The effects of behavioural obesity treatment in Iceland with or without surgical intervention on weight loss, body composition, physical work capacity, and physical activity:

A 4-year follow-up

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Thesis for the degree of Master of Public Health Sciences

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HEILBRIGÐISVÍSINDASVIÐ

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Áhrif atferlismeðferðar við offitu með eða án magahjáveituaðgerðar á þyngd, líkamssamsetningu, líkamlega afkastagetu og hreyfivenjur:
4 ára eftirfylgd

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Abstract

Background Obesity is one of world's largest health problems. Since 2001, the Reykjalundur Rehabilitation Centre in Iceland has utilized multidisciplinary obesity treatment involving a behavioural approach for severely obese patients (BMI ≥ 35 kg/m²) with possible pairing with Laparoscopic Roux-en-Y gastric bypass (LRYGB).

Aims The main aim of this 4-year follow-up study is to investigate the outcome of severely obese patients after undergoing behavioural obesity treatment at Reykjalundur as well as to identify any interaction between surgical treatment status (LRYGB or not) and the success of the behavioural obesity treatment.

Methods In this observational longitudinal study, subjects' bodyweight, body mass index (BMI), waist circumference, body composition, maximal physical work capacity on an ergometer cycle, and regular physical activity were recorded at the beginning of treatment (in years 2006-2008) and at a 4-year follow-up appointment. Patients non-randomly (by their own choice) received behavioural treatment alone (treatment group) or behavioural treatment plus gastric bypass surgery (treatment with surgery group).

Results Ninety of 120 (75%) eligible candidates participated, including 9 men and 81 women with a mean age of 40.3 years. Forty-seven patients (52%) underwent gastric bypass surgery. Both groups had significant ($p<0.05$) reductions in bodyweight, BMI, waist circumference, fat mass (FM), and fat percentage at 4-year follow-up. Both groups also increased their levels of physical activity. However the treatment with surgery group subjects had better results in most outcomes than non-surgically treated subjects. Maximal physical work capacity per weight (W/kg) increased in the treatment with surgery group ($p<0.05$) but remained unchanged in the treatment group.

Conclusion Behavioural obesity treatment was shown to be an effective therapeutic technique for severely obese patients, as patients showed significant improvements in BMI, waist circumference, body composition, and physical activity levels regardless of surgical treatment status. The treatment with surgery group showed significantly more improvements on most outcomes. It is important to investigate if greater improvements can be achieved among those who seek behavioural obesity treatment but do not wish to have gastric bypass surgery.

Keywords: Obesity, maximal physical work capacity, body composition, gastric bypass surgery, weight loss, exercise.

Ágrip

Bakgrunnur: Offita er ein helsta heilbrigðisvá samtímans. Á Reykjalundi hefur verið boðið upp á þverfaglega atferlismeðferð fyrir alvarlega offeita einstaklinga (BMI ≥ 35 kg/m²) frá árinu 2001 sem ýmist fara í magahjáveituaðgerð eða ekki.

Markmið: Meginmarkmið þessarar rannsóknar er að kanna árangur fólks í offitumeðferðinni á Reykjalundi 4 árum eftir upphaf meðferðar. Einnig bera saman árangur þeirra sem jafnframt fara í magahjáveituaðgerð og þeirra sem ekki fara í slíka aðgerð.

Aðferð: Rannsóknin er langsniðsrannsókn. Mælingar voru framkvæmdar í upphafi meðferðar á göngudeild og 4 árum eftir upphaf meðferðar. Þátttakendum var skipt í tvo hópa, aðgerðarhóp og þá sem ekki fóru í magahjáveituaðgerð. Gerðar voru mælingar á holdarfari (BMI), mittismáli, líkamssamsetningu með rafleiðnimælingu og gerð mæling á líkamlegri afkastagetu með hámarksþolprófi á þrekhjóli. Einnig voru þátttakendur spurðir út í hreyfivenjur.

Niðurstöður: Alls tóku 90 af 120 þátt eða 75%. Þar af voru 9 karlar og 81 kona. Meðalaldur var 40,3 ár. Það fóru 47 í magahjáveituaðgerð (52%). Niðurstöður í heild sýna marktækan árangur beggja rannsóknarhópa hvað varðar þyngd, líkamsþyngdarstuðul, mittismál, fituhlutfall og fitumassa ($p<0{,}05$). Aðgerðarhópur náði marktækt betri árangri en þeir sem ekki fóru í magahjáveituaðgerð á öllum fyrrgreindum þáttum. Aðgerðarhópur jók einnig þrektölu (W/kg) sína marktækt ($p<0{,}05$) meðan sá hópur sem ekki fór í aðgerð stóð í stað. Hjá báðum rannsóknarhópum jókst reglubundin hreyfing.

Ályktun: Þverfagleg atferlismeðferð við offitu á Reykjalundi leiðir til marktæks þyngdartaps, minna mittismáls, hagstæðari líkamssamsetningar og aukinnar reglubundinnar hreyfingar bæði hjá þeim sem fara í magahjáveituaðgerð og þeim sem ekki fara í þá aðgerð. Aðgerðarhópurinn nær marktækt betri árangri í flestum þáttum rannsóknarinnar. Mikilvægt er að huga að hvort og þá hvernig hægt er að bæta árangur þeirra sem ekki fara í magahjáveituaðgerð.

Þakkir

Ritgerð þessi er lokaverkefni Guðlaugs Birgissonar til meistaragráðu í lýðheilsuvísindum við Háskóla Íslands og jafngildir hún 60 ECTS einingum. Leiðbeinandi verkefnisins var Dr. Marta Guðjónsdóttir. Kann ég henni sérstakar þakkir fyrir leiðsögnina í gegnum allt ferlið. Ludvig Á. Guðmundsson yfirlæknir á offitusviði Reykjalundar var ábyrgðarmaður rannsóknarinnar, var með í öllu ferli hennar, undirbúningi, skipulagi og framkvæmd. Fyrir það kann ég honum bestu þakkir. Auk Mörtu og Ludvigs í meistaranefndinni var Sigrún Vala Björnsdóttir lektor við námsbraut í sjúkraþjálfun í HÍ. Kærar þakkir fær Sigrún Vala sem og aðrir í meistaranefndinni fyrir þá leiðsögn og hvatningu sem þau lögðu til verkefnisins. Sérstakar þakkir fær Reykjalundur fyrir að gera mér kleift að sinna náminu samhliða vinnu minni þar. Vísindasjóður Reykjalundar lagði til fjárstyrk til rannsóknarinnar, sem unnin er á Reykjalundi og það ber sannarlega að þakka. Maríönnu Þórðardóttur sem vann rannsókn á sama þýði vil ég þakka góð kynni og fyrirtaks faglega samvinnu. Kærar þakkir fær Thor Aspelund tölfræðingur sem veitti góð ráð og aðstoðaði við tölfræðilega úrvinnslu. Framlag þeirra sem komu að þolprófum og öðrum mælingum í rannsókninni er mikils metið, sér í lagi Ludvigs Á Guðmundssonar og Karls Kristjánssonar. Halldór Halldórsson fær þakkir fyrir skráningu þolprófa. Sarah Lucht fær kærar þakkir fyrir prófarkalestur.

Nánustu fjölskyldu minni þakka ég ríka þolinmæði og hvers kyns stuðning við vinnslu verkefnisins. Frábæru samstarfsfólki mínu á Reykjalundi innan sem utan offituteymis, sem kom með einum eða öðrum hætti að ráðgjöf og hvatningu við vinnslu rannsóknarinnar kann ég sérstakar þakkir. Það er mikil gæfa að starfa með slíku fólki.

Síðast en ekki síst vil ég tileinka meistaraverkefnið föður mínum Birgi Guðlaugssyni sem lést árið 2007 en hefur verið mér einstök fyrirmynd í lífinu.

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BMI = Body mass index

FM = Fat mass

LM = Lean mass

WHO = World Health Organization

RYGB = Roux-en-Y gastric bypass

LRYGB = Laparoscopic Roux-en-Y gastric bypass

MVPA = Moderate-to-vigorous physical activity

6MWT = Six-minute walking test

SD = Standard deviation

NS = Non-significant

Introduction

Obesity as a health problem

Obesity has become a global health problem. According to the World Health Organization (WHO), obesity levels worldwide have nearly doubled since 1980. In 2008, more than 1.4 billion adults over the age of 20 were overweight (BMI ≥ 25 kg/m²). Of these, over 200 million men and nearly 300 million women were obese (BMI ≥ 30 kg/m²) (1). Diseases related to obesity have become major health problems in many countries all over the world and account for both physical and mental health problems as well as social dysfunction.

In clinical settings, patients are categorized as "overweight" or "obese" based on their Body Mass Index (BMI), which is defined as the weight in kilograms divided by the square of the height in metres (kg/m^2). Even though it does not give accurate information about body composition, BMI is a useful tool to estimate people's physical condition. Using BMI scores, patients are classified into normal (18.5-24.9 kg/m²), overweight (25-29.9 kg/m²), and obese (>30 kg/m²) weight categories (2). While there is an ongoing debate as to whether mortality is higher for overweight persons compared with those with normal weight, studies have however confirmed higher rates of mortality for obese persons compared with people of normal weight (3). Studies also show that excess weight (overweight or obese) at the age of 40 years reduces life expectancy by at least three to six years (4).

The Public Health Institute of Iceland investigated the trends in obesity in Iceland from 1990 to 2007 and found a great increase in incidence of obesity for both genders. In 1990, 7.2% of Icelandic adult men were obese, but that number had risen to 18.9% by 2007. For adult women in Iceland, the incidence of obesity rose from 9.5% to 21.3% between 1990 and 2007 (5). These surveys were based on self-reported height and weight; therefore some bias towards underestimation could have influenced the results. In the same survey, the majority of men (66.6%) and women (53.5%) were either overweight or obese. This increase in the number of overweight and obese adults is of growing concern for the Icelandic population and a similar trend has been reported the last decades in many other countries worldwide.

Obesity is associated with a variety of comorbidities including type 2 diabetes, cardiovascular diseases, various kinds of cancer, obstructive sleep apnea, gastroesophageal reflux disease, osteoarthritis, chronic back pain, vertebral disc diseases, fatty liver disease and dyslipidemias (6). In addition, obesity affects mental health, including providing an increased risk for the development of depression (7).

The causes of obesity are complex and not fully understood. It is indeed a multifactoral disease. There can for example be social, genetic, metabolic, cultural and behavioural attributes. Furthermore obese people often feel discriminated against in societies where slender body images are the standard (8-10). Two of the main causes for obesity are unhealthy nutrition and low levels of physical activity. Weight gain is often attributed to the consumption of more calories than those expended, and excess weight is the result of a chronic surplus in energy intake relative to expenditure. There has been an increase in marketing for unhealthy food for the last decades, and people are consuming more energy dense food. Consumption of ''fast food'' as well as sweets has been on the rise and is often cheaper than consuming less processed and more natural food sources such as fruits and vegetables. In relation to marketing and advertisement, people are frequently urged to lose weight with quick-fix solutions that usually do not lead to healthy long-term results (11, 12).

The role of physical activity

As mentioned above, physical activity plays a role in the energy balance of daily life and therefore in obesity. Regular exercise is important for weight control and studies have looked at possible factors influencing activity levels for decades. Due to technological advances, there has been a change in physical activity levels of people‘s daily lives. The introduction of the modern computer has led to dramatic changes in work conditions. As a result, more people are sedentary than before in different kinds of work. Certain work that was considered physically active before is now becoming more inactive due to technological advances, such as in industry and agriculture. New methods of transportation to and from work have also had an impact. It is estimated that 80% of all Europeans travel to work in their private car instead of walking, cycling or using public transportation (13, 14). The multimedia environment of today can reduce our physical activity level and it has been shown that TV-viewing and increased use of computer games have led to less physical activity among children and adolescents (15).

The preventative power of higher levels of physical activity against weight gain is logical. Maher et al. (16) studied the relationship of moderate-to-vigorous physical activity (MVPA) and obesity among 5083 adults. They found that MVPA was consistently inversely associated with obesity and that even small differences in MVPA (5-10 minutes per day) in daily life were associated with relatively large differences in risk of obesity.

Physical exercise is one of the main factors in prevention as well as treatment of obesity. For the last 15 years, many studies on the influence of environmental planning on daily physical activity have been conducted. Sallis et al. (17) studied a sample of 11541 subjects from 11 different countries. Their study results showed that environmental variables, including low-cost recreation facilities and the presence of sidewalks, were significantly related to meeting physical activity guidelines. Frank et al. (18) studied environmental factors and their relationship with recommended daily physical activity. In that study, 37% of those living in the most walkable environment met the daily physical activity recommendations of at least 30 minutes per day. On the other hand of those living in the least walkable environment only 18% met the recommendations. Future urban planning should consider these environmental factors in order to encourage higher levels of daily physical acitivity through increased accessibility to designated areas for exercise.

As previously described, an association between increased BMI and higher risk of mortality has been described in several studies. In addition, increased physical activity level results in better health independent from body weight, as it plays a critical role in improving cardiovascular health, particularly in persons with obesity and weight-related health complications (19). In the Aerobic Center Longitudinal Study, Lee et al. (20, 21) examined more than 21000 men and found lower death rates due to cardiovascular diseases among men who were fat but fit compared to those who were lean but unfit. Several studies even go as far as to say that low cardiorespiratory fitness and inactivity are a greater health threat than obesity (22). Therefore, regardless of its effect on weight loss, physical exercise should be a fundamental factor in the treatment of obesity because of its general health benefits. Thus to date, physical activity has a critical role to play in lifestyle interventions for weight management.

Treatment options for obesity

Current approaches in the treatment of obesity aim at accomplishing weight loss through decreasing energy intake, increasing energy expenditure, or a combination of both. Some methods also consider other behavioural, psychologic and social aspects in treatment. These treatment options include dietary programs, medical nutrition therapy, physical activity, behaviour therapy, psychologic programs, pharmaceutical therapy, bariatric surgery, or a combination of approaches (23, 24). Two of the most commonly used treatment methods for severely obese individuals are behavioural obesity treatment and gastric bypass surgery. The nature of those treatments and outcome to date will be discussed.

Behavioural obesity treatment

Behavioural treatment is an approach used to help individuals develop a set of skills to achieve a healthier weight. It includes helping people to identify which lifestyle changes are necessary as well as helping them understand how to implement these changes. The behaviour change process is facilitated through the use of self-monitoring, goal setting, and problem solving (25). Behavioural obesity treatment focuses on the behaviour and thus the lifestyle of the individual, as it supports the idea that sustained loss of excess weight requires significant and lasting changes in behaviour. That includes not only a change in dietary habits and physical activity but also in many other aspects of daily living, psychological and social aspects. In order to modify behaviour related to obesity it is important to have a multi-disciplinary approach. Since the nature and causes of obesity are complex, involvement of more diverse and relevant health professionals in the team may increase the efficacy of the treatment (26, 27). This approach gives the patient an oppourtunity to work with his psychological and social aspects of obesity as well as medical and cultural.

A team of health professionals utilizing behavioural therapy treatment may include, but is not limited to: a nutritionist, a physical therapist, a nurse, a doctor, a psychologist, a social worker, and an exercise physiologist. These health professionals give individualized advice and information to each obese person on how he or she can lose weight and maintain weight loss, and it is essential that the patient feels his or her lifestyle changes are maintainable. Thus a number of strategies are used to assist obese patients in making gradual changes that can realistically be incorporated into their lives.

Behavioural management in obesity is a relatively inexpensive strategy for weight control and non-invasive, which makes it more economical and accessible than surgical or pharmacological approaches (28).

Behavioural obesity treatment and long-term weight loss

One of the main difficulties in assessing the efficacy of treatments for long-term weight loss is the lack of a concrete definition for success. How much weight loss is a success?

Following behavioural obesity treatment, it has been established that moderate but sustained weight loss of 5-10% of baseline bodyweight represents a degree of success (29). Obesity experts also define this degree of weight loss as clinically important, since 5-10%

weight loss may improve lipid, glucose, and blood pressure levels, along with reducing cardiovascular disease (30-34).

Results from several studies have shown promising results for long-term weight loss following behavioural obesity treatment. In a Swedish study conducted in 1995, Bjorvell and Rossner (35) reported a follow-up of severely obese patients in which 74 subjects had lost an average of 11.7 kg at four years post-treatment. The Diabetes Prevention Project has shown similar success in people of high risk for diabetes (36). While these two studies show positive long-term results after using behavioural obesity treatment, not all obesity programs have been as successful. In a systematic review of 16 dietary/lifestyle therapy studies involving 5698 subjects, Douketis et al. (37) reported that mean weight loss in these studies was less than five kilos (3.5 ± 2.4 kg) at two to three years follow-up and similar after four to seven years (3.6 ± 2.6 kg). Middleton et al. (38) also reported in a systematic review and meta-analysis that while behavioural weight management interventions for obesity generally lead to 8-10% reductions in body weight, most participants regain weight after treatment ends. After the end of treatment, individuals typically experienced significant weight regain, regaining on average one-third to one-half of lost weight within the first year following treatment and returning to baseline weight within three to five years after end of treatment (24, 39).

Behavioural obesity treatment and body composition

While there are several different methods used to measure body composition, one of the most commonly used methods in clinical research today is dual-energy X-ray absorbtiometry (DXA). In DXA, two distinct low energy X-ray beams are used to penetrate bone and soft tissue areas of the body to a depth of approximately 30 cm. Computer software reconstructs the attenuated X-ray beams to produce an image of the underlying tissues and quantify bone mineral content, total fat mass and fat free mass. While the DXA is time consuming, expensive, and not useful in clinical practice, it is an accurate way of estimating body composition in research (40-43). A second method for measuring body composition involves Archimedes' principle applied to hydrostatic weighing (or underwater weighing). This method computes percentage body fat from body density, which is the ratio of body mass to body volume, and is also quite accurate (40).

Another way to measure body composition measurement uses a bioelectrical impedance test, where harmless electrical current is sent through the body where different conductivity is seen in lean tissue compared with fat tissue due to differences in water content. Usual recommended procedures are followed (44). Bioelectrical impedance technique has shown to be a reliable and valid approach for the estimation of human body composition (45, 46) . Several other methods exist for measuring body composition with lower accuracy, such as prediction of body fat percentage from skinfold thickness measurements (40). All previously mentioned body composition measurements give information about body fat and lean mass percentages.

In general, the total body fat percentage, which includes essential plus storage fat, is between 12% and 15% for young men and between 25% and 28% for young women (47). While different authorities have developed different recommendations for ideal body fat percentages, an example of reference values for fat percentages and their classification for both genders are shown in Table 1. Apart from being gender-specific, body fat percentage is age-related as it tends to increase with age (48).

Table 1. Body fat percentages for males and females and their classification (47).

Males	**Females**	**Rating**
5-10	8-15	Athletic
11-14	16-23	Good
15-20	24-30	Acceptable
21-24	31-36	Overweight
>24	>37	Obese

Fewer studies have investigated the influence of behavioural obesity treatment or its components on body composition than on weight loss. In a randomized controlled trial, Velthuis et al. (49) examined the influence of a 12-month moderate-to-vigorous exercise program on body composition in 189 sedentary postmenopausal women. The exercise program, which consisted of both aerobic and muscle strength training, resulted in a significant reduction in fat mass (-0.33 kg compared to control group) and fat percentage (-0.43 %) as well as an increase in lean mass (0.31 kg). In another study, a 10-week structured diet and exercise program for obese sedentary women showed a significant reduction in fat mass (2.3 ± 3.5 kg) (50). Hassapidou et al. (51) also found a significant reduction in fat mass (8 kg) after completion of a nine-month nutritional intervention in obese patients with severe mental illness. There was a high rate of dropping out in this study, as 989 patients started and only 145 finished the program. Research has also been conducted concerning the influence of high protein diet and strength training on body composition in overweight or obese patients with type 2 diabetes (52). Participants who finished the 16-week program showed a reduction of fat mass (11.1 ± 3.7 kg) and of lean mass (2.0 ± 2.3 kg). Zahouani et al. (53) investigated the effect of a very low caloric diet on body composition after three months and one year of treatment. After following 1389 obese outpatients for up to 12 months of treatment, they found that reductions of fat mass (11.6 ± 8.1 kg) as well as of lean mass (1.8 ± 2.9 kg).

All the studies mentioned above report short-term results, and few studies have investigated behavioural obesity treatment with respect to long-term influences on body composition. As mentioned before, previous studies on weight loss show weight regain after treatment ends. In theory, this would mean altered body composition, as seen in an increase in fat mass as well as fat percentage.

Behavioural obesity treatment and physical exercise capacity

Physical work capacity can be measured using paced and self-paced exercise tests when comparing the status at the beginning of an obesity treatment program to that at the end of the program. In paced tests there are pre-organized protocols with certain increments in work output, such as the incremental treadmill test (54, 55). It can be used as a maximal physical work capacity test or as submaximal. When it is used as a maximal physical work capacity test, it can also be used to measure maximal oxygen uptake (55). Another paced test to measure maximal physical work capacity is the ramp ergometer cycle test. This test is a measure of maximal capacity and can also be used as a measure of maximal oxygen uptake (55, 56). The pedalling rate in this test is constantly kept at 60-65 revolutions per minute (rpm). The load starts at 10-30 watts and is increased every minute, 10-30 watts each step (depending on the patient's exercise history) until exhaustion. The aim is to achieve test duration of 10 minutes as recommended for exercise tests (57). In a self-paced test, the patient decides the speed/effort. One example of a self-paced test is the six-minute walking test (6MWT). This test is a submaximal test where the patient walks for six minutes and the distance walked is recorded as well as pulse rate at beginning and at the end (58).

Ekman et al. (59) investigated the influence of a seven-month weight reduction program on physical work capacity in 129 obese patients. Using the 6MWT at baseline and at the end of the program, they found that the mean distance walked changed significantly from 535 m to 599 m. Based on these results, they concluded that the 6MWT may be used to evaluate intervention success beyond weight loss in obese subjects. A similar study in Brazil also used the 6MWT (60) to evaluate the results of a 30-minute weekly supervised exercise program for 6 months for morbidly obese patients. The results showed a significant increase in distance walked during the 6MWT with a mean increase of 69.8 ± 48.6 m.

Church et al. (61) examined the effects of different doses of exercise on fitness in overweight and obese postmenopausal women. Participants were randomly assigned to either the non-exercise control group or to one of three groups with prescription of 50, 100 and 150% of the NIH Concensus Development Panel recommended physical activity dose for women. In this was a six-month intervention, the ergometer cycle test was used to assess the fitness level at baseline and at six months and aerobic fitness was quantified using peak absolute oxygen consumption (L/min). Members of the 50, 100, and 150% exercise groups increased their peak absolute oxygen consumption compared to the non-exercise group by 4.2%, 6% and 8.2%, respectively, with graded dose-response change in fitness.

Another study examined the long-term effects of weight loss with and without additional aerobic and weight training exercises on exercise tolerance and cardiorespiratory fitness in obese women (62). All participants, 31 healthy obese women, underwent a weight loss program consisting of low calorie diet and behaviour therapy for a minimum of 46 weeks. Subjects were randomly assigned to one of four groups with all groups having a diet program while only two of the four groups included an aerobic exercise regime. Peak oxygen consumption on an ergometer cycle test was measured as well as peak oxygen consumption per bodyweight (ml/kg/min). At the end of the study, only groups performing aerobic exercises showed evidence of improved aerobic fitness.

Sarsan et al. (63) compared the effects of aerobic and resistance exercise on cardiovascular fitness in obese women who were not on an energy-restricted diet. Sixty obese women were assigned to one of three groups: aerobic exercise (n=20), resistance exercise (n=20), or control group (n=20). All subjects were evaluated at the beginning and the end of a 12-week period using an ergometer cycle test to measure peak oxygen consumption. The 6MWT was also used for measuring submaximal fitness. Both exercise groups significantly increased their peak oxygen consumption and distanced walked on the 6MWT while control group did not. The distance walked in the aerobic exercise and resistance exercise groups changed on average from 490.5 ± 75 m to 644.7 ± 104.2 m and 484.4 ± 93.8 m to 602.7 ± 99.6 m, respectively. Another study conducted in the U.S.A. (64) measured the influences of diet, exercise or both on cardiorespiratory fitness in obese women. Results from that study indicate that moderate aerobic exercise training during a 12-week period improves cardiorespiratory fitness in dieting obese women. Furthermore changes in fitness and physical activity of overweight and obese subjects with type 2 diabetes have been shown to positively correlate with weight loss after one year of intensive lifestyle weight loss intervention (65).

While there are many studies examining short-term effects on physical work capacity, there still is a shortage of studies examining the long-term effects of behavioural obesity treatment on physical work capacity.

Gastric bypass surgery

The great prevalence of overweight and obesity with associated comorbidities, as well as limited results of conventional obesity treatments, has led to the development of different surgical obesity interventions. One of those surgeries is the Roux-en-Y gastric bypass (RYGB), a laparoscopic approach introduced by Wittgrove et.al. (66) in 1994. This surgery promotes weight loss through restrictive and malabsorptive effects. A gastric pouch is created, separated from the stomach, and the old stomach is stapled shut. During a meal the pouch quickly fills and creates satiety, which results in calorie intake restriction during the first months after surgery. In addition to reducing the size of the stomach, the surgeon also divides the small intestines, attaches them to the pouch, and bypasses a large portion of the small intestines including the duodenum and part of the jejunum, which are involved in absorbing calories and nutrients. This creates another mechanism that makes the patient lose weight. With good long-term results, this type of surgery has gained popularity. Recently, RYGB has been the most frequently performed bariatric surgery in the United States (67).

In Iceland, Laparoscopic RYGB has been utilized in treating morbid obesity at Landspitali University Hospital in Reykjavik, for more than a decade. It is recommended that RYGB should be considered for all patients with a BMI greater than 40 kg/m² as well as for patients with a BMI greater than 35 kg/m² with comorbid obesity-related conditions after failure of conventional treatment (68). Further criteria for undergoing gastric bypass are (69):

-Age between 16 and 65.

-Acceptable operative risks.

-Documented failure of nonsurgical approaches to long-term weight loss.

-A psychologically stable patient with realistic expectations.

-A well-informed and motivated patient that is committed to prolonged lifestyle changes.

-Resolution of alcohol or substance use and absence of active psychosis and severe depression.

Gastric bypass surgery and long-term weight loss

One of the important outcomes of gastric bypass surgery is weight loss, especially long-term weight loss. Several studies have recently examined the effect of gastric bypass surgery on long-term weight loss and change in BMI. The results from 12 such studies can be seen in Table 2. The outcomes of these studies are differently presented as some give their changes in body weight in kilograms while others show changes in BMI and in weight in percentages from baseline. Furthermore, in some research studies, weight loss is presented as mean percentage of excess weight loss, i.e. how much of the weight above BMI=25kg/m² is lost. Maximal weight loss is reached one to two years after surgery (70). One of the main reasons for this is that while a patient‘s caloric intake is drastically reduced for the first months post-op leading to maximal weight loss, patients tend to regain weight slowly as the years go by (70). Nevertheless some of these studies do show remarkable sustained weight loss from five to 15 years post-op (70-73).

These studies support that Laparoscopic RYGB is an effective tool in treating morbidly obese patients.

Table 2. Long-term weight loss after laparoscopic Roux-en-Y gastric bypass surgery.

Reference	Number of subjects (n)	Length of follow-up (years)	Weight/BMI change
Laurenius et al 2010 (74)	**19**	**3**	**Mean BMI decreased from 57.8kg/m² to 39.8kg/m²**
Kruseman et al 2010 (71)	**141**	**8**	**Mean weight loss of 30.7 kg. Patients lost a mean of 55.6% of excess weight (i.e. BMI>25kg/m²)**
Snyder et al 2010 (75)	**320**	**2**	**Mean BMI decreased from 49.1kg/m² to 32.5kg/m²**
Adams et al 2010 (76)	**420**	**2.3**	**Mean BMI decreased from 47.97kg/m² to 32.2kg/m². Mean weight changed from 144 kg to 99.2 kg (44.8 kg weight loss).**
Batsis et al 2009 (77)	**148**	**4**	**Mean BMI decreased from 46.9kg/m² to 31.9kg/m². Mean weight decreased from 132 kg to 90 kg (42 kg weight loss).**
Suter et al 2009 (72)	**492**	**6**	**Mean BMI decreased from 43.2kg/m² to 30.2kg/m². Mean weight decreased from 119.4 kg to 83.5 kg (35.9 kg weight loss).**

Table 2. (continued).

Reference	Number of subjects (n)	Length of follow-up (years)	Weight/BMI change
Kolotkin et al 2009 (78)	308	2	Mean weight loss from baseline 34.2%
Rea et al 2007 (79)	505	2	Mean BMI decreased from 48.3kg/m^2 to 28.3kg/m^2.
Sjöström et al 2007 (70)	265	15	Maximal weight loss after 1-2 years post-op (32% of baseline weight). Mean weight loss at 10 years was 25% and at 15 years 27%.
Gould et al 2006 (80)	260	2	Mean weight loss of 54.5 kg. Mean loss of excess weight 70.9%
Santos et al 2006 (73)	50	5	86.5% of patients lost more than 50% of excess weight.
Suter et al 2006 (81)	466	4	Of those who were morbidly obese (BMI 40-49 kg/m^2) at baseline, 71.4% lost more than 50% of excess weight.

Gastric bypass surgery and body composition

Since such considerable weight loss occurs following gastric bypass surgery, scientists have been interested to know what happens to body composition during this time. Tamboli et al. (82) assessed body composition of 29 obese patients (mean BMI: 46.3 ± 5.5 kg/m²) before RYGB as well as six months and 12 months after surgery. At 12 months post-op, the study found that lean mass constituted 27.8 ± 10.2% of total weight loss achieved, with majority of lean mass loss occuring in the first six months following RYGB. Furthermore fat mass had reduced close to 50% at one year post-op, and similar to lean mass, most of the fat mass reduction occured during the first six months after surgery. This study suggests that loss of lean mass after RYGB is significant and strategies to maintain lean mass after surgery should be explored.

A similar pattern of lean mass change was found in another study (83). In that study, body composition was examined in 42 obese women before surgery, at three, six, and 12 months after surgery. Total fat mass reduction at 12 months post-op for participants was 26.0 ± 9.1 kg, as it went from 57.4 ± 10.7 to 31.4 ± 9.7 kg. In addition to the reduction in total fat mass, lean mass decreased from 61.5 ± 7.8 to 51.7 ± 6.7 kg during the same time. Most of the lean mass reduction occurred during the first three months after surgery and then plateaued after three to six months. The rate of loss in fat mass was also highest during the first three months after RYGB, then slowed down as fat mass continued to decrease. From these two studies, it is clear that weight loss after RYGB mainly occurs as a consequence of reduction in fat mass with a lesser impact, though present, on lean mass. These results are further supported by other studies (84, 85). In a study by Madan et al. (86) on 151 patients, fat mass reduced after gastric bypass surgery from 64 kg pre-surgery to 30 kg at the one-year follow-up. In the same study, fat percentage of total body weight also decreased from 49% to 35% during the first year. Das et.al. (87) examined body composition 14 months after RYGB in 30 extremely obese patients. Fat mass reduced by 42.1 ± 18.3 kg at 14 months post-op. Fat percentage of total body weight decreased during the same period by 17.4 ± 7.7%.

Few studies have examined the long-term effect of RYGB on body composition. One large study with a two-year follow-up period (76) examined 420 patients who had a mean BMI of 47.7 kg/m² and mean weight of 144 kg at baseline. After RYGB, body fat percentage decreased from 45.6% at baseline to 31.4% at two years follow-up, which is a reduction in body fat of 14.2%. The longest follow-up found in the litterature concerning body composition after RYGB was conducted by Kruseman et al. (71). They followed a cohort of 80 obese women for an average of 8 ± 1.2 years after RYGB. On average, patients lost 20 kg of fat mass (33% of baseline) from pre-surgery to follow-up. Lean mass also decreased but to a lesser extent than fat mass.

Gastric bypass surgery and physical exercise capacity

In theory, rapid weight loss alone by restriction in caloric intake through dietary program or surgery cannot increase aerobic fitness of the morbidly obese (88). Changes in physical activity and aerobic training are necessary to increase peak oxygen uptake. Exercise capacity and physical function can be measured in different ways.

Tompkins et al. (89) utilized the 6MWT on 25 obese patients undergoing RYGB to measure the distance walked pre-surgery, at three months post-surgery, and at six months post-surgery. Walking distance increased significantly at each follow-up, being 414.1 ± 103.7 m at baseline, 505.2 ± 98 m at three months, and 551.5 ± 101.2 m at six months post-op. This increase in walking ability corresponds to 55.1% of normal walking distance at baseline, to 75.4% of normal walking distance at six months follow-up. In the same study, findings from the SF-36 Questionnaire, which measures health status based on a score 0-100 integrating mental health and physical functioning (90), showed increases in the physical functioning score from 34.4 pre-surgery to 52.1 at six months follow-up. Josbeno et al. (91) also used the 6MWT in their study to assess 20 patients pre-surgery and at three months follow-up and found that the walking distance increased significantly during that time from 393 +/- 62.08 m to 446 +/- 41.39 m. In the same study, pedometers were also used to measure physical activity, and the average daily steps increased significantly (from 4621 +/- 3701 to 7370 +/- 4240 steps per day). In another study 28 morbidly obese men and women also showed improvement in physical function soon after RYGB (92). In that study, scores on a self-reported questionnaire regarding physical function improved at three months post-op compared to baseline. Selected measures showed less impairment and disability in as few as three weeks after surgery. The authors concluded that RYGB increases mobility and improves performance very soon after surgery.

Rosenberger et al. (93) examined the effect of RYGB on physical activity in 131 obese subjects through measuring physical activity pre-surgery and 12 months after surgery. Overall 37.4% of participants reported no episodes of physical activity preoperatively whereas the same number had reduced dramatically to only 7.6% at 12 months post-op. The frequency and intensity of physical activity also increased significantly during the same time from 32.9% of participants reporting at least one weekly episode of moderate or strenuous physical activity preoperatively to 74.8% at one year post-op.

There is a shortage of studies examining the effect of RYGB on long-term physical activity and physical work capacity in morbidly obese patients. In the eight year follow-up study by Kruseman et al. (71) mentioned earlier, patients carried a pedometer for five days before the eight years post-op visit. Therefore no comparison with baseline measurements could be made, but they found that patients who had lost more than 50% of their excess weight (the weight above BMI = 25kg/m^2) at eight years post-op had more steps per day at follow-up than those who lost less than 50% of excess weight (6103 steps per day vs. 5040 steps per day).

Obesity treatment at Reykjalundur Rehabilitation Centre

Reykjalundur Rehabilitation Centre is a health institution located in Mosfellsbær, Iceland, just outside the Icelandic capital of Reykjavik. It offers multidisciplinary treatment methods for nine different health problems, one of which is an obesity treatment program that started in 2001. For the last decade Reykjalundur has practised multi-disciplinary obesity treatment with behavioural approach for severely obese patients (BMI $\geq$ 35 kg/m^2). In addition to fulfilling the weight criteria, the patient also has to show willingness to implement lifestyle changes, capacity for fulfilling the guidelines, and ability to remain abstinent from alcohol, smoking, and/or drugs in order to qualify. While only some patients undergo Laparoscopic RYGB (LRYGB), all receive the same basic behavioural obesity treatment. The surgical vs. non-surgical groups are not randomly selected, but all patients who choose to undergo LRYGB have to meet certain additional criteria. These criteria include initial BMI above 40 kg/m^2 or BMI above 35 kg/m^2 with obesity-related co-morbidities such as type 2 diabetes, heart disease, sleep apnea, multiple sclerosis, and severe musculoskeletal problems. The surgery-patient also needs to be between the ages of 18-65, a non-smoker, abstinent from alcohol and/or drug abuse, mentally stable, educated about the protocol, and able to follow the guidelines. Furthermore the patient needs to have lost approximately 10% of his or her highest measured weight for the past two years to be qualified for LRYGB. In 2002, Reykjalundur and Landspitali University Hospital in Reykjavik entered into a cooperating relationship where Reykjalundur prepares patients for Laparoscopic RYGB and both Landspitali and Reykjalundur take care of the following treatment post-surgery.

The obesity team of professionals at Reykjalundur includes a nutritionist, physician, social worker, nurses, physical therapist, psychologist, occupational therapist, and an exercise physiologist. The main goal of the treatment is to help severely obese individuals re-organize their lifestyle with focus on weight loss, exercise, nutrition, and overall mental and physical quality of life. The treatment is considered a permanent lifestyle change instead of an intensive diet and is based on the ideas of rehabilitation. As such, it is designed to facilitate the process of recovery from a disease to as normal of a condition as possible.

The obesity program

The program consists of several treatment intervals, which can be viewed in Fig.1. The treatment begins with a three- to nine-month outpatient program followed by a five-week inpatient program. This is followed by six months of outpatient treatment, a second inpatient program lasting 3 weeks, and lastly regular outpatient follow-up visits for up to two years.

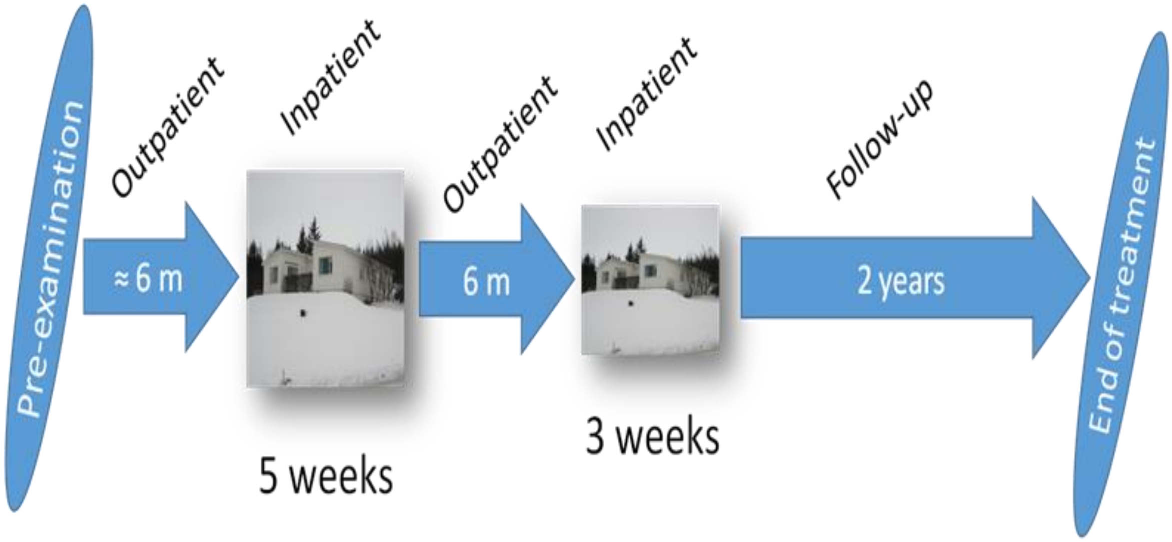

Figure 1. Overview of the obesity treatment at Reykjalundur Rehabilitation Centre.
Abbreviation: m, months.

At the beginning of treatment, a visit to the doctor for pre-examination is required. The doctor evaluates the patient’s health using medical history and relevant measurements in order to decide which obesity team member the patient is best suited for continued care. The first outpatient program involves a visit every two to four weeks to different health professionals where the patient is encouraged and supported to make lifestyle changes in terms of nutrition habits, physical exercise, and psychological aspects. To qualify for the first inpatient program, patients have to show changes in health behaviour and approximately 5-7% weight loss through healthy changes in lifestyle.

The first inpatient program consists of physical activities, lectures and guidance in organizing daily life, nutritional counselling, and psychological health promotion. The basic program is four to five hours three days a week for a total of five weeks. Most patients also choose to participate in an extra program for two days, thus staying five days/week from Monday to Friday. This inpatient program is based on group treatment with two groups of eight patients each. Despite this emphasis on groups, the obesity team ensures that each individual´s needs are met with individual meetings. During the six-month second outpatient period that follows, patients are free to arrange a visit with any of the obesity team professionals if they feel the need to do so. At the mid-point of this second outpatient period, the group comes to Reykjalundur for a one-day visit to update and plan for the near future. Those who undergo Laparoscopic RYGB usually do so during this period. After the six months outpatient period, the second inpatient program lasting three weeks begins. Just as during the first inpatient program, the second one includes a blend of activity and lectures for at least four hours three days a week.

After the second inpatient program ends, the patient comes for six one-day visits to Reykjalundur during the next two years. At each visit, the patient is given support from several obesity team members and participates in physical activity and education. Physical and psychological measurements are performed at regular intervals during the whole treatment process in order to record each patient's results. These measurements include height, weight, waist circumference, and body composition as well as psychological measurements using questionnaires such as Beck´s Depression Inventory (94), the Beck's Anxiety Inventory (95) and the Obesity-related Problems scale (OP scale) (96, 97).

The physical exercise component

As previously stated, physical activity is a fundamental aspects of the obesity treatment at Reykjalundur. Following the pre-examination at the beginning of treatment, each patient undergoes a ramp ergometer cycle test to determine maximal physical work capacity. This test is good for screening heart and blood pressure problems using electrocardiography and blood pressure measurements throughout the test. If high blood pressure problems are detected during the ergometer test, the physician immediately prescribes medication as well as giving advice regarding physical activity to control the pressure. The results of this test are helpful for prescribing appropriate physical activity in high-risk populations. Furthermore the results can be useful for reducing patients' fears of exercising. Based on these results, the patient is encouraged to engage in proper and regular physical activity.

Based on exercise history in the doctor's pre-examination and results from the ergometer cycle test, many patients have regular visits to the physical therapist or the exercise physiologist of the obesity team. These regular visits occur every two to four weeks during the first outpatient period. The individual is first advised to exercise at least three times per week using an exercise method of choice within professional limitations. These three exercise sessions per week can differ considerably in duration and intensity based on each individual's fitness level. For many, exercising in water is recommended as it reduces the stress on weight-bearing joints such as the hips, knees and ankles. Exercise history is one of several important factors looked at when estimating if the patient is qualified for the first inpatient program.

At the beginning of the first inpatient program, each patient meets with the physical therapist for professional guidance for quantifying the exercise load the patient undertakes during the program. Musculosceletal problems are also assessed. During the first five-week inpatient program, a range of different exercise modalities is purposefully presented to the patient. This variety includes water gymnastics, walking, swimming, pole-walking, strength training in the gym, table tennis, badminton, and aerobics. The individual is provided with a program schedule and is asked to participate in each exercise session on his or her own terms regarding pace and duration. As musculosceletal problems are common in this group, everybody is also advised to respect the symptoms during exercise and be careful not to over-exercise. Furthermore some of the training sessions, such as for walking, are offered at various levels of difficulty. All participants get two group lectures regarding physical activity with one including recommendations and information concerning the health benefits of exercises and one about future training schedules and relapse reaction. During this program, each patient trains for 1 - 2.5 hours three days a week, with an option of an extra two days a week as previously described. At the end of the first inpatient program, patients plan their training schedule for the coming months.

During the second outpatient program, which lasts for six months, patients exercise according to the personal physical activity plan they made. This exercise plan can vary from exercising three times per week to exercising every day. The patient can order a visit regarding physical activity recommendations or support any time during that period.

The physical activity during the second inpatient three-week program is similar to the first inpatient program, as it includes a range of training modalities, further support, and encouragement. During this time the individual exercises for 1 - 2.5 hours a day for three days a week with an option of extra two days a week. At the end of that period, the patient again makes a personal physical activity plan for the future.

After the second inpatient program, there are six scheduled one-day follow-up visits over two years. In each visit the patient´s physical activity is discussed and reviewed with an emphasis on providing further support and recommendations.

Several measurements regarding results of physical activity are performed at certain time-points throughout the obesity treatment. These include the 6MWT (58) as well as the 2-kilometre walking test (98). Other related measurements obtained include body weight, waist circumference, and body composition. These measurements are used to assess results of physical activity as well as acting as motivational factors and part of a learning process for the patient.

Previous findings from the Reykjalundur Obesity Treatment Program

While three studies have been conducted regarding the short-term effects of the obesity treatment at Reykjalundur Rehabilitation Centre (99-101), no published study has been conducted in Iceland on the long-term effects of a behavioural obesity treatment. All of the short-term studies show positive results for up to two years follow-up of the treatment in terms of decreased BMI and increased quality of life.

Hannesdottir et al. (100) examined weight changes, body composition, and maximal physical work capacity at the beginning of treatment and at the end of the first inpatient period. In that study, 47 women between the ages of 20-60 years participated in the behaviour obesity treatment. At the time of latter measurement, no subject had undergone laparoscopic RYGB so no stratification by surgical status was performed. Results showed an average of 3.9 kg/m² decrease in BMI, a significant 12% increase in maximal physical work capacity on the ergometer cycle test, and a 21% increased in fitness (watts/kg). In the same study, considerable changes were also seen in body composition, as fat mass decreased by eight kilos, body fat percentage reduced by four, and lean mass decreased by two kilos.

Njalsdottir et al. (99) compared surgical group (gastric bypass and behavioural treatment) and non-surgical group (behavioural treatment alone) outcomes in terms of weight loss and body composition. Both groups were followed from beginning of treatment to the follow-up point two years after the second inpatient program. The surgical group showed better results than the non-surgical group in terms of weight loss, fat mass, and body fat percentage. The average weight in the surgical group went from 125.5 ± 16.4 to 82.5 ± 13.8 kg. In the same period of time, the non-surgery group´s average weight went from 108.2 ± 15 to 103 ± 18.9, but this change was not statistically significant. The BMI of the surgery and non-surgery groups changed from 45.1 ± 3.9 to 29.7 ± 3.8 kg/m² significant decrease and 41 ± 3.6 to 39.1 ± 6.1 kg/m² non-significant change, respectively. In the same study, fat percentage of body weight decreased by 13.4 in the surgery group while remaining unchanged in the non-surgery group. Both groups showed significant reduction in average waist circumference.

One study in Iceland (102) examined short-term weight loss for 150 patients after undergoing Laparoscopic RYGB at Landspitali University Hospital in Reykjavik. In this study, patients lost an average of at least 80% of excess weight (weight in excess of BMI = 25 kg/m²) at 18 months after surgery. Most, but not all, of the patients in this study went through the behavioural program at Reykjalundur Rehabilitation Centre. While this study shows the benefit of surgical treatment, they are short-term, solely focused on weight loss, and with no comparison of results for surgery vs. non-surgery patients.

The aim of this study

This is an observational longitudinal study investigating the long-term results of a behavioural obesity treatment at Reykjalundur Rehabilitation Centre in Mosfellsbær, Iceland. The main aim of this study is to investigate the 4-year follow-up outcome of severely obese patients (BMI ≥ 35 kg/m²) after undergoing obesity treatment at Reykjalundur Rehabilitation Centre.

The specific aim of this study is to determine if there is a difference in outcome between people receiving behavioural obesity treatment alone and people undergoing gastric bypass as well, as measured in terms of bodyweight, BMI, waist circumference, body composition, maximal physical work capacity and physical activity.

The research questions are as follows:

1) Does behavioural obesity treatment at Reykjalundur for severely obese patients (BMI $\geq$ 35 kg/m²) have an effect on long-term outcomes for patients in terms of BMI, waist circumference, body composition, maximal physical work capacity and physical activity?
2) Is there a difference in outcome between people undergoing behavioural obesity treatment alone and people undergoing gastric bypass as well, as measured in terms of BMI, waist circumference, body composition, maximal physical work capacity and physical activity?

Our hypothesis was that behavioural obesity treatment at Reykjalundur would affect BMI, waist circumference, body composition, maximal physical work capacity and physical activity and that greater improvements in these outcomes would be seen in those that were surgically treated than in the non-surgically treated subjects.

Article

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The effects of behavioural obesity treatment in Iceland with or without surgical intervention on weight loss, body composition, physical work capacity and physical activity: A 4-year follow-up

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Running title: Results 4 years after beginning of behavioural obesity treatment in Iceland

Abstract

Background Obesity is one of world's largest health problems. Since 2001, Reykjalundur Rehabilitation Centre in Iceland has utilized a multidisciplinary obesity treatment with behavioural approach for severely obese patients (BMI $\geq$ 35 kg/m²) who have an option to undergo Laparoscopic Roux-en-Y gastric bypass (LRYGB) surgery.

Aims The main aim of this study is to investigate the 4-year follow-up outcome of severely obese patients having undergone behavioural obesity treatment at Reykjalundur and also to determine if there are differences in outcome based on surgical treatment status.

Methods This is an observational longitudinal study. Subjects' health statistics were measured at the beginning of treatment (in years 2006-2008) and at 4 years follow-up. They non-randomly (by their own choice) received either behavioural treatment alone (treatment group) or behavioural treatment plus gastric bypass surgery (treatment with surgery group). Bodyweight, BMI, waist circumference, body composition, maximal physical work capacity on an ergometer cycle, and self-reported physical activity levels were measured.

Results Ninety of 120 (75%) eligible candidates participated, including 9 men and 81 women with a mean age of 40.3 years. Of these, 47 patients (52%) underwent gastric bypass surgery. While both groups had significant ($p<0.05$) reductions in bodyweight, BMI, waist circumference, fat mass (FM), and fat percentage at 4 years follow-up, the treatment with surgery group subjects had better results than non-surgically treated subjects. Maximal physical work capacity per weight (w/kg) increased in the treatment with surgery group ($p<0.05$) but remained unchanged in the treatment group. Both groups increased their physical activity.

Conclusion Based on the 4-year follow-up data, behavioural obesity treatment at Reykjalundur Rehabilitation Centre results in significant improvements for both treatment group and treatment with surgery group in terms of BMI, waist circumference, body composition, and physical activity. The treatment with surgery group shows significantly more improvements on most of these outcomes. It is important to investigate if more improvements can be achieved using behavioural obesity treatment for patients who do not wish to have gastric bypass surgery.

Keywords: Obesity, maximal physical work capacity, body composition, gastric bypass surgery, weight loss, exercise.

Introduction

Obesity has become a global health problem. According to the World Health Organization (WHO), obesity levels in the world have nearly doubled since 1980. In 2008, more than 1.4 billion adults over the age of 20 were overweight. Of these, over 200 million men and nearly 300 million women were obese (1). Severely obese people (Body Mass Index, BMI ≥ 35 kg/m²) are at greater risk for developing heart disease, type 2 diabetes, hypertension, osteoarthritis, dyslipidemia, gastroesophageal reflux, certain types of cancer, and sleep apnea than people within normal BMI (18.5 kg/m² - 25 kg/m²) (103, 104). In Iceland, 21.7% of women and 18.9% of men were obese (BMI ≥ 30 kg/m²) in 2007 (5). These statistics are of growing concern for the Icelandic public and show a similar trend to many other countries throughout the world for the last decades. A 40-year-old person with a BMI over 25 kg/m² has three to six years less life expectancy than a person of the same age with a normal BMI (4). In the same study Peeters et al (4) found out that 40-year-old female nonsmokers lost 7.1 years of life expectancy and 40-year-old male nonsmokers lost 5.8 years because of obesity. Obesity can lead to psychological disorders as well as physical diseases. Furthermore, obese people often feel discriminated in societies where emphasis is on slender body image (8-10).

People become obese from different causes. Two main causes for obesity are unhealthy and excess nutrition and low physical activity. In terms of these factors, obesity is the result of a chronic surplus in energy intake relative to expenditure. Physical activity plays an important role in the energy balance of daily life and therefore in obesity. In addition, physical activity plays a critical role in improving cardiovascular health, particularly in persons with obesity and its related health complications (19). In the Aerobic Center Longitudinal Study, Lee et.al. (20, 21) examined more than 21.000 men and found that men who were overweight but fit had lower rates of cardiovascular death than those who were lean but unfit.

Many studies have looked at what possible factors have influenced our activity level for the last decades. Through technology there has been a change in many different ways of daily life. Relatively more and more work is less physical than before. As an example, the introduction of the modern computer has led to dramatic change in work conditions. New kind of transportation to and from work has also had an impact, and it is estimated that 80% of all Europeans travel to work in their private car instead of walking, cycling, or using public transportation (13, 14).

Many surgical and non-surgical treatment options for obesity have been established. Traditional non-surgical obesity treatments including different nutritional, psychological, and physical approaches have shown only small health benefits (24, 37, 39). Surgical treatments for obesity have been promising, especially Laparoscopic Roux-en-Y gastric bypass (LRYGB). Studies have shown that gastric bypass surgery has been successful for weight loss as well as for improving health and quality of life for the short-term (78-80), but more evidence is needed for long-term results especially regarding body composition and maximal work capacity.

Few studies have investigated follow-up outcomes more than two years after LRYGB, but the limited studies show promising results for weight loss and better quality of life (70, 72-74, 77, 105). No published study has been conducted in Iceland on the long-term effect of a behavioural obesity treatment alone or behavioural treatment with LRYGB.

For the last decade, Reykjalundur Rehabilitation Centre has utilized and developed a multidisciplinary obesity treatment with behavioural approach for severely obese patients (BMI ≥ 35 kg/m²). While LRYGB is optional for these patients, both groups receive the same basic behavioural obesity treatment.

One study has been conducted regarding the obesity treatment at Reykjalundur Rehabilitation Centre (100). That study showed positive short-term results for BMI, quality of life as well as maximal ergometer test scores and body composition. One study in Iceland (102) examined short-term weight loss for 150 patients after undergoing gastric bypass at Landspitali University Hospital in Reykjavík. Results from this study were promising, as the patients lost on average at least 80% of excess weight (weight in excess of BMI=25 kg/m²) by 18 months after surgery. Most, but not all, of the patients in that study (102) also went through the behavioural program at Reykjalundur Rehabilitation Centre both before and after surgery. Nevertheless these results are short-term, exclusive for weight loss and include no comparison of surgery vs. non-surgery patients.

The main aim of this study is to investigate the 4-year follow-up outcome of severely obese patients (BMI ≥ 35 kg/m²) after undergoing obesity treatment at Reykjalundur Rehabilitation Centre. The specific aim is to determine if there is a difference in outcome between surgically treated subjects (behavioural obesity treatment with LRYGB) and non-surgically treated subjects (behavioural obesity treatment alone) in terms of bodyweight, BMI, waist circumference, body composition, maximal physical work capacity, and physical activity.

Materials and methods

Study design

This is an observational longitudinal study investigating the long-term effects of behavioural obesity treatment at Reykjalundur Rehabilitation Centre in Mosfellsbær, Iceland. To be qualified for the treatment, the patient need to be severely obese (BMI $\geq$ 35 kg/m^2) and be motivated for lifestyle changes in accordance with the program. People who smoke are required to quit smoking and those who abuse alcohol are required to be abstinent. The treatment consists of several periods and can be viewed in Fig. 2. The first outpatient period involves a visit every two to four weeks to different health professionals where the patient is encouraged and supported to start lifestyle changes in terms of nutritional habits, physical and psychological health promotion. To qualify for the first inpatient program, patients have to show marked changes in health behaviour according to clinical valuation of compliance by the obesity team at Reykjalundur and 5-7% weight loss through healthy changes in lifestyle. The inpatient periods consist of physical activities, lectures and guidance in organizing daily life, nutritional counselling, and psychological health promotion. During the two-year follow-up, the patient comes for six one-day visits to Reykjalundur and is given support from several obesity team members. The multidisciplinary obesity team of professionals at Reykjalundur includes a nutritionist, a physician, a social worker, nurses, a physical therapist, a psychologist, an occupational therapist, and an exercise physiologist.

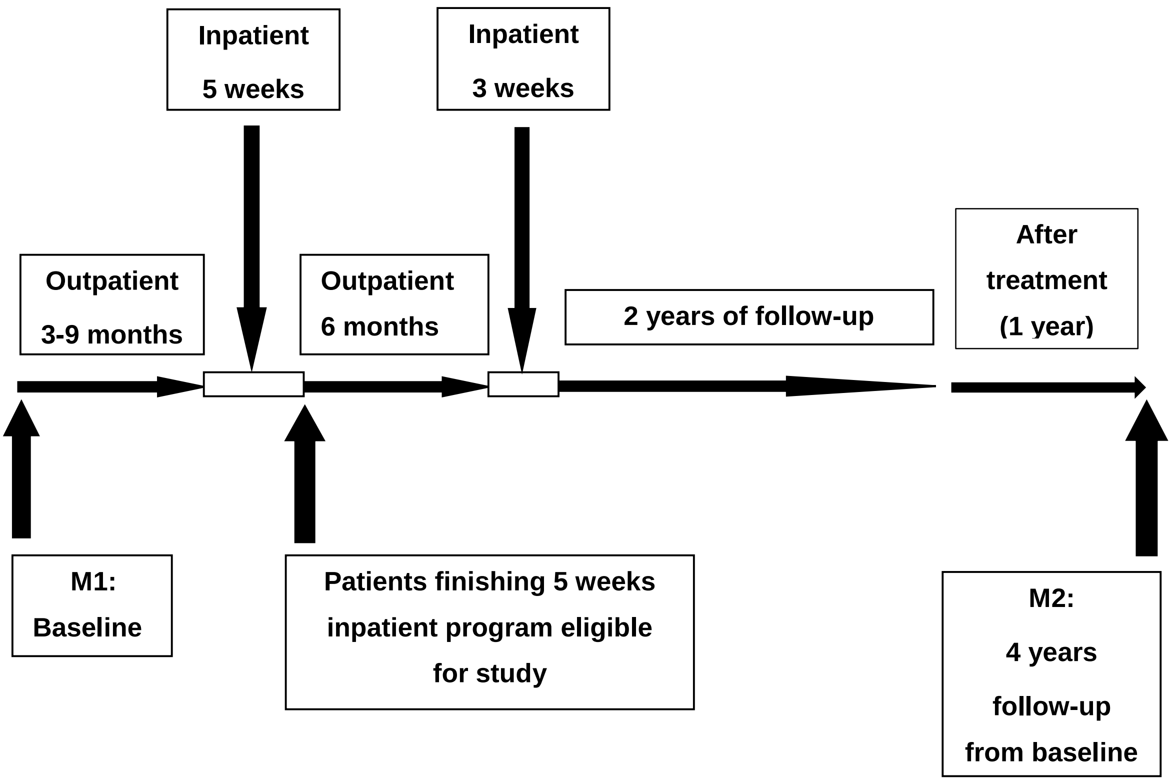

Figure 2. Treatment plan and time-points of measurements.
Abbreviations: M1, measurement 1; M2, measurement 2.

Study participants

The study population consists of patients that finished the first inpatient obesity treatment period at Reykjalundur Rehabilitation Centre from September 2007 through December 2008. They were invited to take part in the 4-year follow-up by an invitation letter sent via mail. All patients that finished the first five-week inpatient period (see Fig.2) were qualified to participate in the study. Patients were divided into two non-random groups based primarily on their own preference; a behavioural obesity treatment with patients also having undergone LRYGB and behavioural obesity treatment with no gastric bypass surgery. Most of the patients who chose to undergo gastric bypass surgery at Landspitali University Hospital in Reykjavik did so midway through the second outpatient period at Reykjalundur. Apart from the gastric bypass surgery, both groups received the same behavioural obesity treatment at Reykjalundur including follow-up visits up to two years. Patients who underwent LRYGB got extra follow-up support from Landspitali University Hospital, including eight follow-up visits concerning nutritional guidance for three years post-surgery. All patients who chose to undergo LRYGB had to meet certain criteria. These criteria were similar for those seeking obesity treatment at

Reykjalundur Rehabilitation Centre and included initial BMI above 40 kg/m² or BMI above 35 kg/m² if obesity-related comorbidities existed, such as type 2 diabetes, heart diseases, obstructive sleep apnea and more. The patient needed to be a non-smoker, abstinent from alcohol or drug abuse, be mentally stable, understand the protocol and be able to follow the guidelines. Furthermore the patient needed to have lost approximately 10% of the highest weight measured for the past two years to be qualified for LRYGB and be 18-65 years of age. The patients wanting LRYGB with BMIs between 35 kg/m² and 40 kg/m² but no existing obesity-related comorbidities were not eligible for the surgery thus went on to be part of the treatment group. There were 120 possible candidates for this study both male and female between the ages of 19 and 71. All were severely obese (BMI ≥ 35 kg/m²) at the beginning of treatment, and participation in the study was voluntary and cost-free. Participants living more than one hour driving distance from Reykjalundur were offered a refund for travel expenses. There are no ethical issues regarding this study. Informed consent was obtained from all subjects before participation. The National Bioethics Committee granted permission for this study in August 2011 (VSNb2011060008/03.7). The Data Protection Authority was notified of the study.

Outcome measures

BMI

Patient‘s height was measured with a wall-mounted stadiometer to the nearest 0.5 cm at the beginning of treatment (M1, Fig.2). The measured height for baseline was also used for the 4-year follow-up (M2, Fig.2). Body weight was always measured at the same time of day using the same kind of digital scale (Soehnle Professional 2755, Backnang, Germany). Weight was measured to the nearest 0.1 kg with the subject wearing only light clothing and no shoes. Lastly, BMI was calculated using weight and height measurements (kg/m²).

Waist circumference

Waist circumference was measured with a standardized tape measure, and the same physician did most measurements. The patient stood in upright position with equal weight on both legs. The tape measure was laid comfortably tight on the skin without any extra pressure. Waist circumference was measured where the waist was leanest at a height between the lowest ribs and crista iliaca. This measurement was done with 0.1 cm accuracy.

Body composition

A bioelectrical impedance test utilizing the Biodynamics Model 310 Body Composition Analyzer (Biodynamics Corporation, Seattle, Washington, USA) was used for measuring body composition according to the recommended procedures (44) . The subjects were asked not to exercise, eat, or drink four hours prior to testing, but no control for diuretics was performed. The subject lay in a supine position. Two electrodes were placed on bare skin on the back of the wrist and another two were placed on the base of the foot five centimeters apart on each site. All electrodes were used on the same side of the body. The Analyzer send a harmless electrical current through the body. Lean tissue conducts the current well but on the contrary fat tissue is nonconductive due to its low water content. The Analyzer gave information about bioresistance (ohms), percentage body fat (%), fat mass (FM) in kilograms, lean mass (LM) in kilograms, basal metabolic rate, and total body water in liters. The formula the Analyzer uses to calculate LM is:

$$LM\ (\text{lean mass}) = (a \times \text{height}^2) + (b \times \text{weight}) + (c \times \text{age}) + (d \times \text{resistance}) + e$$

Variables a, b, c, d, and e in the formula represent constant coefficients calculated by regression analysis in each instance (106). Bioelectrical impedance technique has shown to be a reliable and valid approach for the estimation of human body composition (45, 46). Nearly all body compostition measurements were done at the same time of day.

Maximal physical work capacity

For measuring maximal physical work capacity we used a maximal ramp ergometer cycle test, which is a symptom-limited and graded maximal exercise test. Subjects were asked not to eat a heavy meal or drink any caffeine drinks two hours before the test. They were also asked not to perform any strenuous activity on testing day, not to smoke 30 minutes before the test, and to take their prescribed drugs as usually on the day of testing. The kind of ergometer cycle used was the Monark 839 Ergomedic (Monark Exercise AB, Sweden). A computerized Schiller CS-200 electrocardiograph was also used (SCHILLER AG, Baar, Switzerland). A 12-lead ECG was placed on bare skin with 10 electrodes and recorded throughout the test. The systolic and diastolic blood pressure was measured at rest and during the test using a Trimline mercury manometer (PyMaH Corporation, Branchburg, USA). The pedalling rate was 60-65 revolutions per minute (rpm). The load started at 15-30 watts and was increased every minute by 15-30 watts each step (depending on the patient's exercise history) until exhaustion. The aim was to achieve test duration of 10 minutes as recommended for exercise tests (57). The reason for ending the test was recorded such as exhaustion and muscle fatique in legs. A physical therapist and a physician controlled each test. For percentage of predicted values of maximal physical work capacity in watts (Wmax), reference values from formulas for both men and women from two Swedish studies were used (107, 108). Based on these formulas, Wmax values were calculated for each subject for each test at baseline and at follow-up. Furthermore based on subjects' actual Wmax scores, percentage predicted values for Wmax were calculated. From Wmax and the weight of each patient, maximal physical work capacity per kilogram (W/kg) was also calculated. In an effort to get percentage predicted values for W/kg, the following procedure was used:

a) Examination of each subject's reference value for Wmax.
b) Given the reference value for Wmax, calculation of predicted value for W/kg based on if each subject's weight was in accordance with normal BMI = 25 kg/m^2.
c) Comparison of the actual W/kg score to the predicted one for each subject to get percentage predicted W/kg.

Self-reported standardized exercise questions

At 4-year follow-up, subjects were asked two questions about their physical training frequency before treatment and at present. Those two questions were part of a standardized questionnaire connected to lifestyle before and after behavioral obesity treatment at Reykjalundur and were as follows:

1) How often did you exercise before treatment at Reykjalundur?
2) How often do you exercise now?

Possible answers to both these exercise questions were as follows:

a) Never
b) Seldom and irregularly
c) Once a week
d) 2-3 times per week
e) 4-5 times per week
f) 6-7 times per week

Statistical procedures

Microsoft Excel and the Statistical Analysis Software, SAS Enterprise Guide 4.3 (SAS Institute Inc, Cary, North Carolina, USA) were used for statistical analysis. Summary statistics was used to analyze the characteristics of the study population. Descriptive statistics were used for main trends in outcome measures (BMI, waist circumference, body composition, physical work capacity and physical activity). Results are expressed as means ± SDs unless otherwise specified. A paired t-test was used to examine changes over time for each patient. A two-sample t-test was performed to test for differences between the two groups with respect to background factors and baseline outcome measures. Linear regression for repeated measures using a random effect for subject (PROC MIXED) was used to analyze the relationship between treatment modalities and outcome. An interaction between the two treatment forms was examined to investigate whether there was a difference in improvements between research groups during treatment. Adjustment was made for age since there was statistical difference in age between research groups at baseline. The significance level was set at $p<0.05$.

Results

Subjects and baseline characteristics

Data gathering and the 4-year follow-up measurements were obtained from September 2011 through May 2012. Of 120 possible candidates for this study, 90 participated (75%), including 9 men and 81 women and representing the usual gender distribution in the obesity treatment at Reykjalundur Rehabilitation Centre. The mean age was 40.3 ± 11.6 years at baseline. There were 43 (48%) in the treatment group and 47 (52%) in the treatment with surgery group. While few, the male participants were evenly distributed between research groups with five in the treatment group and four in the treatment with surgery group. Of those 30 who did not participate in the study, most declined because they were too busy at work (8/30), were sick (7/30), or did not respond to the invitation letter or follow-up phone call (4/30). Mean time from baseline to follow-up was 4.2 ± 0.6 years. The mean time from gastric bypass surgery to follow-up in the treatment with surgery group was 3 ± 0.8 years. All of the 90 participants had valid baseline and follow-up measurements for age, body weight, and BMI. A majority of participants (88) had valid measurements at both times for body composition, body fat percentage, fat mass (FM), and lean mass (LM). Eighty-seven had valid measurements at both times for waist circumference. Lastly, 75 had two valid measurements for maximal physical work capacity on an ergometer cycle test. Twelve subjects did not undertake the ergometer bicycle test at follow-up with the most common reasons being musculoskeletal pain (5/12), home visit (4/12) and more than three months pregnancy (2/12). Basic characteristics of both research groups are shown in Table 3. Patients in the treatment with surgery group were younger, heavier, and with greater waist circumference than those in the treatment group. Furthermore, subjects in the treatment with surgery group had greater FM, body fat percentage, and LM compared to treatment group subjects at baseline.

BMI, waist circumference, and body composition

Results for changes in weight, BMI, waist circumference, and body composition measurements are presented in Fig.3. The treatment group had reduced bodyweight from 117.4 ± 18.6 kg at baseline to 110 ± 18.7 kg at 4 years follow-up. This is a reduction of 7.4 ± 14.6 kg. In comparison, the treatment with surgery group reduced bodyweight significantly more ($p<0.001$) than those who did not have surgery from 129.5 ± 19.3 kg at baseline to 85.3 ± 15.4 kg, which is a reduction of 44.2 ± 15.2 kg. The weight loss in the treatment with surgery group corresponds to 74.4% loss of excess weight (weight in excess of BMI = 25 kg/m²). Excess weight loss in the treatment group is 15.8%.

Both groups had significant ($p<0.05$) reduction in BMI, FM, body fat percentage, and waist circumference at 4-year follow-up, and the treatment with the surgery group showed significantly more reduction than the treatment group ($p<0.001$). BMI changed from 41.5 ± 5.3 to 38.9 ± 5.9 kg/m² in the treatment group and from 46.1 ± 4.8 to 30.4 ± 4.8 kg/m² in the treatment with surgery group. The treatment group lost on average 5.2 ± 1.3 kg of FM while treatment with surgery group lost on average 31.5 ± 1.3 kg of FM. Lean mass was reduced in both groups ($p<0.05$), but the treatment with surgery group losing significantly more LM ($p<0.001$) than the treatment group. Absolute values for LM went from 64.7 ± 10.3 to 62.5 ± 10.5 kg in the treatment group compared to 68.7 ± 11.6 to 55.6 ± 8.4 kg in the treatment with surgery group. Both research groups showed similar relative FM loss (Fig.4).

Maximal physical work capacity

Results from the ramp ergometer cycle test are shown in Table 4. At baseline, there was a difference between the groups with respect to maximal work capacity per weight and percent of predicted maximal physical work capacity per weight (W/kg). The treatment group had a higher score on both of these outcomes. Maximal physical work capacity in watts (Wmax) at ergometer cycle test was reduced at 4-year follow-up in the treatment with surgery group ($p<0.001$) but no changes were observed in the treatment group. Similar results were noticed when the groups were compared in terms of percentage predicted of maximal watts, where the treatment with surgery group had worsened ($p<0.001$). Patients in the treatment with surgery group increased their performance ($p<0.05$) in W/kg while performance remained unchanged in the treatment group. Both the treatment and the treatment with surgery groups showed increased percentage of predicted W/kg ($p<0.05$) though the treatment with surgery group showed significantly more increases ($p<0.001$).

Self-reported physical activity

Responses from two structured exercise questions regarding exercise frequency before treatment and at follow-up are shown in Fig.5. In all, 80 patients of 90 (88.9%) answered the question regarding exercise frequency before treatment and 89 of 90 (98.9%) answered the question regarding exercise frequency at follow-up. Both groups increased their exercise frequency at follow-up compared to before treatment. Of those who answered in the treatment group, 64.3% exercised never or less than once a week before treatment but only 31% at follow-up. Scores for the same question for the treatment with surgery group were 76.6% and 40.4% respectively. Of those who answered in the treatment group, 4.7% exercised three times a week or more before treatment but increased to 19% at follow-up. On the same question, scores for the treatment with surgery group went from 10.6% to 19.2%.

Discussion

The results of this study show that multidisciplinary behavioural obesity treatment at Reykjalundur Rehabilitation Centre for severely obese patients leads to significant and positive results for both treatment group and treatment with surgery group in terms of decreased bodyweight, BMI, waist circumference, improved body composition as well as increased physical activity. Furthermore, severely obese patients who attend the behavioural treatment and undergo LRYGB show more improvements in terms of BMI, waist circumference, body composition, and fitness (W/kg) than those who attended behavioural treatment alone.

The weight loss of the treatment group was on average 7.4 kg at follow-up, which corresponds to 6.3% of initial weight. Following behavioural obesity treatment, it is generally accepted that moderate but sustained weight loss of about 5-10% of baseline bodyweight represents a definite degree of success (29). Obesity experts also define this weight loss as clinically important, since 5-10% weight loss may improve lipid, glucose, and blood pressure levels, as well as potentially reducing cardiovascular diseases levels (30-34). Therefore, it can be stated that the weight loss of the treatment group in this study is successful and clinically important. The weight loss, excess weight loss, and reduction of BMI in the treatment with surgery group three years after surgery is similar to what has been reported in other studies with comparable length of follow-up (74, 75, 77, 78, 80).

To the author's knowledge, no study has reported long-term results regarding body composition in patients who attended behavioural treatment for obesity alone without surgery. Few studies have also examined the long-term effects of LRYGB on body composition. One large study with a follow-up of two years examined 420 patients (76) and found that body fat percentage reduced from 45.6% at baseline to 31.4% at two-year follow-up, which is a reduction of 14.2 percentage body fat. This is similar to the results of the treatment with surgery group in our study, although our follow-up after surgery is one year longer. The longest follow-up, to our knowledge, examining body composition after LRYGB was done by Kruseman et al. (71). They followed a cohort of 80 obese women for an average of 8 ± 1.2 years after LRYGB. On average, patients lost 20 kg of FM from presurgery to eight years follow-up or 33% of their baseline FM. Lean mass also decreased but to a lesser extent than FM. In our study, FM loss in treatment with surgery group was 31.5 kg, but it is important to note that our follow-up was on average three years after surgery and that maximal weight loss is generally reached one to two years after LRYGB (70). One of the main reasons for this is that patients caloric intake is drastically reduced especially during the first months post-op. After maximal weight loss is reached, patients tend to regain weight slowly as the years go by (70).

One interesting finding in our study is that according to body composition measurements, both research groups show the same FM loss in relation to total weight loss. Thus, 70% of total weight loss in each group is due to loss of FM.

To our knowledge no other study has examined maximal physical work capacity on ergometer cycle test such a long time after treatment or treatment with surgery in this patient population. In our study, maximal physical work capacity on an ergometer cycle test did not change among the people in the treatment group but was reduced among those in the treatment with surgery group. One possible explanation of this reduced physical work capacity in the treatment with surgery group is LM loss. This group lost on average 13.1 kg of LM, mainly due to loss in muscle tissue. Since muscle strength and function are important for performance on the ergometer cycle test, it can be speculated that the surgery group results in reduced physical work capacity due to LM loss to more extent than the treatment group. On the other hand, the surgery group showed increase in maximal physical work capacity per bodyweight

(W/kg) at follow-up due to greater weight loss. As for measuring maximal physical work capacity, we did not control for blood pressure medication. Also, in all ergometer tests in our study, the different reasons for terminating the test were not controlled for.

Both research groups showed increased physical activity level at 4-year follow-up compared to start of treatment. This finding is of great value since increasing physical activity is one of fundamental changes in lifestyle needed in order to lose weight and improve health through behavioural treatment. It is also important to see that the individuals in the treatment group, which generally lost less weight compared to those in the treatment with surgery group, increased their physical activity level similarily to those who underwent LRYGB. Still, the findings of physical activity before treatment could be influenced by recall bias as patients were only asked about their exercise frequency before treatment and at 4 years follow-up.

One weakness of this study is that individuals in the research groups examined were not randomly selected. Some patients chose to undergo LRYGB and therefore became part of treatment with surgery group, while others chose not to and became part of treatment group. Some subjects aimed at surgery in the beginning of treatment but later on decided against it and vice versa. Also, seven patients who wanted LRYGB and had BMI between 35 kg/m² and 40 kg/m² but no existing obesity-related comorbidities were not eligible for the surgery and thus went on to be part of the treatment group. One thing to bear in mind when comparing results between research groups in this study is difference in follow-up support. Both groups received the same six one-day visits during two years follow-up at Reykjalundur, but the treatment with surgery group obtained extra support from eight visits to Landspitali University Hospital in Reykjavik during 3 years post-op. Another weakness is the fact that there is no control group due to ethical concerns. It would have been ethically unacceptable to form a control group of severely obese patients seeking treatment and have them waiting for four years without any treatment. Lastly, since only nine of 90 participants were men, these results cannot be generalized for men.

There are several strengths to our study. Firstly, it has a long follow-up period of four years. The participation in such a long follow-up was also good, as 75% of initial patients enrolled completed the 4-year follow-up (approximately 3.5 years from time-point of definition of the study population). For the 25% drop-out group, there is a possibility that those subjects did not participate because of lack of success in terms of weight loss and therefore be a selective loss to follow-up. The authors asked The National Bioethics Committee for permission to investigate health statistics from subjects in the 25% drop-out group but were not granted permission to do so. Another strength of this study is that it has measurement findings from long-term follow-up. Not many studies have done that before in this group of patients with outcomes such as body composition, maximal physical work capacity and physical activity. Furthermore it compares results from those who attended behavioural treatment program to those attending the same program but also underwent gastric bypass surgery. Therefore it is of practical value to observe any differences between the groups as to what extent one treatment method is beneficial for this patient population over the other.

Future research should strive to do an even longer follow-up with the same group of patients to see how long the treatment effects last in terms of the measurements executed in this study for both treatment and treatment with surgery group.

Conclusion

We conclude that multidisciplinary behavioural obesity treatment is successful regardless of surgical intervention or not. This applies to positive results in terms of bodyweight, BMI, waist circumference, and body composition, however the patients undergoing surgical intervention showing significantly more improvements than those without. Those who underwent LRYGB lessened their maximal physical work capacity probably due to lost LM but increased their fitness level (watts per bodyweight). Both research groups increased their physical activity at 4-year follow-up. It is important to investigate in the future if better results can be accomplished for those who seek obesity treatment but do not attend gastric bypass surgery.

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Conflict of interest

The authors declare no conflict of interest.

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Tables

Table 3. Baseline characteristics of research groups.

	Treatment (n=43)	Treatment+Surgery (n=47)	P-value
Gender (female/male)	*38/5*	43/4	
Age (years)	43 ± 12.3	37.8 ± 10.4	<0.001
Height (cm)	168 ± 8	167.3 ± 6.8	NS
Weight (kg)	117.5 ± 18.4	129.7 ± 19.5	<0.001
BMI (kg/m²)	41.5 ± 5.2	46.2 ± 4.8	<0.001
Waist circumference (cm)	115.4 ± 12.5	120.5 ± 12.4	<0.001
Fat mass (kg)	52.7 ± 11.2	61 ± 9.9	<0.001
Percentage body fat (%)	44.7 ± 4.3	47.1 ± 3.3	<0.001
Lean mass (kg)	64.7 ± 10.3	68.7 ± 11.6	<0.005

Abbreviations: BMI, body mass index; NS, nonsignificant.

Table 4. Maximal physical work capacity on ergometer cycle test.

	Treatment (n=43)			Treatment + surgery (n=47)		
	M1	M2	P-value	M1	M2	P-value
Maximal work capacity (watts).	*159.3 ± 38.7*	155.8 ± 43	NS	165.2 ± 34.4	149.4 ± 37.9	<0.001
Percent of predicted maximal work capacity (%).	84.5 ± 16.6	85.2 ± 16.3	NS	83.9 ± 13	77.6 ± 14.9	<0.001
Maximal work capacity per weight (watts/kg).	1.38 ± 0.32	1.43 ± 0.36	NS	1.28 ± 0.26*	1.79 ± 0.44	<0.001
Percent of predicted maximal work capacity per weight (%).	52.2 ± 12.3	56.1 ± 13	<0.05	46.2 ± 9.5*	66.3 ± 15.7	<0.001

Table 5. Maximal physical work capacity on ergometer cycle test.

** = p<0.05 T vs T+S group at baseline.*

Abbreviation: M1, measurement 1 (baseline); M2, measurement 2 (4 years follow-up); NS, nonsignificant.

Figures

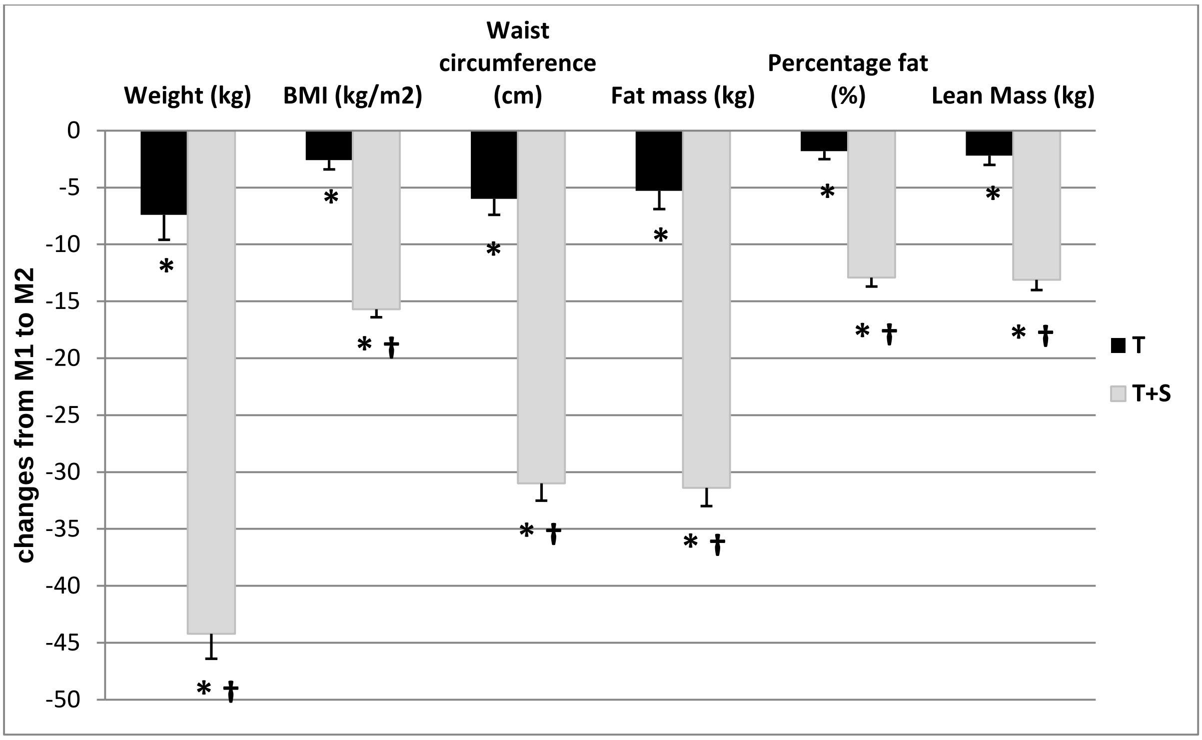

Figure 3. Changes in body composition during research period. Values are mean and standard error. * = **p<0.05 for changes from M1 to M2. † = p<0.05 comparing changes between T and T+S.**

Abbreviations: T, treatment group; T+S, treatment with surgery group; BMI, body mass index; M1, measurement 1 (baseline); M2, measurement 2 (4 years follow-up).

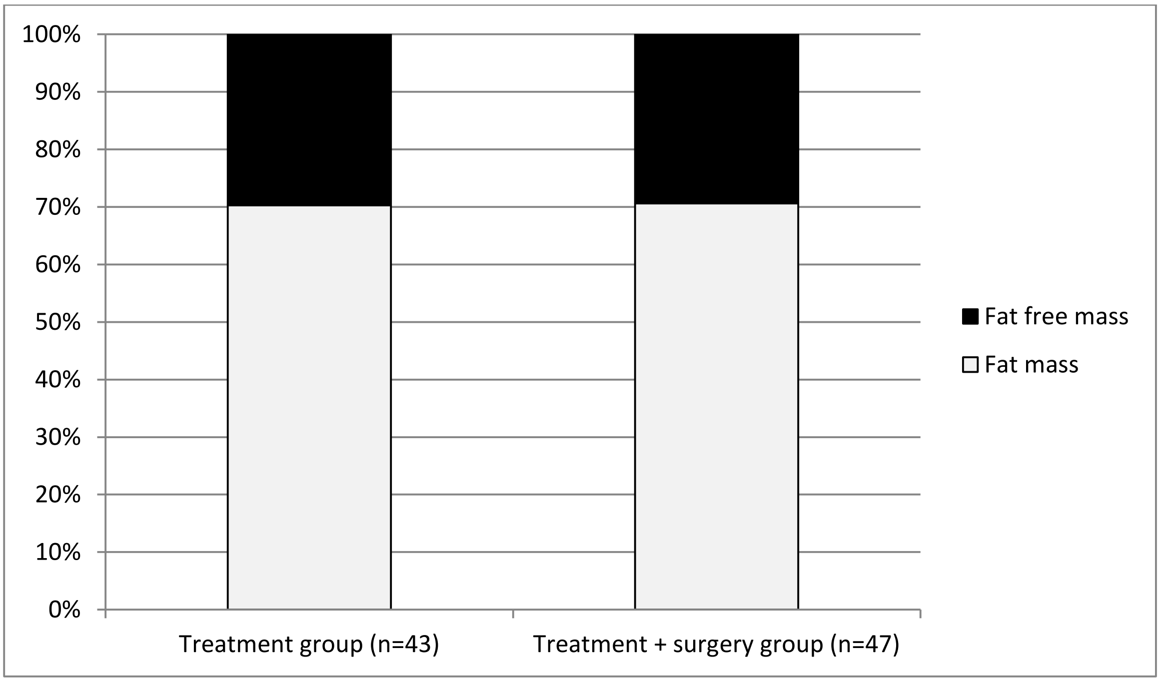

Figure 4. Relative fat loss of total weight loss in research groups.

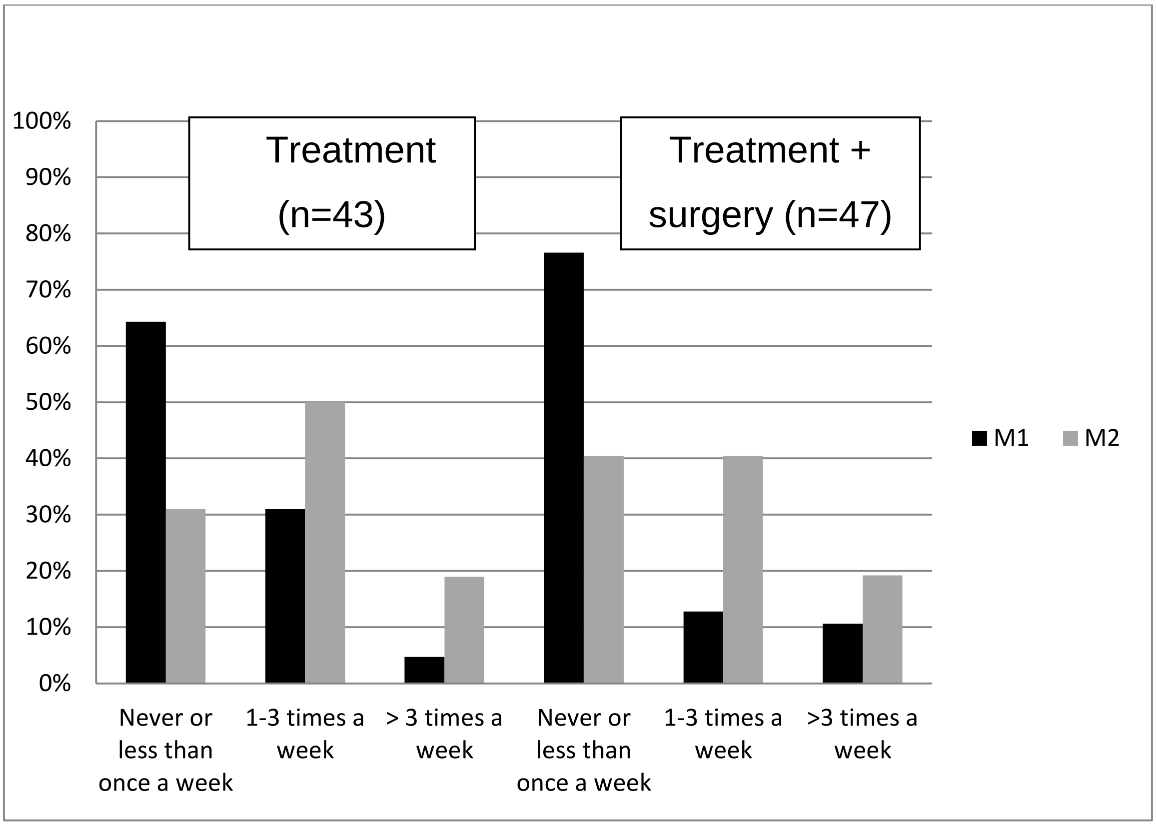

Figure 5. Percentage of self-reported exercise frequency at baseline (M1) and 4 years follow-up (M2).

Appendix 1: General question list.

Almennar spurningar

Í spurningum 1-3 má merkja við fleiri en einn valmöguleika ef þörf er á.

1. **Hver er menntun þín?**
   - ☐ Grunnskólamenntun
   - ☐ Framhaldsskólamenntun/stúdentspróf
   - ☐ Iðnnám
   - ☐ Háskólamenntun

2. **Hver er hjúskaparstaða þín í dag?**
   - ☐ Gift(ur)
   - ☐ Ógift(ur)/ekki í sambúð
   - ☐ Í sambúð
   - ☐ Fráskilin(n)
   - ☐ Ekkja/ekkill

3. **Hver er staða þín á atvinnumarkaðnum?**
   - ☐ Í vinnu _____%
   - ☐ Atvinnulaus
   - ☐ Öryrki
   - ☐ Í námi

Svaraðu eftirfarandi spurningum með því að merkja við einn svarmöguleika í hverri spurningu.

4. **Fórst þú í magahjáveituaðgerð?**
   - ☐ Já   Hvenær? Mánuður_____ ár_____
   - ☐ Nei, óskaði ekki eftir því
   - ☐ Nei, ég vildi fara en uppfyllti ekki skilyrði til að fara

5. **Hafir þú farið í magahjáveituaðgerð, ertu ánægð(ur) með þá ákvörðun?**
   - ☐ Já
   - ☐ Nei

6. **Reyktir þú áður en þú byrjaðir í offitumeðferðinni á Reykjalundi?**
   - ☐ Já
   - ☐ Nei

7. **Ef já, hættir þú að reykja eftir að meðferð hófst á Reykjalundi?**
   - ☐ Já
   - ☐ Nei

8. Reykir þú í dag?

- ☐ Já
- ☐ Nei

9. Stundaðir þú hreyfingu/líkamsþjálfun áður en meðferð hófst á Reykjalundi?

- ☐ Aldrei
- ☐ Sjaldan og óreglulega
- ☐ Einu sinni í viku
- ☐ 2-3 svar í viku
- ☐ 4-5 sinnum í viku
- ☐ 6-7 sinnum í viku

10. Stundar þú hreyfingu/líkamsrækt núna?

- ☐ Aldrei
- ☐ Sjaldan og óreglulega
- ☐ Einu sinni í viku
- ☐ 2-3 svar í viku
- ☐ 4-5 sinnum í viku
- ☐ 6-7 sinnum í viku

11. Ef þú stundar hreyfingu/líkamsrækt núna, hversu lengi varir hún í hvert skipti?

- ☐ 15-30 mínútur
- ☐ 31-45 mínútur
- ☐ 46-60 mínútur
- ☐ 61 mínútu eða meira

12. Ertu sátt(ur) við þann árangur <u>hvað varðar þyngdartap</u> sem þú náðir í meðferðinni á Reykjalundi?

- ☐ Mjög sátt(ur)
- ☐ Frekar sátt(ur)
- ☐ Hlutlaus
- ☐ Frekar ósátt(ur)
- ☐ Mjög ósátt(ur)

13. Ertu sátt(ur) við árangur (annan en þyngdartap) sem þú náðir í meðferðinni á Reykjalundi? (líkamleg, andleg líðan o.fl.)

- ☐ Mjög sátt(ur)
- ☐ Frekar sátt(ur)
- ☐ Hlutlaus
- ☐ Frekar ósátt(ur)
- ☐ Mjög ósátt(ur)

14. Myndir þú mæla með meðferðinni við aðra?

- ☐ Já
- ☐ Nei

15. **Ef við á, hver er ástæða þess að þú komst ekki í boðaðan tíma í lokaendurkomu (2 ára endurkomu)?**
    - ☐ Komst ekki vegna vinnu/skóla
    - ☐ Vegna fjarlægðar frá Reykjalundi (bý á landsbyggðinni, var erlendis)
    - ☐ Vegna peningaleysis
    - ☐ Vegna veikinda
    - ☐ Fannst ég ekki þurfa þess, hefur gengið það vel
    - ☐ Fannst ég ekki hafa verið nógu dugleg(ur) í lífsstílsbreytingu / hef þyngst
    - ☐ Finnst endurkomurnar ekki hafa nýst mér
    - ☐ Ég var ekki boðuð/boðaður í endurkomu
    - ☐ Ég mætti í boðaða endurkomu
    - ☐ Annað? Hvað: ____
    ____

16. **Hvað telur þú að mætti betur fara í offitumeðferðinni á Reykjalundi? (Hér er átt við alla meðferðina, frá forskoðun að eftirfylgd)**

    ____
    ____
    ____

17. **Er eitthvað sem þér finnst vanta í meðferðina? Ef já, hvað?**

    ____
    ____
    ____

18. **Hvað í meðferðinni finnst þér hafa gagnast/nýst þér best? (Hér má forgangsraða ef um marga þætti er að ræða)**

    ____
    ____
    ____

19. **Er eitthvað annað sem þú vilt taka fram? Allar ábendingar vel þegnar.**

    ____
    ____
    ____

Appendix 2: Study approvals.

VÍSINDASIÐANEFND

Hafnarhúsið, Tryggvagata 17
101 Reykjavík,

Sími: 551 7100, Bréfsími: 551 1444

netfang: visindasidanefnd@vsn.stjr.is

Ludvig Guðmundsson, læknir og ábyrgðarmaður
Dalaþingi 14
203 Kópavogur

Reykjavík 30. ágúst 2011
Tilv.: VSNb2011060008/03.7

Efni: Varðar: 11-097-S1. Atferlismeðferð með eða án magahjáveituaðgerðar hjá alvarlega offeitum (BMI>35), 3. til 4. ára eftirfylgd.

Vísindasiðanefnd þakkar svarbréf þitt, dags. 24.08.2011 vegna áðursendra athugasemda við ofangreinda rannsóknaráætlun sbr. bréf nefndarinnar dags. 28.06.2011. Í bréfinu koma fram svör og skýringar til samræmis við athugasemdir Vísindasiðanefndar.

Fjallað var um svarbréf þitt og önnur innsend gögn á fundi Vísindasiðanefndar 30.08.2011 og voru þau talin fullnægjandi.

Rannsóknaráætlunin er endanlega samþykkt af Vísindasiðanefnd.

Vísindasiðanefnd bendir rannsakendum vinsamlegast á að birta VSN tilvísunarnúmer rannsóknarinnar þar sem vitnað er í leyfi nefndarinnar í birtum greinum um rannsóknina. Jafnframt fer Vísindasiðanefnd fram á að fá send afrit af, eða tilvísun í, birtar greinar um rannsóknina. Rannsakendur eru minntir á að tilkynna rannsóknarlok til nefndarinnar.

Með kveðju,
f.h. Vísindasiðanefndar,

dr. med., Björn Rúnar Lúðvíksson, læknir, formaður

REYKJALUNDUR endurhæfing

Umsókn um leyfi fyrir rannsóknarverkefni til lækningaforstjóra

Rannsóknastjóri apríl 2008

Titill rannsóknar

Árangur atferlismeðferðar með eða án magahjáveituaðgerðar hjá alvarlega offeitum (BMI≥35), 3-4 ára eftirfylgd.

Ábyrgðarmaður (nafn, staða, stofnun)

Ludvig Guðmundsson, yfirlæknir á offitusviði Reykjalundar

Aðrir rannsóknaraðilar (nafn, staða, stofnun)

Guðlaugur Birgisson sjúkraþjálfari á offitusviði Reykjalundar og mastersnemi í HÍ
Maríanna Þórðardóttir mastersnemi í HÍ

Inntak rannsóknar og markmið í hnotskurn

Meginmarkmið rannsóknarinnar er að kanna 3-4 ára árangur af offitumeðferð á Reykjalundi hjá alvarlega offeitum einstaklingum (BMI≥35). Ennfremur verður rannsakað hvort munur er á árangri þátttakenda eftir því hvort þeir hafa farið í magahjáveituaðgerð eða ekki. Rannsóknin er tvíþætt og unnar verða úr henni tvö meistaraverkefni. Guðlaugur mun kanna árangur er varðar holdafar, líkamlega afkastagetu og hluta lífsgæða. Maríanna mun kanna árangur er varðar holdafar, andlega líðan og félagslega virkni.
Sjá nánar um inntak rannsóknar og mælingar sem verða framkvæmdar í meðfylgjandi rannsóknaráætlunum.

Tímaáætlun og verkaskipting rannsóknaraðila

Áætluð tímalengd rannsóknar er:
- -Gagnasöfnun sept 2011-mars 2012
- -Úrvinnsla apríl 2012-júní 2012
- -Skrif mastersritgerða júlí 2012-nóv 2012
- -Skil nóv/des 2012

Sjá nánar um verkaskiptingu rannsóknaraðila í meðfylgjandi rannsóknaráætlunum

Rannsókn kynnt fyrir yfirlækni(um) meðferðarsviðs(a) (dagsetning og nafn læknis)

9. mars 2011 Ludvig Guðmundsson

Dagsetning og undirskrift ábyrgðarmanns

Reykjalundi 14.júní 2011 Ludvig Guðmundsson [signature]

☒ **Leyfi veitt**

Dagsetning og undirskrift lækningaforstjóra

15/6'11 [signature]

Vakin er athygli á því að setja þarf dagál í sjúkraskrá þeirra sjúklinga sem taka þátt í rannsókninni þar sem eftirfarandi þarf að koma fram:
- ✓ **Hvenær sjúklingur gaf upplýst samþykki (dagsetning)**
- ✓ **Heiti rannsóknarinnar**
- ✓ **Ábyrgðarmaður rannsóknarinnar**
- ✓ **Tilvísunarnúmer rannsóknarinnar hjá Vísindasiðanefnd**

Appendix 3: Introductory letter.

REYKJALUNDUR
endurhæfing

SIGILLUM UNIVERSITATIS ISLANDIAE

Árangur atferlismeðferðar með eða án magahjáveituaðgerðar hjá offeitum einstaklingum (BMI ≥35), 4 ára eftirfylgd.

Kynningarbréf

September 2011.

Kæri viðtakandi

Um þessar mundir stendur yfir rannsókn á heilsufarslegum breytingum sjúklinga sem luku fimm vikna dagdeildarprógrammi á tímabilinu frá september 2007 til desember 2008.

Markmið þessarar rannsóknar er að kanna áhrif offitumeðferðar á Reykjalundi á holdafar, þol, púls- og blóðþrýstingssvörun á þolprófi, heilsutengd lífsgæði, félagslega líðan, þunglyndi og kvíða 3-4 árum eftir að fimm vikna dagdeildartímabili lýkur.

Með þessu bréfi viljum við fara góðfúslega á leit við þig að þú takir þátt í þessari rannsókn. Rannsóknin er jafnframt liður í meistaraverkefni Guðlaugs Birgissonar og Maríönnu Þórðardóttur í Lýðheilsuvísindum við Háskóla Íslands og er hún unnin í samstarfi við offitu- og næringarsvið Reykjalundar. Ábyrgðarmaður rannsóknar er Ludvig Á. Guðmundsson, yfirlæknir offitu- og næringarsviðs Reykjalundar. Leiðbeinendur rannsóknarverkefnis eru Unnur Anna Valdimarsdóttir, dósent við Háskóla Íslands, Marta Guðjónsdóttir, lektor við Háskóla Íslands, Arna Hauksdóttir, lektor við Háskóla Íslands og Sigrún Vala Björnsdóttir, lektor við Háskóla Íslands.

Rannsókn þessi er mjög mikilvæg. Þörf er á rannsóknum á mismunandi meðferðarleiðum við offitu og mikilvægt er að endurskoða og meta í sífellu þau úrræði til að sem bestur árangur náist. Þetta kemur ekki einungis þeim meðferðaraðilum og skjólstæðingum til góða sem tengjast Reykjalundi heldur einnig öðrum sem fást við offitumeðferð. Þátttakendur í rannsókninni munu jafnframt fá nákvæmar upplýsingar um eigið líkamsþrek.

Í rannsókninni verður unnið með mælingar úr sjúkraskrá frá forskoðun á göngudeild og við lok fimm vikna dagdeildarprógramms. Þær verða bornar saman við niðurstöður þeirra mælinga sem nú verða gerðar en þá eru liðin 3-4 ár frá lokum fimm vikna dagdeildarprógramms. Rannsóknin fer fram á Reykjalundi, þar sem þátttakendur mæta í þolpróf á hjóli og mælingar og svara spurningalistum. Mælingar innihalda hæð, þyngd, mittismál og fitumælingu. Spurningalistinn inniheldur spurningar um heilsutengd lífsgæði, félagslega líðan, þunglyndi og kvíða en þeir hafa einnig verið lagðir fyrir fyrr í meðferðinni. Gera þarf ráð fyrir að hvert þolpróf og aðrar mælingar taki um 35 mínútur og útfylling við spurningalista um það bil 20-25 mínútur.

Við vörslu persónuupplýsinga verður ítrustu öryggisráðstafana gætt og kemur nafn þátttakenda hvergi fram við úrvinnslu eða birtingu rannsóknar. Farið verður með allar upplýsingar sem trúnaðarmál. Þannig fær hver þátttakandi sérstakt kóðanúmer sem rannsóknargögnin verða merkt með. Lykillinn að kóðanum verður í læstri geymslu ábyrgðarmanns rannsóknarinnar. Þátttakandi getur á hvaða stigi rannsóknarinnar sem er hætt við þátttöku, líka eftir að öllum gögnum hefur verið safnað. Gögnum viðkomandi verður þá samstundis eytt.

Líkamleg áhætta sem fylgir rannsókninni er óveruleg eða engin. Læknir mun vera viðstaddur framkvæmd á hámarksþolprófum á hjóli. Þátttakendur munu framkvæma samskonar þolpróf og gert var við upphaf meðferðarinnar á Reykjalundi.

Taka skal fram að þátttakendur eru tryggðir í gegnum sjúklingatryggingar Reykjalundur á meðan á rannsókn stendur.

Hægt er að staðfesta þátttöku í tölvupósti til Maríönnu (mth5@hi.is) eða Guðlaugs (gullib@reykjalundur.is). Ef ekki berst svar innan tveggja vikna frá dagsetningu þessa bréfs verður haft samband símleiðis og óskað eftir þátttöku.

Hafir þú spurningar um rétt þinn sem þátttakandi í vísindarannsókn eða vilt hætta þátttöku í rannsókninni getur þú snúið þér til Vísindasiðanefndar í Hafnarhúsinu, Tryggvagötu 17, 101 Reykjavík. Sími: 551-7100, fax: 551-1444.

Með þökk og kærri kveðju,

Ludvig Á. Guðmundsson, yfirlæknir offitu- og næringarsviðs RL

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Appendix 4: Informed consent.

REYKJALUNDUR
endurhæfing

Árangur atferlismeðferðar með eða án hjáveituaðgerðar hjá alvarlega offeitum einstaklingum (BMI ≥35), 4 ára eftirfylgd.

Yfirlýsing um upplýst samþykki

Ég hef lesið kynningu á rannsókninni og samþykki þátttöku mína í öllum þáttum rannsóknarinnar, auk notkun tilgreindra gagna um mig úr forskoðun offitumeðferðar og við lok 5 vikna dagdeildartímabils í sjúkraskrá.

Ávinningur og/eða áhætta samfara rannsókninni hefur verið útskýrð fyrir mér. Mér er ljóst að ég get hvenær sem er dregið þátttöku mína í rannsókninni til baka án allra eftirmála af hálfu rannsakenda. Farið verður með allar upplýsingar sem trúnaðarmál og þær verða ekki persónugreinanlegar í neinum niðurstöðum.

Rannsóknin er gerð með leyfi Vísindasiðanefndar og Persónuverndar.

Staður og dagsetning: ____

Nafn þátttakanda:________________________________Kennitala:____________

Leiðsögukennarar:
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