

The effect of lifestyle treatment on physical capacity, maximal strength, eating behavior and quality of life in patients with morbid obesity (LIFETIME).

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Background

Severe obesity is associated with an increased risk of developing type 2 diabetes, obstructive sleep apnea, cardiovascular disease, certain types of cancer and early death (1, 2). The main objective for the treatment of morbid obesity is weight reduction through behavioral change. There is evidence that a weight loss of 5-10% reduces the risk of cardiovascular disease in patients with obesity (3, 4), while patients with morbid obesity should achieve a greater weight loss in order to achieve improvement in the obesity-related disease (5, 6). More knowledge is needed for establishing the most effective treatment methods to reduce weight-related complications and health risk associated with obesity.

Severe obesity is associated with reduced health-related quality of life (HRQOL) (7, 8). HRQOL is about how people perceive different aspects of their state of health before, during and after an intervention or a course. Usually, the HRQOL is measured using standardized questionnaires that measure different aspects (physical, mental, emotional, work-related HRQOL, etc.). HRQOL is an important parameter for assessing the accuracy of a treatment in relation to how the results are perceived. Morbid obesity is associated with overeating and an unfortunate eating pattern. It is therefore also important to map the patients' intake of food and also attitudes to and experiences with meal situations.

Physical inactivity may lead to reduced years of life, physical capacity, physical strength, quality of life, energy expenditure, sleep quality, appetite regulation, and increased degree of dysfunctional eating behavior (9-11). Increased physical activity prevents overweight and helps reduce weight (12, 13) and some studies have suggested that an increase in physical capacity of 8-21% can increase daily energy expenditure by 70-500 kilocalories, which may result in 1.5 to 10 kg weight reduction in one year (14, 15). Physical capacity may also be important for weight stabilization after weight loss (9, 16). A combination of physical activity and calorie reduction is therefore appropriate to decrease body weight (17). One of the few studies that mapped physical capacity after a lifestyle treatment found no significant change in body weight or physical capacity (18). However, the researchers found greatest weight loss in patients with the greatest progress in physical capacity. However, it is not clear how physical activity and capacity affect the loss or maintenance of body weight in patients with morbid obesity. Implementing strength training in weight-reducing treatment of people with morbid obesity can lead to reduced loss or increased muscle mass and maximum muscle strength (19-21). Some studies suggest that maintenance or an increase in muscle mass during weight reduction is beneficial to increase total energy expenditure (21). A 1-3 kg increase in muscle mass can result in increased energy expenditure at rest of 8-10% (11, 22). Some studies suggest that maintenance or an increase in muscle mass during weight reduction is beneficial to increase total energy consumption (23-25).

In summary, there is still uncertainty about which is the most effective lifestyle treatment method to achieve reduced body weight and increased quality of life. Increased physical capacity and muscle mass lead to increased energy expenditure, thus explaining parts of the difference in weight loss achieved after lifestyle treatment. However, literature in this area is limited and needs better documentation of how, and to what extent increased physical capacity and muscle mass can affect the effect of lifestyle treatment offered to patients in the health service.

Research questions

In this study, we will investigate whether more intensive day-based lifestyle treatment process have a better effect on weight loss and health-related quality of life than a previous treatment (26). We also want to investigate whether patients with good physical capacity (maximal oxygen uptake) and leg strength (maximum leg strength) before initiating treatment and / or after 3 and 6 months intensive training may have greater weight loss 1 and 2 years after treatment than patients with lower physical capacity and leg strength.

This issue will be illustrate by the following hypotheses:

1. An intensification of treatment will result in greater weight loss and increase health-related quality of life than previous treatment.
2. Physical capacity (maximum oxygen uptake) before treatment is associate with increase weight loss after 3-6 months and 1-2 years.
3. Increase leg strength (maximal leg strength) after 3-6 months is associate with increase weight loss after 1-2 years.

Data

Standard treatment at Vestfold Hospital Trust, the following data is obtained at baseline, between 3-6 months and between 1-2 years after treatment start: body weight, hip circumference, waist circumference, body composition, body mass index, height, age, sex, physical capacity (maximal oxygen uptake) and leg strength (maximal leg strength). In the study, we will use data from 600 patients to research the study's hypotheses over a period of 8 years (2017-2025).

Body weight and height will be measure with light clothing, without shoes. The BMI is calculate as the weight (kg) divided by the square height (m). The waist circumference (cm) will be measure midway between the lower edge of the lower rib and the upper part of the hip joint in the horizontal plane. Hips circumference (cm) will be measure on the widest part of the back in the horizontal plane. Body composition is analyzed using bioimpedance analysis (Tanita BC-418). Physical capacity will be measure as maximum oxygen uptake (VO₂max) by indirect calorimetry (Jaeger Oxycon Pro). Indirect calorimetry is to be regard as a gold standard for measurement of maximum oxygen uptake. The test will be conduct as an individual custom protocol with gradual increase of incline and / or speed on treadmill (Woodway®) up to voluntary maximum fatigue. Maximum bone strength will be measure with a leg press device (OPS161 Interchangeable Leg Press). The test will be conduct as an individual adapted protocol with gradual loading until voluntary maximum bone strength is achieve.

Data relating to the HRLK will be collect electronically through online survey form in the SurveyXact program, administered by the University of Agder. Patients are register with a project number and must answer questionnaires via Ipad or PC. Patients will sit at the outpatient clinic and have the opportunity to ask project staff for help if this should be necessary. Data is encrypt and register on a secured server, where project employee at the University of Agder can access the database through dual security routines. Project staff at the university cannot access the link key. This is stored at

Vestfold Hospital trust's research server. There is a separate data processing agreement between Rambøll Management and the University of Agder, which ensures data and data delivery.

The following questionnaire must be answered; RAND 36-Item Short Form Health Survey (RAND-36), Impact on Weight Questionnaire (IWQOL-Lite), 3. Weight-Related Symptom Measure (WRSM), Power of Food Scale (PFS), Three Factor Eating Questionnaire (TFEQ - R21) and Binge Eating Scale (BES). All forms are translated to Norwegian.

Informed consent

We wish to obtain the written informed consent from all new patients who received day-based intensive lifestyle treatment for morbid obesity at Vestfold Hospital Trust. Data included in the project is already obtained in existing treatment program, and patients are not exposed to any deviations from the standard treatment at Vestfold Hospital Trust. Patients complete self-assessment forms for testing and exercise at the start of the treatment program. We want to emphasize that research will be conducted on unidentified data, and the results will not be linked to the individual patient. Patient information will be treated strictly confidential. Researchers will only use anonymized data.

Statistical methods

Intention to treat analyses will be performed in order to compare the effects of the treatment. Differences in outcome measures between patients will be assessed using analysis of covariance (ANCOVA), including baseline value of the dependent variable as covariate. Simple and multiple logistic regression will be implemented to assess the changes of variables.

Research group

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Kilder

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