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Single-centre, non-randomised clinical trial at a tertiary care centre to investigate 1-year changes in social experiences and biomarkers of well-being after bariatric surgery in individuals with severe obesity: protocol for the Bariatric Surgery and Social Experiences (BaSES) study

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ABSTRACT

Introduction Obesity is linked to increased loneliness and less enjoyment of social interactions. While bariatric surgery is the most effective treatment targeting severe obesity, there is limited understanding as to whether patients experience social interactions differently after surgery. The Bariatric Surgery and Social Experiences study is designed to assess potential changes in how much patients enjoy and engage in daily social interactions 1 year after Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG).

Methods and analysis Single-centre, non-randomised clinical trial carried out at the Department of Endocrinology, Obesity and Nutrition at Vestfold Hospital Trust, Norway. Eligible patients (N=113) will undergo either RYGB, SG or single anastomosis sleeve ileal (SASI) bypass. The primary outcome measure is change in the social experience score (assessed with a questionnaire) from a presurgery to a follow-up assessment 1 year after RYGB and SG. The respective changes after SASI bypass will be assessed and considered exploratory.

Ethics and dissemination The most recent protocol version of this study was reviewed and approved by the Regional Committee for Medical Research Ethics South East Norway (REK sør-øst A) on 29 August 2022 (ref: 238406). The results will be disseminated to academic and health professional audiences and the public via publications in international peer-reviewed journals and conferences.

Trial registration number NCT05207917.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The primary outcome (frequency and quality of social interactions) is assessed over a 14-day period per measurement timepoint to comprehensibly capture daily variation.
⇒ Multiple clinically relevant secondary outcomes including hair cortisol, endocannabinoid and fasting ghrelin concentrations, cardiovascular risk factors and health-related and psychological patient-reported outcomes are assessed.
⇒ The sample size is limited and thus may not provide sufficient statistical power to compare the effects of Roux-en-Y gastric bypass and sleeve gastrectomy on secondary outcomes.

INTRODUCTION

Obesity is one of the world's most serious public health problems as defined by the WHO. Currently, the most effective treatment at achieving lasting weight loss and long-term reduction in obesity-related comorbidities is bariatric surgery.[1 2] The two most commonly performed procedures are sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB),[3] but more recently a combination of both (single anastomosis sleeve ileal (SASI) bypass) has been introduced.[4]

The effectiveness of bariatric surgery has most often been measured as weight loss and reductions in obesity-related complications and/or comorbidities, while effects on social interaction and subjective experience have received much less attention (see Broadhead *et al*, Uchino and Rubino *et al*[5–7]). This appears to be an important omission as there is ample evidence that (supportive) social relationships promote health[8] and decrease

mortality risk.[9] Social relationships can affect a range of other health conditions such as cardiovascular disease, cancer and immune function.[8] However, individuals with obesity may experience social interactions as less positive than normal-weight individuals. Studies have reported that individuals with obesity avoid social events and relationships, but also career opportunities, shopping and other activities where they might feel observed[10–12] because of weight stigma. Such avoidance behaviour can lead to a 'chronic disengagement' of diverse aspects of social life, which in turn might decrease interpersonal skills.[13] Further investigations into the link between social behaviour and eating found that greater emotional eating was associated with greater social avoidance.[14] Eating was described as a means to cope with loneliness on the one hand, while on the other hand aggravating feelings of being alone due to the stigma associated with obesity.[15] As such, loneliness and obesity can create a vicious circle. Similarly, individuals with severe obesity reported deriving less enjoyment from social contacts[16] and often feel more socially isolated than normal-weight individuals.[17]

Only a few studies have investigated how bariatric surgery influences social interactions. One 10 year follow-up study found improvements in social interactions for bariatric surgery, but not for conventional weight loss treatment.[18] A retrospective study observed a positive association between weight loss after bariatric surgery and the participants' social connections.[19] In qualitative studies, many participants reported that they received more positive social feedback following bariatric surgery,[20] and also that they enjoyed social activities more than before,[21] while others have described ambiguous feelings,[22] or even negative psychosocial experiences.[23]

The current clinical trial will address this important knowledge gap and investigate the effects of the two most common bariatric surgery procedures (RYGB and SG) on patients' subjective experience of daily social interactions 1 year after surgery. Additionally, biological and psychological markers of social experiences will be assessed in this trial.

Objectives

Primary objectives

The primary objective of this study is to determine 1 year changes in patients' subjective experience of daily social interactions after bariatric surgery (either RYGB or SG).

Secondary objectives

Key secondary objectives are the examination of changes in variables assessing broader aspects of social experiences as secondary endpoints (affect and reactivity to social inclusion and exclusion, response to pleasant caress-like touch and one's preferred velocity for self-applied caress-like touch) and biomarkers of well-being (cortisol and endocannabinoid concentrations from hair samples). Moreover, we will explore whether the primary and secondary endpoints also change in a short-term follow-up (6 weeks after surgery; T1) and whether RYGB leads to larger changes in social interactions and in secondary endpoints related to social experiences than SG. In addition, we will explore changes in psychological (reward responsivity, social network and belonging, body image and interoceptive ability, self-reported eating behaviour) and health-related (obesity-related quality of life, psychological distress) patient-reported outcomes (PROs), changes in gut hormones (ghrelin) and changes in anthropometric measures, body composition and cardiovascular risk factors in the surgery groups 6 weeks (T1) and 1 year (T2) after surgery. All outcomes will be considered exploratory.

Trial design

This study is a single-centre, non-randomised clinical trial with two experimental groups (RYGB, SG). A third exploratory group will constitute of patients undergoing SASI bypass.

METHODS AND ANALYSIS

This protocol follows the SPIRIT reporting guidelines.[24]

Study setting

The study is conducted at a tertiary healthcare centre, the Department of Endocrinology, Obesity and Nutrition, Vestfold Hospital Trust (Norway). Before the COVID-19 pandemic, about 180–200 bariatric surgeries were performed per year (about 65% RYGB and 35% SG). During the pandemic, the number of bariatric surgeries decreased to about 120 per year (with a similar distribution of the two surgery types as before the pandemic). The SASI bypass procedure was first implemented in 2022.

Patient and public involvement

A patient representative serves on the study steering committee to ensure that patients' interests and opinions are taken into consideration during all study phases. The patients will be informed about published findings during the study period.

Eligibility criteria

Inclusion criteria

1. Eligibility for one of the surgery types
2. Scheduled surgery
3. Willingness and ability to give informed consent for study participation
4. Aged between 18 and 80 years
5. Good understanding of written and spoken Norwegian in order to answer the PRO-related questionnaires

Exclusion criteria

1. Pregnancy and breast feeding
2. Severe chronic diseases such as endocrine, heart, neurological, lung, gastrointestinal or kidney conditions
3. Cancer
4. Acute psychotic episode

Experimental groups

The current trial is not an intervention study. All participants will undergo one type of bariatric surgery and will thus be assigned to an experimental group, but this assignment will not directly influence study outcomes. The study outcome variables will only be observed before and after each surgery type. All surgical procedures will be performed laparoscopically by experienced surgical teams at Vestfold Hospital Trust.

Experimental group 1: RYGB

In RYGB, the left crus will be dissected free and significant hiatal hernias repaired with posterior cruraplasty. The minor curvature will be opened at the second vessel and the lesser sac entered. A 25 mL gastric pouch will be created by firing one horizontal and two vertical staple loads. The ligament of Treitz is then identified and a proximal loop of small intestine anastomosed to the pouch 60 cm from the ligament of Treitz with one linear stapler using the full length of the stapler, creating an antecolic, antegastric alimentary limb. The opening will then be closed using a single row, running absorbable suture. An entero-enteroanastomosis will be made 120 cm distal of the gastro-enteroanastomosis. The introductory opening is closed with a single row, running absorbable suture. Finally, the small intestine will be divided with one load between the gastro-entero-enteroanastomosis and the entero-enteroanastomosis in order to complete a bypass with an alimentary limb of 120 cm and a biliopancreatic limb of 60 cm.

Experimental group 2: SG

In SG, a large part (80%) of the ventricle is removed. The greater curvature will be dissected free starting 1–2 cm from the pylorus up to the angle of Hiss. The left crus is then visualised and inspected for hiatal hernia. Clinically significant hiatal hernias will be repaired with posterior cruraplasty. The ventricle will then be lifted and any adhesions in the lesser sac divided. A 35 Fr bougie is placed down to the pylorus guiding the creation of a tubular sleeve with linear staplers. The first two loads are always purple, while tan loads are used for the rest of the ventricle. The last stapler is placed 5–10 mm laterally to the angle of Hiss. The staple line will then be inspected and secured with clips for additional haemostasis; no oversewing or buttressing material is routinely used.

Experimental group 3: SASI bypass

The SG is performed as described above, with the exception that the division of the stomach starts 6 cm proximal to the pylorus. The small bowel is measured 300 cm from the ileocecal valve, in sequences of 5 cm, with the small bowel stretched and markers placed on the graspers. The antrum is opened ventrally 5 cm proximal to the pylorus, just below the horizontal axis of canalis pylori and connected to the small bowel with a 30 mm stapled anastomosis completed with an absorbable running suture. The mesenteric defect is not closed.

Box 1 Secondary outcome measures

Social experience facets
⇒ Inclusion/exclusion experience
⇒ Preferred velocity of self-applied touch
⇒ Pleasantness of self-applied touch
⇒ Pleasantness of other-applied touch
Biomarkers of well-being
⇒ Hair cortisol concentration
⇒ Endocannabinoid concentration
Psychological patient-reported outcomes
⇒ Reward responsivity
⇒ Social network and belonging
⇒ Body image and interoceptive ability
⇒ Self-reported eating behaviour
Gut hormones
⇒ Fasting ghrelin concentrations
Health-related patient-reported outcomes
⇒ Health-related quality of life
⇒ Obesity-related quality of life
⇒ Psychological distress
Body weight and composition
⇒ Body weight, body mass index, waist and hip circumference
⇒ Body composition
Standard blood tests and cardiovascular risk factors
⇒ Resting systolic and diastolic blood pressure
⇒ Cholesterol and triglyceride levels
⇒ Glucose metabolites

Concomitant care

Patients will follow standard treatment procedures at the Department of Endocrinology, Obesity and Nutrition, Vestfold Hospital Trust. There are no specific concomitant care or interventions that are permitted or prohibited during the trial.

Outcome measures

Primary outcome measure

Change in social experience score (PRO: *The SOcial Experiences' DaiLy Occurrence (SOLO)*[25] *Scale*) from 4 weeks before surgery to 1 year after surgery. The SOLO is a short questionnaire assessing occurrence and quality of participants' daily social interactions (both meaningful and superficial) in the 14 days following each visit.

Secondary outcome measures

Secondary outcome measures are listed in box 1, and are assessed as summary measures such as mean/median or proportions (when appropriate) for each group. Outcome variables constitute the assessed values/scores per measurement time point and changes from baseline (Baseline: 4 weeks prior to surgery) to the short-term follow-up (T1: 6 weeks after surgery) and to the long-term follow-up (T2: 1 year after surgery); see table 1.

Participant timeline

The Bariatric Surgery and Social Experiences (BaSES) study includes four time points where the patients are invited to the Department of Endocrinology, Obesity

Table 1 Patient visit schedule

	Screening/ information meeting	Baseline	T1 follow-up	T2 follow-up
		~4 weeks prior to surgery	~6 weeks after surgery	~1 year after surgery
Visit	**1**	**2**	**3**	**4**
Inclusion and exclusion criteria	x			
Signed informed consent	x			
Demographic data		x	x	x
PRO: SOLO		x	x	x
Psychological and health-related PROs		x	x	x
Social experience tasks		x	x	x
Regular medication		x	x	x
Hair samples		x	x	x
Blood samples		x	x	x
Body composition		x	x	x
Anthropometric measures		x	x	x

PROs, patient-reported outcomes; SOLO, The SOcial Experiences' DaiLy Occurrence Scale.

and Nutrition. Study enrolment started in May 2022 with screening meetings. The baseline assessment takes place approximately 4 weeks before surgery, the short-term follow-up is scheduled approximately 6 weeks after surgery (T1) and the long-term follow-up is scheduled approximately 1 year after surgery (T2). Up until the end of 2022, 26 patients underwent the baseline assessments. It is expected that the long-term follow-up (T2) will be finished in 2025 (table 1).

Sample size

This study has one primary outcome ('changes in the social experience score' from before to after surgery) that served as reference for sample size calculations. A small to medium effect size for this change from baseline to the long-term follow-up (T2) was assumed based on related literature.[18 26–28] Power calculations were conducted with G*Power[29] for a dependent t-test with the following parameters: effect size of d_z=0.4, two-tailed significance, alpha=0.05 and a power of >95%. The result recommended a sample size of 84 participants in total. Accounting for a drop-out rate of ≤35% (because of the time between baseline and the follow-up 1 year after surgery), we aim to recruit 113 participants in total, with similar patient numbers following RYGB and SG. Should the number of recruited patients in the two surgery groups differ considerably during inclusion, we will aim to recruit further participants in the smaller group to align the number of participants for both groups.

Recruitment

Potential patients are informed about the BaSES study during courses and group sessions by trained staff at the Department of Endocrinology, Obesity and Nutrition. Patients from the waiting list for bariatric surgery will be individually contacted by phone and invited to an information/screening meeting in the weeks before surgery. Study inclusion will be assessed according to inclusion and exclusion criteria during this meeting. Patients who approve participation and pass eligibility criteria will then sign the informed consent form and will be enrolled in the study.

Allocation: sequence generation and concealment

Participants will be numbered sequentially based on enrolment. No concealment regarding surgery type is implemented.

Blinding

Due to the nature of the non-randomised controlled trial, neither participants nor staff will be blinded to the surgery type.

Data collection methods

Primary outcome

Changes in the social experience score: after each BaSES study visit, participants are asked to fill in the SOLO[25] Scale in the 14 days following their visit. The SOLO is a 14-item questionnaire assessing occurrence and quality of one's daily social interactions. The questionnaire is supposed to be filled in at the end of the day, taking between 2 and 5 min. It is available either in an online version or on paper. Participants will receive individual reminders each day in order to enhance compliance. A total item score will be calculated over the 14 assessment days at the three visits (Baseline, T1, T2). A change in the total SOLO score from baseline to the long-term follow-up (T2), irrespective of surgery type, constitutes the primary outcome.

Secondary and exploratory outcomes

See online supplemental materials for a detailed description of the measurement of affect and reactivity to social inclusion and exclusion, and of subjective experience of

caress-like other-applied and self-applied touch. Cortisol and endocannabinoid concentrations will be measured from hair samples and analysed by Dresden LabService GmBH (Dresden, Germany). The full list of the administered psychological and health-related questionnaires and a detailed description of the assessed anthropometric measures is provided in online supplemental materials. Routine laboratory measurements will be performed at the Central Laboratory, Vestfold Hospital Trust, while C-peptide analyses will be performed at the Hormone Laboratory, Oslo University Hospital. Both laboratories are certified according to NO-EN ISO 15189. A detailed list of method principles, sample matrix, units and analytical precision of biological outcomes are provided in online supplemental table S1.

Retention

Participants may withdraw from the study for any reason at any time but may also be excluded by study personnel in order to protect their safety and/or if they are unable/unwilling to comply with the study procedures. However, reasonable effort is made by the study personal to prevent attrition throughout the study period. Loss to follow-up measurement sessions of the primary outcome is estimated to be ≤35%.

Data management

Trained study personnel will enter all data into online case report forms (CRFs) during the study visits. CRFs will be saved on an encrypted server that requires two-factor authentication of authorised personal (TSD—Service for Sensitive Data, University of Oslo). SOLO data are directly transferred and saved on this server. The log files from the tasks assessing experience of social inclusion/exclusion and touch will be manually transferred to this server. Data integrity is continuously monitored by members of the steering committee.

Data will be stored in a pseudoanonymised way because study-generated participant codes will be used. Participants' data will be stored for a period of at least 5 years after completion of the study.

Statistical methods

Descriptive data will be presented as mean (SD), median (range) or number (percentage). Within-group comparisons of differences between baseline and T2 (primary objective), and baseline and T1 will be calculated with dependent t-tests or non-parametric alternatives. Between-group comparisons of differences between RYGB and SG (and SASI bypass in an explorative manner) will be calculated with independent t-tests, one-way analysis of variance (ANOVA) or non-parametric alternatives. Interactions between within-group and between-group comparisons will be analysed using either a multilevel modelling approach (where appropriate; also to handle missing data) or mixed ANOVAs. Correlation and regression approaches will be used for the exploration of mediating or independent effects of surgery type, hormone concentrations or PRO scores on the primary outcome and selected secondary outcomes.

Data monitoring

The steering committee consists of a team of healthcare professionals, researchers and a patient representative. Members of the steering committee meet every 12 months to safeguard the interests of patients participating in BaSES. It further monitors the progress and overall conduct of the clinical trial. Adverse events will be consecutively reported. The harms of the applied experimental assessments are extremely low and pose no risk for participants. Due to the low-risk nature of BaSES, the steering committee also assumes the role of the data monitoring committee.

Ethics and dissemination

Research ethics approval

The study protocol was registered in an international trial register (ClinicalTrials.gov). The study is conducted in accordance with Good Clinical Practice, International Council of Harmonization (ICH) guidelines and the latest revision of the Declaration of Helsinki.

Protocol amendments

Significant amendments to the protocol have been and will be made only after ethical approval by the regional ethics committee.

Informed consent

Individual informed consent was obtained in information/screening meetings consisting of either individual patients or small patient groups.

Ancillary studies

Additional blood samples will be obtained and stored for use in future studies. Information about storage and analyses of these samples is covered in the informed consent.

Confidentiality

Each participant is given a study ID that will be used during data collection and analysis. The key linking participants' names and study ID are stored on a high-security server with two-factor authentification. No participant information will be released outside the study.

Access to data

Electronically authorised data access is available only to selected study personnel. Data analyses must either be performed according to the preplanned statistical analysis plan or should be authorised by the study principal investigators before they are carried out. Deanonymised individual participant data can be made available following publication on reasonable request to authors US and JH. Data will be shared according to the consent given by the participants and Norwegian laws and legislation.

Ancillary and post-trial care

All patients will receive post-trial follow-up care according to national guidelines.[30]

Dissemination

The protocol and the results of the study will be published in international peer-reviewed journals in accordance with the ICMJE criteria for authorship (http://www.icmje.org/). Furthermore, study findings will be disseminated via scientific networks, conferences, professionals, policymakers and commissioners of weight management.

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Contributors Original idea of the study was given by US and JH. US, DMP, JKH and JH designed the study. DMP helped in study implementation. MS and ML provided input to methods. Data curation was done by DMP. DMP wrote the first version of the manuscript. JH and US acquired funding. All authors contributed and agreed to the final version of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

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SUPPLEMENTARY MATERIALS

Title BaSES trial

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Detailed description of outcome measures

1. Primary outcome

The SOcial Experiences' DaiLy Occurrence Scale (*SOLO* (14))

The SOLO is a 14-item questionnaire assessing frequency and quality of daily social interactions. It consists of two sub-scales: (1) Being in the company of others, (2) Being in one's own company. The questionnaire is filled in at the end of the day, during the consecutive 14 days following the study visits. Scale 1 (Being in the company of others) was designed to measure enjoyment of being with others and the duration of social contact (10 items), higher values indicate greater enjoyment and a higher frequency of social contact. Scale 2 (Being in one's own company) was designed to measure enjoyment of being in one's own company (3 items), higher values indicate greater enjoyment of one's own company. An additional item at the beginning of the scale asks how many people the respondent has had social contact with during the day. The answers of scales 1 and 2 will be aggregated into one total score. The original Norwegian version and a translated English version can be found on the Open Science Forum: https://osf.io/xcwek/?view_only=5fd1798a7535469f9b169429266210bf.

2. Secondary outcomes

Social experience facets

Affect following social inclusion and exclusion will be assessed with the PANAS questionnaire (1), The PANAS is a self-report measure of two scales with 10 mood adjectives each, one measuring positive affect and the other one measuring negative affect. (1) Positive Affect Scale (higher values indicate higher positive affect); (2) Negative Affect Scale (higher values indicate higher negative affect).

Reactivity following social inclusion and exclusion will be measured with the Need-Threat Scale (2), and three Cyberball experience ratings as in the original study of the Cyberball paradigm (2,3). The Cyberball experience ratings consist of three questions: (1) how often participants estimated to have received the ball (in percent), (2) how much they felt included by the other players during the task (9-point Likert scale), and (3) how they felt during the task (9-point Likert scale). The Need-Threat Scale consists of four sub-scales: (1) Belonging, (2) Self-Esteem, (3) Meaningful existence, (4) Control; higher values per scale indicate more belonging, higher self-esteem, higher meaningful existence, and more control.

Responses to caress-like touch will be assessed via visual analogue scales (VAS) presented electronically. Participants will provide subjective ratings on how pleasant they experienced being touched with different velocities with a brush on the left forearm (other-applied touch) and applying touch by themselves (self-applied touch). Participants will also provide subjective ratings on how physically intense they experienced being touched by the brush (other-applied touch) and by their own hand (self-applied touch).

Preferred velocity of self-applied touch will be calculated based on how long participants take to make ten back-and-forth strokes with their right hand over a 10 cm distance on their left forearm (in seconds; calculation is based on the formula velocity = distance/time).

Psychological Patient-Reported-Outcomes (PROs)

Body image will be assessed with the Appearance Evaluation Scale (AES) and the Body Areas Satisfaction Scale (BASS) (4). The AES was designed to measure overall satisfaction/dissatisfaction with one's appearance and physical attractiveness. It consists of 7 items with high scores indicating body satisfaction and low scores indicating body dissatisfaction. The BASS was designed to measure the degree of (dis)satisfaction with specific body areas and attributes. High scores indicate greater body satisfaction and low scores indicate greater body dissatisfaction.

Reward responsivity will be assessed with the Temporal Experience of Pleasure Scale (TEPS) (5). The TEPS was designed to measure individual trait dispositions in both anticipatory and consummatory experiences of pleasure. It consists of 18 items, of which 10 form the (1) anticipatory pleasure scale, and (2) 8 items form the consummatory pleasure scale. Higher values on (1) indicate enhanced reward responsiveness and imagery, while higher values on (2) indicate higher openness to different experiences and appreciation of positive stimuli (i.e., higher reward responsivity).

Interoceptive ability will be assessed with the Body Awareness Questionnaire (BAQ) (6). The BAQ was designed to assess self-reported attentiveness to normal nonemotive body processes, such as sensitivity to body rhythms, ability to detect small changes in normal bodily functioning, and one's ability to anticipate bodily reactions. It consists of 18 items. Higher values indicate a higher sensitivity and awareness of one's bodily states.

Self-reported eating behaviour will be assessed with the Three Factor Eating Questionnaire-R 21 (TFEQ-R21) (7). The TFEQ-R21 measures eating behaviour and has been validated for use in individuals with obesity. It consists of 21 items comprising three domain scores; (1) uncontrolled eating; assessing the tendency to lose control over eating when feeling hungry or when exposed to external stimuli, (2) cognitive restraint; assessing the conscious restriction of food intake to control body weight or body shape, and (3) emotional eating; assessing overeating related to negative mood states. The domain scores were transformed to 0-100 scales to facilitate comparison; a higher score indicates more uncontrolled, restraint, or emotional eating.

Pfabigan DM, *et al. BMJ Open* 2023; 13:e071332. doi: 10.1136/bmjopen-2022-071332

Social network and belonging will be assessed with the Social Network Index (SNI) (8) and the Social Connectedness Scale Revised and the Social Assurance Scale (SCS-R/SAS) (9).

The SNI was designed to measure three aspects of one's social networks: (1) network diversity, (2) number of people in the network, and (3) number of embedded networks. Each of the three sub-scales is assessed on 12 items. (1) refers to the number of high-contact roles, with higher values indicating a higher number of social roles. (2) refers to the total number of people with whom the respondent has regular contact, which will be summed for the 12 items. Higher numbers indicate more people in one's network. The embedded network scale (3) reflects the number of different network domains in which a respondent is active, with higher numbers indicating activity in more network domains.

The SCS-R was designed to measure a psychological sense of belonging, or how individuals cognitively construe interpersonal closeness with others in their social world. It consists of 20 items, with higher values indicating a higher sense of belonging. The SAS was designed to measure the importance of assurance from one's social group. It consists of 8 items, with higher values indicating a higher need for social assurance.

In addition, a 1-item assessment of loneliness (10) will be administered after the completion of the SNI to measure subjectively experienced loneliness.

Health-related PROs

Psychological distress will be assessed with the Hospital Anxiety and Depression Scale (HADS) (9). The HADS measures symptoms of anxiety and depression with 14 items It is decomposed into two domains measuring depression (HADS-D) and anxiety (HADS-A), both consisting of seven items each.

Generic health-related quality-of-life

The Short Form-36 Health Survey (SF-36) (11) is a 4-week recall self-report measure with 36 items, assessing one’s general health status in eight following domains: vitality, physical function, bodily pain, general health, physical role, emotional role, social role, and mental health. The dimensional scores are combined into two norm-based summary scores: Physical Component Summary (PCS) and Mental Component Summary (MCS). Higher scores indicate better health-related quality of life.

Obesity-related quality-of-life will be assessed with two questionnaires.

The obesity-specific Weight-related Symptom Measure (WRSM) (12), is a 20-item self-report measure for the presence and bothersomeness of weight-related symptoms (shortness of breath, tiredness, sleep problems, sensitivity of cold, increased thirst, increased irritability, back pain, frequent urination, pain in the joints, water retention, foot problems, sensitivity to heat, snoring, increased appetite, leakage of urine, light-headedness, increased sweating, loss of sexual desire, decreased physical stamina, and skin irritation), using two different sets of items. The first set of items assesses whether or not an individual is experiencing specific symptoms, and the second set assesses the level of distress caused by these symptoms.

The Impact of Weight on Quality of Life-Lite (IWQOL-lite) (13) is a 31-item measure of weight-related quality of life. Five domain scores (Physical Function, Self-Esteem, Sexual Life, Public Distress and Work) and a total score can be calculated, with lower scores indicating greater impairment.

Anthropometric measures and body composition

- Percent total body weight loss from Baseline to T2 and T1
- Changes in BMI (kg/m^2) from Baseline to T2 and T1
- Changes in waist and hip circumferences (cm) from Baseline to T2 and T1
- Changes in body fat (%) from Baseline to T2 and T1
- Changes in fat-free mass (kg) from Baseline to T2 and T1
- Changes bone mass (kg) from Baseline to T2 and T1

Measurements will be conducted in light clothing using an Inbody 770 body composition analyzer (Inbody Co Ltd., Seoul, South Korea) for participants ≤ 270 kg. For participants > 270 kg, body weight will be measured using a digital personal scale (Soehnle Professional, Backnang, Germany) and no body composition data will be available.

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Table S1. Laboratory method principles, sample matrix, units and analytical precision of measurements

Analyte	**Method principle**	**Sample matrix**	**Unit**	**Precision** (CV, analytical)	**Time point for collection** (visit number)*
Ferritin	ECLIA	Serum	µg/l	5·0 %	Baseline, T1 and T2
C-reactive protein	Photometry	Serum	mg/l	5·0 %	Baseline, T1 and T2
Creatinine	Photometry	Serum	µmol/l	2·3 %	Baseline, T1 and T2
Sodium	ISE	Serum	mmol/l	1·0 %	Baseline, T1 and T2
Potassium	ISE	Serum	mmol/l	1·2 %	Baseline, T1 and T2
Calcium	Photometry	Serum	mmol/l	1·5 %	Baseline, T1 and T2
Magnesium	Photometry	Serum	mmol/l	3·0 %	Baseline, T1 and T2
Phosphate	Photometry	Serum	mmol/l	3·9 %	Baseline, T1 and T2
Albumin	Photometry	Serum	g/l	2·5 %	Baseline, T1 and T2
Total protein	Photometry	Serum	g/l	2·0 %	Baseline, T1 and T2
Uric acid	Photometry	Serum	µmol/l	2·0 %	Baseline, T1 and T2
Alanine aminotransferase	Photometry	Serum	U/l	5·0 %	Baseline, T1 and T2
Aspartate transaminase	Photometry	Serum	U/l	8·0 %	Baseline, T1 and T2
Alkaline phosphatase	Photometry	Serum	U/l	3·0 %	Baseline, T1 and T2
Gamma-glutamyl transpeptidase	Photometry	Serum	U/l	4·0 %	Baseline, T1 and T2
Lactate dehydrogenase	Photometry	Serum	U/l	3·0 %	Baseline, T1 and T2
Bilirubin	Photometry	Serum	µmol/l	4·0 %	Baseline, T1 and T2
Total cholesterol	Photometry	Serum	mmol/l	3·0 %	Baseline, T1 and T2
HDL-cholesterol	Photometry	Serum	mmol/l	2·0 %	Baseline, T1 and T2
LDL-cholesterol	Photometry	Serum	mmol/l	3·0 %	Baseline, T1 and T2
Triglycerides	Photometry	Serum	mmol/l	3·0 %	Baseline, T1 and T2
Thyroid stimulating hormone	ECLIA	Serum	mIE/l	5·0 %	Baseline, T1 and T2
Unbound thyroxine	ECLIA	Serum	pmol/l	5·0 %	Baseline, T1 and T2
C-peptide	RIA	Serum	pmol/l	4·0 %	Baseline, T1 and T2
HbA1c	HPLC	Blood	%	2·5 %	Baseline, T1 and T2
Cortisol (morning)	ECLIA	Serum	nmol/l	5·0 %	Baseline, T1 and T2
Complete blood count (including Hb)	Photometry Impedance Flow cytometry	Blood	g/dl % Cells/l	1·0-10·0 %	Baseline, T1 and T2

Ghrelin	Millipore Human Ghrelin Elisa	Plasma (-80 C) EDTA		< 10%	Baseline, T1 and T2
Cortisol		Hair			Baseline, T1 and T2
Endocannabinoids		Hair			Baseline, T1 and T2
Samples for storage (biobanking)		Serum, plasma, whole blood			Baseline, T1 and T2

Abbreviations: CV: coefficient of variation, ECLIA: electro-chemiluminescence immunoassay, HPLC: High-performance liquid chromatography, ISE: ion selective electrode

3. Informed consent document

SYKEHUSET I VESTFOLD

VIL DU DELTA I FORSKNINGSPROSJEKTET «PÅVIRKER VEKTREDUSERENDE KIRURGI SOSIALE ERFARINGER GJENNOM ENDRINGER I KROPPSBILDE, VELVÆRE OG BELØNNING?»

FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT

Dette er et spørsmål til deg om å delta i et forskningsprosjekt som planlegger å undersøke effekten av tre typer vektreduserende kirurgiske inngrep. De tre metodene er gastrisk bypass, sleeve gastrektomi og SASI (single anastomosis sleeve ileal bypass). Du forespørres om deltakelse fordi du skal opereres med en av disse metodene. Prosjektet vil i tillegg undersøke sosiale erfaringer og opplevelser før og etter vektreduserende kirurgi, og om/hvordan disse påvirkes av stress- og bukhormoner.

Vi har i dag en del kunnskap om de medisinske effektene av vektreduserende kirurgi (f.eks. hvordan kirurgi påvirker diabetes), mens vi vet mindre om i hvilken grad vektreduserende kirurgi påvirker hvordan man opplever sosialt samvær i ulike sammenhenger. Det er viktig å få mer kunnskap om hvordan og i hvilken grad vektreduserende kirurgi har innvirkning på sosiale interaksjoner, opplevelser og velvære gjennom endringer i kroppsbilde, belønningsrespons og tarmhormoner knyttet til belønning. Slik kunnskap er viktig å erverve for å kunne gi de riktige anbefalingene til hver enkelt pasient, samt viktig for folkehelsen siden et tilfredsstillende sosialt liv gjør individer mer motstandsdyktige mot miljømessige utfordringer og bidrar til generell helse. Vi spør deg om deltakelse i denne studien fordi du planlegger vektreduserende kirurgi ved Sykehuset i Vestfold.

HVA INNEBÆRER PROSJEKTET FOR DEG?

Utover et ordinært pasientforløp innebærer prosjektet at vi vil samle inn data fra deg på tre tidspunkter: én måned før operasjonen, 6 uker etter operasjonen, og ett år etter operasjonen. Prosedyren er den samme ved alle tre tidspunktene. Vi gjør det tre ganger for å få pålitelige data, og for å kunne dokumentere eventuelle endringer over tid. Som deltaker i prosjektet vil vi ved de tre ovennevnte tidspunktene:

- Be deg å fylle ut et kort spørreskjema (1 side) hjemme hver kveld over en periode på 14 dager. Dette kan du gjøre på papir eller online. Du vil bli spurt om dine sosiale kontakter den dagen, hvordan du har følt deg, hvor positiv eller negativ den sterkeste interaksjonen var den dagen, og ditt ønske om å være alene eller sammen med andre. Det vil ta ca. 5-10 minutter å fylle ut hver dag.
- Kartlegge din helsestatus gjennom måling, veiing, analyse av kroppssammensetning og blodprøver. Det vil tas en standard blodprøve for å kartlegge generelle blodverdier, blodprøve for biobank, samt blodprøve for analyse av stresshormoner.
- Ta en hårprøve for å analysere stresshormoner. Ettersom stresshormoner bygges inn i håret kan man på den måten få et bilde over ditt nivå over et lengre tidsintervall. Vi vil klippe av et tynt (3-5 mm) hårstrå fra underhåret, dvs. et sted der det ikke synes.
- Be deg fylle ut flere spørreskjemaer for kartlegging av generell og helserelatert livskvalitet, psykisk helse, levevaner, spiseatferd, søvnvaner, kroppsbilde, belønningsrespons, samt kroppsopplevelse og - bevissthet.
- Be deg å utføre forskjellige oppgaver: a) Vurdere ulike typer av berøring gjennomført med en myk pensel på underarmen, b) vurdere berøringen av underarmen som du utfører selv med den frie hånden, c) gjennomføre et dataspill om mental forestilling.

Prøvetakingen og oppgavene vil til sammen ta 1.5 – 2 timer. Undersøkelsene vil bli utført av forskere og helsepersonell ved SSO.

I prosjektet vil vi innhente og registrere helseopplysninger om deg. Vi vil registrere blodprøveresultater, spørreskjemaopplysninger, stresshormonverdier fra hår, resultat fra dataspilloppgavene, og bedømmelser av berøring.

MULIGE FORDELER OG ULEMPER

Studien har ikke noen umiddelbare fordeler for deg bortsett fra at du vil motta noen ekstra studiespesifikke kontroller som vil medføre litt tettere oppføling ut over ordinært behandlingsforløp. Noe ubehag kan oppleves i forbindelse med blodprøvetaking. Noen kan oppleve dataspillet og spørsmålene om kroppsbildet som ubehagelig.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Det vil ikke ha noen negative konsekvenser for deg eller din behandling hvis du ikke vil delta eller senere velger å trekke deg. Dersom du trekker tilbake samtykket, vil det ikke forskes videre på dine helseopplysninger og ditt biologiske materiale. Du kan kreve innsyn i opplysningene som er lagret om deg, og opplysningene vil da utleveres innen 30 dager. Du kan også kreve at dine helseopplysninger i prosjektet slettes og at det biologiske materialet destrueres. Adgangen til å kreve destruksjon, sletting eller utlevering gjelder ikke dersom materialet eller opplysningene er anonymisert eller publisert. Denne adgangen kan også begrenses dersom opplysningene er inngått i utførte analyser.

Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder (se kontaktinformasjon på siste side).

HVA SKJER MED OPPLYSNINGENE OM DEG?

Opplysningene som registreres om deg skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til i prosjektperioden som er satt fra 01.08.2021 til 31.07.2031. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra REK og andre relevante myndigheter. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av dine opplysninger til Datatilsynet og institusjonen sitt personvernombud.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektleder Jøran Hjelmeseth, forskningsleder Jens Kristoffer Hertel samt forskningsadministrator ved Senter for sykelig overvekt i Helse Sør-Øst ved Sykehuset i Vestfold som har tilgang til denne listen.

Publisering av resultater er en nødvendig del av forskningsprosessen. All publisering skal gjøres slik at enkeltdeltakere ikke skal kunne gjenkjennes, men vi plikter å informere deg om at vi ikke kan utelukke at det kan skje.

Opplysningene om deg vil bli oppbevart i fem år etter prosjektslutt av kontrollhensyn, deretter vil datamaterialet anonymiseres og koblingsnøkkel slettes.

DELING AV OPPLYSNINGER OG OVERFØRING TIL UTLANDET

Ved å delta i prosjektet, samtykker du også til at kodede opplysninger kan overføres til utlandet som ledd i forskningssamarbeid og publisering i tråd med formålet angitt innledningsvis. Dette kan være land med lover som ikke tilfredsstiller europeisk personvernlovgivning, men prosjektleder vil sikre at dine opplysninger blir ivaretatt på en trygg måte. Koden som knytter deg til dine personidentifiserbare opplysninger vil ikke bli utlevert.

Ved å samtykke til å delta i studien samtykker du også til at de anonymiserte dataene vil bli gjort tilgjengelige for gjenbruk i forskning utover formålet angitt innledningsvis.

HVA SKJER MED PRØVER SOM BLIR TATT AV DEG?

Blodprøvene som blir tatt vil bli lagret i en godkjent prosjektspesifikk forskningsbiobank (BaSES-biobank) ved Senter for sykelig overvekt i Helse Sør-Øst ved Sykehuset i Vestfold. Ansvarshavende for biobanken er seksjonsleder/forskningsleder Jens Kristoffer Hertel. Hvis du

sier ja til å delta i studien, gir du også samtykke til at det biologiske materialet og analyseresultater inngår i biobanken. Det biologiske materialet kan bare brukes i tråd med studiens formål. Biobanken opphører ved prosjektslutt.

Hårprøvene vil analyseres av Dresden LabService GmbH, Dresden, Tyskland, mens blodprøvene vil bli undersøkt ved samarbeidspartner ved Universitetet i København i Danmark. Det innsamlede biologiske materialet vil bli oppbevart avidentifisert og destruert ved prosjektperiodens utløp.

FORSIKRING

Deltakere er forsikret gjennom pasientskadeloven.

GODKJENNINGER

Regional komité for medisinsk og helsefaglig forskningsetikk har gjort en forskningsetisk vurdering og godkjent prosjektet. [REK sør-øst A, nr. 238406]

Etter ny personopplysningslov har Sykehuset i Vestfold (behandlingsansvarlig) og prosjektleder Jøran

Hjelmesæth et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning artikkel 6a og 9a.

Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du ta kontakt med Jøran Hjelmesæth på telefonnummer 33342320.

Du kan ta kontakt med institusjonens personvernombud dersom du har spørsmål om behandlingen av dine personopplysninger i prosjektet. Telefonnummer Sykehuset i Vestfold: 33 34 20 00

Utfyllende informasjon om studien er gitt av forskningspersonell

Sted og dato Prosjektmedarbeider

_____

Prosjektmedarbeiders navn med trykte bokstaver

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER OG MITT BIOLOGISKE MATERIALE BRUKES SLIK DET ER BESKREVET

_____

Sted og dato Deltakers signatur

_____

Deltakers navn med trykte bokstaver

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