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Inpatient Intensive Lifestyle Intervention for the Treatment of Severe Obesity:

– Beyond the weight reduction, and experiences with physical activity.

DISSERTATION FROM THE NORWEGIAN SCHOOL OF SPORT SCIENCES • 2015

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Kjersti Karoline Danielsen

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List of papers

This thesis is based on the following original research papers, which are referred to in the text by their Roman numerals:

I. Mæhlum S., Danielsen K.K., Heggebø L.K., Schiøll. The Hjelp24 NIMI Ringerike obesity clinic: an inpatient programme to address morbid obesity in adults. *Br J Sports Med* 2010.

II. Danielsen K.K., Svendsen M., Mæhlum S., Sundgot-Borgen J. Changes in Body Composition, Cardiovascular Disease Risk Factors, and Eating Behavior after an Intensive Lifestyle Intervention with High Volume of Physical Activity in Severely Obese Subjects: A Prospective Clinical Controlled Trial. *Journal of Obesity* 2013

III. Danielsen K.K., Sundgot-Borgen J., Mæhlum S., Svendsen M. Beyond weight reduction: Improvements in quality of life after an intensive lifestyle intervention in subjects with severe obesity. *Annals of Medicine* 2014

IV. Danielsen K.K., Sundgot-Borgen J., Rugseth G. Severe Obesity and the Ambivalence of Attending Physical Activity - Exploring Lived Experiences. *Submitted to Qualitative Health Research.*

Abbreviations

BED	Binge Eating Disorder
BES	Binge Eating Scale
BIA	Bioelectrical Impedance Analysis
BMI	Body Mass Index
CI	Confidence Interval
CVD	Cardiovascular Disease
CR	Cognitive Restraint
DXA	Dual-energy X-ray Absorptiometry
EE	Emotional Eating
FFM	Fat Free Mass
FM	Fat Mass
HADS	Hospital Anxiety and Depression Scale
HDL-C	High Density Lipoprotein Cholesterol
HRQL	Health related quality of life
ILI	Intensive Lifestyle Intervention
LDL-L	Low Density Lipoprotein Cholesterol
MCS	the Mental Component Summaries (of SF-36)
MID	Minimally Important Difference
NIH	Norges Idrettshøgskole (English: Norwegian School of Sports Sciences)
NIMI	Norsk Idrettsmedisinsk Institutt (English:Norwegian Institute of Sports Medicine)
PCS	the Physical Component Summaries (of SF-36)
QoL	Quality of Life
REE	Resting Energy Expenditure
SF-36	36-Item Short Form Health Survey
SOS	the Swedish Obesity Study
STC	Systematic Text Condensation
TFEQ	Three-Factor Eating Questionnaire
UE	Uncontrolled Eating
VFA	Visceral Fat Area
VO_{2max}	Maximal Oxygen Consumption
WHO	World Health Organization

Sammendrag

Bakgrunn: Økt forekomst av sykelig overvekt har ført til et stort behov for effektive ikke-kirurgiske behandlings alternativer, og økt fokus på intensive livsstilsendrings programmer, for denne fedme populasjonen. Det er også mangel på kvalitativ forskning som utforsker deltakernes erfaringer med fysisk aktivitet i løpet av slike livsstilsendringsprogram. **Formål:** 1) Beskrive og evaluere et inneliggende livsstilsendringsprogram ved NIMI Ringerike for behandling av sykelig overvekt, i forhold til endringer i kroppssammensetning, spiseatferd, psykologiske faktorer og helserelatert livskvalitet (HRQL). 2) Utforske deltakernes erfaringer med fysisk aktivitet før, under og etter behandlingen. **Metode:** Hundre deltakere fullførte det 10-14 ukers inneliggende behandlings-opphold og ble inkludert i en klinisk studie, og 71 % fullførte den 12 måneders prospektiv oppfølgingsstudien. Kontroller (n = 39) ble rekruttert fra en venteliste, og 85 % fullførte kontrollperioden. Behandlingsprogrammet fokuserte på å øke fysisk aktivitetsnivå, endre energi- og næringsinntak, og lære mestringsstrategier. Kroppssammensetning ble målt med bioelektriske impedanse analyse, og spiseatferd, psykologiske faktorer og HRQL ble målt med følgende spørreskjema; TFEQ-R21, BES, HADS og SF-36v2. Fem kvinner og tre menn deltok i den komplementære kvalitative studien. Intervjuer ble gjennomført 2-3 år etter det inneliggende oppholdet og ble analysert ved hjelp av systematisk tekstkondensering. **Hovedresultater:** Under det innleggende oppholdet, som inkluderte ≥ 90 min fysisk aktivitet fem dager/uke (paper I), oppnådde deltakerne en betydelig vektreduksjon med minimal reduksjon i fettfri masse. Etter 12 måneder oppnådde 68 % av deltakerne ≥ 10 % vektreduksjon (paper II). Vi observerte gunstige endringer i spiseatferd, symptomer på depresjon og mental og fysisk HRQL. De største endringene skjedde under det inneliggende oppholdet, og forble relativt stabile i løpet av oppfølgingsperioden. Vektreduksjon var relatert til bedringer i spiseatferd og fysisk HRQL (paper III). Deltakernes erfaringer med fysisk aktivitet ble oppsummert som en "ambivalens i forhold til å delta i fysisk aktivitet". Ambivalensen er karakterisert både av en endring i hvordan deltakerne erfarte aktiviteten i løpet av det inneliggende oppholdet, og som en kontinuerlig og stadig skiftende erfaring med slik aktivitet (paper IV). **Perspektiver:** Gjennom en intensiv inneliggende livsstils intervensjon, med stor mengde fysisk aktivitet, kan personer med sykelig overvekt oppnå betydelig vektreduksjon med minimal reduksjon i fettfri masse og gunstige endringer i spiseatferd, psykologiske faktorer og HRQL, som i stor grad opprettholdes etter ett år. Deltakernes erfaringer med fysisk aktivitet var imidlertid svært ambivalent, preget av tvil, frykt og motstand, samt komfort, glede og nytelse. Å ta opp og reflektere over slike erfaringer med deltakerne kan være av stor verdi i løpet av behandlingen. Det er behov for langvarige oppfølgingsstudier og mer kvalitativ forskning for å utforske deltakernes erfaringer.

Summary

Background

The recent increase in the prevalence of severe obesity has led to an urgent need for non-surgical treatment options and increased focus and priority on lifestyle interventions specifically targeted toward this obesity population. Previous studies have shown that intensive lifestyle interventions may cause clinically meaningful weight loss the first year post treatment for patients with severe obesity. However, few studies have "gone beyond the weight reduction" and investigated changes in body composition, eating behavior, psychological factors and health related quality of life (HRQL) following an inpatient treatment program with high volume of physical activity. There is also a lack of qualitative research exploring the participant's experiences with physical activity during and following these lifestyle modification programs. The aims of this thesis were therefore to describe and evaluate an already existing inpatient program for the treatment of severe obesity, in relation to changes in body composition, eating behavior, psychological factors and HRQL, as well as to explore the participant's experiences with physical activity prior to, during and following the treatment program.

Methods

In 2010-2011 we invited patients from the NIMI Ringerike Obesity clinic to participate in a clinical trial. Hundred subjects with severe obesity completed the main 10-14 weeks inpatient treatment and were enrolled in the study, and 71 % completed the 12 months prospective follow-up study. All subjects received the same lifestyle modification program focusing on increasing the physical activity level, adjusting energy and nutrition intake, and learning coping strategies (paper I). In addition we recruited controls (n=39) from a waiting list in the autumn 2011, and 85 % completed the control period. We measured body composition using bioelectrical impedance analysis (paper II), and to assess eating behavior, psychological factors and HRQL the participants completed the following questionnaires; the 21-item Three-Factor Eating Questionnaire, the Binge Eating Scale, the Hospital Anxiety and Depression Scale, and The Medical Outcome Study 36-Item Short Form Health Survey (paper III). Five women and three men from the prospective clinical trial were invited to participate in the complementary qualitative study 2-3 years after they started at the inpatient program. The interviews were analyzed using the principles of Systematic Text Condensation (paper IV).

Main results

During the 10-14 weeks inpatient period, including minimum 90 min of physical activity five days/week (paper I and II), the participants achieved a substantial weight loss with minimal reduction in fat free mass (paper II). The changes remained quite stable during follow-up, and 68 % of the participants achieved ≥ 10% weight loss at 12 months. Furthermore weight loss was related to increased cognitive restraint and decreased uncontrolled eating (paper II). We observed favorable changes in self-reported symptoms of binge eating and depression, and in mental and physical HRQL (paper III). The main changes occurred during the 10-14 weeks of the inpatient period and remained relatively stable thereafter during the first year. Improvements in binge eating and physical HRQL were associated with weight loss (Paper III). When further exploring the participant's experiences with physical activity, we summarized our findings into one overall theme: "ambivalence of attending physical activity". The ambivalence was experienced as a shift in how participants feel about physical activity during the inpatient period, and as an ongoing, dynamic and constantly shifting experience during such activity (paper IV).

Perspectives

The results of the current thesis suggest that through an inpatient intensive lifestyle intervention, with high volume of physical activity, subjects with severe obesity may achieve substantial weight loss with minimal reduction in fat free mass. Furthermore these subjects may achieve improvements in eating behavior, psychological factors and HRQL during the inpatient period, which are mostly maintained after one year. Moreover, improvements in eating behavior and physical HRQL are associated with weight loss. The subjects managed to participate in high volume of adapted physical activity. However, their experiences with physical activity were highly ambivalent, characterized by doubt, fear and resistance as well as comfort, joy and pleasure. To address and reflect upon such experiences with the participants, and acknowledge ambivalence as a legitimate part of being physically active, might be important within obesity treatment. Long-term follow-up studies of such inpatient intensive lifestyle interventions for the treatment of severe obesity is needed, and we recommend future investigations to include qualitative studies to further explore the participant's experiences.

The complex system of obesity

..... a system in which we have influence but not control....

.....the opposite of complexity is linearity.

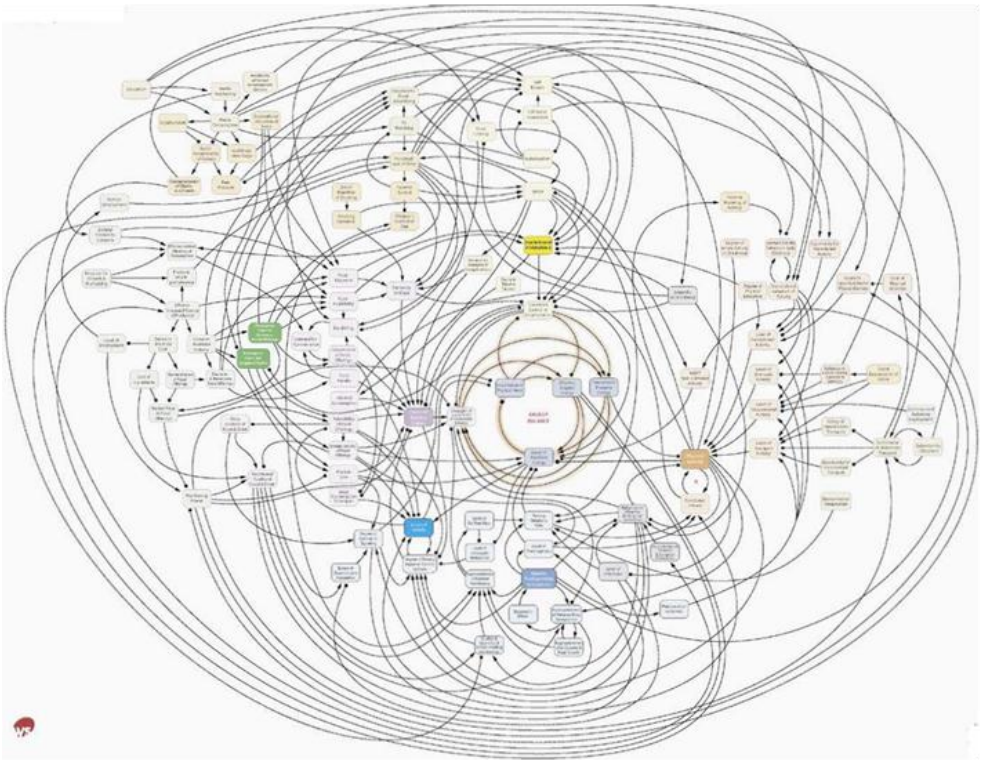


Figure: Tackling obesities: future choices – full system map.
https://www.gov.uk/government/publications/reducing-obesity-obesity-system-map

"To me the complex of obesity is so overwhelming; where do I start, when everything is connected to everything?" (The thoughts of a worried PhD student)

"The answer is: It doesn't matter where you start. Start where you are!" (Øyvind Glosvik)

"...At NIMI Ringerike Obesity Clinic in Norway" (Reassured PhD student)

Inspired and cited with permission from Øyvind Glosvik,
at the Balestrand obesity conference: "The complexity of obesity: Scandinavian perspectives", Norway 2014

Introduction

Due to the rapidly increasing prevalence of severe obesity and the impact this magnitude of excess body weight has on health and health related quality of life [1-10], there is a need for effective therapies for treatment-seeking individuals with severe obesity. In regard of weight loss per se, bariatric surgery is considered the most effective [11-13]. However, not all patients want or can have bariatric surgery [14], and moreover the capacity of weight loss surgeries makes it an unlikely public health solution for the rapidly increasing prevalence of severe obesity. Thus it is crucial to develop non-surgical treatment options.

In Norway about 100 000 individuals can be classified as severely obese [10]. According to the Norwegian guidelines, treatment seeking individuals with severe obesity should be offered either conservative or surgical therapy [15-17]. All patients are initially treated non-surgically, and if weight loss of clinical importance is not achieved in treatment programs in primary or secondary care, patients are referred to more comprehensive lifestyle interventions in tertiary care. In 2004 the Norwegian health authorities decided that all the four health regions should provide non-surgical treatment options for these patients. In this context the Norwegian Institute of Sports Medicine (NIMI), a private healthcare provider, started an inpatient program at NIMI Ringerike obesity clinic for the treatment of severe obesity funded by the Health Region South-East in 2006. This thesis is focused on the effects of this intensive lifestyle intervention, and also the participant's experiences of the physical activity component included in the intervention program. Originally, the treatment program offered at NIMI Ringerike obesity clinic was not planned to be a scientific research project. Rather it was a wish to evaluate the program in the clinic that emerged. Thus in the work with this project, we had to deal with an established program and had no possibility to influence either the provided intervention, or the methodological choices. In addition the "real life" setting presented challenges to conduct a "streamlined" research project.

Severe obesity

Definition

According to the World Health Organization (WHO) overweight and obesity are defined as: "abnormal or excessive fat accumulation that may impair health". Assessment of body fat and its distribution may be conducted with several methods varying in degrees of accuracy and availability [18-21]. Due to practical, economical and clinical reasons body mass index (BMI),

calculated as body weight in kilograms divided by height in meters squared (kg/m^2), is commonly used for defining obesity in relation to risk of comorbidities. Based on epidemiological studies WHO has defined cut-offs in relation to BMI (table 1). In Western countries the term *severe obesity* (also named morbid, extreme or class III obesity) in adults refers to a BMI ≥ 40kg/m^2. Severe obesity is also often used to refer to people with BMI 35 to 39.99 kg/m^2 who have significant health problems associated with obesity, and in this thesis the definition of severe obesity refers to "a BMI ≥ 40 kg/m^2 or BMI 35-39.99 kg/m^2 combined with at least one weight-related comorbidity" [22,23], unless otherwise stated.

Table 1. The International Classification of obesity in Caucasian adults according to BMI and WC. Derived and modified from WHO (2000) [24] and Ardern (2004) [25].

Classification	Cut-off BMI (kg/m^2)	Risk of comorbidities	WC cut-off (cm)
Overweight	≥25.00 (25.00 - 29.99)	Increased	Men: ≥ 100 Women: ≥ 90
Obese	≥30.00		
Obese class I	30.00 - 34.99	Moderate	Men: ≥ 110 Women: ≥ 105
Obese class II	35.00 - 39.99	Severe	Men: ≥ 125 Women: ≥ 115
Obese class III	≥40.00	Very severe	
Super obese	≥50.00		

It is well known that the calculation of the BMI does not distinguish between the different components of body composition, e.g. fat mass (FM) and fat free mass (FFM), and its distribution. As waist circumference (WC) is the most practical method for estimating abdominal obesity this measure is frequently used in combination with BMI [24,26]. WC cut-offs within gender are developed to determine degree of obesity in according to increase of health risk [24]. However higher cut-offs have been suggested in subjects with BMI ≥ 35 kg/m^2 (table 1) [25,27]. Research strongly suggest that at any given BMI, the risk of developing diabetes and cardiovascular disease (CVD) are higher in some ethnic groups than others, and lowering BMI and WC cut-off points specific for Asian populations have been recommended [28,29].

Prevalence

The prevalence of obesity is widespread and growing [24,30]. Numerous studies have provided epidemiological data, however the lack of accounting for comorbidities challenge the mapping of the (exact) prevalence of severe obesity as defined in this thesis. The prevalence of what is defined as class III obesity (table 1/BMI ≥ 40.0 kg/m^2) though increases with higher frequencies than any other degree of obesity among adults in the USA [5,8,9], and in 2009-2010 it was 4 % in

men and 8 % in women [31]. Data from a large epidemiological study in Norway, The Nord-Trøndelag Health Study (The HUNT Study), shows that the prevalence of obesity class III increased from approximately 0.1 % to 0,5 % in men and 0.7 % to 1,5 % in women between 1984/86 to 2006/08 [10]. In the same period the prevalence of class II obesity increased from 0.8 % to 3.2 % in men and 2.6 % to 5.0 % in women. These findings indicate that severe obesity is increasing in Norway, and it is likely that about 2 % can be defined as severely obese [10,32]. Comparable prevalence is reported in other Nordic countries [33,34].

Causes

The underlying causes of severe obesity are complex and multifactorial, and the etiology is based on the interaction of genetics, environmental, psychosocial and lifestyle factors [35,36]. Severe obesity is a result of prolonged imbalance between energy intake and expenditure, leading to a positive energy balance and fat accumulation. However in some cases the imbalance is due to genetic defects, hypothalamic damage or medications [36-39]. In addition, psychological factors and eating disorders (i.e. binge eating disorder and night eating syndrome) are associated with weight gain and obesity [2,40-42].

Body weight is regulated through a dynamic interplay among homeostatic, hedonic, and cognitive feedback processes [43-45]. Physiological responses (endocrine feedback signals) to over-and underfeeding, explain how food is consumed in order to maintain energy balance at homeostatic levels (a set point). However, food is also consumed for its hedonic properties, independent of energy status [45]. This reward-related system and cognitive processes in brain can result in caloric intake exceeding requirements, and is considered a major contributor to the rapidly increasing rates of obesity in developed countries [43,44]. Finally, social, economic and environmental factors play important roles in modulating both food intake and physical activity behaviors which in turn result in alterations in weight over time [43].

It is widely acknowledged that genetics do play a role in the individual's tendency to gain excess weight, as well as the influence of treatment, weight loss and weight loss maintenance [46-49]. Variations in genes may predispose to common obesity and especially certain variants of the FTO (fat mass and obesity associated) gene has been shown to be correlated to obesity in several large studies [50-52], and also in subjects with severe obesity [53,54]. The function of FTO is incompletely understood, but it plays an important role in the control of eating behavior (the

center of energy balance) in hypothalamus, and individuals with certain variants of the gene are hence more likely to overeat [50-52].

In addition to genetic factors, lifestyle factors, including diet and physical inactivity, are important contributors to weight gain and obesity. The last decades of environmental changes [55], with increased availability of energy-dense food in combination with the reduced requirements to be physically active, have consequently made individuals with a genetic predisposition more likely to develop obesity than previously. This environment is referred to as an «obesogenic environment» [56]. Environmental adaptions (diet and exercise) may also affect the gene expression (epigenetics) and result in obesity. Hence a gene-environment interaction is explaining the individual vulnerability to weight gain [47], and may be of special importance related to severe obesity [36]. On the other hand a physically active lifestyle seams to attenuate the genetic predisposition to common obesity [57], and also the weight gain and obesity in those with an underlying FTO genetic predisposition (i.e. the increased risk of obesity owing to genetic susceptibility by FTO variants can be blunted through physical activity) [50-52,58,59].

Health consequences

Severe obesity is associated with higher prevalence of comorbidities and mortality rates compared with lower degrees of obesity and overweight [2-4,6,60,61].

Physical health

In general severe obesity is characterized with large increase in FM, in particular increased intra-abdominal fat or visceral fat area (VFA) [19] which is associated with increased health risk [62-64]. Due to the increased body weight, the burdens on parts of the body are substantial and weight bearing limbs, such as lower back, hips, knees and ankles are often painful [65,66]. Common comorbidities related to obesity are CVD, type 2 diabetes, metabolic syndrome [62,63], musculoskeletal pain, osteoarthritis and certain kinds of cancer [65,67,68]. Other important health consequences of obesity include fatty liver disease, kidney disease, obstructive sleep apnea, gallbladder disease, polycystic ovarian syndrome and infertility. Increased body weight and fatness also have a detrimental effect on aerobic capacity, and low maximal oxygen consumption (VO_{2max}) as relative to body weight (ml·kg-1·min-1) has been reported among subjects with severe obesity [69,70]. Individuals with severe obesity are also shown to be less physically active

than individuals with normal weight and a lower degree of obesity [71,72], which may be both a cause and consequence of the increased body mass and decreased physical fitness.

Eating behavior and psychological factors

Although many subjects with severe obesity have a good mental health, severe obesity is also associated with an increased risk of psychological complications, including binge eating, anxiety and depression. There is however a "chicken or the egg causality dilemma", i.e. which came first, the obesity or the psychological complications? A reciprocal association between obesity and depression has been found, with the highest prevalence of depression among individuals with severe obesity [2,7,37,42,73,74]. "Dysfunctional eating" (e.g. emotional eating and night eating) and binge eating ("loss of control" eating) are common among obese individuals seeking weight loss treatment [2,41]. Subjects with severe obesity report more symptoms of binge eating as compared to subjects with lower degree of obesity [75,76], and they often exhibit recurrent episodes of binge eating, which may include a DSM-IV defined unspecified eating disorder or a binge eating disorder (BED, characterized by rapid ingestion of large amounts of food, with a feeling of loss of control and subsequent guilt and self-condemnation)[2,77]. Depending on the population and gender, as well as definition and method of measurement used, incidences of BED, sub-clinical binge eating and binge eating symptoms in subjects with severe obesity ranging from five to 50 % have been reported [2,40,75,76]. These eating patterns serve to regulate or suppress negative emotional states, which may result in overconsumption of energy-dense food [78,79], and can hence be perceived as both a cause and consequence of obesity. Binge eating may also account for and mediate the relationship between obesity and psychological factors [37,80-82].

Furthermore, psychological factors may have an impact on weight loss outcome. The empirical evidence regarding the association between symptoms of depression and binge eating with weight loss is however not settled, and varies according to definitions used, whether measurements are performed pre-treatment, post-treatment or as changes in symptoms, whether change in weight or exact maintained weight is reported, as well as the sample (and gender) included [83-92]. It is also important to have in mind that depression and anxiety is affected by both genetic and environmental influences and a complex of psychosocial factors other than body weight [93,94].

The double-burden

In addition to medical considerations, being overweight and obese is a cultural, contextual, relational and individual experienced phenomenon [2,95-97]. In wealthy and western societies today it is expected that all are "thin and healthy". Obese individuals seem to "break the rules," and may be considered unhealthy, lazy or weak-willed when it comes to food and exercise, and unmotivated and noncompliant with weight loss treatment [98,99]. These stereotypes leave overweight and obese persons vulnerable to stigma and discrimination, which exists in multiple domains of living including workplace, the mass media, fitness centers and even in the health care system and family [98-102]. Living with stigma is considered as unhealthy as well, and therefore it can be said that people who are obese face a "double-burden"; living an unhealthy bodily condition and being stigmatized for it [103]. Subjects with severe obesity receive even greater social rejection and bias [2,104], as well as frequently embarrassed by problems with clothes that do not fit, limitations in hallways, small chairs, and difficulty with cleanliness and odor [2].

Health related quality of life

The physical and psychosocial health consequences related to severe obesity may also affect quality of life (QoL). The term *health related quality of life* (HRQL) can be understood as the overall impact of an illness or condition and/or its treatment on physical and mental functioning and well-being as subjectively evaluated and reported by the person [105,106]. Several studies have revealed impaired HRQL among subjects with severe obesity, especially in physical domains [1,2,7,75,107,108]. Evidence suggests that there is a relationship between obesity and HRQL that varies by both BMI and intensity of treatment sought, with individuals with severe obesity seeking surgical treatment reporting greater impairment in HRQL than do other obesity sub-groups including non-treatment seeking individuals with severe obesity [1,2,109,110]. Due to the related comorbidities, poor physical fitness and musculoskeletal pain, severe obesity is also associated with increased risk of disabilities in terms of limited mobility and activities of daily living, which again is related to work inability, sick leave and reduced HRQL [111,112].

Socio economic

In addition to being a burden to the individual's health, obesity also results in significant direct and indirect economic costs to society [113-115]. Severe obesity is shown to cause greater increase in the medical costs compared to overweight and obesity grade I and II [115-117]. Hence effective prevention strategies of obesity are demanded, as well as treatment options.

Treatment of severe obesity

The main goals in the treatment of severe obesity are to reduce comorbidity and mortality, as well as to improve QoL. In overweight and obese individuals a 5-10 % reduction of body weight can provide significant health benefits, and ≥ 10 % weight reduction is often regarded as clinical meaningful and is being recommended as a treatment goal [17,118]. However weight loss targets should be based on comorbidities and risks (rather than on body weight alone), and a greater weight reduction (15-20 %) has been suggested for the treatment of severe obesity [17,118,119]. For health benefits in the long-term, it is also essential that the weight loss is maintained.

The primary objective in relation to weight loss is the reduction of FM, especially VFA, leading to improvements in obesity-related CVD risk factors [62-64]. In addition with respect to long-term effects of weight loss programs it is desirable to maintain FFM in order to minimize the anticipated decrease in resting energy expenditure (REE) following weight loss [120-122]. Reduction in total body mass will however lead to reduced resting metabolism and decreased energy needs [123]. During weight reduction (negative energy balance) the body also tends to defend a possible genetic determined weight range (set point), and chemical and psychological feedback control mechanisms initiate metabolic, autonomic, neuroendocrine, and behavioral adaptations that favor weight regain. Reduced body weight is associated with reduced sympathetic nervous system activity, alterations in leptin and thyroid hormones creating optimal circumstances for weight regain [124-127]. In the weight-reduced state energy expenditure and fat metabolism is decreased (both in active and resting states) to levels that goes beyond what could be predicted from the changes in FM and FFM (i.e. adaptive thermogenesis), largely due to increased skeletal muscle work efficiency. In addition energy intake increases due to increased hunger and reduced satiety [124,125,127,128]. These processes are multi-causal and go beyond good compliance with diet prescriptions and exercise programs [124,128]. To maintain a reduced body weight most participants will have to continue their energy reduced diet and/or increased activity levels for the rest of their life, while at the same time experiencing an augmented drive to eat as compared to before the weight reduction [129,130]. In some vulnerable individuals the adaptive thermogenesis is quantitatively significant to compensate for a given prescribed energy deficit, and hence partly explain the unsuccessful weight loss maintenance [124,128]. In sum this means that individuals who reduce their body weight will have to work even "harder" to continue weight reduction (due to both the reduced energy request, as well as an energy deficit to further reduce weight). Maintaining weight loss is therefore a great achievement, and to maintain a

clinical relevant weight reduction should be emphasized rather than further weight reduction. Unsuccessful weight loss maintenance, upon return to initial weight, is associated with lower energy expenditure that might predispose to further weight gain or difficulty trying to lose weight again, and variations in body weight seem to be a determinant of adaptive thermogenesis. Severe obesity is a progressive condition associated with innumerable failed attempts at change and repeated relapses [102,131]. Hence long-term (sometimes lifelong) follow-up is required in the treatment, with a risk of relapses [17].

The cornerstone of obesity treatment is change of lifestyle or behavior. Severe obesity can be treated through pharmaceutical, surgical or lifestyle interventions. Lifestyle intervention within weight loss treatment and research is a generic term referring to different diet modification, physical activity and exercise programs and behavioral therapy. In this section a short overview of the main treatment strategies will be provided, whereas physical activity and what can be considered as intensive lifestyle interventions will be further elaborated.

Drug treatment

Drug treatment can be used both for initially weight loss and in the maintaining phase. Several pharmaceutical products have been shown to modestly improve weight loss, have differing effects on CVD risk factors, but do often have unpleasant side-effects. In addition the drop-out and non-adherence rates are rather high, and long-term studies are sparse [132-134]. New products are being studied [133], but due to safety reasons several products have not received approval. Orlistat (Xenical) is currently the only approved drug in Norway. In a systematic review and meta-analysis adding this drug to lifestyle changes was associated with a weight loss of ~ 3 kg for up to two years, and improvements in total and LDL cholesterol, blood pressure and glycemic control in obese subjects [132,134]. Although subjects with severe obesity or BMI $\geq$ 40 kg/m^2 were included in these studies, results were not specified for this population. Intensive lifestyle interventions including drug treatment have shown a 12 % and 5 % reduction in body weight at one [135] and two [136] years follow-up respectively. Supplement of leptin seem to be less effective in promoting weight loss, but may partly reverse the adaptive thermogenesis that favor weight regain in weight-reduced individuals [125,137].

Bariatric surgery

Bariatric surgery is gastrointestinal surgery performed to induce weight loss, based on two principles: 1) gastric restriction (i.e. decreasing of the volume of the stomach in order to cause early satiety during meals), and 2) bypass of various lengths of the small intestine (i.e. mal-absorptive procedures in order to reduce nutrient absorption), or a combination of these two [11]. In addition the procedures induce favorable metabolic and hormonal effects, and changes in eating behavior [138]. Depending on the procedure performed varying weight loss is achieved, and various side-effects are common [11-13,139]. In general bariatric surgery is clearly more efficient in inducing and maintain weight loss as compared to non-surgical treatment options [11,12]. Moreover there is strong evidence that bariatric surgery leads to reduction in many obesity-related comorbidities and morbidity, as well as improved psychological health and HRQL [11,12,140-144]. Both nationally and internationally the annual number of weight loss surgeries performed has increased dramatically in recent years [145,146]. Between 2003 and 2012 the annual number of weight loss surgeries performed in the Norwegian public health care system increased from 24 to 1890 [146]. In addition an increasing number of Norwegians undergo bariatric surgery at private clinics or abroad, however the exact number is unknown. Nevertheless, bariatric surgery is an unlikely public health solution for the rapidly increasing prevalence of severe obesity. Furthermore, not all subjects with severe obesity want or can have bariatric surgery [14], and adverse physical and psychosocial complications have been reported [12,13,102,144,147,148]. Hence it is imperative to develop and offer effective lifestyle interventions. In addition sustained weight loss following bariatric surgery depends finally on the patient's changes in lifestyle, in terms of diet and need for regular exercise, and careful bariatric follow-up evaluation [11].

Behavioral treatment

Behavioral treatment in weight loss refers to approaches used to help individuals to develop a set of skills to achieve a healthier weight. The treatment is characterized by being goal and process-oriented, and advocates small changes [149,150]. In order to achieve a sustained weight loss the participants have to learn specific skills to facilitate behavioral changes. Behavioral principles and techniques are used with the aim to change the participant's behavior and habits, as well as for overcoming barriers to compliance with diet and/or physical activity [27]. Behavioral treatment usually involves the use of multiple components, such as self-monitoring, stimulus-control, goal-setting and cognitive therapy [26,27,149,150]. The behavioral treatment in obesity studies is

however often poorly defined and described [151], and more research is needed to define the most effective components of the behavioral treatment “package" to achieve long-term weight loss in severe obesity.

Dietary modification

Diet modification is one of the cornerstones in the treatment of obesity. There is convincing evidence that energy reduced diets either by energy reduced diet plans, moderation in portion sizes or reduction in intake of certain food groups are effective for weight loss [152]. Generally, a moderate reduction in energy intake by 500-1000 kcal per day is estimated to reduce body weight by 0.5-1.0 kg per week [17,35,152]. There are a numbers of different diets with various total daily energy intakes, including periods of fasting or use of meal replacements to different combinations of macro-nutrients. Research is inconclusive regarding which diet is the most effective, and the dietary adherence seems to be more important than dietary macronutrient composition for weight reduction [153-155]. However beneficial effect on weight maintenance of a high intake of protein has been found in overweight and obese subjects, probably through increases of satiety and thermogenesis [156,157]. So far, the Mediterranean diet has been linked to better cardiovascular outcomes [158-160]. In a multicenter randomized trial (the PREDIMED study) this diet was shown to reduce the incidence of major cardiovascular events among persons at high cardiovascular risk [159,160]. In this study almost 50 % had a BMI above 30 kg/m^2, and analysis revealed additional beneficial effect in this group as compared to lower BMI-groups. Furthermore the Nordic healthy diet, based on the Nordic Nutrition Recommendations from 2004 and inspired by the Mediterranean diet, is shown to reduce CVD risk factors [161,162], documentation is however lacking in subjects with severe obesity.

In general each diets seams to modestly reduce body weight and improve several CVD risk factors in the short and middle term. On average the weight reduction phase is typically followed by weight gain, and main factor associated with maintenance of weight loss and improvements in health seem to be compliance to the diet and reduction in energy intake, regardless of the diet [132,163,164]. Also in subjects with severe obesity energy intake, not macro nutrient composition, seem to determine weight loss in response to low-energy diets over a short time period [165]. Furthermore intensive lifestyle interventions including the use of meal replacement and very low calorie diets have shown promising long-term effects [166-170]. Nevertheless subjects with severe obesity participating in intensive lifestyle interventions are often prescribed

diet with a macronutrient composition of approximately 50-60 E % of carbohydrates and < 30 E % from fat, with emphasize on fruit, vegetables, whole grain and fiber [69,171-173].

A recent systematic review of studies intending to promote weight loss revealed a lack of evidence to fully understand the impact of dietary modification on HRQL. Most studies reported improvements in HRQL over time. However it was unclear whether implementing dietary changes positively or negatively affects HRQL independent of weight loss and/or health improvements. Importantly, if dietary interventions adversely affect HRQL through social and economic domains, this may possible influence maintenance of the dietary changes [174].

Physical activity

Physical activity has been part of numerous of weight loss programs and is considered a crucial part of lifestyle modification programs. Both exercise (e.g. participants exercise regularly by for example walking, cycling, swimming or strength training) and increase in everyday activities/lifestyle exercise (e.g. climbing stairs instead of using the lift), or a combination of these, can be used in the treatment of obesity [26,175]. In addition, reducing sedentary time is a method to increase activity level [26].

Weight loss and weight loss maintenance

The recommendations regarding physical activity for weight loss in the treatment of overweight and obesity have ranged from about 150 min/week to 90 min/day of moderate to vigorous intensity physical activity [175-177], and reserch regarding the effect of strength training is limited [175]. There is however a lack of evidence based recommandation on physical activity prescription specific for subjects with severe obesity [118,178].

The prescription of amount of physical activity included in weight loss studies has also varied. However without a reduction in energy intake, physical activity seems at best to have only modest influence in decreasing body weight, with a dose-response relationship between physical activity and weight loss [179-184]. Research is currently lacking to conclude on the effect of physical activity alone on body weight in subjects with severe obesity [178], but in subjects with overweight and lower degree of obesity a mean weight loss of 1-3 kg is typically achieved with physical activity alone within 6-12 months after initiating treatment [177,182-184]. Furthermore, even if the litteratur is unclear, the effects of physical activity on weight loss seems to be additive

to what is observed with a dietary intervention alone [177,181,182,184], and similar additive effect of physical activity has been found in subjects with severe obesity [173,185].

Low adherence to the prescribed physical activity, as well as the fact that most physical activity prescriptions involves small amounts of physical activity, are probably important reasons for the modest and/or variations in weight reduction achieved [177,182-185]. Studies have shown that clinically significant weight loss is possible with physical activity without caloric restriction in subjects with BMI < 35 kg/m^2. [179,184,186,187]. However approximately 60 minutes of physical activity of moderate intensity every day, or daily exercise sessions with an energy expenditure of minimum 500-1000 kcal, is required to reach an energy imbalance producing a significant weight loss (0.5-1 kg/week) [179,184,186,187]. For most individuals with severe obesity such volume of physical activity is challenging to complete [188-190].

In addition to behavioral factors, physiological and psychological factors also contribute to interindividual variability in weight loss resulting from physical activity [182,191,192]. An individual variability in appetite control and compensatory eating following exercise has been shown, and seems to be part of what distinguishes "responders" from "non-responders" of achieving weight loss following exercise [192-194]. Exercise and physical actvity may have a positive influence on appetite regulation by increased sensitivity for satiety signals, as well as through effects on psychological factors and improved eating behavior [195-199]. Research in subjects with severe obesity suggests that supported exercise improves weight loss and controlled eating through improvements in psychological factors (i.e. psychological pathways), rather than by caloric expenditure (i.e. physiological pathways) [200-202].

Both prospective and retrospective studies suggest that physical activity is important for maintenance of weight loss, and compelling research suggest that a minimum of 60-90 minutes of moderate intensity activity each day is required to prevent weight regain in formerly obese individuals [176,177,203,204]. Studies also suggests that physical activity plays a crucial role in weight loss maintenance in individuals with severe obesity [69,171]. Hence a progression of individuals with severe obesity to an adequate dose of physical activity needs to be incorporated into clinical interventions for weight control, and a combination of physical activity and diet seems preferable.

Health

Reduction of body weight is not the only end point of physical activity. Physical activity is also considered a key component of any weight management program because of its positive impact on health [184,205]. No studies have investigated changes in body composition with physical activity alone in subjects with severe obesity [178]. However beneficial effects on FM when adding physical activity to diet has been shown [173]. Physical activity can lead to favorable changes in body composition, e.g. reduction in total FM, WC and VFA, despite minimal weight loss in subjects with a BMI < 35 kg/m^2 [179,187,206-208]. In a systematic review Ross and Janssen found that the increase in physical activity, expressed as energy expended per week, was positively related to reductions in total FM in a dose-response manner [209]. Physical activity was also associated with a reduction in visceral fat, but there was insufficient evidence to determine a dose-response relationship [209]. However, aerobic exercise of high intensity appears to have the best potential to reduce both FM and visceral fat [208,210,211]. If being physically active during weight loss overweight and obese subjects may also maintain FFM, and resistance training seems necessary to increase skeletal muscle mass [212]. The amount of physical activity required to maintain FFM in subjects with severe obesity is unknown. Studies of treatment of overweight individuals indicates that exercise of high intensity may lead to favorable changes in body composition, however this is believed to be difficult to realize in subjects with severe obesity due to low cardiovascular fitness [120].

In addition to body composition, cardiorespiratory fitness is also an important quality of health-related fitness [213,214]. There is a lack of studies regarding the effect of physical activity alone on cardiorespiratory fitness in subjects with severe obesity. However increased physical activity level over 1 year has been shown to increase cardiorespiratory fitness as measured by VO_{2max} in subjects with severe obesity following an intensive lifestyle intervention [70,215]. Both physical activity of low and high intensity is shown to increase VO_{2max} significantly in obese women and men, however high intensity activities provide the greatest increase [211]. Lack of compliance with the prescribed physical activity probably attenuates the effect, and there is also individual variation in the response to exercise regarding VO_{2max} in obese subjects [216]. Importantly weight loss per se will increase cardiorespiratory fitness measured as relative VO_{2max} or walking performance [70,70,217], and it is therefore difficult to determine changes in cardio respiratory fitness beyond the direct effects of weight loss. Exercise interventions however suggest that

cardiorespiratory fitness may increase independent of weight loss in overweight and obese subjects [187,192,206].

Both body fatness and fitness are strong predictors of CVD risk factors, morbidity and mortality. The relative and combined contributions of fitness and fatness to health are however controversial [218]. In subjects with a BMI < 35 kg/m^2 substantial evidence suggests that cardiovascular fitness attenuates the risk independent of BMI [218-220] and have led to development of the concept "fit but fat" (i.e. being overweight and healthy) [218]. Physical activity can also reduce morbidity and mortality [184,219,221-223]. However, no studies have adequately assessed the impact of physical fitness and physical activity on the prognosis of subjects with severe obesity [178,218].

Population studies have shown associations between physical activity and psychological well-being [224,225]. Physical activity is also shown to reduce anxiety and depression [226-229], as well as symptoms of binge eating [230-232]. However the relationship between physical activity, on the one hand, and depression and obesity on the other, has been shown to be bidirectional [42]. Thus, physical activity may serve as protection from and reduction of obesity as well as depression. Research regarding the effects of physical activity on psychological factors and HRQL in subjects with severe obesity is sparse [178], however in cross-sectional studies higher levels of physical activity is shown to be related to higher life-satisfaction and physical HRQL in subjects with severe obesity [108,233].

Intensive lifestyle intervention

In this thesis *intensive lifestyle interventions* (ILI) refers to comprehensive lifestyle modification programs combining diet modification, increased physical activity and behavioral treatment, which are planned, structured and carried out by a multidisciplinary team. Such multi-component interventions by health-professionals are found to be the most effective non-surgery weight management practice in subjects with overweight and lower degrees of obesity [151,234].

In according to the Norwegian guidelines individuals with severe obesity should be referred to different treatment modalities (i.e. ILI or bariatric surgery) in tertiary care if weight loss of clinical importance is not achieved within a reasonable time (~ six months) in less intensive treatment programs in primary or secondary care [17]. Until recently few published clinical trials had been

specially designed to determine the effectiveness of ILIs in subjects with severe obesity [69,86,165-167,235,236] (Appendix I). Treatment guidelines regarding lifestyle treatment for this patient group have also mainly been based on studies including subjects with lower degree of obesity or other patient groups, reports or opinions of expert committees, and/or clinical experience from respected authorities and the health care professionals that developed the guidelines [15,17,26,27,118,237].

ILI can be conducted as day- and inpatient treatment, and the treatments provided by the different health regions and hospitals in Norway vary regarding content and duration. The concept of residential programs in specialized weight loss centers (composed as one single stay at the residential clinic or as several intermittent stays) for the treatment of severe obesity is relatively new. Few data were available at the onset of this study [69,171,235,236,238,239], and most studies included relatively short inpatient periods (2-6 weeks), and 4-7 % acute weight loss [69,235,236,238] (Appendix I). Two studies included longer inpatient periods and showed improved initial weight loss as compared to what had been reported following shorter inpatient periods [171,239]. However, formal follow-up and re-admission, which seems important for weight loss maintenance after ILI [166,167,236], was lacking after the longer inpatient stays [171,239]. Based on the existing knowledge best practice was yet to be found, and the effectiveness of inpatient ILI for the treatment of severe obesity had not been settled. Thus one aim of this study was to describe an ongoing inpatient treatment program for patients with severe obesity, with a relatively long inpatient stay and two follow-up stays, provided by a clinic with broad experience in sports medicine and applying exercise as a treatment option (paper I), as well as to provide some preliminary data (paper I). Furthermore we aimed to undertake a prospective observational study at the clinic on a population of subjects with severe obesity (paper II-III).

The recent increase in the prevalence of severe obesity has led to an urgent need for non-surgical treatment options and an increased focus and high priority on lifestyle interventions specifically targeted toward this obesity population [8]. Consequently, various studies have been initiated to evaluate different ILIs varying in relation to type of intervention and duration (Appendix I). Recent studies will be included in the discussion section later in this thesis. However none of the previously or recently published studies have included a non-treated control group.

Physical health – Body composition

Because of the health benefits related to changes in body composition, as well as maintenance of FFM to minimize the reduction in energy expenditure seen after weight loss, evaluation of lifestyle interventions should aim to determine changes in body composition. Prior to the onset of this study, only three studies had investigated changes in body composition during inpatient ILI in subjects with severe obesity [69,236,239], and there were great variations in the included interventions in relation to the duration of the inpatient stay and the physical activity component (Appendix I). No further follow-up had been reported following long inpatient stays.

Eating behavior, psychological factors and HRQL

Studies investigating the effects of inpatient ILI with regard to eating behavior, psychological factors and HRQL among subjects with severe obesity were also sparse (Appendix I). However, one study found that weight changes correlated with degree of psychosocial difficulties and eating behavior problems five years after a six weeks inpatient program [236]. Another observational pilot study showed an immediately improvement in HRQL and a reduced proportion of suggestive binge eaters at six months follow-up after a one month inpatient stay [238]. The Swedish Obesity Study (SOS), however, showed no changes in HRQL, nor any weight loss, following conventional treatment which only involved advertises of diet and physical activity [140]. Nevertheless, based on results from the Look AHEAD study, including subjects with lower degree of obesity having type 2 diabetes mellitus, it was reasonable to expect improvements in HRQL and decrease in symptoms of depression during an ILI leading to significant weight loss, as well as greater weight losses observed in participants who stop binge eating [240,241]. Major depressive disorder and BED were also associated with less weight loss following a 16 weeks outpatient ILI in subjects with severe obesity [86].

Experiences with physical activity

Besides the healthy physiological and psychological effects of physical activity, being physically active is also inextricably bound to meaning [242]. Nevertheless, most studies of ILI for subjects with severe obesity focuses on the quantifiable effects. In an era where physical activity is considered a crucial part of lifestyle interventions and numerous studies have documented its health benefits, little is known about the participants' actual experiences with physical activity during these ILIs, as well as prior to and after such interventions.

Individuals with severe obesity may have difficulty with physical activity due to increased body weight, reduced mobility or medical problems related to obesity [14,102,188,190] [189,243]. In line with this, it has been claimed that exercise programs may be de-motivational and unhelpful in the treatment of subjects with severe obesity [244]. Individuals with severe obesity have also reported feelings of not "fitting in" in gym and exercise groups, and feelings of being critically stared at in public, and such experiences may discourage or stop them from exercising [188,189]. On the other hand, individuals with severe obesity also report that they like being physically active and have positive experiences with adapted physical activity [188-190]. Exercising together with other individuals with severe obesity, and being introduced to adapted exercises and special equipment may be of great importance in order for this population to increase compliance in physical activity interventions [188,243].

Qualitative research can make a contribution to existing knowledge regarding how subjects with severe obesity experience being physically active, the role of physical activity and exercise in their lives [188,242], and can provide valuable knowledge to clinicians and participants, as well as researchers. A common perception in weight loss programs is that "obese individuals have to change", but, qualitative methodology can provide more nuanced knowledge regarding how treatment programs are experienced, and such knowledge can contribute to a better adaptation of the content of the programs to participants' needs. Within this context, we aimed to explore the experiences of physical activity from a participant perspective prior to, during and following an inpatient ILI, including high volume of adapted physical activity, for the treatment of severe obesity (paper IV).

Aims of the thesis

The aim of this thesis was to go "beyond the weight reduction", by firstly describe an inpatient ILI including high volume of physical activity for the treatment of severe obesity, secondly investigate the changes in body composition and QoL components following this ILI, and thirdly explore the participants experience with physical activity. The specific aims of the separate papers were as follows:

1) To describe an inpatient intensive lifestyle modification program for the treatment of subjects with severe obesity, offered by the Norwegian Health Care system (paper I).

2) To examine the effect of the inpatient lifestyle modification program on body composition, and further observe whether changes in body composition were maintained at six and 12 months follow-up from baseline (paper II).

3) To examine the acute and 12 months effects of the inpatient lifestyle modification program on eating behavior, psychological factors and HRQL, and to study associations between changes in eating behavior, psychological factors and HRQL with weight changes after 12 months (paper III).

4) To explore the experiences of physical activity from a participant perspective prior to, during and following the inpatient lifestyle modification program (paper IV)

Methods

This thesis is based on a quantitative study conducted in 2010 to 2012 to evaluate the effects of an inpatient lifestyle modification program for the treatment of severe obesity at NIMI Ringerike, with a complementary qualitative study performed in the spring of 2013. **Paper I** describes the inpatient treatment program. The intervention period was shortened from 14 to 10 weeks during the study, and **paper II and III** evaluates the effects of the 10 and 14 weeks treatment program as a whole. **Paper IV** is based on findings from the qualitative study exploring the participant's experiences with physical activity.

Study design and participants

Prior to the overall study a descriptive paper was provided (paper I). This paper was written in collaboration with the responsible medical doctor (first author), the former leader of the treatment (third author) and a psychologist at the clinic (last author). A description of the treatment program was written, including descriptions of its components, intention and the evaluation and examination conducted for internal research. Finally some preliminary results from former patients were included, as well as description of "what was learned so far" based on the experiences of the authors and the other staff at the clinic. This corroborated the need for further research and the overall research project.

Multimethod design

This thesis is based on what can be referred to as a "sequential QUAN → qual" multimethod design [245]. First we conducted a quantitative study, followed by a qualitative study. The quantitative study was almost completed prior to initiation of the qualitative study, and each study was independent. The studies were planned and conducted by different research teams to answer particular sub-questions, and were hence complete in their selves. Data was treated and analyzed as two separate data sets, and the results were compiled to form a comprehensive whole in this thesis.

Quantitative study

The quantitative study constituted a non-randomized controlled trial and a prospective follow-up study. The study sample consisted of patients referred to NIMI Ringerike obesity clinic from secondary health care clinics in Norway. Admission criteria for treatment at the clinic are; being

defined as severely obese (i.e. BMI ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 with comorbidities) at the time of referring, age between 18 and 65 years, and being able to walk slowly for approximately 20 minutes. Patients from two treatment groups starting at the inpatient treatment program at the clinic were invited to participate (ILI group) in autumn 2010 and in spring 2011, and they were prospectively followed for one year from baseline. We continuously recruited controls from patients being referred to the clinic but still on a waiting list during autumn 2011. The control group was followed for a time period comparable to the intervention, and received no treatment from the clinic during the control period. Following the 10 –14 week control period they received the same inpatient treatment program as the ILI group.

Qualitative study

In the qualitative study some of the participants included in the quantitative study were invited to participate in in-depth interviews 2-3 years after their start of the treatment program.

Recruitment and participants

Quantitative study

The quantitative study (Paper II and III) included the two groups of participants from the clinical control trial with the one year prospective follow-up study. The flow of patients is shown in figure 1.

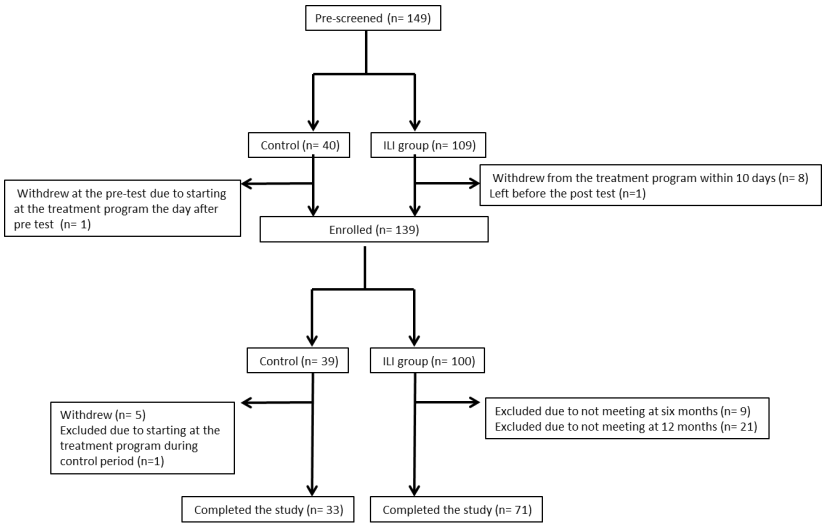


Figure 1: Flow of the quantitative part of the study (paper II and II)

The first group was pre-screened in September 2010 and the second in January 2011. Exclusion criteria for enrollment in the study were pregnancy or participation in previous treatment programs at the clinic. Moreover the participants in the ILI group had to complete the main inpatient treatment program to be enrolled. The controls were continuously recruited as they were referred to the waiting list. The completion rate at one year follow-up was 71 % in the ILI group, and 85 % in the control group after the control period. Baseline characteristics of the participants who completed the study are shown in table 2. The ILI group was older than the control group, but no other significant differences between the two study groups were seen at baseline.

Table 2: Subject characteristics at baseline (paper II-III), comparing Intensive Lifestyle Intervention (ILI) group (n=71) and control group (n=33). Data are given as mean values (standard deviation) or number of subjects and percentages.

	ILI (n=71)		Control (n=33)		
	N	%	N	%	P value
Female/Male	42/29	59.2/40.8	21/12	63.6/36.4	0.663[a]
Age (year)	45.2 (9.5)		38.5 (9.8)		0.001[b]
Height (cm)	173.2 (8.6)		172.3 (10.4)		0.626[b]
Body Mass Index (kg/m²)	42.8 (4.6)		42.8 (6.3)		0.983[b]
Body Weight (kg)	128.9 (19.4)		127.1 (21.6)		0.680[b]
Highest Education					
Primary/secondary school	8[c]	12.9	7	21.2	0.178[a]
High school	32[c]	51.6	20	60.6	
Higher education	22[c]	35.5	6	18.2	
Employment (full time job)	34[d]	52.3	16[e]	50.0	0.831[a]
Current smoker	15[f]	23.4	6	18.2	0.552[a]

[a]=Chi-Square; [b]= Independent-samples t-test; [c]n= 62, [d]n=65, [e]n=32, [f]n=64

Qualitative study

The inclusion criteria for the qualitative study were that the participants had fulfilled the treatment program as well as a "home-period" (i.e., a period with no formal follow-up) afterwards (paper IV). We used purposive sampling to obtain concrete descriptions of experiences from the participants who had experienced being severely obese and taken part in the treatment program. The study sample was selected strategically aiming to gain insight into the diverse experiences: a psychologist, the clinical leader of the treatment team at the clinic, was asked to choose eligible former participants from the quantitative study. He was asked to choose from both genders, with a range in age and degree of obesity, as well as a variation in weight loss during the inpatient stay and weight loss maintenance afterwards. The participants were first contacted by phone or email from this leader and invited to take part in an approximately one hour interview mostly related to their experiences with physical activity prior, during and

following the treatment program. All invited participants agreed to participate and were then contacted by the first author to arrange the time for the interviews. The participants included five women and three men aged 35-63 years. Three of the participants had been overweight as a child, and their BMI and body weight at the entrance of the treatment program ranged from 37 to 60 kg/m^2 and 96 to 185 kg respectively. Weight loss during the inpatient period ranged from 10 to 29 kg, whereas at one year follow-up it ranged from 11 to 46 kg. At the time of the interview body weight was not measured. However some of the participants said they had regained some or all their initial weight loss, while others had maintained (including increase and decrease several kg) or further reduced their body weight.

Lifestyle modification program

The treatment program comprised one main 10-14 weeks inpatient stay, and two follow-up weeks at approximately six and 12 months from baseline (figure 2). The participants were tested pre and post treatment, and at the two follow-up weeks. During the first home period (between discharge and the six months stay) the follow-up was based on the patients individual choice, and were the following; monthly phone calls, weekly structured e-mail or "when needed" e-mail communication. No formal follow-up between six and 12 months was provided. The ILI group and the controls were not measured at the same point in time (date), but following a similar timeline.

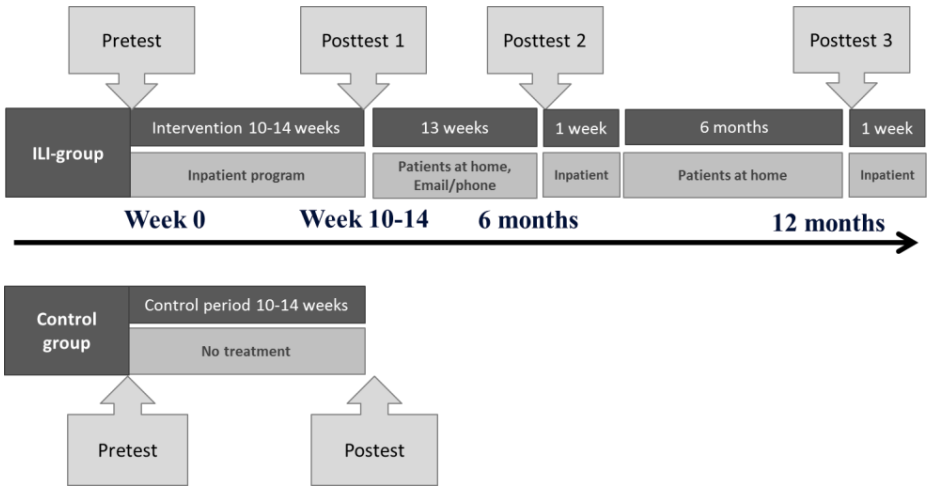


Figure 2: Structure of the stays and testing during the treatment period

The inpatient stays

A multidisciplinary team including a medical doctor, a psychologist, a clinical nutritionist, nurses, exercise scientists and physiotherapists provided the treatment program. During the main 10-14 weeks inpatient stay the patients were living at the clinic. From week 4 they were allowed to go home for the weekends. All patients received the same lifestyle modification program focusing on increasing the physical activity level, adjusting energy and nutrition intake and learning coping strategies adapted to their own challenges. Both theoretical and practical lessons were provided, and a typically week-day during the inpatient stay is shown in table 3. During the two inpatient follow-up weeks, after six and 12 months, reminders of coping techniques were given, and the subjects' motivation for exercise and healthy eating was refreshed.

Table 3: Typical day during inpatient stay

Time	Day-plan
07:00-07:30	Voluntary exercise
07:30-08:30	Breakfast
08:40-08:50	«Kick-off», with presentation of the program of the day
09:00-10:00	MANDATORY EXERCISE SESSION 1: ≥ 45 min E.g. Nordic walking, with strength training
10:00-10:30	Snack
10:30-12:00	Nutrition/Training kitchen, including lunch
12:30-13:15	Coping strategies
14:00-15:00	MANDATORY EXERCISE SESSION 2: ≥ 45 min E.g. Spinning/Bicycle
15:00-15:30	Snack
17:00-17:45	Dinner
18:00-19:00	Voluntary exercise
19:30-20:00	Snack

Physical activity component

During the inpatient period the participants typically participated in two to three exercise sessions five days per week. Two mandatory exercise sessions of minimum of 45 min were provided in the week days, eventually one long walk. For aerobic exercise indoor and outdoor bicycling and Nordic pole walking were mostly used, as well as different dance/aerobic exercises. During the first 2–3 weeks patients undertook low to moderate intensity continuous aerobic exercise. As

they progressed, interval training and higher intensity sessions were gradually introduced. Strength training was performed using machines or free weights, or circle training system. Yoga and Pilates sessions were conducted weekly to improve agility and balance. The participants were also introduced to BOSU and fitness balls, and different exercise/sport activities as ball games and walking tours. If any of the participants were injured or for some reason could not attend the mandatory exercise sessions, modification, exemption, or alternative exercise could be given by physiotherapists, psychologists or doctors depending on the type of injury/problem. In addition most participants conducted exercise sessions (e.g. brisk walking) on their own before breakfast and in the evenings. The participants were also encouraged to exercise in the weekends.

Dietary component

Regarding dietary intake breakfast and lunch were served as buffets and dinner at plates, whereas the three between-meal snacks were free options of fruit, vegetables or yoghurt. Portion sizes according to restricted energy levels (1900 kcal/d for men and 1600 kcal/d for women) where demonstrated in the eating-room by nutritionists in the start of the inpatient period. The macronutrient composition of the diet was planned to be < 30 E % from fat, ~ 20 E % from protein and 50-60 E % from carbohydrates. The participants also learned about healthy eating habits (focus on meal frequency; 3-4 hours between the meals) and how to prepare nutritionally good meals (e.g. the use of whole grains and vegetables) in theoretical and practical group sessions (7-10 x 60-90 minutes) presented by the nutritionists/registered dietitians. In addition they were offered a minimum of 2 x 30 min individual dietary nutritional consultations.

Coping strategies

The treatment also included a part with coping strategy. All participants attended a structure-course with four hours of theoretical lessons and seven hours of group sessions. The course included instructions and practice in methods for behavior modification and coping strategies, with the purpose to help the participants change and withstand their altered/modified lifestyle post hospitalization. The two key methodological elements were short-term goal setting with specific tasks (mainly in physical activity and nutrition) which had to be completed daily/weekly to reach the goal, and a weekly routine of evaluating the past week's performance and results, as well as planning the upcoming week. The participants were also offered individual consultations with a psychologist when needed. Between week 10-14 and six months follow-up the plan was monitored by email, or by individual calls when needed.

Data collection and analysis quantitative study

Data were collected at the NIMI Ringerike clinic and at the Norwegian School of Sport Sciences (NIH), at the start (week 0), the end (week 10-14) of the main inpatient treatment program and at the two follow-up weeks (six and 12 months) (figure 2). The test-battery included measurement of body composition, eating behavior, psychological factors and HRQL. The participants also filled out a questionnaire regarding demographic data, socioeconomic and medical history. In addition the participants in the ILI group underwent a medical examination by a physician at the beginning and end of the main inpatient stay, as well as at the two follow-up weeks.

Outcomes and instruments

Body composition and physical health

The primary outcome variables in **paper II** were body weight, BMI, FM, FFM and VFA. All anthropometric measures were assessed with subjects wearing light clothing without shoes. Body composition estimates were obtained using InBody 720 (Body Composition Analyzer, Biospace Co. Ltd), a direct Segmental Multifrequency (SMF) bioelectrical impedance analysis (BIA), following the manufacturer's recommended protocol including a minimum of two hours fasting, no drinking or hard training prior to the test [246], and at approximately the same time of the day for each subject at each test-period. Height was measured twice to the nearest 0.5 cm in a standing position using a wall-mounted stadiometer. This measure was used to calculate BMI as weight in kilograms divided by the square of the height in meters (kg/m^2). The participants were also encouraged to measure their body weight on a stationary scale at the clinic, in order to monitor weekly changes in body weight.

Secondary outcomes within the ILI group in **paper II** were CVD Risk Factors, WC, metabolic syndrome and exercise capacity. Blood samples were collected between 7 and 8 am after an overnight fast, and analyzed for serum glucose and lipids including cholesterol and triglycerides (mmol/L) using standard laboratory techniques at Ringerike hospital; Vestre Viken Hospital Trust, 3004 Drammen, Norway. Blood pressure (mmHg) was measured ones in sitting position after 5-10 minutes rest, using the Reister, big ben round apparatus, cuff size large (arm size 33-41). A medical doctor registered the use of blood pressure-, lipid-, or glucose-lowering medication at baseline. We measured WC at the level of the narrowest point between the lower costal (10th rib) border and the iliac crest [247] using a non-stretchable tape specially designed for

obese individuals. The modified ATP III criteria [248] was used to define the metabolic syndrome. Only participants with measurement of all the five diagnosis criteria at all four measurement times were included in the analyses (n = 52). Use of medication was only recorded at baseline, and hence subjects taking antihypertensive or blood glucose reducing pharmacotherapy at baseline were defined with elevated blood pressure and fasting glucose, respectively at all four measurement times. We monitored exercise capacity using the 10-metre Shuttle Run Test [249,250] and time spent on a 750-metre walk/run test. Exercise time (min and sec) was used as outcome measure.

Eating behavior, psychological factors and HRQL

To assess eating behavior, psychological factors and HRQL the participants independently (by themselves and without the influence of research or treatment team) completed a set of standard questionnaires (Appendix II).

In paper II we also wanted to study the possible influence of the ILI on eating behavior. We used the Norwegian version of the 21-item Three-Factor Eating Questionnaire (TFEQ-R21), a recognized instrument to measure eating behavior in subjects with obesity [251,252]. The TFEQ-21 comprises 21 items and covers three eating behavior subscales; cognitive restraint (CR; 6 items: the tendency to control food intake in order to influence body weight and body shape), uncontrolled eating (UE; 9 items: the tendency to lose control over eating when feeling hungry or when exposed to external stimuli) and emotional eating (EE; 6 items: the propensity to overeat in relation to negative mood states, e.g., when feeling lonely, anxious, or depressed). Each subscale ranges from 0 to 100, and a higher scores indicates a greater tendency to exhibit the particular eating behavior characteristics, i.e. more restraint, uncontrolled, and emotional eating. Unanswered questions were scored as zero, and an individual's scale score was calculated only if the person had answered at least one-half of that subscale's item (the half-scale method) [251-254]. As guidelines in relation to multiple crosses is lacking, we scored it as missing value.

The primary outcome variables in **paper III** were symptoms of binge eating, anxiety and depression, and HRQL. We assessed symptoms of binge eating by using the Norwegian version of Binge Eating scale (BES), a questionnaire designed to assess the severity of binge eating in obese subjects, considering both the behavioral manifestations of a binge and the feelings that follow a binge [255]. The BES consists of 16 sets of 3 – 4 statements that reflect a range of

severity for each characteristic, and the subject is asked to endorse the one item from each set which best describes his or her eating behavior. The statements are independently assigned scores from zero (0) to three (3), and a total score was calculated by summing the scores for the 16 individual statements. The total BES score ranged from zero to 46, with high scores reflecting more severe binge eating problems [255]. We used a score of 18 or more as suggestive of BED (i.e. suggestive binge eaters), and scores of 17 or less are suggestive of the absence of BED (i.e. non-binge eaters) [256,257]. In the BES scoring manual there is no guidelines for how to handle missing or multiple values [255], hence we applied the half-scale method and both was treated as missing values and scored by implementing the mean value of the remaining answers/cross. The BES is a recognized and frequently used instrument in the evaluation of obesity treatment [255-258].

Symptoms of anxiety and depression were measures by the Hospital Anxiety and Depression Scale (HADS), a questionnaire shown to be well suited for assessing the symptom severity and caseness of anxiety and depression in the general population and in somatic, psychiatric, and primary care patients [259-261], and to have good responsiveness to change in subjects with severe obesity undergoing bariatric surgery [140]. The HADS consists of 14 items, of which seven items assess symptoms of depression (HADS-D) and seven items measure symptoms of anxiety (HADS-A). The questions are scored on a four-point scale from zero (not present) to three (considerable), and added into a total HADS score. In accordance with the scoring manual a total score on the HADS was estimated if maximum of two questions were unanswered [259]. The sum score was then divided by the number of answered questions and multiplied by 14, providing the estimated total score. As no instruction is provided in the manual, we treated multiple cross as missing values. The total score was divided into subscale scores on the HADS-D and HADS-A, and a lower scores represent better psychological health with regard to anxiety and depression [259]. A score of eight or more on the sub-scales was used to indicate "possible cases" of anxiety disorders and/or depression [259,261,262].

For measuring HRQL we used a modified Norwegian version of The Medical Outcome Study 36-Item Short Form Health Survey version 2.0 (SF-36v2), a well-established self-administered generic measure of the health burden of chronic diseases [263-266]. The SF-36 consists of 36 items, with eight sub-scales of which four reflect components of physical health (Physical Functioning, Physical Role Limitation, Bodily Pain, General Health) and four reflect components

of mental health (Vitality, Social Functioning, Emotional Role Limitation, and Mental Health). The two summary scores, the Physical Components Summaries (PCS) and the Mental Component Summaries (MCS), were used as the outcome variables. The validity of the two summary scores from SF-36 version 1 has been verified in subjects with severe obesity [267]. The SF-36 was scored according to published scoring procedures, and using the Quality Metric Scoring Software™ [264]. Missing values were treated in accordance with the guidelines, and due to lack of guidelines multiple answers were treated as missing values. Each summary scale ranges from zero (poorest, worst possible HRQL) to 100 (optimal, best possible HRQL), and a higher score represents better HRQL [265].

Statistics

Power analysis

Based on the results from the treatment group a priori power analysis was performed to determine the sample size of the control group to detect differences between the groups. The acute weight loss for the treatment group was approximately 17 kg (13.5 %), and with α fixed level at 0.05 and a power set at 0.80 a minimum of 40 participants in the control group would be required to investigate both 5 % and 10 % weight reduction in the ILI group compared to the control group, allowing for a 3.5 kg weight loss in the control group due to the placebo effect/changing in lifestyle on their own.

Statistical methods

Data were analyzed using SPSS software version 18 (SPSS Inc, Chicago, IL, USA). **In paper II and III** data were included for subjects in the ILI group who were measured at all four measurement times (n=70), and at both pre and post-test in the control group (n=33). Subject characteristics are reported as mean (standard deviation), or (95% CI), or number (%). Independent samples t-tests, Mann-Whitney U test, and Chi-square were used as appropriate to compare groups in relation to body composition, eating behavior, psychological factors and HRQL. Likewise, changes within the ILI group were assessed using paired samples t-tests and Wilcoxon rank tests. All tests were two sided, and statistical significance was accepted when $P < 0.05$. There was marginal change in the P-values, and hence no change in the conclusion, using nonparametric tests. Thus, data were reported as mean with P-values from parametric tests unless stated otherwise.

In paper II repeated measurement general linear model (GLM) was used to assess changes within the ILI group in CVD risk factors, with adjustment for gender, age, and use of relevant medicine (i.e., blood pressure-, lipid-, or glucose-lowering medication) at baseline. As data for changes in use of medicine during the treatment period were lacking, we also conducted sub-group analyzes of participants not using medication at baseline. Cochran's Q test was used to assess change in the proportion of participants diagnosed with metabolic syndrome across the four measurement time points: week 0, weeks 10–14, six, and 12 months. Only subjects with measurement at all four measurement times were included in the analysis for each variable.

The association between change in UE, EE and CR (independent variables) and change in body weight (dependent variable) were analyzed using change scores between the four time points (change week 0 to 12 months, week 0 to 10–14, weeks 10–14 to six months and six months to 12 months) in a Univariate GLM. Subjects with measurement at the two measurement times were included in the analysis for each change period.

In paper III only subjects with satisfactory completion of each questionnaire (i.e. in accordance with the scoring manuals for the BES, HADS and SF-36) were included in the analysis for each variable, and hence the subjects included (n) vary from variable to variable. Cochran's Q test was used to assess change in the proportion of participants characterized as suggestive binge eaters, and in possible cases of anxiety and depression across the four measurement time points: week 0, week 10-14, and six and 12 months. To explore the possible associations between changes in symptoms of binge eating, anxiety and depression, as well HRQL (independent variables), with changes in body weight (dependent variable) between baseline and week 10-14 or 12 months we used univariate GLM. The analyses were also performed controlling for age, gender, and education. This did not change the results and are therefore not reported in the paper or in the thesis.

Drop-out analysis

Drop-out analysis within the ILI group showed no significant differences in any of the baseline characteristics between the completers and non-completers, or in weight reduction from week 0 to week 10–14 (data not reported in the paper or in the thesis). However, subjects who dropped out during follow-up had a smaller reduction in body weight between weeks 10–14 and six months (−3.8 (95% CI: −6.2 to −1.3) kg, P = 0.003) as compared to the completers.

Additional analysis

In the papers per-protocol analysis are reported. However, for the purpose of this thesis additional analysis, including all the 109 participants referred to treatment and pre-screened for the ILI group, were conducted. This was done to provide the intention to treat (ITT) effectiveness. After applying Missing Value Analysis and Analyze Patterns for missing data, missing values for body weight at follow-ups were imputed using multiple imputations. The imputation model consisted of the following predictor and imputation variables: body weight at 10-14 week, six and 12 months. Gender, age, marital status, education level, baseline weight, baseline BMI, and change in body weight (kg) during the 12 months (i.e. change from baseline to 10-14 weeks, from 10-14 weeks to six months, from six to 12 months) included as predictor variables only. Linear regression was applied as the prediction method, and 20 complete datasets for each of the variables were generated with 10 iterations per dataset. Statistical analysis (paired samples t-test and descriptive statistics) were then performed within each dataset and pooled estimates (data not shown). Pooled estimates revealed: mean weight loss of 18.5 (95 % CI: -15.5 to -21.5) kg ($P<0.0001$) and 13.7 % at 12 months, and 63.3 % achieved ≥ 10 % weight loss. ITT analysis where baseline values were carried forward for the drop-outs (data not shown), showed a 13.5 kg (10.6 %) weight loss at 12 months follow-up within the ILI group ($P<0.0001$).

To investigate whether reduced duration of the inpatient stay impacted on the outcome analyses we compared the weight loss in relation to duration of the inpatient stay (data not shown). There were no differences in the average rate of weight loss (defined as kg change in body weight/weeks of inpatient stay). A greater mean weight loss (-20.5 kg) was observed among the participants in the ILI group staying at the clinic 14 weeks (n=31), as compared to the mean weight loss (-15.2 kg) observed in the participants staying for 10 weeks (n=40) ($P<0.0001$). However there were no significant differences between the two groups at one year.

One of the main goals in the treatment of severe obesity is to improve QoL. Even if HRQL changes are statistically significant, they may not be clinically meaningful [268]. Thus to evaluate the clinical relevance of changes in HRQL additional analysis were conducted for the purpose of this thesis. Regarding the summary scales of SF-36v2, a ≥ 3.8 points change in PCS and ≥ 4.6 points change in MCS can be interpreted as the minimally important difference (MID) [269]. At 12 months follow-up a total of 68 % and 42 % of the participants achieved MID in PCS and MCS score respectively (data not shown).

Data collection and analysis qualitative study

Methodological approach and theoretical perspectives

To illuminate the participant's experiences with physical activity during the treatment program and in their daily life (paper IV) an exploratory qualitative study was performed based on semi-structured interviews [270]. We aimed to present the experiences of physical activity as expressed by the participants themselves, rather than exploring possible underlying meaning of what was said. To analyze the empirical data the principles of systematic text condensation (STC) as described by Kirsti Malterud [271,272], and inspired by Amadeo Giorgi's descriptive phenomenological method [273], were chosen.

Physical activity in obesity treatment

As elaborated in the general introduction to this thesis considerable research has shown that increased physical activity is associated with increased physical fitness and reduced comorbidity, as well as increased well-being and improvements in psychological factors [184,219,226-229,274]. Physical activity is also the main means to increase energy expenditure during weight loss and is shown to be important for weight loss maintenance [175-177,184,203,204]. Thus increased physical activity is considered a crucial part of lifestyle interventions in the treatment of obesity. Subjects with severe obesity may have difficulties with physical activity, and adapted exercise with others in the same condition has therefore been considered important for this population to increase compliance in physical activity programs [188,189,243]. The aim of the physical activity component in the present treatment program is for the participants to increase their physical fitness and master technical aspects of different activities during the treatment in order to continue a physically active lifestyle at home. Our findings are assessed and discussed in relation to this. Moreover, drop-out in obesity treatment is relatively high, and research shows that increased physical activity level and weight loss in subjects with severe obesity is poorly maintained [102,171,185,275-277]. These findings became important in the process of interpreting the data.

Lifeworld and lived experiences

STC is inspired by phenomenology, and during the research process we have also been inspired by the phenomenological lifeworld perspective and the descriptive phenomenological method as described by Giorgi [273]. The focus is then on how the participant experience physical activity rather than the biomedical and physiological perspective of physical activity, obesity and health.

Phenomenology is the study of the phenomena as it presents itself to us. In this study "being physically active" is the phenomenon being studied, and physical activity also includes exercise. Within phenomenology, the common, everyday world into which each of us are born and live, i.e. *lifeworld* and *everyday experiences*, is highlighted as an important source of knowledge and available for research [273,278]. Lifeworld belongs to the phenomenological tradition of Edmund Husserl (1859 – 1938), and can be seen as the "ground world" or basic for all experience. Referring to Giorgi it includes everything a person engages in, i.e. "getting up, wash, have breakfast, go to work, come home, meet with friends and family, have dinner, relax and go to bed" (Giorgi, 2009, p 10-11)[273]. Lifeworld describes the subjective perception of these conditions, and it is based on the lifeworld we live that something appears as meaningful to us. STC also share this foundation of lifeworld experiences as valid knowledge [271]. Furthermore phenomenology investigates the first-person perspective, i.e. the *lived experience*, and looks at the phenomena from the perspective of how they are experienced by the subject [273]. The participants in this study have experienced being physically active through different kinds of exercises and sports activities at the clinic and at home, as well as activities of daily living. How these experiences manifest themselves will however be influenced by the subject in the situation, and depend on the subject's experience, background and values. The experience of a participant is also different from the experience of a clinician or a researcher [278,279]. Although the physical activity component included in this treatment program is considered to be adapted to the participants regarding type of exercise, progression and equipment, and hence seems justifiable, the participants' experiences might be entirely different.

The implications of the lifeworld have further been developed by Merleau-Ponty (1908 – 1961) to be understood as the world we have access to through our bodies, i.e. the body as linking self and world in an ongoing dynamic inter-relationship, referred to as *the lived body* [278,280]. We constantly perceive and move around in the world through our bodies. Related to the theme in this study, there is no such thing as obesity "in itself". Living a heavy body is always both an individual bodily experience, and at the same time it is lived in relation to the surroundings and socio-cultural meaning of obesity. In this perspective obesity is far more than BMI and comorbidities. Obesity is always lived and experienced by a subject, and understood from a subjective, unique perspective. This also means that if the participants' body weight and physical fitness change they will perceive themselves, and the world, from a changed perspective [278]. In this regard, the experienced meaning of physical activity for the participants in this study may

change due to contextual experiences of the treatment program, as well as because of changes in body composition, physical fitness, self-confidence and physical and psychosocial health. Their dealings with the world and the present relationship with physical activity, how it is perceived and experienced, will however always be affected by past experiences, as well the open future of expectations [278]. Phenomenology thereby builds on the experiencing subject and the interaction between a person (the body) and the world, and this interaction creates meaning and understanding [273,279].

Inspired by Giorgi we aimed to obtain concrete and detailed descriptions of experiences from the participants who "had lived through the experience" of which we were interested (Giorgi 2009, p 96) [273], thus qualitative in depth interview was found to be relevant collecting the empirical material [270,273,279]. In according to Giorgi one should not "go beyond what is given" in the empiric during the process of analyzing the empirical data, and interpretation based upon any "'non-given factors', such as assumption, hypothesis or theory, should be avoided" (Giorgi 2009, p 89, 127) [273]. Furthermore, in the descriptions one should avoid the use of theoretical terms and expressions, and use the language given by the participants within their natural attitude and reproduce the details of lived situations. Finally, the findings should be interpreted in relation to implications of the findings within the discussion.

Interviews

The empirical material in this qualitative study was collected through eight in depth interviews [270,279], carried out in private rooms at NIH during the spring of 2013. The last co-author conducted two, and I six, of the interviews. Prior to the interviews we developed an interview guide (appendix III) that circled on specific themes focused on the research topic, i.e. physical activity [270,279]. Before the interviews the participants were informed about the interview and the aim of the study, as well as being asked for permission to audiotape. The interview guide included questions regarding their experiences with physical activity. However, the opening statement: "I would now like to hear about your experiences with physical activity before, during and after treatment", was designed to encourage participants to express their own views and experiences.

A semi-structured interview was utilized, including three open-ended questions formulated to act as a trigger or stimulus for further conversation, and to encourage the participants to speak freely

about experiences of physical activity prior to, during and following their inpatient stay [270]. We tried to be active listeners, and helping questions were used to make the participants reflect upon, exemplify or add further depth in response to questions or statements, and to elaborate on different themes [270,279]. The interviews were exploratory within the participants' experiences with physical activity, and one of the main questions was: "Can you describe your experience with physical activity during the inpatient period?" Furthermore, we aimed to create openness to new and unexpected themes during the interviews through being curious and sensitive to what was actually said, and we were not "tied" to the interview guide [270]. This means that if the participants started to talk about other aspects or parts of the treatment than the physical activity component they were allowed and not interrupted. E.g. the "Bubble" was a theme that emerged during the interviews. Notably, the interview format was tested in one pilot interview, and the interview format was retained over the course of the research process. In addition the pilot-participant was included in the analysis. Nevertheless, even though we had an interview guide, each interview was different depending on the experiences that emerged. A learning process occurred during the interviews, and there were openness to changes and reflection processes. All of the interviews were digitally recorded (with a back-up) and lasted about 60 minutes. Afterwards a debriefing was provided to give the participants the opportunity to ask questions, clarify misunderstandings or take back things they regret they had said.

The interviews were transcribed and checked by me and/or a secretary. The transcriptions included different "codes" used to signal words that were emphasized by the participants and brakes, as well as writing down if participants were laughing or crying. The final material consisted of 107 written pages (times new roman, font size 12, single line spacing). The two interviewers read all the transcribed interviews, whereas the second co-author read quotes that were highlighted during the process of analyzing the data and the final analysis.

The process of analysis

The focus of the analysis was to explore the participants' experiences with physical activity. To create a wider analytic space the analytical work was conducted as collaborative discussion between me and the last co-authors. In the course of our discussions, themes and subthemes were gradually developed. The analysis was exploratory, descriptive and based on the empirical data, and we aimed to display descriptions related to the participants' experiences with physical activity. A step-wise approach as described by Malterud was used [271,272]; however the analytic

process was characterized as an ongoing and dynamic process. We had an attitude and approach to do justice to the increasing knowledge provided from the empirical data [272]. Thus, as devised by Malterud, themes and codes were treated as flexible entities and were reconsidered and reorganized several times as new patterns appeared. Furthermore, we integrated writing during the process, and some modifications to the method were made. Collaboration and discussion with the co-author was especially fruitful, as she revealed "analytical points" for further reflection and discussions. The four steps in STC, and a condensed description of the followed procedure, are described below.

Step 1: Total impression – from chaos to themes: We both read the transcribed interviews separately to obtain an overall impression. Preliminary themes associated with the participants' experiences of physical activity prior to, during and after the treatment program were identified and discussed. Early in the process we found that the themes that emerged prior to the treatment rather constituted reasons for *not* being physically active. Thus during the analytical process we categorized these experiences into what we considered as "corporal and contextual experiences" (although being aware that there is no either or). Already at this stage the themes identified during and following the treatment constituted different opposites, i.e. "pain and pleasure", "hated and hilarious", "addicted and aversion". In addition the previously mentioned theme "bubble" was highlighted, and "the battle" emerged as an opposite.

Step 2: Identifying and sorting meaning units – from themes to codes: At this stage each transcript was reviewed systematically line by line to identify meaning units in the texts. The meaning units were coded and marked with different colours with the themes found in step 1 as road signs. The interviews were then reread, and meaning units containing relevant information were decontextualized and inserted into detailed tables of each interview. In these tables the meaning units were coded thematically. The meaning units were also coded in s in order to describe different aspects, nuances and key terms of the themes (i.e. sub-themes). For example the theme "pleasure" had code names like "enjoy" and "tired, sweat and good feeling". The coding system was flexible, and rather included too much text as meaning units. Some meaning units were also coded within several themes. Examples of meaning units coded under the sub-theme "tired, sweat and good feeling" were: "...but after a while I stepped off my bike and was happy; there was a pond of sweat on the floor, I had trained hard and was really exhausted", and "...once I get started and really feel I do something, that I work hard....it's indescribable. It's really good. It's

really great". The first meaning unit was also coded as "gradual development". During this stage we also visualized themes and codes in provisional figures to get a view of the interrelations between the themes and sub-themes, as well as how the experiences with physical activity changed during the treatment program and from before and after. During this process themes were discussed several times and consequently renamed and merged due to overlap, as well as new themes emerging. Accordingly codes were re-defined. E.g. the themes "hated and hilarious" and "pain and pleasure" were merged. The sub-groups were also removed across themes several times.

Step 3: Condensation – from code to meaning: In this stage the meaning units were sorted thematically across individual participants, with the code groups as starting points. Each code group (theme) included several different nuances and ambiguity, thus the meaning units of each code group (theme) were sorted into a few s (with the sub-themes found in step 2 as road signs). The content of each was reduced and re-formulated to general descriptions (condensates) based on the participants' experiences, comprising the content of every meaning unit. Notably, each sub-group consisted of large amounts of material, making it difficult and un-natural to create artificial quotes. Thus we rather developed a condensed text summarizing the main content in each (a deviation from Malterud). At the same time we maintained, as far as possible, the original terminology applied by the participants. Finally "golden quotes" that in the best possible manner illustrated what was abstracted in the text were chosen.

Step 4: Synthesizing – from condensation to descriptions and concepts: At this stage the contents of the "condensates" were synthesized to develop re-descriptions of the participants' experiences with physical activity grounded in the empirical data. We also started the writing process of the findings for paper IV, involving collaborative discussion with the co-authors. The content in quotes was also "extracted and abstracted" "piece by piece" written in third form. During this stage we had several rounds of discussion and re-writings, in relation to which sub-groups that were most relevant to the further work with the text in terms of illustrating the research questions. Importantly the two of us noticed different nuances of the themes. Thus the themes and sub themes were re-considered, and e.g. "desire and duty" were identified as new themes, whereas the theme "addiction and aversion" were removed due overlap with the new themes. These themes had also contained few meaning units during the process of condensation. In a way the analysis and writing took new directions, however always through cross-checking by re-

readings of and verifying in the empirical data. Indeed we took one step back, and reorganize the meaning units and re-formulated the condensates. This means that during this stage the analytical process was characterized as moving across the steps and driven by the empiric.

Furthermore, as the experiences constituted a shift in how the participants feel about physical activity during the intervention period and as an ongoing, dynamic and constantly shifting experience during such activity, systemising and writing the analytical text was challenging. After several discussions and re-writings of the findings, we developed a descriptive text organized in different sections the participants' experiences with physical activity prior to, during and after the treatment. Within each section the experiences with physical activity were categorized thematically, while at the same time aiming to show the changes in the experiences and different nuances of the themes. Category headings for each theme were developed and formulated from the participants own words, describing similarities, variations and contrasts in the experiences. To be true to the richness and variation in the participants' descriptions, the findings (in paper IV) were presented as condensed and detailed descriptions of the experiences. Shorter quotations were chosen to illustrate each theme. The validity of the descriptions (and category headings) was cross-checked by verifying against the tables from step 2 to and/or the transcribed text.

Finally we assessed and reviewed our findings according to existing research. Accordingly the themes were re-considered again. We considered the themes which had emerged related to experiences prior to the treatment as reasons for not being physically active and mostly described in previous research. Thus, we emphasized on six recurrent main themes related to the participant's experiences *with* physical activity as exercise, representing three pairs of opposites: "pain and pleasure", "desire and duty," and "bubble and battle". In addition, during the analytical process we were constantly dwelling and discussing upon the opposite, ambivalence and ambiguity in the participants' experiences of attending such physical activity. Consequently we summarized our findings into one overall theme; "the ambivalence of attending physical activity".

Ethical issues

The Regional Committee for medical and health research ethics in Norway approved both the quantitative and qualitative study (appendix IV), and written informed consent was obtained from each participant (appendix V). They were informed about the aim of the study, that participation was voluntary, and assured that anonymity would be preserved when the results were published. The study meets the standards of the Declaration of Helsinki, and is registered in the ClinicalTrials.gov-registry under the unique trial number NCT01675713.

The interviews were tape-recorded with the participants' permission. They were informed that the data presented in the study would mainly be used in the thesis and included publications, but will also be presented at national and international conferences and seminars, hospital/treatment clinics and lectures at colleges and universities. Notably, participants had finished all follow-ups at the clinic before invited to participate in the qualitative study, indicating that the experience of a pressure to participate in fear of not receiving treatment could be ruled out. In the beginning of the interviews the participants were told that the interview could be terminated if they wished, and that they had the right to withdraw or not answer questions, at any time, without explanation.

Ethical research practice is however not just following guidelines and procedures. The meeting with participants both for the objective measurements in the quantitative study and interview setting in the qualitative study involved several challenging experiences. As examples during the data collection in the quantitative study I found it difficult to only meet the participants for a few minutes for the measurements, as I really wanted to listen to their experiences, thoughts and opinions. Whilst the face-to –face interviews in the qualitative study included a fine ethical balance between exploring rich and interesting data and at the same time maintaining sufficient distance out of respect for the participant. Being aware of sensitive issues in the conversations, and cautioned that to be obese is commonly associated with shame, feelings of inadequacy and not being good enough, I made efforts to establish an atmosphere of trust so that the participants would feel comfortable sharing their personal thoughts and feelings. One risk was that informants who had not maintained the increased activity level and weight loss post treatment would experience this as a defeat. I tried to prepare for this, and responded to statements of shame by assuring the participants that this was not my way of understanding it and that knowledge about such experiences was part of the reason we wanted to talk with them. At the same time I aimed to respect their dignity so that they would not feel obliged to reveal

experiences and thoughts that they would regret afterwards. The participants were also asked if they needed a break or wanted to stop if they looked uncomfortable during the interview. One participant admitted feeling uncomfortable with the tape-recording and another participant started crying during the interview, but none of the participants wanted to stop the interview. The experience was that the participants appreciated the opportunity to talk about their experiences of the treatment and physical activity, and that they really wanted to talk about their challenges. I was also aware that as researcher being lean, fit and "a fan of" physical activity could inhibit their willingness to share troublesome experiences with me, and that the participants might think that it was impossible for me to understand their experiences with physical activity. It was also a risk they just told me what they believed I "wanted" them to say. Furthermore, the fact that they all had met with me during the physical testing in the clinical trial, and that I had participated in a few of their lessons at the clinic, could reinforce a sense of obligation and guilt for poor results. This was however not my impression, on the contrary the participants seemed to appreciate the opportunity to talk about their experiences. This was also confirmed by the fact that they told us stories about the treatment and the clinical staff that the staff did not know. Furthermore, the participants might also have felt the situation comfortable because they actually had met me.

Summary of the paper results

The findings in this thesis are presented in paper I-IV. The papers are interrelated in the way that they all deal with subjects with severe obesity and inpatient treatment with high volume of physical activity, and in this section the main findings of each paper are briefly summarizes.

Paper I

In this paper we described the inpatient treatment program at NIMI Ringerike obesity clinic which this study was initiated to evaluate. The patients spend a total of 16 (14+1+1) weeks at the clinic (paper I). The treatment program is focused on three main areas: 1) Physical activity, 2) Nutrition and 3) Coping strategies. NIMI has long and broad experience in sports medicine, and the present treatment program involves participation in high volumes of physical activity, i.e. a minimum of 90 minutes of adapted physical activity 5 days/week. Exercise takes place in groups of participants who are in reasonably similar physical fitness. The participants are introduced to a variety of exercise/sport activities, e.g. spinning, outdoor bicycling and Nordic pole walking, as well as different dance/aerobic exercises. A nutritional, energy restricted diet according to the National Standards in Norway is provided. In addition the participants learn coping techniques to help maintain their change of lifestyle.

Paper II

In this paper we examined the effects of the inpatient ILI program on body composition, CVD risk factors, and eating behavior (CR, UE, EE). The results are based on the 104 participants completing the prospective clinical controlled trial. Compared to controls, body weight (-17.0 kg), FM (-15.2 kg), FFM (-1.2 kg) and VFA (-86.6 cm^2) were reduced in the ILI group during the 10-14 weeks inpatient period. Within the ILI group this corresponded to a mean 13 % weight loss after 10–14 weeks. Furthermore systolic blood pressure, glucose, triglycerides, and LDL-C were reduced, and HDL-C was increased, after 10–14 weeks within the ILI group. At six and 12 months mean weight loss within the ILI group was 18 % and 16 % respectively, as compared to baseline. The reduction in glucose and increase in HDL-C were sustained at 12 months, and a total of 68 % of the participants achieved ≥ 10 % weight loss. We also found that weight loss was related to increased CR and decreased UE at 12 months.

Paper III

In this paper we investigated the effects of the inpatient ILI program with regard to changes in eating behavior, psychological factors and HRQL, and the associations with weight loss in subjects with severe obesity. Compared to controls, self-reported binge eating (-6.4), anxiety (-1.7), and depression (-3.0) were reduced, and physical (8.0) and mental (7.6) HRQL increased, in the ILI group during the inpatient period. After 12 months, reduction in self-reported binge eating (-7.2) and depression (-3.4), and increase in physical (8.9) and mental (3.6) HRQL, were maintained within the ILI group. Furthermore reductions in symptoms of binge eating and increased physical HRQL were associated with weight reduction after 12 months.

Paper IV

In this paper we explored the participant's experiences with physical activity prior, during and after the 10-14 weeks inpatient treatment. The empirical material is drawn on individual interviews with five women and three men conducted 2-3 years after they started at the treatment program. The participants' experiences with physical activity as exercise during and following the treatment program represented different opposites: "pain and pleasure", "desire and duty" and "bubble and battle". Their experiences with physical activity were highly ambivalent, characterized by doubt, fear and resistance as well as comfort, joy and pleasure, and the findings were summarized into one overall theme; "the ambivalence of attending physical activity". The ambivalence is experienced as a shift in how participants feel about physical activity during the intervention period and as an ongoing, dynamic and constantly shifting experience during such activity.

Discussion

In this section methodological considerations and main findings will be discussed, ending with perspectives and clinical implications.

Methodological consideration

Multimethod approach

The multimethod approach represents a major strength of the overall research project. By conducting a quantitative study followed by a qualitative study, we obtained different levels of data [245]. Furthermore, even if these studies were conducted sequently and independently (not mixed methods), together they provide a more comprehensive picture of inpatient ILI and its physical activity component for the treatment of severe obesity, than either would alone. We believe our qualitative study adds meaning and insight to the numbers in the quantitative study.

Nevertheless, although the two studies complement each other, they also "pull in opposite directions", as there is a scientific dichotomy between quantitative and qualitative research approaches [272,281-284]. They are based on different paradigms, ontology and epistemology, and the difference is apparent in relation to objective, methodological procedures and criteria in evaluation of quality [272,281,281-287]. Historically there has also been a tension between followers of the two approaches, or paradigms. Thus, working within two research approaches, trying to combine the studies also implied challenges. Several concepts and principles which were highly relevant in the quantitative study were rather unrecognizable in the qualitative, and vice versa. For example the term "effect" which was essential within the quantitative study, did not exist in the qualitative research process where the objective was understanding rather than generalization from cause to effect. Furthermore, as data consisted of numbers versus text, different procedures related to collecting and dealing with data were needed, and importantly our roles as researchers were quite different [272,278]. In contrast to the objectively quantitative methodology, the researcher in qualitative research is involved in the research process on a different level, as "the instrument" and a "co-producer" of meaning together with the participants [272,284].

Due to differences in relation to aims, methodology and the role of the researcher, structuring this thesis also emerged challenging. It appeared difficult to combine and describe the two studies

in a "reasonable" manner, and at the same time maintain respect for and comply with each methodology. The aim was not to merge the results of the two studies, and as different approaches are appropriate to answer different research questions [282] the methodological considerations are discussed separately in the following sections. It is however important to have in mind, that regardless of research approach, the underlying principles and goals of reflexivity, internal and external validity are much the same [272,282,284,285].

Study samples

As shown in figure 2 the treatment program evaluated in this project is rather advanced. Hence the participants included in this study are probably a selected group of the total population of individuals with severe obesity; being highly motivated, having the ability to take time off from work, as well as a possibility to be away from family. Notably, as in most similar Norwegian studies, the patients only paid a small deductible of the cost for treatment. Furthermore at the onset of the treatment the participants had to be able to walk 20 minutes and not have any particular physical limitations that precluded them from initiating the demanding physical activity component. Similarly programs are however provided in most Norwegian health regions today, so even if knowledge is sparse regarding the population of individuals with severe obesity in general, we know more about the sub-population of Norwegian patients who have applied and been referred to these treatments. The generalizability to other sub-groups of severe obesity, e.g. surgery patients or not treatment seeking subjects, is therefore questionable as they may differ in relation to motivation, physical and mental health as well as preference of treatment options [14]. It is also important to be aware that even within the sub-group of patients with severe obesity seeking lifestyle treatment, what the participants have in common is their "outside" body weight, whereas "inside" there is a great diversity related to causes and complications which may affect the outcome and experience of the treatment.

Study sample quantitative study (paper II and III)

The quantitative study is limited by a relatively small sample size, and furthermore mostly comprised of women. It was however enough power to detect changes in the main outcomes, but power to determine gender differences was limited. The distribution of gender is typical within the population of subjects with severe obesity included in lifestyle intervention, and mean age is similar to what is reported in comparable studies [70,239,288-290]. Notably a relatively high proportion of the participants had finished high school or higher education. This is however

quite comparable to the few studies of ILI in subjects with severe obesity reporting education [290,291]. Most subjects were Norwegians of origin, the results can however probably be generalized to other Nordic populations as well, whereas the generalizability to populations with great cultural inequalities is questionable. The control group is most likely representative for the ILI group as they were recruited from the same sub-groups, and similar at baseline. However, the difference in age may reflect features that we have not measured, i.e. that the population being referred has changed. Nevertheless, given the results present this seems to be of minor importance.

Subjects with severe obesity are heterogeneous with respect to psychological characteristics and HRQL [1,2]. Prevalence of binge eating varies widely according to population, definition and measurement used. However mean baseline score on BES is comparable to the 157 women and 152 men included in the Scandinavian Multicenter study of Obese subjects with the Metabolic Syndrome [292]. Even though the mean BMI was lower compared to our study population, subjects with severe obesity was included. In this regard, it seems that our prevalence data are in agreement with a Scandinavian obese treatment seeking population. Our subjects reported fewer symptoms of anxiety and depression and better HRQL at baseline as compared to what has been reported in Norwegian studies of subjects undergoing bariatric surgery [90,290]. However, compared to a general Norwegian population [293] our subjects seems to have slightly more of these symptoms. Few studies have measured psychological factors and dysfunctional eating in subjects with severe obesity participating in ILI, and different methods of measurements have been used. Nevertheless, HRQL at baseline was almost in accordance with other obese subjects participating in ILI [290,291,294], but lower than reported in a general Norwegian population , especially in the PCS [263]. The sample is also relatively homogenous and has a relatively small number of participants categorized as possible cases of anxiety and depression, with regard to investigate associations between changes in weight and psychological factors.

The sample might also be a rather selective group as only subjects who completed the inpatient period were enrolled in the study. However, it takes time to change habits, as well as increasing physical fitness, and we aimed to evaluate the effect of the whole 10 -14 weeks program. Furthermore, twenty nine percent of the ILI group was lost to follow-up. The subjects lost to follow-up did not differ from the completers with relation to the assessed physical and psychological health factors at baseline. Nevertheless, participants lost to follow-up at 12 months

had achieved a smaller weight reduction between the main inpatient stay and six months follow-up, indicating that participants might drop out as a result of lack of success. On the other side when contacting participants by telephone, their reasons for not coming to follow-up was about "50/50" between failing to maintain weight loss and contextual factors (i.e. they didn't want to go to the clinic when cold and snow, had to work or they didn't feel they needed any follow-up due to doing well on their own). In the papers we only reported per protocol analysis. However we acknowledge that in the perspective of treatment effectiveness it's valuable to know the effect of the treatment of all that were referred to the treatment. Thus additional analysis was included in the thesis. ITT analysis with multiple imputations of data did not change the results in weight loss within the ILI group. Whereas the ITT analysis, including the drop-outs with baseline values carried forward, deteriorated the mean weight loss at 12 months.

Study sample qualitative study (paper IV)

All participants in this study had been severely obese for several years, and they were considered to have sufficient experiences as participants in ILI with high volume of physical activity, as well as incentive to maintain physical activity and exercise for several months. They are hence considered as information-rich sources, providing varied and rich narratives of physical activity during the inpatient period as well as after. As the psychologist who was the leader of the treatment initially recruited the participants, and they agreed to participate, it could be argued that the sample can be characterized as more successful and resourceful in describing their experiences. Participants considered as positive or more likely to say yes than no may have been chosen, or those who were asked may have felt obliged to participate or reluctant to criticize the treatment program. These circumstances were, however, carefully considered and are described in the section about recruitment of participants to the qualitative study, and no patients who were asked to participate declined. Notably a step-wise recruitment and interview of participants until achievement of "saturation" was not conducted. Rather the empirical data were considered as sufficient to elucidate the study question and provide relevant examples to provide new thinking after all eight interviews were conducted. We only recruited participants who had completed the main 10-14 weeks inpatient program, and our findings cannot be generalized to the population of subjects with severe obesity as a whole. Nevertheless it seems reasonable to transfer the findings to similar context situations and to other similar groups fulfilling the same selection criteria and circumstances in other respects [273,284]

Study design

Quantitative study (paper II and III)

To date, our study is the first to include a non-treated control group to investigate the effect of an inpatient ILI in the treatment of subjects with severe obesity. Furthermore, the external validity is strengthened by the evaluation of a real life treatment approach, which is already implemented in the treatment of severe obesity in the Norwegian health care system.

Ideally when conducting a controlled trial the participants should be randomly assigned to either of the groups. It would also have been preferable to follow the control group for the 12 months period. However, when patients with severe obesity who have already failed previous attempts to benefit from less intensive treatment programs in primary and secondary care are referred to treatment in tertiary care, it would be rather unethical to randomly assign patients to a control group and deny them treatment when possible. Also in according to the Norwegian treatment guidelines, all treatment-seeking individuals with severe obesity should be offered either conservative or surgical treatment [17]. We acknowledge that it is a limitation of the study that the ILI group and control group were not recruited, tested and followed at the exact same time. There was however no differences in baseline characteristics between the two groups, with the exception of the controls being in average 4 years younger. A "placebo-effect" in relation to weight reduction was also taken into account during power analysis, and the results regarding changes in eating behavior, physical and psychological health indicate that no major changes in lifestyle has taken place within the control group.

Adherence to the physical activity component and prescribed diet is shown to be low in subjects with severe obesity during outpatient ILI [185], suggesting that mandatory exercise during an inpatient stay is a good model to study the effects of the physical activity component in weight loss programs for patients with severe obesity. The responsibility and motivation to adhere to the exercise is less placed on the individual and their self-efficacy to be physically active. Major limitations with the present study are that we do not have objectively measurements of compliance with the dietary recommendations and physical activity, i.e. the two main interventions in the treatment program. However, a key feature of this study and the inpatient treatment is the controlled setting and the exercise sessions being supervised and mandatory, as well as most of the meals being served. The physical activity level is more easily controlled, and attendance can be used as a measure of compliance. Moreover, we have examined the effect of a

lifestyle intervention program as a whole, and probably all of the various components might be critical (and not necessarily redundant) in reaching the main treatment goals, i.e. long-term weight loss and increased QoL. Nevertheless we acknowledge that if we had objectively measured physical activity level, we might have been able to determine how much of the improvements in eating behavior, physical and psychological health can be attributed to exercise. Furthermore we acknowledge that most likely the participants in our study did not continue such high levels of physical activity when returning back home [275,295]. However, weight loss maintenance may be achieved through a relatively modest permanent lifestyle intervention [295]. Moreover, with a modest intervention from the start, time to achieve the same weight loss would probably have been prolonged significantly [295]. Finally, we also acknowledge the relatively short follow-up period limits the value of the obtained results.

Qualitative study (paper IV)

A novelty and strength of this project is the inclusion of a qualitative study exploring the participant's experiences with physical activity during and following an inpatient ILI for the treatment of severe obesity. We acknowledge, however, that the retrospective design encounter vulnerability related to forgetful or distorting experiences by the participants. The time between the end of the inpatient stay and the interviews might have influenced the participant's perception and experiences with the treatment program and the physical activity component. Nevertheless, even if this is true at a factual level and we should be mindful to this limitation when interpreting the findings, it does not reduce the value or impair the quality of the approach [273]. We aimed to explore how the participants currently understand the experience when they are looking back on the treatment, and not the most "correct" reproduction of something that happened some years ago. Furthermore, the criterion is not perfection, but a description that is sufficiently expressive so that new insightful knowledge about the phenomenon can be obtained [273]. Based on existing knowledge from quantitative research, we know that the curve for mean weight loss following different treatment options of obesity (included ILI for the treatment of severe obesity) typically turns (from decrease to increase) between six and 12 months [132,163,164,296]. This indicates that old habits are hard to break, and we therefore consider our follow-up time of 2-3 years as a strength of the study. Another strength is that our design also managed to explore how the experiences changes over time, e.g. during and after the treatment, as well as in relation to weight, health, physical fitness and contextual factors.

Measurements quantitative study (paper II and III)

Measurement of body composition and physical health

Severe obesity is associated with large alterations in body composition, causing practical and methodological challenges when it comes to conducting and accurately measuring FM [19,297]. We measured body composition using BIA, and ideally we would have used Dual-energy X-ray absorptiometry (DXA). Based on existing knowledge we know that individuals with severe obesity seems to have an increased total body water, and a high extracellular water/intracellular water ratio, that may lead to an overestimation of FFM and underestimation of FM and thus affecting the validation and interpretation of the impedance measure [19]. This is however minimized by the SMF-BIA used in this study [298,299]. The eight-polar BIA InBody is shown to provide accurate estimates of total body water and extracellular water in women with severe obesity when compared to the deuterium dilution method [300], as well as reasonable estimates of whole body FM and FFM compared to DXA in subjects with severe obesity (89 % women). Moreover, we investigated changes in body composition, and SMF-BIA in general is shown to provide valid estimates at group level of changes in body composition in subjects with severe obesity when compared to DXA [301-303]. Nevertheless, before drawing direct comparison with findings from other studies, we should keep in mind that the use of different methods for measuring body composition provides challenges when interpreting and comparing the results. Moreover, detection of small changes in FFM are challenging for most available methods for measuring body composition [304,305].

Based on existing knowledge we know that adaptive thermogenesis (which happens in spite of good compliance to exercise programs) contributes to a decrease in energy expenditure in the weight-reduced phase that goes beyond what can be predicted from changes in FM and FMM [124,125,127,128]. As well as energy intake increasing due to increased hunger and reduced satiety [124,127,128]. A limitation of the study is therefor that we did not directly measured REE, appetite-related hormones or other components involved in adaptive thermogenesis. Hence we cannot determine how much REE is affected by the weight reduction. These measurements could also have explained why some individuals did not succeed in maintaining their weight loss, and even further weight gain [124,128]. Nevertheless our findings from the measurement of eating behaviors, indicates improved eating habits, in spite of unknown and possible changes in appetite-related hormones.

Another limitation is that we did not directly measured cardiorespiratory fitness. Some of the improvements in walking tests may also be due to a learning effect and increased effort [306]. Nevertheless, results from the walking tests indicated improved physical fitness during the main inpatient stay, which was also maintained at 12 months. Consistent with other studies of ILI in the treatment of severe obesity we measured CVD risk factors after standardized laboratory methods. However, as use of medication was only measured at baseline, we were not able to examine changes in use of medication, which might have underestimated the observed effect in these risk factors.

Assessment of eating behavior, psychological factors and HRQL

Severe obesity is associated with increased risk of psychosocial complications, dysfunctional eating and decreased HRQL. In the present study we included highly standardized and validated questionnaires assessing these factors, which is a major strength of the study. A weakness, however, is that we did not measure binge eating, anxiety, and depression using clinical interviews. Compared to interviews self-report questionnaires assessing symptoms may be more biased by confounding covariates [42]. Questionnaires are not diagnostic instruments, and the use of questionnaires may overestimate the prevalence of the conditions [258,307]. On the other side when analyzing the questionnaire regarding eating behavior, unanswered questions or multiple crosses were scored as zero, meaning that the subjects in both cases got a low score on the eating behavior. Furthermore, the results of self-report questionnaires can change depending on the time of assessment [308]. Thus as we measured psychological factors at the time when the participants had already been assigned to and started at the treatment, it is conceivable that some improvements as compared to before being referred to the treatment might already have occurred and hence underestimate the changes.

As with the other questionnaires, the questionnaire for measuring HRQL was chosen based on what was already in use at the clinic. Small modifications had been made without approval of OptumInsight Life Sciences (QualityMetric) to the SF-36v2, which may threaten reliability and validity, and hence the possibility of comparing results to other data or normative data. However, all response items do match the QualityMetric version of the SF-36v2, Standard (4-week) recall Norwegian Health Survey. SF-36 is a generic and frequently used questionnaire, and the scores can hence be compared across studies and populations. We acknowledge that inclusion of an additional obesity-specific HRQL instrument containing items of relevance for obese individuals

would have been valuable, as such instruments, reflect characteristics and problems related to obesity and burdens of obesity specific symptoms [309,310]. Furthermore as we only used the two summary scales of SF-36, detailed information is probably lost. However the validity of the eight subscales of SF-36 version 1 has been found questionable in subjects with severe obesity undergoing bariatric surgery [267].

Beneath the surface of HRQL measurement, there is a risk that response shift can obfuscate differences, and physical and social environment may also have an impact on HRQL [311]. Thus, the circumstances related to the inpatient setting might have had an impact on the filling out of the questionnaires. Both at the start and end of the inpatient setting, the thoughts and feelings of being part of the treatment program could have had a positive impact on their eating behavior, psychological health and QoL, as well as worries about what they were embarking on affecting in the opposite direction. If this contributed to improvements at the beginning and deterioration at the end of the inpatient setting, an underestimation of the effect would happen.

When drawing comparison with other studies of eating behavior, psychological factors and HRQL, it is important to be aware of the use of different questionnaires, procedures of analysis and definitions, as well as baseline characteristics. In addition what is considered as clinically meaningful changes in HRQL also vary across studies [268]. Finally, it is important to notice that QoL is a subjective concept. Questionnaires for measuring HRQL usually involve self-reported status of symptoms or health, and the main purpose is to describe the burden of disease of the population studied. However, the consequences of obesity varies from individual to individual, and individuals may have equal status of health or BMI, but still have a different QoL [268].

Methodological approach qualitative study (paper IV)

Reflexivity and dealing with preconceptions

My interest with how the participants experienced physical activity emerged while meeting with the participants during the test periods in the quantitative study. This made me ask new questions that I needed other approaches to elucidate, and was hence an important part of the motivation to initiate the qualitative study. Based on my meetings with the participants I expected to find that participants gradually mastered the physical activity component during the inpatient period, as well as experiencing increased physical fitness and well-being related to such activity. My knowledge of the field, as well as my relation to the treatment program and participants, from the

quantitative study was an advantage as it provided a basis for understanding. However, it also provided some challenges, and could possibly be a hindrance to discovering nuances that were not in accordance with my own experience. My reflexivity was enhanced by reading previous qualitative studies on obesity and experiences with physical activity, as well as through discussions of the literature with the co-authors and other researchers investigating experiences with obesity treatment and exercise. The authors had different scientific background and methodological qualifications/training, experiences from different research topics and educational background. This facilitated critically questioning during the whole research process. We were to researchers conducting the analysis together [271,272], and our discussions enriched the process of analysis. Nevertheless, we acknowledge that the same data can lead to different findings and other interviewers would probably have obtained and revealed different experiences and nuances from the same participants [312].

During the research process we aimed to adopt a phenomenological attitude, i.e. we tried to explore physical activity in an open and naive manner [279]. According to Giorgi's descriptive perspective, researchers are encouraged to *bracket* prior knowledge and assumptions related to the studied phenomenon, or at least attempt to identify these clearly and set them aside in order to reduce the potentially harmful effects of preconceptions related to the research [273,313]. Thus bracketing is a process whereby the researchers draws awareness to and critically reflect upon scientific and theoretical presuppositions, and personal views, regarding the research topic [313]. These methodological principles are, however, challenging and hard to accomplish. We tried to meet the challenges in various ways through the research process.

Malterud highlights the aspect of researchers' preconceptions [272,314]. Inspired by Malterud, an aiming to deal with my preconceptions, I wrote a note of some of my most obvious pre-understanding and preconceptions when planning the qualitative study. In according to Malterud "the question is not whether the researcher(s) affect the research process, but how" (Malterud, 2013, p 37, my translation) [272]. My preconceptions to this qualitative study was based on my knowledge from exercise is medicine and my experience in applying exercise as a treatment option to severe obesity, my work with and experience from the quantitative study, as well as my own experiences with physical activity through being an elite athlete. This means that my pre-understanding of physical activity was characterized by the positive effects on physical and mental health shown through quantitative research, as well as the fact that a life without exercise

would be rather unimaginable for me (and others in the research group). I reflected upon how being a PhD candidate with background in a quantitative research approach in exercise and sports science, with a professional terminology, as well as a positive relation to and believe in physical activity, might affect both the empirical data and the analysis. Reflection upon the influence on the empirical data has been provided in ethical considerations previously in this thesis. Nevertheless, as many of the questions are prepared and posed on the basis of my experiences from the quantitative study, there is no doubt that "my voice" is visible in the material. Furthermore, my pre-understanding is my "vantage point" for what I "hear" during the interviews and "see" when reading the transcripts [272]. As an example I acknowledge that during the interviews I might have been more conscious to the positive experiences with the physical activity component of the treatment, and thus interested in further elaboration of the enthusiasm about the spinning. Whereas I might have paid less attention to the experienced pain in the beginning of the treatment, which for me was considered as a natural part of starting with exercise. However, during reading the transcripts and discussing with my co-author I became more aware of the pain and the fear the participants had gone through.

This means that during the research process I experienced it as difficult to put aside my knowledge regarding sports medicine and my hypothesis about the participant' experiences with physical activity achieved through the quantitative study. To deal with this I constantly asked myself, and sometimes also my co-authors, whether the process and product were influenced by my particular standpoint related to physical activity, and reflected upon the conditions governing the entry to my knowledge. I have also tried to be conscious of not only carry forward or reveal a confirmation of my preconceptions from the quantitative study.

Methodological approach

The exploring of how physical activity is experienced from the perspectives of the subjects with severe obesity themselves is an important strength of our methodological approach. However, other methodological approaches and methods of analysis, like grounded theory, could have been valuable to get a greater understanding of the contextual and social aspects at the clinic. Within phenomenology there is a continuum from descriptive (or transcendental) to more hermeneutic (or interpretive) phenomenological methodology [273,278,315,316] and using a more hermeneutic phenomenological approach could have provided more understanding of the experienced meaning of physical activity.

We were alert of the distinction between descriptions and interpretations during the analyzes [273,278], and aimed to analyze the descriptions solely based upon what was presented in the empirical data (Giorgi 2009, p 127) [273]. Nevertheless, we believe that any analysis is selective and inherently interpretive. Furthermore, we aimed to describe the participant's experiences with physical activity prior to, during and after the treatment as accurately as possible, keeping in mind Giorgi's statement that "the result of a descriptive analysis is a second-order description" (Giorgi, 2009, p 127) [273]. However, as with the analysis, we acknowledge that as researcher we are "visible" as acting in the themes and text [272,284].

Interview

Aiming to ask about the participant's own experiences we chose interview as our method for collecting the empirical material. Interview is a commonly used method for data-collection in qualitative research [279], and through the qualitative interviews we were able to gain insight into similarities or differences between the participant's experiences with physical activity. We aimed to achieve "naïve description" of the experiences with physical activity from and in the words of the participants. Nevertheless, we acknowledge that their language and concepts when describing and talking about physical activity was probably impacted by and a result of what they had learned at the inpatient stay at the clinic, and thus affected by the language of the treatment team. We were searching for thorough descriptions of the experience with physical activity, and at the same time we were aware of the distinction between directing and leading the participants [273]. Notably the participants mainly spoke about experiences with physical activity *as exercise* during the treatment program. However it was our aim to explore the experience with the physical activity component in the treatment program, i.e. such physical activity. Another important issue is the importance of voice tone and emphasis in talking about emotion-laden experiences. Good qualitative research and its mode of presentation are difficult. In retrospect, another possible way of doing the interviews could have been to interview our participants more than once, and circled back problems, views, feelings, stories of experiences that remain to be confirmed, clarified or complicated by careful reading of the first transcripts.

The application of STC

A rigor of our qualitative study is reflected in the implementation of Malterud's principles of STC, as it represents a relatively pragmatic, systematic and transparent analytical tool [271]. Within qualitative research there is however a tension between rigor and creativity [281]. Thus an

objection to STC as a methodological approach is the limited space for flexibility, creative interpretations and elegant conclusions [271], and might seem to be more concerned about the method rather than gaining insight. Meaning that there is a danger that the way the analysis is conducted becomes more important than new directions in the analysis, as well as discovering new things and raising the important insights. We aimed to mitigate this risk through doing justice to the increasing knowledge provided from the empirical data. In this regard, as we were immersed in and engulfed by the process of analysis and writing, creativity as opposed to emphasis on the scientific method resulted in modifications of the STC. As STC involves cross-case line of thematic analysis, we acknowledge that individual context may have been lost in the decontextualizing of data [271]. However, during the multiple steps of reducing information included in the analysis, information is always lost [271]. STC was also limited in our aim to describe longitudinal changes in the participant's experiences; however the separating into findings prior to, during and following the treatment helped us solve this challenge.

Discussion of main findings

This thesis had three main findings. First, substantial weight loss with minimal reduction in FFM was achieved in subjects with severe obesity during an inpatient ILI with high volume of physical activity. Second, improvements in eating behavior, psychological factors and HRQL were reported. Thirdly, the participants experienced an ambivalence of attending physical activity.

Substantial weight loss with minimal reduction of fat free mass (paper II)

During weight loss it is desirable to maintain FFM (much of which is skeletal muscle mass) to minimize the anticipated decrease in REE, as well as maintaining strength and function [120-122]. The findings showed that during an inpatient ILI, with high volume of physical activity, substantial weight loss with minimal reduction in FFM was achieved. Furthermore, the results from the study proved evidence that subjects with severe obesity manage to participate in high volume of physical activity, and contradicts claims that exercise programs are unhelpful for this population due to reduced mobility [244]. This is also supported by recent studies of other inpatient ILI for the treatment of severe obesity including comparable physical activity components [70,215,275,288,290,317].

In most inpatient ILI for the treatment of severe obesity the average rate of weight loss is typically 1-1.5 kg/week and thus the initial weight loss seems to depend on the duration of the first inpatient stay [69,171,215,236,238,239,275,288]. Our 13 % initial weight loss is in accordance with studies of comparable duration [171,239,288]. Exercise added to low-calorie diet programs appears to increase relative FM loss with no change in FFM losses in subjects with lower degree of obesity [305,318]. This also seems to be the case in subjects with severe obesity [275,277,295]. In our study the fraction of total weight loss coming from FFM (ΔFFM/ΔWeight %) was 10 % during the inpatient stay. This is in between results from other studies where the investigators report changes in body composition after inpatient ILI [69,165,275]. In one study the FFM fraction of total weight loss was 24 % during three weeks inpatient treatment including about half the volume of physical activity compared to our study [69]. In another study with comparable amount of physical activity to our study, the FFM fraction of total weight loss was 15 % [275]. Whereas in a third study, no reduction in FFM was seen after six weeks inpatient treatment including higher volume of physical activity (two hours five days a week) and higher intake of dietary protein [165].

A dose-response relationship between increased physical activity and reduction in FM has been shown among subjects with severe obesity [185,275], and has also been seen among subjects with lower degree of obesity [209]. In our study a minimum of 90 minutes of physical activity five days per week was provided. We may only speculate if the high volume of physical activity in the present study has contributed to increased reduction in FM and thus a low FFM fraction of total weight loss. However, future studies are needed to verify this. Furthermore, rate of weight loss, temporal trends (i.e. early vs later weight loss), energy deficit, diet composition, metabolic-hormonal mechanisms, gender, as well as intensity of and individual response to physical activity are major contributors that should be taken into account [184,275,277,295,305] [120,318]. Nevertheless, in summary the relative loss of FFM in our study is less as compared to other ILI for the treatment of severe obesity, and this in spite of a great total weight loss.

Quantitative definition of what is considered "excessive loss of FFM" is lacking. However, historically a FFM fraction of about 25 % of total weight loss has been considered acceptable [305,319-321]. FFM fraction of total weight loss following dietary and behavioral interventions is shown to range from 9 % to 36 % [305,318]. In this regard, our findings are at the lower end. Notably, the proportion of FFM loss is influenced by the degree of caloric restriction, rate of

weight loss and physical activity [120,318]. Indeed, low calorie diets combined with aerobic physical activity has been shown to provide the best retention of FFM [318]. Taken together this indicates favorable preservation of FFM in the present study, and it is reasonable to assume that the participation in high volume of physical activity has contributed to a better maintenance of FFM. Moreover, although the observed reduction in FFM during the inpatient period was statistically significant, the clinical relevance of this reduction is probably limited compared to the reduction in REE due to the adaptive thermogenesis [185,277,322]. Thus with substantial weight loss high levels of physical activity seems to be needed to compensate for these metabolic changes to maintain body weight.

Both day- and inpatient ILI are shown to cause ≥ 5-10 % weight loss the first year post treatment for patients with severe obesity [69,72,171,173,215,236,238,239,275,276,288]. In general mean percentage weight loss and the proportion of the participants achieving a weight loss ≥ 10 % at one year are greater following inpatient treatments compared to outpatient treatment. Moreover, the greatest one year weight loss outcomes are reported following longer inpatient stays [69,171,239,275,288]. We found a mean reduction in body weight of 16 % one year after the start of the inpatient treatment, and almost 70 % of the participants achieved a weight loss of ≥ 10 %. This seems to be at the upper limits of what is found in the literature. We may only speculate that the successful results are partly explained by the duration of the inpatient stay and that the great initial weight loss during the inpatient period is a major contributing factor [289,323]. It has also been suggested that a minimum of 10 weeks is probably what it takes to change habits if done every day [324], and the inpatient period in the present ILI may have provided sufficient time for the participants to establish new eating and exercise habits. Furthermore, as re-admissions at the clinic seem important for weight reduction and maintenance [69,166,167,171,239,275,288], we assume the two follow-up weeks in the present study also contributed to the one year results.

Studies involving measurement of body composition in subjects with lower degree of obesity shows that exercise can preferentially reduce VFA [208-211]. Our participants reduced their VFA with approximately 30 % during the inpatient stay, which was maintained at 12 months. As such magnitude of reduction has been proposed to be associated with 5-10 % weight loss and improvements in metabolic markers of CVD risk [63], we consider this finding clinically relevant. This is in agreement with the study by Goodpaster et al [173] showing that including physical activity promoted greater reductions in VFA and FM compared to diet alone [173].

Favorable changes in CVD risk factors the first year following both day- and inpatient ILI have been reported in subjects with severe obesity [69,72,172,173,215,275,276,288]. Notably Hofsø et al found that most of the metabolic effects were observed with a ≥ 10 % weight reduction [172]. This magnitude of weight loss was also shown to have beneficial impact on several CVD risk factors in subjects with severe obesity participating in outpatient ILI, even if participants remained severely obese [276]. Our findings with improvements in CVD risk factors, and almost halving of the prevalence of metabolic syndrome during the first year, add to research showing that ILI may lead to clinically meaningful weight loss. However, long-term follow-up should be provided.

Improvements in eating behavior, psychological factors and HRQL (paper II and III)

Our findings demonstrated that an inpatient ILI including a high volume of physical activity in subjects with severe obesity improved eating behavior, reduced symptoms of depression and anxiety, and increased physical and mental HRQL. With the exception of anxiety, the favorable changes in eating behavior and physical and psychological parameters achieved during the inpatient treatment were almost maintained for one year.

These results are in line with findings from other ILI studies [238,291,294]. Bannert et al found significant improvements in psychological symptoms and eating habits during 8-12 weeks inpatient treatment [294], Clini et al found a reduction in the proportion of binge eaters six months after a one month inpatient program [238] and Faulconbridge et al found that an outpatient lifestyle modification program reduced symptoms of depression comparable to what was seen after bariatric surgery one year after treatment [291]. Taken together it seem like subjects with severe obesity may achieve improvements in eating behavior and psychological factors during ILI. However, despite an overall improvement during the study we found a slight deterioration of eating behavior, symptoms of depression and MCS from six to 12 months. The deterioration in mental health are in accordance with the study of Faulconbridge et al [325]. Notably, the deteriorations occurred during the six months period with no formal follow-up. It is conceivable that the acute and six months improvements reflect positive effects of the treatment itself, the group support, social relations and motivation, and good feelings by being physically active [290,325]. Thus lack of formal follow-up may have contributed to the deterioration in eating behavior and psychological factors between six and 12 months [291]. Our findings from the qualitative study corroborate these assumptions, however further research is needed.

Within the ILI group we found that increased cognitive restraint, decreased uncontrolled eating and a decrease in binge eating were related to weight loss after one year. To the best of our knowledge, only one study has reported similar findings in subjects with severe obesity participating in inpatient ILI [236]. In their study Golay et al showed that five years change in weight following a six weeks inpatient treatment was correlated with encountered eating behavior and binge eating disorder. They also found higher scores for uncontrolled eating behavior among subjects gaining weight compared to those losing weight. Improvements in eating behavior have also been related to weight loss in less obese subjects [89,240,326,327]. Similarly in a report from The National Weight Control Registry, weight gainers showed greater increase in binge eating than maintainers [328]. Physical activity has also been shown to improve adherence to calorie restriction [185] and have positive influence on appetite regulation by increased sensitivity for satiety signals, improvements in eating self-regulation and decreased binge eating [192,196-199,230,231,329,330]. Our findings demonstrates that subjects with severe obesity participating in an inpatient ILI, with the food being served and physical activity being mandatory, may have enhanced their weight loss by increasing cognitive restraint and decreased uncontrolled eating. Moreover, the reduction in binge eating may be a key factor for maintaining weight reduction, and indeed we observed a reduction in the prevalence of suggestive binge eaters during the study period. Nevertheless, change in binge eating only explained about 10 % of the variation in weight reduction, indicating that change in reduced episodes of binge eating represents a small proportion of the variation in weight loss. In addition, future studies including large samples of men and women, to clearify eventually gender differences are needed.

Our finding of a significant reduction in mean depression score at 12 months is in agreement with findings from a systematic review of weight loss trials including subjects with lower degree of obesity [331]. Findings from our qualitative study suggest that the participants gradually experienced well-being in relation to the improved fitness. Even though, physical activity has been related to reduction in symptoms of depression and anxiety [229,332-334], a lifestyle program including both physical activity and dietary modifications has been shown to improve symptoms of depression and HRQL more compared to exercise or diet alone [335]. Furthermore contact with a supportive group and the treatment team is also a factor that might improve psychological factors [336]. Hence, the overall comprehensive ILI, not only the adapted physical activity, seems to have contributed to the positive impact on psychological factors in the present study.

We also found that symptoms of depression were reduced more than symptoms of anxiety, and at 12 months our observed improvements in anxiety were no longer maintained. Less improvement in anxiety as compared to depression is also reported after bariatric surgery [90,337], and likewise, Aasprang et al found a transient reduction in anxiety with no improvements after five years [337]. It is conceivable that worries about regaining weight partly explain why our subjects remain anxious, as shown in subjects undergoing bariatric surgery [338]. This is supported by the findings in our qualitative study, revealing that they feared going back to old habits and body weight. Possible explanations for the recurrence in symptoms of anxiety in the present study may also be psychosocial stress related to the participants "return to real life at home". Challenges related to body dissatisfaction, self-concept, eating problems and the fear of exercising in public, as well as social relations, socioeconomic factors, stigmatization, and discrimination that were "partly forgotten" during the inpatient period may also be involved [90,188,189,338-341]. Further research, including in depth analysis and qualitative studies, is needed to explain this finding.

Interestingly, changes in anxiety and depression scores were not associated with change in body weight. This is in line with the study by Bannert et al in subjects with severe obesity and psychological comorbidity [294]. In contrast, Golay et al found that five year weight change was correlated with encountered psychosocial difficulties [236]. Likewise, Faulconbridge et al found a positive correlation between magnitude of weight loss and change in symptoms of depression when increasing sample size by collapsing ILI-participants and surgery-participants into one group [291]. They also reported that weight loss at one time point predicted symtpoms of depression at the next time point, but not vica versa. Thus suggesting that decreased symptoms in depression follows weight loss, whereas weight loss does not necessarly follow reductions in depression. These mixed findings are however in accordance with the empirical evidence regarding the association between depression and weight loss in less obese subjects [37,85,342,343]. Similar variation in findings have also been reported following bariatric surgey [344,345]. In agreement with our findings Andersen et al found that change in BMI was not correlated with change in HADS scores in bariatric surgery patients [90]. The association between anxiety and obesity has in general been less investigated as compared to the association between depression and obesity. However research suggests that anxiety and depression may be affected in different ways by weight loss [140]. We can only speculate on the reasons for our findings. It might be that the symptoms of depression and anxiety in our participants were not related to

their obesity, or that the degree of weight loss was not large enough to cause differences in symptoms of anxiety and depression [90,140]. Importantly, depression and anxiety are affected by many complex psychosocial factors [93,94], thus weight loss may have minor effects on changes in these factors. Interestingly, despite greater weight loss, subjects undergoing bariatric surgery did not have greater reduction in symptoms of depression compared to subjects participating in ILI [291]. This supports that reductions in symptoms of depression may be explained by other factors than weight loss.

The present study showed that through participating in an inpatient treatment program subjects with severe obesity increased their HRQL. Favorable changes in HRQL following ILI in subjects with severe obesity were also shown in two recent Norwegian studies [290,317]. However, we found greater improvements in PCS than seen in the study by Karlsen et al [290]. This may be due to greater weight loss [290,317]. The physical components of HRQL are shown to be inversely correlated with weight loss following bariatric surgery [140,337,346]. In line with this, we found that PCS was associated with weight loss during the 12 months study. This is in line with findings from Karlsen et al [290]. However interestingly, Faulconbridge et al found similar improvements in PCS in the ILI and surgery group despite greater weight loss in the surgery group [291]. With regard to the mental HRQL, we found no association between changes in MCS and weight loss at 12 months. This is in line with the finding by Bannert et al reporting the effects of ILI in MCS [294]. In contrast the two studies reporting the effects on weight loss on mental HRQL including bariatric surgery patients, found that weight loss was associated with increase MCS [290,291]. Taken together it seems to be a positive relationship between weight loss achieved by an ILI and improvements in physical HRQL, while less convincing evidence exist for improvement in the mental HRQL. In this regard a positive relationship between physical activity and physical functioning has been shown in subjects with severe obesity [233], thus changes in physical activity levels and fitness might also have contributed to the observed changes in PCS in the present study. The long inpatient stay with social support, adaption of exercise and increase in physical fitness may have played a role in improving HRQL independent of weight loss, [108,112,233,347]. This assumption was also supported by findings in our qualitative study.

The factors related to mental HRQL of subjects with severe obesity, seems to be different from those related to their physical HRQL [108,112,337], i.e. as expressed by Aasprang et al MCS score seems to tell a different story than PCS [337]. Thus it might be that the inpatient treatment

program with high volume of adapted physical activity have led to greater enhancement in physical health, whereas environmental factors at home affecting mental health have not changed. Unexpectedly we also found that weight loss was associated to a decrease in MCS during the inpatient period. It may be that the last day of the inpatient period when the participants filled out the questionnaires was experienced as stressful, and that thoughts and feelings regarding how to manage eating habits and physical activity levels at home were more stressful for subjects who achieved the most pronounced weight reduction. Eventually these subjects had made the greatest changes from their original lives. It may also be that subjects with severe obesity with a lower mental HRQL have a greater motivation to change their lifestyle [323]. Nevertheless, other factors such as employment, age, physical activity, psychological factors, BED and personal charcters seems to be important contributors to HRQL [108,111,112,233]. Thus, further research into weight-independent effects is needed, as well as further exploration of the relation between mental HRQL and weight loss.

The effect of obesity on HRQL has been suggested as one of the main reasons for obese subjects to seek treatment [348], and that motivation for changing lifestyle in subjects with severe obesity occurs due to large physical and mental health problems, rather than by the weight per se [349]. Improvement in QoL is also considered a main goal in the treatment of severe obesity. However, how much weight loss is needed to achieve clinically important improvements in HRQL is not clear. In this regard, the SOS-study with follow-up data for more than 10 years has shown that maintaining a weight loss of about 10 % is sufficient for positive long-term effects on HRQL [140]. However, a recent study suggested that a weight reduction of ≥ 20 % is required to achieve long-term clinically important differences in HRQL in subjects with severe obesity [142]. Both studies indicated that only bariatric surgery led to weight reductions necessary to achieve long-term improvements in PCS and MCS. In comparison our observed mean change in PCS at 12 months can be interpreted as a clinically meaningfully change, and moreover 68 % and 42 % of the participants achieved MID in PCS and MCS respectively. In this regard, our results are promising and indicate that an inpatient ILI, including a high volume of physical activity, may have a positive influence on HRQL. Clearly there is a need for future research on the long-term effects.

Ambivalence of attending physical activity (paper IV)

Our findings showed that through an intensive inpatient lifestyle modification program subjects with severe obesity managed to participate in high volume of adapted physical activity. However, their experiences with physical activity were highly ambivalent, characterized by doubt, fear and resistance as well as comfort, joy and pleasure. The ambivalence was experienced as a shift in how participants felt about physical activity during the intervention period and as an ongoing, dynamic and constantly shifting experience during such activity.

In accordance with previous research, our findings showed that low activity level in individuals with severe obesity is explained as a combination of corporal and contextual factors. Prior to the treatment their bodies were experienced as too heavy obstacles to physical activities, and causes of exhaustion and pain [14,102,188,190,350,351]. In addition usual contexts for exercising were perceived as not meant for them; they experienced a bodily "differentness" and felt uncomfortable when exercising with other people who were not obese [97,188,190,351].

Our findings also showed that exercising in a group of individuals with severe obesity, with adapted activities and instructors specialized in physical activity and health, appeared to promote a sense of acceptance and motivation to engage in physical activity as exercise for several of the participants. This is in accordance with findings of previous studies [350-352], and contrasted with participants' previous experiences with or avoidance of fitness centers. However, it is important to note the opposite experience of being a member of a group, the feeling of not fitting in, even while together with people who appear to share your own challenges.

The intention of the physical activity component in the treatment program was for the participants to increase their physical fitness, master and enjoy being physically active in order to increase their physical activity level following the treatment program [353]. In this regard, and not surprisingly, most of the participants described how their corporal limitations gradually changed after some weeks of effort and struggle during the inpatient period. Furthermore they shared feelings of achievement and pleasure in relation to the activities, and also experienced a feeling of well-being and improved physical fitness. This findings show that severe obesity is experienced as a burden, but does not necessarily keep one from being physically active. Every human situation includes our bodies, and according to a phenomenological understanding of being a body, the body is, tangibly, the subject's perspective on the world. This perspective is constantly changing,

and responds to new circumstances [280,315]. The participants were living a heavy body, however changes in body composition, physical fitness, physical health, self-confidence and mental health during the treatment, as well as by the treatment setting and context itself, may have caused a change in participants' experiences of physical activity and exercise during their inpatient stay [280,315].

Nevertheless, the findings from our study also call attention to feelings of pain, discomfort and fear related to exercise. Although the exercise program was targeted to be adapted to the participants, the exercise promoted bodily discomfort and pain, and was described as a stressful and weighty experience. Similar experiences have also been reported in other studies of subjects with severe obesity [350,351]. Notably, despite these negative experiences, the participants remained in the treatment, and endured all the pain and fear, in order to reduce their body weight and enhance health. These experiences are informative and indicate what the participants were willing to go through, and are particularly interesting to relate to the common belief in the society that obese individuals are lazy, unmotivated, weak-willed and noncompliant with weight loss treatment [98-100,102]. The gradual reduction in pain and anxiety, and increased coping is in accordance with the experiences of the employees described in paper I [353]. Nevertheless, the "hate", "hell" and "fear" feelings may be a reason why some participants drop out, make their own modifications or skip exercise sessions [350], and should be explored in future research including participants dropping out of treatment.

In line with previous research the participants in the present study experienced an ambivalence between desire and duty related to exercise following the inpatient program [351]. A desire to exercise for pleasure and well-being were important for the participants in our study, at the same time they experienced exercise as a duty and something they "had to do" in order to control their weight (as well as health and physical fitness) and not return to their former habits and body weight. These findings are interesting to compare to the aim of the treatment program, which was to introduce the participants to physical activity and exercise as pleasurable, and not "something they have to do to lose weight" [353]. At the same time, weight loss was an outcome goal of the treatment, as well as our culture strongly emphasizes individual responsibility for one's own health. This can be construed as a communication that strongly relates exercise to discipline and duty, with little room for experiences of ambivalence. In this regard an ambivalent attitude is something inherent in the treatment program(s). It is not just the participants who

experience such ambivalence; they do so in a social and cultural context in which such ambivalence is normative. In addition, experience of ambivalence related to exercise is something anyone can have, and is not something that characterizes only obese individuals. Thus it is important that the participants experience ambivalence as an expected, natural part of the program, not a problem, and acknowledge that such ambivalence is to be expected and is experienced by most involved in physical activity and exercise. Such experiences should also be understood as continuous and moveable, not determined once and for all. What is pleasurable can sometimes be experienced as a duty, and vice versa.

The experience of exercise is always contextual [278], and as found in another qualitative study the participants experienced difficulties continuing with the same activity-level and focus after the treatment program [102]. The participants used the word "bubble" when talking about the context at the clinic, and most of them described the contextual shift from the treatment setting to their return home as large and daunting. To return to their everyday lives challenged the participants in continuing with the lifestyle changes accomplished during the treatment. It is also important to be aware of the adaptive thermogenesis following weight reduction leading to decreased energy needs, and most participants will have to continue their energy reduced diet and/or high levels of physical activity for the rest of their lives to maintain their reduced body weight, and at the same time increased drive to eat than before the weight reduction [130]. In order to understand and prevent the often observed and reported relapses in obesity treatment [102,171], it is important to acknowledge the "battle" some of the participants experienced following the treatment program in this and other qualitative studies [102,354].

During the treatment program, the participants increased their physical fitness and experienced mastery of technical aspects of different sport activities. Enthusiasm about managing activities, improving physical fitness and achieving goals were also reported in a recent qualitative study of experiences of a comparable inpatient ILI for the treatment of severe obesity, as well as a desire to be active following the treatment [352]. Nevertheless, in contrast to the inherent expectation of causality and coherence in the aim of the treatment program, this does not mean that physical activity automatically was acquired as a habit and that the participants continued these activities when they got home. In according to Merleau-Ponty acquisition of habits is individual, it is about our body "understanding", the habit gaining a new meaning and significance, and a relational process related to norms and rules [355,356]. This means that if the participants experience

physical activity as meaningful in itself, and/or what physical activity seems to imply (e.g. weight loss and better health), the habit is acquisitioned in a more profound and lasting manner. Furthermore, when trying to be physically active when returning back home after treatment, the "norms and rules" in their social and relational setting will affect the acquisition of physical activity as a habit. Many participants experienced acquiring of exercise as a habit as difficult.

Even if the participants said they were more active in their everyday lives now, as compared to before the treatment, most of them said that they did not exercise as much as they thought or believed they should. Exercise provided joy, physical changes and better health, but also feelings of guilt and failure. Some of them did not exercise enough to maintain their reduced body weight, and previous research has revealed that regaining weight following lifestyle interventions, and not achieving permanent weight loss afterwards, may lead participants to choose weight loss surgery [102]. With respect to this it is useful to pose the questions, what is the treatment program communicating through its emphasis on quantity, and how should participants understand this in their everyday post-treatment lives? What is "enough" in the context of exercise? Who is telling them when "enough is enough"? And "enough for what"? Weight loss maintenance, joy, well-being, QoL? Do the participants really want to exercise afterwards? Or do they do it in fear of weight gain? Our findings challenge the underlying assumption that such physical activity is "good for everything" and gives meaning to "everybody", and suggests that physical activity for individuals with severe obesity should not be viewed from an exclusively biological and physiological perspective. Personal and contextual experiences may at least partly account for relatively high drop-out numbers from treatment programs and lack of persistence with the weight maintenance behavior. Being obese is also experienced and emerges in different ways at a treatment clinics as compared to in the participants homes [97]. Clearly this indicates a need for future qualitative research to investigate the meaning of physical activity, including studies of "how things are at home", as this is much about the context.

Perspectives and implications

Whether working with research or treatment of obesity, it's essential to have in mind that obesity is not just about too much energy intake in relation to energy consumption. It is a very complex issue, in relation to causes, complications, effects, prevention and treatment, both within the individual and at a community and environmental level. Both quantitative and qualitative research can provide valuable information about how healthcare professionals can help patients to

strengthen their health processes [283]. Nevertheless, as stated by Malterud; "there are no research methods that can fully describe people lives, minds, and realities". Hence within obesity research and treatment we should remind ourselves that scientific knowledge is not always the most important or relevant type of information when dealing with people [285].

The trend

We observed a greater weight reduction compared to what is found in most previous studies of ILI in the treatment of severe obesity; however we are aware of the trend. The main reduction in body weight in the present ILI occurred during the 10–14 weeks inpatient period. The changes remained quite stable during follow-up, however a slight increase in body weight was observed from six to 12 months. This seems to be the critical time for weight management, and such turn or plateau in the weight reduction curve is reported following most non-surgery obesity treatment strategies [27,132,163,164,296,357], including ILI for the treatment of severe obesity [276]. Failure to adhere to the dietary and/or physical activity prescriptions are probably major factors [215,275]. Challenges in maintaining (relatively high levels of) physical activity following ILI were also confirmed in our qualitative study. Thus although our study showed a clinical meaning full weight loss at one year follow-up, the challenges with lifestyle interventions are to incorporate the behavioral changes. These changes have to be maintained and even increased to counteract the compensatory mechanisms in energy expenditure seen after weight loss [185,277]. Thus weight loss and weight loss maintenance might require different approaches. Interestingly the profile curves of the changes in eating behavior, psychological factors and HRQL look rather similar to the profile of the weight reduction, with a turn between six and 12 months. The great improvements just after the treatment may partly be interpreted as a "honeymoon" effect, as proposed following bariatric surgery [91,358], because of being part of a treatment program and the initial weight loss. This assumption was confirmed by the findings in our qualitative study.

Research regarding prolonged (> one year) effects of ILI in the treatment of severe obesity is sparse and less promising [171,276,289,359]. Whether our observed turn in the weight reduction curve is a trend or just a small recurrence is to date an unanswered question. We acknowledge that long-term follow-up should be provided. Nevertheless, studies have shown that the regain typically observed following ILI levels of between 2 to 4 years [167,171]. Better long-term weight loss maintenance is also reported following a greater initial weight loss, as well as when some sort of re-admission at the clinic is provided [171,289,360].

Usually weight loss efficacy is reported with mean weight loss. However, importantly it seems that some individuals are "responders" to ILI, i.e. for those ILI is an effective treatment option to achieve a clinically relevant weight loss, even in the long-term [171]. [361]. Whereas others aren't responders at all, both in relation to weight loss and HRQL, and for those maintaining behavioral changes and weight loss through non-surgical treatment options seems to be difficult. Drop-out is a problem within obesity treatment, and the reason for drop-out is unknown. However, regain of weight following ILI has been found to make participants choose to go through weight loss surgery [102], and Andersen et al found that by six years after an inpatient ILI 80 % of the participants had undergone bariatric surgery or were scheduled for surgery [359].

Taken together it seems that lifestyle intervention for the treatment of severe obesity needs to be comprehensive. "Intensity", duration and follow-up are important factors for one year outcomes, and weight loss first year is important for long-term weight loss. Strategies to maintain weight loss and health benefits are however needed, and more intensive treatment and follow-up is important for those who struggle and drop out. Adherence to seems to be the best predictor of weight loss efficacy expressed as mean weight loss and proportion achieving ≥ 5 % and ≥ 10 % weight loss. The challenge is however that adherence cannot be measured in advance. Thus, best practice is yet to be found and future research needs to focus on better understanding of adherence. There is also a need to better understand subjects with poor weight loss or HRQL outcomes, i.e. through qualitative studies, and to find out what each individual benefit from.

Clinical implications

Worldwide millions people are currently defined as overweight or obese. As stated by Monaghan [103]; "Weight or 'fatness' is certainly problematic for many people (or it is made problematic for and by many people) but should it be?". Whether or not obesity is negative for health and should be treated is also an ongoing debate, and an obesity paradox does exist [362]. Nevertheless, individuals with severe obesity experiencing mobility difficulties, high levels of comorbidities, health risk and discrimination, and who seek help should be offered treatment [17,103,218].

This inpatient ILI has proven to provide indications for effectiveness in a group of subjects with severe obesity, and is likely to favor obese patients who have not achieved a clinically meaningful weight loss in less intensive treatment options. Serious considerations should be given by health care systems to incorporate and/or continue inpatient ILI similar to the one used in the present

study. However, the slightly turn in weight loss and HRQL underline the need for a longer and/or more intense follow-up, as this turn was observed during a long period with no follow-up. Notably, our drop-out analysis and missing value analysis indicates that for subjects achieving a small weight loss at six months, additional follow-up should be provided. Alternative approaches could be addition of outpatient follow-up, especially for those who struggle, to aid changes in their real life settings. Treatment should also aim to help with other factors important for HRQL (even if weight loss is not achieved), e.g. psycho-social and work situation.

Research regarding the mean effects of ILI, gives an idea about what can be expected of changes in weight loss, physical and mental health, which can be discussed with the patients. Nevertheless, there is great diversity in relation to causes, complications, effects and experiences, which has a significant impact on how the treatment is experienced and affect each participant. Inpatient ILI is not a treatment option that "fit's all", and to adopt an open, listening and receptive approach to patients both at assessment of treatment and follow-up may prove valuable. All patients are individuals, with individual goals and history. Thus, discussion and measures of QoL should also be used in the clinic, together with the patients as a motivator for change. Furthermore, one should also be wary of what to assess when considering treatment options. Indeed, in a moralistic perspective, it would be rather unethical if people with certain characteristics should not receive one type of treatment and not be given the opportunity to "have a good time" during an inpatient stay, just because there is a risk that they do not succeed. On the other side, severe obesity is a condition associated with failed attempts at change and repeated relapses [102,131], and it is not desirable to experience yet another defeat. The idea behind group treatment is that those who are struggling with the same thing can learn from each other and feel less alone. It is however important for health care providers to realize that not all participants have positive experiences being part of a group. Some feel that they don't fit in to the group. Recognizing this may be crucial in relation to their continuing in and benefiting from the treatment. Subjects with severe obesity are a very heterogenic group, who respond differently, and a challenging group dynamic often emerges when putting such a different group together.

The biomedical perspective of physical activity has been dominant in both research and clinical practice. Losing weight is however often the patient's wish, thus this measurable and quantifiable perspective should be taken into account. Nevertheless, clinicians should also discuss feelings, experiences and considerations related to physical activity and exercise, including the diversity

and ambivalence. In groups the clinicians and participants could discuss, challenge and problematize experiences with physical activity. Exercise might provide joy, physical changes and better health, as well as a feeling of guilt, failure and opposites. There is a complex and moving relationship between internal and external motivation. Participants who do not enjoy exercise may often be considered as disturbing, sniveling and disruptive. It is however important that the participants experience ambivalence as a natural part, not a problem, and acknowledge that this ambivalence is experienced among most that are involved in physical activity. The participants should be offered individual consultations in relation to both corporal and contextual experiences related to physical activity, as is normal in relation to eating behavior. In the treatment context ("the bubble") it is not difficult to exercise, "the battle" and ambivalence is likely to become more apparent when back home. It is important to be open regarding the experienced ambivalence towards exercise, as well as the "battle" to maintain reduced body weight.

Our intent was not to compare our results with bariatric surgery, nor do we recommend that ILI replace bariatric surgery. To the contrary, it is quite clear that bariatric surgery should continue to play an important role in the treatment of severe obesity. However, this is a treatment approach for those who cannot or does not want to undergo bariatric surgery. We are also aware of the resources required for this type of treatment program, and that long inpatient stay is a potentially high source of increasing the costs. Although specific analysis could have shown beneficial results in terms of cost, this was not the aim of the present study. Moreover, the high costs and the individual's pain and comorbidities caused by severe obesity should however act as rationale for ILIs. The prevalence of severe obesity is increasing and this thesis showed that an inpatient ILI can be an alternative to bariatric surgery in some patients. Prevention is certainly important; however this is beyond the scope of this thesis. Nevertheless, despite a greater weight loss showed following bariatric surgery as compared to ILI, it is important to keep in mind the possible spillover effect of lifestyle changes to other family members, especially in relation children and the prevention of development of severe obesity as a result of genetics and environmental factors. For some individuals, however, bariatric surgery is necessary to succeed in changing lifestyle, and successful bariatric surgery also requires changes in lifestyle. There is a need to learn more, i.e. who is the ones who will benefit the most. Nevertheless, based on current knowledge and the findings in this thesis, focusing on lifestyle changes seems to be associated with less risk, as compared to lying on the couch and wait for someone to document this.

Conclusions

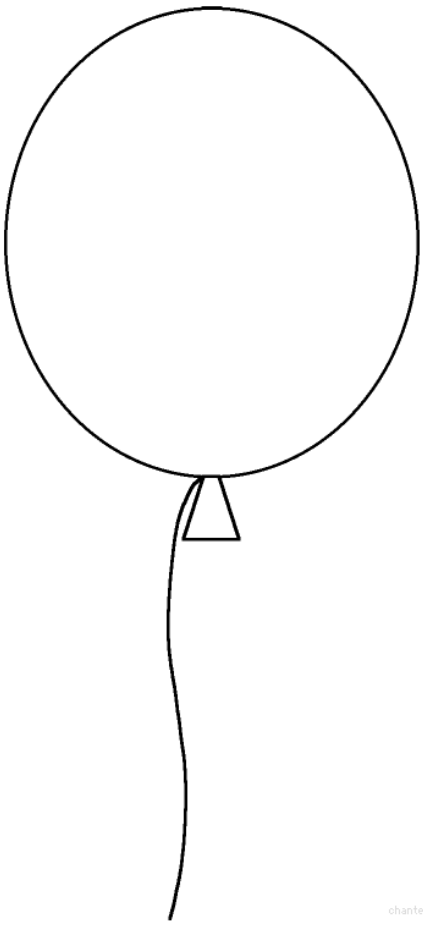
This thesis has three conclusions:

1. An intensive inpatient lifestyle intervention with high volume of physical activity resulted in substantial weight loss with almost maintenance of fat free mass.

2. Subjects with severe obesity following an inpatient intensive lifestyle intervention reported favorable changes in eating behavior, psychological factors and health related quality of life. Weight loss was related to improvements in eating behavior and physical health related quality of life at 12 months follow-up.

3. Individuals with severe obesity participating in an inpatient intensive lifestyle intervention experienced coping with a high volume of adapted physical activity during their inpatient stay. However, their experiences with physical activity as exercise were characterized by ambivalence. There was a shift in how they felt about physical activity from the start of the treatment to the end of it, as well as an ongoing, dynamic and constantly shifting experience during such activity.

The (my) knowledge about obesity



Øyvind Glosvik (referring to Hofstadter 1979): ***"If you start with little or no knowledge it is like a deflated balloon, as you acquire knowledge it inflates the balloon, increases the surface of the balloon and allows more knowledge to be gained. At the same time, the more knowledge you gain, the more you realize how much knowledge is outside the perimeter of your balloon".***

"Again the complex and knowledge of obesity is so overwhelming"
(The thoughts of a "re-worried" PhD student)

Inspired and cited by permission from Øyvind Glosvik,
at the Balestrand obesity conference: "The complexity of obesity: Scandinavian perspectives", Norway 2014

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Paper I

The Hjelp24 NIMI Ringerike obesity clinic: an inpatient programme to address morbid obesity in adults

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ABSTRACT
An inpatient programme for the treatment of morbidly obese patients is described. The programme targets physical training, nutrition and coping strategies for behaviour change management. The patients spend 14 weeks at the clinic followed by two 1-week visits 16 and 32 weeks postdischarge. Preliminary data from the 166 patients treated during 2006 are given.

INTRODUCTION

The number of obese people in the world has reached epidemic proportions. More than 300 million adults are classified as obese.[1 2] In the USA more than 30% of the population has a body mass index (BMI) >30 kg/m^2.[3 4] Norway has seen a similar phenomenon over the past decade and now almost 20% of the population is obese.[5]

Physical inactivity is a major factor that underpins the prevalence of obesity.[6] The inactivity/obesity epidemic is accompanied by chronic diseases such as type 2 diabetes,[7] cardiovascular disease,[8] some cancers,[9] mental disorders, musculoskeletal diseases, and an increased risk of early death. The number of excess deaths attributable to obesity has been estimated at 30 000 in the UK[10] and 300 000 in the USA[11] Thus, the increased prevalence of inactive/obese persons strains both the primary and secondary health services. In addition, many obese persons drop out of the work force for periods of time and an increased number of people have to retire altogether. Norway aims to combat this inactivity/obesity epidemic for the sake of the affected individuals themselves as well as for society.

Norway is divided into four health regions. Each region has a designated outpatient obesity clinic in the regional hospital; patients see a multidisciplinary team and consider different treatment options. Even though the number of bariatric surgeries is increasing, most patients are treated non-surgically either on an ambulatory basis, or when necessary as inpatients.

Hjelp24 NIMI AS is a private healthcare provider that has a 25-year record of excellence in sports medicine and rehabilitation. The clinic has broad experience in applying exercise as a treatment option in all our medical treatment programmes. As one of the private healthcare providers funded by the Health Region South-East, we started an inpatient programme for the treatment of morbidly obese patients at Hjelp24 NIMI Ringerike in January 2006.

The present paper outlines the programme and gives an interim evaluation of the first year's patients.

PATIENTS

Patients were initially admitted in groups of 55 people. However, in the autumn of 2007, we were given funding to admit groups of 66 people. They are all recruited from the regional obesity clinics in Norway and defined as being morbidly obese (ie, BMI >35 with additional weight related illnesses or a BMI >40 without additional illnesses). To benefit maximally from our treatment, patients have to be independent in activities of daily living and be able to walk (albeit slowly) for around 20 min. The main inpatient programme lasts for 14 weeks. The patients are then discharged and they return for 1 week after 16 and 32 weeks, respectively. They will therefore during the course of the year spend a total of 16 (14+1+1) weeks in our institution. Thus, we presently treat nearly 200 patients per year.

EVALUATION ON ADMISSION

On admission all patients undergo a physical examination and their height and weight is measured on a bioimpedance scale. Weight is registered each week throughout the programme. In addition, patients have their physical capacity evaluated at admission and discharge. This is done using a modified beep test and a walk test. They also fill in a standard set of forms including the Three-Factor Eating Questionnaire (TFEQ), Binge Eating Scale (BES), Hospital Anxiety and Depression Scale, SF36, and the Dartmouth COOP/WONCA chart. Blood is taken and analysed for lipids (total cholesterol, high density lipoprotein and low density lipoprotein cholesterol, and triglycerides), liver function and blood glucose. When necessary other blood analyses are also performed.

TREATMENT PROGRAMME

The treatment programme is focused on three main areas:

(1) physical activity
(2) nutrition
(3) coping strategies.

A typical week programme (week 7 in the 14-week course) is depicted in table 1.

Physical activity

On admission, the majority of our patients have a very low physical fitness. Most have been inactive for years and initial attempts at training typically resulted in 'nothing but aches and pains'. We want patients to increase their fitness to enable them to experience how it feels to be active and in good shape. Our aim is that they can enjoy a physically

Table 1 Week programme for overweight patients (week 7)

Time	Monday	Tuesday	Wednesday	Thursday	Friday
0745–0830	Breakfast	Breakfast	Breakfast	Breakfast	Breakfast
0840–0850	'Kick-off'	'Kick-off'	'Kick-off'	'Kick-off'	'Kick-off'
0900–1000	Nordic pole walking, distance, outdoors (G)	Strength training, circle training, gym (B)	Nutrition lecture, classroom	Nordic pole walking, intervals, campus (R)	Strength training, free weights, gym (B)
1000–1030	Snack	Snack	Snack	Snack	Snack
1100–1200	Bicycling, spinning room (R)	Lecture on diabetes, classroom	Large ball exercises, classroom (B)	Yoga, classroom (G)	Nordic pole walking/ bicycling, outdoors (G)
1230–1315	Lunch	Lunch	Lunch	Lunch	Lunch
1400–1500	Lecture on back problems, classroom	Pilates, classroom (G)	Bicycling, spinning room (B)	Motivation mastering, classroom	Nordic pole walking distance, outdoors (G)
1500–1530	Snack	Snack	Snack	Snack	Snack
1730–1815	Dinner	Dinner	Dinner	Dinner	Dinner
20–2030	Snack	Snack	Snack	Snack	Snack

(G), easy training (level 1); (B), intermediate training (level 2); (R), hard training (level 3).

active lifestyle. Such improvements in physical fitness take time. In our experience, 6–8 weeks are a minimum for patients to stop associating physical activity with pain and anxiety. In addition, it takes several weeks to 'master' technical aspects of different sport activities that they are supposed to continue at home.

Each day, patients participate in two to three training sessions each of which lasts for 45 min. Training occurs in three groups stratified by the results of the admission beep test. Thus, exercise occurs with people who are in reasonably similar physical fitness. For aerobic exercise we mostly use indoor and outdoor bicycling and Nordic pole walking, as well as different dance/aerobic exercises. During the first 2–3 weeks patients undertake low intensity continuous aerobic exercise. As they progress, we gradually introduce interval training and somewhat higher intensity sessions. To control and help the patients follow the predetermined intensity at the different sessions, they use a Polar heart rate watch. Strength training is performed using machines or free weights. We often use a circuit training system. Patients also undertake yoga and Pilates exercises as well as activities with Bosu and fitness balls to improve agility and balance.

In addition, we introduce patients to a variety of different exercise/sport activities in the hope that they will find an activity they can learn to master and enjoy. They then hopefully will keep doing it when they return home. This is important since we believe that a primary determinant of success in keeping up an active life after discharge is that people enjoy physical activity. They should not look upon exercise as "something I have to do to lose weight", but rather as an enjoyable activity; hence, the importance of patients finding an activity that they like.

Nutrition

During the first week, all patients see a psychologist for a semi-structured interview about their relationship with food. Based on information about eating habits and problems identified in these consultations, patients are advised to participate in relevant theme groups and/or offered new appointments with a psychologist/nutritionist during their stay to work on their specific food related problems. As mentioned above, patients complete the TFEQ and BES upon admission, and those who are found to have different eating disorders are treated in smaller groups by our psychologists. Scores from these forms can also help other clinicians (doctor, nutritionist) to pinpoint relevant eating problems.

The whole group is given a nutritional, low calorie diet according to the National Standards in Norway. In addition to being given a nutritionally correct diet they are:

- lectured about different aspects of nutrition in general and especially how to lose or maintain weight. They also learn about the relationship between nutrition and physical exercise
- taught how to prepare nutritionally good meals. This is a practical 'exercise'. They have to make lunch for their training group. This is valuable since many of our patients have the responsibility for preparing meals at home.

Coping strategies

Most obese patients have experienced that keeping up the 'new active lifestyle' for a prolonged period periodically is difficult. Thus, they need to learn coping techniques to help them maintain their change of lifestyle.

They do this in smaller groups under guidance of our psychologists. The thrust in the different groups will vary depending on what each patient feels is his/her greatest challenge. Topics include, but are not limited to, relationship to food, the ability to stick to a plan, as well as interrelation with others.

An initial inpatient stay of 14 weeks may seem long. However, our patients are basically required to make dramatic changes in their lifestyle to be successful in losing weight and maintaining their new weight. Such processes take time. They are supposed to get in reasonable shape, they must learn activities that they can keep up at home, and acquire techniques that enable them to manage a change of lifestyle. Many of them also will have to change their eating habits. In our experience 14 weeks is appropriate for such an endeavour.

The patients are then readmitted for two 1-week control stays 16 and 32 weeks after discharge. During these two control weeks the main point is to 'refresh' their motivation for exercise and diet. Also , especially during the latter week, there is a demand for further information about coping techniques since many of them have experienced how hard it is to change lifestyle once they return home from the first 14-week stay. In between the control stays the patients are followed up according to a structured plan either by phone or by email.

After the routine stays of 14+1+1 weeks the patients have the option to come in for a brief follow-up stay/seminar lasting a few days twice a year. They will then be there with patients from other groups and they may get to share their experiences with a larger patient base.

PRELIMINARY RESULTS

In our first year (2006) 114 women and 52 men came through the programme. Fifty-one per cent were married or cohabitant, 28% were single, and 20% divorced. Regarding employment status, 42% were on disability pension, 25% were on partial or total sick leave, and 31% were working (23% full time, 8% part time basis). Two per cent were homemakers. The number of years of education following elementary school averaged 4.5±3.8 years. Altogether 42 patients (16 in OV1, 11 in OV2 and 15 in OV3) had diabetes. Of these 11 were treated with insulin injections; the other 31 were treated with oral hypoglycaemic agents. It can be seen from table 2 that the group as a whole had fairly normal blood pressure, lipid values, blood glucose and liver function.

Of the 166 patients, 106 (64%) attended the first 1-week control stay while 111 (67%) attended the second. Thus, about 35% of patients did not attend the control stays. It should be noted that the absentees were not always the same during these control weeks. We have at the present time no hard information regarding why these patients failed to attend. Thus, more studies are needed to establish whether the failure to attend was due to the patients not being able to maintain their weight loss, or whether they were simply unable to attend for other reasons—they were working, they had family engagements, etc. It should be mentioned that we have managed to increase the number of participants in the control weeks for the patients enrolled the last 2 years. This has been obtained in part by underscoring the importance of 'staying the course' but also and perhaps more important through reports from earlier patients who claim that these two control weeks are important for the long term success.

The mean weight changes are depicted in table 3. The groups lost on average 12% of their bodyweight during the 14 weeks' stay. This seems to be at the upper limits of what is found in the literature.[12] There was no difference between men and women. There was a trend towards the heaviest patients losing more weight. The mean weight was maintained after 1 year. This has been shown in other studies as well.[12] However, 35% of our patients did not attend the control stay. These patients may in theory have gained weight and thus increase the group mean. Of the 111 patients we did see at control week 2, only six weighed more than at admittance.

If we define success for an individual as loss of 10% or more of bodyweight and maintaining it for up to a year, the success rate was 44%. We have then classified all patients who did not attend the control weeks as unsuccessful. This probably tends to underestimate the success rate. The mean BMI on admission was 45.8±8.6 and at discharge 40.3±6.6. After a year (at control week 2) the mean BMI was 39.8±6.5.

Ten patients had had bariatric surgery at a time before their clinic admittance; most of these were performed during the 1980s. Following the treatment year, a further 13 of the patients underwent bariatric surgery. Eleven patients have been admitted to our clinic for a second treatment of 14+1+1 weeks during one of the following 2 years.

Table 2 Demographic parameters on admittance of groups 1–3 during 2006 (n=166)

Age (years)	42.1±10.6
Height (cm)	172±9
Weight (kg)	136.0±22.7
BMI (kg/m^2)	45.7±8.6
Blood pressure (mm Hg)	137/85±16/8
Total cholesterol (mM)	4.5±0.9
LDL cholesterol (mM)	2.8±0.8
HDL cholesterol (mM)	1.1±0.3
Triglycerides (mM)	1.33±0.6
AST (U/l)	32±16
ALT (U/l)	42±21
Fasting blood glucose (mM)	5.9+1.9

Values are presented as mean±SD.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; HDL, high density lipoprotein; LDL, low density lipoprotein.

Table 3 Weight changes (kg) for groups 1–3 during 2006 (n=166)

Time	Weight (kg)
At admittance (n=166)	136.0±22.7
At discharge (after 14 weeks) (n=106)	119.5±23.5
At 2nd control stay (1 year after initial admittance) (n=111)	118.4±13.6

Values are presented as mean±SD.

WHAT HAVE WE LEARNT?

In the opinion of our trainers all the patients trained hard. Two to three training sessions daily is quite considerable compared with these persons' prior activity. We had feared that such increased physical activity would result in a high number of injuries, but we have seen very few. Admittedly, many patients complain about pains and aches during the initial weeks, but very few have to be seen by the doctor and even fewer abstain from training. And after 6–8 weeks, the vast majority report that they thoroughly enjoy the exercise sessions. Many of them also point out that following their 14-week stay, they are able to enjoy physical activity at home for the first time in decades. Thus, one lesson has been that it is indeed possible to get morbidly obese patients to increase their physical fitness and through that enjoy physical activity—but it takes time.

Another aspect worth noting is that our patients report back that one important factor behind this 'success' is that fact that the training took place in groups with other people having the same challenge.

Regarding the nutrition part, the lesson learnt so far tells us that patients struggle with a variety of challenges related to food and nutrition. These include the amount of food, type of food, food preparation, eating for comfort or for reward, time, economy, etc. For many patients these problems are a major hurdle to their success in losing weight and must be dealt with.

Another important lesson is that most patients tend to underestimate the practical difficulties they encounter when they return home following our 14-week treatment. Thus, during our two control weeks, and especially during the last one, they realise they need more information and knowledge about coping techniques to enable them to maintain their new lifestyle. Having access to skilled psychologists who can focus on coping and motivational strategies is therefore a success criterion.

The programme is extensive. Being away from home for 14+1+1 weeks is quite long. For some patients, however, the primary stressors in connection with their weight problem are located in their home environment. For these patients spending 14 weeks at our clinic may represent a 'fresh start'. Other

What is already known on this topic

- The number of obese persons is increasing worldwide. Most obese people are also physically inactive; and the inactivity is said to be the main cause for their many 'weight-related' chronic diseases.
- Non-surgical treatment of obesity has traditionally been focused on diet and exercise. It may result in weight loss, but a vast majority of patients regain their weight after such intervention.
- The main problem seems to be in helping patients to maintain a change in lifestyle for prolonged periods of time.

What this study adds

- This study shows that, even initially, almost completely untrained obese people can manage an aggressive physical training programme with two to three sessions every day. Very few injuries occur, and the participants get in much better shape.
- Following the programme our patients report that they 'enjoy' physical activity—for many, for the first time in their life. When combined with a nutritionally sound diet and instruction in coping techniques, the patients lose weight at a rate of about 1 kg per week. Close to a half will have a 10% weight loss which they will maintain for a year.
- The main challenge following our programme is for the patients to keep up the change in life style. A systematic follow-up regimen in addition to psychological help with coping techniques will help patients succeed in keeping up an active lifestyle.

patients with a more supportive home environment can be treated on an ambulatory basis provided the travel to the outpatient clinic is not too long. The patients who at the start of the treatment are working, must obtain a leave of absence from their work. However, in Norway a majority of these patients either have or are on the verge of dropping out of the workforce. Many therefore see our programme as a 'last chance' to stay employed. All in all we therefore feel that the patients in our programme are representative of the morbidly obese patients in our country.

Competing interests None.

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Paper II

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Clinical Study

Changes in Body Composition, Cardiovascular Disease Risk Factors, and Eating Behavior after an Intensive Lifestyle Intervention with High Volume of Physical Activity in Severely Obese Subjects: A Prospective Clinical Controlled Trial

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We examined the effects of a 10–14-weeks inpatient lifestyle modification program, including minimum 90 min of physical activity (PA) five days/week, on body composition, CVD risk factors, and eating behavior in 139 obese subjects (BMI 42.6 ± 5.2 kg/m^2). Completion rate was 71% ($n = 71$) in the intensive lifestyle intervention (ILI) group and 85%($n = 33$) among waiting list controls. Compared to controls body weight (−17.0 (95% CI: −18.7, −15.3) kg, $P < 0.0001$), fat mass (−15.2 (95% CI: −17.4,−13.1) kg, $P < 0.0001$), fat free mass (−1.2 (95% CI: −2.2, −0.2) kg, $P = 0.016$) and visceral fat (−86.6 (95% CI: −97.4, −75.7) cm^2, $P < 0.0001$) were reduced in the ILI-group after 10–14 weeks. Within the ILI-group weight loss was −23.8 (95% CI: −25.9, −21.7) kg, $P < 0.0001$ and −20.3 (95% CI: −23.3, −17.3) kg, $P < 0.0001$, after six and 12 months, respectively. Systolic BP, glucose, triglycerides, and LDL-C were reduced, and HDL-C was increased (all $P \leq 0.006$) after 10–14 weeks within the ILI group. The reduction in glucose and increase in HDL-C were sustained after 12 months (all $P < 0.0001$). After one year, weight loss was related to increased cognitive restraint and decreased uncontrolled eating (all $P < 0.05$). Thus, ILI including high volume of PA resulted in weight loss with almost maintenance of fat-free mass, favorable changes in CVD risk factors, and eating behavior in subjects with severe obesity.

1. Introduction

Severe obesity (SO: BMI ≥ 40 kg/m^2 or BMI 35–39.9 kg/m^2 combined with at least one weight-related comorbidity) is associated with a high prevalence of comorbidities as well as high mortality rates and represents a significant public health concern [1–3]. The main goals in the treatment of SO are to reduce comorbidity and mortality. Reduction of fat mass (FM), especially visceral fat area (VFA), and maintenance of fat-free mass (FFM) may lead to improvements in obesity-related cardiovascular disease (CVD) risk factors [4] and minimize the decrease in resting energy expenditure (REE) following weight loss [5–9].

In subjects with a BMI < 35 kg/m^2 physical activity (PA) and cardiorespiratory fitness have been shown to reduce morbidity and CVD mortality [10–13]. Despite minimal weight loss, favorable changes in body composition (BC) by PA have been demonstrated [14–16], and increased PA is recommended for weight loss maintenance [17, 18]. The mechanisms for the influence of PA on weight loss maintenance are not fully understood, but in addition to PA affecting weight directly through energy expenditure, increased sensitivity for satiety signals and increased inhibitory control of the drive to eat may be involved [19]. However, subjects with SO often experience difficulties with PA due to increased body weight (BW), reduced mobility, and medical problems [20–23]. Some

subjects with SO therefore feel that surgery-induced weight loss is necessary for them to increase their PA level [21]. In line with this, it has been claimed that exercise programs may be unhelpful in the treatment of subjects with SO [24]. On the other side, subjects with SO have also reported that they like being physically active and have positive experiences with adapted PA [20–22]. Exercising together with other SO subjects and being introduced to adapted exercises and special equipment may be of great importance in order for this population to increase compliance in PA interventions [21, 23].

Both day and inpatient lifestyle interventions cause clinically meaningful weight loss (≥5–10%) the first year after treatment of patients with SO [25–30]. However, data on changes in BC after an inpatient intervention are sparse [31]. Also, none of the previously published studies have included a nontreated control group. One advantage of inpatient treatment, with all PA being mandatory, is that the PA level can more easily be controlled, and attendance can be used as a measure of compliance.

The primary aim of this nonrandomized clinical controlled trial was to examine the effects of a 10–14-week inpatient lifestyle modification program, including minimum 90 min of PA five days per week, on BC: BW, FM, FFM, and VFA in SO men and women. Secondly, we wanted to investigate changes in CVD risk factors within the intervention group and also observe whether changes in BC and CVD risk factors were maintained at six- and 12-month followup from baseline. Moreover, we studied the possible influence of the intensive lifestyle intervention on appetite regulation by an assessment of eating behavior.

2. Materials and Methods

2.1. Study Design. This study was conducted from September 2010 to March 2012. The first part of the study was a nonrandomized controlled clinical trial. The intervention was a predefined comprehensive inpatient lifestyle intervention (ILI) for the treatment of men and women with SO provided by The NIMI Ringerike obesity clinic in Norway. A control group with subjects referred to the clinic, but still on waiting list to start the treatment program, was included in the study, and the group was followed for a time period comparable to the intervention. The controls received no treatment from the clinic during the intervention period. In the second part we prospectively followed the subjects in the ILI group for a one-year period. The design and flow schedule of the study are shown in Figure 1. The program consisted of one 14-weeks inpatient program, which was shortened to 10 weeks during the study. The subjects were then discharged and returned to the clinic for one week of inpatient followup at approximately six and 12 months after the start of the inpatient program. Data were collected at the start (week 0) and the end (weeks 10–14) of the main inpatient treatment program, and at the two follow-up weeks (six and 12 months). The Regional Committee for Medical and Health Research Ethics in Norway approved the protocol, and all the participants provided written informed consent. The study meets the standards of the Declaration of Helsinki and is registered in the ClinicalTrial-registry under the unique trial number NCT01675713.

2.2. Study Sample. The study sample consisted of patients referred to the clinic from tertiary care obesity centers when weight loss of clinical importance was not achieved in less-intensive treatment programs in primary or secondary care. The inclusion criteria for participation in the treatment program were BMI ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 with comorbidities at the time of referring, age between 18 and 65 years, and that the subjects had to be able to walk slowly for approximately 20 minutes. Some subjects left the treatment within the first few days. Hence to be enrolled in the study, participants in the ILI group had to fulfill the main inpatient treatment program. The controls were continuously recruited as they were referred to the waiting list. Exclusion criteria for enrollment in the study were pregnancy or participation in previous treatment programs at the clinic. Of the 149 subjects eligible for the study, a total of 139 (100 in the ILI-group and 39 in the control group) were enrolled. A flow chart of the participants is shown in Figure 2. The completion rate was 71% ($n = 71$) in the ILI-group and 85% ($n = 33$) in the control group.

2.3. Intervention

2.3.1. Main Inpatient Treatment Program. A multidisciplinary team including a medical doctor, a psychologist, a clinical nutritionist, nurses, exercise scientists, and physiotherapists provided the ILI. During the 10–14-week inpatient program the subjects were living at the clinic. From week 4 the subjects were allowed to go home for the weekends. All subjects received the same inpatient intensive lifestyle modification program focusing on increasing the PA level, adjusting energy and nutrition intake, and learning coping strategies. Details regarding the program used in this study have been published previously [32]. Both theoretical and practical lessons were provided. During the inpatient periods the subjects participated in two to three mandatory training sessions during the weekdays, each lasting for a minimum of 45 min and supervised by exercise scientists and physiotherapists. Aerobic, strength, agility, and balance training were all included in the training program, as well as different sport activities, games, walking tour, and a day trip. Duration and intensity of the training sessions were gradually progressed. In addition most participants conducted training sessions (e.g., brisk walking) on their own before breakfast and in the evenings, and they were encouraged to work out in the weekends. Regarding dietary intake breakfast and lunch were served as buffets and dinner at plates, whereas the three between-meal snacks were free options of fruit, vegetables, or yoghurt. Portion sizes according to restricted energy levels (1900 kcal/d for men and 1600 kcal/d for women) were demonstrated in the eating room by nutritionists. The macronutrient composition of the diet was planned to be <30 E% from fat, ~20 E% from protein, and 50–60 E% from carbohydrates. In addition the subjects were offered a minimum of 2 × 30 min individual dietary nutritional consultations. Moreover, all subjects attended

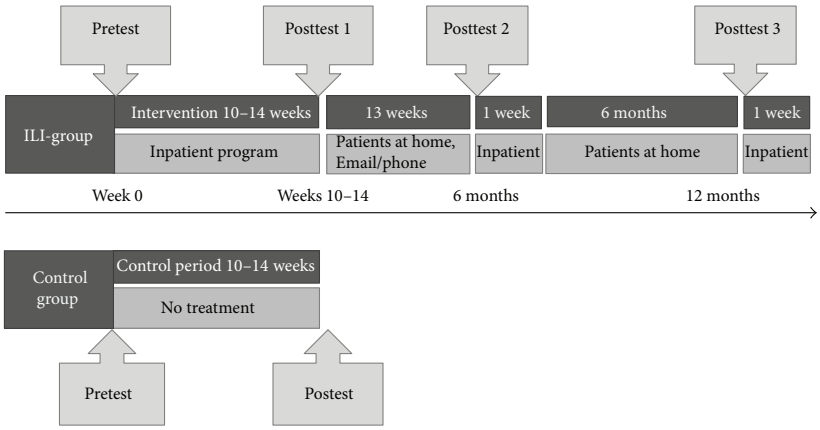

Figure 1: The schedule of the nonrandomised controlled clinical trial and the prospective follow-up study; participant recruitment, assessments, and stays during the lifestyle programme at NIMI Ringerike.

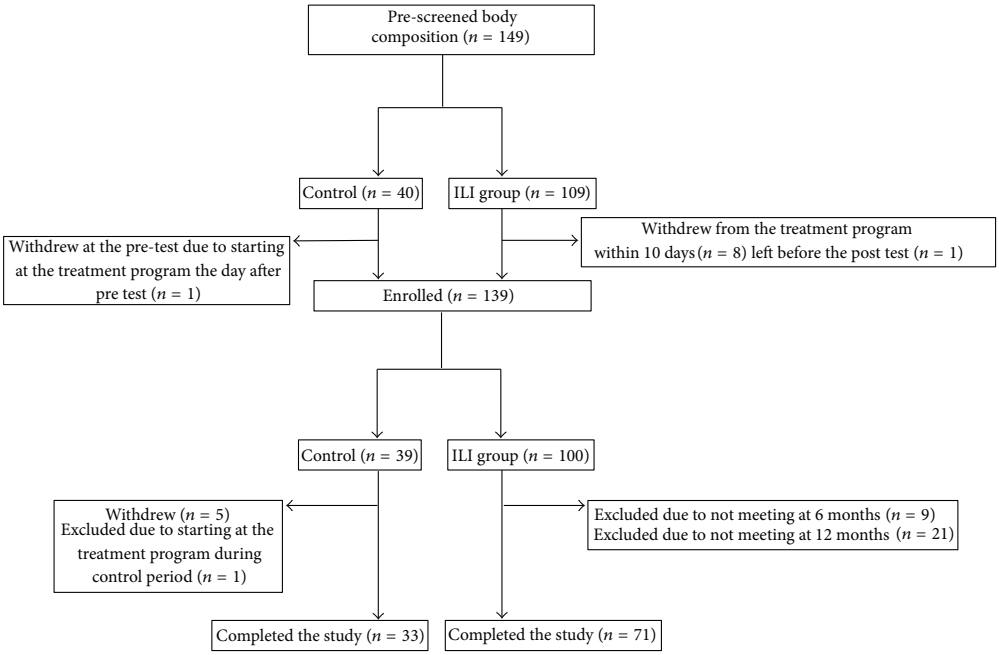

Figure 2: Flow of participants throughout the study.

group session including instructions and practice in methods for behavior modification and coping strategies. The purpose of the course was to help subjects change and sustain their change of lifestyle after finishing the program after hospitalization. The methodological elements were short-term goal setting with specific tasks (in physical activity and nutrition), problem solving, and evaluation. The subjects were also offered individual consultations with a psychologist when needed.

2.3.2. Followup. Followup between the main inpatient program and six months was not structured and was of individual choice (phone calls or e-mail communications). No formal followup between six and 12 months was provided.

During the two inpatient follow-up weeks after six and 12 months reminders of coping techniques were given, and the subjects' motivation for exercise and healthy eating was refreshed.

2.4. Measurements

2.4.1. Body Composition. All anthropometric measures were assessed with subjects wearing light clothing without shoes. BC was measured using direct segmental multifrequency (DSM) bioelectrical impedance (Inbody 720, Body Composition Analyzer, Biospace Co. Ltd.), after standardized procedures including a minimum of 2-hour fasting and no drinking or hard training prior to the test. The eight-polar BIA Inbody used in the present study is shown to offer accurate estimates of total body water and extracellular water in SO women with a BMI up to 48.2 kg/m^2 [33]. Repeated measurements were conducted at approximately the same time of the day for each subject. Height was measured in a standing position at baseline, and this measure was used to calculate BMI (kg/m^2).

2.4.2. Cardiovascular Disease Risk Factors. Blood samples were collected between 7 and 8 a.m. after an overnight fast and analyzed for triglycerides (TG), serum glucose, total, low-density lipoprotein (LDL), and high-density lipoprotein (HDL) cholesterol (mmol/L) using standard laboratory techniques at Ringerike hospital; Vestre Viken Hospital Trust, 3004 Drammen, Norway. Blood pressure (BP: mmHg) was measured once in sitting position after 5–10-minute rest, using the Reister, big ben round apparatus, cuff size large (arm size 33–41). A medical doctor registered the use of blood pressure-, lipid-, or glucose-lowering medication at baseline. Metabolic syndrome was defined according to the modified ATP III criteria [34]. Waist circumference (WC) was measured at the level of the narrowest point between the lower costal (10th rib) border and the iliac crest [35]. Only subjects with measurement of all the five diagnosis criteria of the metabolic syndrome (i.e., elevated WC, TG, BP, fasting glucose, and reduced HDL) at all four measurement times were included in the analyses ($n = 52$). The use of medication was only recorded at baseline; therefore subjects taking antihypertensive or blood glucose reducing pharmacotherapy were defined with elevated BP and fasting glucose, respectively, in the categorization of metabolic syndrome at all four measurement times.

2.4.3. Eating Behavior. The 21-item Three-Factor Eating Questionnaire (TFEQ-R21) was used in the assessment of eating behavior. The TFEQ-21 comprises 21 items and covers three eating behavior scales ranging from 0 to 100: cognitive restraint (CR: the tendency to control food intake in order to influence body weight and body shape), uncontrolled eating (UE: the tendency to lose control over eating when feeling hungry or when exposed to external stimuli) and emotional eating (EE: the propensity to overeat in relation to negative mood states, e.g., when feeling lonely, anxious, or depressed). Higher scores indicate more restraint, uncontrolled, and emotional eating [36].

2.4.4. Exercise Capacity. As a measure of compliance, changes in exercise capacity were monitored within the ILI-group using the 10-metre shuttle run test [37, 38] and time spent on a 750-metre walk/run test before and after the 10–14-week inpatient period.

2.5. Statistical Analysis. Data are reported as mean (standard deviation), or (95% CI), or number (%). Independent samples t-tests, Mann-Whitney U test, and Chi-square were used as appropriate to compare groups. Likewise, paired samples t-tests and Wilcoxon rank tests were used to assess changes within the ILI group. All tests were two sided, and statistical significance was accepted when $P < 0.05$. There was little change in the P values, and hence there was no change in the conclusion, using nonparametric tests. Data are therefor reported as mean (standard deviation), or (95% CI), or number (%), and P values from parametric tests unless stated otherwise. Repeated measurement general linear model (GLM) was used to assess within group changes in CVD risk factors, with adjustment for gender, age, and use of relevant medicine (i.e., blood pressure-, lipid-, or glucose-lowering medication) at baseline, whereas Cochran's Q test was used to assess change in the proportion of participants diagnosed with metabolic syndrome across the four measurement time points: week 0, weeks 10–14, six, and 12 months. Only subjects with measurement at all four measurement times were included in the analysis for each variable. Regression analysis was performed using univariate GLM; changes in weight were used as dependent variables, and changes in eating behavior as independent variables. Subjects with measurement at the two measurement times were included in the analysis for each change period. Drop-out analysis within the ILI-group showed no significant differences in any of the baseline characteristics between the completers and noncompleters, or in weight reduction from week 0 to week 10–14 (data not shown). However, subjects who dropped out during followup had a smaller BW reduction than the completers between weeks 10–14 and six months (−3.8 (95% CI: −6.2 to −1.3) kg, $P = 0.003$). Data were analyzed using SPSS software version 18 (SPSS Inc, Chicago, IL, USA).

2.5.1. Power Analysis. Based on the results from the treatment group a priori power analysis was performed to determine the sample size of the control group to detect differences between the groups. The acute weight loss for the treatment group was ~17 kg (13.5%), and with α fixed level at 0.05 and a power set at 0.80 a minimum of 40 participants in the control group would be required to investigate both 5% and 10% weight reduction in the ILI-group compared to the control group, allowing for a 3.5 kg weight loss in the control group due to the placebo effect/changing in lifestyle on their own.

3. Results

3.1. Baseline Characteristics. Baseline characteristics of the participants who completed the study are shown in Table 1. The ILI-group was older than the control group, but no other

Table 1: Characteristics of participants and body composition at baseline in the intensive lifestyle intervention (ILI) group and control group. Data are given as mean values (standard deviation) or number of subjects and percentages.

	ILI ($n = 71$)		Control ($n = 33$)		P value
	N	%	N	%	
Female/male	42/29	59.2/40.8	21/12	63.6/36.4	0.663[a]
Age (year)	45.2 (9.5)		38.5 (9.8)		0.001[b]
Height (cm)	173.2 (8.6)		172.3 (10.4)		0.626[b]
Body mass index (kg/m^2)	42.8 (4.6)		42.8 (6.3)		0.983[b]
Body weight (kg)	128.9 (19.4)		127.1 (21.6)		0.680[b]
Fat mass (kg)	60.5 (11.0)		60.4 (13.5)		0.986[b]
Fat-free mass (kg)	68.3 (13.2)		67.1 (12.8)		0.676[b]
Skeletal muscle mass (kg)	38.4 (7.9)		37.9 (7.4)		0.760[b]
Visceral fat area (cm^2)	255.7 (64.7)		245.6 (66.3)		0.464[b]
Highest education					
Primary and/or secondary school	8[c]	12.9	7	21.2	0.178[a]
High school	32[c]	51.6	20	60.6	
Higher education	22[c]	35.5	6	18.2	
Employment (full-time job)	34[d]	52.3	16[e]	50.0	0.831[a]
Current smoker (yes)	15[f]	23.4	6	18.2	0.552[a]

[a]Chi-square; [b]independent-samples t test; [c]$n = 62$, [d]$n = 65$, [e]$n = 32$, [f]$n = 64$.

significant differences between the two study groups were seen at baseline.

3.2. Between-Group Changes in Body Composition. Compared to the control group, reductions in all BC variables were seen in the ILI-group from baseline to weeks 10–14 (Table 2 and Figure 3).

3.3. Changes in Weight and Body Composition within the ILI-Group. Changes in BC within the ILI-group at weeks 10–14, six, and 12 months are shown in Table 3. After six- and 12-month followup BW reduction was −23.8 ((95% CI: −25.9, −21.7) kg, $P < 0.0001$) and −20.3 ((95% CI: −23.3, −17.3) kg, $P < 0.0001$), respectively, compared with baseline. Within the ILI-group, the mean (SD) percentage weight loss at 12 months was 15.6% (9.2%), and VFA and FM were reduced by 30.8% (21.1%) and 28.8% (17.4%) compared to baseline, respectively, (Figure 3).

The proportions of subjects in the ILI-group achieving ≥5%, 10%, 15%, and 20% reduction of their initial weight, respectively, are shown in Table 4.

Figure 4 shows the development in BMI of each subject in the ILI-group. Fifty-two (73.2%) of the subjects had BMI ≥ 40.0 kg/m^2 at week 0, and 51 (71.8%) had BMI < 40.0 kg/m^2 at 12-month followup.

3.4. Changes in Cardiovascular Disease Risk Factors, Metabolic Syndrome, and Exercise Capacity within the ILI-Group. At baseline a total of 27 (38.0%), eight (11.3%), and six (8.5%) in the ILI-group were using blood pressure-, lipid- and glucose-lowering medication, respectively. Changes in CVD risk factors and exercise capacity within the ILI-group are shown in Tables 5 and 6. The prevalence of metabolic syndrome was reduced significantly ($P < 0.0001$) within the ILI-group across the four time points (Figure 5).

3.5. Eating Behavior before and after Intervention. Group comparisons of scores on the TFEQ-R21 showed no differences in eating behavior at baseline (Table 7). Eating behavior in the ILI-group and controls prior to and after treatment is shown in Figure 6. Together these changes resulted in a significant reduction in UE and EE ($P = 0.033$ and $P < 0.0001$) and increase in CR ($P < 0.0001$) scores from week 0 to 12 months of followup within the ILI-group, where the main changes occurred during the intervention period and remained quite stable thereafter.

Table 8 shows the univariate GLM analysis with respect to changes in weight and eating behaviour, respectively.

4. Discussion

The major findings of this study were that men and women with SO reduced FM and VFA, with a minimal reduction in FFM, during an intensive lifestyle intervention including a minimum of 90 minutes of PA five days a week. The main changes in BC occurred during the 10–14 weeks of the intervention period. The changes remained quite stable during followup and almost 50% achieved ≥15% weight reduction at 12 months.

We found that BW decreased by 1.5 kg per week during the intervention. This is in line with other studies investigating inpatient treatment programs for SO subjects [25, 31] but greater than reported following outpatient treatment programs [25, 27, 28]. The important finding in this study was that FFM was almost maintained during weight loss. In the present study the minimum amount of PA was 90 minutes five days per week and the reduction in FFM accounted for 10% of total weight loss during the intervention period. The amount of PA was higher in our study as compared to the five training sessions of 30–40 minutes per week reported by Maffiuletti et al. [31] and the 60-minutes sessions five

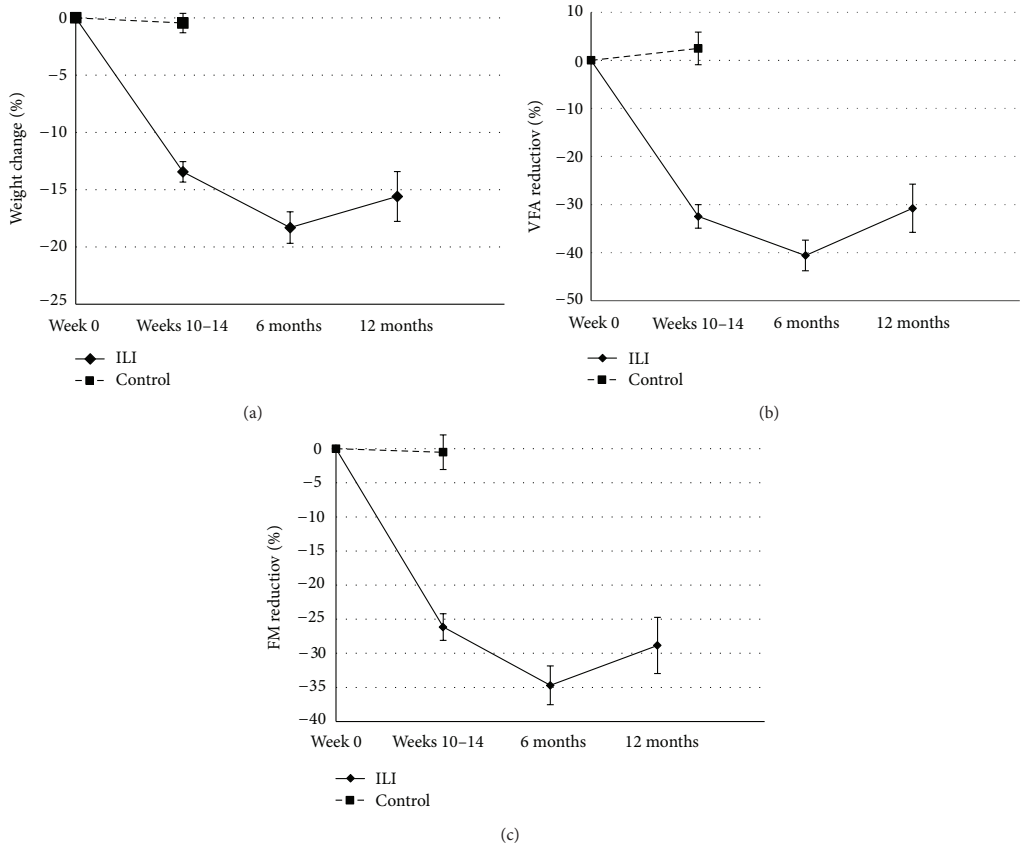

Figure 3: (a) Mean (95% CI) percentage weight loss during followup. (b) Mean (95% CI) percentage reduction in VFA during followup. (c) Mean (95% CI) percentage reduction in FM during followup.

Table 2: Between-group differences in changes in body composition from week 0 to weeks 10–14. Data are mean values (standard deviation or 95% CI).

	ILI ($n = 71$)	Control ($n = 33$)	Between-group differences, mean (95% CI)	P value[a]
Body mass index (kg/m^2)	−5.8 (1.8)	−0.2 (1.0)	−5.6 (−6.2, −5.1)	<0.0001
Body weight (kg)	−17.5 (6.1)	−0.5 (2.8)	−17.0 (−18.7, −15.3)	<0.0001
Fat mass (kg)	−15.7 (5.3)	−0.4 (5.0)	−15.2 (−17.4, −13.1)	<0.0001
Fat-free mass (kg)	−1.7 (2.5)	−0.5 (2.1)	−1.2 (−2.2, −0.2)	0.016
Skeletal muscle mass (kg)	−1.2 (1.5)	0.2 (3.6)	−1.4 (−2.4, −0.4)	0.005
Visceral fat area (cm^2)	−82.3 (31.6)	4.3 (22.7)	−86.6 (−97.4, −75.7)	<0.0001

[a]Independent samples t-test.

days a week reported by Goodpaster et al. [27]. Loss of FFM constituted 24% and 22% of total BW reduction, respectively, in these studies. In addition, the total loss of BW and FM in our study at six months was twice the reductions reported by Goodpaster et al. However, the reduction in kg FFM was almost the same. Taken collectively it seems that a minimum of 90 minutes of PA five days per week may be necessary during a weight reduction period to maintain FFM in SO subjects.

Maintenance of FFM is of particular importance in obesity treatment in order to minimize the reduction in energy expenditure seen after weight loss [5, 7–9, 39–41]. Skeletal

Table 3: Change in body composition from week 0 to 12 months within the ILI group ($n = 71$).

	Mean change (95% CI) Week 0 to 12 months	P value[a]	Mean change (95% CI) Week 0 to weeks 10–14	P value[a]	Mean change (95% CI) Weeks 10–14 to six months	P value[a]	Mean change (95% CI) Six to 12 months	P value[a]
Body mass index (kg/m^2)	−6.7 (−7.6, −5.7)	<0.0001	−5.8 (−6.2, −5.4)	<0.0001	−2.1 (−2.5, −1.7)	<0.0001	1.2 (0.7, 1.7)	<0.0001
Body weight (kg)	−20.3 (−23.3, −17.3)	<0.0001	−17.5 (−18.9, −16.1)	<0.0001	−6.3 (−7.5, −5.1)	<0.0001	3.5 (2.0, 5.1)	<0.0001
Fat mass (kg)	−17.5 (−20.1, −14.9)	<0.0001	−15.7 (−17.0, −14.4)	<0.0001	−5.2 (−6.2, −4.1)	<0.0001	3.4 (2.1, 4.7)	<0.0001
Fat-free mass (kg)	−2.8 (−3.6, −2.0)	<0.0001	−1.7 (−2.3, −1.2)	<0.0001	−1.1 (−1.5, −0.7)	<0.0001	0.1 (−0.3, 0.6)	0.585
Skeletal muscle mass (kg)	−1.7 (−2.2, −1.3)	<0.0001	−1.2 (−1.6, −0.9)	<0.0001	−0.7 (−0.9, −0.5)	<0.0001	0.2 (−0.1, 0.5)	0.225
Visceral fat area (cm^2)	−81.0 (−95.3, −66.7)	<0.0001	−82.3 (−89.8, −74.8)	<0.0001	−22.0 (−28.1, −15.9)	<0.0001	23.3 (15.5, 31.1)	<0.0001

[a]Paired samples t-test.

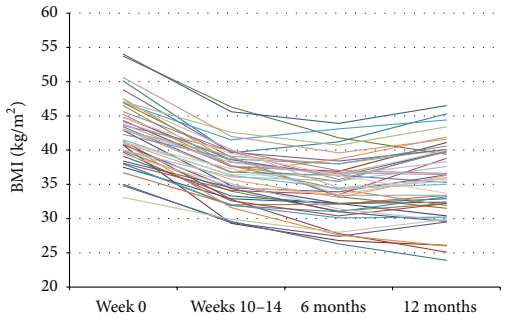

Figure 4: BMI value for each subject within the ILI-group at week 0, week, 10–14, six, and 12 months. Note: two subjects had a BMI < 35 kg/m^2 at week 0 due to a small weight reduction between the time of referring and the start of the treatment program.

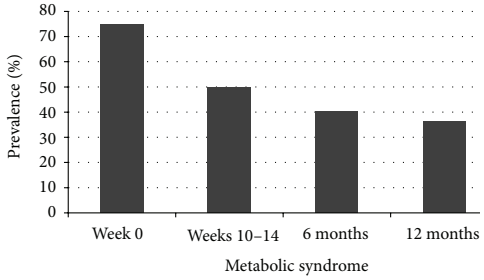

Figure 5: The prevalence of metabolic syndrome within the ILI-group at week 0, weeks 10–14, six, and 12 months ($n = 52$). $P < 0.0001$ for change in the proportion of participants diagnosed with metabolic syndrome across the four measurement time points (Cochran's Q test).

muscle mass (SMM) was reduced by about 0.1 kg per week during the intervention period and accounted for 71% of the reduction in FFM. Despite the strength training included in our ILI, no increase in SMM was observed. This may be due to the negative energy balance [42, 43], lower BW and hence less stimulation for muscle growth in the lower limbs. However, an increase in muscle growth was not the aim of the strength training program/exercises used in our intervention program.

Table 4: Subjects in the ILI-group achieving ≥5%, 10%, 15%, and 20% weight loss from initial weight at weeks 10–14, six, and 12 months. Data are number of subjects (percentage).

	Weeks 10–14	Six months	12 months
≥5% weight loss	71 (100.0%)	71 (100.0%)	65 (91.5%)
≥10% weight loss	57 (80.3%)	67 (94.4%)	48 (67.6%)
≥15% weight loss	20 (28.2%)	21 (29.6%)	35 (49.3%)
≥20% weight loss	4 (5.6%)	27 (38.0%)	19 (26.8%)

In the present study, a decrease of 30% in VFA was achieved at weeks 10–14 and maintained at 12 months. This might be explained by the high volume of exercise included in our study, as a dose-response relationship between amount of exercise and the improvements in central obesity has been shown in less obese subjects [15, 44]. A significant reduction in the prevalence of metabolic syndrome was observed within the ILI-group during the study. Furthermore we observed significant favorable changes in most CVD risk factors following the inpatient period; the exception being diastolic BP and total cholesterol. However, we found an increase in HDL cholesterol and a decrease in the level of glucose, changes that remained significant at 12 months. This is in accordance with the increase in HDL cholesterol seen in SO subjects reporting PA energy expenditure of 450 kcal min per day after a mean weight loss of 45 kg [45]. Thus the high level of PA may be partly responsible for the favourable changes in these metabolic risk factors. The observed lack of sustained improvements in the other CVD risk factors has also been reported by others [27, 31] and may be due to low baseline comorbidity. Moreover, changes in the use of medication may also have influenced the results as supported by the decrease in systolic and diastolic BP seen at 12-month follow up among the subjects not using BP-lowering medication.

Table 5: Change in values for cardiovascular disease risk factors within the ILI-group. Data are mean values (SD or 95% CI).

	Mean Week 0	Mean change Week 0 to 12 months	*P* value	Mean change Week 0 to weeks 10–14	*P* value	Mean change Weeks 10–14 to six months	*P* value	Mean change Six to 12 months	*P* value
s-BP (mmHg)									
All (n = 57)	132.3 (10.7)	−2.8 (−6.0, 0.4)	0.082[a]	−6.4 (−9.1, −3.7)	<0.0001[a]	1.1 (−1.7, 4.0)	0.431[a]	2.5 (−0.5, 5.4)	0.097[a]
No blood pressure lowering (n = 37)	130.4 (8.8)	−3.8 (−6.9, −0.7)	0.018[b]	−5.4 (−8.4, −2.4)	0.001[b]	0.3 (−3.2, 3.8)	0.877[b]	1.4 (−1.7, 4.4)	0.368[b]
d-BT (mmHg)									
All (n = 57)	83.7 (6.1)	−1.8 (−4.0, 0.3)	0.094[a]	−1.3 (−3.2, 0.6)	0.175[a]	−2.0 (−4.3, 0.3)	0.088[a]	1.5 (−0.7, 3.7)	0.173[a]
No blood pressure lowering (n = 37)	83.2 (5.4)	−3.5 (−6.3, −0.7)	0.015[b]	−2.8 (−5.0, −0.7)	0.012[b]	−2.3 (−5.2, 0.6)	0.112[b]	1.6 (−1.2, 4.4)	0.245[b]
GLUC (mmol/L)									
All (n = 58)	5.8 (1.3)	−0.5 (−0.7, −0.3)	<0.0001[a]	−0.7 (−0.9, −0.5)	<0.0001[a]	0.1 (−0.1, 0.2)	0.258[a]	0.1 (0.0, 0.3)	0.150[a]
No glucose lowering (n = 54)	5.6 (0.8)	−0.4 (−0.6, −0.2)	<0.0001[b]	−0.6 (−0.8, −0.4)	<0.0001[b]	0.1 (−0.1, 0.2)	0.260[b]	0.1 (−0.1, 0.2)	0.300[b]
HDL (mmol/L)									
All (n = 60)	1.1 (0.3)	0.3 (0.3, 0.4)	<0.0001[a]	0.1 (0.0, 0.1)	0.001[a]	0.2 (0.1, 0.2)	<0.0001[a]	0.1 (0.0, 0.2)	0.001[a]
No lipid lowering (n = 52)	1.1 (0.3)	0.3 (0.3, 0.4)	<0.0001[b]	0.1 (0.0, 0.1)	0.002[b]	0.2 (0.1, 0.2)	<0.0001[b]	0.1 (0.0, 0.2)	0.004[b]
LDL (mmol/L)									
All (n = 59)	2.9 (0.9)	0.4 (0.2, 0.6)	<0.0001[a]	−0.2 (−0.3, −0.1)	0.005[a]	0.3 (0.2, 0.4)	<0.0001[a]	0.3 (0.2, 0.4)	<0.0001[a]
No lipid lowering (n = 51)	3.1 (0.8)	0.3 (0.1, 0.5)	0.002[b]	−0.3 (−0.4, −0.1)	<0.0001[b]	0.2 (0.1, 0.3)	<0.0001[b]	0.3 (0.2, 0.5)	<0.0001[b]
TG (mmol/L)									
All (n = 59)	1.4 (0.6)	−0.1 (−0.2, 0.1)	0.231[a]	−0.2 (−0.3, −0.2)	<0.0001[a]	0.0 (0.0, 0.2)	0.066[a]	0.1 (−0.1, 0.2)	0.420[a]
No lipid lowering (n = 51)	1.4 (0.6)	−0.1 (−0.3, 0.1)	0.185[b]	−0.2 (−0.3, −0.2)	<0.0001[b]	0.0 (−0.1, 0.1)	0.451[b]	0.1 (0.0, 0.3)	0.126[b]
Tot C (mmol/L)									
All (n = 60)	4.7 (1.1)	0.5 (0.3, 0.7)	<0.0001[a]	−0.1 (−0.3, 0.0)	0.155[a]	0.4 (0.2, 0.5)	<0.0001[a]	0.3 (0.1, 0.4)	0.002[a]
No lipid lowering (n = 52)	4.9 (1.0)	0.4 (0.2, 0.6)	<0.0001[b]	−0.2 (−0.3, 0.0)	0.015[b]	0.3 (0.2, 0.5)	<0.0001[b]	0.3 (0.1, 0.5)	0.002[b]
Waist circumferences (cm)									
All (n = 70)	123.5 (12.8)	−14.9 (−16.9, −13.0)	<0.0001[a]	−14.0 (−14.9, −13.0)	<0.0001[a]	−4.6 (−5.6, −3.5)	<0.0001[a]	3.6 (2.5, 4.7)	<0.0001[a]

s-BP: blood pressure systolic, d-BP: blood pressure diastolic, GLUC: fasting glucose, HDL: high-density lipoprotein cholesterol, LDL: low-density lipoprotein cholesterol, TG: triglycerides, Tot C: total cholesterol. [a]GLM adjusted for age, gender, and relevant medication at baseline (HDL, LDL, Tot C, and TG adjusted for lipid-lowering medication at baseline; s-BP and d-BP adjusted for blood pressure-lowering medication at baseline; and GLUC adjusted for glucose-lowering medication at baseline), [b]subgroup analysis of participants not using relevant medication at baseline, GLM adjusted for age and gender.

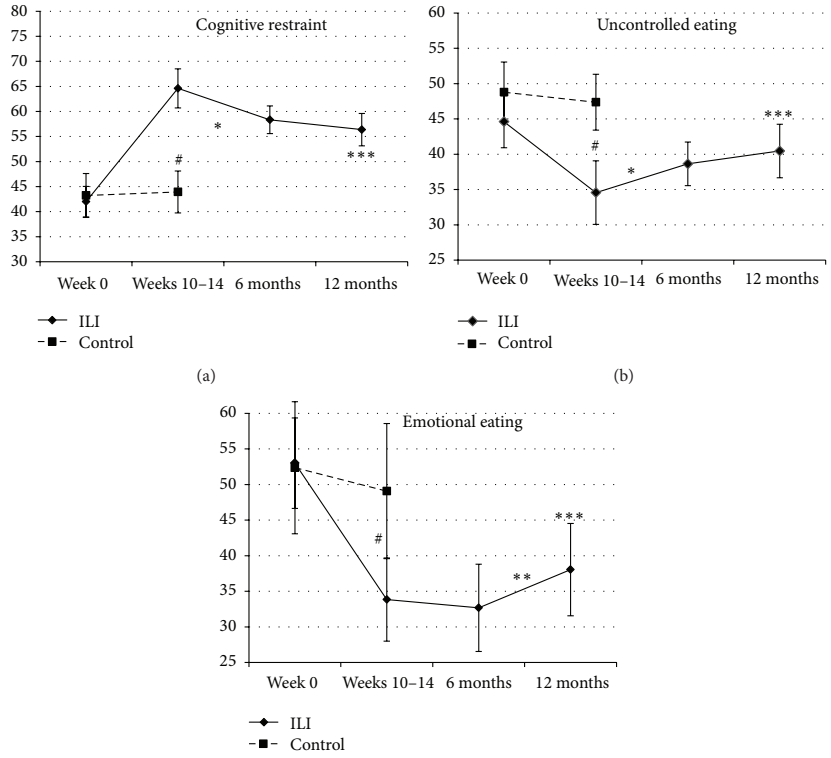

Figure 6: Mean (95% CI) scores of eating behavior (TFEQ-21) at week 0, weeks 10–14, six, and 12 months followup. $^{\#}P < 0.007$ for differences in changes between ILI-group and controls, $^{*}P < 0.02$ for changes within the ILI-group from weeks 10–14 to six months, $^{**}P = 0.012$ for changes within the ILI-group from six to 12 months, and $^{***}P < 0.04$ for changes within the ILI-group from week 0 to 12 months.

Table 6: Change in exercise capacity within the ILI-group. Data are mean values (SD or 95% CI).

	Mean Week 0	Mean change Week 0 to 12 months	*P* value	Mean change Week 0 to weeks 10–14	*P* value	Mean change Weeks 10–14 to six months	*P* value	Mean change Six to 12 months	*P* value
10-metre shuttle run test, exercise time (min) ($n = 43$)	9.3 (2.9)	4.2 (3.3, 5.2)	<0.0001[a]	4.7 (3.9, 5.6)	<0.0001[a]	0.7 (0.3, 1.1)	0.002[a]	−1.2 (−1.6, −0.7)	<0.0001[a]
750-metre walk test, exercise time (min) ($n = 47$)	6.9 (1.0)	−1.4 (−1.6, −1.1)	<0.0001[a]	−1.2 (−1.4, −1.0)	<0.0001[a]	−0.4 (−0.5, −03)	<0.0001[a]	0.2 (0, 0.4)	00.015[a]

[a]Paired samples *t*-test.

Table 7: Self-assessment of eating behavior (TFEQ-R21) at baseline in the intensive lifestyle intervention (ILI) group and control group. Data are given as mean values (standard deviation).

	ILI	Control	*P* value[a]
TFEQ CR	42.0 (11.4)[b]	43.2 (12.4)[d]	0.635
TFEQ UE	44.6 (13.6)[c]	48.8 (12.0)[d]	0.150
TFEQ EE	53.0 (23.5)[c]	52.4 (26.2)[d]	0.907

[a]Independent samples *t*-test, [b]$n = 56$, [c]$n = 55$, [d]$n = 33$.
UE: Uncontrolled eating, CR: cognitive restraint, EE: emotional eating.

PA is associated with weight loss and increased cardiorespiratory fitness in subjects with SO undergoing lifestyle treatment [29]. In addition to the well-known effect of PA on body weight through energy expenditure, different research lines also suggest an indirect effect through the positive influence of PA on appetite regulation and eating behavior [19, 46–51]. Increasing restrictive eating and decreasing uncontrolled and emotional eating are important for weight maintenance after weight loss [47, 51, 52]. In the present study we found that increased cognitive restraint and decreased uncontrolled

Table 8: Univariate GLM between changes in eating behavior and weight change.

Parameter/independent variable	B	95% CI	*P* value
Regression 1 ($n = 60$): dependent variable weight change week 0 to 12 months			
Change CR week 0 to 12 months	−0.310	−0.501, −0.120	0.002
Change UE week 0 to 12 months	0.252	0.008, 0.496	0.043
Change EE week 0 to 12 months	0.016	−0.135, 0.167	0.831
Regression 2 ($n = 62$): dependent variable weight change week 0 to weeks 10–14			
Change CR week 0 to 10–14	−0.152	−0.230, −0.074	0.000
Change UE week 0 to 10–14	0.064	−0.049, 0.177	0.262
Change EE week 0 to 10–14	0.008	−0.089, 0.073	0.843
Regression 3 ($n = 62$): dependent variable weight change weeks 10–14 to 6 months			
Change CR weeks 10–14 to 6 months	0.005	−0.079, 0.090	0.898
Change UE weeks 10–14 to 6 months	0.011	−0.112, 0.135	0.856
Change EE weeks 10–14 to 6 months	0.087	0.007, 0.168	0.033
Regression 4 ($n = 61$): dependent variable weight change 6 to 12 months			
Change CR week 6 months to 12 months	−0.108	−0.274, 0.057	0.196
Change UE week 6 months to 12 months	−0.019	−0.212, 0.173	0.842
Change EE week 6 months to 12 months	0.030	−0.100, 0.160	0.647

eating were related to weight loss after one year. Indeed, it has been shown that PA has positive influence on appetite regulation by increased sensitivity for satiety signals and improvements in eating behaviors [19, 46, 47, 49–51]. We speculate that the severely obese subjects in the present study by increasing PA also increase their cognitive restraint by a spillover effects as shown by others [47, 49].

The present study has some strengths and limitations. The main strength was the mandatory PA program in an inpatient setting. We also measured BC and were able to assess the changes in BC in a weight loss intervention with high volume of PA. The main limitations of the study were that we did not objectively measure PA level or energy intake, and hence we cannot determine how much of the weight loss and improvements in health risk to be attributed to altered caloric restriction, change in nutrient composition, or exercise, but we have examined the effect of an lifestyle intervention program as a whole. Another limitation of our study was that we did not measure cardiorespiratory fitness and appetite-related hormones. However, results from the walking tests and TFEQ indicated improved fitness and eating habits. Finally we have described changes in BC and CVD risk factors for a relatively short time period; whether the results achieved will persist in the long term remains to be seen. There is also a need for studies of mechanisms regarding the influence of PA on appetite regulation.

5. Conclusion

This study shows that weight loss achieved by an intensive inpatient lifestyle intervention with high volume of PA resulted in an almost maintenance of FFM and favorable changes in CVD risk factors and eating behavior in subjects with SO. The mean reduction of VFA was 30% one year after the start of the intervention and may partly explain the changes seen in the metabolic risk factors. After one year, about 50% of severely obese subjects maintained more than 15% weight loss. Moreover, the weight loss was related to increased cognitive restraint and decreased uncontrolled eating behavior.

Conflict of Interests

The authors declared that they have no conflict of interests.

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Paper III

Paper IV

Severe Obesity and the Ambivalence of Attending Physical Activity –Exploring Lived Experiences

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Abstract:

Physical activity is considered fundamental in lifestyle interventions. We explore experiences of physical activity prior to, during and following a 10-14 weeks inpatient lifestyle modification program, including high volume of physical activity, for the treatment of severe obesity. Eight participants from a prospective clinical trial were selected to participate in a complementary qualitative study. The participants' experiences with physical activity during and following the treatment program represented different opposites: "pain and pleasure", "desire and duty" and "bubble and battle". We summarized the findings into one overall theme: "the ambivalence of attending physical activity". The ambivalence is experienced as a shift in how participants feel about physical activity during the intervention period and as an ongoing, dynamic and constantly shifting experience during such activity. To address and reflect upon such experiences with the participants, and acknowledge ambivalence as a legitimate part of being physically active, might be important within obesity treatment. (ClinicalTrials.gov.number, NCT01675713).

Keywords

Descriptive methods, Exercise/physical activity, Interviews, Obesity/overweight, Qualitative analysis

MANUSCRIPT

The focus in this article is experiences of physical activity among adults with severe obesity, defined by a body mass index (BMI) ≥ 40.0 kg/m^2 or 35.0 -39.9 kg/m^2 with obesity-related comorbidities. Given the increasing prevalence of severe obesity, with its related physical comorbidities, mortality, psychosocial complications and reduced quality of life, effective treatment programs are needed (Kolotkin, Crosby, & Williams, 2002; Hsu et al., 2002; Van Hout, Van, I, & van Heck, 2004; Wadden et al., 2006; McTigue et al., 2006; Sturm, 2007; Lerdal et al., 2011; Yanovski & Yanovski, 2011). There is, however, a complex diversity among overweight and obese individuals that cannot be measured and weighed. Being overweight and obese is also a cultural, contextual, relational and individually experienced phenomenon (Skårderud, 1991; Murray, 2005; Rugseth, 2011). In wealthy and western societies today it is expected that all are "thin and healthy." Obese individuals seem to "break the rules," and may be considered unhealthy, lazy or weak-willed when it comes to food and exercise, and unmotivated and noncompliant with weight-loss treatment (Puhl & Heuer, 2009; Puhl & Heuer, 2010).

Physical activity is a generic term that includes many different kinds of activity (Caspersen, Powell, & Christenson, 1985), and it has been studied within various scientific traditions, generally with a more quantitative than qualitative focus (Pearce, 2009). Both day- and inpatient lifestyle interventions including physical activity have been shown to cause clinically meaningful weight loss (≥ 5-10 %) the first year post treatment in subjects with severe obesity (Goodpaster et al., 2010; Martins et al., 2010; Unick et al., 2011; Aadland & Robertson, 2012; Gjevestad, Karlsen, Røislien, Maehlum, & Hjelmesaeth, 2013). There is also substantial quantitative research to suggest that physical activity is associated with reduced morbidity and mortality, favourable changes in body composition and mental health (Ross et al., 2000; Paluska & Schwenk, 2000; Goodwin, 2003; Slentz et al., 2004; Weinstein

et al., 2008; Martinsen, 2008; Fogelholm, 2010; Carek, Laibstain, & Carek, 2011; Swift, Johannsen, Lavie, Earnest, & Church, 2014), as well as weight loss maintenance in overweight and obese subjects (BMI < 35 kg/m^2) (Saris et al., 2003; Donnelly et al., 2009; Swift et al., 2014).

Besides the healthy physiological effects of activity, being physically active is also inextricably bound to meaning (Pearce, 2009). Qualitative research has revealed that individuals with severe obesity may have difficulty with physical activity because of increased body weight, reduced mobility or medical problems related to obesity (Gronning, Scambler, & Tjora, 2013; Christiansen, Borge, & Fagermoen, 2012; Knutsen, Terragni, & Foss, 2011; Wiklund, Olsen, & Willen, 2010; Strømmen et al., 2009). In line with this, it has been claimed that exercise programs may be de-motivational and unhelpful in the treatment of subjects with severe obesity (Monkhouse, Morgan, Bates, & Norton, 2009). Individuals with severe obesity have reported feelings of not "fitting in" in gym and exercise groups, and feelings of being critically stared at in public, and such experiences may discourage or stop them from exercising (Wiklund et al., 2010; Knutsen et al., 2011). However, individuals with severe obesity also report liking being physically active, and have positive experiences with adapted physical activity (Knutsen et al., 2011). Exercising with others in the same condition and being introduced to adapted exercise and special equipment has therefore been considered important for this population to increase compliance in physical activity programs (Poston, Suminski, & Foreyt.J.p, 2000; Wiklund et al., 2010).

However, little is known about the participants' actual experiences with physical activity during these lifestyle interventions, as well as prior to and after such interventions (Gronning et al., 2013; Dahl, Rise, Kulseng, & Steinsbekk, 2014). Qualitative research can make a contribution to existing knowledge regarding how severely obese subjects experience being physically active, the role of physical activity and exercise in their lives (Pearce, 2009;

Wiklund et al., 2010), and can provide valuable knowledge to clinicians and participants, as well as researchers. The long-term effect of treatment of severe obesity is less clear and promising than the acute effect, with many obese individuals dropping out of treatment (Bjorvell & Rossner, 1985; Bjorvell & Rossner, 1992; Christiansen, Bruun, Madsen, & Richelsen, 2007; Gronning et al., 2013; Martins, Strommen, & Kulseng, 2013; Unick et al., 2013). Hence best practice is yet to be determined. A common perception in weight-loss programs is that "obese individuals have to change," but, qualitative methodology can provide more nuanced knowledge regarding how treatment programs are experienced, and such knowledge can contribute to a better adaptation of the content of the programs to participants' needs.

Within this context, the purpose of our study was to explore the experiences of physical activity from a participant perspective prior to, during and following an intensive inpatient lifestyle modification program including a high volume of adapted physical activity for the treatment of severe obesity.

Methods

During the research process we were inspired by the descriptive phenomenological method as described by Amadeo Giorgi, and used a methodology drawing particular inspiration from Amadeo Giorgi (Giorgi, 2009) and Kirsti Malterud (Malterud, 2012; Malterud, 2013). Within phenomenology the common, everyday world into which we all are born and live is designated, i.e., a "lifeworld perspective", and "everyday experience" is highlighted as an important source of knowledge (Dahlberg, Dahlberg, & Nystrom, 2008; Giorgi, 2009). Phenomenology investigates the first-person perspective, i.e. the *"lived experience"*, and looks at the phenomena from the perspective of how they are experienced by the subject

(Giorgi, 2009). In this study "being physically active" is the phenomenon being studied, and physical activity also includes exercise.

Study design

This qualitative study was supplementary to a clinical controlled trial with a one-year prospective follow-up study (Author et al 2013, 2014). The quantitative study examined the effects of a 10- to 14- week inpatient lifestyle modification program for subjects with severe obesity subjects. Details regarding the trial and the treatment program used in this study have been published previously (Author et al 2012, 2013). Findings from the quantitative study showed a mean weight-loss of 16 % and favourable changes in psychological factors and health related quality of life (HRQL) at 12 months from the start of the treatment (Author 2013, 2014). The main reduction in body weight and improvements in psychological factors and HRQL occurred during the 10‑14 weeks inpatient period. The changes remained quite stable during follow up, however a slight increase in bodyweight and impairment in psychological factors and mental components of HRQL were observed from six to 12 months.

A key part of the treatment program was the very high volume of physical activity: two to three exercise sessions five days a week during the inpatient period, each lasting for a minimum of 45 minutes. Aiming to increase compliance with this physical activity regimen, the activity was supervised by exercise scientists and physiotherapists, the participants were introduced to adapted physical activity and equipment, and exercised together with other individuals with severe obesity. The intention was to present what was possible for the participants and the experience of mastering and enjoying being physically active, in order to increase physical fitness and their physical activity level following the treatment program (Author et al 2012). In the qualitative part of this study we wanted to examine how the high

doses of physical activity were experienced and what useful knowledge could be derived from such experiences.

Participants

The participants were recruited from the study sample in the clinical trial (Author et al 2013, 2014). They were recruited 2-3 years after the start of the treatment program, and the inclusion criteria were that the participants had completed the treatment program as well as a "home-period" (i.e., a period with no formal follow-up) afterwards. The study sample was selected strategically aiming to gain insight into the diverse experiences: a psychologist, the clinical leader of the treatment team at the clinic, was asked to choose eligible former participants from the treatment study. He was asked to choose from both genders, with a variety in age, degree of obesity and weight-loss during the inpatient stay, as well as variation in weight-loss maintenance and lack of maintenance. The participants were first contacted by phone or email from this clinical leader and invited to participate in an interview in which their experiences with physical activity prior to, during and following the treatment program would be the main focus. All invited participants agreed to participate and were then contacted by the first author to arrange for the interview. The participants included five women and three men aged 35-63 years; six of them were married/cohabitants and two were single. Three of the participants had been overweight as a child, and their BMI and body weight at the entrance of the treatment program ranged from 37 kg/m^2 to 60 kg/m^2 and 96 to 185 kg respectively. Weight-loss during the inpatient period ranged from 10 to 29 kg, and at one year follow-up it ranged from 11 to 46 kg. At the time of the interviews some of the participants said they had regained the weight and some had maintained, whereas other were "going up and down". Furthermore, there were great variations in terms of activity levels and experiences with physical activity and exercise in childhood, youth and early adulthood.

Data collection

All of the interviews were carried out by the first or the last author during the autumn of 2013. We used a semistructured interview, including open-ended questions formulated to act as a trigger or stimulus for further conversation, and to encourage the participants to speak freely about experiences of physical activity prior to, during and following their inpatient stay. Helping questions were used to make the participants reflect on, exemplify or add further depth in response to questions or statements, and to elaborate on different themes. Each interview lasted about 60 minutes, was audiotaped and transcribed verbatim and checked by the first author and/or a secretary. The first and last authors read all the transcribed interviews, whereas the second author read quotes that were highlighted during the process of analysing the data and the final analysis.

Data analysis

We analysed the interviews using the principles of Systematic Text Condensation (STC) (Malterud, 2012; Malterud, 2013), inspired by Giorgi's approach (Giorgi, 2009). To create a wider analytic space the analytical work was conducted as collaborative negotiations between the first and last author. In the course of this discussion, themes and subthemes were gradually developed. A step-wise approach as described by Malterud was used (Malterud, 2012; Malterud, 2013), however, the analytic process was characterized as an ongoing and dynamic process and themes and codes were treated as flexible entities being reconsidered and reorganized several times as new patterns appeared. The four steps comprised: (a) We read the transcribed interviews separately to obtain an overall impression, and preliminary themes were identified and discussed; (b) Each transcript was reviewed systematically line by line to identify meaning units in text, with the themes found in step 1 as road signs. Meaning units containing relevant information of different aspects of the participants' experiences of

physical activity prior to, during and after the treatment program were decontextualized and coded thematically into detailed tables of each interview. During this process, themes were discussed and consequently renamed and merged because of overlap, as well as new themes emerging. Codes were re-defined accordingly. (c) The meaning units were reread, and with the code groups as starting points the meaning units were sorted thematically across individual participants. A condensed text summarizing the main content in each code-group was then developed, and “golden quotes" were chosen. Finally, (d) The condensed text were converted into an analytical text concerning the participants experiences with physical activity. Then we assessed our findings according to existing research.

The aspect of researchers’ preconceptions is highlighted by Malterud (Malterud, 2001; Malterud, 2013). In this study, the research team consisted of a PhD candidate in sports science, a professor in physical activity and health, and an associate professor with substantial experience in qualitative method and the use of interviews of obese individuals. The motivation for this study arose from the first authors meeting with the participants in the previous quantitative study, and from knowledge within quantifiable effects of physical activity in the treatment of obesity. Prior to and during the research process we reflected on our own background and preconceptions, and how they could affect the prepared research questions and the way of understanding the participant’s distinctive challenges. This helped us to be aware of and understand our preconceptions as a resource for new questions during the interview, and created an informed platform to understand our participants in new ways. We also discussed the conduction of the interviews, e.g., the distinction between directing and leading the participants. The intention was to do a descriptive analysis and we were therefore especially aware of the distinction between descriptions and interpretations of data (Giorgi, 2009). Nevertheless, as issued by Malterud, our background and pre-understanding is a necessary condition for our understanding, and we acknowledge that as researcher we are

always “visible” as acting in the themes and text (Malterud, 2013; Hallberg, 2013). We aimed to describe the participant’s experiences with physical activity prior to, during and after the treatment as accurately as possible, keeping in mind Giorgi's statement that “the result of a descriptive analysis is a second-order description” (Giorgi, 2009).

Ethical considerations and procedures

The Regional Committee for medical and health research ethics in Norway approved the protocol for both the quantitative and qualitative part of the study. A written consent to the overall study was signed by the participants. The participants were informed about the aim of the study and that their participation was voluntary. Assurance was also made that anonymity would be preserved when the results were published. The interviews were tape-recorded with the participant’s permission. The participants were informed that the interview could be terminated if they wished, and that they had the right to withdraw or not answer questions, at any time, without explanation.

To be obese is commonly associated with shame, feelings of inadequacy and not being good enough. Therefore we made efforts to establish an atmosphere of trust so that the participants would feel comfortable sharing their personal thoughts and feelings. One risk was that informants who had not maintained the increased activity level and weight-loss post treatment would experience this as a defeat. As interviewers we were prepared for this, and responded to statements of shame by assuring the participants that this was not our way of understanding it and that knowledge about such experiences was part of the reason we wanted to talk with them. The first author had met all the participants when measuring body composition in connection with the four testing periods in the clinical trial, which could reinforce a sense of obligation and guilt for poor results. Also, representing a school of sport science and generally being lean, fit and a “fan” of physical activity could inhibit their

willingness to share troublesome experiences with us. This was, however, not our impression. The participants seemed to appreciate the opportunity to talk about their experiences of the intervention program and their experiences with physical activity.

Findings

The participants' experiences with physical activity during and following the treatment represented different opposites: "pain and pleasure", "desire and duty" and "bubble and battle". Their experiences with physical activity were highly ambivalent, characterised by doubt, fear and resistance as well as comfort, joy and pleasure. We summarized the findings into one overall theme: "the ambivalence of attending physical activity". The ambivalence is experienced as a shift in how participants feel about physical activity during the intervention period and as an ongoing, dynamic and constantly shifting experience during such activity.

Below the findings are organised by presenting in different sections the participants' experiences with physical activity prior to, during and after the treatment. Experiences are further presented thematically. Themes are formulated from the participants own words, describing similarities, variations and contrasts in the experiences. To be true to the richness and variation in the participants' descriptions findings are presented as condensed and detailed descriptions of the experiences. Quotations are provided to illustrate the themes.

Experiences with physical activity prior to the treatment

Physical activity - restricted to necessary daily activities. The participants mostly described their activity level prior to the treatment as restricted to what they had to do during work-hours and other daily life activities, and as "low" or «none» in relation to their spare time. When asked how they understood their low activity level it was explained as corporal experiences of being heavy. Such experiences had evolved gradually as their body weight and

size had increased. In the words of one participant, “I was so heavy that I couldn’t do anything”. Living a heavy body was experienced as an obstacle and a hindrance “in itself” and the feeling of not being able to do anything was prominent. Most of them became exhausted from daily activity and from movement such as walking short distances or up a staircase. Exhaustion was accompanied by a feeling of losing breath and being “constantly tired.” One participant expressed this experience by saying, “It was hard to bend down, I was breathing like a walrus when I went up to the second floor, I had no energy and I was sleepy and tired all the time”. To feel sleepy and tired all the time stood in the way of her to engaging in anything other than the most necessary daily activities.

To cope with the experienced exhaustion and to preserve energy through the day, the participants had developed various strategies. One participant said,

> “You are constantly seeking the simple solutions, typically when you go to the supermarket and you want to park right next to the door rather than walk 100 meters over the parking area. And also you are always taking elevators and escalators etc., instead of taking the stairs”.

For him it was critical to save energy in all the things he had to do during the day, and to park close to the entrance of the supermarket was a strategic choice. Others talked about choosing to telephone or send email to colleagues next door.

The limited mobility was also connected to experienced pain. As described by one participant, “At the same time it all caused pain, I had pain in my knees and ankles, my back was about to

collapse and stuff, at least it felt that way". The loads on parts of the body were experienced as substantial, and pain in weight-bearing limbs, such as hips, knees and ankles, was common.

Not fitting in to the context of exercise. Experiencing breathlessness, being out of energy, and constantly exhausted, the participants perceived exercise as out of the question. They also experienced themselves as not fitting in to contexts for exercise, and described a feeling of bodily "differentness." As articulated by one participant: "As when you enter Elixia [national fitness center] with 140 kg and all the others are highly trained people, then you feel a bit like that .... you know what I mean?". He felt out of place and different from the others attending the fitness center. Based on similar experiences, attending a regular gym was out of the question for most participants. Another participant said, "I would never have gone into a regular gym. It was not an option for me". For her the only way she could approach a gym was if she had an "ally" on the inside, perhaps "that would mean a personal trainer." However, a personal trainer wasn`t actually considered as an available option, "that threshold was also too high ...." The reasons the gym was such a difficult place to attend were diverse, and associated with other attendees' fitness level, appearance, dress code, etc. Like one participants said,

> "I had always imagined that at the gym there were these women with, this music video not long ago where there are many of those women in leotards, that was what I imagined, that was how I imagined you had to look to go there. So it has always been a great barrier for me to go there".

Based on what she had seen in commercials and announcements, she would not fit in as one of the women at the gym. However, during the interviews some said that they had tried to

exercise or that they had been occasionally active, but life events, circumstances and lack of time had made it difficult for them to manage. As one woman said,

> "During adolescence and as a young mother I used to exercise a lot. I was really into aerobics ... but then I didn't exercise at all for years ... several other things came along ... ... I was a single mother of three, working full time (?) and tried my best to get the days to add up ... ".

For her, being a mother in combination with work and studies meant no time for activity, at least not of any certain volume. Pregnancies, motherhood, studies, illnesses and mental health problems were among the explanations for the participants giving up exercising. Some of the informants also considered their family and friends as rather sedentary, and said that exercise was not common in their milieu. One man noted,

> "I have not really been interested in it [exercise] ... none of those I grew up or hung out with have been exercise dependent types. I don't know anyone who has exercised ...So, I think that [not being physically active or exercising] is a result of the environment you are in ... and the fact that one doesn't have any particular interest in exercise. I was never really introduced to the environment [where exercise took place] at all".

For him interests and the milieu were important reasons for not being physically active or exercising. The lack of introduction to and participation in exercise during childhood and adolescence were also described by other participants. They added that the only activity they were introduced to was PE classes.

Experiences with physical activity during the treatment

Exercise is painful. During the initial weeks of the intervention all the participants experienced physical activity and exercise as painful. Going from almost no physical activity to high frequency of hard exercise sessions was expressed as a "heavy experience." Although informed about the duration and intensity of the activity program, their shared experience was the surprise of "how hard" it was. The pain experienced in different body parts before they attended the treatment program increased, and although the activity caused pain and exhaustion they were required to participate in all the activities. As a result their bodies and muscles felt stiff and sore. One participant reported,

> I've never had so much pain. I felt so much stiffness and soreness. I was stiff and sore from my little toe up to the earlobe. (...) We all had to back down the stairs because we were not able to walk the right way.

In addition to pain and exhaustion it became clear that the participants were frightened by the exercise. They were uncertain about how much they actually could do without getting injured, ill or worse. They actually thought about the possibility of not surviving. As one said, "I was sure I should die. Yeah I thought the first week; I thought that I'm going to die here, I was completely convinced". For this woman, living with obesity was living at risk and she was afraid that her body couldn`t take any more activity. Because of all this pain and experienced pressure some of them said they "hated" being at the clinic, and hated the activities. Some even used the metaphor "being in hell" when talking about the first weeks. Spinning on a stationary bicycle was highlighted as the absolutely worst experience, and as one participant said, "It was hard, painful to sit on the bike, and it was even painful getting off the bicycle."

Taken together, these findings show how sensations like pain and hate dominated their experiences with exercise during the first weeks of the treatment stay.

Pain becomes pleasure. When speaking about their experiences related to exercise at the clinic the participants mostly segregated the inpatient period into "the first few weeks" and "the rest of the stay," referring to an experience of change underway. As the weeks progressed they managed to do the activities in a more efficient way, the pain gradually lessened, their physical fitness increased and body weight decreased. One of the participants described the transformation,

> It was such a gradual improvement as you manage it [the activities] more and more, you have less and less pain, and then there is more and more joy in it. It's a gradual progression, you are being pushed time after time and when you just keep on long enough it gradually becomes more and more all right. After a while, you kind of notice the pain less.

While exercising more and more, and getting used to the exercise, the pain felt during exercise was gradually reduced. Most of them started to enjoy exercise, which was no longer just pain. Some even expressed a "good feeling" of sweating and heart pumping. These experiences contrasted with their previous experiences of these bodily signs as shameful, provoking anxiety and a wish to calm down or even leave the gym and avoid activity. Now, being tired and sweaty more commonly evoked a good and comforting feeling.

Some even expressed the experience changing from "hate" to "hilarious." They used words like "fantastic" and "really fun," and some described getting "a rush" or "a kick" both during and after exercising. Spinning was again highlighted, and almost all started to feel

enthusiastic about it during the treatment period. As they gradually managed to cope with it in a less painful way, it became something they liked, and someone even called spinning “the best” or “my thing.”

Still, the participants described many of the other activities embedded in the treatment as something they just “could not stand.” Whereas someone liked Pilates and yoga, others described it as absolutely “horrible” or “totally tragic” and one participant said she “felt as a fish out of water”. So the experiences with exercise were individual, as well as activity-specific.

One participant didn’t change her feelings about exercise at all. She “could not stand” all the “pushing” and “screaming” involved in the spinning and just didn´t like to exercise: “Oh no (laughing), I don’t like to exercise, I can’t stand exercising (laughter)". Even if she “had to admit” that exercise gave her a good feeling afterwards and made her feel vigorous and a bit more fit, it was not enough to make her like exercise on a regular basis.

“Being in the same boat”. The experience of exercising in a group was also a theme revealed in the interviews. Most of the participants indicated positive experiences with being in a group during the inpatient stay, exercising with others “in the same situation” and “being in the same boat.” As one participant reported,

> It was motivating. Because most of them were in the same boat as me, they wanted to exercise and they got a ‘kick’ from exercising. They wanted to exercise more and to get involved and engaged, and so we motivated each other. (...) The vast majority was very positive and was very keen on exercising and being physically active and helping each other get started.

Being part of a group was experienced as a motivator, and turned out to be a promoter and driving force to continue exercising for several of the participants. They described a challenge to "try things," and because they were all overweight, the embarrassment and the threat were not problems any more. One woman explained, "We looked a little similar, everything was in a way very safe", and another women noted "It was okay to breathe and wheeze and it was okay to [let the fat] wiggle and all this, you know, when we exercised". Adding to the feeling of having a lot in common, some emphasized the atmosphere in the room when describing the spinning at the clinic. As described by one participant,

> Especially the spinning, I thought it was fantastic. We were 15-20 persons in a small room, we dimmed the light and turned the music up and the pace increased. Then you are kind of carried away, and you just have to give what you have each time, you can't sneak away or fiddle with the button where you tune the resistance on the bike, you kind of give what you are supposed to, and then you feel that it makes a difference, and I think that's good, that part I actually like, and I've never done that before, I think.

He was absorbed by the atmosphere and felt committed to the others in the room. Being part of the group made him try harder to do his best to achieve his goals.

One participant had a different experience with the group setting: "Just because it is a group of 15 obese individuals, you are no more equal than others". She experienced the enthusiasm expressed by the others as provocative and had problems identifying with the rest of the group just because they were all obese. Whereas many were excited to take bicycling outside the spinning room, she experienced that kind of activity as meaningless and the way the others talked about it as provocative: "Everybody says 'Ooooh so lovely, and oh God I'm

going to run 3 miles, and bicycle around Tyrifjorden [a 70 km bicycle race]', and I just say: 'Kiss my ass. It's nonsense'." Finally, she did not want to be part of the group and consequently, except for the mandatory group activities, she chose to spend time on her own:

> I've never liked to be controlled, that way, like the group pressure and things like that, I can't stand it. (...) At the clinic I stayed by myself, I dropped out of the group. (...) When you feel that you are completely 'drawn into' something that you don't really want to be part of, then I would rather be alone. I have no problem being alone. So it was no loss (laughter). I enjoyed it and had a good time.

Experiences with physical activity after the treatment

Exercise- a desire. Immediately after the inpatient stay most of the participants tried to exercise nearly every day. As one of the participants explained, "When I returned home [after the inpatient period], I was spinning 5-6 times a week. I was completely hooked". Several emphasized the need for exercise to retain or promote a feeling of vigor and better mood. The "well-being" after exercise that the participants had revealed during the inpatient stay now became an important incentive for exercising. In contrast to prior experiences they now reported exercise as giving more energy. For example one participant reported,

> Now I notice that I get a lot more energy from being active. Therefore, if I'm tired, going to the gym or going for a walk or doing something [physical activity] is useful for me.

In addition to energizing them, exercise also made some of them feel "satisfied and proud" about themselves. Experience of being "addicted" to exercise as something they had to do to

feel good about themselves was also reported. Furthermore, the participants experienced how the improved physical fitness had led to a participation in activities they had not been able to do before, such as playing with grandchildren, climbing a mountain or participating in a bicycle race. For some, this led to a qualitative change in lifestyle and self-perception. As one participant articulated it, “Before I was a spectator in my own life, now I’m participating”.

Exercise - a duty. Participants also reported other reasons than pleasure, such as persistence in weight regulation grounded in a fundamental fear of gaining weight. What they feared the most was to “go back to where I was.” Exercise came to be perceived as a “life necessity.” Some also talked about exercise as a “duty” or “obligation,” describing it as something they “had to do.” Skipping one day could make them feel guilty of failure. One participant reported, “I have failed completely in terms of strength training and it's not a good feeling”. To drop out of exercise had a direct impact on self-esteem. As one woman said, “I have betrayed myself, yeah (laughs). Because I think I should have made it”, and as another woman pointed out, “Then [when I have not exercised] nothing makes me enjoy myself”. Not exercising or being active was a source of feelings of guilt and shame for the participants.

The “bubble” and the “battle”. Looking back, most of the participants described the inpatient setting as “being in a bubble” in which all had the same focus, and the time afterwards was described as “coming out” of the bubble. While in the clinic, eating and exercising were the main focus, and they were also supported by experts and likeminded. However, when returning home they experienced exercise as time-consuming and often in conflict with other activities and social events. This posed a dilemma for the participants, and they had to choose. “You have to give up other things in order to exercise” (Female 2). Engaging in exercise was experienced as provoking conflict with other important things in

their lives, like time spent with family and friends. The activities and social settings they used to join and appreciate before the treatment were now experienced as conflicting with and a hindrance to exercise. For some this felt complicated and had consequences for their relations with others. As one woman described it,

> Previously, I used to meet with friends for a glass of wine or a snack or something. They think I've become a bit boring now, because I can't go out to eat in the middle of the week, I can't afford it. Or my body can't afford it. But they don't understand, claiming; 'You never call anymore, you're absolutely impossible to reach' (Female 5).

For her, being on a diet and spending time exercising had to be given first priority, and that made her friends react and ask questions about her commitment to their friendship. Such experiences led participants to reflect on how hard it was for them to keep up with exercise on a regular basis and integrate it into the normal pattern of their lives. One participant said, "Exercise is sort of the hardest to establish with good routines. When something pops up, something unexpected, then it's always exercise being dropped".

Among other explanations for not exercising were bad weather, holidays and repairing their houses, experienced as challenges to their new routines. Others had contrasting experiences, finding it relatively easy to adapt the exercise to other daily activities and social events, reporting that being physically active and exercising were new ways of spending time with friends. As described by one participant "Now I might be social in some other ways as well. I meet with friends to walk or to do something active. We use exercise as a social activity".

Even if continuing exercise for some of the participants was experienced as difficult when they "came out of the bubble," most of them expressed being more physically active

than before treatment, more active in daily living activities. They no longer depended on elevators or finding the closest parking spot, and they found different methods to adopt and increase daily physical activity. As one participant said,

> "I promised myself that I would take the stairs instead of the elevator, and I have to park a short distance away from the entrance of the supermarket... I have made rules for myself. And I have a total ban against elevators no matter how high up I'm supposed to walk the stairs. Sometimes I have regretted it, like when I'm supposed to end up on the seventh floor, and I think, damn, I can't take the elevator (laughter). But I have decided that I will not take the elevator. And so far I've made it" .

Most participants now perceived their activity level as "changeable." During this process of trying to be active, their stories were characterized by pros and cons, negotiable contraries and ambivalence. In a way their new "project" (including exercise) was a challenge to their lives, just as their earlier lives were experienced as a challenge to their new project. For some the upcoming years (their future lives) were seen as "a battle." As so aptly described by one participant,

> Exercise is not so fun, it is necessary. It is always a "battle". It's not like losing weight and then you stay there.(...) The "battle" is about constantly thinking about what to eat, you have to constantly think and keep exercising. You cannot relax a bit or go back to the old diet or habits. Something happens, and you think "Oh, God, I'm fattening up", "do I have to worry and struggle all my life?" I think a lot about that.

This person made a distinction between exercise as fun and exercise as necessity, placing it for herself in the latter category. Also she understood herself as engaged in battle, a battle about what, when and why to eat, and how to balance eating and exercise.

Discussion

In this study we aimed to describe experiences of physical activity in subjects with severe obesity participating in an inpatient lifestyle modification program with a high volume of physical activity. The intention of the physical activity component of the treatment program was for the participants to increase their physical fitness, master and enjoy being physically active in order to increase their physical activity level following the treatment program (Author et al 2012). Hence there is an inherent expectation of causality and coherence in the aim of the treatment, whereas our findings show ambivalence about physical activity during and after the treatment. The experience of physical activity is ongoing, dynamic, constantly shifting.

Prior to the treatment, the participants described their level of physical activity as low and restricted to necessary daily activities. As it appears in our data and in other qualitative studies, a low activity level in individuals with severe obesity is explained as a combination of bodily and contextual factors (Groven, Raheim, & Engelsrud, 2013; Gronning et al., 2013; Christiansen et al., 2012; Wiklund et al., 2010; Groven & Engelsrud, 2010; Strømmen et al., 2009). The participants experience their bodies as too heavy, obstacles to physical activities, causes of exhaustion and pain (Gronning et al., 2013; Groven et al., 2013; Christiansen et al., 2012; Wiklund et al., 2010; Groven & Engelsrud, 2010; Strømmen et al., 2009). In addition, the usual context for exercising is perceived as not meant for them. They experience a body "differentness" that is intrusive and embarrassing, and feel uncomfortable when exercising

with other people who are not overweight (Wiklund et al., 2010; Groven & Engelsrud, 2010; Rugseth, 2011; Christiansen et al., 2012).

Pleasure and pain

Based on our findings, exercising in a group of individuals with severe obesity, with adapted activities and instructors specialized in physical activity and health, appeared to promote a sense of acceptance and motivation to engage in physical activities and exercise for several of the participants. With one exception, they spoke very enthusiastically about the group setting. They felt more comfortable exercising together with individuals in the same situation as themselves, and indicated that it felt safe to expose their own obesity. The group was also for most experienced as a motivator to participate in the activities, to push harder and fulfill the treatment program. It was a social arena where they could share their positive and negative experiences. This is in accordance with findings of previous studies (Groven & Engelsrud, 2010; Groven et al., 2013; Dahl et al., 2014), and contrasted with participants' previous experiences with or avoidance of fitness centers. However, it is important to note the opposite experience of being a member of a group, the feeling of not fitting in, even though together with people who appear to share your own challenges.

After some weeks of effort and struggle during the inpatient period, most of the participants described how their corporal limitations gradually changed. They shared feelings of achievement in the activities that gradually became likeable, and experienced a feeling of well-being and improved physical fitness. Severe obesity is experienced as a burden, but does not necessarily keep one from being physically active. The change in participants' experiences of physical activity and exercise during their inpatient stay might be explained by changes in body composition, physical fitness, physical health, self-confidence and mental

health during the treatment, as well as by the treatment setting/context itself (Allen-Collinson, 2009; Martinkova & Parry, 2009).

However, the findings from our study also call attention to feelings of pain, discomfort and fear related to exercise. During the first weeks of the inpatient stay exercise was a very difficult experience for the participants; some experienced it as life-threatening. Although the exercise program was adapted to the participants regarding type of exercise, pace, progression and equipment, the amount of physical activity (i.e., the frequency, intensity and duration of each session) was experienced as stressful. In agreement with previous research findings, exercise might promote bodily discomfort and pain, and be an especially weighty experience for individuals with severe obesity (Groven & Engelsrud, 2010; Groven et al., 2013). Pushing oneself despite discomfort and pain is however regarded as necessary in order to lose weight (Groven & Engelsrud, 2010), and our study offers several examples of this belief. It is worth recognizing that despite their negative experiences, the participants chose to remain in the treatment program. These experiences are informative and indicate what the participants were willing to go through. It is particularly interesting to relate these findings to the common belief in the society that obese individuals are lazy, unmotivated, weak-willed and noncompliant with weight-loss treatment (Puhl & Brownell, 2006; Puhl & Heuer, 2009; Puhl & Heuer, 2010; Gronning et al., 2013). The participants endured a lot of pain and fear to reduce their body weight and enhance their health. There is, however, no straight linear direction, the “hate”, “hell” and “fear” feelings might take various directions, and can be a reason why some participants drop out or make their own modifications or skip exercise sessions (Groven et al., 2013). Recall another finding in our study concerning the woman who “could not stand” all the “pushing” and “screaming” involved in the exercise. A possible and prescribed “good feeling afterwards” was not enough to make her start liking exercise.

Desire and duty

After the inpatient treatment, participants' motivation for exercise derived partly from the pleasure and enjoyment of the exercise/activity itself, as well as their feeling well afterwards. However, the specific benefits they experienced from maintaining exercise, related to bodyweight and physical fitness, were also described. It is interesting to note that although a desire to exercise for pleasure and well-being were important for the participants in our study, at the same time they experienced exercise as a duty and something they "had to do" in order to control their weight (as well as health and physical fitness) and not return to their former habits and bodyweight. This is in line with a qualitative study by Groven and Engelsrud in which the participants experienced the exercise as something they felt obliged to do to achieve a slimmer and fitter body, some kind of a duty that was not just pleasant (Groven & Engelsrud, 2010). For the participants in the present study there was a commonly experienced ambivalence between desire and duty related to exercise that seems to become further apparent following the inpatient program. This is, however, experience anyone can have, and is not something that characterizes only obese individuals. So it is important that the participants experience ambivalence as an expected, natural part of the program, not a problem, and acknowledge that such ambivalence is to be expected and is experienced by most individuals involved in physical activity and exercise. Furthermore, such experiences should be understood as continuous and moveable, not determined once and for all. What is pleasurable can sometimes be experienced as a duty and vice versa. The aim of the present treatment program was to introduce the participants to physical activity and exercise as pleasurable, not "something they have to do to lose weight" (Author et al 2012). At the same time, weight loss was an outcome goal of the treatment. In addition, our culture strongly emphasises individual responsibility for one's own health, part of goal-setting and planning of physical activity. This can be construed as a communication that strongly relates exercise to

discipline and duty, with little room for experiences of ambivalence. In this regard an ambivalent attitude is something inherent in the treatment program(s). It is not just the participants who experience such ambivalence; they do so in a social and cultural context in which such ambivalence is normative.

Bubble and battle

The experience of exercise is always contextual, emerging and changing. The "bubble" is the participants' own word for context, and the contextual shift from the treatment setting to their return home was described by most of them as large and daunting. Their experience of difficulties continuing with the same activity-level and focus afterwards has been reported by others (Gronning et al., 2013). To return to their everyday lives challenges participants to continue with the lifestyle changes accomplished during the treatment. When they compared themselves after inpatient treatment to their experience before treatment, participants said they were more active in their everyday lives. However, most of them say that they do not exercise as much as they think or believe they should. Exercise provided joy, physical changes and better health, but also left a felt residue of guilt and failure. The shame participants earlier experienced related to their bodies and to being fat shifted in some measure to being ashamed of themselves for not exercising enough. It is useful to put the question, what is the treatment program communicating through its emphasis on quantity, and how should participants understand this in their everyday post-treatment lives? What is "enough" in the context of exercise? Who is telling them when "enough is enough"? And "enough for what"? Weight-loss maintenance, joy, well-being, quality of life?

Even if the participants are more physically active—and findings from the preceding quantitative study show that in mean they have improved their health and HRQL compared to prior to the treatment (Author et al 2014, 2103)—some of them do not exercise enough to

maintain their reduced body weight. Notably there was a slight increase in bodyweight and impairments in psychological factors mental components of HRQL between six to 12 months follow-up (Author et al 2013, 2014). Previous research has revealed that regaining weight following lifestyle interventions, not achieving permanent weight-loss afterwards, has led some participants to choose weight-loss surgery (Gronning et al., 2013). In order to understand and prevent the often observed and reported relapses in obesity treatment, it is important to acknowledge the "battle" some of the participants experienced following the treatment program in this and other qualitative studies (Gronning et al., 2013; Kirk et al., 2014). In light of this "battle" and the less promising long-term results regarding lifestyle intervention for the treatment of severe obesity (Christiansen et al., 2007; Gronning et al., 2013), it is important to be aware of the fact that weight reduction leads to decreased energy expenditure in combination with increased hunger and reduced satiety (i.e. adaptive thermogenesis) (Major, Doucet, Trayhurn, Astrup, & Tremblay, 2007; Rosenbaum & Leibel, 2010; Rosenbaum, Kissileff, Mayer, Hirsch, & Leibel, 2010; Sumithran & Proietto, 2013). Most participants will have to continue their energy reduced diet and/or high levels of physical activity for the rest of their lives to maintain their reduced bodyweight (MacLean, Bergouignan, Cornier, & Jackman, 2011; Johannsen et al., 2012; Reed, Chaput, Tremblay, & Doucet, 2013; Delany, Kelley, Hames, Jakicic, & Goodpaster, 2014), and will have to work even "harder" to continue weight reduction.

Methodological considerations

Participants provided retrospective reflections of their experiences with physical activity prior to, during and immediately after the inpatient period, whereas their experiences with later physical activity were provided through present time reflections. The time span between the end of the inpatient stay and the interviews might have influenced the

participant's perception and experiences in the treatment program and its physical activity component. The role of retrospection has to be properly understood. We aimed to explore how the participants currently understand the experience when they "look back on" the treatment, and not the most "correct" reproduction of something that happened some years ago. The criterion is not perfection, but a description that is sufficiently expressive so that new insightful knowledge about the phenomenon can be obtained (Giorgi, 2009). Furthermore, our intention was to interview participants who had participated in the same treatment program to compare and contrast their experiences. It could be argued that an interview at one particular time might elicit answers that are not necessarily reflective of that person's general experiences. Still, all participants in this study had been severely obese for several years, and they were considered to have sufficient experiences as participants in an intensive lifestyle intervention with high volume of physical activity, as well as incentive to maintain physical activity and exercise for several months. They are hence considered as information-rich sources that provide varied and rich narratives of physical activity during the inpatient period as well as after.

Asking the psychologist who was leader of the treatment to initially recruit the participants may have influenced the sample. Participants considered as positive or more likely to say yes than no may have been chosen, or those who were asked may have felt obliged to participate or reluctant to criticize the treatment program. These circumstances were, however, carefully considered and are described thoroughly in the section ''participants", and no patients who were asked to participate declined.

Findings from a qualitative study cannot be generalized in a statistical sense for the population of severe obesity as a whole, but are rather descriptions applicable within a specified setting (Malterud, 2001). The general description of physical activity in this context should not be considered as complete, and our study results are not generalizable to the

background population of subjects with severe obesity. Still, because of the detailed nature of the description, it seems reasonable to consider the findings in relation to similar contexts in other clinical subpopulations with severe obesity. To encourage individuals with severe obesity to narrate their experiences of physical activity in a particular context and in their own words, has contributed new knowledge regarding how individuals with severe obesity understand physical activity, as well as the role of such activity and exercise in their lives.

Implications for clinical practice

The knowledge provided in this study is important for those working in the field to take in to account when designing, implementing and evaluating treatment programs, as well as communicating with participants. What the population of subjects with severe obesity has in common is their bodyweight (OR: BMI). Other than that there is great diversity in relation to causes, complications, effects and experiences, a diversity which has a significant impact on how the treatment is experienced and is affecting each participant. There are no certain "truths" that can be determined about how a treatment program "works" and affects individual participants, and programs must take different experiences into account. An exploration of individual experiences is essential for programs to serve individual participants. Increased knowledge about individual variations in experiences may therefore be important in creating more individualized treatment and a context or environment for growth and development in participants' experiences.

Obesity treatment programs should look beyond the effect of physical activity on weight-reduction, put the participant's experiences of physical activity and exercise in the foreground, and encourage reflection on and empathic understanding of how it actually feels to be an exercising body (Allen-Collinson, 2009). Participants commonly distrust their own bodies prior to the treatment. It is essential for professionals to realise that the experience of

confidence related to exercise can become meaningful for this group of patients. Severe obesity is a condition associated with failed attempts at change and repeated relapses (Rippe, McInnis, & Melanson, 2001; Gronning et al., 2013), and it is not desirable that these individuals should experience yet another defeat. When "being in the bubble" (the treatment context) it is not "difficult" to exercise, the "battle" and ambivalence is likely to become more apparent when back home. It is therefore important to be open regarding the experienced ambivalence toward exercise, as well as the "battle" to maintain reduced body weight. Obese individuals may also be "different" persons in their homes, as compared to the treatment setting (Rugseth, 2011). A promising direction of future treatment and research should focus on the homes and lives of the participants, and aim to talk with such participants when they have returned to their families and communities.

It is also important for educators and health care providers to realise that not all participants have positive experiences being part of a group. Some feel that they don't fit in to the group. Recognizing this may be crucial in relation to their continuing in the treatment program and benefiting from it.

Concluding comments

Individuals with severe obesity participating in an intensive inpatient lifestyle modification program experienced coping with a high volume of adapted physical activity during their inpatient stay. However, their experiences were characterized by ambivalence. There was a shift in how they felt about physical activity as exercise from the start of the treatment to the end of it, as well as an on-going, dynamic and constantly shifting experience during being physically active. These findings challenge the underlying assumption that such physical activity is "good for everything" and gives meaning to "everybody." Our findings suggest that physical activity for individuals with severe obesity should not be viewed from an exclusively

biological and physiological perspective. Personal and contextual experiences may at least partly account for relatively high dropout numbers from treatment programs and lack of persistence with the weight maintenance behaviour. The experiences revealed in our findings constitute knowledge about an ambivalence of attending physical activity that should be included in the treatment programs, and communicated during the treatment.

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Appendix I

Appendix I: An overview of intensive lifestyle interventions (ILI) for the treatment of severe obesity (1985-2014)

Reference* Design	Participants n (% female)	Lifestyle intervention description	Follow-up time (% completion rate) Changes in BW compared to baseline:%	BC, PF, EB, HRQL (Methods) Key findings related to ILI
		BEFORE THE ONSET OF THIS STUDY		
Björvell & Rössner 1985, 1992 [166,167] *Non-randomized clinical trial?*	n = 68 (78 %) F:46 years BMI 40.5 kg/m² BW: 111.4 kg M:41 years BMI: 52.9 kg/m² BW: 137.9kg	**6 weeks day care program** -Diet: 600kcal/day -PA: adapted exercise 3times/weeks, groups/individual w/physiotherapist, + other activities (swimming, walking, "shopping exercises") - Lessons on behavioral modification 2times/week **4 year follow-up:** weekly booster sessions -Followed up by phone/letter if didn't show up -Two weeks periods at the ward to avoid relapse **Compared to:* *I: Jaw fixation* *II: Control: 2x45 min interviews of 45 minutes* *-Written program on reducing weight + invited to ordinary program after 1 year.*	**6 weeks** (100 %): F:↓~9%, M:↓~9% **6 months** F:↓~15%,M:↓~22% **1 year:** (91%): F:↓~14%,M:↓~22% **2 year** (87 %): F:↓~12%,M:↓~18% **3 year (**82 %)**:** F:↓~9%,M:↓~12 % **4 year** (82 %): F:↓10 %,M:↓13 % **10 years** (72 %): F: ↓~9%,M:↓~12%	NR
Hakala et al 1993 [235] Randomized clinical trial	n = 30 (67 %) F:41 years BMI 43.6 kg/m² BW: 120.7 kg M:39 years BMI:143.6kg/m² BW: 137.9kg	**2 weeks inpatient program** -Diet: 1200kcal/day, 15 hours of nutrition counseling -PA: 15 hours of physical activation and training - 15 hours of occupational therapy **Follow-up:** -Opportunity to participate in groups sessions once a week over 6 weeks, every other week next ten months, and once a month during the second intervention year (together 40 hours during two years) -Individual appointments with the physician at 4 month intervals **Compared to individual counselling with physiotherapist*	**2 weeks** (100 %): F:↓4%, M:↓5% **3 months** (100 %): F:↓13%,M:↓11% **8 months** (100 %): F:↓13%,M:↓9% **1 year:** (100%): F:↓13%,M:↓9% **2 year** (100 %): F:↓4%,M:↓1% **4 year** (93%): F:↓~2 %,M:↓ ~2%	NR
Golay et al 1996 [165] *Randomized trial	n = 22 (86 %) 41 year BMI: 42.7 kg/m² BW: 107 kg	**6 weeks inpatient program** -Diet: 1000kcal/day (15 % carbohydrate) -PA: 1 hour of aerobic exercise training + 1 hour pool PA each day -Cognitive behavioral techniques, relapse prevention, psychologist **Compared to diet with different content of protein*	**6 weeks** (100 %): ↓7 %	BC (Mean value of Skinfold thickness and BIA – RJL Systems, Detroit, MI)) **6 weeks:** ΔBW/weeks = 1.3 kg ΔFM/ΔBW=113 %

Golay et al 2004 [236] Prospective case-control study	n = 69 48 % BED 67 % moderate/ major depression n=55 (82 %)* 49 years BMI: 40.0 kg/m^2 BW: 106.7 kg **follow-up 5 years*	**6 weeks inpatient program** -Diet: 1200kcal/day -PA: 1 h of aerobic exercise training + 1 hour pool PA each day -Cognitive behavioral techniques, relapse prevention, >10 psychologist sessions **Follow-up:** Subsequently hospitalized for 1 day every 4th month Regularly followed by GP 4-5 years, Regular diet reviews Diet: - 500 kcal/day, PA: 1-2 X 30-60 minutes of moderate PA	**6 weeks:** ↓ 7% **5 years:** NR	EB (DSM-IV, EDI) PF (Beck's depression scale, DSM-IV) Weight changes correlated with degree of psychosocial difficulties and eating behavior problems.
Maffiuletti et al 2005 [69] 1-year prospective cohort study	n = 64 (70%) 30 years BMI: 41.3 kg/m^2 BW: ~ 113.4 kg	**3 weeks inpatient program** - Diet: 1200–1800 kcal/day, ~ 500 kcal from basal energy expenditure - PA: 5 individually supervised sessions/week: 30–40-min aerobic activities at 40–70% of individual VO_2 max + 15 x 40–70% of 1RM. - Psychological counselling: individual or cognitive-behavioral strategies **No formal follow-up, encouraged to control their diet and PA** + telephone contact at 6 months	**3 weeks:** (100 % ?) ↓ ~ 4% **1 year:** (100 % ?) ↓ ~ 6 %	BC (BIA – Human IM, Dietosystem, Milan, Italy) **3 weeks:** ΔBW/weeks ~ 1.6 kg ΔFFM/ΔBW=24 %
Pedersen et al 2006 [239] Prospective cohort study	n=27 (56 %) 33 years BMI: 46 kg/m^2 BW: 139 kg	**15 weeks inpatient program** -Diet: calculated intended to cause 1% body weight reduction/week -PA: < 2-3 hours supervised 5 days/week + 30 minutes before breakfast **No follow-up reported**	**15 weeks** (42 %): ↓ 11%	BC (BIA – Quantum X, RJL, system MI, USA) **15 weeks:** ΔBW/weeks=0.9 kg ΔFFM/ΔBW: could not be calculated
Clini et al 2006 [238] Observational pilot study	n = 59 (69 %) 60 years BMI: 47 kg/m^2 BW: 122 kg All with sleep disturbance 88 % BED	**1 month inpatient program** -Diet: individually tailored low-calorie diet -PA: 2 x 1 hour moderate to low intensity activities per day -Twice weekly sessions of psychotherapy **Follow-up:** A brief non-structured telephone at ~ 3 months Subsequently hospitalized to make measurements at 6 months	**1 month:** ↓~5 % **6 month** ↓~ 6%	HRQL (Sat-P questionnaire) PF (MMPI-2) EB (EDI-2,BES) Immediately improvement in HRQL and a reduced proportion of suggestive binge eaters at six months follow-up
Pagoto et al 2007 [86] Retrospective study	n=131 ~49 years BMI: 43 kg/m^2 BW: ~120 kg 13 % MDD 17 % BED 17% MDD+ BED	**16 weeks outpatient program** -Weekly sessions, group delivery: dietitian (5 sessions), exercise physiologist (5 sessions), and clinical health psychologist (6 sessions). - Six instructional small-group exercise classes were offered to each patient -Diet: 500 to 1000 daily calorie reduction -PA: 150 minutes of moderate activity weekly 6 months maintenance phase involved monthly "alumni" groups Toolbox including: step counters, recipe swapping, newsletters, and an electronic resource library.	**16 weeks:** BED ↓ 3.1 % MDD ↓ 3.3 % Non BED↓ 5.4 % Non MDD↓ 5.3 %	MDD and BED (DSM-IV) MDD and BED are associated with less weight loss

Christiansen et al 2007 [171] Retrospective follow- up study	249 (72 %) (NB! 70% of the eligible sample) 39 years BMI: 47.5 kg/m^2 BW: 142 kg	**21 weeks inpatient program** -Diet: 2190 kcal/day (readjusted during the program) -PA: 120 min/day, structured PA supervised by physiotherapist, group based: swimming, aerobic, strength training, walking, and ergometer bicycling, estimated intensity of 50- 60% of VO_2max -Sessions with focus on cognitive strategies **No follow-up reported**	**21 weeks:** (100%) ↓15 % **2 year:** (11%) ↓7 % **3 year:** (49%) ↓6 % **4 year:** (40%) ↓5 %	NR
AFTER THE ONSET OF THIS STUDY				
[a]Goodpaster et al 2010 [173] [b]DeLany et al 2014 [185] Randomized trial	67 (85 %) 46 years BMI: 43.5 kg/m^2 BW: 120.6 kg	**1 year outpatient program** **Initial PA (IPA) group,** i.e. diet and PA 12 months: -Combination of group, individual and telephone contact -PA: Prescription of a progressive program until 60 min of moderate intensity 5 d/week, goal>10 000 steps/d. Self-monitor in weekly diary. -Diet: 1200-2100 kcal/d, some meal replacements.	**6 months** (90 %): ↓9 % **12 months** (73 %): ↓10 %	BC (DXA, air displacement plethysmography and CT) [a]**6 months:** ΔBW/weeks=0.4 kg ΔFFM/ΔBW=22 % [b] FM increased with increased physical activity, whereas no differences in FFM
	63 (92 %) 48 years BMI: 43.7 kg/m^2 BW: 117.4 kg	**Delayed PA (DPA) group**, i.e. identical dietary intervention, PA delayed for 6 months	**6 months** (90%): ↓7 % **12 months** (83%): ↓ 8%	
[a]Hofsø et al 2010 [172] [b]Karlsen et al 2013 [290] MOBILstudy: *Non-randomized controlled Study	66 (~ 70 %) 47 years BMI: 43.3 kg/m^2 BW: 125 kg	**4 intermittent inpatient stays (1-4-1-1 weeks)** -10, 13, 23 weeks home periods between - Diet: asked to reduce daily total energy intake, follow guidelines of the Norwegian National Council of Nutrition -PA: 3–4 hour organized PA/day - 3–4 hour different psychosocially oriented interventions, individual consultations and group sessions, each day. Motivational interviewing - Home-periods: contacted by phone once every 2 weeks. Self-monitor eating habits and PA, and visit their GP once every 4 weeks **Compared to Roux-en Y gastric bypass*	[a]**1 year:** (95 %): ↓8 %	[b]HRQL (SF-36, OWLQOL, WRSM) Moderate changes in HRQL, associations between weight loss and change in HRQL
Unick et al 2011,2013 [72,276] Look AHEAD Comparison across BMI groups	562 (66%) 56 years BMI 44.8 kg/m^2 BW: 124 kg With type 2 diabetes	**1 year outpatient** -Months 0-6: 3 weekly group sessions/month + 1 individual counseling with registered dietitian, behavioral psychologist or exercise physiologist -Months 7–12: 2 group meetings + 1 individual session/month -Diet: Prescribed calorie goal of 1,200–1,800 kcal/d, Meal replacements -PA: Home-based exercise plan, gradually increase to ≥175 min of moderate PA (e.g., brisk walking)/week first 6 months. -Behavioral techniques and goal-setting, stimulus control + a "toolbox" with advanced behavioral strategies and pharmacotherapy for participants struggling	**1 year:** (99%?): ↓ 9 % **2 years:** ↓ ~ 6.5 % **3 years:** ↓ ~ 5.5 % **4 year:** ↓5%	NR

Martins et al 2011 [288] *Non-randomized study	64 (58%) 42 years BMI: 45.3 kg/m² BW: 137 kg	**3 intermitted inpatient periods (8 to 10-4-2 weeks)** 8 weeks and 4-5 months home periods between -Diet: nutrition education program, energy intake not reported -PA: 2 group sessions and 1 individual/day, supervised by a PA therapist -Dynamic group-based psychotherapy **Follow-up:** 2 weeks inpatient stay every 6 months up to 5 years	**1 year** (88 %): ↓13%	NR
**Compared to Roux-en Y gastric bypass*	30 (70%) 38.4 years BMI: 48.3 kg/m² BW: 144 kg	**21 weeks inpatient program** -Diet: conventional low calorie diet, energy intake not reported -PA: Daily intensive PA, supervised by PA physiotherapist, ≥ 120 min/day -Weekly sessions with focus on cognitive strategies (more details, see Christiansen et al 2007 table 2) **Follow-up:** Meeting with a psychiatric nurse every 2 week,	**1 year** (90 %): ↓15 %	
	57 (82%) 41.4 years BMI: 44.3 kg/m² BW: 126 kg	**6 months outpatient Program** -Regular individual meetings with a physiotherapist to increase PA: first 2 months: 3 times/week, 2 times/week last 4 months + 1 h/week self-training -2,5 hour/week group meetings **6 months weight maintenance program** -Weekly group meeting with physiotherapist, group meetings every 2 months at hospital	**1 year** (81 %): ↓5 %	
Bannert et al 2011 [294] Retrospective study	64 (67.7 %) 44 years BMI: 50.0 kg/m² BW: 143.3 kg With psychological comorbidities	**8-12 weeks Inpatient Weight Reduction Program** -Diet: non-diet, but nutrition information in group 2x60 min, individual counselling 1x 60 min, energy intake not reported -PA: Aqua-gymnastic 2x30 min, Music-gymnastic/low-impact 2x30min, Walking 2 x 30 min -Psychology: psychiatric consultation 1 x 60 min, individual therapy 2 x 50 min, group intervention: 2 x 60 min, skills and social competence training 2 x 60 min, self-image 1 x 60 min, relaxation 1 x 60 min	**8-12 weeks:** ↓ 7 % **1 year:** (27%) NR?	BC (BIA – DATA INPUT Nutriguard-M) **8-12 weeks:** ΔBW/weeks =1kg ΔFFM/ΔBW=20 % EB (TFEQ-FEV), PF (BDI, SCL-90 R), HRQL (SF-36). Significant improvements in EB, PF and HRQL. Few PF correlated with weight loss, weight loss not related to HRQL

Faulconbridge et al 2012 [291] Prospective, Observational Study	49 (79.6%) 44 years BMI: 44.3 kg/m^2 BW: 125.8 kg With BED	**One year outpatient group program of lifestyle modification**: -90 minutes sessions by a clinical psychologist. Weeks 1-20 weekly, weeks 22-40 bi-weekly and week 40-51monthly session -Diet: week 0-2:1800-2000kcal/day -Week 3-14 1200, Week: 1-20 weekly, weeks 1300 kcal/d – Week 18 --> 1400-1600kcal/day, liquid meal replacement. -PA :Encouraged to gradually increase to 180 minutes/week of aerobic PA -Behavioral techniques, relapse prevention, 90 minutes by a psychologist **Compared to Roux-en Y gastric bypass*	**2 months:** ↓5 % **6 months:** ↓11 % **12 month:** ↓10 %	EB (EDE, DSM-V),PF (BDI-II), HRQL (SF-36) Significant improvements in binge eating, symptoms of depression and HRQL at 6 months. Slight increase in binge eating and symptom of depression between 6 and 12 months. Weight loss predicted changes in symptoms of depression, not vise versa.
Gjevestad et al 2013 [317] *1 year non-randomized controlled pragmatic clinical trial	232 (65 %) 43 years BMI: 43.0 kg/m^2 BW: 126.7 kg	**Outpatient Intensive lifestyle Intervention** -Diet: energy restriction of 1000kcal/d of calculated total energy expenditure - Week 1-12: Treatment sessions 6 hour 3 days/week. Two supervised training sessions for 60-90 minutes (mainly aerobic exercise of moderate-high intensity, 8 MET's), followed by lectures on nutrition, PA and motivation. Lifestyle modification intervention to change behavior -Week 13-52: monthly follow-up, alternating between group-based and individual sessions. Water based exercise first hour, 2 hour of lifestyle modification intervention including lectures on PA and nutrition **Compared to outpatient moderate lifestyle intervention (MLI)*	**3 months:** (97 %): ↓ ~ 8 % **1 year:** (78 %): ↓ 11 %	HRQL (SF-12, OWLQOL) ILI greater improvements in HRQL than MLI.
Andersen et al 2013 [359] 6-years prospective cohort study	41 (62 %) 40 years BMI: 50.2kg/m^2 BW: 151.6 kg	**2 x 16 weeks inpatient periods (8 weeks in between)** -Participants engaged in daily physical activity and were provided with a healthy diet and emotional support.	**6 years (85 %)** **Un-operated (32 %)** ↓ 13 %	80 % had undergone/were scheduled for bariatric surgery.
Aadland et al 2012-2014 [275] The Haugland Obesity Study 1-year prospective cohort study	49 (76 %) 43 years BMI: 42.0 kg/m^2 BW: 123.9 kg	**3 intermittent inpatient periods (6-3-3weeks)** ~14 and 27 weeks home periods between -Diet: reduced-energy meal plan based on Nordic recommendations, taught how to prepare healthy meals -PA: supervised and structured exercise program: 20-30 minutes brisk walking before breakfast, 2 x 45-60 minutes exercise sessions individually/group 5 d/week. No specific intensity target. Encouraged to perform PA on their own. Developed plan for PA at home. -Cognitive behavior therapy Multidisciplinary team, theoretical and practical sessions **No systematic follow-up at home** Contact the clinic or GP if needed	**6 weeks:** (98%): ↓ 9 % **Week 53:** (71%): ↓6 %	BC (BIA – BC420 S, MA, Tanita Corp, Tokyo Japan) **6 weeks:** ΔBW/weeks ~1 kg ΔFFM/ΔBW~15 % Increased PA intensity associated with FM loss in men and women, PA duration associated with FM loss in men

Martins et al 2013 [289] A retrospective follow-up study	81 (64 %) 41 years BMI: 44.9 kg/m² BW: 134 kg	**5 intermittent stays at a rehabilitation center (8-4-2-2-2weeks)** -8 weeks, 4-5 month, 6 months, 6 months home periods between **-**Supervised PA: 2 group session + 1 individual/d) -Nutrition education program. 6 meals/d (4 main meals + 2 snacks) provided by the kitchen or by the participants in groups with help of dietician and a chef. All food/meals provided ad libitum and followed guidelines. Participants asked to follow same guidelines in home stays -Dynamic group-based psychotherapy, each patient in charge of their own treatment. Effort on translating new knowledge/practices acquired at the clinic to the home and establishing long-term support at home	**8 weeks** (100 %) ↓9% **1 year:** (90 %): ↓ 16% **2 years** (64 %): ↓13%	NR
	98 (66 %) 42 years BMI: 43.3 kg/m² BW: 126 kg	**5 intermittent stays at a rehabilitation center (2-4-2-2-2weeks)** -content of program same as program above	**4 weeks** (100 %): ↓3 % **1 year:** (91 %): ↓ 11% **2 years** (66 %): ↓6%	

Abbreviations: BC = body composition, BDI = Beck Depression Inventory, BES = Binge Eating Scale, BIA= Bioelectrical Impedance Analysis, BMI= body mass index, BW = body weight, CT = computed tomography, DSM-IV= Diagnostic and Statistical Manual of Mental Disorders 4th Edition, DXA = Dual-energy X-ray absorptiometry, EB = eating behavior, EDE = Eating Disorder Examination, EDI =Eating Disorder Inventory, F=female, HRQL= Health related quality of life, M= male, MDD = major depressive disorder, MMPI = Minnesota Multiphasic Personality Inventory, NR = Not reported, OWLQOL = Obesity and Weight loss Quality of Life Instrument, PA = physical activity, PF= psychosocial factors, SCL = Symptom Checklist, SF-36 (12) = 36 (12)-Item Short Form Health Survey, TFEQ = Three Factor Eating Questionnaire, WRSM = the Weight-Related Symptom Measure. Symbols: * reference number in thesis,↓=reduction, ~could not be calculated accurately due to lack of data/information in paper, ? = could not be calculated due to lack of data/information in paper, Δ = change, ΔBW/weeks = change in body weight divided by the duration of the inpatient stay, ΔFFM/ΔBW = the fraction of total weight loss coming from FFM . Notably studies including intensive interventions based on meal replacement or medication are not included. Notably: ILI using drug treatment is not included.

Appendix II

Appendix II: Questionnaires quantitative study (paper II-II)

BES: VEILEDNING:
På de følgende sider er det grupper av nummererte uttalelser. Les alle uttalelser i hver gruppe og sett et kryss ved den uttalelse i hver gruppe som best beskriver dine følelser i forhold til de problemer du har med å kontrollere dine spisevaner.

1.

1.	□	Jeg er ikke flau over vekten min eller størrelsen på kroppen min når jeg er sammen med andre.
2.	□	Jeg tenker på hvordan andre ser meg, men det gjør med normalt ikke skuffet over meg selv.
3.	□	Jeg blir flau over mitt utseende og vekten min, og det gjør meg skuffet over meg selv.
4.	□	Jeg er veldig flau over vekten min og jeg føler ofte dyp skam og avsky for meg selv. Jeg prøver å unngå kontakt med mennesker, fordi jeg er så flau.

2.

1.	□	Jeg har ingen vanskeligheter med å spise behersket og sakte.
2.	□	Selv om jeg later til å "sluke" maten, føler jeg meg ikke overmett fordi jeg har spist for mye.
3.	□	Noen ganger har jeg en tendens til å spise fort, og da føler jeg meg ubehagelig mett etterpå.
4.	□	Jeg har for vane å sluke maten, uten å tygge den ordentlig. Når jeg føler det, føler jeg meg som regel ubehagelig overmett, fordi jeg har spist for mye.

3.

1.	□	Jeg føler jeg kan beherske min spisetrang når jeg vil.
2.	□	Jeg har en følelse av at jeg er dårligere til å beherske spisingen min enn gjennomsnittsmenneske.
3.	□	Jeg føler meg helt hjelpesløs når det gjelder å beherske min spisetrang.
4.	□	Fordi jeg føler meg så hjelpesløs når det gjelder å beherske spisingen min, er jeg blitt helt desperat for å prøve å få kontroll.

4.

1.	□	Jeg har ikke for vane å spise, når jeg kjeder meg.
2.	□	Iblant spiser jeg, når jeg kjeder meg, men ofte klarer jeg å "finne på" noe for å få tankene bort fra mat.
3.	□	Jeg har for vane å "kjedespise" men det hender at jeg kan foreta meg noe for å få tankene vekk fra å spise.
4.	□	Jeg har en innbitt vane med å "kjedespise". Ingenting synes å hjelpe meg til å bli kvitt denne vanen.

5.

1.	□	Som regel er jeg fysisk sulten når jeg spiser noe.
2.	□	Noen ganger spiser jeg noe helt impulsivt, selv om jeg egentlig ikke er sulten.
3.	□	Jeg har den uvane og stadig spise mat som egentlig ikke smaker meg for å tilfredsstille en sultfølelse, enda jeg ikke trenger maten rent fysisk.
4.	□	Selv om jeg ikke er fysisk sulten, får jeg en følelse av sult i munnen, som bare ser ut til å kunne tilfredsstilles hvis jeg spiser noe mat, f.eks. et stykke smørbrød som fyller munnen min. Noen ganger, når jeg spiser mat for å tilfredsstille munnsulten, spytter jeg ut maten for ikke å legge på meg.

6.

1.	□	Jeg føler ikke skyld eller selvforakt etter at jeg har spist for mye.
2.	□	Når jeg har spist for mye føler jeg iblant skyld eller selvforakt.
3.	□	Nesten hele tiden føler jeg skyld eller selvforakt når jeg har spist for mye.

7.

1.	□	Jeg mister ikke helt kontrollen med spisingen min under en slankekur, selv etter perioder hvor jeg har spist for mye.
2.	□	Noen ganger når jeg har spist mye "forbudt" mens jeg er på slankekur, føler jeg at nå har jeg ødelagt alt og så spiser jeg enda mer.
3.	□	Jeg sier ofte til meg selv, når jeg har spist for mye under en slankekur: "nå har jeg ødelagt det, så nå kan jeg like gjerne fortsette". Når det hender, spiser jeg enda mer.
4.	□	Jeg starter regelmessig på en streng slankekur, men jeg bryter kuren ved å begynne et "etegilde". Mitt liv ser ut til å være enten et "etegilde" eller en slankekur.

8.

1.	□	Jeg spiser sjelden så mye at jeg føler meg ubehagelig mett etterpå.
2.	□	Noen ganger (kanskje en gang i måneden) spiser jeg så mye mat, at jeg ender opp med å føle meg ubehagelig overmett.
3.	□	Jeg har regelmessige perioder i hver måned, jeg konsumerer store mengder mat, enten til måltidene eller som mellommåltider.
4.	□	Jeg spiser så mye mat at jeg stadig føler meg meget uvel etter å ha spist, og noen ganger litt kvalm.

9.

1.	□	Mitt kalori-inntak hverken stiger eller synker meget på en regelmessig basis.
2.	□	Noen ganger etter at jeg har spist for mye, prøver jeg å redusere kalori-inntaket mitt til nesten ingenting for å kompensere for de ekstra kaloriene, jeg har spist.
3.	□	Jeg spiser for mye om kvelden. Det virker som om der er naturlig for meg å ikke være sulten om morgenen, men å spise for mye om kvelden.
4.	□	I mitt voksne liv har jeg hatt ukelange perioder hvor jeg nesten har sultet meg. Disse har etterfulgt perioder, hvor jeg har "overspist". Jeg synes å leve et liv enten i matorgier eller sult.

10.

1.	□	Jeg er normalt i stand til å slutte å spise, når jeg vil det. Jeg vet når "nok er nok".
2.	□	En gang i mellom får jeg en tvingende trang til å spise som jeg ikke synes å beherske.
3.	□	Jeg får ofte en voldsom trang til å spise som jeg ikke synes å kunne beherske, men andre ganger har jeg min spisetrang under kontroll.
4.	□	Jeg føler meg ute av stand til å beherske trangen til å spise. Jeg er redd for ikke å kunne stanse å spise frivillig.

11.

1.	□	Jeg har ingen problemer med å slutte å spise, når jeg føler meg mett.
2.	□	Jeg kan som regel slutte å spise, når jeg er mett, men iblant spiser jeg for mye, så blir jeg ubehagelig mett.
3.	□	Jeg har vanskelig for slutte å spise når jeg først har begynt. Vanligvis føler jeg meg ubehagelig overmett etter ett måltid.
4.	□	Fordi jeg ikke klarer å slutte å spise når jeg vil, må jeg noen ganger tvinge meg til å kaste opp for å lette på følelsen av å ha spist for mye.

12.

1.	□	Det synes som om jeg spiser akkurat like mye når jeg er sammen med andre (familie, i selskaper) som når jeg er alene.
2.	□	Noen ganger, når jeg spiser sammen med andre, spiser jeg ikke så mye som jeg har lyst til, fordi jeg er flau over spisingen min.
3.	□	Ofte spiser jeg bare litt når det er andre tilstede, fordi jeg er så veldig flau over spisingen min.
4.	□	Jeg skammer meg sånn over den overdrevne spisingen min at jeg velger å "ete" på tider da jeg vet at ingen ser meg. Jeg føler meg som en "skap-eter".

13.

1.	□	Jeg spiser tre måltider om dagen og tar bare i blant et mellommåltid.
2.	□	Jeg spiser tre måltider om dagen, men jeg spiser normalt også litt mellom måltidene.
3.	□	Når jeg småspiser for mye vender jeg meg til å hoppe over ordentlige måltider.
4.	□	Det er hele perioder, hvor jeg later til å spise uavbrutt, uten noen planlagte måltider.

14.

1.	□	Jeg tenker ikke mye på å prøve å beherske min uønskede spisetrang.
2.	□	Jeg føler i det minste noe av tiden, at tankene kretser om å prøve å beherske min spisetrang.
3.	□	Jeg føler at jeg ofte bruker mye tid på å tenke på hvor mye jeg spiser eller på å prøve å ikke spise mer.
4.	□	Jeg synes at jeg mesteparten av mitt våkne liv er opptatt med tanke om å spise eller ikke spise. Jeg føler det som om jeg stadig kjemper for å ikke spise.

15.

1.	□	Jeg tenker ikke særlig på mat.
2.	□	Jeg har sterke anfall av trang til mat, men de er kortvarige.
3.	□	Det er dager, hvor det virker som om jeg ikke kan tenke på annet enn mat.
4.	□	Det meste av min tid synes å være opptatt med tanker på mat. Jeg føler at jeg lever for å spise.

16.

1.	□	Jeg vet normalt om jeg er fysisk sulten eller ikke. Jeg spiser en passende porsjon for å bli mett.
2.	□	Det hender at jeg er usikker på om jeg er fysisk sulten eller ikke. Da er det vanskelig å vite hvor mye mat jeg skal spise for å bli mett.
3.	□	Selv om jeg vet hvor mange kalorier jeg bør spise, har jeg ikke noen ide om hva som er "normal" mengde mat for meg.

<u>TFEQ:</u> Avsnittene nedenfor handler om matvaner og sultfølelse. Les hver påstand eller spørsmål og angi hvilket svar som passer best til deg.
Sett et kryss i avkrysningsboksen til venstre for det svaret som passer best.

1. Jeg tar med hensikt små porsjoner for å holde kroppsvekten nede.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

2. Når jeg føler meg urolig, oppdager jeg ofte at jeg spiser.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

3. Av og til når jeg begynner å spise, er det akkurat som om jeg ikke klarer å slutte.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

4. Når jeg føler meg nedstemt, spiser jeg ofte for mye.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

5. Jeg unngår visse typer mat fordi de er fetende for meg.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

6. Når jeg er sammen med andre som spiser, får jeg selv ofte lyst på mat og begynner å spise.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

7. Når jeg er anspent eller "oppgiret", føler jeg ofte trang til å spise.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

8. Jeg får ofte så lyst på mat at magen føles som et stort hull som ikke kan fylles.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

9. Jeg har alltid lyst på mat, så det er vanskelig for meg å slutte å spise før jeg har spist opp alt på tallerkenen.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

10. Når jeg føler meg ensom, trøster jeg meg selv med å spise.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

11. Jeg holder bevisst igjen ved måltidene for ikke å gå opp i vekt.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

12. Når jeg kjenner lukten av en biff som stekes eller ser en saftig kjøttbit, er det veldig vanskelig å la være å spise selv om jeg akkurat har avsluttet måltidet.
- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

<u>TFEQ:</u> Avsnittene nedenfor handler om matvaner og sultfølelse. Les hver påstand eller spørsmål og angi hvilket svar som passer best til deg.
Sett et kryss i avkrysningsboksen til venstre for det svaret som passer best.

13. Jeg har alltid lyst på noe å spise, så jeg kan spise når som helst.

- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

14. Hvis jeg kjenner meg ille til mote, forsøker jeg å dempe ubehaget med å spise.

- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

15. Når jeg ser noe som ser veldig godt ut, får jeg ofte så lyst på det at jeg må det spise med en gang.

- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

16. Når jeg føler meg dyster til sinns eller lei meg, vil jeg ha noe å spise.

- ☐ Stemmer helt
- ☐ Stemmer ganske bra
- ☐ Stemmer ikke særlig bra
- ☐ Stemmer ikke i det hele tatt

17. Hvor ofte unngår du å ha fristende mat tilgjengelig?

- ☐ Nesten aldri
- ☐ Sjelden
- ☐ Ofte
- ☐ Nesten alltid

18. Hvor sannsynlig er det at du bevisst spiser mindre enn det du vil ha?

- ☐ Usannsynlig
- ☐ Ikke særlig sannsynlig
- ☐ Ganske sannsynlig
- ☐ Veldig sannsynlig

19. Fortsetter du å spise selv om du ikke er sulten lenger?

- ☐ Aldri
- ☐ Sjelden
- ☐ Iblant
- ☐ Minst en gang i uken

20. Hvor ofte har du lyst på mat?

- ☐ Bare til måltidene
- ☐ Iblant mellom måltidene
- ☐ Ofte mellom måltidene
- ☐ Neste alltid

21. På en skala fra 1 til 8, der 1 står for ingen begrensning (spiser hva jeg vil, når jeg vil) og 8 står for streng begrensning (begrenser alltid matinntaket, gir aldri etter), hvor på skalaen befinner du deg?
Sett en ring rundt det tallet som passer best for deg.

1	2	3	4	5	6	7	8
Spiser hva jeg vil, når jeg vil							*Begrenser alltid matinntaket, gir aldri etter*

HADS:

Her kommer noen spørsmål om hvorledes du føler deg. For hvert spørsmål setter du kryss for ett av de fire svarene som best beskriver dine følelser **den siste uka**. Ikke tenk for lenge på svaret – de spontane svarene er best.

1. Jeg føler meg nervøs og urolig

- ☐ 3 – Mesteparten av tiden
- ☐ 2 – Mye av tiden
- ☐ 1 – Fra tid til annen
- ☐ 0 – Ikke i det hele tatt

2. Jeg gleder meg fortsatt over tingene slik jeg pleide før.

- ☐ 0 – Avgjort like mye
- ☐ 1 – Ikke fullt så mye
- ☐ 2 – Bare lite grann
- ☐ 3 – Ikke i det hele tatt

3. Jeg har en uroføelse som om noe forferdelig vil skje.

- ☐ 3 – Ja, og noe svært ille
- ☐ 2 – Ja, ikke så veldig ille
- ☐ 1 – Litt, bekymrer meg lite
- ☐ 0 – Ikke i det hele tatt

4. Jeg kan le og se det morsomme i situasjoner

- ☐ 0 – Like mye nå som før
- ☐ 1 – Ikke like mye nå som før
- ☐ 2 – Avgjort ikke som før
- ☐ 3 – Ikke i det hele tatt

5. Jeg har hodet fullt av bekymringer

- ☐ 3 – Veldig ofte
- ☐ 2 – Ganske ofte
- ☐ 1 – Av og til
- ☐ 0 – En gang i blant

6. Jeg er i godt humør

- ☐ 3 – Aldri
- ☐ 2 – Noen ganger
- ☐ 1 – Ganske ofte
- ☐ 0 – For det meste

7. Jeg kan sitte i fred og ro og kjenne at jeg er avslappet

- ☐ 0 – Ja, helt klart
- ☐ 1 – Vanligvis
- ☐ 2 – Ikke så ofte
- ☐ 3 – Ikke i det hele tatt

8. Jeg føler meg som om alt går langsommere

- ☐ 3 – Nesten hele tiden
- ☐ 2 – Svært ofte
- ☐ 1 – Fra tid til annen
- ☐ 0 – Ikke i det hele tatt

9. Jeg føler meg urolig som om jeg har sommerfugler i magen

- ☐ 0 – Ikke i det hele tatt
- ☐ 1 – Fra tid til annen
- ☐ 2 – Ganske ofte
- ☐ 3 – Svært ofte

10. Jeg bryr meg ikke lenger om hvordan jeg ser ut

- ☐ 3 – Ja, har sluttet å bry meg
- ☐ 2 – Ikke som jeg burde
- ☐ 1 – Kan hende ikke nok
- ☐ 0 – Bryr meg som før

11. Jeg er rastløs som om jeg stadig må være aktiv

- ☐ 3 – Uten tvil svært mye
- ☐ 2 – Ganske mye
- ☐ 1 – Ikke så veldig mye
- ☐ 0 – Ikke i det hel tatt

12. Jeg ser med glede frem til hendelser og ting

- ☐ 0 – Like mye som før
- ☐ 1 – Heller mindre enn før
- ☐ 2 – Avgjort mindre enn før
- ☐ 3 – Nesten ikke i det hele tatt

13. Jeg kan plutselig få en følelse av panikk

- ☐ 3 – Uten tvil svært ofte
- ☐ 2 – Ganske ofte
- ☐ 1 – Ikke så veldig ofte
- ☐ 0 – Ikke i det hel tatt

14. Jeg kan glede meg over gode bøker, radio og TV

- ☐ 0 – Ofte
- ☐ 1 – Fra tid til annen
- ☐ 2 – Ikke så ofte
- ☐ 3 – Svært sjelden

SF-36: INTRODUKSJON: Dette spørreskjema handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å få vite hvordan du har det og hvordan du er i stand til å utføre dine daglige gjøremål.

Hvert spørsmål skal besvares ved å sette ett kryss (X) i den boksen som passer best for deg. Hvis du er usikker på hva du skal svare, vennligst svar så godt du kan.

1. Stort sett, vil du si at din helse er:

Utmerket	**Meget god**	**God**	**Nokså god**	**Dårlig**
☐	☐	☐	☐	☐

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

Mye bedre nå enn for et år siden	**Litt bedre nå enn for et år siden**	**Omtrent den samme som for et år siden**	**Litt dårligere nå enn for et år siden**	**Mye dårligere nå enn for et år siden**
☐	☐	☐	☐	☐

3. De neste spørsmålene handler om aktiviteter som du kanskje utøver 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	☐	☐	☐
b. **Moderate aktiviteter** som å flytte et bord, støvsuge, gå en tur eller drive med hagearbeid	☐	☐	☐
c. Løfte eller bære en handlekurv	☐	☐	☐
d. Gå opp trappen **flere** etasjer	☐	☐	☐
e. Gå opp trappen **en** etasje	☐	☐	☐
f. Bøye deg eller sitte på huk	☐	☐	☐
g. Gå **mer enn to kilometer**	☐	☐	☐
h. Gå **noen hundre meter**	☐	☐	☐
i. Gå **hundre meter**	☐	☐	☐
j. Vaske deg eller kle på deg	☐	☐	☐

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

	Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke I det hele tatt
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	☐	☐	☐	☐	☐
b. Du har **utrettet mindre** enn du hadde ønsket	☐	☐	☐	☐	☐
c. Du har vært hindret i å utføre **visse typer** arbeid eller gjøremål	☐	☐	☐	☐	☐
d. Du har hatt **problemer** med å gjennomføre arbeidet eller andre gjøremål (for eksempel fordi det krevde ekstra anstrengelser)	☐	☐	☐	☐	☐

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

	Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	☐	☐	☐	☐	☐
b. Du har **utrettet mindre** enn du hadde ønsket	☐	☐	☐	☐	☐
c. Du har utført arbeidet eller andre gjøremål mindre **grundig** enn vanlig	☐	☐	☐	☐	☐

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

Ikke i det hele tatt	Litt	En del	Mye	Svært mye
☐	☐	☐	☐	☐

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

Ingen	Meget svake	Svake	Moderate	Sterke	Meget sterke
☐	☐	☐	☐	☐	☐

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

Ikke i det hele tatt	Litt	En del	Mye	Svært mye
☐	☐	☐	☐	☐

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 svarsalternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 ukene har du:

	Hele tiden	**Mye av tiden**	**En del av tiden**	**Litt av tiden**	**Ikke i det hele tatt**
a. Følt deg full av liv?	☐	☐	☐	☐	☐
b. Følt deg veldig nervøs?	☐	☐	☐	☐	☐
c. Vært så langt nede at ingenting har kunnet muntre deg opp?	☐	☐	☐	☐	☐
d. Følt deg rolig og harmonisk?	☐	☐	☐	☐	☐
e. Hatt mye overskudd?	☐	☐	☐	☐	☐
f. Følt deg nedfor og deprimert?	☐	☐	☐	☐	☐
g. Følt deg sliten?	☐	☐	☐	☐	☐
h. Følt deg glad?	☐	☐	☐	☐	☐
i. Følt deg trett?	☐	☐	☐	☐	☐

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

Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
☐	☐	☐	☐	☐

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

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

Appendix III

Appendix III: Interview guide qualitative study (paper IV)

Jeg vil nå gjerne høre litt om <u>dine erfaringer med fysisk aktivitet</u> før, under og etter behandlingen?

1: Hvilke erfaringer hadde du med fysisk aktivitet og trening FØR du startet på behandlingsopplegget?

- **Kan du beskrive ditt aktivitetsnivå i tiden før behandlingen?**
    - Var du fysisk aktiv før behandlingen?
    - Hvis ja: Hvor mye og hva?
- **Når du ser tilbake, hva var det som eventuelt gjorde at du ikke var fysisk aktiv før?**
    - Kan du prøve å fortelle litt om hva konkret som har stoppet deg fra å drive regelmessig fysisk aktivitet?
    - Var/er familie og venner aktive?
        - Hvordan var miljøet du var i? Var det "in" å trene? Hva følte du om det?
    - Har du tidligere prøvd å komme i gang med fysisk aktivitet?
- **Har du (også) tidligere hatt perioder hvor du har vært regelmessig fysisk aktiv?**
- **Hva var det som gjorde at det ikke ble varig?**
- **Hva har forandret seg siden den gang?**

2: Kan du beskrive din erfaring med fysisk aktivitet UNDER behandlingsoppholdet?

- Dere deltok i opptil 2-3 økter per dag, **hvordan var dine erfaringer med all treningen?**
    - Hvordan vil du beskrive all treningen?
    - Hva ga det deg?
    - Hva gjorde at du da (under oppholdet) fikk til å være i fysisk aktivitet
    - Hvordan var det å trene sammen med andre som også har sykelig overvekt?
    - Hvordan vil du beskrive viktigheten av instruktørene?
        - Trygghet/kunnskap/erfaring?
        - Hvordan opplever du å bli pushet av en instruktør?
    - Evt. utstyr/fasiliteter?
    - Hva likte du best?
    - Hva motiverte deg?
    - Var det noen aktivitetsformer du likte bedre enn andre?
        - Natur? Gruppetrening? Styrke? Kondisjon?
        - Hva føler du har stoppet deg fra å gjøre det?
    - Hva var annerledes enn dine tidligere erfaringer med fysisk aktivitet?

3: Kan du beskrive dine erfaringer med fysisk aktivitet nå etter behandlingen?

- **Kan du beskrive ditt aktivitetsnivå nå i tiden etter behandlingen?**
    - Var du fysisk aktiv før behandlingen?
    - Hvis ja: Hvor mye og hva?
- **Hvordan opplever du å være i fysisk aktivitet nå?**
- **Hva er annerledes i forhold til før behandlingsoppholdet?**
    - Hvordan var det å være fysisk aktiv tidligere?
- **Hva har hatt betydning for at du nå er i mer regelmessig fysisk aktivitet?**
    - Har du fortsatt med fysisk aktivitet etter behandlingen?
        - Hva, hvor ofte, hvor, med hvem?
    - Føles det som en barriere?
    - Føler du at du har nok kunnskap om trening for å kunne drive med det?
    - Hvordan motiverer du deg sjølv dersom du har veldig liten lyst til å dra på trening? Har du noen "knep" på en tung dag?
    - Hva er en god og vellykket treningsøkt for deg?
- **Har det oppstått nye dilemmaer for deg nå knyttet til det å være fysisk aktiv?**
- **Hva tenker du på når du er fysisk aktiv?**
- **Hva er det ved det å være fysisk aktiv som er attraktivt for deg?**
- **Hva er det som er vanskelig ved det å være fysisk aktiv synes du?**
- **Evt: Har du noen tankar om hvorfor dette ikke har gått helt som du ønsket?**
    - Hvorfor du ikke er fysisk aktiv?

Appendix IV

UNIVERSITETET I OSLO
DET MEDISINSKE FAKULTET

Sjeflege og professor 2 Sverre Mæhlum
Hjelp24 NIMI AS
Postboks 4903 Nydalen
0423 Oslo

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

Telefon: 22 84 46 67
E-post: post@helseforskning.etikkom.no
Nettadresse: http://helseforskning.etikkom.no

Dato: 28.01.2010
Deres ref.:
Vår ref.: 2009/1699 (oppgis ved henvendelse)

Livsstilsendring for personer med sykelig overvekt

Vi viser til tilbakemelding på komiteens merknader til ovennevnte prosjekt, slik de fremkom i brev av 13.11.09. Tilbakemeldingen ble mottatt 23.12.09.

Komiteen behandlet prosjektet første gang på møte 29.10.09, og fattet følgende vedtak: *Vedtak utsettes i påvente av at ovennevnte merknader besvares. Når svar foreligger, vil komiteens leder ta stilling til spørsmålet om godkjenning.* Merknadene var knyttet til spørsmål om ansøkte forskningsbiobank, innhenting av aktivt samtykke til deltakelse og revisjon av informasjonsskriv.

Komiteens leder har behandlet prosjektet på delegert fullmakt 12.01.2010. Studien er vurdert i henhold til lov av 20. juni 2008 nr. 44, om medisinsk og helsefaglig forskning (helseforskningsloven) kapittel 3, med tilhørende forskrift om organisering av medisinsk og helsefaglig forskning av 1. juli 2009 nr 0955.

Forskningsetisk vurdering
Komiteen har ingen forskningsetiske innvendinger til studien.

Det søkes i tilbakemeldingen om å kunne forespørre aktuelle deltakere om å delta i oppfølgingsstudien, samt å inkludere spørreskjema for langtidsoppfølging, ved utsendelse av informasjonsskriv og samtykkeerklæring. Komiteen har ingen innvendinger til denne fremgangsmåten.

Forskningsbiobank
Det søkes om opprettelse av en spesifikk forskningsbiobank for prosjektet. Biobanken har navn *Langvarige effekter av livsstilsendring for pasienter med sykelig overvekt.* Dette er en allerede eksisterende diagnostisk biobank, som ønskes omgjort til forskningsbiobank.

Forskningsansvarlig og ansvarshavende for biobanken er Professor 2 Sverre Mæhlum.

Materiale og opplysninger vil oppbevares til 2019, hvoretter det skal slettes.

Innførsel eller utførsel av materiale er ikke aktuelt.

Informasjonsskriv og samtykkeerklæring
Komiteen har ingen innvendinger til den forelagte informasjonen.

Vedtak:
Prosjektet godkjennes.

Komiteen godkjenner opprettelse av forskningsbiobanken *Langvarige effekter av livsstilsendring for pasienter med sykelig overvekt.* Biobankregisteret blir underrettet ved kopi av dette brevet.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden og protokollen, samt i tilsvar til komiteen av 23.12.09, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Tillatelsen gjelder til 31.12.2014. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 31.12.2019. Opplysningene skal lagres avidentifisert, dvs. atskilt i en nøkkel- og en opplysningsfil. Prosjektet skal sende sluttmelding på eget skjema, jf. helseforskningsloven § 12, senest et halvt år etter prosjektslutt.

Hvis det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK. Vi gjør oppmerksom på at hvis endringene er vesentlige, må prosjektleder sende ny søknad, eller REK kan pålegge at det sendes ny søknad.

Hvis forskningsbiobanken opphører, nedlegges eller overtas av andre, skal det søkes REK om tillatelse, jf. § 30.

Med vennlig hilsen

Arvid Heiberg (sign.)
professor dr. med.
leder

Øyvind Grønlie Olsen
rådgiver

UNIVERSITETET I OSLO
DET MEDISINSKE FAKULTET

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Telefon: 22 84 46 67
E-post: t.e.svanes@medisin.uio.no
Nettadresse: http://helseforskning.etikkom.no

Dato: 24.11.10
Deres ref.:
Vår ref.: 2009/1699 (oppgis ved henvendelse)

Livsstilsendring for personer med sykelig overvekt

Vi viser til skjema for prosjektendring datert 04.11.2010.
Det søkes om følgende endringer:
1: Økning i antall deltakere:
Inklusjon av følgende antall nye deltakere til prospektiv del av studien: ca 70 pasienter ved Hjelp24 NIMI Ringerike og ca 50 pasienter ved Hjelp24 NIMI Ekeberg.

Søknaden er gitt både praktisk og faglig begrunnelse.

2. Det søkes om å ringe tidligere pasientene for å purre på tilbakesending av samtykkeerklæring (retrospektiv studie av akutte og langvarige effekter) og spørreskjema (kun for gruppen inkludert i langvarige effekter), samt gjennomføre et kort intervju med utvalgte spørsmål fra spørreskjema per telefon for de som er ønsket i langtidsoppfølgingsstudien. Det vil da spørres om dagens vekt, arbeidssituasjon, sivil status, om de har forsøkt andre behandlingsmetoder (evt. hvilke), evt. tilleggssykdommer og medisinbruk, spisevaner og kosthold, planlegging og fysisk aktivitet.

Komiteens vurdering
Komiteens nestleder har vurdert endringssøknaden på delegert fullmakt fra komiteen.

Komiteen har ingen innvendinger til søknad om utvidelse av studien med antall deltakere.

Ad endring 2, så er det ut fra et forskningsetisk perspektiv viktig å ivareta forskningsdeltakeres frivillighet og respektere deres ønske om ikke å delta i forskning. Komiteen tillater én telefonoppringing og i den forbindelse eventuelt intervju per telefon. Det forutsettes imidlertid at det ikke utøves noen form for press til deltakelse og at det også på telefon gis uttrykkelig informasjon om at deltakelse er frivillig, og at dersom de ikke ønsker å delta vil det ikke få noen som helst konsekvenser for videre behandling.

Vedtak
Komiteen godkjenner endringssøknaden med det vilkår som fremkommer av komiteens vurdering.

Komiteen godkjenner prosjektet slik det nå foreligger med hjemmel i helseforskningsloven § 11.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokollen, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriftens kap. 2, og Helsedirektoratets veileder for "Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren" (http://www.helsedirektoratet.no/samspill/informasjonssikkerhet/norm_for_informasjonssikkerhet_i_helsesektoren_232354)

Prosjektet skal sende sluttmelding på eget skjema (se helseforskningsloven § 12) senest et halvt år etter prosjektslutt.

Med vennlig hilsen

Grete Dyb (sign.)
nestleder

Julianne Krohn-Hansen
seniorrådgiver

UNIVERSITETET I OSLO
DET MEDISINSKE FAKULTET

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0423 Oslo

Regional komité for medisinsk forskningsetikk
REK Sør- Øst B (REK Sør-Øst B)
Postboks 1130 Blindern

Telefon: 22844624

E-post: katrine.ore@medisin.uio.no
Nettadresse: www.etikkom.no

Dato: 18.02.11
Deres ref.:
Vår ref.: 2010/1656

Livsstilsendring for personer med sykelig overvekt

Saksfremstilling
Vi viser til innsendt endringsmelding datert 15.01.2010. Endringene som søkes godkjent er et ønske om at deltaker-antallet i studien økes med ca 60 fra Hjelp24 NIMI Ringerike og ca 15 fra Hjelp24 NIMI Ekeberg. Samlet deltakerantall ønskes økt til ca 200. Den vitenskapelige begrunnelse for å endre antall inkluderte i studien er begrunnet med økt statistisk styrke og at samtlige pasienter allrede i klinikk gjennomfører tester og målinger som beskrevet i forskningsprotokollen. Det er ikke nødvendig å endre informasjonsskriv eller samtykkeerklæring for studien.

Forskningsetisk vurdering
Komiteen har ingen forskningsetiske innvendinger til at studien kan gjennomføres med de innmeldte endringene som beskrevet ovenfor.

Vedtak
Komiteen godkjenner prosjektet slik det nå foreligger.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad, godkjente endringsmeldinger og forskningsprotokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren». Personidentifiserbare data slettes straks det ikke lenger er behov for dem og senest ved prosjektets avslutning.

Prosjektet skal sende sluttmelding på eget skjema, senest et halvt år etter prosjektslutt jfr helseforskningsloven § 12

Vi ber om at alle henvendelser sendes inn via vår saksportal: http://helseforskning.etikkom.no eller på e-post til: post@helseforskning.etikkom.no

UNIVERSITETET I OSLO
DET MEDISINSKE FAKULTET

Vennligst oppgi vårt referansenummer i korrespondansen.

Vennlig hilsen

Stein Opjordsmoen Ilner
Professor dr. med
Komitéleder

Katrine Ore
Komitésekretær/Rådgiver

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Katrine Ore	22845517	29.09.2011	2009/1699/REK sør-øst B
			Deres dato:	**Deres referanse:**
			05.09.2011 og 15.09.2011	

Vår referanse må oppgis ved alle henvendelser

Sjeflege, professor II dr. med Sverre Mæhlum

Hjelp24 NIMI AS

Livsstilsendring for personer med sykelig overvekt

Vi viser til innsendt skjema for prosjektendringer 05.09.2011 og e-post 15.09.2011. Det er sendt inn følgende vedlegg:

- Revidert informasjonsskriv

De omsøkte endringene dreier seg om endringer i rekrutteringsprosedyrer

Prosjektleder viser til godkjent prosjektsøknad fra 05.10.2009. Det er nå ønskelig å starte rekruttering av "kontroller" som beskrevet i godkjent prosjekt. På bakgrunn av styrkeberegninger for prospektiv studie er det ønskelig å inkluderer 60 antall "kontroller"/ventelistepasienter. "Kontroller" vil hentes fra ventelister for pasienter som venter på behandling for sykelig overvekt. Disse vil rekrutteres fra pasienter som får tilbud om behandling ved hjelp24 NIMI Ringerike eller Ekeberg, eller fra ventelister ved Senter for Sykelig Overvekt i Vestfold og/eller Aker. Deltakerne vil først bli invitert til deltakelse via skriftlig invitasjon til deltakelse/samtykke som sende via post sammen med innkalling til tilbud om behandlingsopphold. Kort tid etter til deltakerne også bli kontaktet per telefon for å forsikre om at invitasjon mottatt og gi nærmere informasjon om studien, samt invitere til deltakelse. Deltakerne vil få tilbud om pre-test til individuell til ved Norges Idrettshøgskole eller Hjelp24 NIMI Ringerike, post-test vil inngå som del av innkomst-tester ved oppstart behandlingsopphold.

Forskningsetisk vurdering

Komiteens leder Stein Opjordsmoen Ilner har på delegert fullmakt vurdert endringssøknaden.

REK sør-øst B har ingen forskningsetiske innvendinger til at prosjektet videreføres med de omsøkte prosjektendringene.

Besøksadresse:
Gullhaug torg 4 A, Nydalen,
0484 Oslo

Telefon: 22845511
E-post:
post@helseforskning.etikkom.no
Web:
http://helseforskning.etikkom.no/

Vedtak

Komiteen har vurdert endringsmeldingen og godkjenner prosjektet slik det nå foreligger med hjemmel i helseforskningsloven § 11.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i tidligere godkjent søknad, med de innarbeidelser av endringer komiteen har fått tilsendt som beskrevet i dette vedtaksbrevet, samt de bestemmelser som følger av helseforskningsloven med forskrifter.

Dersom det skal gjøres vesentlige endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren».

Prosjektet skal sende sluttmelding på eget skjema senest et halvt år etter prosjektslutt.jfr helseforskningsloven § 12.

Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. Forvaltningslovens § 28 flg. Eventuell klage sendes til REK Sør-øst. Klagefristen er tre uker fra mottak av dette brevet.

Vi ber om at alle henvendelser sendes inn via vår saksportal: http://helseforskning.etikkom.no eller på e-post til: post@helseforskning.etikkom.no

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen,

Stein Opjordsmoen Ilner (sign.)
professor dr med
Komiteens leder

Katrine Ore
komitésekretær/rådgiver REK sør-øst B,

Kopi til: hans.andresen@nih.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Harsha Gajjar Mikkelsen	22845513	10.08.2012	2009/1699 REK sør-øst B
			Deres dato:	**Deres referanse:**
			29.06.2012	

Vår referanse må oppgis ved alle henvendelser

Sverre Mæhlum
Hjelp24 NIMI AS

2009/1699b Livsstilsendring for personer med sykelig overvekt

Forskningsansvarlig: Norges idrettshøgskole
Prosjektleder: Sverre Mæhlum

Vi viser til innsendt søknad om prosjektendring datert 29.06.2012 for ovennevnte forskningsprosjekt.

De omsøkte endringer er beskrevet i skjema for prosjektendringer og dreier seg om:

1. Det informeres også om endringer med prosjektarbeidere. Gro Rugseth skal inn som ny prosjektmedarbeider.
2. Det ønskes å innhente ny data fra samme utvalgsgruppe for å øke kunnskapen om faktorer som er avgjørende for å lykkes i behandlingsprogrammet. Det ønskes å utvide studien til å inkludere bruk av kvalitativ metoder g gjennomføre dybde-intervju av 20 pasienter som har deltatt i livsstilendringsbehandling og allerede er inkludert i den prospektive studien.
3. Det informeres om endringer i rekrutteringsprosydyrer. Forespørsel om å delta i den kvalitative delen av studien sendes deltakere via email/post/telefon fra Hjelp24. Deltakerne skal rekrutteres og intervjues høsten 2012 og våren 2013.

Vurdering
Komiteens leder Stein Opjordsmoen Ilner har på delegert fullmakt vurdert endringssøknaden.

REK sør-øst B har ingen forskningsetiske innvendinger til prosjektet slik det nå foreligger.

Vedtak
Komiteen har vurdert endringsmeldingen og godkjenner prosjektet slik det nå foreligger med hjemmel i helseforskningsloven § 11.

Tillatelsen er gitt under forutsetning av at prosjektendringen gjennomføres slik det er beskrevet i prosjektendringsmeldingen, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «*Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren*».

Vi ber om at alle henvendelser sendes inn via vår saksportal: http://helseforskning.etikkom.no eller på e-post til post@helseforskning.etikkom.no.

Besøksadresse:
Nydalen allé 37 B, 0484 Oslo

Telefon: 22845511
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Stein Opjordsmoen Ilner
Professor dr. med.
Komitéleder

Harsha Gajjar Mikkelsen
førstekonsulent

Kopi til: *Avdelingsleder Hans T. Andresen, Norges idrettshøgskole*

Appendix V

FORESPØRSEL OM BRUK AV DATA TIL FORSKNINGSPROSJEKTET
Livsstilsendring for personer med sykelig overvekt

BAKGRUNN OG HENSIKT
Dette er en forespørsel til deg om å delta i en forskningsstudie hvor formålet er å evaluere effekten av behandlingsopplegget ved Hjelp 24 NIMI Ringerike i forhold til endring i vekt, følgesykdommer og ulike fysiske og psykiske helsevariabler akutt og over tid.

Det finnes i dag ulike behandlingsopplegg og kurstilbud for pasienter med sykelig overvekt. For å bidra til at pasientene får et best mulig tilpasset opplegg, er det nødvendig at tilbudene blir evaluert og videreutviklet. Ved hvert opphold ved Hjelp 24 NIMI Ringerike ber vi derfor om at deltakerne våre om å utføre ulike tester og besvare spørreskjemaer. I tillegg tas det også blodprøver og antropometriske målinger av deltakerne. For å vurdere suksessen av behandlingstilbudet ved Hjelp 24 NIMI Ringerike er det ønskelig at deltakerne gir oss tillatelse til å bruke de dataene vi får gjennom tester, prøver og spørreskjemaer.

Formålet med prosjektet er å undersøke effekten av et 16 ukers behandlingsopplegg for mennesker med sykelig overvekt på fysisk og psykisk helse, samt øke kunnskapen om viktige og/eller avgjørende faktorer for vellykket behandling og hva som kjennetegner de som har effekt av programmet. Målet er å øke kunnskapen om effekt av livsstilsendring for mennesker med sykelig overvekt. Prosjektet er et samarbeid mellom Hjelp 24 NIMI Ringerike, Hjelp 24 NIMI Ekeberg og Norges Idrettshøgskole (NIH), med Hjelp 24 NIMI som ansvarlig.

HVA INNEBÆRER STUDIEN
Informasjonen fra prøver, målinger, skjemaer og tester fra ditt opphold ved Hjelp 24 NIMI Ringerike vil bli registrert i din medisinske journal, og vi spør nå om vi kan bruke disse opplysningene for å gjennomføre denne studien.

MULIGE FORDELER OG ULEMPER
Du vil ikke ha noen spesielle fordeler av studien, men erfaringer fra studien vil senere kunne hjelpe andre med samme diagnose.

HVA SKJER MED PRØVENE OG INFORMASJONEN OM DEG?
Informasjonen som er registrert om deg og prøvene som er tatt skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn, fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres. Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger. Opplysningene blir senest slettet 2019.

FRIVILLIG DELTAKELSE
Det er frivillig å delta i studien. Dersom du ikke ønsker å delta, trenger du ikke å oppgi noen grunn, og det får ingen konsekvenser for den videre behandlingen du får ved sykehuset. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på denne siden. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling på sykehuset. Dersom du senere ønsker å trekke deg, kan du kontakte Stipendiat Kjersti Karoline Danielsen telefon 23 26 22 63/93 86 26 04 eller prosjektleder Prof/Dr Sverre Mæhlum telefon 48 11 67 06.

HVIS DU GODTAR AT DINE DATA BENYTTES
Dersom du godtar at dine data fra ditt behandlingsopphold ved Hjelp 24 NIMI Ringerike kan brukes til forskning ber vi deg fylle ut svararket under.

Samtykke til deltakelse i studien

JEG GODTAR AT MINE DATA BENYTTES

Jeg har mottatt skriftlig informasjon og **godtar at mine data benyttes** til forskning og statistiske fremstillinger ift behandlingsresultat

NAVN (med blokkbokstaver):_____

Dato Underskrift

Forespørsel om deltakelse i forskningsprosjektet

Livsstilsendring for personer med sykelig overvekt

I forbindelse med at du skal delta i/innkalles til behandlings opplegg med livsstilsendring, spør vi deg nå om du kan tenke deg å delta i en forskningsstudie. Vi ønsker å undersøke effekten av hele behandlingsopplegget for personer med sykelig overvekt ved Hjelp 24 NIMI Ringerike. Prosjektet er et samarbeid mellom Hjelp 24 NIMI Ringerike, Hjelp 24 NIMI Ekeberg og Norges Idrettshøgskole (NIH), med Hjelp 24 NIMI som ansvarlig.

For at pasienter med sykelig overvekt skal få et best mulig behandlingsopplegg, er det helt nødvendig at tilbudene hele tiden vurderes og forbedres. I forbindelse med prosjektet vil vi altså undersøke effekten av et 12-16 ukers behandlingsopplegg ved Hjelp 24 NIMI Ringerike både når det gjelder fysisk og psykisk helse, samt det å få økt kunnskap om viktige faktorer for vellykket behandling. Ved hvert opphold ved Hjelp 24 NIMI Ringerike svarer deltakerne på spørreskjema, det tas blodprøver og prøver som ser på kroppens sammensetning. Dette er først og fremst for å registrere utviklingen hos den enkelte deltaker, men disse registreringene benyttes også i forskningsdelen.

For at vi skal få undersøkt effekten av behandlingsopplegget ved Hjelp24 NIMI Ringerike er det ønskelig å sammenligne resultatene fra de som allerede har fått behandling med hvordan situasjonen er for de som «venter» på behandling. I forskningssammenheng kalles en slik «ventegruppe» en kontrollgruppe. Du er en av mange som er i en slik ventegruppe og vi spør deg derfor om du kan tenke deg å være med i en slik undersøkelse.

HVA MÅ DU DA VÆRE MED PÅ?
Dersom du velger å bli med innebærer det at du må møte til testing en gang i løpet av ukene 41-44 høsten 2011 ved Hjelp 24 NIMI Ringerike eller Norges Idrettshøgskole i Oslo. Det vil også være en test ved oppstart av eget behandlingsopplegg i januar 2012. Den testen må du ha uavhengig av om du er med i kontrollgruppen eller ikke for å få et utgangspunkt for hvordan ulike forhold (blodprøver, vekt, aktivitet osv.) er før du starter livsstilssendringen. Du vil så videre følge det vanlige behandlingsopplegget. Testingen innebærer måling av kroppssammensetning ved bruk av impedansevekt, måling av livvidde og utfylling av spørreskjema. Du vil få dekket reisegodtgjørelse med 3,65 kr per km, el billigste reisemåte, i forbindelse med denne første testingen. Fly eller taxi vil ikke dekkes.

HVA HAR DU IGJEN FOR Å VÆRE MED?
Som deltaker i forskningsstudien vil du få mulighet til å gjennomføre en grundig analyse av kroppssammensetning. Du vil få anledning til å teste ut det som også blir testene i forbindelse med selve behandlingen.

HVA SKJER MED PRØVENE OG INFORMASJONEN OM DEG?
Resultater fra de ulike testene skal kun brukes av autorisert personell i behandlingsgruppen og av forskerne som inngår i prosjektet. Alle opplysningene og prøvene vil bli behandlet uten navn, fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres. Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger. Opplysningene blir senest slettet 2019.

FRIVILLIG

Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte:

Stipendiat Kjersti Karoline Danielsen ved Norges Idrettshøgskole:
Mail: kjersti.karoline.danielsen@nih.no
Tlf: + 47 23 26 22 63/ + 47 93 86 26 04

Prosjektleder Prof/Dr Sverre Mæhlum ved Hjelp 24 NIMI:
Mail: sverre.maehlum@hjelp24.no
Tlf: +47 48 11 67 06

Samtykke til deltakelse i studien

Jeg har mottatt skriftlig informasjon og er villig til å delta i studien

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Dato Navn