circumference. It is an indicator of abdominal fat, which is considered a special health hazard. In Caucasian adults, waist circumference of ≥ 94 centimetres (cm) in men and ≥ 80 cm in women, corresponding to being overweight, indicates increased risk of metabolic complications. Waist circumference ≥ 102 cm in men and ≥ 88 cm in women, corresponding to being obese, is considered a substantially increased risk (WHO, 2000). For use in severely obese individuals, higher cut-off points have been proposed (Ardern, Janssen, Ross, & Katzmarzyk, 2004).

Fat mass is a third anthropometric measure used in relation to overweight and obesity. In young adults, body fat > 25% in men and > 35% in women is defined as obesity (Deurenberg, Yap, & van Staveren, 1998). Determination of fat mass can be done using techniques such as measurement of total body water, densitometry, or dual energy X-ray absorptiometry, all of which require sophisticated equipment and are impractical in many clinical and research settings. A more convenient method is bioelectrical impedance analysis. A device sends a weak current from hand to hand, or foot to foot, provides a measure of total body water, and gives estimates of body fat and fat free mass (Jebb et al., 2009).

Although correlations between these anthropometric measures may vary by age, gender, and ethnicity (Deurenberg et al., 1998), studies conclude that BMI, waist circumference, and fat mass are highly correlated and all associated with risk of cardio-metabolic disease (Festa et al., 2001; Taylor et al., 2010).

1.3 Causes and drivers of obesity

The direct physiological cause of obesity is an imbalance in intake (i.e., diet) and expenditure (i.e., physical activity) of energy over time, but there are controversies

regarding the actual contribution of reduced levels of physical activity and changed diet to increases in weight on the population level (McAllister et al., 2009; Speakman & O'Rahilly, 2012). Underlying mechanisms and drivers of overweight and obesity comprise a complex interaction of individual, social, environmental, and political components connected by a diversity of pathways (Frood, Johnston, Matteson, & Finegood, 2013; Gortmaker et al., 2011; Swinburn et al., 2011).

On the individual level, predisposing genes contribute significantly to the development of obesity (Silventoinen & Kaprio, 2009; Silventoinen, Rokholm, Kaprio, & Sorensen, 2010) and seem to interact with factors such as physical activity, diet, and attempts of weight loss (Choquet & Meyre, 2011). Many biological factors are in play and interplay with environmental influences, e.g., endocrine disrupters, microorganisms, and medication use (Dhurandhar & Keith, 2014; McAllister et al., 2009). Societal changes over time affect individual behaviours and lead to more sedentary living (Bauman et al., 2011), low levels of physical activity (Hansen, Kolle, Dyrstad, Holme, & Anderssen, 2012), motorised transport habits (Fyhri, Hjorthol, Mackett, Fotel, & Kytta, 2011; McCormack & Virk, 2014), and poor dieting (Caraher et al., 2010; Perez-Escamilla et al., 2012), thus contributing to the rise of obesity (Swinburn et al., 2011). Factors in the family, such as unfavourable eating patterns (Fulkerson, Larson, Horning, & Neumark-Sztainer, 2014; Skardal, Western, Ask, & Overby, 2014), lack of healthy food, and lack of equipment and family support for physical activity (Kegler, Swan, Alcantara, Feldman, & Glanz, 2014), impact negatively on health-related behaviours and body weight of individuals (Sund, Jones, & Midthjell, 2010). The experience of stigma related to obesity seems to lead to more eating in individuals who are or perceive themselves as overweight (Major, Hunger, Bunyan, & Miller, 2014; Tomiyama, 2014).

In high-income countries, the prevalence of obesity is generally highest in individuals with low socio-economic status (McLaren, 2007; Mitchell, Catenacci, Wyatt, & Hill, 2011; Roskam et al., 2010; Sund et al., 2010). Obesity spreads along social ties (Christakis & Fowler, 2007) and is boosted by neighbourhood environment and

characteristics, in terms of low educational level (Sund et al., 2010; Wang, Kim, Gonzalez, MacLeod, & Winkleby, 2007), lack of economic resources (Ludwig et al., 2011; Wang et al., 2007), poor facilities for physical activity (Black & Macinko, 2008; Kegler et al., 2014; Toftager et al., 2011), and poor access to high-quality food (Black & Macinko, 2008; Wang et al., 2007).

On an overall level, policy, regulations, and structural factors affect health-related behaviours and obesity. Examples of areas of relevance are food production and trade, taxation, marketing, built, school, work place, other local environments, transportation, empowerment of populations, etc. (Allender et al., 2012; Barton, 2009; Caraher et al., 2010; Gortmaker et al., 2011; Jamison et al., 2013; Kohl et al., 2012; C. Mitchell, Cowburn, & Foster, 2011; Ottersen et al., 2014; Swinburn et al., 2011).

To illustrate the complexity of obesity, the British Foresight Group has mapped more than 100 variables with multiple linkages and feedback loops in what they call the obesity system (Vandenbroeck, Goossens, & Clemens, 2007). The map represents a socio-ecological understanding of obesity. Socio-ecological frameworks acknowledge that human behaviour and health problems are influenced by factors on many levels, i.e., the individual, interpersonal, social, environmental, and policy level, and recognise the connections between these levels (Green & Kreuter, 2005; McLeroy, Bibeau, Steckler, & Glanz, 1988; Stokols, 1996).

1.4 Consequences of obesity

Severe obesity reduces life expectancy by eight to ten years in high-income countries (Prospective Studies Collaboration, 2009). The spectrum of obesity-related comorbidities includes cardiovascular disease (Poirier et al., 2006), type 2 diabetes (Ginter & Simko, 2012), several cancers (Bhaskaran et al., 2014; De Pergola & Silvestris, 2013), obstructive sleep apnoea (Shah & Roux, 2009), muscular skeletal problems (Vincent, Heywood, Connelly, & Hurley, 2012), migraine (Bond, Roth, Nash, & Wing, 2011) and others. Anxiety, depression, and work-related problems are

prevalent in obese adults (Jagielski, Brown, Hosseini-Araghi, Thomas, & Taheri, 2014), and obesity leads to productivity losses (Neovius, Rehnberg, Rasmussen, & Neovius, 2012) and increases health care expenditures (von Lengerke & Krauth, 2011).

An inverse relationship between obesity and dimensions of quality of life has been demonstrated in many studies (Jagielski et al., 2014; Jia & Lubetkin, 2005; Larsson, Karlsson, & Sullivan, 2002; Soltoft, Hammer, & Kragh, 2009; Ul-Haq, Mackay, Fenwick, & Pell, 2013). Hence, obese adults participating in population studies have reported impaired overall satisfaction with life (Strine, Chapman, Balluz, Moriarty, & Mokdad, 2008; Wadsworth & Pendergast, 2014). Using generic questionnaires, other epidemiological studies have documented associations between high BMI and reduced health-related quality of life (Jia & Lubetkin, 2005; Larsson et al., 2002; Soltoft et al., 2009). A meta-analysis of studies, using sum-scores obtained from the generic instrument Medical Outcomes Study Short-Form 36 Health Survey (SF-36), revealed that the higher the BMI class (excluding underweight individuals) the worse the scores on the physical domain of health-related quality of life. The severely obese participants also reported impairment of the mental dimension (Ul-Haq et al., 2013). However, closer examinations, using generic or obesity-specific quality of life instruments, have suggested that severely obese individuals do not constitute a homogenous group. A comparative study by Kolotkin et al. (2002) found poorer obesity-specific quality of life in obese individuals seeking lifestyle interventions than in non-treatment seekers. The poorest quality of life has been found in obesity surgery seekers (Karlsson, Taft, Sjostrom, Torgerson, & Sullivan, 2003; Kolotkin et al., 2002; van Nunen, Wouters, Vingerhoets, Hox, & Geenen, 2007).

1.5 Management of severe obesity

When an individual experiences obesity-related problems serious enough to turn for help (Kolotkin et al., 2002; van Nunen et al., 2007) the health sector has the responsibility (Mechanick, Garber, Handelsman, & Garvey, 2012; Nygaard & Karikstad, 2009; Tsigos et al., 2008). Obesity *per se* is regarded a disease of a

progressive and relapsing nature (WHO, 2000), and it has been on the WHO International Classification of Diseases (ICD) list since it replaced the International List of Causes of Death in 1948 ("International Classification of Diseases", 2014). In Norway, severe obesity gives access to the health care system (Nygaard & Karikstad, 2009). The obligation to ameliorate the ailing health, functioning, and quality of life of treatment-seeking severely obese individuals (Kolotkin et al., 2002; van Nunen et al., 2007) has led to development of the three treatment modalities obesity surgery, obesity pharmacotherapy, and lifestyle interventions (Gloy et al., 2013; Tsigos et al., 2008). Obesity surgery works via physiological and functional changes which directly or indirectly lead to weight loss (Arterburn & Courcoulas, 2014; Kissler & Settmacher, 2013; Tsigos et al., 2008). Anti-obesity drugs have modest effect on weight loss in combination with change of diet (Franz et al., 2007; Li et al., 2005). Only one generic drug, Orlistat, is approved in Norway (*[Felleskatalogen]*, 2014). Multi-component lifestyle interventions work through self-management and individual modifications of health-related behaviours, i.e., diet and physical activity (Dalle Grave et al., 2013; Kirk et al., 2012; Wadden, Webb, Moran, & Bailer, 2012). When compared, obesity surgery seekers generally have higher BMI than lifestyle intervention seekers (Kolotkin et al., 2002; van Nunen et al., 2007). In terms of weight loss, surgery is usually more successful than lifestyle interventions (Gloy et al., 2013; Karlsen, Lund, et al., 2013), whereas multi-component lifestyle interventions seem to result in more favourable diet patterns (Johnson et al., 2013) and higher levels of physical activity (Hofso et al., 2010). Weight loss of 5-10% is regarded sufficient to gain health effects and reduce risks of obesity-related comorbidities (Cannon & Kumar, 2009; Dalle Grave et al., 2013; Goodpaster et al., 2010; Tsigos et al., 2008).

1.6 Lifestyle interventions

The term “lifestyle” in relation to severely obese individuals is very often used narrowly with reference to individual choices over individual health-related behaviours. This diverges from an understanding of the complexity of and a socio-ecological perspective on obesity. However, broader understandings of the concept of

lifestyle recognise that the choices and behaviours of individuals are interdependent on structures shaped by social class, age, gender, education, material resources, belonging to social groups, etc. Taking everything into consideration, it appears that change of individual lifestyle may be very challenging and include many potential barriers, not only due to individual but also extra-personal factors (Cockerham, 2005; Green & Kreuter, 2005; McLeroy et al., 1988).

Despite their significance, social and environmental factors are usually not considered in obesity management. Individual approaches are dominating (Kirk & Penney, 2013; Kirk et al., 2012), and reviews summarising the body of knowledge on lifestyle interventions recommend intrapersonal modification of physical activity and diet and includes behavioural therapy (Dalle Grave et al., 2013; Kirk et al., 2012; Shaw, O'Rourke, Del Mar, & Kenardy, 2005; Wadden et al., 2012). This kind of multi-component programmes has demonstrated better weight-related outcomes than single-component interventions (Dalle Grave et al., 2013; Johnston et al., 2014; Kirk et al., 2012; Wadden et al., 2012). Group based programmes seem to produce more weight loss than individual therapy (Cresci et al., 2007; Paul-Ebhohimhen & Avenell, 2009; Renjilian et al., 2001). Allocation of trained health professionals (Dalle Grave et al., 2013; Kirk et al., 2012) and follow-up over time (Franz et al., 2007; Kirk et al., 2012) are emphasised to achieve sustained behaviour change. Continued adherence to changed behaviour and maintenance of weight loss are namely unresolved challenges in the lifestyle management of obesity (Dalle Grave et al., 2013; Kirk et al., 2012).

Much research on lifestyle interventions have examined the effect on body weight (Aadland, Andersen, Anderssen, & Kvalheim, 2013; Anderson, Conley, & Nicholas, 2007; Dalle Grave et al., 2013; Danielsen, Svendsen, Maehlum, & Sundgot-Borgen, 2013; Goodpaster et al., 2010; Karlsen, Sohagen, & Hjelmesaeth, 2013; Kirk et al., 2012; Wadden et al., 2012). A meta-analysis of obesity interventions, excluding obesity surgery, observed a 5% to 9% weight loss during the first six month, followed by a level off to 4.8% to 8% at year one and 2% to 5% at year two (Franz et al., 2007). The Look AHEAD study, which is unique because of the large number of participants (N = 5,145), the randomisation to either an intervention (prescription of diet and

physical activity combined with group and individual support sessions) or a control (usual care) group, the low attrition, and the length of the intervention (i.e., eight years), reported a 4.7% weight loss at year eight in overweight to severely obese subjects with type 2 diabetes (Look Ahead Research Group, 2014). Multi-component lifestyle interventions also benefit body composition and reduce cardio-metabolic risk factors (Aadland, Andersen, et al., 2013; Anderson et al., 2007; Danielsen et al., 2013; Goodpaster et al., 2010).

1.6.1 Cognitive behavioural therapy

So, in multi-component lifestyle interventions for severely obese adults, cognitive behavioural therapy constitutes one of the three cornerstones. The therapy targets thinking habits and provide strategies and tools which support modification of physical activity and diet and maintenance of the changed behaviours. Goal setting, self-monitoring, stimulus control, alternative behaviours, addressing dysfunctional thinking, cognitive restructuring, and problem solving are amongst the techniques which should be learned from the therapy (Dalle Grave et al., 2013; Tsigos et al., 2008; Wadden et al., 2012).

1.6.2 Diet

Diet is the second cornerstones of lifestyle interventions (Dalle Grave et al., 2013; Kirk et al., 2012; Wadden et al., 2012). For weight loss, a relative reduction of energy intake of 500-1,000 kcal/day is recommended to produce a weight loss of 0.5-1.0 kg/week (Dalle Grave et al., 2013). Individuals with body weight < 114 kg should consume 1,200-1,500 kcal/day, whereas persons with weight ≥ 114 kg need 1,500-1,800 kcal/day (Dalle Grave et al., 2013; Wadden et al., 2012). The effect of a variety of specific dietary regimes of various macronutrient compositions has been studied, and the overall conclusion is that reduction of calorie intake is more critical for weight loss than prescription of specific regimes (Johnston et al., 2014; Kirk et al., 2012; Wadden et al., 2012). Thus, recommendations are usually general and emphasise a balanced diet including ≤ 30% of calories from fat, with 7-10% from saturated fat, 15% from proteins, and ≤ 55% from carbohydrates, with ≤ 10% from refined sugar

(Becker et al., 2004; Wadden et al., 2012), but medical comorbidities, personal preferences, and long-term adherence should also guide the diet composition (Wadden et al., 2012).

1.6.3 Physical activity

Physical activity is the third cornerstone of multi-component lifestyle interventions (Dalle Grave et al., 2013; Kirk et al., 2012; Wadden et al., 2012), and, as stated earlier, it is the health-related behaviour examined in this thesis. Physical activity is defined as: "any bodily movement produced by skeletal muscles that results in energy expenditure" (Caspersen, Powell, & Christenson, 1985, p. 126). Physical activity is a complex behaviour (Biddle & Fuchs, 2009; Caspersen et al., 1985), which, in line with other lifestyle factors (Cockerham, 2005; Green & Kreuter, 2005; McLeroy et al., 1988), is under the influence of individual choices as well as social and environmental factors (Bauman et al., 2012; Black & Macinko, 2008; Fyhri et al., 2011; Kegler et al., 2014; McCormack & Virk, 2014; Toftager et al., 2011). Multiple psychological factors influence the physical activity of individuals, e.g., self-efficacy and perceived control (Biddle & Fuchs, 2009). Physical activity includes sports and non-sports activities, such as house-hold, occupational, and leisure-time activities, and transportation (Plasqui & Westerterp, 2007). For public health purposes, the Norwegian recommendation for adults is to complete a minimum of 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity physical activity per week or a combination of these. The activity may be accumulated of bouts of at least ten minutes duration. This should be combined with strength training at least two days per week. Sedentary time should be reduced. Objectively assessed physical activity in the Norwegian adult population revealed that only 31% (34% of women and 28% of men) reached the recommended 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity physical activity per week. Higher education increased the probability of reaching the minimum recommendations, whereas overweight and obesity were related to lower levels of physical activity (Hansen, Kolle, & Anderssen, 2014). This association has also been documented in many other studies (Hagstromer,

Oja, & Sjostrom, 2007; Hansen, Holme, Anderssen, & Kolle, 2013; Tudor-Locke, Brashear, Johnson, & Katzmarzyk, 2010).

The recommendation for physical activity for weight loss is 180 minutes/week of moderate-intensity aerobic activity such as brisk walking, preferably combined with strength training. For maintenance of weight loss, physical activity should increase to 200-300 minutes/week. Bouts of activity can be as short as ten minutes (Wadden et al., 2012). Due to the negative energy balance imposed, diet modifications generally produce more weight loss than physical activity (Curioni & Lourenco, 2005; Franz et al., 2007; Wadden et al., 2012; Wu, Gao, Chen, & van Dam, 2009). Relying solely on physical activity for weight loss is problematic, because it requires an unrealistic volume for most individuals (Wadden et al., 2012). Still, physical activity plays a significant role in multi-component lifestyle interventions for several reasons (Dalle Grave et al., 2013; Kirk et al., 2012; Wadden et al., 2012). First, in combination with modifications of diet, it contributes to weight loss and maintenance of weight loss (Catenacci & Wyatt, 2007; Curioni & Lourenco, 2005; Look Ahead Research Group, 2014; Wadden et al., 2012). In the Look AHEAD study, self-reported physical activity was associated with initial and maintained weight loss in overweight to severely obese adults with type 2 diabetes (Look Ahead Research Group, 2014). A review has estimated that a prescription of 30-60 minutes of moderate-intensity physical activity 3-5 days per week resulted in 1-3 kg weight loss in overweight to obese adults (Aadland & Anderssen, 2013). Beyond weight loss, physical activity benefits body composition (Aadland, Jepsen, Andersen, & Anderssen, 2014; Miller et al., 2013), improves aerobic fitness (Aadland, Jepsen, Andersen, & Anderssen, 2013; Miller et al., 2013), and reduces cardio-metabolic comorbidities (Fogelholm, 2010; Gill & Malkova, 2006; Goodpaster et al., 2010).

For evaluation of interventions involving physical activity, monitoring of actual activity is important (Prince et al., 2008; Warren et al., 2010). Motion sensors, e.g., accelerometers or pedometers, provide objective assessments of physical activity, which offer more accuracy than self-reported data from questionnaires or activity diaries (Plasqui & Westerterp, 2007; Prince et al., 2008). Accelerometers are typically

waist-mounted, measure acceleration of the body, and are especially suitable for monitoring of walking and running. The raw data are converted to counts, which is an arbitrary unit derived from the frequency and the amplitude of the vertical accelerations obtained (Warren et al., 2010). Only recently, studies started assessing the actual physical activity of participants in lifestyle interventions using objective measures, and research on associations with subjective phenomena – as for example quality of life – are missing (Aadland, 2013).

1.6.4 Quality of life and lifestyle interventions

Generally, prospective studies examining the quality of life of participants in lifestyle interventions have found significant improvements over time (Blissmer et al., 2006; Danielsen, Sundgot-Borgen, Maehlum, & Svendsen, 2014; Karlsen, Lund, et al., 2013; Kaukua, Pekkarinen, Sane, & Mustajoki, 2003). In the study by Blissmer et al. (2006), the improvement was independent of reduction of BMI, whereas Danielsen et al. (2014) found that improvement in the physical dimension of quality of life was associated with weight loss. The authors of all the studies proposed that physical activity could be a contributor to unexplained improvements in quality of life during the interventions but the proposal has not been examined (Blissmer et al., 2006; Danielsen et al., 2014; Karlsen, Lund, et al., 2013; Kaukua et al., 2003). However, cross-sectional data on overweight to severely obese individuals have demonstrated associations between self-reported physical activity and quality of life outcomes (Lerdal et al., 2011; Wang, Sereika, Styn, & Burke, 2013). A review of population and intervention studies using self-reports found a similar relationship but did not consider the interaction of BMI (Bize, Johnson, & Plotnikoff, 2007).

1.6.5 The complexity of lifestyle interventions

Taking everything into consideration, multi-component lifestyle interventions are clearly not simple measures with linear working mechanisms, straightforward change processes, and easily achieved endpoints (Lian, 2012; Ottersen et al., 2014). Rather, they include many features characterising complex interventions, e.g., several interacting components, challenges in providing support tailored for the individual,

complexities of behaviour change processes, and a variety of relevant endpoints. Recognising multi-component lifestyle interventions as complex implies that they should be described in details, change processes should be understood, and a variety of endpoints be examined (Craig et al., 2008).

1.7 Health promotion

In Norway, as well as internationally, lifestyle interventions for severely obese individuals are situated in the health sector (Mechanick et al., 2012; Tsigos et al., 2008) and guided by a medical paradigm (Kirk & Penney, 2013; Lian, 2012; Ottersen et al., 2014). Severe obesity is a medical diagnosis (WHO, 2014), the individuals are labelled as patients, and the condition gives right to specialist health care (Nygaard & Karikstad, 2009). A commonly used Norwegian term for lifestyle intervention is "lifestyle treatment" [livsstilsbehandling]. The word "treatment" indicates that "something (…) is done to cure an illness or injury" (Hornby, Wehmeier, & Ashby, 2000, p. 1386), which – in health care – implies that a health professional or a team of health professionals does something to a patient to cause a positive effect on a health problem (Lian, 2012; Ottersen et al., 2014). However, it could be questioned if the use of the term "treatment" about multi-component lifestyle interventions gives full justification to their complexity, as described in chapter 1.6.

To summarise, this thesis is concerned with a complex problem (severe obesity), a complex intervention (multi-component lifestyle intervention), and substantial challenges for the severely obese individuals and health professionals involved (change of health-related behaviour). This has called for a broader approach than a simplistic cause-and-effect approach as in the medical paradigm (Lian, 2012; Ottersen et al., 2014). Therefore, this thesis has found inspiration in a health promotion framework. The Ottawa Charter's definition of health promotion is well in line with the aim of multi-component lifestyle interventions: "(…) the process of enabling people to increase control over, and to improve, their health" (*Ottawa Charter for Health Promotion*, 1986, p. 1). The Ottawa Charter highlighted the wider political and social circumstances framing health and quality of life of groups and individuals. The

shift it represented, when it was developed in the 1980's, from disease management and prevention to a broad conceptualisation of health and its contributors, has inspired many health professionals (Scriven, 2005; Stokols, 1996). Scriven (2005) has proposed a four levelled classification of health promotion practice. Interventions targeting individuals or groups who are either healthy or at-risk of health problems belong to the primary and secondary level, respectively. The tertiary level of health promotion activities is concerned with individuals with a chronic condition, and the quaternary level encompasses terminally ill individuals. Defining severe obesity as a chronic condition (WHO, 2000) implies that this thesis deals with health promotion practice on the tertiary level (Scriven, 2005).

1.8 The PRECEDE-PROCEED model

The PRECEDE-PROCEED model (Figure 1) is a framework for health promotion practice and research based on socio-ecological theoretical principles (Green & Kreuter, 2005). As stated earlier, this implies recognition of interrelated, multi-levelled mechanisms and drivers, which contribute to the health and health-related behaviour of individuals and groups (Green & Kreuter, 2005; McLeroy et al., 1988; Stokols, 1996). The PRECEDE-PROCEED model was developed by Green and Kreuter (2005) as a framework to guide planning and evaluation of health promoting programmes. PRECEDE is an abbreviation for *p*redisposing, *r*einforcing, and *e*nabling *c*onstructs in *e*ducational/*e*cological *d*iagnosis and *e*valuation, whereas PROCEED stands for *p*olicy, *r*egulatory, and *o*rganisational *c*onstructs in *e*ducational and *e*nvironmental *d*evelopment. Phase 1-4 of the model constitute steps of pre-intervention assessments and planning. Phase 5 is the implementation phase. Phase 6-8 represent evaluation of programmes, including processes of change, impact on factors which affect health-related behaviours, and outcomes or endpoints. The boxes illustrate multi-levelled factors affecting health and quality of life of individuals and groups, and the arrows indicate interrelationships (Figure 1). Although most of the arrows suggest one-way directions, Green and Kreuter acknowledged that associations between factors may be bi-directional (Green & Kreuter, 2005).

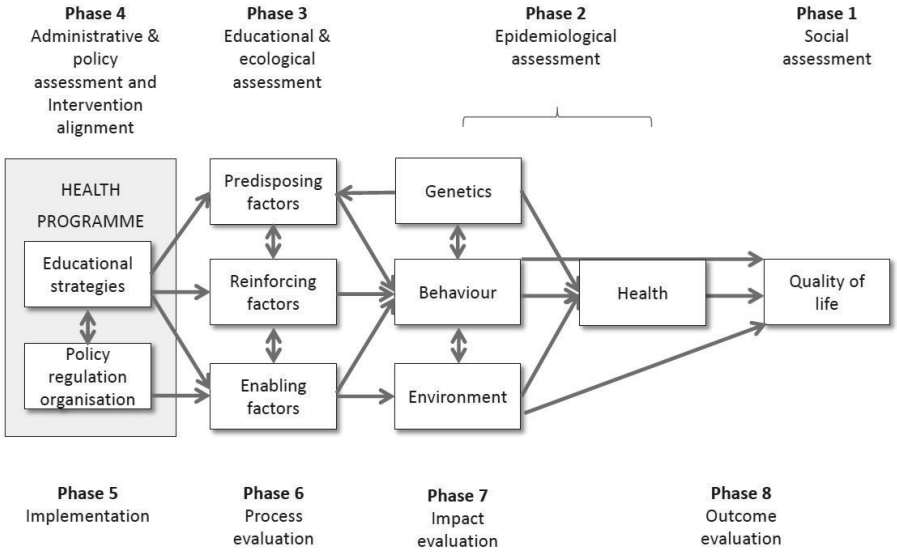

Figure 1 The PRECEDE-PROCEED model (adapted from Green and Kreuter (2005, p. 10))

The PRECEDE-PROCEED model has been applied for many purposes, in various fields, and on many levels, e.g., health care for patient groups, community programmes, and policy analyses and planning (Green & Kreuter, 2005). In many cases, only parts of the model have been applied. To illustrate, some studies are descriptive, pre-intervention assessments, such as a study on factors related to the diet of male Hispanics in Mississippi (Cuy Castellanos et al., 2013). Other studies have evaluated outcomes of health programmes, for instance effects of web-based information about colorectal cancer screening (Chen, Yamada, & Smith, 2014). The PRECEDE-PROCEED model has been evaluated as a solid framework for complex health problems and interventions (Cuy Castellanos et al., 2013; Phillips, Rolley, & Davidson, 2012; Tramm, McCarthy, & Yates, 2012).

1.9 Patient-reported outcomes

Many dimensions of relevance for health interventions and research are subjective of nature. To capture patient perspectives, self-reported outcomes are essential. In quantitative research, self-reported outcomes are often assessed using questionnaires (Ahmed et al., 2012; Coulman et al., 2013). Linked to the PRECEDE-PROCEED model, self-reported data can provide information about quality of life, and dimensions of health (depending on the definition of health, refer to chapter 1.9.1), behaviour, and environmental factors as well as predisposing, reinforcing, and enabling factors. Thus, self-reported data should be included in both pre-intervention assessments and process, impact, and outcome evaluations (Figure 1) (Green & Kreuter, 2005). This thesis used self-reported data on quality of life outcomes and predisposing factors for physical activity.

1.9.1 Quality of life

According to Green and Kreuter (2005), quality of life is the point of departure for health promotion assessments and the desired endpoint for health promotion interventions (Figure 1). Thus, in the PRECEDE-PROCEED model, health and quality of life are separated. In order to define the distinction between them and avoid overlap (Fayers & Machin, 2007), this thesis has operationalised health as a narrow, bio-medical construct inspired by Boorse (1977). Disease is thus understood as biological and physiological statistical deviation from normality, implying that health is the absence of disease. The present thesis has used BMI as a proxy for health, justified by the positive associations between obesity and a variety of health hazards (Bhaskaran et al., 2014; Bond et al., 2011; De Pergola & Silvestris, 2013; Ginter & Simko, 2012; Poirier et al., 2006; Shah & Roux, 2009; Vincent et al., 2012).

Quality of life, thus, is a construct beyond the health-disease dichotomy, although it is influenced by it (Green & Kreuter, 2005). The term is used extensively without being well defined, but there is broad consensus that quality of life is based on personal appraisal and therefore subjective and non-static by nature (Fayers & Machin, 2007;

Moons, Budts, & De Geest, 2006). Most researchers also agree that quality of life is multi-dimensional (Fayers & Machin, 2007). Acknowledging that health has impact on quality of life, the concept health-related quality of life is commonly applied in health research. Usually, assessments of health-related quality of life include at least physical, mental, and social dimensions. For application and comparison across patient and general populations, generic instruments are useful. For disease-, condition-, or domain-specific purposes, a variety of instruments are available. They measure specific issues most pertinent to specific groups (Fayers & Machin, 2007). In obesity research, it is recommended to use both generic and obesity-specific instruments to assess health-related quality of life (Karlsson et al., 2003).

Compared to health-related and condition-specific quality of life, life satisfaction is a broader construct, which represents a global, relative, and multi-dimensional assessment of life reaching beyond health-related dimensions (McDowell, 2010). One-item instruments are widely applied in research, and psychometric testing has concluded that they are reliable and valid (Zimmerman et al., 2006). Similar one-item measures on self-reported health predicted mortality in 23 out of 27 community studies included in the review by Idler and Benyamini (1997).

1.9.2 Predisposing factors for physical activity

According to Green and Kreuter (2005), predisposing factors are antecedents of behaviour change and include "a person's or population's knowledge, attitudes, beliefs, values, and perceptions that facilitate or hinder motivation for change" (Green & Kreuter, 2005, p. 14). Through various, indirect working mechanisms, socio-demographic characteristics are included in predisposing factors (Green & Kreuter, 2005).

Multi-component lifestyle interventions for severely obese adults target predisposing factors as a means to increase the physical activity of the participants (Olander et al., 2013). Self-efficacy, perceived behavioural control, and self-identity are examples of

predisposing factors which interventions including physical activity may have an impact on (Stokols, 1996).

Self-efficacy is a component of Bandura's social cognitive theory (Bandura, 1997). The theory recognises that people exercise control and act under the influence of individual as well as social and environmental factors. Actions require not only skills but also self-efficacy which refers to "a belief about what one can do under different sets of conditions with whatever skills one possesses" (Bandura, 1997, p. 37). Self-efficacy is modifiable and dynamic and thus related to experience, reflectivity, and learning individually and in interplay with the environment (Bandura, 1997). One review concluded that self-efficacy predicted change in various health-related behaviours (Strecher, DeVellis, Becker, & Rosenstock, 1986), and another suggested that it predicted weight loss in overweight to obese adults participating in lifestyle interventions (Teixeira, Going, Sardinha, & Lohman, 2005). Bandura acknowledged that change of health-related behaviour, such as physical activity, is challenging due to many potential barriers. Amongst these are psychological barriers, meaning difficulties to get oneself to be physically active when one is tired, sad, or otherwise not feeling well (Bandura, 1997). Self-efficacy in the face of psychological barriers has shown positive cross-sectional associations with accelerometer assessed physical activity (Hansen, Ommundsen, Holme, Kolle, & Anderssen, 2014) and has been proposed as a valid target for physical activity interventions (Hansen, Ommundsen, et al., 2014; Lorentzen, Ommundsen, & Holme, 2007).

Perceived behavioural control is a component of Ajzen and Madden's theory on planned behaviour (Ajzen & Madden, 1986). They defined it as a "person's belief as to how easy or difficult performance of the behaviour is likely to be" (Ajzen & Madden, 1986, p. 457). It has been disputed if self-efficacy and perceived behavioural control may be synonymous (Ajzen, 1991; Conner & Armitage, 1998; Conner & Sparks, 2005). However, the "can do" wording of self-efficacy instruments (Bandura, 1997; Conner & Sparks, 2005) is supplemented with items on perceived difficulties in questionnaires measuring perceived behavioural control, thus capturing a different

construct (Conner & Sparks, 2005; Sparks, Guthrie, & Shepherd, 1997). Perceived behavioural control seems to operate as an explanatory factor for various health-related behaviours (Godin & Kok, 1996). It has shown positive cross-sectional associations with accelerometer assessed physical activity (Hansen, Ommundsen, et al., 2014) and has been proposed as a valid target for physical activity interventions (Hansen, Ommundsen, et al., 2014; Lorentzen et al., 2007).

A person's self-identity grows out of a dynamic interrelation between personal behaviours and experiences on the one side and social expectations, perceptions, and responses on the other. The stronger and more essential a role-identity is for a person the more expected it is to predict behaviour (Charng, Piliavin, & Callero, 1988). The concept of physical activity identity represents self-identification with being a physically active person (Lorentzen et al., 2007). It has shown predictive value for self-reported physical activity (Jackson, Smith, & Conner, 2003) and positive cross-sectional associations with accelerometer assessed physical activity (Hansen, Ommundsen, et al., 2014). Physical activity self-identity may be a predisposing factor for change in physical activity (Lorentzen et al., 2007) and has been proposed as a valid target for physical activity interventions (Hansen, Ommundsen, et al., 2014; Jackson et al., 2003; Lorentzen et al., 2007).

2. Purpose of the study

In summary, this thesis has drawn on a complexity and socio-ecological understanding of obesity and has been inspired by the PRECEDE-PROCEED model. Knowledge on associations between objectively assessed physical activity and self-reported data, including predisposing factors and quality of life outcomes, is limited in severely obese adults participating in multi-component lifestyle interventions. Therefore, the aims of this thesis were:

1. To investigate the associations between objectively measured physical activity and life satisfaction, physical functioning, and mental health in severely obese adults prior to the beginning of a lifestyle intervention (**Paper I** (Jepsen, Aadland, Andersen, & Natvig, 2013)).

2. To investigate the associations between the independent variables: change in self-efficacy for physical activity in the face of psychological barriers, perceived behavioural control over physical activity, and self-identity for physical activity and the dependent variable change of physical activity in severely obese adults during a two-year, multi-component lifestyle intervention (**Paper II** (Jepsen et al., 2014)).

3. To examine the associations between change in objectively assessed physical activity as the independent variable and change in physical, change in mental, and change in obesity-specific domains of health-related quality of life and change in life satisfaction as the dependent variables during a two-year, multi-component lifestyle intervention for severely obese adults (**Paper III** (Jepsen et al., In press)).

3. Materials and methods

This thesis is part of the Haugland Obesity Study which was a two-year prospective, observational study on severely obese adults participating in a two-year, intermittently residential lifestyle intervention at Red Cross Haugland Rehabilitation Centre (RCHRC) in Norway. The intervention was funded by the regional health authorities. For patients with jobs, the social welfare system paid sick leave benefits during the residential periods.

Referral of patients was done by general practitioners. In order to assess motivation for change and ability to function in a group, referred patients were called in to a two-week stay at RCHRC (Figure 2). Before discharge, further participation in the programme was decided. Due to limited capacity of the centre, the time from referral to this assessment stay was up to two years. Fifty-three patients, divided in four groups, started the actual intervention and were all offered inclusion in the study. After the intake of these four groups the health authorities reduced the funding, and the intervention for future patients was cut down to a one-year programme, including three shorter residential stays. Thus, further inclusion of study participants was hampered (Jepsen et al, 2014).

Inclusion criteria were age between 18-60 years and severe obesity, i.e., BMI ≥ 40 kg/m^2 with or without comorbidities, or ≥ 35 kg/m^2 with comorbidities (Nygaard & Karikstad, 2009). Exclusion criteria were: referral to, or, previous obesity surgery, severe cardiovascular disease, pregnancy, alcohol or substance abuse, and mental illness or physical impairment that would compromise adherence to the intervention (Jepsen et al., 2013, Jepsen et al., 2014; Jepsen et al., In press).

The data collection was accomplished between February 2010 and October 2012. We assessed the participants before, during, and between residential periods. For Paper I (Jepsen et al., 2013) we used baseline data and for Paper II (Jepsen et al., 2014) and III (Jepsen et al., In press), we used data from four time points. The baseline data (T0)

were collected prior to the start of the intervention. The second data collection (T1) took place six weeks later at the end of the first residential stay. The third (T2) and fourth (T3) data collection were completed before the residential stay one and two years from baseline (Figure 2).

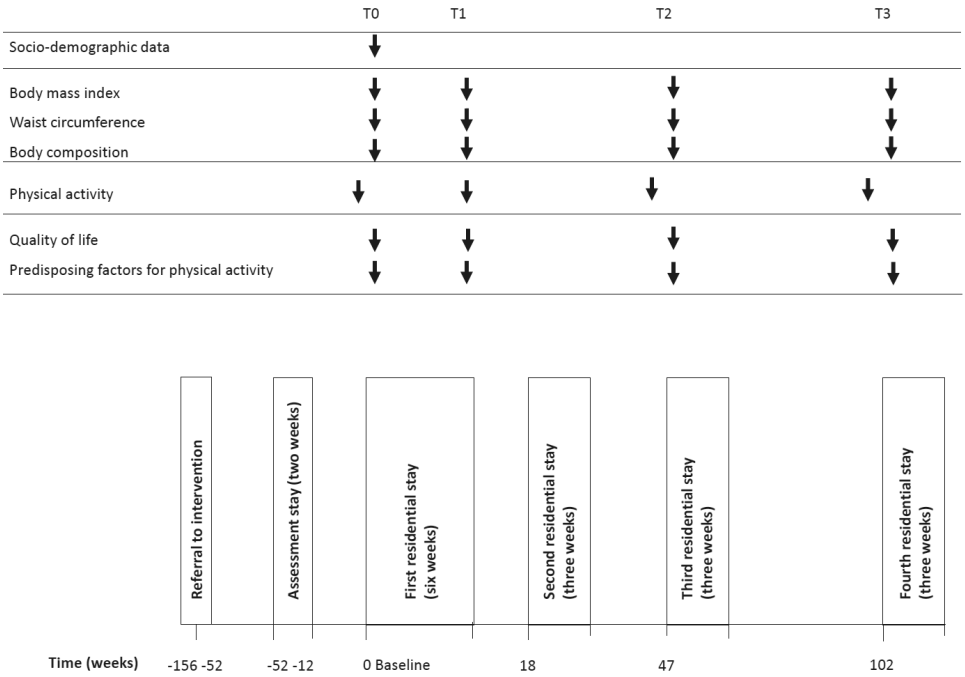

Figure 2 Study protocol (adapted from Aadland (2013, p. 37)

3.1 Intervention

The multi-component lifestyle intervention was described in details in Paper II of this thesis (Jepsen, et al., 2014). It was developed by the health professionals at RCHRC, based on recommendations for best practice (Dalle Grave et al., 2013; Kirk et al., 2012; Olander et al., 2013; Shaw et al., 2005) and prior experience. The aim was a sustainable increase of physical activity and improvement of diet. The intervention covered 15 weeks over two years with four residential stays of six, three, three, and three weeks' duration (Figure 2). A team of physicians, nurses, physiotherapists, exercise therapist, and dietician delivered mandatory practical and theoretical sessions

on physical activity, diet, and cognitive behavioural therapy. The physical activity consisted of supervised and un-supervised out- and indoor activities, in groups and individually. Brisk walking, swimming, strength training, ball games, and aerobics were the predominant activities during the residential periods, bringing on moderate to vigorous intensities of physical activity. The scheduled physical activity lasted 20-60 minutes per session, in total nine to eleven hours per week. In addition, the patients were encouraged to carry out physical activity on their own initiative. Each patient developed a plan for physical activity for home periods, taking limitations, preferences, and long-term adherence into account. The plan was discussed with staff. A combination of endurance and strength training for at least 60 daily minutes, which could be accumulated of bouts of down to ten minutes, were recommended (Becker et al., 2004; Wadden et al., 2012). Thus, no standard exercise programme was performed in between the residential periods.

The main goal regarding diet was adaptation to a sustainable, healthy diet and a favourable eating-pattern. The meal plan at RCHRC was based on the Nordic Nutrition Recommendations including ≤ 30% of calories from fat, with ≤ 10% from saturated fat, 15% from proteins, ≤ 55% from carbohydrates, with ≤ 10% from refined sugar (Becker et al., 2004). The composition of the meal plan included three low-fat, high-fibre, and energy-reduced meals and two to three snacks per day. Severe energy-restriction was not applied. Most of the meals were provided by the canteen, but the patients prepared some of their meals in groups supervised by the dietician, and they ate together. They were advised to comply with the same dietary principles at home.

In total, eleven group sessions of cognitive behavioural therapy took place. They were led by members of the health care team who had training in cognitive behavioural therapy. Five sessions were scheduled during the six-week residential stay and two during each of the subsequent three three-week periods. Before the end of each session, home work was given, and the following session started with a review of that. In sessions 1-5, during the first stay, the methods and instruments of cognitive behavioural therapy were introduced and related to change in physical activity and

diet. When the patients came back for the subsequent stays, experiences from the home periods were discussed in sessions 6-11 within the framework of cognitive behavioural therapy. For eight patients who expressed a need, individual cognitive behavioural therapy was also provided.

Goal setting, problem solving, planning, time management, barrier identification, relapse prevention and management, and control training were practiced to strengthen self-management of physical activity and diet (Dalle Grave et al., 2013; Olander et al., 2013). Instruction, practice, and feedback were used to improve knowledge and skills in the physical activity sessions, and the group-based activities were meant to stimulate peer support (Olander et al., 2013). Self-monitoring was promoted using physical activity diaries (Dalle Grave et al., 2013; Olander et al., 2013; Wadden et al., 2012), which the patients sent to RCHRC every month during the home periods. Feedback was not given, and there was no other structured follow-up of patients between the residential stays. Instead, they were encouraged to contact their general practitioner if they needed more support. There was no involvement of relatives in the intervention.

3.2 Measures

3.2.1 Physical activity

In all three papers, data on physical activity were obtained using the ActiGraph GTI M accelerometer (ActiGraph, Fort Walton Beach, FL, USA). The accelerometer is an electronic movement sensor that registers vertical acceleration and converts it into the unit “counts” which increases with the magnitude of the work rate for walking. The participants were instructed to wear the accelerometer over the right hip for seven consecutive days while awake, except during water activities. The baseline (T0), year one (T2), and year two (T3) assessments took place in home periods, while the week six (T1) assessment was carried out at the end of the first residential stay. The ActiGraph software ActiLife v. 5.3 was used for the data analysis. The criterion for a valid measure was wear-time of ≥ ten hours per day for ≥ four days. Non-wear-time

was defined as periods of ≥ 60 consecutive minutes without counts, however allowing for up to two minutes of counts within these 60 minutes (Sirard, Forsyth, Oakes, & Schmitz, 2011; Trost, McIver, & Pate, 2005). The overall physical activity level, given as counts per minute, was calculated as total counts divided by total valid wear-time. The accelerometer has shown validity in severely obese individuals (Aadland & Anderssen, 2012), and accelerometer-assessed physical activity offers more accuracy than self-reported data (Prince et al., 2008).

3.2.2 Quality of life

SF-36

In Paper I (Jepsen et al., 2013) and III (Jepsen et al., In press), we used the generic instrument SF-36, Norwegian version 1.2 to assess health-related quality of life. SF-36 has 36 items of which scoring of 35 gives eight subscales representing physical functioning, physical role functioning, bodily pain, general health, vitality, social functioning, emotional role functioning, and mental health (Ware, Kosinski, & Gandek, 2000). We used the subscales on physical functioning and mental health as primary outcomes in Paper I (Jepsen et al., 2013), whereas the physical component summary (PCS) score and mental component summary (MCS) score (Ware & Kosinksi, 2001) were used as main SF-36 outcomes in Paper III (Jepsen et al., In press). PCS and MCS were generated from the subscales using the oblique method to account for correlations between physical and mental dimensions and standardised to a population normal distribution (mean = 50 and standard deviation (SD) = ten) (Ware & Kosinksi, 2001). The subscales cover a range from 0-100, with higher scores representing better health-related quality of life (Ware et al., 2000). PCS ranges from 15.4 to 62.1 and MCS from 10.1 to 64.0. For comparison we used Norwegian population data (Loge, Kaasa, Hjermstad, & Kvien, 1998). Extensive psychometric testing has shown that SF-36 is reliable and valid. It has been used in a considerable number of studies on a diversity of patient and general populations (Ware, 2000). SF-36 has been applied in many obesity studies (Ul-Haq et al., 2013; van Nunen et al., 2007), discriminates between subgroups of severely obese adults (van Nunen et al.,

2007), and is sensitive to change during lifestyle interventions (Danielsen et al., 2014; Karlsen, Lund, et al., 2013).

Obesity-Related Problems Scale

In paper III (Jepsen et al., In press), we used the obesity-specific instrument Obesity-Related Problems Scale (OP), Norwegian version 1.2, to assess everyday, psychosocial, obesity-related problems (Karlsson et al., 2003). OP comprises eight items regarding visits to restaurants, going on holiday, participating in community activities, swimming in public places, trying on and buying clothes, and intimate/sexual situations with four response alternatives from 1 ("definitely bothered") to 4 ("definitely not bothered"). The calibrated score ranges from 0-100 (< 40 mild, ≥ 40 to < 60 moderate, ≥ 60 to < 80 severe, and ≥ 80 extreme problems). In psychometric testing, OP version 1.1 demonstrated high reliability, discriminated between weight groups, and was sensitive to change during obesity treatment (Karlsson et al., 2003). A recent validation study of the Norwegian version 1.2 confirmed the reliability (Cronbach alpha coefficient = 0.89) and validity in severely obese adults (Aasprang, Andersen, Vage, Kolotkin, & Natvig, 2014).

Life satisfaction

In Paper I (Jepsen et al., 2013) and III (Jepsen et al., In press), life satisfaction was measured using a single item on a seven-step scale with alternatives from "very satisfied" to "very dissatisfied". One-item instruments on life satisfaction have demonstrated reliability in health research (Zimmerman et al., 2006). In Norwegian population studies, the instrument used in the present study has shown predictive value for later onset of type 2 diabetes (Naess, Eriksen, Midthjell, Tambs, & Nord-Trondelag Health Study, 2005) and strong associations with mental problems, poor self-reported health, and lack of social relations (Helvik, Engedal, Krokstad, & Selbaek, 2011).

3.2.3 Predisposing factors for physical activity

In paper II, we used three questionnaires to assess predisposing factors for physical activity (which were called psychological factors in the paper) (Jepsen, et al., 2014).

Self-efficacy for physical activity was assessed using a five-item instrument. The participants indicated the extent to which they were confident in their capability to perform planned physical activity in the face of psychological barriers (i.e., feeling tired, depressed, anxious, angry, and stressed) on a seven-point scale from 1 ("not at all confident") to 7 ("very confident"). The scale is a shortened and moderated version of the original instrument developed by Bandura (2001). The version used in this study has demonstrated excellent internal consistency with a Cronbach alpha coefficient of 0.91 (Hansen, Ommundsen, et al., 2014). The instrument has shown positive cross-sectional associations with objectively assessed physical activity in adults (Hansen, Ommundsen, et al., 2014).

Perceived behavioural control over physical activity was also assessed using a five-item instrument. The participants rated their agreement with three positive (e.g., "I have total control over being regularly physically active") and two negative statements (e.g., "Being regularly physically active is difficult for me") on a seven-point scale from 1 ("totally agree") to 7 ("don't agree at all"). The scale is an extended and moderated version of the original instrument developed by Norman and Smith (1995). The version used in this study has demonstrated acceptable internal consistency with a Cronbach alpha coefficient of 0.67 (Hansen, Ommundsen, et al., 2014). The instrument has shown positive cross-sectional associations with objectively assessed physical activity in adults (Hansen, Ommundsen, et al., 2014).

Physical activity self-identity was assessed using a three-item instrument. The participants indicated the extent to which they agreed with statements such as "Being physically active is a big part of who I am" on a five-point scale from 1 ("fits poorly") to 5 ("fits well"). The scale is a shortened and moderated version of the original instrument developed by Anderson and Cychosz (1994). The version used in this study

has demonstrated excellent internal consistency with a Cronbach alpha coefficient of 0.91 (Hansen, Ommundsen, et al., 2014). It has shown positive cross-sectional associations with objectively assessed physical activity in adults (Hansen, Ommundsen, et al., 2014).

3.2.4 Anthropometrics

Anthropometric data were collected by health staff at RCHRC. Height was measured without shoes to the nearest 0.5 cm using a wall mounted stadiometer (SECA, Germany). Weight and fat mass were measured in the morning, in a fasting state, after voiding, and in light clothes on a bioelectrical impedance analysis device (BC 420S MA, Tanita Corp, Tokyo, Japan). Weight and fat mass were reported to the nearest 0.1 kg. Waist circumference was measured twice at exhalation at the level of the umbilicus and reported as the mean of the two measurements.

3.2.5 Socio-demographic information

Socio-demographic information on age, gender, civil status, children, educational level, and work participation was obtained from self-reported questionnaires at baseline (T0).

3.2.6 Use of the PRECEDE-PROCEED model

The lifestyle intervention addressed in the present thesis was planned and implemented by staff at RCHRC before the start of the research project. The data collection comprised objective and self-reported data. Aadland and colleagues did a series of studies, exclusively using objective data, on patterns of change during the first year of intervention. Change in accelerometer assessed physical activity was the independent variable in three papers, which found a positive association with change in aerobic fitness (Aadland, Jepsen, et al., 2013), an inverse association with change in fat mass (Aadland et al., 2014), and favourable associations with change in lipoproteins (Aadland, Andersen, et al., 2013). The present thesis included data from the full length

of the intervention (i.e., two years) and combined objective data on physical activity with self-reported data on predisposing factors and quality of life.

Paper I

Figure 3 illustrates the use of the PRECEDE-PROCEED model (Green & Kreuter, 2005) in Paper I (Jepsen et al., 2013). The study was a pre-intervention assessment, in which we examined the association between accelerometer assessed physical activity and quality of life outcomes, i.e., physical functioning and mental health obtained from SF-36 and life satisfaction. We performed unadjusted and adjusted regression analyses. BMI was considered a proxy for health and used as control variable in addition to age and gender.

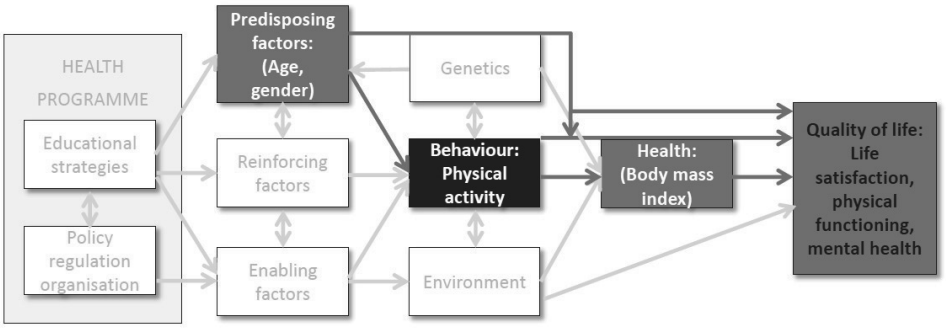

Figure 3 The PRECEDE-PROCEED model in Paper I (adapted from Green and Kreuter (2005, p. 10) (Jepsen et al., 2013)
Black box: independent variable; black writing: dependent variables; brackets: control variables

Paper II

Figure 4 illustrates the use of the PRECEDE-PROCEED model (Green & Kreuter, 2005) in Paper II (Jepsen et al., 2014). This study had a longitudinal design using data from all four time points. The intervention, which – as mentioned earlier – was developed and offered under the right to treatment in the specialist health care service (Nygaard & Karikstad, 2009) (refer to policy regulation and organisation in the model), was described in details (refer to educational strategies in the model). The arrow from the intervention indicates the intended influence on the three predisposing

factors, which were used as independent variables, i.e., self-efficacy for physical activity in the face of psychological barriers, perceived behavioural control over physical activity, and physical activity self-identity. We examined the associations between change in these variables and change in the dependent variable accelerometer assessed physical activity. We performed unadjusted and adjusted regression analyses. Age and gender were used as control variables in the latter. Again, change in BMI was considered a proxy for health and used as control variable. It should be added, that the intervention also targeted skills in physical activity, which falls under enabling factors (Green & Kreuter, 2005) but skills were not examined in the present study and therefore not brought out in Figure 4. Nor were enabling factors in the form of support from health staff and peers (Green & Kreuter, 2005).

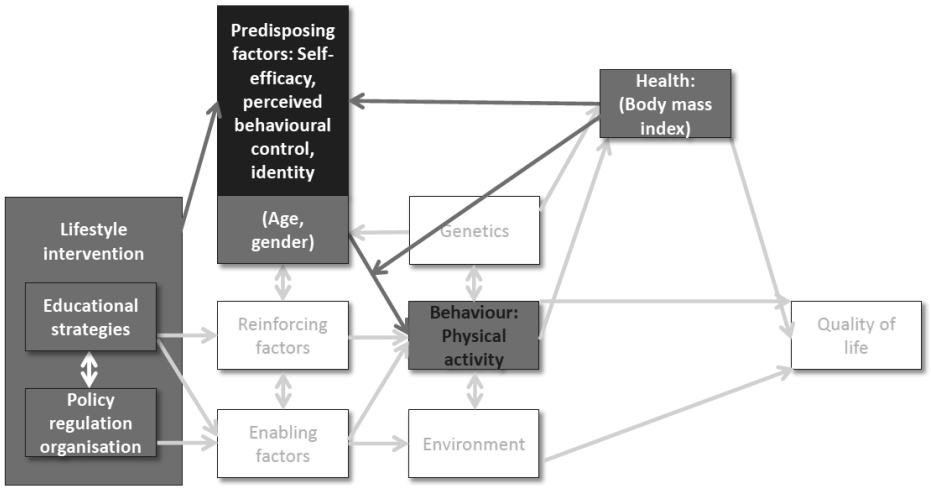

Figure 4 The PRECEDE-PROCEED model in Paper II (adapted from Green and Kreuter (2005, p. 10) (Jepsen et al., 2014)
Black: independent variables; black writing: dependent variable; brackets: control variables

Paper III

Figure 5 illustrates the use of the PRECEDE-PROCEED model (Green & Kreuter, 2005) in Paper III (Jepsen et al., In press). The study had a longitudinal design using data from all four time points. Change in accelerometer assessed physical activity was

the independent variable and we examined associations with change in quality of life outcomes, i.e., PCS and MCS derived from SF-36, obesity-specific quality of life, and life satisfaction. We performed unadjusted and adjusted regression analyses. As before, change in BMI was considered a proxy for health and used as control variable in addition to age and gender.

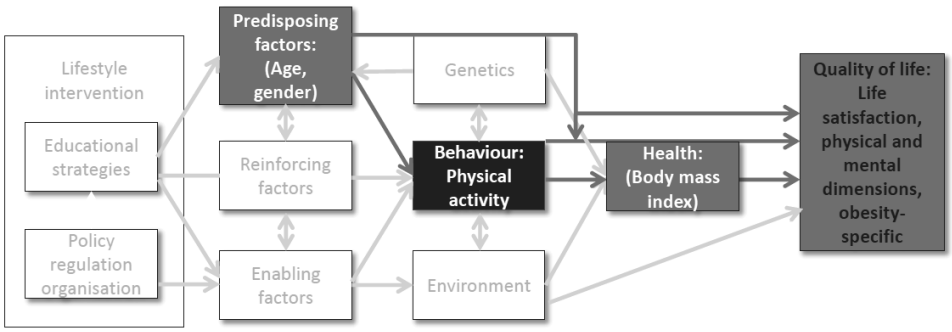

Figure 5 The PRECEDE-PROCEED model in Paper III (adapted from Green and Kreuter (2005, p. 10) (Jepsen et al., In press)
Black: independent variable; black writing: dependent variables; brackets: control variables

3.3 Statistical analyses

The scale on life satisfaction and the three positively worded items on perceived behavioural control over physical activity were reversed before data analysis. Thus, higher scores represented better life satisfaction and perceived control. Cronbach alpha was used to determine the internal consistency of the scale on self-efficacy for physical activity in the face of psychological barriers (0.92), perceived behavioural control over physical activity (0.67), physical activity self-identity (0.93), and OP (0.91).

Data on civil status, having children, educational level, and employment were dichotomised before data analysis. BMI was calculated as weight in kilograms divided by the square of the height in meters.

Anthropometric data, physical activity, and all self-reported data were analysed using descriptive statistics and presented as mean values and SD. Attrition analyses were done using the chi-squared test for differences in categorical variables and the independent samples *t*-test for differences in continuous variables.

In paper II (Jepsen et al., 2014) and III (Jepsen et al., In press), a linear mixed model based on restricted maximum likelihood estimation with random intercept for subjects was used in all analyses for change over time (Twisk, 2013), using least significant difference from baseline. The associations between the independent and the dependent variables were analysed using linear regression, applying delta scores between time points ($\Delta y_1 = y_1 - y_0$; $\Delta x_1 = x_1 - x_0$; $\Delta y_2 = y_2 - y_1$, etc.). For the independent and dependent variables, the differences between T0 and T1 (Δ1), T1 and T2 (Δ2), and T2 and T3 (Δ3) were used (Twisk, 2013). For Paper III (Jepsen et al., In press), a secondary analysis was performed using the conservative baseline-observation-carried-forward approach for missing values (Liu-Seifert, Zhang, D'Souza, & Skljarevski, 2010).

Changes from T0 to each of the subsequent time points obtained from the linear mixed model were presented as means with 95% confidence intervals (CI). Effect sizes (ES) for change were calculated by subtracting the mean T1, T2, and T3 estimates from the mean T0 estimate, divided by the SD of T0. ES for differences between the SF-36 data and population norms were calculated by subtracting the norms from the mean scores of the study participants divided by the SD of the latter. The ES were judged against the standard criteria proposed by Cohen: Trivial (< 0.2), small (0.2 to < 0.5), moderate (0.5 to < 0.8) and large (≥ 0.8) (Ellis, 2011).

Unadjusted and adjusted linear regression analyses were used to examine associations between the independent and dependent variables. Due to skewness of the data, a 1000-repetion bootstrap analysis was used to calculate 95% CI of the regression coefficients in Paper II (Jepsen et al., 2014) and III (Jepsen et al., In press).

Sample size calculations were done prior to the Haugland Obesity Study and reported by Aadland (2013). A power of 0.80, a significance level of 0.05, and subclasses of low density lipoproteins particle concentration as the main outcome variable were used. An effect size of 1 was assumed. The calculation resulted in a needed sample size of 20, which was also considered sufficient to detect changes in body weight, fat mass, and aerobic fitness. To reach valid cut-off points for accelerometer data used by Aadland (2013) and allow for multiple regression analysis, the aim was to include 50 participants in the study (Aadland, 2013). In order to calculate the sample size and power needed for the self-reported variables used in the present thesis, the GPower version 3.1 was used.

Statistical analyses were conducted using SPSS for Windows, version 20.0 (SPSS Inc., Chicago, USA). A two-sided *p*-value of ≤ 0.05 indicated statistical significance.

3.4 Ethics

In accordance with the Helsinki Declaration, written, informed consent was obtained from the participants prior to the study. The Regional Committee for Medical and Health Research Ethics for South-East Norway gave ethical approval to the study (registration number 2010/159a).

4. Results

4.1 Participants

Forty-nine patients out of 53 invited consented to participate in the study (Figure 6). Of these, women constituted 75.5% (n = 37) (Jepsen et al., 2013; Jepsen, et al., 2014; Jepsen et al., In press). Baseline socio-demographic and anthropometric characteristics of the participants are presented in Table 2.

Table 2 Characteristics of the study participants at baseline

Age, mean (SD), *N* = 49	43.6 (9.4)
Gender, n (%), *N* = 49	
Women	37 (75.5)
Socio-demographic status, n (%), *N* = 49	
Married/cohabiting	30 (61.2)
Having children	27 (55.1)
Formal education ≥ 15 years	22 (44.9)
Employed	41 (83.7)
Anthropometrics, mean (SD)	
Body mass index, kg/m^2, *N* = 49	42.1 (6.0)
Fat mass, per cent, *N* = 49	47.0 (6.2)
Waist circumference, cm, *N* = 48	128.3 (13.0)

SD: standard deviation

Twenty-two participants (44.9%, 16 women and six men) were lost to follow-up at year two (Figure 6). Some discontinued participation in the intervention and thus withdrew from the study for reasons such as referral to obesity surgery, having reached personal weight goal, pregnancy, health problems, or obligations that interfered with the residential periods. Six participants dropped out for unknown reasons. Five participants withdrew from the study, although they completed the intervention, due to problems with the repeated blood tests or assessments of maximal oxygen

consumption, which were included in the Haugland Obesity Study protocol. The non-completers did not differ from those who completed the study with regards to gender, age, BMI, physical activity, psychological factors, or quality of life outcomes at baseline. Nor were there differences in relation to early changes (T0 to T1) in BMI, physical activity, psychological factors, or quality of life outcomes. Additional missing data for self-reported data resulted from participants being absent when the questionnaires were administered at RKHRC. Furthermore, some of the accelerometer-obtained data failed to fulfil the validity requirements (Jepsen, et al., 2014; Jepsen et al., In press). Available data and drop-outs for all time points are displayed in Figure 6.

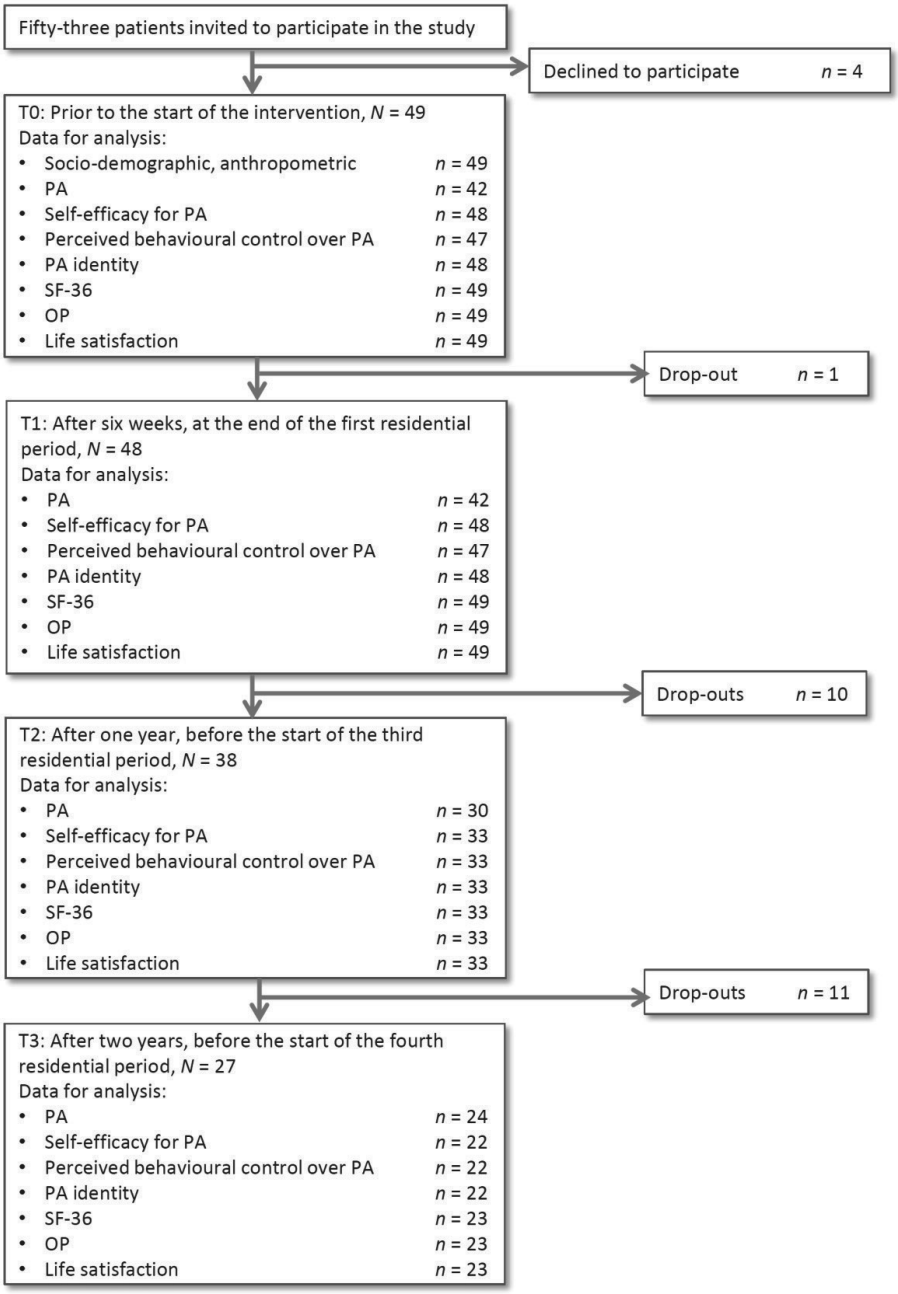

Figure 6 Flowchart for the prospective study on severely obese adults participating in a two-year lifestyle intervention (Adapted from Jepsen et al., 2014; Jepsen et al., In press)
Physical activity: PA; Medical Outcomes Study Short-Form 36 Health Survey: SF-36; Obesity-Related Problems Scale: OP.

4.2 Physical activity and body mass index

Changes in physical activity and BMI are shown in Table 3. Physical activity increased significantly during the first residential stay and was partly maintained at year one. At year two, it had returned to baseline level. Compared to baseline, BMI was significantly lower at the three subsequent assessments. However, the one-year weight loss was only partly maintained at year two (Jepsen, et al., 2014; Jepsen, et al., In press).

Table 3 Mixed-effect model estimates: Physical activity and body mass index during the two-year lifestyle intervention for severely obese adults

	Baseline	Week six		Year one		Year two	
	Mean (95% CI)	Mean (95% CI)	p^*	Mean (95% CI)	p^*	Mean (95% CI)	p^*
Accelerometer assessed physical activity,	$n = 42$	$n = 43$		$n = 30$		$n = 24$	
counts per minute	276 (241, 311)	452 (417, 486)	**< .001**	327 (286, 368)	**.036**	290 (244, 335)	.606
Body mass index, kg/m^2	$n = 49$	$n = 48$		$n = 38$		$n = 27$	
	42.1 (40.3, 43.8)	40.1 (38.4, 41.8)	**< .001**	39.4 (37.6, 41.1)	**< .001**	40.7 (38.9, 42.5)	**.001**
Weight loss from baseline, per cent		4.8		6.4		3.3	

Significant p-values (≤ 0.05) in bold.

$^*p$-values for change from baseline.

Confidence interval: CI.

4.3 Predisposing factors for physical activity

4.3.1 Longitudinal changes

Self-efficacy for physical activity in the face of psychological barriers, perceived behavioural control over physical activity, and physical activity identity were all significantly strengthened at the end of the first residential stay (Table 4). The improvement in perceived behavioural control persisted at year one and year two. The same applied to physical activity identity. The ES for change from baseline to year two were moderate for perceived behavioural control (ES = 0.51) and physical activity identity (ES = 0.74) (Ellis, 2011). For self-efficacy, the improvements from baseline were not maintained at year one or year two (Jepsen et al., 2014).

Table 4 Mixed-effect model estimates: Psychological factors for physical activity during the two-year lifestyle intervention for severely obese adults

	Baseline	Week six		Year one		Year two	
	Mean (95% CI)	Mean (95% CI)	p^d	Mean (95% CI)	p^d	Mean (95% CI)	p^d
Self-efficacy for physical activity in the face of psychological barriers[a]	5.1 (4.7, 5.5)	5.6 (4.1, 6.0)	**.029**	5.4 (5.0, 5.9)	.141	5.5 (5.0, 6.0)	.154
Perceived behavioural control over physical activity[b]	4.8 (4.5, 5.1)	5.4 (5.0, 5.7)	**.003**	5.3 (4.9, 5.7)	**.026**	5.4 (4.9, 5.8)	**.022**
Physical activity identity[c]	2.7 (2.5, 3.0)	3.1 (2.9, 3.4)	**.001**	3.2 (2.9, 3.5)	**<.001**	3.4 (3.1, 3.7)	**<.001**

Significant *p*-values (≤ 0.05) in bold.

[a]Scale 1-7; higher scores represent stronger self-efficacy for physical activity in the face of psychological barriers.

[b]Scale 1-7; higher scores represent stronger perceived behavioural control over physical activity.

[c]Scale 1-5; higher scores represent stronger physical activity identity.

[d]*p*-values for change from baseline.

Confidence interval: CI.

4.3.2 Associations during two years

Adjusted regression analyses (Table 5) showed that change in physical activity was independently associated with change in perceived behavioural control over physical activity but not with change in self-efficacy for physical activity in the face of psychological barriers or physical activity identity during the two-year intervention (Jepsen et al., 2014).

Table 5 Simple and multiple linear regression analysis with change in counts per minute as the dependent variable

	Crude			Adjusted*		
	Reg. coeff. (95% CI)	Stand. coeff.	*p*	Reg. coeff. (95% CI)	Stand. coeff.	*P*
Age	-1.95 (-6.45, 2.54)	-.09	.390	-1.52 (-6.23, 3.19)	-.07	.522
Gender (refer to women)	34.73 (-66.26, 135.72)	.08	.496	18.69 (-84.53, 121.90)	.04	.719
Change in body mass index	-44.63 (-65.53, -23.74)	-.44	**<.001**	-45.74 (-69.31, -22.17)	-.44	**<.001**
Change in self-efficacy for physical activity	28.29 (-12.56, 69.15)	.16	.172	22.99 (-14.79, 60.77)	.13	.229
Change in perceived behavioural control over physical activity	66.51 (31.40, 101.63)	.41	**<.001**	51.18 (16.96, 85.41)	.32	**.004**
Change in physical activity identity	40.78 (-25.11, 106.68)	.14	.221	7.36 (-56.69, 71.42)	.03	.819

Regression coefficients: reg. coeff.; confidence interval: CI; standardized coefficients: stand. coeff.

*Number of observations: 71. Age, gender, and change of body mass index were included as covariates in the adjusted model.

Significant *p*-values in bold.

4.4 Quality of life outcomes

4.4.1 Associations at baseline

Adjusted regression analyses revealed positive, independent associations between physical activity and life satisfaction and physical functioning before the start of the intervention. Mental health was not associated with physical activity (Table 6) (Jepsen et al., 2013).

Table 6 Simple and multiple linear regression analyses with quality of life outcomes as the dependent variables, ***N*** = 42

	Life satisfaction[b]			Physical functioning[c]			Mental health[c]		
	Reg. coeff. (95 % CI)	Stand. coeff.	*p*	Reg. coeff. (95 % CI)	Stand. coeff.	*p*	Reg. coeff. (95 % CI)	Stand. coeff.	*p*
Gender = male									
Unadjusted	0.31 (-0.29, 0.90)	0.16	.306	14.8 (0.9, 28.6)	0.32	**.037**	-1.5 (-12.1, 9.0)	-0.05	.771
Adjusted	0.45 (-0.15, 1.05)	0.24	.140	15.2 (2.5, 27.8)	0.33	**.020**	1.3 (-9.6, 12.1)	0.04	.815
Age									
Unadjusted	-0.00 (-0.03, 0.03)	0.01	.928	-0.2 (-0.09, 0.4)	-0.11	.501	0.4 (-0.1, 0.8)	0.24	.122
Adjusted	0.01 (-0.02, 0.03)	0.09	.599	-0.2 (-0.7, 0.4)	-0.08	.580	0.5 (-0.4, 0.9)	0.24	.069
Body mass index									
Unadjusted	-0.00 (-0.05, 0.04)	-0.03	.844	-1.3 (-2.2, -0.3)	-0.40	**.008**	0.3 (-0.5, 1.0)	0.12	.454
Adjusted	0.02 (-0.03, 0.06)	0.13	.446	-0.9 (-1.8, 0.04)	-0.28	.060	0.6 (-0.3, 1.3)	0.23	.191
Physical activity [d]									
Unadjusted	0.003 (0.000, 0.005)	0.31	**.047**	0.08 (0.02, 0.13)	0.39	**.011**	0.01 (-0.04, 0.05)	0.04	.787
Adjusted	0.003 (0.000, 0.006)	0.39	**.024**	0.07 (0.01, 0.12)	0.34	**.025**	0.02 (-0.03, 0.07)	0.15	.376
Adjusted R^2	0.06			0.29			0.01		

Significant *p*-values (< 0.05) in bold

[a] All variables in the first column.

[b] Continuous scale. Higher scores represent better life satisfaction.

[c] Medical Outcomes Study Short Form 36 Health Survey subscales. Continuous scales. Higher scores represent better health-related quality of life.

[d] Accelerometer measured.

Regression coefficients: Reg. coeff.; confidence interval: CI; standardized coefficients: Stand. coeff.

4.4.2 Longitudinal changes

Table 7 shows changes in the four quality of life outcomes from baseline. After an initial peak in PCS at the end of the first residential stay, the improvement was partly maintained at year one and two. MCS also peaked after six weeks, where after the improvement disappeared. OP responded differently, showing continuous improvement during the two years. Life satisfaction had improved at week six and year one, but after two years it had returned to the baseline level (Jepsen, et al., In press).

Table 7 Mixed-effect model estimates: mean changes (95% CI) in quality of life outcomes during the two-year lifestyle intervention for severely obese adults

Measure	T1: Change from T0	T2: Change from T0	T3: Change from T0
SF-36 Physical component summary[a]	5.7 (7.4, 4.0) $p <$ **.001**	4.4 (6.3, 2.5) $p <$ **.001**	3.3 (5.5, 1.1) $p =$ **.004**
Effect size	0.61	0.54	0.48
SF-36 Mental component summary[b]	5.9 (8.6, 3.1) $p <$ **.001**	-0.4 (-2.7, 3.5) $p = .794$	-1.8 (-1.8, 5.3) $p = .327$
Effect size	0.55	0.02	-0.06
Obesity-related problems scale[c]	-8.4 (-2.9, -13.9) $p =$ **.003**	-11.2 (-5.0, -17.4) $p =$ **.001**	-13.3 (-6.2, -20.4) $p <$ **.001**
Effect size	0.30	0.49	0.57
Life satisfaction[d]	0.99 (1.30, 0.67) $p <$ **.001**	0.47 (0.82, 0.12) $p =$ **.009**	0.20 (0.60, 0.20) $p = .324$
Effect size	1.00	0.55	0.22

T0: before the intervention ($n = 49$); T1: after six weeks ($n = 48$); T2: year one ($n = 38$); T3: year two ($n = 27$).

[a]Scale 15.4-62.1; higher scores represent better quality of life. Medical Outcomes Study Short-Form 36 Health Survey.

[b]Scale 10.1-64.0; higher scores represent better quality of life. Medical Outcomes Study Short-Form 36 Health Survey

[c]Scale 0-100; higher scores represent more obesity-related problems.

[d]Scale 1-7; higher scores represent better life satisfaction.

Significant *p*-values (≤ 0.05) in bold.

Effect sizes for the within-group changes were calculated by subtracting the mean estimates of follow-ups from the mean estimates at baseline divided by the SD of the latter.
Confidence interval: CI.

4.4.3 Comparison with population norms

In addition to the analysis presented in Paper I-III (Jepsen et al., 2013; Jepsen et al., 2014; Jepsen et al., In press), Norwegian population data on SF-36 (Loge & Kaasa, 1998) were used for comparison with the total scores on all four assessment points (Table 8). Before the intervention, PCS differed more from the norm score than MCS. After six weeks of intervention, they were better than population norms, where after both stabilised close to the norms. Of the subscales, physical functioning, general health, and vitality differed mostly from the norm scores at baseline. After six weeks, they were closer to the norms. At year one and two, the difference had increased again.

Table 8 Scores on life satisfaction and health related quality of life during the two-year lifestyle intervention for severely obese adults

	Baseline	Week six	Year one	Year two	Population norm
Life satisfaction[a]	*n* = 49	*n* = 46	*n* = 33	*n* = 23	
	4.6 (0.9)	5.5 (1.0)	5.1 (0.9)	4.8 (0.9)	n/a
SF-36[b]	*n* = 49	*n* = 47	*n* = 33	*n* = 23	
Physical functioning	72.1 (21.0)	84.0 (15.0)	86.1 (14.4)	86.1 (15.5)	89.2
Effect size	-0.81	-0.35	-0.22	-0.20	
Role physical	65.8 (38.1)	87.2 (27.5)	74.2 (37.2)	77.2 (34.5)	82.0
Effect size	-0.43	0.19	-0.21	-0.14	
Bodily pain	62.5 (25.8)	69.3 (20.2)	72.6(21.2)	66.8 (25.4)	75.6
Effect size	-0.51	-0.31	-0.14	-0.35	
General health	61.0 (20.7)	72.5 (20.1)	71.4 (20.2)	70.7 (16.8)	78.3
Effect size	-0.84	-0.29	-0.34	-0.45	
Vitality	45.0 (20.7)	65.9 (17.9)	54.1 (23.8)	50.2 (18.2)	60.0
Effect size	-0.72	0.33	-0.25	-0.54	
Social functioning	79.8 (22.4)	90.2 (15.4)	81.8 (25.8)	82.6 (21.6)	86.0
Effect size	-0.28	0.27	-0.16	-0.16	
Role emotional	73.5 (36.6)	88.7 (28.0)	75.8 (36.6)	75.4 (35.1)	84.1
Effect size	-0.29	0.16	-0.23	-0.25	
Mental health	73.7 (13.7)	82.6 (10.5)	75.5 (18.8)	73.7 (15.8)	78.5
Effect size	-0.35	0.39	-0.16	-0.30	
Physical component summary	45.3 (9.6)	51.2 (7.3)	50.5 (7.8)	49.9 (7.6)	49.0
Effect size	-0.39	0.30	0.19	0.12	
Mental component summary	48.4 (10.2)	54.0 (7.7)	48.6 (12.8)	47.8 (10.7)	49.0
Effect size	-0.06	0.65	-0.03	-0.11	
Obesity-related problems[c]	*n* = 49	*n* = 46	*n* = 33	*n* = 23	
	44.6 (26.3)	36.7 (25.0)	31.8 (28.0)	29.7 (24.4)	n/a

The data for the study participants are presented as means and standard deviations (SD).
[a]Scale 1-7; higher scores represent stronger life satisfaction.
[b]Scale 0-100; higher scores represent higher health-related quality of life. Medical Outcomes Study Short-Form Health Survey (SF 36). The SF-36 data for the norm population (*n* = 2,323) are adjusted for gender and age and presented as means. Effect sizes for differences between the study participants and the norm population are calculated by subtracting the mean score of the population norm from the mean score of the study participants divided by the SD of the latter.
[c]Scale 0-100; higher scores represent more obesity-related problems. Obesity-related problems scale.

4.4.4 Associations during two years

Adjusted regression analyses (Table 9) showed that change in physical activity was independently associated with change in PCS, MCS, OP, and life satisfaction during the two-year lifestyle intervention (Jepsen, et al., In press). The correlation between change in physical activity and quality of life outcomes was strongest for change in MCS and weakest for change in OP (refer to Figure 2 in Paper III (Jepsen et al., In press)).

Table 9 Reg. coeff. with 95% CI and stand. coeff. (β) for simple and multiple[a] linear associations between change in physical activity as the independent and change in quality of life outcomes as the dependent variables

	Change in PCS[b]			Change in MCS[b]			Change in OP[c]			Change in life satisfaction[d]		
	Reg. coeff. (95 % CI)	β	*p*	Reg. coeff. (95 % CI)	β	*p*	Reg. coeff. (95 % CI)	β	*p*	Reg. coeff. (95 % CI)	β	*p*
Gender = male												
Crude	0.31 (-2.66, 3.26)	.02	.838	2.10 (-2.63, 6.84)	.09	.380	-0.68 (-9.28, 7.93)	-.02	.876	-0.13 (-0.76, 0.51)	-.04	.691
Adj.	-0.65 (-3.39, 1.96)	-.05	.635	1.77 (-2.81, 6.73)	.07	.472	-1.40 (-11.89, 8.32)	-.03	.783	-0.22 (-0.97, 0.49)	-.07	.530
Age												
Crude	0.09 (-0.04, 0.23)	.13	.179	0.05 (-0.17, 0.27)	.04	.658	-0.18 (-0.58, 0.22)	-.09	.375	0.01 (-0.02, 0.04)	.06	.555
Adj.	0.04 (-0.13, 0.20)	.06	.650	0.08 (-0.18, 0.34)	.07	.537	-0.21 (-0.71, 0.24)	-.10	.363	0.003 (-0.027, 0.031)	.02	.852
Change of BMI												
Crude	-0.92 (-1.56, -0.29)	-.28	**.005**	-1.36 (-2.41, -0.32)	-.26	**.011**	1.82 (-0.09, 3.73)	.19	.061	-0.18 (-0.31, -0.04)	-.26	**.011**
Adj.	-0.34 (-1.32, 0.38)	-.11	.434	-0.03 (-1.44, 1.33)	-.01	.960	-0.24 (-3.03, 2.80)	-.03	.850	-.003 (-0.181, 0.142)	-.01	.974
Change of physical activity[e]												
Crude	0.011 (0.005, 0.017)	.39	**< .001**	0.028 (0.017, 0.039)	.50	**< .001**	-0.027 (-0.048, -0.007)	-.29	**.011**	0.003 (0.001, 0.004)	.39	**.001**
Adj.	0.010 (0.001, 0.019)	.35	**.033**	0.028 (0.014, 0.044)	.51	**.001**	-0.029 (-0.058, -0.008)	-.31	**.018**	0.003 (0.001, 0.004)	.39	**.004**
Adj. R^2	0.13			0.22			0.04			0.11		

[a]All variables in the first column.
[b]Physical component summary (PCS) and mental component summary (MCS) of the Medical Outcomes Study Short-Form Health Survey (SF-36). Continuous scales. Higher scores represent better quality of life.
[c]Obesity-related problems scale. Continuous scale. Higher scores represent more obesity-related problems.
[d]Continuous scale. Higher scores represent better life satisfaction.
[e]Accelerometer assessed.
Regression coefficients: reg. coeff.; confidence interval: CI; standardized coefficients: stand. coeff.; adjusted: adj.; body mass index: BMI.
*Number of observations: change in PCS: 73; change in MCS: 73; change in OP: 72; change in life satisfaction: 71.
Significant *p*-values (≤ 0.05) in bold.

The present study had 71 to 73 observations for the main outcomes (Table 5 and 9) (Jepsen, et al., 2014; Jepsen et al., In press). Given 71 observations, a power of 0.80, and significance level of 0.05, the study should have power to detect a medium ES (standardized coefficient of 0.32) (Ellis, 2011).

5. Discussion

5.1 Main findings

The primary aim of the present thesis was to develop new knowledge on associations. The two-year prospective design provided pre-intervention information and data from three subsequent time points, which were used for examination of associations during a process of change. The study gave information on final endpoints as well, although this was not within the primary scope of the research project. So, the thesis has two main findings. First, physical activity was independently and positively associated with quality of life outcomes prior to and during the two-year lifestyle intervention for severely obese adults. Second, perceived behavioural control was independently and positively associated with physical activity during the intervention.

5.2 Associations

Thus, the unanswered proposal from several researchers, that physical activity may explain parts of the improvements in quality of life reported by severely obese adults participating in lifestyle interventions (Blissmer et al., 2006; Danielsen et al., 2014; Karlsen, Lund, et al., 2013; Kaukua et al., 2003) was confirmed by the findings. In the examination of associations during the follow-up time, a comprehensive approach was used and demonstrated that the patterns of change in all the included dimensions of quality of life, i.e., global, physical, mental, and obesity-specific, were positively related to change in objectively assessed physical activity. A similar association was demonstrated prior to the start of the intervention. This supports the significance of health-related behaviours on quality of life as proposed by the PRECEDE-PROCEED model (Green & Kreuter, 2005). Also supportive of the present findings, a meta-analysis, which examined quality of life outcomes from physical activity interventions for patients with other chronic conditions than severe obesity (e.g., diabetes, cardiac disease, arthritis, and cancer), reported improvements in quality of life. The largest

effect sizes were found when interventions were supervised by staff in health care centres which may be comparable to the RKHRC (Conn, Hafdahl, & Brown, 2009).

Although other studies have suggested that weight loss is associated with improvements in quality of life dimensions (Danielsen et al., 2014; Karlsson, Taft, Ryden, Sjostrom, & Sullivan, 2007), the finding that the association between physical activity and quality of life was independent of weight loss indicates that weight loss should not be considered an adequate proxy for quality of life in severely obese participants in lifestyle interventions. This is in line with the PRECEDE-PROCEED model's distinction between quality of life and health factors (Green & Kreuter, 2005), recommendations of combinations of objectively and self-reported measures in clinical studies (Ahmed et al., 2012), and the fact that clinical outcomes are not always the strongest determinants for patients' assessment of quality of life (Fayers & Machin, 2007). Kolotkin et al. (2001) have proposed that expectations of improvements in quality of life could operate as a long-term motivational factor in obesity treatment. A more specific proposal could be added, based on the new knowledge of this thesis, namely that expectations of improvements in quality of life may have the potential to operate as a long-term motivational factor for physical activity in lifestyle interventions for severely obese adults.

Perceived behavioural control, which was positively associated with physical activity in the present study, is considered a predisposing factor for actual behaviour (Ajzen, 1991). That is in agreement with the assumptions behind the PRECEDE-PROCEED model (Green & Kreuter, 2005). However, the association may have been bi-directional (Green & Kreuter, 2005). According to Ajzen (1991), a realistic level of perceived behavioural control is influenced by experience with the behaviour in question. Thus, a dynamic effect between the two associated variables may have occurred during the expose to and participation in a variety of physical activities during the residential periods.

5.3 Changes and endpoints

Although change and endpoints as such were not the primary focus of the research project, some findings will be discussed. First, this thesis confirms the commonly reported challenge of maintenance of weight loss within the 5-10% range (Dalle Grave et al., 2013; Kirk et al., 2012) which is recommended for positive health effects (Cannon & Kumar, 2009; Dalle Grave et al., 2013; Goodpaster et al., 2010; Tsigos et al., 2008). Despite early indications, that long-term follow-up could promote sustained weight loss (Bjorvell & Rossner, 1985, 1992), interventions often last for one year (Danielsen et al., 2014; Goodpaster et al., 2010; Karlsen, Lund, et al., 2013) or less (Blissmer et al., 2006; Kaukua et al., 2003). The recent publication on weight loss outcomes of the Look AHEAD study supports the notion that extended care can be successful (Look Ahead Research Group, 2014). Hence, it is a paradox that other patient groups with chronic conditions, e.g., diabetes and coronary heart disease, often receive lifelong follow-up, while severely obese individuals are expected to manage on their own after relatively short interventions. Taking the complexities of obesity into consideration, adults with severe obesity may benefit from regular, long-term support from well-qualified health professionals (Kirk et al., 2012).

Second, the initial increase in the level of physical activity was not maintained. This is similar to reports from studies using self-reported data (Borg, Kukkonen-Harjula, Fogelholm, & Pasanen, 2002). The finding suggests that integration of altered physical activity behaviour was difficult in daily life and in the home situation. Given the variety of intra- and extra-personal factors which influence lifestyle and health-related behaviours, there are probably many factors that must be overcome, changed, or managed in the integration of a modified behaviour (Cockerham, 2005; Green & Kreuter, 2005; McLeroy et al., 1988). During home periods and after termination of the intervention, it may be worth encouraging continued peer support through organisation of groups who can be physically active together. Mobilisation of support from family members or involvement of work places may also contribute to greater adherence (Olander et al., 2013). Systematic use of webpages, smartphone apps, or

other technological resources may also be of help (Okorodudu, Bosworth, & Corsino, 2014).

The thesis also generated information about the actual levels of physical activity. At baseline and at the end of the intervention it was similar to the level of obese adults in Norway (Hansen et al., 2013) and their American counterparts (Tudor-Locke et al., 2010). Not surprisingly, the activity level was significantly higher towards the end of the first residential stay, which included scheduled, mandatory physical activity sessions. Actually, the participants reached levels well above the mean level of normal weight Norwegians (Hansen et al., 2013) and Americans (Tudor-Locke et al., 2010). Because the primary purpose of the study was to examine associations – and not actual change – the raw unit counts per minute was chosen for physical activity. The alternatives would have been reporting of intensity or duration. However, interpretation of raw accelerometer data is a challenge in the severely obese (Aadland & Anderssen, 2012) and therefore it was omitted.

The continuous improvements in physical activity identity and obesity-specific quality of life, also after physical activity had returned to the baseline level at year two, are interesting. The data and analyses do not explain these findings, but one hypothesis could be that positive experiences in a supportive, non-judging environment together with peers and well-qualified staff contributed to a growing and lasting feeling of better self-worth. The rehabilitation centre may have offered a health-promoting contrast to the stigmatisation which severely obese individuals are exposed to in many arenas, including health care settings (Malterud & Ulriksen, 2011; Puhl & Heuer, 2009). This could have had the positive impact on the self-identity and psychosocial functioning of the participants, which were captured by the physical activity identity instrument and the OP scale (Charng et al., 1988; Karlsson et al., 2003).

The supplemental analysis of change in the SF-36 subscales presented in Table 8, gave results similar to findings by others. Thus, physical functioning (Blissmer et al., 2006; Kaukua et al., 2003), general health, (Kaukua et al., 2003), and vitality (Blissmer et al.,

2006; Kaukua et al., 2003) seem to get a positive boost during the most intensive phase of interventions.

5.4 Socio-demographic characteristics

The majority of the participants were women, which is commonly reported in research on lifestyle interventions for severely obese adults (Danielsen et al., 2014; Karlsen, Lund, et al., 2013; van Nunen et al., 2007). Whether this could be because women are more inclined to seek treatment than men due to less acceptance for and more stigmatisation of female obesity (Puhl, Andreyeva, & Brownell, 2008) and more impaired quality of life (Duval et al., 2006; Kolotkin et al., 2002; White, O'Neil, Kolotkin, & Byrne, 2004) cannot be determined based on the data of this thesis. A contributing factor could also be the higher prevalence of severe obesity among women than men (An, 2014; Midthjell et al., 2013).

The participants in the present study seemed to have longer education and higher work participation than obesity surgery patients from the nearest hospital to RCHRC (N = 160, education ≥ 13 years: 25.6%, employed: 64.4 %) (Andersen, Aadland, Nilsen, & Vage, 2014).

5.5 Methodological considerations

5.5.1 Study design

Change of health-related behaviour generally and physical activity especially is complex and challenging (Biddle & Fuchs, 2009; Cockerham, 2005; Green & Kreuter, 2005; McLeroy et al., 1988). Thus, knowledge on patterns of change and associates is important to inform patients and health staff and contribute to further development of interventions. In that respect, data collection at several time points, as in the Haugland Obesity Study, can generate important insight into processes of change.

5.5.2 Study sample and generalisability

The size of the study sample was dependent on the continuation of the specific two-year lifestyle intervention, which in turn was subject to decisions and priorities of the regional health authorities. When it was decided to shorten the programme to one year, further inclusion of study participants was hampered. Thus, the study sample became rather small. In addition, men comprised only one quarter of the total sample. All in all, the study did not have power to examine differences between subgroups. Due to the right to treatment implying a maximum of 52 weeks on a waiting list (Nygaard & Karikstad, 2009), it was not possible to establish a control group which would have increased the validity of the study.

The participants were a self-selected group and the intervention was provided within the frames of the Norwegian, publicly financed health care system with universal rights (Raphael, 2013). Thus, the findings may not be representative in other populations or different settings. However, associations between quality of life and perceived behavioural control on the one side and physical activity on the other may carry an element of universality across populations, cultures, and settings. It will thus be interesting to see if future research will lead to similar results.

5.5.3 Data quality

The present study has four main strengths regarding data quality. First, the use of accelerometers in research on lifestyle interventions is new and so far probably unique to the Haugland Obesity Study. The objective assessment of physical activity increased the validity of the findings compared to self-reported measures such as physical activity diaries or physical activity questionnaires (Plasqui & Westerterp, 2007; Prince et al., 2008). When interventions target behaviour, examination of processes of behaviour change calls for measures which ensure the highest, practically obtainable accuracy. Moreover, associations with quality of life seem to be stronger for objectively assessed than for self-reported physical activity. This was found in a population study, which used accelerometers to measure physical activity objectively and a questionnaire to measure it subjectively. The EuroQol-5 instrument was used to

assess health-related quality of life (Anokye, Trueman, Green, Pavey, & Taylor, 2012).

Second, the instruments used to examine psychological, predisposing factors were specific for physical activity and developed on solid theoretical ground (Anderson & Cychosz, 1994; Bandura, 2001; Norman & Smith, 1995). Third, in accordance with recommendations (Karlsson et al., 2003), quality of life was assessed comprehensively using validated global, generic, and condition-specific questionnaires. Last, anthropometric measurements were performed by trained health staff. The alternative would have been self-reports, which are known to be imprecise and systematically biased (Connor Gorber, Tremblay, Moher, & Gorber, 2007).

5.5.4 Statisticical considerations

Although not uncommon in studies on lifestyle interventions for severely obese adults (Blissmer et al., 2006; Kaukua et al., 2003), the high attrition and the intermittent missing data were a challenge, especially in analyses of change over time. To increase the power of the study, the use of mixed model analysis in Paper II (Jepsen et al., 2014) and III (Jepsen et al., In press) had the advantage that all available data were included. The mixed model approach assumes that missing data are missing at random. However, this assumption cannot be decided with certainty (Twisk, 2013). Thus, for the robustness of the conclusions, chi-square and *t*-tests were used to detect possible differences between completers and non-completers. Flow-charts were provided for detailed information on missing data and drop-outs. In Paper III (Jepsen et al., In press), the secondary analysis using an baseline-observation-carried-forward approach (Liu-Seifert et al., 2010) confirmed the statistical level of change obtained from the primary analysis.

Associations do not imply causation so the results of this thesis should be interpreted with caution. However, using valid instruments for repeated measures, performing regression analyses, and building on solid theoretical ground may imply that the relationships between physical activity and quality of life outcomes are likely to be causal.

5.6 Conceptual considerations

This thesis found inspiration in socio-ecological and health promotion frameworks and the structure and theoretical underpinnings of the PRECEDE-PROCEED model (Green & Kreuter, 2005; McLeroy et al., 1988; *Ottawa Charter for Health Promotion*, 1986; Scriven, 2005). Although the lifestyle intervention tried to enable severely obese individuals to gain better quality of life and increase control over their health – and thus went well with the definition of health promotion (*Ottawa Charter for Health Promotion*, 1986) – it did not target the inter-relational, social, environmental, and political dimensions of lifestyle and physical activity (Biddle & Fuchs, 2009; Cockerham, 2005; Green & Kreuter, 2005; Kirk et al., 2012; McLeroy et al., 1988). The intervention – and the research design – focused on change on the individual level and went along with the dominant paradigm that obesity and levels of physical activity are individual problems which should find individual solutions (Kirk & Penney, 2013; Kirk et al., 2012).

The reference to health promotion and the PRECEDE-PROCEED model thus displays a tension inherent in – not only the present, but also other – lifestyle interventions (Kirk & Penney, 2013; Kirk et al., 2012). Still, it could potentially open to wider perspectives of relevance for clinical practice and research within the field of severe obesity and physical activity. As already indicated, the position taken illustrates shortcomings of the thesis on one side. On the other, it gives room for wider perspectives on the presented findings. When all comes to all, the efforts made by severely obese individuals and health professionals in order to increase physical activity may have met not only intra-personal barriers but also strong, antagonistic forces in the obesogenic society (Cockerham, 2005; Green & Kreuter, 2005; Kirk & Penney, 2013; Kirk et al., 2012; Swinburn et al., 2011). As Kirk et al. (2012, p. 184) put it: ”(...) without a better understanding of the causes of obesity, along with the creation of a supportive environment, can we really expect individual attempts at weight management to be completely successful?”.

5.7 Implications for practice

Despite the shortcomings of this thesis, the findings can inform severely obese lifestyle intervention seekers and health professionals about aspects which have not been examined previously. Now, the suggestion that physical activity has the potential to improve quality of life (Blissmer et al., 2006; Danielsen et al., 2014; Karlsen, Lund, et al., 2013; Kaukua et al., 2003) has a research basis, which can strengthen the message. Thus, health staff can inform lifestyle intervention seekers not only about the benefits of physical activity in relation to health hazards (Aadland, Andersen, et al., 2013; Fogelholm, 2010; Gill & Malkova, 2006) but also the subjective phenomena quality of life. The findings also suggest that perceived control over physical activity may be a valid target in lifestyle interventions.

6. Conclusions

This thesis has three conclusions based on the purposes of Paper I-III:

1. Physical activity was positively associated with life satisfaction and physical functioning but not with mental health prior to the beginning of the lifestyle intervention for severely obese adults (Jepsen et al., 2013).

2. Change in perceived behavioural control over physical activity was positively associated with change in physical activity during the two-year lifestyle intervention for severely obese adults. Change in self-efficacy for physical activity in the face of psychological barriers and change in physical activity identity were not associated with change in physical activity during the two-year lifestyle intervention (Jepsen et al., 2014).

3. Change in physical activity was positively associated with change in physical, mental, and obesity-specific dimensions of quality of life and life satisfaction during the two-year lifestyle intervention for severely obese adults (Jepsen et al., In press).

7. Future perspectives

Within a socio-ecological approach in research on physical activity, the significance of psychological factors in complex behaviour should not be overlooked (Biddle & Fuchs, 2009). Hence, more research is needed to understand the psychological mechanisms behind successful and sustained increase of physical activity during multi-component lifestyle interventions and how psychological, predisposing factors best can be strengthened.

The associations between physical activity and global, physical, mental, and obesity-specific dimensions of quality of life found in this research project should be further examined. Although the findings were independent of gender and age, larger samples could make subgroup analyses possible. The associations should be examined in other intervention programmes, which are different in relation to for example intervention site, length, and contents. If possible, control groups should be established.

Generally, the complex, multi-levelled, and multi-factorial nature of severe obesity and the intra- and extra-personal obstacles to change of physical activity behaviour should be taken into consideration in research on multi-component lifestyle interventions (Kirk et al., 2012). Thus, socio-ecological frameworks, such as the PRECEDE-PROCEED model, could guide future study designs. Factors related to family, work place, network, local community, health services, socio-economic situation etc. are of significance for individuals who participate in lifestyle interventions and probably influence the process of change and adherence to new behaviour (Cockerham, 2005; Green & Kreuter, 2005; McLeroy et al., 1988). Qualitative, quantitative, and mixed method study designs all have the potential to generate knowledge on different aspects of these complexities and contribute to more knowledge on physical activity and its associates.

Participatory approaches (Tapp, White, Steuerwald, & Dulin, 2013) are widely missing in designing and translation of research within the field of severe obesity. In

agreement with bottom-up approaches inherent in health promotion framework (*Ottawa Charter for Health Promotion*, 1986), collaborative initiatives involving researchers and severely obese treatment-seeking individuals may give rise to new ideas and directions.

In a Norwegian public health perspective, not only adulthood but also childhood overweight and obesity are of concern (Juliusson et al., 2010; Wijnhoven et al., 2014). In order to reverse the obesity trend, primary and secondary health promotion activities (Scriven, 2005) should target a variety of the multi-levelled contributors, linkages, and feedback loops illustrated by the obesity system map by the British Foresight Group (Vandenbroeck et al., 2007). But even if public health initiatives would slow down and reverse the obesogenic drivers in society (Swinburn et al., 2011), it is imperative not to lose those who struggle with severe obesity of sight (Kolotkin et al., 2002; van Nunen et al., 2007). There will still be need for interventions going beyond primary and secondary health promotion actions. The results of the eight-year Look AHEAD study give reason for optimism. Attrition was low, weight losses after eight years were clinically meaningful, and weight regain levelled off after four to six years. A drawback is that the study did not provide data on quality of life or similar subjective assessments, but the most successful participants in terms of weight loss reported more physical activity and lower calorie intake at the end of the intervention (Look Ahead Research Group, 2014). Again, the recommendations for continued follow-up (Kirk et al., 2012; Look Ahead Research Group, 2014) are supported by the notion of obesity being a chronic condition (WHO, 2000).

Severe obesity will challenge individuals, societies, and health care in many more years to come and research should constantly seek to contribute to improved interventions.

Source of data

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HEALTH AND QUALITY OF LIFE OUTCOMES

RESEARCH Open Access

Associations between physical activity and quality of life outcomes in adults with severe obesity: a cross-sectional study prior to the beginning of a lifestyle intervention

Randi Jepsen[1,2*], Eivind Aadland[1], John R Andersen[1,3] and Gerd K Natvig[1,2]

Abstract

Background: Severely obese individuals who seek lifestyle interventions have impaired quality of life (QoL). Research suggests that physical activity (PA) plays a role in weight reduction and improved health in this group, but knowledge about the association of PA with QoL outcomes is sparse and inconsistent. The aim of this study was to investigate whether a higher level of PA was independently associated with higher QoL in severely obese individuals prior to the beginning of a lifestyle intervention.

Methods: During 2010, a total of 49 severely obese individuals who began a lifestyle intervention programme in Western Norway agreed to participate in the study. Data were collected prior to the beginning of the intervention. QoL was measured by a one-item scale on life satisfaction and the SF-36, PA was measured by an accelerometer, and clinical data were collected by health staff. Linear regression analyses were used to determine the associations between PA and QoL outcomes (life satisfaction, physical functioning, and mental health), adjusting for age, gender, and body mass index (BMI).

Results: In the adjusted analyses, we found positive relationships between PA and life satisfaction (Stand. coeff. 0.39, $p = 0.024$) and physical functioning (Stand. coeff. 0.34, $p = 0.025$). There was no association between PA and mental health (Stand. coeff. 0.15, $p = 0.376$).

Conclusion: This study detected associations between objectively measured PA and life satisfaction as well as physical functioning in a group of severely obese individuals before they began a lifestyle intervention programme.

Keywords: Severe obesity, BMI, Quality of life, Life satisfaction, SF-36, Physical activity, Accelerometer

Introduction

Severe obesity affects a growing proportion of individuals [1]. Its direct cause is an imbalance in intake (diet) and expenditure (physical activity (PA)) of energy, but the underlying mechanisms include complex political, environmental, sociocultural, genetic, and personal factors. Medical consequences, such as type 2 diabetes, cardiovascular disease, and certain types of cancer, contribute to morbidity and mortality in the severely obese population [2]. Moreover, psychosocial problems are common [3], and, although severely obese individuals do not constitute a homogenous group, many report poorer quality of life (QoL) compared to the general population [4,5]. QoL is a global, multidimensional construct representing overall relative satisfaction with life. In health research, life satisfaction is measured either with a single item or with multi-item scales. Health-related quality of life (HRQoL) is limited to QoL aspects that are related to health and illness [6,7]. It is often assessed with questions that are relevant across populations and conditions [8].

Severely obese individuals with a desire to ameliorate their situation may seek lifestyle interventions. This desire seems to be related to impaired QoL, growing health

* Correspondence: randi.jepsen@hisf.no
[1]Faculty of Health Studies, Sogn og Fjordane University College, N-6803 Førde, Norway
[2]Department of Global Public Health and Primary Care, University of Bergen, N-5020 Bergen, Norway
Full list of author information is available at the end of the article

problems, and reduced functioning [4,5]. Seeking a lifestyle intervention should imply a decision about increasing one's level of PA, which usually constitutes one of the components of this type of programme [9]. PA promotes and helps to maintain weight reduction in obese individuals, although the strength of the effect is debated [10,11]. In addition, PA protects against medical conditions such as cardiovascular disease and type 2 diabetes in all Body Mass Index (BMI) categories [12,13]. Nevertheless, despite the potential benefits, it seems very difficult for obese individuals to increase their PA levels, especially in the long run [14]. Improved health has a long-term perspective [12,13]. Weight loss is a less distant outcome, but expectations are often unrealistically high and may result in disappointment [15,16]. As a motivational factor, it may be more useful to maintain a realistic short-time effect, and improved QoL may play a role in this regard. Thus, it is vital to determine whether PA is associated with QoL outcomes in severely obese individuals. Such a relationship has been detected for the physical domain in individuals awaiting gastric-bypass surgery [17] or other obesity treatment [18] and in the mental and physical domains in overweight to obese subjects [19]. Wang et al. found associations between PA and the physical domain in a study of overweight and obese adults at the beginning of a behavioural weight loss trial [20]. However, to our knowledge, no studies have targeted severely obese subjects seeking lifestyle interventions. Therefore, the aim of this study was to investigate the associations among objectively measured PA and life satisfaction, physical functioning, and mental health in severely obese subjects prior to the beginning of a lifestyle intervention programme.

Methods

Design and participants

This study is part of an observational cohort study with a two-year follow-up and a variety of data. In the present study, we included baseline data for 49 adults with severe obesity who began a two-year lifestyle intervention at The Red Cross Haugland Rehabilitation Centre (RCHRC) in Western Norway during 2010. After inclusion of the 49 participants, the intervention was radically changed, which hampered further inclusion.

Inclusion criteria were age 18–60 years and BMI ≥ 40 kg/m^2 with or without comorbidities or ≥ 35 kg/m^2 with comorbidities at the time of referral (i.e., individuals included in the right to treatment in the Norwegian public specialist health service). Exclusion criteria were referral to or previous obesity surgery, pregnancy, severe cardiovascular disease, alcohol or substance abuse, or mental illness or physical impairment that prevented the participants from adhering to the intervention. All of the patients accepted for the intervention were eligible for inclusion in the study.

Setting

The intervention included four residential periods and was managed by a multi-professional team. It combined PA, a balanced diet, and cognitive behavioural therapy. The desired outcomes were improved QoL, better general health, weight loss, and reduction of obesity-related medical problems.

Ethical approval

Verbal and written information about the study was provided by the staff at the rehabilitation centre, and written informed consent was obtained from each participant prior to the study. This study met the standards of the Declaration of Helsinki and was approved by the Regional Committee for Medical and Health Research Ethics (registration number 2010/159a).

Measures and procedures

Data collection

All data were collected prior to the beginning of the lifestyle intervention. PA was measured four weeks prior to the first residential stay in the rehabilitation centre, and all other data were collected on arrival. Anthropometric data were obtained by trained health staff, and all questionnaires were self-administered.

Quality of life outcomes

Life satisfaction was measured with a single item on a seven-step scale with alternatives from "very satisfied" to "very dissatisfied". The scores were reversed before data analysis so that higher scores indicated higher life satisfaction. The scale on life satisfaction has been widely applied in Norwegian population studies. It has shown predictive value for later onset of type 2 diabetes [21] and strong direct associations with poor self-reported health, mental problems, and lack of social relations [22]. HRQoL was measured with the multidimensional Medical Outcomes Study Short-Form 36 Health Survey (SF-36) version 1.2. From its 36 items, eight sub-domains were derived in accordance with the standard procedure for SF-36 subscale scoring. Each scale ranged from 0 (worst) to 100 (best) [8]. The SF-36 has demonstrated good reliability and validity in obesity research [4]. The subscale on physical functioning has ten items related to self-care, mobility, and light and strenuous activities, whereas the mental health subscale comprises five questions about positive as well as negative emotions and mood states [8]. The other six subscales of the SF-36 (role physical, bodily pain, general health, vitality, social functioning, and role emotional) served as secondary outcomes.

Socio-demographic information

The participants gave information on age, gender, civil status ("married/cohabiting" versus "single/divorced"),

educational level ("< 15 years" versus "≥ 15 years of schooling" (i.e., college/university)), and employment ("employed" versus "not working" (i.e., being unemployed or receiving pensions or benefits)).

Anthropometry

Body weight and fat mass were measured on a bioelectrical impedance analysis device (BC 420S MA, Tanita Corp, Tokyo, Japan) in the morning, in light clothes, in a fasting state, and after voiding. Weight was reported to the nearest 0.1 kg. Height was measured without shoes to the nearest 0.5 cm using a stadiometer. Waist circumference was measured twice at the level of the umbilicus at exhalation and reported as the mean value of the two measurements. BMI was calculated as weight in kilograms divided by the square of height in meters.

Physical activity

Free-living PA was measured with the Actigraph GT1 M accelerometer (Actigraph, Fort Walton Beach, FL, USA). This accelerometer is a frequently used hip-worn electronic motion sensor. Acceleration is converted into activity counts that increase linearly with the magnitude of the acceleration and work rate. The participants were instructed to wear the accelerometers for seven full days, except during water activities or while sleeping. A wear-time of ≥ 10 hours/day for ≥ four days was used as the criterion for a valid measure. Non-wear time was defined as periods of ≥ 60 consecutive minutes with zero counts, with allowance for two minutes of counts greater than zero. Data were analysed with the Actigraph software ActiLife v. 5.3. The counts were summed and averaged over the total wearing time to indicate the overall PA and reported as total counts per minute. Accelerometer-measured PA is considered to have superior validity compared to self-reported information [23].

Statistical analysis

The data were analysed using SPSS for Windows (Version 20.0. Armonk, NY: IBM Corp). Categorical variables are presented as percentages, and continuous variables are presented as means and standard deviations (SD). For unadjusted and adjusted linear regression, only participants with complete data sets were included. Three separate unadjusted and adjusted linear regression analyses were performed to evaluate the associations between PA and QoL outcomes. Gender, age, and BMI served as covariates in the adjusted analyses. A two-sided p-value < 0.05 indicated statistical significance.

Results

Sample characteristics

Forty-nine (92.5%) of the 53 invited patients agreed to participate in the study. The data collection was complete for all 49, except from accelerometer-measured PA, for which valid data were obtained from 42 participants. In addition, there was one missing measure of waist circumference. The missing data on PA were due to two cases of invalid measurements and five with no measurements at all. Socio-demographic characteristics, anthropometrics, PA, and scores on QoL outcomes are presented in Table 1.

Main and secondary outcomes

Increased PA levels were associated with higher life satisfaction and physical functioning in both unadjusted and adjusted models (Table 2). In the adjusted analyses PA had a stronger association with life satisfaction (Stand. coeff. 0.39, $p = 0.024$) than with physical functioning (Stand. coeff. 0.34, $p = 0.025$). According to Cohen 0.3 is the cut-off point for a medium effect size, which applies to both associations [24]. In contrast, there was no association between PA and mental health. Lower BMI was related to better physical

Table 1 Characteristics of the participating adults with severe obesity

Age, mean (SD), $N = 49$		43.6 (9.4)
Gender, n (%), $N = 49$		
Women		37 (75.5)
Socio-demographic status, n (%), $N = 49$		
Married/cohabiting		30 (61.2)
Having children		27 (55.1)
Formal education ≥ 15 years		22 (44.9)
Employed		41 (83.7)
Anthropometrics, mean (SD)		
Body mass index, kg/m^2, $N = 49$		42.1 (6.0)
Fat mass, percent, $N = 49$		47.0 (6.2)
Waist circumference, cm, $N = 48$		128.3 (13.0)
Physical activity, mean (SD), $N = 42$		
Accelerometer-measured counts per minute		280 (100)
Quality of life outcomes, mean (SD), $N = 49$		
Main outcomes		
	Life satisfaction[a]	4.6 (0.9)
	Physical functioning[b]	72.1 (21.0)
	Mental health[b]	73.7 (13.7)
Secondary outcomes		
	Role physical[b]	65.8 (38.1)
	Bodily pain[b]	62.5 (25.8)
	General health[b]	61.0 (20.7)
	Vitality[b]	45.0 (20.7)
	Social functioning[b]	79.8 (22.4)
	Role emotional[b]	73.5 (36.6)

[a]Life satisfaction (scale 1–7; higher scores represent higher life satisfaction).
[b]Medical Outcomes Study Short-Form 36 Health Survey (scale 0–100; higher scores represent better quality of life outcomes).

functioning in the unadjusted analysis, but not the adjusted analysis. Male gender predicted better physical functioning in both analyses. Age had no associations with any of the QoL outcomes. Of the six subscales of the SF-36 defined as secondary outcomes, only general health showed a statistically significant association with PA (unadjusted: Stand. coeff. 0.31, $p = 0.045$; adjusted: Stand. coeff. 0.35, $p = 0.042$).

Discussion

In this cross-sectional study of associations between PA and QoL outcomes in severely obese adults prior to the beginning of a lifestyle intervention, the main findings were that PA was positively associated with life satisfaction and physical functioning independent of age, gender, and BMI, but it was not associated with mental health. The association was stronger for life satisfaction than for physical functioning.

Previous studies have shown a similar association between PA and physical functioning [17-20]. However, none of these studies are directly comparable to the present study. First, the previous studies used self-reported data on PA, not objectively measured data. Second, the participants may differ considerably. Lerdal et al. studied severely obese waiting-list patients who were not yet referred for either obesity surgery or lifestyle intervention [18], whereas Bond et al. reported on obesity surgery candidates [17]. Wang et al. recruited overweight and obese adults for a behavioural intervention trial, so their subjects' BMI was considerably lower compared to the present study [20]. Martin et al. studied the effect of exercise sessions rather than all-day activities on overweight to obese sedentary women [19]. Lastly, a review by Bize et al. of population studies concluded that there seemed to be an association between PA and the physical domain of HRQoL, but the authors did not consider BMI, and PA was self-reported in most of the included original studies [25]. Nevertheless, from a conceptual perspective, it seems plausible that a scale ranging from light daily functioning to more strenuous activities, such as climbing several stairs and running, is related to PA in severely obese individuals [8].

It was interesting that PA showed the strongest positive association with life satisfaction amongst the QoL outcomes we used. Compared to limitations in physical functioning, which are concrete and related to daily activities, life satisfaction is a relative concept that includes all major dimensions of life. As opposed to a negative approach concerned with problems, limitations, and suffering, the subjective assessment of life satisfaction takes a positive point of departure [6,7]. In the present study, life satisfaction was represented by a single question. Similarly, Idler and Benyamini found that self-rated health, measured by one question, predicted mortality in almost all of the 27

Table 2 Regression coefficients (Reg. coeff.) with 95% confidence interval (CI) and standardised coefficients (Stand. coeff.) for unadjusted and adjusted[a] linear association of quality of life outcomes in severely obese adults

	Life satisfaction[b]			Physical functioning[c]			Mental health[c]		
	N = 42			*N* = 42			*N* = 42		
	Reg. coeff. (95% CI)	Stand. coeff.	*p*	Reg. coeff. (95% CI)	Stand. coeff.	*p*	Reg. coeff. (95% CI)	Stand. coeff.	*p*
Gender = male									
Unadjusted	0.31 (−0.29, 0.90)	0.16	.306	14.8 (0.9, 28.6)	0.32	**.037**	−1.5 (−12.1, 9.0)	−0.05	.771
Adjusted	0.45 (−0.15, 1.05)	0.24	.140	15.2 (2.5, 27.8)	0.33	**.020**	1.3 (−9.6, 12.1)	0.04	.815
Age									
Unadjusted	−0.00 (−0.03, 0.03)	0.01	.928	−0.2 (−0.09, 0.4)	−0.11	.501	0.4 (−0.1, 0.8)	0.24	.122
Adjusted	0.01 (−0.02, 0.03)	0.09	.599	−0.2 (−0.7, 0.4)	−0.08	.580	0.5 (−0.4, 0.9)	0.24	.069
Body mass index									
Unadjusted	−0.00 (−0.05, 0.04)	−0.03	.844	−1.3 (−2.2, -0.3)	−0.40	**.008**	0.3 (−0.5, 1.0)	0.12	.454
Adjusted	0.02 (−0.03, 0.06)	0.13	.446	−0.9 (−1.8, 0.04)	−0.28	.060	0.6 (−0.3, 1.3)	0.23	.191
Physical activity[d]									
Unadjusted	0.003 (0.000, 0.005)	0.31	**.047**	0.08 (0.02, 0.13)	0.39	**.011**	0.01 (−0.04, 0.05)	0.04	.787
Adjusted	0.003 (0.000, 0.006)	0.39	**.024**	0.07 (0.01, 0.12)	0.34	**.025**	0.02 (−0.03, 0.07)	0.15	.376
Adjusted R^2	0.06			0.29			0.01		

Significant p-values (< 0.05) in bold.
[a]All variables in the first column.
[b]Continuous scale. Higher scores represent higher life satisfaction.
[c]Medical Outcomes Study Short Form 36 Health Survey subscales. Continuous scales. Higher scores represent higher health-related quality of life.
[d]Accelerometer measured.

community studies they reviewed, indicating that single-item scales possess the power to capture the complexity of global concepts [26].

The global character of life satisfaction also differs considerably from the narrow SF-36 mental health scale, with its five items related to current emotions such as anxiousness, depressive moods, and calmness [8]. Therefore, it should not be assumed that life satisfaction shares associations with mental health. Moreover, our finding that PA was not associated with mental health is in line with the study by Lerdal et al. on severely obese waiting-list patients [18], whereas Martin et al. found such a relation in their sample of overweight to obese sedentary women [19]. In the original studies reviewed by Bize et al. the associations between PA and mental health were inconsistent between studies, and, as mentioned, the authors did not include BMI as a variable in the review [25].

Distress works as an incitement for care-seeking [7]. Thus, studies have revealed that severely obese individuals seeking lifestyle interventions experience impaired QoL, health problems, and reduced functioning. Although this distress is not to the same degree as that of obesity surgery seekers, it is still significantly more than the group of severely obese people who do not seek treatment [4,27]. Our study shows that variation in QoL outcomes within a group of lifestyle intervention seekers is associated with their level of PA. A possible explanation for our finding may be that the participants are situated around a balance point with impairment and the threat of further deterioration on the one side and health-promoting options on the other side. Considering the cross-sectional design of the study, we can only speculate that a higher level of PA contributes to keeping participants on the positive side of this balance point (i.e., contributes to higher life satisfaction and better physical functioning). However, a bidirectional effect may be the case, in which QoL outcomes predict PA level.

Our study may provide the first indication that QoL outcomes could be used as short-term goals related to PA in severely obese individuals in lifestyle intervention programmes. However, intervention studies are needed to determine whether this is true.

Methodological considerations

By using accelerometers to objectively measure PA, our study is original and has greater validity than previous studies. To the best of our knowledge, we are the first to report such results. Although accelerometers underestimate some activities, they capture walking very well [28], and walking was the most frequent mode of PA in this severely obese population [29].

A second strength of this study is that we used validated instruments to assess QoL outcomes. Instead of using the SF-36 subscales on physical functioning and mental health, we could have chosen the physical and mental summary scores, which summarise more items into two broader components [30]. A drawback of the summary scores is that they are less distinct than the subscales; therefore, we suspect that they may be less valid for the purpose [8]. However, Bond et al. found associations between PA and the physical summary score in their study of gastric-bypass candidates [17]. This should be examined in future research.

This study has several limitations. First, due to the limited size of the cohort in the intervention programme, the number of participants was quite small restricting the number of covariates included in the regression analyses. Furthermore, the sample was gender biased in that there were few men. Consequently, we could not determine if there were gender differences in the associations between PA and QoL outcomes. This issue should be examined in larger samples. However, the gender bias in the current study is typical in the obese population seeking lifestyle interventions [4]. Additionally, although the inclusion rate was high (92.5%), not all participants were included in the regression analysis due to missing accelerometer data. Wearing an accelerometer for seven days requires effort, and there may be many reasons for not strictly adhering to the procedure.

As mentioned, because our study was cross-sectional, we cannot assume any causal relationships among the variables. Moreover, we do not know whether an increase in PA will improve QoL outcomes in the long term. Longitudinal designs and intervention studies should be conducted to examine these issues.

The participants in this study are most likely not representative for all severely obese individuals. As mentioned, lifestyle intervention seekers are known to differ from obesity surgery and non-treatment seekers, so the results cannot be generalised to the severely obese population as a whole [4,27].

Conclusion

In this cross-sectional study of severely obese adults prior to the beginning of a lifestyle intervention, we found positive associations between PA and life satisfaction as well as physical functioning. The association was stronger for life satisfaction than for physical functioning. Further research is needed to determine causal relationships between the variables, and intervention studies should be performed to evaluate the possible effect of PA on QoL in severely obese individuals in lifestyle intervention programmes.

Abbreviations

BMI: Body mass index; HRQoL: Health-related quality of life; QoL: Quality of life; RCHRC: Red Cross Haugland rehabilitation centre; SPSS: Statistical package for the social sciences; SF-36: Medical outcomes study short-form 36 health survey.

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
RJ participated in the design of the study, analysed the data, and drafted the manuscript. EA participated in the design of the study, collected data, analysed the data, and revised and helped draft the manuscript. JRA participated in the design of the study, analysed the data, and revised and helped draft the manuscript. GKN participated in the design of the study, helped with the statistical analysis, and revised and helped draft the manuscript. All authors read and approved the final manuscript.

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Author details
[1]Faculty of Health Studies, Sogn og Fjordane University College, N-6803 Førde, Norway. [2]Department of Global Public Health and Primary Care, University of Bergen, N-5020 Bergen, Norway. [3]Førde Health Enterprise, N-6807 Førde, Norway.

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Factors and associations for physical activity in severely obese adults during a two-year lifestyle intervention

Randi Jepsen[1,2], Eivind Aadland[1], Lesley Robertson[3], Merete Kristiansen[4], John Roger Andersen[1,5] and Gerd Karin Natvig[2]

[1] Faculty of Health Studies, Sogn og Fjordane University College, Førde, Norway
[2] Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway
[3] Red Cross Haugland Rehabilitation Centre, Flekke, Norway
[4] Faculty of Teacher Education and Sport, Sogn og Fjordane University College, Sogndal, Norway
[5] Førde Health Trust, Førde, Norway

ABSTRACT

Objective. This study of severely obese adults participating in a two-year lifestyle intervention investigates associations between the independent variables: change in self-efficacy for physical activity (PA) in the face of psychological barriers, perceived behavioural control over PA, and PA self-identity and the dependent variable of change in objectively assessed PA. The intervention comprised four residential periods in a rehabilitation centre and combined diet, physical activity, and cognitive behavioural therapy.

Materials and Methods. Forty-nine severely obese adults (37 women, mean body mass index 42.1 kg/m^2) were included in the study. Assessment was done four times using questionnaires and an accelerometer. A linear mixed model based on restricted maximum likelihood was used in analyses for change over time. Associations were studied using linear regression analyses. Age, gender, and change in body mass index were used as control variables.

Results. In the adjusted analyses, change in perceived behavioural control over PA was associated with change in PA (Stand. coeff. = 0.32, $p = .005$). Change in PA was not associated with either change in self-efficacy over PA in the face of psychological barriers (Stand. coeff. = 0.13, $p = .259$) or PA self-identity (Stand. coeff. = −0.07, $p = .538$).

Conclusion. Perceived behavioural control may be a valid target to increase and maintain PA in severely obese adults participating in lifestyle interventions. More research is needed to investigate the process of behaviour change in this population.

Subjects Nursing, Public Health
Keywords Severe obesity, Physical activity, Lifestyle intervention, Self-identity, Self-efficacy, Perceived behavioural control, Accelerometer

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Corresponding author
Randi Jepsen, randi.jepsen@hisf.no

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INTRODUCTION

A web of political, societal, and environmental factors contributes to the growing prevalence of overweight and obesity in Western countries (*Swinburn et al., 2011*). Alarmingly, the group classified as severely obese has increased the most (*Sturm, 2007*; *Midthjell et al., 2013*). In obesogenic societies (*Swinburn et al., 2011*), the health services

have responsibility to ameliorate the ailing health, functioning, and quality of life experienced by severely obese individuals (*van Nunen et al., 2007*). Thus, various obesity surgeries and lifestyle interventions have been developed. Obesity surgery brings about physiological and functional changes, enforcing altered eating behaviours and thus leading to weight loss (*Kissler & Settmacher, 2013*). By contrast, lifestyle interventions work exclusively through individual modifications and self-management of health-related behaviour (*Kirk et al., 2012*). A weight loss of 5–10% is regarded as sufficient to gain health effects and reduce the risk of obesity-related comorbidities (*Tsigos et al., 2008*; *Dalle Grave, Calugi & El Ghoch, 2013*). The most extensive weight losses are obtained through obesity surgery (*Karlsen et al., 2013*), whereas subjects attending lifestyle interventions seem to develop more favourable dietary patterns (*Johnson et al., 2013*). Both intervention types improve health-related quality of life (*Karlsen et al., 2013*).

In combination with diet modification, physical activity (PA) constitutes a core component of many lifestyle interventions for severely obese adults (*Kirk et al., 2012*; *Dalle Grave, Calugi & El Ghoch, 2013*). Studies have shown that PA impacts on weight loss and its maintenance (*Catenacci & Wyatt, 2007*; *Butryn, Webb & Wadden, 2011*), improves body composition (*Lee et al., 2005*; *Kay & Fiatarone Singh, 2006*; *Goodpaster et al., 2010*), reduces risk of cardio-metabolic comorbidities (*Fogelholm, 2010*; *Goodpaster et al., 2010*), and is positively associated with quality of life (*Bond et al., 2006*; *Lerdal et al., 2011*; *Jepsen et al., 2013*) in severely obese subjects. Thus, given the chronic nature of severe obesity, adherence to PA is important (*Tsigos et al., 2008*), but unfortunately PA decreases with increasing body mass index (BMI) (*Tudor-Locke et al., 2010*; *Hansen et al., 2013*). Severely obese subjects face many barriers to PA, such as the excess body weight itself (*Wiklund, Olsén & Willén, 2011*; *Christiansen, Borge & Fagermoen, 2012*) and exposure in public (*Wiklund, Olsén & Willén, 2011*). A persistent increase of PA seems to be difficult (*Borg et al., 2002*; *Tate et al., 2007*). Thus, lifestyle interventions should target and strengthen patients' resources for PA through provision of knowledge and skills and reinforcement of psychological factors that are likely to influence PA. Hence, self-efficacy for PA, perceived behavioural control over PA, and PA self-identity have been proposed as targets for PA interventions (*Hagger, Chatzisarantis & Biddle, 2002*; *Jackson, Smith & Conner, 2003*; *Lorentzen, Ommundsen & Holme, 2007*; *Hansen et al., 2014*).

According to *Bandura (1997)*, self-efficacy covers "a belief about what one can do under different sets of conditions with whatever skills one possesses" (p. 37). Self-efficacy is dynamic and modifiable (*Bandura, 1997*), and in relation to PA, it includes the capability of adoption and maintenance of PA in the face of psychological barriers such as feeling depressed, worried, angry, or stressed (*Lorentzen, Ommundsen & Holme, 2007*). Self-efficacy for PA in the face of psychological barriers has shown positive associations with change in PA in community samples (*Lorentzen, Ommundsen & Holme, 2007*). The related concept of perceived behavioural control refers to a person's "belief as to how easy or difficult performance of the behaviour is likely to be" (*Ajzen & Madden, 1986*, p. 457). Perceived behavioural control predicts PA behaviour (*Hagger, Chatzisarantis & Biddle, 2002*) and plays a role in PA behaviour change in community samples

(*Lorentzen, Ommundsen & Holme, 2007*). Identity is a third factor influencing human behaviour. Hence, there is a reciprocal reinforcing relationship between a behaviour-specific identity and repetition of that behaviour. Furthermore, identity is a product of interaction with others (*Charng, Piliavin & Callero, 1988*). PA identity, i.e., "identifying oneself as a physically active person" (*Lorentzen, Ommundsen & Holme, 2007*, p. 95), has shown positive associations with self-reported PA (*Jackson, Smith & Conner, 2003*) and change in PA (*Lorentzen, Ommundsen & Holme, 2007*) in community samples.

Common outcome variables in research on lifestyle interventions for severely obese adults are body weight and risk factors for medical comorbidities (*Anderson, Conley & Nicholas, 2007*; *Goodpaster et al., 2010*; *Danielsen et al., 2013*; *Karlsen, Sohagen & Hjelmesaeth, 2013*). Because the pathway for these outcomes is behaviour change, it is pivotal to understand factors involved in the behaviour change process. However, to our knowledge, no studies have investigated associations in patterns of change between psychological factors and objectively assessed PA in severely obese adults during a lifestyle intervention. Thus, the aim of this study was to investigate associations between the independent variables: change (Δ) in self-efficacy, Δ perceived behavioural control, and Δ self-identity and the dependent variable of Δ PA. The study hypothesis was that there would be positive associations in the patterns of change between self-efficacy for PA in the face of psychological barriers, perceived behavioural control over PA, and PA identity and objectively assessed PA in severely obese adults participating in a two-year lifestyle intervention.

MATERIALS AND METHODS

Participants and setting

The Haugland Obesity Study has a two-year prospective design. We assessed severely obese patients before, during, and between residential periods in Red Cross Haugland Rehabilitation Centre (RCHRC) in Norway, where they participated in a two-year lifestyle intervention. The programme was funded by the public health services. For those with jobs, the social welfare system paid sick leave benefits during the residential periods. Referral to RCHRC was done by general practitioners. Referred patients were called in to a two-week stay, wherein motivation for change and ability to function in a group were assessed and participation in the programme was decided. Due to limited capacity of the centre, the time from referral to this assessment stay was up to two years. Fifty-three patients, divided in four groups, started the actual intervention (the time point which constituted the baseline of the present study) and were all offered inclusion in the present study. After the intake of these four groups, the public health services reduced the funding to RCHRC and cut the intervention for new patients to a one-year programme with shorter residential stays. Thus, we had to discontinue inclusion of participants.

Inclusion criteria for the intervention were age between 18 and 60 years, and BMI $\geq$ 40 kg/m^2 with or without comorbidities, or $\geq$ 35 kg/m^2 with comorbidities, such as type 2 diabetes, treatment-resistant hypertension, and sleep apnoea (*Norwegian Directorate of Health, 2009*). Exclusion criteria were: referral to, or, previous obesity surgery; pregnancy;

severe cardiovascular disease; alcohol or substance abuse; and mental illness or physical impairment that would prevent adherence to the intervention.

Intervention

The lifestyle intervention was a multi-component programme developed by the health professionals at RCHRC, built on recommendations for best practice (*Shaw et al., 2005*; *Kirk et al., 2012*; *Dalle Grave, Calugi & El Ghoch, 2013*; *Olander et al., 2013*) and prior experience. The objective was to strengthen favourable PA and diet-related behaviour. The intervention covered 15 weeks over two years with four residential periods of six, three, three, and three weeks' duration. A team of physicians, nurses, physiotherapists, exercise therapist, and dietician–many with training in cognitive behavioural therapy (CBT) (*Shaw et al., 2005*)–delivered mandatory practical and theoretical sessions on PA, diet, and CBT. The PA consisted of supervised and un-supervised out- and indoor activities, in groups and individually. Brisk walking, swimming, strength training, ball games, and aerobics were the predominant activities during the residential periods, bringing on moderate to high intensities of PA. The scheduled PA lasted 20–60 min per session, in total nine to eleven hours per week. In addition, the patients were encouraged to carry out PA on their own initiative. Taking preferences, limitations, and sustainability into account, each patient developed a plan for PA for home periods and discussed it with staff. Patients were recommended to combine endurance and strength training and undertake at least 60 daily minutes of PA, which could be divided in intervals of down to ten minutes (*Becker et al., 2004*). Thus, no standard exercise programme was performed in the home periods. The main goal regarding diet was adaptation to a sustainable, healthy diet and a favourable eating-pattern. The meal plan at RCHRC was based on the Nordic Nutrition Recommendations (*Becker et al., 2004*) with three low-fat, high-fibre, and energy-reduced meals and two to three snacks per day. Most of the meals were provided by the canteen. However, the patients prepared some of their meals in supervised groups, and they ate together. They were advised to follow the same dietary principles at home. Thus, severe energy-restriction was not applied. In total, eleven group sessions of CBT, led by members of the health care team, took place, five during the six-week residential period and two during each of the subsequent three three-week periods. Before the end of each session, home work was given, and the following session started with a review of that. In sessions 1–5, during the first stay, the methods and instruments of CBT were introduced and related to change in PA and eating. When the patients came back for the subsequent periods, experiences from the home periods were discussed in sessions 6–11 within the framework of CBT. For eight patients who expressed a need, individual CBT was also provided.

Planning, barrier identification, and relapse prevention and management were practiced to strengthen self-management of PA and eating (*Olander et al., 2013*). The group-based activities aimed at stimulating peer support (*Olander et al., 2013*). Self-monitoring in home periods was promoted using PA diaries (*Olander et al., 2013*) in which patients reported on PA and a few added information on diet and success stories. All patients sent their diaries to RCHRC every month. There was no other structured

follow-up between the residential periods. Patients were encouraged to contact their general practitioner if they needed more support and relatives were not involved in the intervention.

Measures and procedures

Data were collected four times between February 2010 and October 2012 (Fig. 1). The first collection, baseline, was done prior to the start of the intervention, the second at the end of the first residential stay and the third before the third stay, one year from baseline. The final data collection took place before the fourth and last stay, two years from baseline. Socio-demographic data in this study are baseline data.

Psychological factors

The psychological factors were assessed using self-reported questionnaires. Self-efficacy for PA was assessed using a five-item measure. The participants indicated the extent to which they were confident in their ability to perform planned PA in the face of psychological barriers (i.e., feeling tired, depressed, anxious, angry, and stressed) on a seven-point scale from 1 ("not at all confident") to 7 ("very confident"). The scale is a shortened and moderated version of the original instrument developed by *Bandura (2001)*. The version used in this study has demonstrated excellent internal consistency with a Cronbach alpha coefficient of 0.91 (*Hansen et al., 2014*). Another five-item measure was used to assess perceived behavioural control. The participants rated their agreement with three positive (e.g., "I have total control over being regularly physically active") and two negative statements (e.g., "Being regularly physically active is difficult for me") on a seven-point scale from 1 ("totally agree") to 7 ("don't agree at all"). The scale is an extended and moderated version of the original instrument developed by *Norman & Smith (1995)*. The version used in this study has demonstrated acceptable internal consistency with a Cronbach alpha coefficient of 0.67 (*Hansen et al., 2014*). PA self-identity was assessed using a three-item measure. The participants indicated the extent to which they agreed with statements such as "Being physically active is a big part of who I am" on a five-point scale from 1 ("fits poorly") to 5 ("fits well"). The scale is a shortened and moderated version of the original instrument developed by *Anderson & Cychosz (1994)*. The version used in this study has demonstrated excellent internal consistency with a Cronbach alpha coefficient of 0.91 (*Hansen et al., 2014*). All three instruments have shown positive cross-sectional associations with objectively assessed PA in adults (*Hansen et al., 2014*).

Physical activity

PA was measured using the accelerometer Actigraph GTI M (Actigraph, Fort Walton Beach, FL, USA), which is a hip-worn electronic movement sensor that converts acceleration into the arbitrary unit "counts". The counts increase with the magnitude of the work rate for walking. The participants were instructed to wear the accelerometer on the right hip for seven consecutive days, except while sleeping or during water activities. The second assessment was completed towards the end of the first residential stay whereas the others took place in home periods (Fig. 1). The data were analysed with the Actigraph

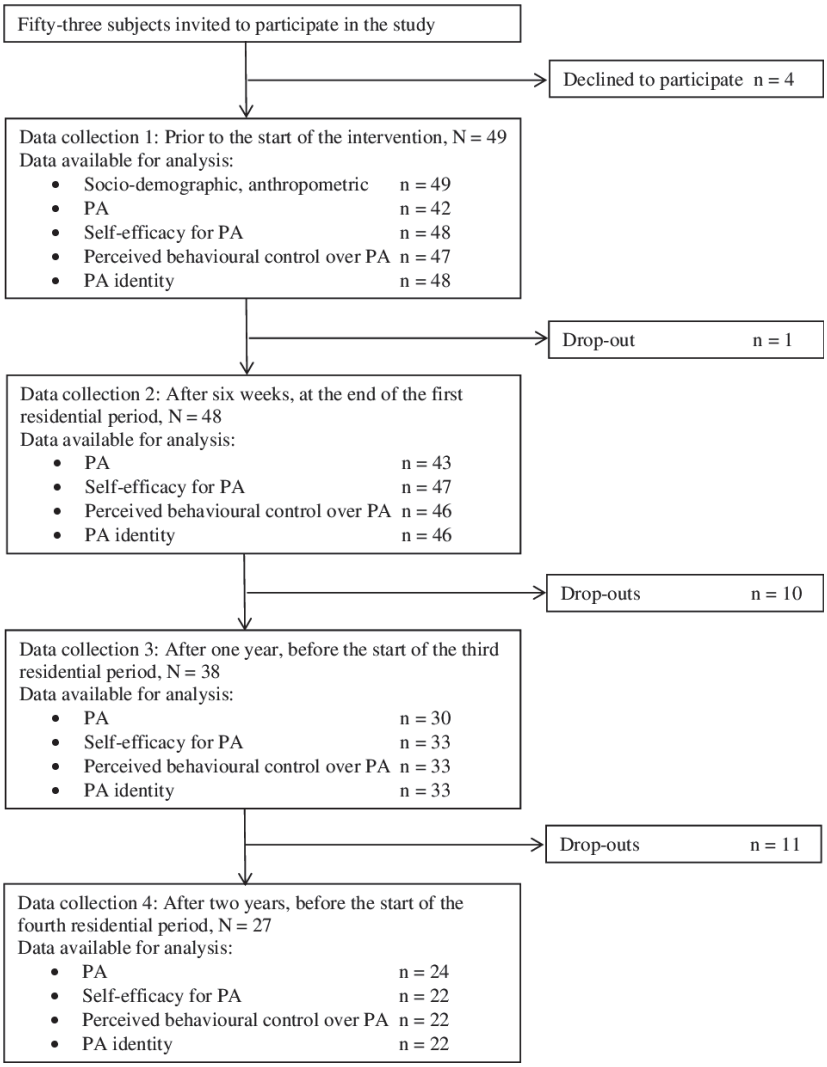

Figure 1 Flow chart for the two-year follow-up study of severely obese adults in a lifestyle intervention. PA, physical activity.

software ActiLife v. 5.3. A wear-time of ≥ten hours per day for ≥four days was the criterion for a valid measure. Periods of ≥60 consecutive minutes without counts were defined as non-wear-time, allowing for up to two minutes of counts greater than zero within these 60 min (*Trost, McIver & Pate, 2005*; *Sirard et al., 2011*). The counts were summed and averaged over the total wear-time to indicate the overall PA in counts per minute

(CPM). The accelerometer has been found to be valid in severely obese adults (*Aadland & Anderssen, 2012*) and accelerometer-assessed PA has superior validity compared to self-reported data (*Prince et al., 2008*).

Socio-demographic information and anthropometry

Socio-demographic information was obtained from questionnaires. Height was measured without shoes to the nearest 0.5 cm with a wall mounted stadiometer (SECA, Germany). Weight was measured on a bioelectrical impedance analysis device (BC 420S MA, Tanita Corp, Tokyo, Japan) and reported to the nearest 0.1 kg.

Ethics

Written informed consent was obtained from all participants prior to the data collection, in accordance with the Helsinki Declaration. Ethical approval was obtained from the Regional Committee for Medical and Health Research Ethics for South-East Norway (registration number 2010/159).

Statistical analysis

Before calculating the mean values for the psychological factors, the three positively worded items for perceived behavioural control were reversed. Thus, higher mean values indicated stronger self-efficacy, perceived control, and identity. Cronbach alpha was used to determine the internal consistency of the instruments.

Data on civil status were dichotomized into "married/cohabiting" vs "single/divorced", educational level into "<15 years of education" vs. "≥15 years of education" (i.e., college/university), and employment into "not working" (i.e., being unemployed or receiving pensions or benefits) vs. "working". BMI was calculated as weight in kilograms divided by the square of the height in meters.

A linear mixed model based on restricted maximum likelihood estimation with random intercept for subjects was used in all analyses for change over time (*Twisk, 2003*), using least significant difference from baseline. Effect size (ES) for change was calculated by subtracting the two-year score from the baseline score, divided by the standard deviation (SD) at baseline. ES were judged against the standard criteria proposed by Cohen: Small change (0.2 to <0.5), moderate change (0.5 to <0.8), and large change (≥0.8) (*Ellis, 2011*).

The associations between the independent variables: Δ self-efficacy for PA in the face of psychological barriers, Δ perceived behavioural control over PA, and Δ PA self-identity and the dependent variable of Δ PA were analysed using linear regression, applying delta scores between time points ($\Delta y_1 = y_1 - y_0$; $\Delta x_1 = x_1 - x_0$; $\Delta y_2 = y_2 - y_1$, etc.) (*Twisk, 2003*). For the independent and dependent variables and BMI, the differences between baseline and week six (Δ1), between week six and year one (Δ2), and between year one and year two (Δ3) were used. The linear mixed model was omitted because the interpretation of the regression coefficients in such a model is difficult, due to mixing of longitudinal (with-in subject) changes and the cross-sectional (between-subject) differences (*Twisk, 2003*). Age, gender, and Δ BMI served as covariates in the multiple regression analyses.

Table 1 **Characteristics of the study sample at baseline, $N = 49$.**

Age, mean (SD)	43.6 (9.4)
Gender, *n* (%)	
Women	37 (75.5)
Socio-demographic status, *n* (%)	
Married/cohabiting	30 (61.2)
Having children	27 (55.1)
Formal education $\geq$ 15 years	22 (44.9)
Employed	41 (83.7)
Anthropometrics, mean (SD)	
Body mass index, kg/m^2	42.1 (6.0)

Notes.
SD, Standard deviation.

A total of $N = 71$ observations was included in the regression analyses. Residuals were normally distributed in all models.

Baseline subject characteristics are presented as percentages for categorical data and mean values (SD) for continuous variables. The estimates, obtained from the linear mixed model, for the psychological factors, PA, and BMI are presented as means with 95% confidence intervals (CI) for the four assessment points. We performed a drop-out analysis with the chi-squared test for difference in gender and the independent samples *t*-test for differences in other variables.

The statistical analyses were done using SPSS v. 20.0 (SPSS Inc., Chicago, USA). A two-sided p-value ≤ 0.05 indicated statistical significance.

RESULTS

Forty-nine patients (37 women, 75.5%) consented to participate in the study. Baseline characteristics are presented in Table 1. Other details of the participants have been presented previously (*Jepsen et al., 2013*; *Aadland et al., 2014*).

Drop-outs and available data for all time points are displayed in Fig. 1. At year two, twenty-two participants (44.9%, 16 women and six men) were lost to follow-up. Reasons for dropping out of the intervention included pregnancy, referral to obesity surgery, having reached personal weight goal, health problems, or obligations that interfered with the intervention. Six participants dropped out for unknown reasons and five withdrew from the study due to problems with the study protocol (repeated blood tests and assessments of maximal oxygen consumption which were included in the Haugland Obesity Study). The participants lost to follow-up did not differ from those who completed the study with regards to gender, age, BMI, PA, or psychological factors at baseline, or initial changes (during the first six weeks) in BMI, PA, or psychological factors. Missing data for psychological factors resulted from participants being absent when the questionnaires were administered at RKHRC. Furthermore, some of the accelerometer-obtained data failed to fulfil the validity requirements.

Table 2 Mixed-effect model estimates: psychological factors, PA, and BMI during the two-year lifestyle intervention for severely obese adults.

	Baseline	Week six		Year one		Year two	
	Mean (95% CI)	Mean (95% CI)	p^d	Mean (95% CI)	p^d	Mean (95% CI)	p^d
Psychological factors							
Self-efficacy for PA in the face of psychological barriers[a]	5.1 (4.7, 5.5)	5.6 (4.1, 6.0)	**.029**	5.4 (5.0, 5.9)	.141	5.5 (5.0, 6.0)	.154
Perceived behavioural control over PA[b]	4.8 (4.5, 5.1)	5.4 (5.0, 5.7)	**.003**	5.3 (4.9, 5.7)	**.026**	5.4 (4.9, 5.8)	**.022**
PA identity[c]	2.7 (2.5, 3.0)	3.1 (2.9, 3.4)	**.001**	3.2 (2.9, 3.5)	**<.001**	3.4 (3.1, 3.7)	**<.001**
Accelerometer assessed PA, counts per minute	276 (241, 311)	452 (417, 486)	**<.001**	327 (286, 368)	**.036**	290 (244, 335)	.606
BMI, kg/m^2	42.1 (40.3, 43.8)	40.1 (38.4, 41.8)	**<.001**	39.4 (37.6, 41.1)	**<.001**	40.7 (38.9, 42.5)	**.001**

Notes.

[a] Scale 1–7; higher scores represent stronger self-efficacy for PA in the face of psychological barriers.

[b] Scale 1–7; higher scores represent stronger perceived behavioural control over PA.

[c] Scale 1–5; higher scores represent stronger PA identity.

[d] *p*-values for change from baseline.

PA, Physical activity; BMI, Body mass index; CI, Confidence interval.

Significant *p*-values ($\leq$0.05) in bold.

The internal consistency of the measures of self-efficacy, perceived behavioural control, and self-identity, calculated at baseline, were acceptable to excellent using Cronbach alpha coefficients of 0.92, 0.67, and 0.93, respectively.

Table 2 shows that PA increased significantly from baseline to the end of the first residential period and remained increased at the one-year follow-up. However, after two years the increase in PA was not maintained (ES = 0.24). All three psychological factors were significantly strengthened at the end of the first residential period (Table 2). However, self-efficacy for PA in the face of psychological barriers decreased thereafter and at one year the improvement had vanished (ES = 0.14). In contrast, perceived behavioural control over PA (ES = 0.51) and PA self-identity (ES = 0.74) remained stronger at year one and two. Compared to baseline, BMI was significantly lower at the three subsequent assessments. However, the weight loss achieved during the first year was only partly maintained at year two (Table 2). The mean weight loss from baseline constituted 4.8% after six weeks, 6.4% at year one, and 3.3% at year two.

Table 3 shows the associations between change in the psychological factors and Δ PA over the two-year intervention. Δ perceived behavioural control was the only independent variable that was significantly associated with Δ PA during the two years.

DISCUSSION

In the present two-year study of associations between change in psychological factors for PA and Δ PA in severely obese adults, we found that Δ perceived behavioural control was associated with Δ PA. By contrast, Δ self-efficacy and Δ self-identity showed no association with Δ PA. Although not directly comparable, our findings differ from a cross-sectional study using the same measures which revealed positive relationships between PA and all the three psychological factors, with self-identity for PA showing the strongest association (*Hansen et al., 2014*).

Table 3 Simple and multiple linear regression analysis with Δ counts per minute as the dependent variable.

	Crude			Adjusted*		
	Reg. coeff. (95% CI)	Stand. coeff.	*p*	Reg. coeff. (95% CI)	Stand. coeff.	*p*
Age	−1.95 (−6.45, 2.54)	−.09	.390	−1.21 (−5.66, 3.25)	−.06	.590
Gender (refer to women)	34.73 (−66.26, 135.72)	.08	.496	13.93 (−83.85, 111.70)	.03	.777
Δ BMI	−44.63 (−65.53, −23.74)	−.44	**<.001**	−39.08 (−61.81, −16.36)	−.38	**.001**
Δ self-efficacy for PA	28.29 (−12.56, 69.15)	.16	.172	21.84 (−16.48, 60.17)	.13	.259
Δ perceived behavioural control over PA	66.51 (31.40, 101.63)	.41	**<.001**	51.11 (16.17, 86.06)	.32	**.005**
Δ PA identity	40.78 (−25.11, 106.68)	.14	.221	−20.14 (−85.07, 44.80)	−.07	.538

Notes.

* Number of observations: 71.

Δ, Change; Reg. coeff., Regression coefficients; CI, Confidence interval; Stand. coeff., Standardized coefficients; BMI, Body mass index; PA, Physical activity.

Age, gender, Δ BMI were included as covariates in the adjusted model.

Significant *p*-values in bold.

It has been proposed that scales on perceived behavioural control reveal aspects of two different dimensions, namely control and difficulty (*Sparks, Guthrie & Shepherd, 1997*). With respect to the instrument used in this study, the positively worded items may capture control while the negative tap into difficulties, which could explain the Cronbach alpha of 0.67. Still, perceived behavioural control over PA was the only independent variable that worked as hypothesised. Not only was it strengthened during the intervention with a moderate ES (*Ellis, 2011*), but the change of it was also associated with Δ PA. Perceived behavioural control has shown cross-sectional associations with self-reported PA in adult obesity surgery patients (*Hunt & Gross, 2009*) and overweight and obese adolescents (*Plotnikoff et al., 2013*). However, to our knowledge, no studies have examined this variable during lifestyle interventions and related it to Δ PA.

Although self-efficacy, as such, is a global concept (*Bandura, 1997*) the measure used in this study was limited to self-efficacy in the face of psychological barriers to PA. The initial strengthening had disappeared at later assessments and was not associated with behaviour change. This could be interpreted as if the intervention did not target or succeed in strengthening self-efficacy in the face of psychological barriers, or it may indicate that psychological barriers did not play a central role in the PA of these subjects. Other barriers, such as time limitations, which we have not investigated, may be of greater significance (*Biddle & Fox, 1998*). Still, a longitudinal study found a positive relationship between moods and PA in overweight to obese adults with diabetes. However, the data were reported by lifestyle coaches, not patients (*Venditti et al., 2014*), implying a possible responder bias (*Ahmed et al., 2012*).

Next, the intervention strengthened the PA self-identity with a moderate ES (*Ellis, 2011*). Embarrassment, poor experience, and non-identification with PA may be obstacles to PA in obese adults (*Biddle & Fox, 1998*; *Hills & Byrne, 2006*). So the strengthening of PA identity could be regarded as positive (*Biddle & Fox, 1998*). However, in our study we could not confirm that strengthened identity translates into more PA. In community samples,

PA identity has shown positive correlations with objectively measured (*Hansen et al., 2014*) and self-reported (*Jackson, Smith & Conner, 2003*) PA. Thus, this phenomenon deserves attention in future research and in clinical practice.

Regarding the impact of body weight, cross-sectional data have demonstrated an adverse relationship between BMI and objectively assessed PA (*Hansen et al., 2013*) and BMI and perceived behavioural control over PA (*Caperchione et al., 2008*). However, when controlling for Δ BMI, Δ perceived behavioural control and Δ PA still showed associations in the present study.

Overall, the findings suggest that factors associated with PA in community samples (*Jackson, Smith & Conner, 2003*; *Lorentzen, Ommundsen & Holme, 2007*; *Hansen et al., 2014*) should not be generalised to samples of severely obese adults in lifestyle interventions without caution and testing. Social and environmental factors, including family, work place, and community, may predict and mediate the mechanisms of change in PA in this population (*Vartanian & Shaprow, 2008*; *Wiklund, Olsén & Willén, 2011*). Thus, future research could take broader perspectives and adopt an ecological approach (*Bauman et al., 2012*).

Our study confirms the findings from other studies (*Borg et al., 2002*; *Tate et al., 2007*) that maintenance of PA is an unresolved challenge. With regards to the overall PA, the initial and year two PA (Table 2) were similar to the PA of American obese adults (288 CPM) (*Tudor-Locke et al., 2010*) and their Norwegian counterparts (women: 276 CPM, men: 290 CPM) (*Hansen et al., 2013*), whereas the mean value from the second assessment (Table 2) was well above the 344 CPM for American normal weight (*Tudor-Locke et al., 2010*) and 352 CPM for women and 368 CPM for men of normal weight in Norway (*Hansen et al., 2013*).

Regarding weight loss, the one-year reduction of BMI (Table 2) was within the criterion for success, defined as 5–10% reduction from the start of an intervention (*Tsigos et al., 2008*; *Dalle Grave, Calugi & El Ghoch, 2013*). However, patients had regained some of the weight at year two which is a common challenge in lifestyle interventions (*Dalle Grave, Calugi & El Ghoch, 2013*).

The present study offered novelty and strength as it used data from four time points and therefore could provide information about patterns of change throughout the two-year intervention. In addition, assessing PA objectively with accelerometers is superior to self-reported PA (*Prince et al., 2008*). However, accelerometers fail to capture water activities, bicycling, and strength training (*Warren et al., 2010*). For the present study, this limitation probably caused a 25% underestimation of the true overall PA for the second assessment (*Aadland et al., 2014*), as such activities were common during the residential period. Still, for the purpose of the study, we decided to avoid reporting of intensity-specific PA, due to difficulties of interpretation when applying count thresholds to separate different intensities of PA generally (*Orme et al., 2014*) and in the severely obese population specifically (*Aadland & Steene-Johannessen, 2012*). Underestimation of PA was probably a minor problem when assessing trends over the home periods, because patients

generally did not engage in such activities (*Aadland & Robertson, 2012*), and because the underestimation would be equally distributed over time.

The main weakness of this study was the relatively high proportion of drop-outs and missing data. Although the drop-out analysis did not reveal differences between the completers and the non-completers, bias cannot be ruled out. However, by using the mixed model based on maximum likelihood estimation and including all valid observations from all four time points, the statistical power increased. Still, our results are based on associations and thus, causal relationships cannot be inferred. Lastly, the participants were a self-selected, treatment-seeking group, participating in a specific intervention programme and there was no control group. While common in clinical studies, these weaknesses limit the generalisability of our results. For transparency and usefulness, we have therefore attempted to report rigorously on the intervention and the flow of the participants (*Vandenbroucke et al., 2007*).

CONCLUSION

Little is known about factors related to the process of change of PA behaviour in severely obese adults participating in lifestyle interventions. We hypothesised that the independent variables: Δ self-efficacy for PA, Δ perceived behavioural control over PA, and Δ PA self-identity would be associated with the dependent variable of Δ PA in the sample of severely obese adults who participated in a two-year programme. However, such an association was only confirmed between Δ perceived behavioural control and Δ PA. More research is required to investigate PA behaviour change processes in severely obese both in non-residential and residential settings and with larger samples and stronger design. An ecological framework may provide a good structure (*Bauman et al., 2012*), with both quantitative and qualitative methods being suitable.

The findings of the present study indicate that perceived behavioural control may be a valid target for increase and maintenance of PA in severely obese adults.

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Competing Interests

Lesley Robertson is employed by the Red Cross Haugland Rehabilitation Centre and John Roger Andersen is employed by the Førde Health Trust. The authors declare there are no competing interests.

Author Contributions

- Randi Jepsen conceived and designed the experiments, performed the experiments, analyzed the data, wrote the paper, prepared figures and/or tables, reviewed drafts of the paper.
- Eivind Aadland conceived and designed the experiments, performed the experiments, analyzed the data, reviewed drafts of the paper.
- Lesley Robertson reviewed drafts of the paper.
- Merete Kristiansen analyzed the data, reviewed drafts of the paper.
- John Roger Andersen and Gerd Karin Natvig conceived and designed the experiments, analyzed the data, reviewed drafts of the paper.

Human Ethics

The following information was supplied relating to ethical approvals (i.e., approving body and any reference numbers):

Ethical approval was obtained from the Regional Committee for Medical and Health Research Ethics for South-East Norway (registration number 2010/159).

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III

Physical activity and quality of life in severely obese adults during a two-year lifestyle intervention programme.

Randi Jepsen [1, 2], Eivind Aadland [1], Lesley Robertson [3], Ronette L. Kolotkin [1, 4, 5, 6, 7], John Roger Andersen [1, 6], Gerd Karin Natvig [2]

[1] Faculty of Health Studies, Sogn og Fjordane University College, NO 6803 Førde, Norway

[2] Department of Global Public Health and Primary Care, University of Bergen, NO 5020 Bergen, Norway

[3] Red Cross Haugland Rehabilitation Centre, NO 6968 Flekke, Norway

[4] Quality of Life Consulting, Durham, NC, USA

[5] Department of Community and Family Medicine, Duke University School of Medicine, Durham, NC, USA

[6] Department of Surgery, Førde Central Hospital, NO 6807 Førde, Norway

[7] Morbid Obesity Centre, Vestfold Hospital Trust, NO 3103 Tønsberg, Norway

Corresponding author:

Randi Jepsen, Sogn og Fjordane University College, Faculty of Health Studies, P.O. Box 523, NO 6803 Førde, Norway. Telephone: +47 57722577. Fax: +47 57722501. E-mail address: randi.jepsen@hisf.no

RJ: randi.jepsen@hisf.no

EA: eivind.aadland@hisf.no

LR: contactlesley61@gmail.com

RLK: rkolotkin@qualityoflifeconsulting.com

JRA: john.andersen@hisf.no

GKN: gerd.natvig@igs.uib.no

Abstract

It is unknown how changes in physical activity may affect changes in quality of life (QoL) outcomes during lifestyle interventions for severely obese adults. The purpose of this study was to examine associations in the patterns of change between objectively assessed physical activity as the independent variable and physical, mental, and obesity-specific QoL and life satisfaction as the dependent variables during a two-year lifestyle intervention. Forty-nine severely obese adults (37 women; 43.6 ± 9.4 years; body mass index 42.1 ± 6.0 kg/m^2) participated in the study. Assessments were conducted four times using Medical Outcomes Study Short-Form Health Survey (SF-36), Obesity-related problems scale (OP), a single item on life satisfaction, and accelerometers. The physical component summary score (PCS) and the mental component summary score (MCS) were used as SF-36 outcomes. Associations were determined using linear regression analyses and reported as standardized coefficients (Stand. coeff). Change in physical activity was independently associated with change in PCS (Stand. coeff. = 0.35, p = .033), MCS (Stand. coeff. = 0.51, p = .001), OP (Stand. coeff. = -.0.31, p = .018), and life satisfaction (Stand. coeff. = 0.39, p = .004) after adjustment for gender, age, and change in body mass index.

Keywords

Severe obesity; Quality of life; Physical activity; Lifestyle intervention; Adults

Introduction

Severely obese adults seeking lifestyle interventions report impaired physical, mental, and obesity-specific quality of life (QoL) [1-3]. Thus, several studies have included QoL as a primary outcome in evaluation of multi-component lifestyle interventions for these individuals [4-7]. These studies have proposed physical activity to be a contributor to unexplained improvements in QoL [4-7]. Danielsen et al. [4] and Karlsen et al. [5] demonstrated improvements in the physical component summary score (PCS) and mental component summary score (MCS) of the Medical Outcomes Study Short-Form 36 Health Survey (SF-36) at the end of one-year, partly residential interventions. Blissmer et al. [7] reported similar findings after a six-month, out-patient intervention for overweight to obese adults. Repeated measures in two of these studies revealed improvements in both PCS and MCS after an initial, intensive intervention phase whereas longer-term maintenance varied [4, 7]. The results reported by Blissmer et al. [7] were independent of weight loss while Danielsen el al. [4] revealed positive associations between weight loss and improvements in PCS but not MCS. With regard to obesity-specific QoL, the Swedish Obese Subjects (SOS) study developed and used the instrument Obesity-related problems scale (OP). After four [2] and ten years [8], the authors found significant improvements in severely obese adults who had received "conventional treatment". However, the treatment was not standardised but provided in accordance with local routines by many primary health care centres. Improvements in OP were positively correlated with weight loss [2, 8]. In contrast, despite weight regain, Kaukua et al. [6] demonstrated improvements in OP at the end of a two-year follow-up of severely obese individuals who completed a four-month, outpatient intervention.

Compared to physical, mental, and obesity-specific QoL, life satisfaction is a broader QoL construct representing a subjective and global assessment of all major dimensions of life [9]. Using single item measures on life satisfaction, obesity was associated with impaired life satisfaction in two U.S. population studies [10, 11], whereas a Danish epidemiological study, controlling for a cluster of lifestyle-related factors including body mass index (BMI), found independent positive associations between self-reported physical activity and life satisfaction [12].

Multi-component lifestyle interventions for severe obesity aim for a sustainable change of behaviour related to diet and physical activity [13]. Physical activity is beneficial for body composition and fitness in obese individuals undergoing dietary energy restriction [14] and reduces adverse cardiovascular outcomes of obesity [15, 16]. In the eight-year follow-up of the Look AHEAD study, self-reported physical activity was associated with initial and maintained weight loss in overweight to obese subjects with type 2 diabetes [17]. Cross-sectional, unadjusted analyses in studies on treatment-seeking severely obese adults have demonstrated positive,

correlations between self-reported physical activity and PCS [18, 19] and MCS [18]. We found positive independent associations between objectively assessed physical activity and life satisfaction prior to a lifestyle intervention for severely obese adults [20] and did a series of studies on patterns of change in the participants during the intervention. We used accelerometers to objectively measure physical activity, collected data at multiple time points, and found positive associations in the patterns of change between physical activity and aerobic fitness [21], fat mass [22], and lipoproteins [23], confirming the importance of physical activity for clinical and anthropometric outcomes in lifestyle interventions. To our knowledge, a similar design has not been used to examine associations between change in physical activity and QoL outcomes over time. Therefore, the present study examines associations between change in objectively assessed physical activity as the independent variable and change in physical, mental, and obesity-specific QoL and life satisfaction as the dependent variables during a two-year, multi-component lifestyle intervention.

Design and methods

This study is part of the Haugland Obesity Study, a prospective cohort study on severely obese adults who participated in a publicly funded two-year lifestyle intervention at Red Cross Haugland Rehabilitation Centre (RCHRC) in Western Norway. Data were collected between February 2010 and October 2012 and the present study used data from four time points: Baseline prior to the intervention (T0), six weeks later at the end of the first residential stay (T1), and prior to the residential stays one (T2) and two years (T3) from baseline.

Referral of patients was done by general practitioners in accordance with the right to admission to the Norwegian specialist health services (i.e., BMI $\geq$ 40 kg/m^2 or $\geq$ 35 kg/m^2 with comorbidities) [24]. In total, 53 eligible patients from the age of 18 to 60 years, divided in four groups, had their first residential stay between February 2010 and October 2011. Exclusion criteria included previous obesity surgery or referral to obesity surgery; severe cardiovascular disease; pregnancy; substance or alcohol abuse; and impaired physical functioning or mental problems which could interfere with adherence to the intervention.

Intervention

The intervention has been described in detail previously [25]. Briefly, the patients spent a total of 15 weeks at RCHRC divided into four stays of six, three (after three months), three (at year one), and three weeks (at year two). A multi-professional team managed the intervention. The overall goal was to improve the QoL of the patients, while weight loss, improved mental health and physical fitness, and reduction of obesity-related

medical problems served as secondary goals. The group-based cognitive behavioural therapy, consisting of eleven sessions over two years, targeted QoL and self-management of physical activity and eating [26]. Scheduled physical activity in the residential periods consisted of brisk walking, swimming, strength training, ball games, and aerobics and amounted to nine to eleven hours weekly divided into bouts of 20-60 minutes. Each patient developed a plan for physical activity, modified to his or her preferences, limitations, and home situation. The diet followed the Nordic Nutrition Recommendations [27] and consisted of three high-fibre, low-fat, and energy-reduced meals and two to three snacks. The patients were advised to follow a similar diet at home. In the home periods, patients kept physical activity diaries which they sent to RCHRC on a monthly basis. There was no other follow-up between the residential periods.

Quality of life measures

SF-36, version 1.2

This is a 36-item measure of general health-related QoL. PCS and MCS are computed from the eight SF-36 subscales. PCS ranges from 15.4 to 62.1 and MCS from 10.1 to 64.0 (with higher scores representing better QoL) [28, 29]. The PCS and MCS have been standardised to a population normal distribution, with a mean of 50 and a standard deviation (SD) of 10. SF-36 has been widely applied in obesity research [1, 30], discriminates between subgroups of severely obese adults [1], and is sensitive to change during lifestyle interventions [4, 5].

OP Scale, version 1.2

This is an eight-item measure of obesity-specific QoL including questions about restaurant visits, holidaying, participation in community activities, swimming in public places, trying on and buying clothes, and intimate/sexual situations. The calibrated score ranges from 0 to 100 (< 40 mild, ≥ 40 to < 60 moderate, ≥ 60 to < 80 severe, and ≥ 80 extreme problems) [2]. OP is reliable and valid in severely obese adults [2, 31]. In the present study, the internal consistency at baseline was excellent with a Cronbach alpha coefficient of 0.91.

Life satisfaction

Life satisfaction was assessed using a global question on current satisfaction with life with seven response alternatives from “very satisfied” to “very dissatisfied”. One-item measures on life satisfaction have demonstrated reliability [32] and validity in health research [33, 34].

Physical activity

To assess physical activity, we used the ActiGraph GTI M accelerometer (ActiGraph, Pensacola, FL, USA), which is an electronic movement sensor. The accelerometer registers vertical acceleration and converts it into the unit "counts" which increases with the magnitude of the work rate for walking. The participants were instructed to wear the accelerometer over the right hip for seven consecutive days while awake, except during water activities. The T0, T2, and T3 assessments took place during home periods, while the T1 assessment was carried out at the end of the first residential period. The ActiGraph software ActiLife v. 5.3 was used for the data analysis. The criterion for a valid measure was wear-time of ≥ ten hours per day for ≥ four days. Non-wear-time was defined as periods of ≥ 60 consecutive minutes without counts, allowing for up to two minutes of counts within these 60 minutes [41, 42]. The overall physical activity, given as counts per minute, was calculated as total counts divided by total valid wear-time. The accelerometer has shown validity in severely obese individuals [43] and accelerometer-assessed physical activity offers more accuracy than self-reported data [44].

Socio-demographic information and anthropometry

Socio-demographic information was self-reported on questionnaires. Health professionals collected the anthropometric data. Height was measured in the standing position without shoes using a stadiometer and reported to the nearest 0.5 cm. Fat mass and weight were measured on a bioelectrical impedance analysis device (BC 420S MA, Tanita Corp, Tokyo, Japan) in the morning, in a fasting state, in light clothes, and after voiding. Weight was reported to the nearest 0.1 kg. Waist circumference was measured twice at exhalation at the level of the umbilicus and reported as the mean of the two measurements.

2.4 Ethics

We obtained written, informed consent from all participants prior to the study in accordance with the Helsinki Declaration. Ethical approval was given by the Regional Committee for Medical and Health Research Ethics for South-East Norway (registration number 2010/159).

2.5 Statistical analysis

The scores on life satisfaction were reversed before analyses so that higher scores indicated better satisfaction with life. BMI was calculated as weight in kilograms divided by height in meters squared. Subject characteristics are presented as means and SD for continuous variables and percentages for categorical data. Observed values

for QoL measures are presented as means and SD. The effect size (ES) for differences between PCS and MSC population norms [35] and the study population scores at the four time points were calculated by subtracting the norms from the mean score of the participants divided by the SD of the latter. We performed an attrition analysis using the chi-squared test for difference in gender and the independent samples *t*-test for differences in other variables.

A linear mixed model based on restricted maximum likelihood estimation with random intercept for subjects was used in all analyses for change (Δ) over time [36], using least significant difference from baseline. The associations between the independent and the dependent variables were analysed using linear regression, applying delta scores between each time point ($\Delta y_1 = y_1 - y_0$; $\Delta x_1 = x_1 - x_0$; $\Delta y_2 = y_2 - y_1$, etc.) [36], giving a total of $n = 73$ (PCS and MCS), 72 (OP), and 71 (life satisfaction) observations. For physical activity, PCS, MCS, OP, life satisfaction, and BMI, the differences between T0 and T1 (Δ1), T1 and T2 (Δ2), and T2 and T3 (Δ3) were used. Gender, age, and change in BMI served as covariates in the adjusted regression analyses. A 1000-repetion bootstrap analysis was used to calculate 95% confidence intervals (CI) of the regression coefficients.

The changes from baseline to each of the time points in QoL measures, physical activity, and BMI, obtained from the linear mixed model, are presented as means with 95% CI. The ES for changes in the dependent variables were calculated by subtracting the mean T1, T2, and T3 estimates from the mean T0 estimate, divided by the SD of T0. Weight loss was calculated as percent change from baseline. A secondary analysis was performed using a baseline-observation-carried-forward approach for missing values.

Effect sizes were judged against the standard criteria proposed by Cohen: Trivial (< 0.2), small (0.2 to < 0.5), moderate (0.5 to < 0.8) and large (≥ 0.8) [37].

Calculation of sample size and power was done using the GPower version 3.1.Statistical analyses were conducted using SPSS for Windows, version 20.0 (SPSS Inc., Chicago, USA). A two-sided *p*-value of ≤ 0.05 indicated statistical significance.

Results

Forty-nine patients (37 women; 43.6 ± 9.4 years; BMI 42.1 ± 6.0 kg/m^2) consented to participate in the study. Baseline socio-demographic and anthropometric characteristics are presented in Table 1. At year two, 16 women and six men (44.9%) were lost to follow-up (Figure 1). Five withdrew from the study due to problems with the study protocol. The rest dropped out of the intervention itself, due to referral to obesity surgery, pregnancy, reaching personal weight goals, health problems, inability to attend the residential stays, or for unknown reasons.

The number of participants at each time point is noted in Table 2. The non-completers did not differ from the completers with regard to gender, age, BMI, physical activity, QoL measures, or changes from T0 to T1 in BMI, physical activity, or QoL measures.

Table 2 documents changes in the QoL measures and the related ES. Over the first six weeks, all scores improved significantly. After two years, MCS and life satisfaction had returned to baseline levels, whereas the improvement in PCS was partly maintained. OP showed a different pattern with continuous improvements. The ES for within-group change was small for OP, moderate for PCS and MCS, and large for life satisfaction after six weeks. At year one, the ES was small for OP and moderate for PCS. Finally, at year two the ES were small for PCS and moderate for OP [37]. Physical activity increased significantly during the first residential stay and was partly maintained at year one. At year two it had returned to baseline level. Weight loss peaked at year one with 6.4% (Table 3).

Scores on PCS, MCS, OP, and life satisfaction are presented in Table 4 including ES for differences between the study population and the Norwegian SF-36 population norm [35]. For PCS, the difference was small at baseline and trivial at year two [37]. For MCS it was trivial both at baseline and after two years. At baseline, the participants reported moderate obesity-related problems. Thereafter the scores on OP reduced to mild problems [2].

Figure 2 illustrates that correlations between change in physical activity and change in QoL measures were strongest for MCS and weakest for OP. This is also demonstrated in Table 5 which presents the results of the regression analyses. In the adjusted analyses, changes in PCS, MCS, OP, and life satisfaction were significantly associated with change in physical activity. The explained variance was moderate for PCS and MCS and small for OP and life satisfaction [37]. Change in BMI was correlated with change in PCS, MCS, and life satisfaction in the unadjusted analyses; however, this association was not statistically significant in the full models. Replacement of change in BMI with change in waist circumference or fat mass did not alter any results (data not shown). We tested for the interaction between physical activity and gender in all four models and found that the women had a stronger association between change in physical activity and change in PCS than the men ($p = 0.012$).

This study has 71 to 73 observations for the main outcomes (Table 5). Given 71 observations, a power of 0.80, and significance level of 0.05, the study should have power to detect a standardized coefficient of 0.32 (medium effect size).

Discussion

Results from this study suggest that change in physical activity is independently associated with change in physical, mental, and obesity-specific QoL and life satisfaction in severely obese adults participating in a lifestyle intervention. In correspondence with the present study, an independent dose-response relationship between exercise and physical and mental SF-36 subscales was reported from a randomized, controlled pre-post-test on a six-month intervention for overweight to obese, menopausal, and hypertensive women [38]. A cross-sectional study on overweight to obese subjects with type 2 diabetes also reported associations between self-reported physical activity and MCS, but not PCS, independent of BMI [39]. By contrast, Ross et al. [40] reported that physical fitness, which may be a proxy for physical activity, did not mediate the association between weight reduction and improvements in SF-36 subscales in obese women enrolled in a six-month intervention. However, the six-minute walk test, which was utilized to assess fitness in the study by Ross et al. [40], may lack accuracy in pre-post-design in obesity research [21]. Bond et al. [19] used self-reported data on physical activity from two time points and found associations with PCS, but not MCS, in obesity surgery-seekers, although these results were not controlled for BMI. With respect to obesity-specific QoL, Kaukua et al. [6] described improvements in OP alongside fluctuations in self-reported physical activity during a lifestyle intervention but did not examine correlations. Regarding life satisfaction, our cross-sectional baseline study from the Haugland Obesity Study found an independent association with physical activity [20]. Population data revealed a positive relationship with self-reported physical activity, though this relationship was not controlled for BMI [10]. A comparison of lifestyle interventions found no difference in life satisfaction between intervention and control groups during a one-year follow-up [41]. However, physical activity was not included in the analyses. So, some studies do not support our finding of associations between change in physical activity and change in all QoL outcomes. One explanation may be that the intervention of the present study clearly differed from other lifestyle interventions in that the overall goal was improvement of QoL. Other interventions have weight management [2, 7] or behaviour change related to physical activity and diet (which should lead to weight loss) [4-6] as primary goals. The inconsistencies across studies may also relate to the cross-sectional design of several of them [10, 20, 39], problems with the reliability of self-reported physical activity [42], the variety of weight classes included in the studies, and other heterogeneities of participants, context, or research designs.

Interestingly, although the unadjusted analyses revealed correlations between changes in BMI and PCS, MCS, and life satisfaction, weight loss did not moderate the associations between the independent and the

dependent variables in the adjusted analyses. Associations between weight loss and improvements in PCS have been found in several studies on patients undergoing lifestyle interventions [4, 5, 43] but not in the study by Blissmer et al. [7]. Findings on the relationship between weight loss and MCS are also inconsistent. Neither Danielsen et al. [4] nor Pazzagli et al. [43] found this association in lifestyle interventions. Neither did Kolotkin et al. [44] after obesity surgery, whereas Karlsen et al. [5] did in a pooled sample of obesity surgery patients and lifestyle intervention completers. Our finding on OP, as the only variable which had a non-significant correlation with change in BMI in the unadjusted analyses, is contradictive to the SOS study which demonstrated short- and long-term decreases in obesity-related problems associated with weight loss [2, 8]. Other obesity-specific measures have also shown associations with weight loss [44]. More research is needed to fully understand the relationship between weight loss and QoL. Noticeably, with regards to the purpose of the present study, none of the above-mentioned studies included physical activity as a variable.

The positive boost in all QoL measures over the first residential stay is noteworthy. PCS and MCS even increased above population norms [35]. Similar improvements on PCS and MCS have been found by Danielsen et al. [4] after an initial, in-patient period and Kaukua et al. [6] at the end of a four-month outpatient programme using the RAND-36 questionnaire, equivalent to the SF-36 [45], and the OP. However, despite the statistically significant effect of physical activity on QoL measures in our analyses, much of the improvements in the dependent variables were left unexplained. Thus, several other aspects may have played a role, such as experience of peer support [46, 47], reduction of anxiety [4], improved eating pattern [48], and improved self-regulation and self-efficacy [49] which have been demonstrated by others after intensive intervention phases, as well as our explicit intervention focus on improvement of QoL. Regarding the patterns of longer-term changes, there are variations across studies. Our finding, that MCS had returned to baseline at year two while moderate ES for the change in PCS was maintained, is opposite to two-year changes reported by Blissmer el al. [7] on overweight to obese subjects. The ES for one-year changes reported for lifestyle intervention-completers by Karlsen et al. [5] is similar to the ES of the present study for PCS (= 0.47), but higher (= 0.32) for MCS. Yet, the baseline scores on PCS (mean = 39, SD = 10) and MCS (mean = 42, SD = 11) were lower compared to our study which may indicate a greater potential for long-term improvements. So, although lifestyle treatment-seekers generally report better QoL than obesity surgery-seekers and worse than non-treatment-seekers [1, 3], variations across study populations in lifestyle interventions may contribute to disparities in research outcomes. Moreover, it may be unrealistic to expect the initial peaks in PCS, MCS, and life satisfaction to last in the long run. In fact, that would imply better PCS and MCS scores than in the general population [35]. For future studies, examining

how favourable outcomes of intensive phases of lifestyle interventions can be maintained – at least partly – over time will be worthwhile. And in that regard, our finding of continued improvement in the OP is of interest. An intervention that can help participants experience less obesity-related problems, despite modest weight loss, may be seen as positive.

Change of health-related behaviours is challenging [13] and the interaction of time is an aspect that deserves consideration. Often, lifestyle interventions are reported to be shorter than the present, e.g., four months [6], six months [7], or one year [4, 5]. The SOS study has published data on long-term follow-up, but the length of the included conventional treatment is not standardised or described [2, 8]. The Look AHEAD study, though including patients of all weight classes from overweight to severely obese, does provide detailed information about lifestyle intervention for adults with type 2 diabetes and is unique with regards to the large number of participants (N = 5,145), the randomisation, and the length of the intervention i.e., eight years [17]. Clearly, more studies are needed to develop a better understanding of long-term effects of lifestyle interventions on QoL outcomes.

Methodological considerations

The present study has several strengths. First, the use of accelerometers to collect data on physical activity increased reliability over self-reporting [42]. Second, as recommended, both general and condition-specific QoL instruments were used [2]. Third, data was collected at four time points and used to reveal associations of patterns of change. Since change of health-related behaviour is complex, increase and maintenance of physical activity are challenging, and subjective constructs like QoL are not straightforward, these findings on patterns of change contribute uniquely to the body of knowledge about lifestyle interventions for severely obese adults.

A limitation of this study was that the number of participants lost to follow-up challenged the statistical power. High attrition is not unusual in research on lifestyle interventions [6, 7] but differences between completers and non-completers vary across studies from none [5, 6] to one [4, 7] or some [50]. In the present study, the attrition analyses revealed no statistical difference in key variables between the drop-outs and the completers. The secondary analysis confirmed the statistical level of change in the QoL measures, counts per minute, and BMI (data not shown). To deal with the challenge of statistical power, all valid data were included in the linear mixed model. Regarding the sample size, the study was powered to detect medium sized effect sizes as found in the regression analysis of this study. Due to the right to treatment [24], including a control group amongst the referred patients was not possible. This study examined associations and therefore, causal

relationships could not be inferred. And the study did not control for change of diet, a possible confounder in the associations we examined [51, 52]. However, physical activity has been found to contribute more to QoL than dieting [53]. In addition, we controlled for change in BMI which may be a proxy for diet, because generally diet modifications produce more weight loss than physical activity [54, 55]. Lastly, the patients were a self-selected, treatment-seeking group although public funding of the intervention gave equal access to all and, therefore, diminished the risk of socio-economic bias [56].

Conclusions

It has been proposed that lifestyle interventions for obese individuals should focus less on weight loss as the primary outcome and pay more attention to independent benefits of physical activity such as reduction of obesity-related health hazards [57] and improvements of QoL [38]. The present study contributes uniquely to the literature on severe obesity, physical activity, and self-reported outcomes and indicates that improved QoL may be a valid result of increased physical activity in multi-component lifestyle interventions. These findings should be further tested in various settings, in larger samples, and with control groups.

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Table 1 Characteristics of the adults with severe obesity at baseline, $N = 49$

Age, mean (SD)	43.6 (9.4)
Gender, *n* (%)	
Women	37 (75.5)
Socio-demographic status, *n* (%)	
Married/cohabiting	31 (63.3)
Having children	27 (55.1)
College/university education	22 (44.9)
Employed	41 (83.7)
Anthropometrics, mean (SD)	
Body mass index, kg/m^2	42.1 (6.0)
Weight, kg	123.9 (18.6)
Waist circumference, cm	128.3 (13.0)
Fat mass, %	58.2 (11.7)

Standard deviation: SD

Table 2 Mixed-effect model estimates: mean changes (95% CI) in quality of life outcomes during the two-year lifestyle intervention for severely obese adults

Measure	T1: Change from T0	T2: Change from T0	T3: Change from T0
SF-36 Physical component summary[a]	5.7 (7.4, 4.0) $p <$ **.001**	4.4 (6.3, 2.5) $p <$ **.001**	3.3 (5.5, 1.1) $p =$ **.004**
Effect size	0.61	0.54	0.48
SF-36 Mental component summary[b]	5.9 (8.6, 3.1) $p <$ **.001**	-0.4 (-2.7, 3.5) $p = .794$	-1.8 (-1.8, 5.3) $p = .327$
Effect size	0.55	0.02	-0.06
Obesity-related problems scale[c]	-8.4 (-2.9, -13.9) $p =$ **.003**	-11.2 (-5.0, -17.4) $p =$ **.001**	-13.3 (-6.2, -20.4) $p <$ **.001**
Effect size	0.30	0.49	0.57
Life satisfaction[d]	0.99 (1.30, 0.67) $p <$ **.001**	0.47 (0.82, 0.12) $p =$ **.009**	0.20 (0.60, 0.20) $p = .324$
Effect size	1.00	0.55	0.22

T0: before the intervention ($n = 49$); T1: after six weeks ($n = 48$); T2: year one ($n = 38$); T3: year two ($n = 27$).
[a]Scale 15.4-62.1; higher scores represent better quality of life. Medical Outcomes Study Short-Form 36 Health Survey.
[b]Scale 10.1-64.0; higher scores represent better quality of life. Medical Outcomes Study Short-Form 36 Health Survey
[c]Scale 0-100; higher scores represent more obesity-related problems.
[d]Scale 1-7; higher scores represent better life satisfaction.
Significant p-values (≤ 0.05) in bold.
Effect sizes for the within-group changes were calculated by subtracting the mean estimates of follow-ups from the mean estimates at baseline divided by the SD of the latter. They were judged against the standard criteria proposed by Cohen: Trivial (< 0.2), small (0.2 to < 0.5), moderate (0.5 to < 0.8) and large (≥ 0.8) [37].
Confidence interval: CI.

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Table 3 Mixed-effect model estimates: Physical activity and BMI during the two-year lifestyle intervention for severely obese adults

	T0	T1		T2		T3	
	Mean (95% CI)	Mean (95% CI)	p^*	Mean (95% CI)	p^*	Mean (95% CI)	p^*
Accelerometer assessed physical activity, CPM†	$n = 42$	$n = 43$		$n = 30$		$n = 24$	
	276 (241, 311)	452 (417, 486)	**< .001**	327 (286, 368)	**.036**	290 (244, 335)	.606
BMI, kg/m^2	$n = 49$	$n = 48$		$n = 38$		$n = 27$	
	42.1 (40.3, 43.8)	40.1 (38.4, 41.8)	**< .001**	39.4 (37.6, 41.1)	**< .001**	40.7 (38.9, 42.5)	**.001**
Weight loss from T0, per cent		4.8		6.4		3.3	

T0: before the intervention; T1: after six weeks; T2: year one; T3: year two.
Significant p-values (≤ 0.05) in bold.
$^*p$-values for change from T0.
Body mass index: BMI; confidence interval: CI; counts per minute: CPM.
†Mean physical activity of American obese adults: 288 CPM [58]. Mean physical activity of Norwegian obese women: 276 CPM and men: 290 CPM [59]. Mean physical activity of American normal weight adults: 344 CPM [58]. Mean physical activity of Norwegian normal weight women: 352 and men: 368 CPM [59].

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Table 4 Mean and standard deviation of quality of life outcomes during the two-year lifestyle intervention for severely obese adults

		T0	T1	T2	T3	Population norm
SF-36[a]		*n* = 49	*n* = 47	*n* = 33	*n* = 23	
	Physical component summary	45.3 (9.6)	51.2 (7.3)	50.5 (7.8)	49.9 (7.6)	49.0
	Effect size	-0.39	0.30	0.19	0.12	
	Mental component summary	48.4 (10.2)	54.0 (7.7)	48.6 (12.8)	47.8 (10.7)	49.0
	Effect size	-0.06	0.65	-0.03	-0.11	
Obesity-related problems[b]		*n* = 49	*n* = 46	*n* = 33	*n* = 23	
		44.6 (26.3)	36.7 (25.0)	31.8 (28.0)	29.7 (24.4)	n/a
Life satisfaction[c]		*n* = 49	*n* = 46	*n* = 33	*n* = 23	
		4.6 (0.9)	5.5 (1.0)	5.1 (0.9)	4.8 (0.9)	n/a

T0: before the intervention; T1: after six weeks; T2: year one; T3: year two.

[a]Scale 0-100; higher scores represent better quality of life. Medical Outcomes Study Short-Form Health Survey (SF 36). The SF-36 data for the norm population (n = 2,323) are adjusted for gender and age [35] and presented as means. Effect sizes for differences between the study participants and the norm population were calculated by subtracting the mean score of the population norm from the mean score of the study participants divided by the SD of the latter. They were judged against the standard criteria proposed by Cohen: Trivial (< 0.2), small (0.2 to < 0.5), moderate (0.5 to < 0.8) and large (≥ 0.8) [37].

[b]Scale 0-100; higher scores represent more obesity-related problems. Obesity-related problems scale.

[c]Scale 1-7; higher scores represent better life satisfaction.

[35] J. H. Loge, S. Kaasa, M. J. Hjermstad, and T. K. Kvien, "Translation and performance of the Norwegian SF-36 Health Survey in patients with rheumatoid arthritis. I. Data quality, scaling assumptions, reliability, and construct validity," *Journal of Clinical Epidemiology*, vol. 51, no. 11, pp. 1069-1076, 1998.

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Table 5 Reg. coeff. with 95% CI and stand. coeff. (β) for simple and multiple[a] linear associations between change in physical activity as the independent and change in quality of life outcomes as the dependent variables

	Change in PCS[b]			Change in MCS[b]			Change in OP[c]			Change in life satisfaction[d]		
	Reg. coeff. (95 % CI)	β	*p*	Reg. coeff. (95 % CI)	β	*p*	Reg. coeff. (95 % CI)	β	*p*	Reg. coeff. (95 % CI)	β	*p*
Gender = male												
Crude	0.31 (-2.66, 3.26)	.02	.838	2.10 (-2.63, 6.84)	.09	.380	-0.68 (-9.28, 7.93)	-.02	.876	-0.13 (-0.76, 0.51)	-.04	.691
Adj.	-0.65 (-3.39, 1.96)	-.05	.635	1.77 (-2.81, 6.73)	.07	.472	-1.40 (-11.89, 8.32)	-.03	.783	-0.22 (-0.97, 0.49)	-.07	.530
Age												
Crude	0.09 (-0.04, 0.23)	.13	.179	0.05 (-0.17, 0.27)	.04	.658	-0.18 (-0.58, 0.22)	-.09	.375	0.01 (-0.02, 0.04)	.06	.555
Adj.	0.04 (-0.13, 0.20)	.06	.650	0.08 (-0.18, 0.34)	.07	.537	-0.21 (-0.71, 0.24)	-.10	.363	0.003 (-0.027, 0.031)	.02	.852
Change of BMI												
Crude	-0.92 (-1.56, -0.29)	-.28	**.005**	-1.36 (-2.41, -0.32)	-.26	**.011**	1.82 (-0.09, 3.73)	.19	.061	-0.18 (-0.31, -0.04)	-.26	**.011**
Adj.	-0.34 (-1.32, 0.38)	-.11	.434	-0.03 (-1.44, 1.33)	-.01	.960	-0.24 (-3.03, 2.80)	-.03	.850	-.003 (-0.181, 0.142)	-.01	.974
Change of physical activity[e]												
Crude	0.011 (0.005, 0.017)	.39	**< .001**	0.028 (0.017, 0.039)	.50	**< .001**	-0.027 (-0.048, -0.007)	-.29	**.011**	0.003 (0.001, 0.004)	.39	**.001**
Adj.	0.010 (0.001, 0.019)	.35	**.033**	0.028 (0.014, 0.044)	.51	**.001**	-0.029 (-0.058, -0.008)	-.31	**.018**	0.003 (0.001, 0.004)	.39	**.004**
Adj. R^2	0.13			0.22			0.04			0.11		

[a]All variables in the first column.
[b]Physical component summary (PCS) and mental component summary (MCS) of the Medical Outcomes Study Short-Form Health Survey (SF-36). Continuous scales. Higher scores represent better quality of life.
[c]Obesity-related problems scale. Continuous scale. Higher scores represent more obesity-related problems.
[d]Continuous scale. Higher scores represent better life satisfaction.
[e]Accelerometer assessed.
Regression coefficients: reg. coeff.; confidence interval: CI; standardized coefficients: stand. coeff.; adjusted: adj.; body mass index: BMI.
*Number of observations: change in PCS: 73; change in MCS: 73; change in OP: 72; change in life satisfaction: 71.
Significant *p*-values (≤ 0.05) in bold.

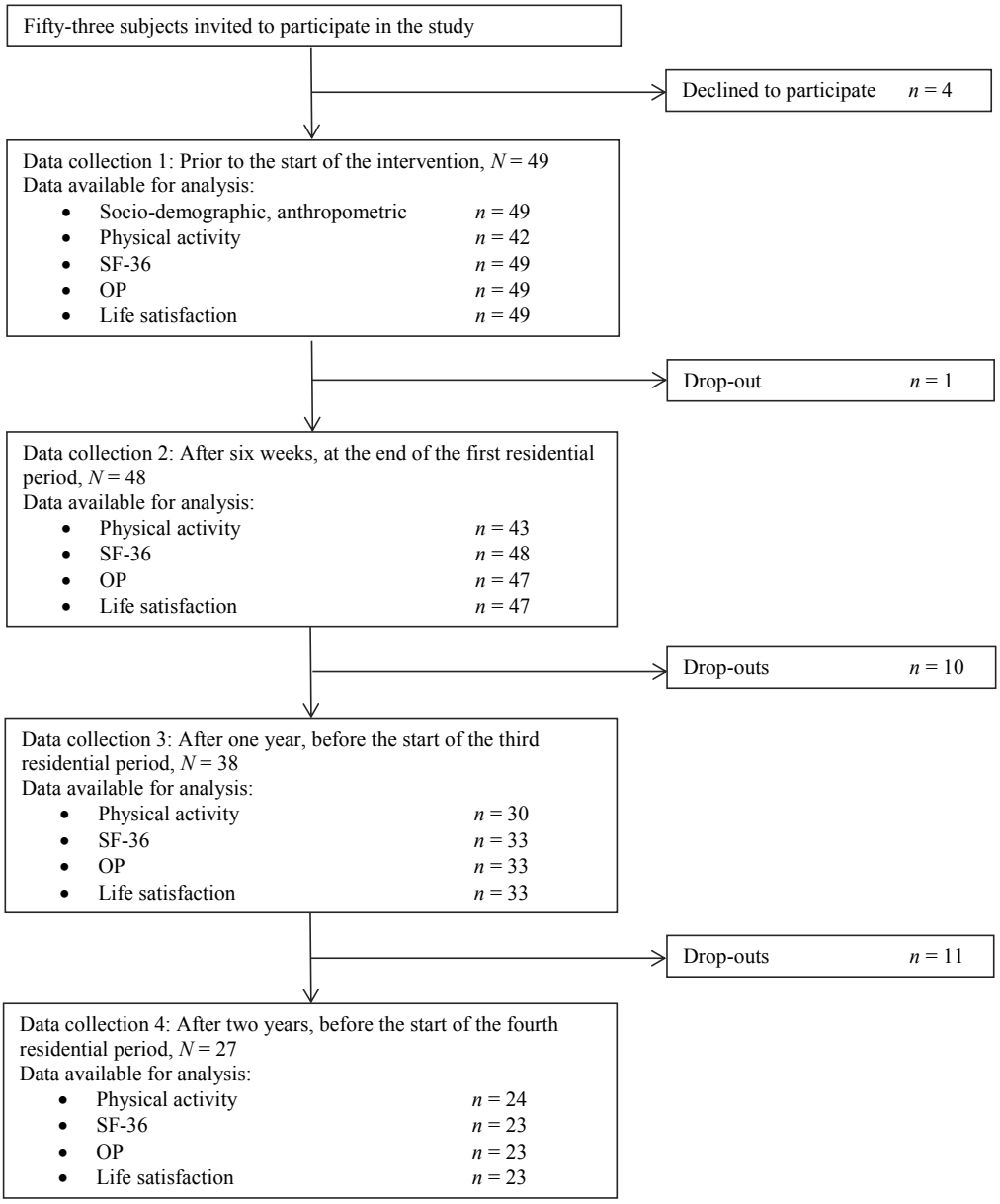


Figure 1. Flow chart for the prospective study of severely obese adults in a two-year lifestyle intervention
Medical Outcomes Study Short-Form 36 Health Survey: SF-36 ; Obesity-related problems scale: OP

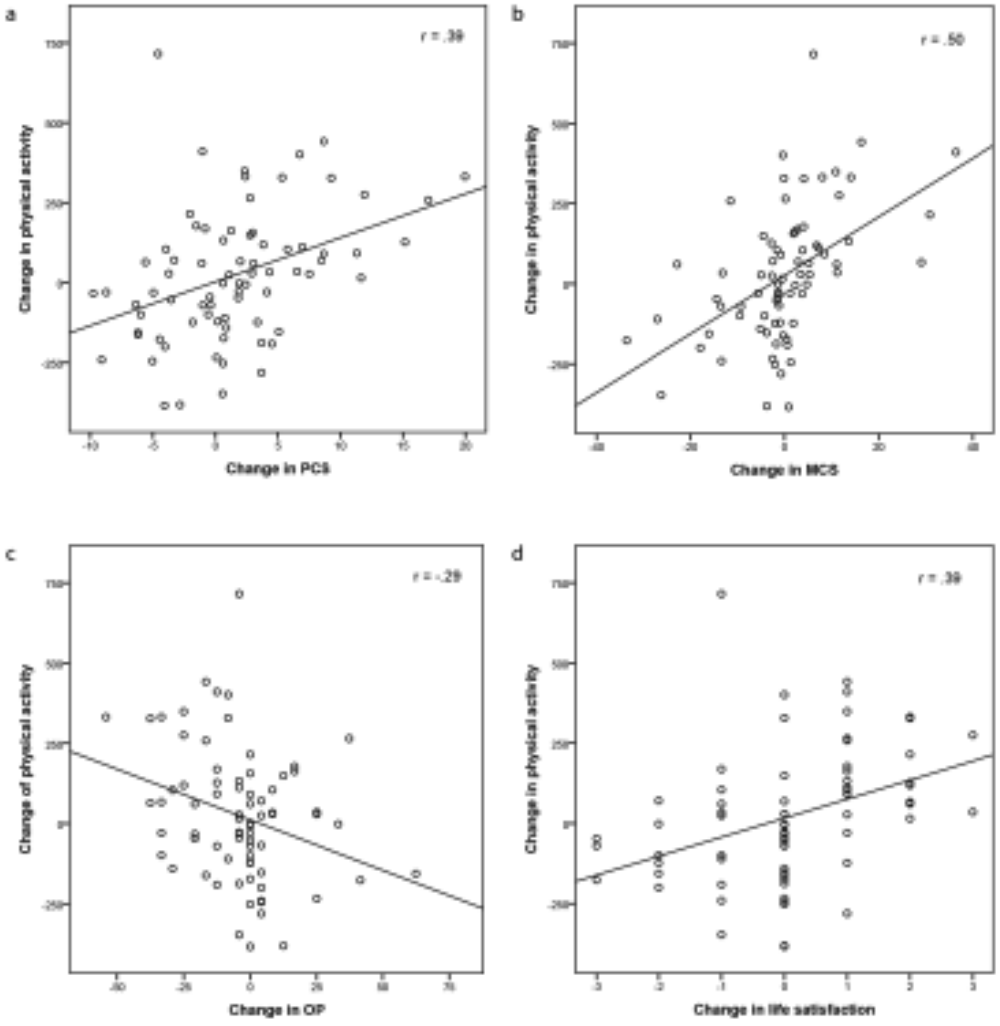


Figure 2a-d Correlations between change in accelerometer assessed physical activity (counts per minute) and change in a) PCS, b) MCS, c) OP, and d) life satisfaction during the two-year lifestyle intervention for severely obese adults

PCS (physical component summary score) of the Medical Outcomes Study Short-Form Health Survey (SF-36). Scale 15.4-62.1. Higher scores represent better health-related quality of life.

MCS (mental component summary score) of the Medical Outcomes Study Short-Form Health Survey (SF-36). Scale 10.1-64.0. Higher scores represent better health-related quality of life.

OP: Obesity-related problems scale. Scale 0-100. Higher scores represent more obesity-related problems.

Life satisfaction. Scale 1-7.Higher scores represent better satisfaction with life.

IV

Appendix I

UNIVERSITETET I OSLO
DET MEDISINSKE FAKULTET

Stipendiat Eivind Aadland
Høgskulen i Sogn og Fjordane
Pb. 133
6851 Sogndal

Regional komité for medisinsk og helsefaglig forskningsetikk Sør-Øst A (REK Sør-Øst A)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 22 84 46 66

E-post: jorgen.hardang@medisin.uio.no
Nettadresse: http://helseforskning.etikkom.no

Dato: 12.02.2010
Deres ref.:
Vår ref.: 2010/159a

2010/159a Livsstilsbehandling av sjukleg overvektige personar ved Hauglandssenteret

Vi viser til søknad om førehandsgodkjenning av det nemnde forskingsprosjektet. Søknaden ble behandla av Regional komité for medisinsk og helsefaglig forskingsetikk i møtet den 28.1.2010. Søknaden er vurdert med grunnlag i lov av 20. juni 2008 nr. 44, om medisinsk og helsefaglig forskning (helseforskingslova) kapittel 3, med forskrift om organisering av medisinsk og helsefaglig forskning av 1. juli 2009 nr 0955.

Prosjektleiar: Stipendiat Eivind Aadland, Høgskulen i Sogn og Fjordane.

Forskingsansvarleg: Høgskulen i Sogn og Fjordane ved dekan Eva Marie Halvorsen.

Prosjektet har som mål å undersøke effekten av eit eitt-årig livsstilsbehandlingsprogram (tre opphald av 6 + 3 + 3 veker), for sjukleg overvektige med omsyn til fysisk aktivitetsnivå, fysisk form, morfologiske variablar, risikofaktorar for hjarte-og karsjukdom og livskvalitet. Studien er ein prospektiv kvantitativ studie der data samlast inn ved baseline og ved ulike intervallar gjennom eit år. Ein vil undersøke 50 personar som vil gi tilstrekkeleg statistisk styrke til å trekke vitskapelege konklusjonar.

Studien har to forskingsspørsmål: 1) Korleis er samanhangen mellom intensitet av fysisk aktivitet målt ved oksygenopptak og akselerometer for sjukleg overvektige. 2) Kva er effekten av fysisk aktivitet gjennom eit eittårig livssstilsbehandlingsopplegg hos sjuklig overvektige på kroppsvekt, fysisk form, risikofaktorar for hjarte- og karsjukdom og helserelatert livskvalitet. Det skal nyttast metodar som gjør at delar av data kan samanliknast med eit norsk normmateriale.

Ulempe for deltakarane er sagt å være at det blir teke blodprøver på 7 ulike tidspunkt over eitt år, at det vil bli målt maksimalt oksygenopptak og at personane vil gå med akselerometer til saman i fire veker over eitt år.

Det kjem fram at personane er identifiserbare, men at identifiserbare opplysningar ikkje vil bli oppgitt til forskingsgruppa, bare til prosjektleiar. Identifiserbare opplysningar vil bli lagra ved institusjonen.

Ettersom det skal takast blodprøve og prøvene skal oppbevarast, blir det søkt om å opprette forskningsbiobank med namnet "Livsstilsbehandling av sjukleg overvektige personar ved Hauglandssenteret". Biobanken er planlagt å vare fram til 2020. Ansvarleg for biobanken er Eirik Fismen. Deltakarene gjev samtykke til oppbevaring av biologisk prøver og til utførsel til University of Oulu and Biocenter Oulu i Finland.

Vilkår for godkjenning:

1. Komiteen går ut frå at rettleiar med forskarkompetanse står som prosjektleiar, jf. Departementets retningslinjer, kapittel 2, der det blir lagt vekt vitskapelig kompetanse for ansvarlig leiar av et medisinsk forskingsprosjekt.

2. Det går ikkje fram av informasjonsskrivet når data skal slettast og det biologiske materialet destruerast, sjølv om de står at forskningsbiobanken skal vare til 2020. Dette må det informerast om i informasjonsskrivet.
3. Det må også stå noe i informasjonsskrivet om kva slags analyser som skal gjerast av det biologiske materialet.

Vedtak

Komiteen godkjenner at prosjektet blir gjennomført under føresetnad av at dei vilkår som er nemnt ovanfor blir innarbeidde før prosjektet blir sett i gang.

Komiteen godkjenner at forskningsbiobanken "Livsstilsbehandling av sjukleg overvektige personar ved Hauglandssenteret" blir oppretta.

Godkjenninga er gitt under føresetnad av at prosjektet gjennomføres slik det er gjort greie for i søknaden og i protokollen, og det som følgjar av helseforskingslova med forskrifter.

Dersom det skal gjerast endringar i prosjektet i forhold til de opplysningar som er gitt i søknaden, må prosjektleiar sende endringsmelding til REK.

Data i forskingsprosjektet skal oppbevarast forsvarleg, sjå personopplysningsforskrifta kapittel 2, og Helsedirektoratets rettleiar «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren». Personidentifiserbare data skal slettast straks det ikkje lenger er behov for dei og seinast ved avslutning av prosjektet.

Godkjenninga gjelder til 1.12.2014. Prosjektet skal sende sluttmelding på eige skjema, sjå helseforskingslova § 12, seinast et halvt år etter prosjektslutt.

Det kan leverast inn klage på vedtaket i komiteen (jf. Forvaltningslova § 28) til Den nasjonale forskningsetiske komiteen for medisin og helsefag. Klaga skal sendes til REK Sørøst A (jf. Forvaltingslova § 32). Klagefristen er tre veker frå den dagen du mottar dette brevet (jf. Forvaltningslova § 29).

Vi ber om at tilbakemelding eller spørsmål blir sendt inn via vår saksportal: http://helseforskning.etikkom.no eller på e-post til: post@helseforskning.etikkom.no

Ver venleg å bruke vårt saksnummer/referansenummer i korrespondansen.

Med venleg helsing

Gunnar Nicolaysen (sign)
Professor
Leiar

Jørgen Hardang
Komitésekretær

Kopi til forskingsansvarleg: Høgskulen i Sogn og Fjordane ved Dekan Eva Marie Halvorsen; Eva.halvorsen@hisf.no

Appendix II

UNIVERSITETET I OSLO

DET MEDISINSKE FAKULTET

Stipendiat Eivind Aadland
Høgskulen i Sogn og Fjordane
Pb. 133
6851 Sogndal

Regional komité for medisinsk og helsefaglig forskningsetikk Sør-Øst A (REK Sør-Øst A)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 22 85 92 03

E-post: post@helseforskning.etikkom.no
Nettadresse: http://helseforskning.etikkom.no

Dato: 20.12.2010
Deres ref.:
Vår ref.: 2010/159a

2010/159a Livsstilsbehandling av sjukleg overvektige personar ved Hauglandssenteret

Vi viser til melding om prosjektendring mottatt den 22.11.2010.

Prosjektleder: Stipendiat Eivind Aadland, Høgskulen i Sogn og Fjordane.

Forskningsansvarlig: Høgskulen i Sogn og Fjordane ved dekan Eva Marie Halvorsen.

Prosjektet ønsker å utvide datainnsamlingen fra ett års oppfølging til å omfatte to års oppfølging. Begrunnelse er for å kunne undersøke hvilken effekt programmet har over en lengre periode. Endringen vil ikke omfatte datainnsamling utover den tiden deltakerne deltar i behandlingsopplegg.

Informasjonsskriv og samtykkeerklæring er oppdatert i samsvar med utvidelse av tidsperiode til to år for datainnsamling.

Komiteen har vurdert endringene, og finner å kunne godkjenne disse.

Vær vennlig å bruke vårt saksnummer/referansenummer i korrespondansen.

Med vennlig hilsen

Gunnar Nicolaysen (sign)
Professor
Leiar

Tone Gangnæs
Seniorrådgiver

Kopi: Høgskulen i Sogn og Fjordane ved Dekan Eva Marie Halvorsen;
Eva.halvorsen@hisf.no

Appendix III

Førespurnad om deltaking i forskingsprosjekt

Fysisk aktivitet, fysisk form, livskvalitet og risikofaktorar for hjarte- og karsjukdom hjå personar til livsstilsbehandling for sjukleg overvekt ved Hauglandssenteret

Bakgrunn og hensikt
Dette er eit spørsmål til deg om å ta del i ein forskingsstudie for å undersøkje effekt av langvarig livsstilsendring hjå sjukleg overvektige. Du blir spurt om å delta fordi du er tatt inn til behandling ved Hauglandssenteret gjennom Helse Vest. Høgskulen i Sogn og Fjordane er ansvarleg for gjennomføring av studien.

Kva innebér studien?
Studien skal undersøkje korleis langvarig livsstilsendring hjå sjukleg overvektige påverkar fysisk aktivitetsnivå, fysisk form, kroppsvekt, kroppssamansetnad, livskvalitet og risikofaktorar for hjarte- og karsjukdom. Å delta i studien vil medføre noko utvida testing og blodprøvetaking i høve til standard behandling. Du blir spurt om bakgrunnsinformasjon som kjønn og alder, sjukdomshistorie og sosioøkonomiske faktorar samt kosthald, livsstil og livskvalitet ved hjelp av spørjeskjema. Vidare vert fysisk aktivitetsnivå, fysisk form, kroppsvekt, midjemål, kroppssamansetnad, blodtrykk og ulike blodvariablar målt på ulike måtar (sjå vedlegg A). Behandlingsopplegget vil vere det same om du tek del i studien eller ikkje.

Moglege fordeler og ulemper
Fordeler med å ta del i studien er at du lærer din eigen kropp å kjenne og får tettare oppfølging i høve til korleis behandlinga fungerer for deg. Ulemper med å ta del i studien er at du må ta nokre ekstra blodprøvar som kan opplevast som ubehageleg. I tillegg må du bere ein aktivitetsmålar i til saman fire veker, og testar av fysisk form vil vere slitsamt.

Kva skjer med prøvane og informasjonen om deg?
Prøvane som er tatt av deg og informasjonen som registrerast om deg skal kun nyttast som beskrive i hensikta med studien. Alle opplysningane og prøvane vil bli behandla utan namn og fødselsnummer eller andre direkte gjenkjennande opplysningar. Ein kode knyter deg til dine opplysningar og prøvar gjennom ei namneliste. Det er kun autorisert personell knyta til prosjektet som har tilgang til namnelista og som kan finne tilbake til deg. Det vil ikkje vere mogleg å identifisere deg i resultata av studien når desse vert publisert.

Frivillig deltaking
Det er frivillig å ta del i studien. Du kan kva tid som helst og utan å oppgi noko grunn trekke ditt samtykke til å delta i studien. Dette vil ikkje få konsekvensar for di vidare behandling. Dersom du ynskjer å ta del i studien, underteiknar du samtykkeerklæringa på siste side. Om du no seier ja til å delta, kan du seinare trekkje tilbake ditt samtykke utan at det påverkar di øvrige behandling. Dersom du seinare ynskjer å trekkje deg eller har spørsmål til studien, kan du kontakte Anne Grethe Lien (tlf 57737177 / 90988542) eller Eivind Aadland (tlf 57676086 / 47623461)

Meir informasjon om studien finn du i vedlegg A –*Utdjuping av kva studien innebér*
Meir informasjon om biobank, personvern og forsikring finn du i vedlegg B –
Personvern, biobank, økonomi og forsikring

Samtykkeerklæring følgjer etter kapittel B.

Vedlegg A Utdjuping av kva studien innebér

Kriterier for deltaking
Utvalet i studien vil vere pasientar med rett til naudsynt helsehjelp i spesialisthelsetenesta for behandling av sjukleg overvekt. Inklusjonskriterier er kroppsmasseindeks (KMI) > 40 eller > 35 med følgjesjukdom og alder 18 – 60 år. Alle som er til behandling i ordinært opplegg på Hauglandssenteret kan ta del i studien.

Bakgrunn for studien
Overvekt og fedme er ei stor utfordring internasjonalt og nasjonalt. Konsekvensane av aukande overvekt er redusert levetid, førekomst av ei rekkje sjukdomar, redusert livskvalitet og økonomiske konsekvensar for den enkelte og samfunnet. Ei rekkje studier har vist at livsstilsbehandling og fysisk aktivitet er gunstig for overvektige (KMI > 25) og personar med fedme (KMI > 30), men svært få studier har undersøkt effekten av denne behandlinga for sjukleg overvektige (personar med KMI > 40 eller > 35 med følgjesjukdom). For denne gruppa er bariatrisk kirurgi den einaste behandlingsforma med god dokumentert effekt, men alle kan ikkje eller ynskjer ikkje slik behandling. Behandlinga kan også ha uheldige sideverknadar som komplikasjonar etter inngrepet og mangeltilstandar grunna redusert opptak av næringsstoff.

Tidlegare studier som har undersøkt livsstilsbehandling har sentrale svakheiter som lite fysisk aktivitet, manglande kontroll på kor mykje fysisk aktivitet som er gjennomført, og kroppsvekt er gjerne einaste eller viktigaste effektmål. Dette fører til at me veit lite om fysisk aktivitet si rolle ved vektreduksjon, og særs lite om livsstilsbehandling for sjukleg overvektige.

Formålet med dette prosjektet er å undersøke effekten av livsstilsbehandling med høgt fysisk aktivitetsnivå for sjukleg overvektige i høve til fleire effektmål. I tillegg til kroppsvekt vert midjemål, kroppssamansetnad, objektivt målt fysisk aktivitetsnivå, fysisk form, livskvalitet og risikofaktorar for hjarte- og karsjukdom undersøkt.

Kva skjer om du vel å ikkje ta del i studien?
Dersom du seier nei til deltaking vil du gjennomføre det same behandlingsopplegget som alle andre. Du vil også gå gjennom standard testing ved Hauglandssenteret, men dette er mindre omfattande enn testinga i prosjektet. Du vil såleis få mindre kjennskap til korleis behandlingsopplegget fungerer for deg.

Tidsskjema –kva skjer og kva tid skjer det?
Du blir spurt om bakgrunnsinformasjon som kjønn og alder, sjukdomshistorie og sosioøkonomiske faktorar samt livsstil og livskvalitet ved hjelp av spørjeskjema på fyrste og tredje opphald. Kroppsvekt, midjemål og kroppssamansetnad vert målt kvar tredje veke under opphald på Hauglandssenteret. Blodtrykk og blodprøvar vert tatt når du møter til opphald og når du reiser frå opphald. I tillegg vert dette målt midtvegs under det fyrste opphaldet. Blodprøvar analyserast for risikofaktorar for hjarte- og karsjukdom som til dømes kolesterolverdiar, blodsukker, insulin og inflammasjonsmarkørar. Fysisk form vert målt ved hjelp av tre ulike testar; maksimal tredemølletest, 6-min gangtest og trappegangtest. Maksimal tredemølletest vert nytta når du møter til fyrste opphald og når du reiser frå tredje opphald, medan dei andre testane vert gjennomført både ved oppmøte og heimreise på alle opphald, samt midtvegs i fyrste opphald. Fysisk aktivitetsnivå vert registrert ved hjelp av aktivitetsmålar og treningsdagbok. Aktivitetsmålaren plasserast på hofta og registrerer kor

mykje du beveger deg i løpet av ei veke. Du skal gå med denne fire veker; før fyrste opphald, under fyrste opphald, mellom fyrste og andre opphald og mellom andre og tredje opphald. I løpet av fyrste opphaldet må du også gå på tredemølle med aktivitetsmålaren for å justere denne til deg. Treningsdagboka nyttast for å registrere alle fysisk aktivitet du gjennomfører den tida du er til behandling på Hauglandssenteret og heime. Du blir også spurt om kosthald ved hjelp av spørjeskjema på dei same tidspunkta som du skal gå med aktivitetsmålaren (til saman fire ganger).

Moglege fordeler
Du som tek del i prosjektet vert noko grundigare testa samanlikna med personar som ikkje deltek i prosjektet og får slik betre kjennskap til eigen kropp og respons på behandlinga. Tilbakemelding om status (vekt, kroppssamansetnad, fysisk form, risikofaktorar for sjukdom) og generelt tettare oppfølging kan vere ei viktig kjelde til motivasjon for å stå på vidare, noko som kan betre effekten av behandlinga.

Moglege ulemper
Alle som er til behandling på Hauglandssenteret gjennomfører det same behandlingsopplegget. Mange testar inngår i opplegget uansett om du vel å ta del i prosjektet eller ikkje, men som deltakar må du gjennomføre nokre ekstra testar. Maksimal tredemølletest inngår kun for prosjektgruppa. Dette vil kunne medføre noko ubehag ettersom testen går til nær utmatting. Blodprøvar vert tatt noko hyppigare for prosjektgruppa, totalt sju prøvar på eit år. Dette kan vere ubehageleg. I tillegg vil dei som tek del i prosjektet gå med aktivitetsmålar i til saman fire veker, der tre av vekene er heime (3 x 1 veke). I desse periodane må ein hugse å gå med aktivitetsmålaren kvar dag, men hugse å ta den av ved vassaktivitet og dusjing. I tillegg må ein rekne med noko tid på å fylle ut spørjeskjema, både heime og under opphald på Hauglandssenteret.

Deltakaren sitt ansvar
Som deltakar i prosjektet har du ansvar for å følgje dei retningslinjene som vert gitt i høve til å svare på spørjeskjema og gjennomføre dei testane du skal gjennom. Det er viktig at du føl retningslinjene, slik at testresultata vert best mogleg. Det er viktig å svare ærleg på spørsmål og yte sitt beste på ulike testar.

Kompensasjon for deltaking
Det vil ikkje bli gitt noko form for kompensasjon for deltaking i studien.

Vedlegg B Personvern, biobank, økonomi og forsikring

Personvern
Opplysningar som registrerast om deg er bakgrunnsinformasjon som kjønn og alder, sjukdomshistorie, sosioøkonomiske faktorar og holdning til fysisk aktivitet, samt fysisk aktivitetsnivå, fysisk form, kroppsvekt, midjemål, feitt- og feittfri masse, blodtrykk og ulike blodvariablar (sjå vedlegg A).

Høgskulen i Sogn og Fjordane ved dekan på avdeling for helsefag er databehandlingsansvarleg. Forskarar frå Norges Idrettshøgskule, Universitetet i Bergen og University of Oulu and Biocenter Oulu (Finland) vil få tilgang til avidentifiserte data.

Biobank
Blodprøvane som vert tatt og informasjonen ein får ut av dette materialet vil bli lagra i ein forskingsbiobank ved Hauglandssenteret. Dersom du seier ja til å ta del i studien, gir du også samtykke til at det biologiske materialet og analyseresultat inngår i biobanken. Overlege Eirik Fismen er ansvarshavande for forskingsbiobanken. Biobanken planleggast å vare til 2020. Etter dette vil materialet og opplysningar bli destruert og sletta etter interne retningslinjer.

Utlevering av materiale og opplysningar til andre
Dersom du seier ja til å delta i studien, gir du også ditt samtykke til at prøvar og avidentifiserte opplysningar utleverast til Norges Idrettshøgskule, Universitetet i Bergen og University of Oulu and Biocenter Oulu (Finland).

Rett til innsyn og sletting av opplysningar om deg og sletting av prøvar
Dersom du seier ja til å ta del i studien, har du rett til innsyn i kva opplysningar som er registrert om deg. Du har vidare rett til å få korrigert eventuelle feil i dei opplysningane me har registrert. Dersom du trekk deg frå studien, kan du krevje å få sletta innsamla prøvar og opplysningar, med mindre opplysningane allereie er nytta i analysar eller vitskaplege publikasjonar.

Økonomi
Studien og biobanken er finansiert gjennom forskingsmidlar frå Høgskulen i Sogn og Fjordane og Helse Vest. Nemnde institusjonar har ingen interessekonfliktar i høve til resultat som kjem fram gjennom studien.

Forsikring
Høgskulen i Sogn og Fjordane er ansvarleg for gjennomføring av studien. Deltakarar er forsikra gjennom pasientskadeerstatningslova.

Informasjon om utfallet av studien
Dersom du seier ja til å ta del i studien har du rett til innsyn i resultata frå studien.

Samtykke til deltaking i studien

Eg er villig til å ta del i studien

(Signert av prosjektdeltakar, dato)

Eg bekreftar å ha gitt informasjon om studien

(Eivind Aadland, prosjektleiar, dato)

Appendix IV

Førespurnad om deltaking i forskingsprosjekt

Fysisk aktivitet, fysisk form, livskvalitet og risikofaktorar for hjarte- og karsjukdom hjå personar til livsstilsbehandling for sjukleg overvekt ved Hauglandssenteret

-utviding av studien til to års oppfølging

Bakgrunn og hensikt
Dette er eit spørsmål til deg om å ta del i forskingsstudien for å undersøkje effekt av langvarig livsstilsendring hjå sjukleg overvektige *over to år*. Du blir spurt om å delta fordi du er tatt inn til behandling ved Hauglandssenteret gjennom Helse Vest og deltek i studien med oppfølging over eitt år. Høgskulen i Sogn og Fjordane er ansvarleg for gjennomføring av studien.

Kva innebér studien?
Studien skal undersøkje korleis langvarig livsstilsendring hjå sjukleg overvektige påverkar fysisk aktivitetsnivå, fysisk form, kroppsvekt, kroppssamansetnad, livskvalitet og risikofaktorar for hjarte- og karsjukdom. Å delta i studien vil medføre noko utvida testing og blodprøvetaking i høve til standard behandling. Du blir spurt om bakgrunnsinformasjon som kjønn og alder, sjukdomshistorie og sosioøkonomiske faktorar samt kosthald, livsstil og livskvalitet ved hjelp av spørjeskjema. Vidare vert fysisk aktivitetsnivå, fysisk form, kroppsvekt, midjemål, kroppssamansetnad, blodtrykk og ulike blodvariablar målt på ulike måtar (sjå vedlegg A). Behandlingsopplegget vil vere det same om du tek del i studien eller ikkje.

Moglege fordeler og ulemper
Fordeler med å ta del i studien er at du lærer din eigen kropp å kjenne og får tettare oppfølging i høve til korleis behandlinga fungerer for deg. Ulemper med å ta del i studien er at du må ta nokre ekstra blodprøvar som kan opplevast som ubehageleg. I tillegg må du bere ein aktivitetsmålar i til saman fem veker, og testar av fysisk form vil vere slitsamt.

Kva skjer med prøvane og informasjonen om deg?
Prøvane som er tatt av deg og informasjonen som registrerast om deg skal kun nyttast som beskrive i hensikta med studien. Alle opplysningane og prøvane vil bli behandla utan namn og fødselsnummer eller andre direkte gjenkjennande opplysningar. Ein kode knyter deg til dine opplysningar og prøvar gjennom ei namneliste. Det er kun autorisert personell knyta til prosjektet som har tilgang til namnelista og som kan finne tilbake til deg. Det vil ikkje vere mogleg å identifisere deg i resultata av studien når desse vert publisert.

Frivillig deltaking
Det er frivillig å ta del i studien. Du kan kva tid som helst og utan å oppgi noko grunn trekke ditt samtykke til å delta i studien. Dette vil ikkje få konsekvensar for di vidare behandling. Dersom du ynskjer å ta del i studien, underteiknar du samtykkeerklæringa på siste side. Om du no seier ja til å delta, kan du seinare trekkje tilbake ditt samtykke utan at det påverkar di øvrige behandling. Dersom du seinare ynskjer å trekkje deg eller har spørsmål til studien, kan du kontakte Anne Grethe Lien (tlf 57737177 / 90988542) eller Eivind Aadland (tlf 57676086 / 47623461).

Meir informasjon om studien finn du i vedlegg A –*Utdjuping av kva studien innebér*
Meir informasjon om biobank, personvern og forsikring finn du i vedlegg B –
Personvern, biobank, økonomi og forsikring

Samtykkeerklæring følgjer etter kapittel B.

Vedlegg A Utdjuping av kva studien innebér

Kriterier for deltaking
Utvalet i studien vil vere pasientar med rett til naudsynt helsehjelp i spesialisthelsetenesta for behandling av sjukleg overvekt. Inklusjonskriterier er kroppsmasseindeks (KMI) > 40 eller > 35 med følgjesjukdom og alder 18 – 60 år. Alle som er til behandling i ordinært opplegg på Hauglandssenteret kan ta del i studien.

Bakgrunn for studien
Overvekt og fedme er ei stor utfordring internasjonalt og nasjonalt. Konsekvensane av aukande overvekt er redusert levetid, førekomst av ei rekkje sjukdomar, redusert livskvalitet og økonomiske konsekvensar for den enkelte og samfunnet. Ei rekkje studier har vist at livsstilsbehandling og fysisk aktivitet er gunstig for overvektige (KMI > 25) og personar med fedme (KMI > 30), men svært få studier har undersøkt effekten av denne behandlinga for sjukleg overvektige (personar med KMI > 40 eller > 35 med følgjesjukdom). For denne gruppa er bariatrisk kirurgi den einaste behandlingsforma med god dokumentert effekt, men alle kan ikkje eller ynskjer ikkje slik behandling. Behandlinga kan også ha uheldige sideverknadar som komplikasjonar etter inngrepet og mangeltilstandar grunna redusert opptak av næringsstoff.

Tidlegare studier som har undersøkt livsstilsbehandling har sentrale svakheiter som lite fysisk aktivitet, manglande kontroll på kor mykje fysisk aktivitet som er gjennomført, og kroppsvekt er gjerne einaste eller viktigaste effektmål. Dette fører til at me veit lite om fysisk aktivitet si rolle ved vektreduksjon, og særs lite om livsstilsbehandling for sjukleg overvektige.

Formålet med dette prosjektet er å undersøke effekten av livsstilsbehandling med høgt fysisk aktivitetsnivå for sjukleg overvektige i høve til fleire effektmål. I tillegg til kroppsvekt vert midjemål, kroppssamansetnad, objektivt målt fysisk aktivitetsnivå, fysisk form, livskvalitet og risikofaktorar for hjarte- og karsjukdom undersøkt.

Kva skjer om du vel å ikkje ta del i studien?
Dersom du seier nei til deltaking vil du gjennomføre det same behandlingsopplegget som alle andre. Du vil også gå gjennom standard testing ved Hauglandssenteret, men dette er mindre omfattande enn testinga i prosjektet. Du vil såleis få mindre kjennskap til korleis behandlingsopplegget fungerer for deg.

Tidsskjema –kva skjer og kva tid skjer det?
Du blir spurt om bakgrunnsinformasjon som kjønn og alder, sjukdomshistorie og sosioøkonomiske faktorar samt livsstil og livskvalitet ved hjelp av spørjeskjema på fyrste, tredje og fjerde opphald. Kroppsvekt, midjemål og kroppssamansetnad vert målt kvar tredje veke under opphald på Hauglandssenteret. Blodtrykk og blodprøvar vert tatt når du møter til opphald og når du reiser frå opphald. I tillegg vert dette målt midtvegs under det fyrste opphaldet. Blodprøvar analyserast for risikofaktorar for hjarte- og karsjukdom som til dømes kolesterolverdiar, blodsukker, insulin og inflammasjonsmarkørar. Fysisk form vert målt ved hjelp av tre ulike testar; maksimal tredemølletest, 6-min gangtest og trappegangtest. Maksimal tredemølletest vert nytta når du møter til fyrste opphald, når du reiser frå tredje opphald og når du reiser frå fjerde opphald, medan dei andre testane vert gjennomført både ved oppmøte og heimreise på alle opphald, samt midtvegs i fyrste opphald. Fysisk aktivitetsnivå vert registrert ved hjelp av aktivitetsmålar og treningsdagbok. Aktivitetsmålaren plasserast på hofta og

registrerer kor mykje du beveger deg i løpet av ei veke. Du skal gå med denne fem veker; før fyrste opphald, under fyrste opphald, og mellom alle opphald. I løpet av fyrste opphaldet må du også gå på tredemølle med aktivitetsmålaren for å justere denne til deg. Treningsdagboka nyttast for å registrere alle fysisk aktivitet du gjennomfører den tida du er til behandling på Hauglandssenteret og heime. Du blir også spurt om kosthald ved hjelp av spørjeskjema på dei same tidspunkta som du skal gå med aktivitetsmålaren (til saman fem ganger).

Presiering: Datainnsamlinga knyta til fjerde opphald på Hauglandssenteret vil føregå på same måte som tidlegare. Det er ingen endringar i data samla inn eller prosedyrar for datainnsamling.

Moglege fordeler
Du som tek del i prosjektet vert noko grundigare testa samanlikna med personar som ikkje deltek i prosjektet og får slik betre kjennskap til eigen kropp og respons på behandlinga. Tilbakemelding om status (vekt, kroppssamansetnad, fysisk form, risikofaktorar for sjukdom) og generelt tettare oppfølging kan vere ei viktig kjelde til motivasjon for å stå på vidare, noko som kan betre effekten av behandlinga.

Moglege ulemper
Alle som er til behandling på Hauglandssenteret gjennomfører det same behandlingsopplegget. Mange testar inngår i opplegget uansett om du vel å ta del i prosjektet eller ikkje, men som deltakar må du gjennomføre nokre ekstra testar. Maksimal tredemølletest inngår kun for prosjektgruppa. Dette vil kunne medføre noko ubehag ettersom testen går til nær utmatting. Blodprøvar vert tatt noko hyppigare for prosjektgruppa, totalt sju prøvar på eit år. Dette kan vere ubehageleg. I tillegg vil dei som tek del i prosjektet gå med aktivitetsmålar i til saman fem veker, der fire av vekene er heime (4 x 1 veke). I desse periodane må ein hugse å gå med aktivitetsmålaren kvar dag, men hugse å ta den av ved vassaktivitet og dusjing. I tillegg må ein rekne med noko tid på å fylle ut spørjeskjema, både heime og under opphald på Hauglandssenteret.

Deltakaren sitt ansvar
Som deltakar i prosjektet har du ansvar for å følgje dei retningslinjene som vert gitt i høve til å svare på spørjeskjema og gjennomføre dei testane du skal gjennom. Det er viktig at du føl retningslinjene, slik at testresultata vert best mogleg. Det er viktig å svare ærleg på spørsmål og yte sitt beste på ulike testar.

Kompensasjon for deltaking
Det vil ikkje bli gitt noko form for kompensasjon for deltaking i studien.

Vedlegg B Personvern, biobank, økonomi og forsikring

Personvern
Opplysningar som registrerast om deg er bakgrunnsinformasjon som kjønn og alder, sjukdomshistorie, sosioøkonomiske faktorar og holdning til fysisk aktivitet, samt fysisk aktivitetsnivå, fysisk form, kroppsvekt, midjemål, feitt- og feittfri masse, blodtrykk og ulike blodvariablar (sjå vedlegg A).

Høgskulen i Sogn og Fjordane ved dekan på avdeling for helsefag er databehandlingsansvarleg. Forskarar frå Norges Idrettshøgskule, Universitetet i Bergen og University of Oulu and Biocenter Oulu (Finland) vil få tilgang til avidentifiserte data.

Biobank
Blodprøvane som vert tatt og informasjonen ein får ut av dette materialet vil bli lagra i ein forskingsbiobank ved Hauglandssenteret. Dersom du seier ja til å ta del i studien, gir du også samtykke til at det biologiske materialet og analyseresultat inngår i biobanken. Overlege Eirik Fismen er ansvarshavande for forskingsbiobanken. Biobanken planleggast å vare til 2020. Etter dette vil materialet og opplysningar bli destruert og sletta etter interne retningslinjer.

Utlevering av materiale og opplysningar til andre
Dersom du seier ja til å delta i studien, gir du også ditt samtykke til at prøvar og avidentifiserte opplysningar utleverast til Norges Idrettshøgskule, Universitetet i Bergen og University of Oulu and Biocenter Oulu (Finland).

Rett til innsyn og sletting av opplysningar om deg og sletting av prøvar
Dersom du seier ja til å ta del i studien, har du rett til innsyn i kva opplysningar som er registrert om deg. Du har vidare rett til å få korrigert eventuelle feil i dei opplysningane me har registrert. Dersom du trekk deg frå studien, kan du krevje å få sletta innsamla prøvar og opplysningar, med mindre opplysningane allereie er nytta i analysar eller vitskaplege publikasjonar.

Økonomi
Studien og biobanken er finansiert gjennom forskingsmidlar frå Høgskulen i Sogn og Fjordane og Helse Vest. Nemnde institusjonar har ingen interessekonfliktar i høve til resultat som kjem fram gjennom studien.

Forsikring
Høgskulen i Sogn og Fjordane er ansvarleg for gjennomføring av studien. Deltakarar er forsikra gjennom pasientskadeerstatningslova.

Informasjon om utfallet av studien
Dersom du seier ja til å ta del i studien har du rett til innsyn i resultata frå studien.

Samtykke til deltaking i studien

Eg er villig til å ta del i studien

(Signert av prosjektdeltakar, dato)

Eg bekreftar å ha gitt informasjon om studien

(Eivind Aadland, prosjektleiar, dato)

Appendix V

Socio-demographic information and question 35, 66, and 37 used in the present thesis.

Kjære deltaker

Ved hjelp av besvarelsen fra deg og andre deltakere vil vi få økt kunnskap om det fysiske aktivitetsnivået og holdninger til fysisk aktivitet hos sykelig overvektige som søker livsstilsbehandling. Spørsmålene er også brukt i andre studier. Derfor er spørsmålene noe generelle og kan oppleves som lite relevante av noen.

Det er viktig at du gir ærlige svar.

Det tar ca. 20 minutter å fylle ut spørreskjemaet. Vennligst følg instruksene underveis.

På forhånd takk for hjelpen!

Bakgrunnsinformasjon

1) Kjønn: ☐ Kvinne ☐ Mann

2) Fødselsår: 19 ☐☐

3) Høyde: ☐☐☐ cm

4) Vekt: ☐☐☐,☐ kg

5) Hvilken utdanning er den høyeste du har fullført? (Sett ett kryss)

- ☐ Mindre enn 7 år grunnskole
- ☐ Grunnskole 7-10 år, framhaldsskole eller folkehøgskole
- ☐ Realskole, middelskole, yrkesskole, 1-2 årig videregående skole
- ☐ Artium, økonomisk gymnas, allmennfaglig retning i videregående skole
- ☐ Høgskole/universitet, mindre enn 4 år
- ☐ Høgskole/universitet, 4 år eller mer

6) Hva er din hovedaktivitet? (Sett ett kryss)

- ☐ Yrkesaktiv heltid
- ☐ Yrkesaktiv deltid
- ☐ Arbeidsledig
- ☐ Hjemmeværende
- ☐ Pensjonist/trygdet
- ☐ Student/militærtjeneste

8) Hvor mange innbyggere er det i din bostedskommune? (sett ett kryss)

- ☐ Under 1000
- ☐ 1001 – 5000
- ☐ 5001 – 10.000
- ☐ 10.001 – 20.000
- ☐ 20.001 – 30.000
- ☐ 30.001 – 100.000
- ☐ Mer enn 100.000

9) Mener du at fysisk aktivitet er viktig for å kunne vedlikeholde egen helse?
(sett ett kryss)

- ☐ Ja, meget viktig for meg
- ☐ Egentlig tenker jeg ikke så mye på det
- ☐ Nei, det er ikke så viktig for meg

10) Har du, eller har hatt: (sett gjerne flere kryss)

- ☐ Astma
- ☐ Kronisk bronkitt/emfysem/KOLS
- ☐ Hjerteinfarkt
- ☐ Angina Pectoris (hjertekrampe)
- ☐ Hjerneslag/hjerneblødning (”drypp”)
- ☐ Kreft
- ☐ Spiseforstyrrelser
- ☐ Allergi
- ☐ Psykiske plager du har søkt hjelp for
- ☐ Sukkersyke (diabetes type I)
- ☐ Sukkersyke (diabetes type II)
- ☐ Benskjørhet/osteoporose
- ☐ Revmatiske lidelser
- ☐ Annet: _____

Fysisk aktivitet

De neste spørsmålene omhandler fysisk aktivitet. Fysisk aktivitet omfatter både:

- fysisk aktivitet i hverdagen (i arbeid, fritid og hjemme, samt hvordan du forflytter deg til og fra arbeid og fritidssysler)
- planlagte aktiviteter (gå på tur, svømming, dansing)
- trening (for å bedre kondisjon, muskelstyrke og andre ferdigheter)

Det er flere nesten like spørsmål - det er meningen

11) Er du *aktivt medlem* av et idrettslag eller en idrettsklubb? (sett ett kryss)

- ☐ Ja
- ☐ Nei, men jeg har vært medlem før
- ☐ Nei, jeg har aldri vært medlem (gå til spm 13)

12) Når ble du medlem for første gang?

Jeg ble medlem da jeg var ☐☐ år gammel

13) Dersom du er fysisk aktiv, hvilke aktiviteter driver du vanligvis med:
(Sett gjerne flere kryss)

☐ Turgåing	☐ Ballspill	☐ Padling/roing
☐ Dans	☐ Stavgang	☐ Sykling/spinning
☐ Golf	☐ Svømming	☐ Jogging
☐ Langrenn	☐ Vanngymnastikk	☐ Skøyter/bandy/hockey
☐ Yoga/pilates	☐ Alpint/snowboard	☐ Trening til musikk i sal
☐ Tennis	☐ Kampsport (karate, judo ol)	☐ Squash/Badminton/Bordtennis

- ☐ Treningsstudio (styrketrening, tredemølle, ergometersykkel, elipsemaskin ol)
- ☐ Annet, hva:_____

14) Hvor ofte trener du på de måtene som er nevnt under?
(Sett ett kryss for hvor ofte du er aktiv på hver måte)

	Aldri	Sjelden	1-3 g/mnd	1 dag/uke	2-3 dag/uke	4-6 dag/uke	Daglig
I idrettslag……..	☐	☐	☐	☐	☐	☐	☐
På treningssenter……	☐	☐	☐	☐	☐	☐	☐
På jobben eller skolen…	☐	☐	☐	☐	☐	☐	☐
Hjemme……..	☐	☐	☐	☐	☐	☐	☐
I nærmiljøet……..	☐	☐	☐	☐	☐	☐	☐
I svømmehall……	☐	☐	☐	☐	☐	☐	☐
Sykler……..	☐	☐	☐	☐	☐	☐	☐
Danser……...	☐	☐	☐	☐	☐	☐	☐
Skitur……..	☐	☐	☐	☐	☐	☐	☐
Fottur……..	☐	☐	☐	☐	☐	☐	☐

15) Hvor mange timer den siste uken har du vært i fysisk aktivitet i hjemmet eller i tilknytning til hjemmet? Det er kun aktiviteter som varer i minst 10 minutter i strekk som skal rapporteres

	Ingen	< 1 time	1-2 timer	3-4 timer	> 4 timer
Lett aktivitet - ikke svett/andpusten……..	☐	☐	☐	☐	☐
Hard aktivitet - svett/andpusten……..	☐	☐	☐	☐	☐

16) Angi bevegelse og kroppslig anstrengelse i din fritid. Hvis aktiviteten varierer meget for eksempel mellom sommer og vinter, så ta et gjennomsnitt.
Spørsmålet gjelder bare det siste året (sett ett kryss i den ruta som passer best)

Lese, ser på fjernsyn eller annen stillesittende beskjeftigelse?..... ☐

Spaserer, sykler eller beveger deg på annen måte minst 4 timer i uka?
(Her skal du regne med gang eller sykling til arbeidsstedet, søndagsturer mm)… ☐

Driver mosjonsidrett, tyngre hagearbeid e.l?
(Merk at aktiviteten skal vare minst 4 timer i uka)…… ☐

Trener hardt eller driver konkurranseidrett regelmessig og flere ganger i uka……. ☐

Når du svarer på spørsmålene 17 - 20:

Meget anstrengende – er fysisk aktivitet som får deg til å puste *mye mer* enn vanlig
Middels anstrengende – er fysisk aktivitet som får deg til å puste *litt mer* enn vanlig

Det er kun aktiviteter som varer **minst 10 minutter i strekk** som skal rapporteres

17a) Hvor mange dager i løpet av de siste 7 dager har du drevet med *meget anstrengende* fysiske aktiviteter som tunge løft, gravearbeid, aerobics eller sykle fort? Tenk bare på aktiviteter som varer *minst 10 minutter i strekk*

☐ Dager per uke

☐ Ingen (gå til spørsmål 18a)

17b) På en vanlig dag hvor du utførte *meget anstrengende* fysiske aktiviteter, hvor lang tid brukte du da på dette?

☐☐ Timer ☐☐ Minutter ☐ Vet ikke/husker ikke

18a) Hvor mange dager i løpet av de siste 7 dager har du drevet med *middels anstrengende* fysiske aktiviteter som å bære lette ting, sykle eller jogge i moderat tempo eller mosjonstennis? Ikke ta med gange, det kommer i neste spørsmål.

☐ Dager per uke

☐ Ingen (gå til spørsmål 19a)

18b) På en vanlig dag hvor du utførte *middels anstrengende* fysiske aktiviteter, hvor lang tid brukte du da på dette?

☐ Timer ☐ Minutter ☐ Vet ikke/husker ikke

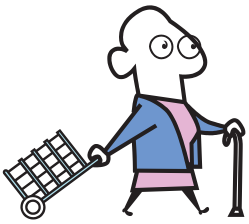
19a) Hvor mange dager i løpet av de siste 7 dager, *gikk du minst 10 minutter* i strekk for å komme deg fra ett sted til et annet? Dette inkluderer gange på jobb og hjemme, gange til buss, eller gange som du gjør på tur eller som trening i fritiden

☐ Dager per uke

☐ Ingen (gå til spørsmål 20)

19b) På en vanlig dag hvor du *gikk* for å komme deg fra et sted til et annet, hvor lang tid brukte du da totalt på å gå?

☐ Timer ☐ Minutter ☐ Vet ikke/husker ikke



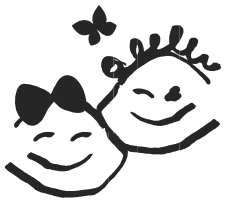
20) Dette spørsmålet omfatter all tid du tilbringer i ro (*sittende*) på jobb, hjemme, på kurs, og på fritiden. Det kan være tiden du sitter ved et arbeidsbord, hos venner, mens du leser eller ligger for å se på TV.

I løpet av de siste 7 dager, hvor land tid brukte du vanligvis totalt på å sitte <u>på en vanlig hverdag</u>?

☐ Timer ☐ Minutter ☐ Vet ikke/husker ikke

21) Nedenfor følger en rekke grunner for å drive med fysisk aktivitet. Vennligst sett ett eller flere kryss for den (de) grunnen(e) som er viktig(e) for deg.

- ☐ Forebygge helseplager
- ☐ Holde vekten nede
- ☐ For å se veltrent ut
- ☐ Øke prestasjonsevnen
- ☐ Gjøre fritiden trivelig
- ☐ For å ha det gøy
- ☐ Føler jeg må
- ☐ Komme i bedre form
- ☐ Anbefalt av lege, fysioterapeut eller liknende
- ☐ Fysisk og psykisk velvære
- ☐ For å treffe og omgås andre mennesker
- ☐ Oppbygging etter sykdom/skade
- ☐ Oppleve spenning/utfordring
- ☐ For å få frisk luft



22) Nedenfor følger en rekke grunner for å *ikke* drive med fysisk aktivitet.
Vennligst sett ett eller flere kryss for den (de) grunnen(e) som er viktig(e) for deg.

- ☐ Har ikke tid
- ☐ Har ikke råd
- ☐ Transportproblemer
- ☐ Negative erfaringer
- ☐ Bevegelsesproblemer
- ☐ Tror ikke jeg får det til
- ☐ Orker ikke
- ☐ Synes jeg er for gammel
- ☐ På grunn av min fysiske helse
- ☐ Har ingen å være fysisk aktiv sammen med
- ☐ Tidspunktet passer meg ikke
- ☐ Kjenner ikke til noe tilbud
- ☐ Engstelig for å gå ut
- ☐ Mangel på tilbud innen mine interesseområder
- ☐ Redd for å bli skadet (falle, forstue)
- ☐ Vil heller bruke tiden min til andre ting
- ☐ Andre grunner, hva: _____

Transport aktiviteter

De neste spørsmålene handler om dine vaner knyttet til transport og omfatter dine vanlige måter å komme fra et sted til et annet, inkludert hvordan du kommer deg til og fra jobb, butikker, kino, fritidssysler og så videre.

Merk at du skal angi dine transportvaner separat for sommer og vinter.

23a) Hvor mange dager *i en vanlig uke* reiser du med et motorisert transportmiddel som tog, buss, bil eller trikk?

Om sommeren

☐ Dager per uke

Om vinteren

☐ Dager per uke

23b) På *en vanlig dag* hvor du reiser med motorisert transportmiddel, hvor lang tid bruker du da totalt i transportmiddelet?

Om sommeren

☐ Timer ☐ Minutter

Om vinteren

☐ Timer ☐ Minutter

24a) Hvor mange dager i *en vanlig uke* sykler du *minst 10 minutter i strekk* for å komme fra et sted til ett annet?

Om sommeren

☐ Dager per uke

Om vinteren

☐ Dager per uke

24b) På *en vanlig dag* hvor du *sykler* for å komme deg fra et sted til ett annet, hvor lang tid bruker du da totalt på å sykle?

Om sommeren

☐ Timer ☐ Minutter

Om vinteren

☐ Timer ☐ Minutter

25a) Hvor mange dager i *en vanlig uke* går du *minst 10 minutter i strekk* for å komme fra et sted til ett annet?

Om sommeren

☐ Dager per uke

Om vinteren

☐ Dager per uke

25b) På *en vanlig dag* hvor du går for å komme deg fra et sted til ett annet, hvor lang tid bruker du da totalt på *å gå*?

Om sommeren

☐ Timer ☐ Minutter

Om vinteren

☐ Timer ☐ Minutter

26) Dersom du er yrkesaktiv, hvordan kommer du deg vanligvis til og fra arbeid?

☐ Bil/motorsykkel
☐ Offentlig transport (tog, buss, og liknende)
☐ Sykkel
☐ Til fots
☐ Ikke aktuelt

TV, PC og søvnvaner

De neste spørsmålene handler om dine vaner knyttet til bruk av **TV og PC utenom jobb.** I tillegg vil vi kartlegge dine søvnvaner

27) Utenom jobb: Hvor mange timer ser du vanligvis på TV og sitter med PC på en hverdag? (Sett ett kryss)

☐ Mindre enn 1 time
☐ 1 - 2 timer
☐ 2 - 3 timer
☐ 3 - 4 timer
☐ 4 - 5 timer
☐ Mer enn 5 timer

28) Utenom jobb: Hvor mange timer ser du vanligvis på TV og sitter med PC på en helgedag? (Sett ett kryss)

☐ Mindre enn 1 time
☐ 1 - 2 timer
☐ 2 - 3 timer
☐ 3 - 4 timer
☐ 4 - 5 timer
☐ Mer enn 5 timer

29) Hvor mange timer i døgnet sover du vanligvis på en hverdag?
(Sett ett kryss)

- ☐ Mindre enn 3 timer
- ☐ 3 - 5 timer
- ☐ 5 - 8 timer
- ☐ 8 - 10 timer
- ☐ 10 timer eller mer

30) Hvor mange timer i døgnet sover du vanligvis på en helgedag eller fridag?
(Sett ett kryss)

- ☐ Mindre enn 3 timer
- ☐ 3 - 5 timer
- ☐ 5 - 8 timer
- ☐ 8 - 10 timer
- ☐ 10 timer eller mer

Røyk

I denne delen av spørreskjemaet er det fokus på dine røykevaner.

31) Har du røykt/røyker du daglig? (sett ett kryss)

☐ Ja, nå ☐ Ja, tidligere ☐ Aldri (Gå videre til spørsmål 34)

32) Hvis du har røykt daglig tidligere, hvor lenge siden er det du sluttet?

☐ år

33) Hvis du røyker daglig nå eller har røykt tidligere:

Hvor mange sigaretter røyker eller røykte du vanligvis daglig?

☐ Antall sigaretter

Hvor gammel var du da du begynte å røyke?

☐ Alder i år

Hvor mange år til sammen har du røykt daglig?

☐ Antall år

34) Bruker du snus? (sett ett kryss)

☐ Ja, daglig ☐ Av og til ☐ Aldri

Holdninger til fysisk aktivitet

I denne siste delen er det fokus på dine holdninger til fysisk aktivitet. Du nærmer deg slutten av skjemaet. **Hold ut** ☺

35) Tenk deg alle former for fysisk aktivitet. Ta stilling til påstanden: *Jeg er sikker på at jeg kan gjennomføre planlagt fysisk aktivitet selv om*:

	Ikke i det hele tatt						**Veldig sikker**
	1	**2**	**3**	**4**	**5**	**6**	**7**
Jeg er trett……	☐	☐	☐	☐	☐	☐	☐
Jeg føler meg nedtrykt……..	☐	☐	☐	☐	☐	☐	☐
Jeg er bekymret…….	☐	☐	☐	☐	☐	☐	☐
Jeg er sint på grunn av noe……	☐	☐	☐	☐	☐	☐	☐
Jeg føler meg stresset……	☐	☐	☐	☐	☐	☐	☐

36) Tenk på alle former for fysisk aktivitet. For hver påstand, angi i hvilken grad du er enig/uenig. (Sett ett kryss for hver påstand)

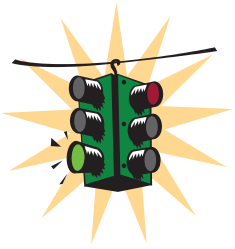
	Helt enig						**Helt uenig**
	1	**2**	**3**	**4**	**5**	**6**	**7**
Om jeg er regelmessig fysisk aktiv eller ikke er helt opp til meg…….	☐	☐	☐	☐	☐	☐	☐
Hvis jeg ville, hadde jeg ikke hatt noen problemer med å være regelmessig fysisk aktiv……	☐	☐	☐	☐	☐	☐	☐
Jeg ville likt å være regelmessig aktiv, men jeg vet ikke riktig om jeg kan……..…	☐	☐	☐	☐	☐	☐	☐
Jeg har full kontroll over å være regelmessig fysisk aktiv…….	☐	☐	☐	☐	☐	☐	☐
Å være regelmessig fysisk aktiv er vanskelig for meg……	☐	☐	☐	☐	☐	☐	☐

37) I hvilken grad beskriver disse påstandene deg som person?
(Sett ett kryss for hver påstand)

	Passer dårlig 1	2	3	4	Passer bra 5
Jeg ser på meg selv som en person som er opptatt av fysisk aktivitet……	☐	☐	☐	☐	☐
Jeg tenker på meg selv som en person som er opptatt av å holde seg i god fysisk form……..…	☐	☐	☐	☐	☐
Å være fysisk aktiv er en stor del av hvem jeg er……	☐	☐	☐	☐	☐

38) Har familien din (medlemmer i husstanden):
(Sett ett kryss for hver påstand)

	Aldri	Sjelden	Noen få ganger	Ofte	Veldig ofte	Passer ikke
Oppmuntret deg til å være fysisk aktiv….....	☐	☐	☐	☐	☐	☐
Diskutert fysisk aktivitet sammen med deg….	☐	☐	☐	☐	☐	☐
Forandret planene sine slik at dere kunne drive fysisk aktivitet sammen……	☐	☐	☐	☐	☐	☐
Overtatt oppgaver for deg, slik at du fikk mer tid til å være fysisk aktiv……..…	☐	☐	☐	☐	☐	☐
Sagt at fysisk aktivitet vil være bra for helsen din……..	☐	☐	☐	☐	☐	☐
Snakket om hvor godt de liker å være fysisk aktive…….	☐	☐	☐	☐	☐	☐



39) Har vennene dine/bekjente/familiemedlemmer utenfor husstanden:
(Sett ett kryss for hver påstand)

	Aldri	Sjelden	Noen få ganger	Ofte	Veldig ofte	Passer ikke
Foreslått at dere skulle drive fysisk aktivitet sammen…….	☐	☐	☐	☐	☐	☐
Oppmuntret deg til å være fysisk aktiv……	☐	☐	☐	☐	☐	☐
Gitt deg hjelpsomme påminnelser om fysisk aktivitet som: ”Skal du mosjonere i kveld?”…..	☐	☐	☐	☐	☐	☐
Forandret planene sine slik at dere kunne drive fysisk aktivitet sammen……..…	☐	☐	☐	☐	☐	☐
Sagt at fysisk aktivitet vil være bra for helsen din…….……..	☐	☐	☐	☐	☐	☐
Snakket om hvor godt de liker å være fysisk aktive……	☐	☐	☐	☐	☐	☐

40) Er det i ditt nærmiljø:
(Sett ett kryss for hver påstand)

	Helt uenig	Litt uenig	Litt enig	Helt enig
Trygge steder å gå (park/friområde, turvei, fortau) som er tilstrekkelig opplyst…….	☐	☐	☐	☐
Mange steder der du kan være fysisk aktiv (utendørs, svømmehall etc.)……	☐	☐	☐	☐
Flere tilrettelagte tilbud om trening og fysisk aktivitet (som kunne være aktuelle for deg)……	☐	☐	☐	☐
Greit å gå til butikker (10-15 min å gå, fortau langs de fleste veiene)…….	☐	☐	☐	☐
Lett tilgang til gang- eller sykkelveier…….……..	☐	☐	☐	☐
Så mye trafikk i gatene at det er vanskelig eller lite hyggelig å gå……	☐	☐	☐	☐
Fotgjengeroverganger og lyssignal som gjør det enklere å krysse veien…….	☐	☐	☐	☐

41) Omtrent hvor lang tid vil det ta deg å gå hjemmefra til:
(Sett ett kryss for hver linje)

	1-5 min	6-10 min	11-20 min	21-30 min	> 30 min	Vet ikke
Butikk for dagligvarer……	☐	☐	☐	☐	☐	☐
Et friområde/park/turvei……	☐	☐	☐	☐	☐	☐
Helsestudio/treningssenter/svømme-hall/idrettshall/utendørs idrettsanlegg	☐	☐	☐	☐	☐	☐
Skog/mark/fjell……	☐	☐	☐	☐	☐	☐

42) I hvilken utstrekning mener du at daglig fysisk aktivitet kan ha gunstig effekt for å forebygge følgende sykdommer: (Sett ett kryss for hver linje)

	Stor effekt	Liten effekt	Ingen effekt	Vet ikke
Hjerte- og karsykdom……	☐	☐	☐	☐
Muskel- og skjelettlidelser……	☐	☐	☐	☐
Diabetes type 2……	☐	☐	☐	☐
Kreft……..……..	☐	☐	☐	☐
Høyt blodtrykk……..…….	☐	☐	☐	☐
Psykiske lidelser……	☐	☐	☐	☐
Overvekt og fedme……	☐	☐	☐	☐
Mage-/tarmsykdommer……	☐	☐	☐	☐
Astma og allergi……..…	☐	☐	☐	☐
KOLS……	☐	☐	☐	☐

Appendix VI

Global livskvalitet

Når du tenker på hvordan du har det for tida, er du stort sett fornøyd med tilværelsen, eller er du stort sett misfornøyd?

(Sett kryss i bare en rute)

☐ Svært fornøyd
☐ Meget fornøyd
☐ Ganske fornøyd
☐ Både/og
☐ Nokså misfornøyd
☐ Meget misfornøyd
☐ Svært misfornøyd

Appendix VII

SF-36 SPØRRESKJEMA OM HELSE

INSTRUKSJON: Dette spørreskjemaet handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å vite hvordan du har det og hvordan du er i stand til å utføre dine daglige gjøremål.

Hvert spørsmål skal besvares ved å krysse av det svaralternativet som passer best for deg. Hvis du er usikker på hva du skal svare, vennligst svar så godt du kan.

1. Stor sett vil du si din helse er

Utmerket…….....	1☐
Meget god……	2☐
God…….....	3☐
Nokså god…….	4☐
Dårlig……	5☐

2. Sammenlignet med for ett år siden, hvordan vil du si at din helse stort sett er nå?

Mye bedre enn for ett år siden….....	1☐
Litt bedre enn for ett år siden……	2☐
Omtrent den samme som for ett år siden	3☐
Litt dårligere nå enn for ett år siden…..	4☐
Mye dårligere nå enn for ett år siden….	5☐

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er din helse slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye?

AKTIVITETER	Ja, begrenser meg mye	Ja. Begrenser meg litt	Nei, begrenser meg ikke i det hele tatt
a. Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett	1☐	2☐	3☐
b. Moderate aktiviteter som å flytte et bord, støvsuge, gå en tur eller drive med hagearbeid	1☐	2☐	3☐
c. Løfte eller bære en handlekurv	1☐	2☐	3☐
d. Gå opp trappen flere etasjer	1☐	2☐	3☐
e. Gå opp trappen en etasje	1☐	2☐	3☐
f. Bøye deg eller sitte på huk	1☐	2☐	3☐
g. Gå mer enn to kilometer	1☐	2☐	3☐
h. Gå noen hundre meter	1☐	2☐	3☐
i. Gå hundre meter	1☐	2☐	3☐
j. Vaske deg eller kle på deg	1☐	2☐	3☐

4. I løpet av de siste 4 ukene, har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

	JA	NEI
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	1☐	2☐
b. Du har **utrettet mindre** enn du hadde ønsket	1☐	2☐
c. Du har vært hindret i å utføre **visse typer** arbeid eller gjøremål	1☐	2☐
d. Du har hatt **problemer** med å gjennomføre arbeidet eller andre gjøremål (f.eks. fordi det krevde ekstra anstrengelser).	1☐	2☐

5. I løpet av de siste 4 ukene, har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av følelsesmessige problemer (som for eksempel å være deprimert eller engstelig).

	JA	NEI
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	1☐	2☐
b. Du har **utrettet mindre** enn du hadde ønsket	1☐	2☐
c. Du har utført arbeidet eller andre gjøremål **mindre grundig** enn vanlig?	1☐	2☐

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

Ikke i det hele tatt…….. 1☐

Litt ……... 2☐

En del……..... 3☐

Mye…….……. 4☐

Svært mye…..…… 5☐

7. Hvor sterke kroppslige smerter har du hatt i løpet av de siste 4 ukene

Ingen…….…….. 1☐

Meget svake ……..... 2☐

Svake..……..... 3☐

Moderate…….……. 4☐

Sterke……..…… 5☐

Meget sterke……... 6☐

(SF-36 Norwegian version 1.2).

8. I løpet av de siste 4 ukene, hvor mye har smerter påvirket ditt daglige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)?

Ikke i det hele tatt…….. 1☐

Litt ……... 2☐

En del……..... 3☐

Mye…….…… 4☐

Svært mye…..…… 5☐

9. De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste 4 ukene. For hvert spørsmål, vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 ukene har du:

	Hele tiden	Nesten hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a. Følt deg full av tiltakslyst?	1☐	2☐	3☐	4☐	5☐	6☐
b. Følt deg veldig nervøs?	1☐	2☐	3☐	4☐	5☐	6☐
c. Vert så langt nede at ingenting har kunnet muntre deg opp?	1☐	2☐	3☐	4☐	5☐	6☐
d. Følt deg rolig og harmonisk	1☐	2☐	3☐	4☐	5☐	6☐
e. Hatt mye overskudd?	1☐	2☐	3☐	4☐	5☐	6☐
f. Følt deg nedfor og trist?	1☐	2☐	3☐	4☐	5☐	6☐
g. Følt deg sliten?	1☐	2☐	3☐	4☐	5☐	6☐
h. Følt deg glad?	1☐	2☐	3☐	4☐	5☐	6☐
i. Følt deg trett?	1☐	2☐	3☐	4☐	5☐	6☐

10. I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følelsesmessige problemer påvirket din sosiale omgang (som å besøke venner, slektninger osv)?

Hele tiden……..	1☐
Mye av tiden…….	2☐
En del av tiden……..	3☐
Litt av tiden…….	4☐
Ikke i det hele tatt……	5☐

11. Hvor RIKTIG eller GAL er hver av følgende påstander for deg?

	Helt riktig	Delvis riktig	Vet ikke	Delvis gal	Helt gal
a. Det virker som jeg blir syk litt lettere enn andre	1☐	2☐	3☐	4☐	5☐
b. Jeg er like frisk som de fleste jeg kjenner	1☐	2☐	3☐	4☐	5☐
c. Jeg tror helsen min vil forverres	1☐	2☐	3☐	4☐	5☐
d. Jeg har utmerket helse	1☐	2☐	3☐	4☐	5☐

Vennligst kontroller at du har besvart alle spørsmålene

Appendix VIII

Føler du at vekta eller kroppsforma di plagar deg i forbindelse med aktivitetane og situasjonane nedanfor?

Kryss av det alternativet som passar best for deg i dagens situasjon

	Mykje plaga	*Ein del plaga*	*Ikkje spesielt plaga*	*Ikkje plaga i det heile*
1. Ha fest, tilstelling heime	1☐	2☐	3☐	4☐
2. Gå ut på fest, tilstelling hos andre	1☐	2☐	3☐	4☐
3. Ete på restaurant	1☐	2☐	3☐	4☐
4. Delta i foreiningsliv, kurs eller liknande	1☐	2☐	3☐	4☐
5. Reise på ferie	1☐	2☐	3☐	4☐
6. Prøve og kjøpe klede	1☐	2☐	3☐	4☐
7. Bade offentleg (symjehall, badeplass)	1☐	2☐	3☐	4☐
8. Seksuelt samvær, intime situasjonar	1☐	2☐	3☐	4☐