

BMJ Open The impact of self-efficacy and health literacy on outcome after bariatric surgery in Sweden: a protocol for a prospective, longitudinal mixed-methods study

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ABSTRACT

Introduction A person-centred approach, to know about a person's individual weaknesses and strengths, is warranted in today's healthcare in Sweden. When a person suffers from obesity, there are not only risks for comorbidities but also increased risk for decreased health-related quality of life (HRQoL). After bariatric surgery, there are also risks for complications; however, healthcare service expects the person to have sufficient ability to handle recovery after surgery. The need is to investigate how a person's self-efficacy and health literacy (HL) skills are important to determine their effect on recovery as well as HRQoL after bariatric surgery. It can, involve the person in the care, improve shared decision-making, and perhaps decrease complications and readmissions.

Method and analysis This is a prospective, longitudinal mixed-methods study with the intent of including 700 patients from three bariatric centres in Sweden (phase 1); 20 patients will be included in a qualitative study (phase 2). Inclusion criteria will be age >17 years, scheduled primary bariatric surgery and ability to read and understand the Swedish language in speech and in writing. Inclusion criteria for the qualitative study will be patients who reported a low self-efficacy, with a selection to ensure maximum variation regarding age and gender. Before bariatric surgery patients will answer a questionnaire including 20 items. Valid and reliable instruments will be used to investigate general self-efficacy (10 items) and functional and communicative and critical HL (10 items). This data collection will then be merged with data from the Scandinavian Obesity Surgery Registry. Analysis will be performed 30 days, 1 year and 2 years after bariatric surgery. One year after bariatric surgery the qualitative study will be performed. The main outcomes are the impact of a person's self-efficacy and HL on recovery after bariatric surgery.

Ethics and dissemination The study has received approval from the ethical review board in Uppsala, Sweden (number 2018/256). The study results will be disseminated through peer-reviewed publications and conference presentations to the scientific community and social media.

Strengths and limitations of this study

- How self-efficacy and health literacy impact outcomes after bariatric surgery has not been investigated previously in Sweden.
- This research addresses a person-centred approach, which is warranted in Swedish healthcare.
- This mixed-methods study aims to provide a deeper understanding of the phenomena.
- Although this study is conducted in multiple centres in hopes to increase the generalisation of study results, this study is limited to Swedish-speaking people undergoing bariatric surgery.

INTRODUCTION

Overweight and obesity in adults are common conditions all over the world.¹ Obesity is associated with increased risk for several severe and chronic diseases, such as diabetes type 2,² cancer² and cardiovascular disease,³ and there is disparity between studies as to whether obesity increases the risk for depression.^{4 5} Bariatric surgery improves obesity-related comorbidities, mortality rates and health-related quality of life (HRQoL).^{6–8} However, the long-term efficacy of bariatric surgery differs between individuals.⁹ In terms of complications, individual characteristics such as age (>50 years), specific obesity-related comorbidities and intraoperative adverse events such as bleeding are associated with increased postoperative complication rates.^{10 11} Patients attending follow-up visits and those with good support appear to achieve better long-term results.^{12 13}

Although modern bariatric surgery can be considered as safe, research investigating postoperative complications, emergency department visits or readmission shows that 8.7% of patients experience postoperative complications within 30 days of surgery,¹⁰ 14% visit

emergency departments¹⁴ and readmission rates are as high as 6%¹⁵ to 8%.¹⁴ Reasons for readmission have been reported to be specific complications (eg, infectious complications or leakage)^{10 16} as well as indications of non-adherence (medication issues or dehydration not related to specific surgical complications).¹⁶ Younger age and female sex have been reported as factors associated with an increased readmission rate due to non-specific indications and poorer postoperative recovery in patients undergoing minor and major surgery.^{17–21} In addition, mental health disorders have also been reported as a risk factor for readmission,²² although this has been contradicted in other studies, where a reduced readmission rate was reported for patients in outpatient psychiatric care.¹⁶

Self-efficacy (ie, *one's capabilities to organise and execute the course of action required for given attainment*)²³ has been reported to influence hospital readmissions,²⁴ and has in an experimental context been reported to influence the immune function²⁵ and perception of pain.^{26 27} Self-efficacy incorporates a person's social, behavioural, cognitive and emotional skills and integrates them into actions during difficult circumstances in order to perform as optimally as possible. The outcome varies between individuals as well as within an individual, depending on fluctuations in one's own personal belief in personal efficacy. To change a habit, for example, to stop overeating high-calorie food, health-promoting behaviour is needed. A person who does not believe the change is possible is likely to give up more easily.²³ Self-efficacy has been reported to influence weight gain after surgery.^{28–30} Still, there is a lack of studies evaluating general self-efficacy (GSE) in populations with different medical conditions. To our knowledge GSE has not been investigated in patients with obesity.

Health literacy (HL) is a concept that includes the ability to assess, understand and use information to maintain or improve one's health.³¹ Limited HL skills are associated with lower income and lower educational level,³² and predict poor postoperative recovery in day surgery patients³³; poor overall general health, especially in elderly persons³⁴; difficulty in adherence to medication³⁴; and difficulty understanding health information.³⁴ But the evidence is weak regarding whether a person with limited HL uses more inpatient and outpatient care.^{33 35–37} This may be due to different settings and samples in the studies performed. Limited HL has also been significantly associated with overweight and obesity in adolescent^{38 39}; however, there is a knowledge gap regarding the association between HL and overweight and obesity in adults.³⁴ To our knowledge, no study has investigated the association between HL and readmission in persons undergoing bariatric surgery.

Obesity can negatively affect a person's HRQoL.⁴⁰ GSE has been significantly correlated with HRQoL.^{41 42} Also, low HRQoL has been significantly correlated with limited HL.^{42 43} However, to our knowledge, these associations have not been studied in a group of people undergoing bariatric surgery.

Our a priori hypotheses are as follows:

GSE has an impact on weight loss.

HL has an impact on readmission.

There is a positive association between HRQoL, HL and GSE.

AIMS

1. To describe GSE and HL in a sample of patients undergoing bariatric surgery, and further, to investigate associations between GSE, HL and weight loss and readmission 30 days after bariatric surgery, as well as whether there are any differences in sex, age and educational level.
2. To investigate the impact of GSE and HL on length of hospital stay, weight loss, sex, complications and HRQoL 30 days, 1 year and 2 years after bariatric surgery.
3. To psychometrically evaluate GSE and HL in a sample of people undergoing bariatric surgery.
4. To investigate associations between HL, GSE and HRQoL.
5. To explore patients' experiences of their recovery after bariatric surgery, in those reporting low self-efficacy.

METHODS AND ANALYSIS

This is a prospective, longitudinal mixed-methods study with an embedded design.⁴⁴ The trial will be conducted at three bariatric centres in Sweden. Study recruitment started in October 2018 and is planned to end in December 2019.

Participants

Inclusion criteria will be age >17 years, scheduled primary bariatric surgery (Roux-en-Y gastric bypass or sleeve gastrectomy) and the ability to read and understand the Swedish language in speech and in writing.

Sample size

Limited HL has been associated with obesity in adolescents³⁴; therefore, it was assumed that a similar association is present in adults. Sample size calculation was based on the assumption of a clinically relevant reduction from the average weight loss after laparoscopic gastric bypass surgery of 82.3% excess body mass index loss (EBMIL)⁴⁵ to 75% EBMIL for persons with limited HL. To detect such a difference with a power of 80% at the 5% significance level, a sample size of 624 patients would be needed, resulting in a sample size of 700 patients to allow for 10% attrition.

Recruitment

During their preoperative consultation the surgeons will verbally provide information about the study. Written information will be provided to the patient preoperatively together with the appointment for the operation. If the patient agrees to participate in the study, written

informed consent will be obtained by the physician or a registered nurse before bariatric surgery.

Data sources

The Scandinavian Obesity Surgery Registry (SOReg) is a national quality and research register covering virtually all bariatric surgical procedures performed in Sweden since 2010.⁴⁶ Data are collected at baseline, during the operation, and at follow-up on day 30 and 1 year, 2 years, 5 years and 10 years after bariatric surgery.

Definitions

Postoperative complications will be classified in accordance with the Clavien–Dindo scale⁴⁷ with complications graded as 3b or more (ie, a complication requiring intervention under general anaesthesia, resulting in single- or multiorgan failure, or death) being considered to be serious complications. Diagnostic laparoscopy with negative finding in the early postoperative phase (during day 0–30) will be considered a serious complication.

Weight loss will be reported as changes in body mass index (BMI), %EBMIL and percentage of total weight loss (%TWL). Furthermore, a good weight-loss result will be defined as EBMIL >50%. The weight before preoperative weight reduction will be considered as baseline weight.

Instruments

General self-efficacy

The original scale was developed in 1995.⁴⁸ The scale consists of 10 items rated on a 4-point Likert scale (ranging from not at all true to exactly true) and it has been translated into different languages. The scale has been psychometrically evaluated with samples from 25 countries. Results showed that internal consistency for the total sample was $\alpha=0.86$, and the hypothesis that the GSE was unidimensional was supported by confirmatory factor analysis.⁴⁹ The GSE has been translated into Swedish, with a Cronbach's alpha for the total sample of $\alpha=0.91$. There is also support that the GSE is unidimensional.⁵⁰

Health literacy

The original scales, functional HL (FHL) and communicative and critical HL (C & C HL) were developed in Japan and tested on patients with type 2 diabetes. These three scales included 14 items in total (FHL, 5 items, and C & C HL, 9 items).⁵¹ A short version of C & C HL (five items) was developed in 2010.⁵²

Functional literacy refers to basic skills in reading and writing to function in everyday life. Communicative literacy refers to advanced skills, whereby the person can also extract information and derive meaning from different types of communication. It also includes the ability to apply new information when circumstances change. Critical literacy refers to more advanced skills: the person can critically analyse information and use information to have greater control of situations and everyday life.⁵³

The Swedish FHL scale has five items, answered on a 5-point Likert scale (never, seldom, sometimes, often

and always).⁵⁴ The Swedish C & C HL scale has five items (ie, translated from the short version of C & C HL⁵²), measured on a 5-point Likert scale.⁵⁴ The data are divided into three categories of HL: inadequate, problematic and sufficiently functional or communicative and critical when analysing results.

Both scales have been found to be reliable and valid in a Swedish context for persons with different age, gender and educational levels^{54 55}; however, more psychometric testing is warranted on broader populations.

SF-36

HRQoL will be measured with Research ANd Development (RAND)/Short Form (SF)-36. RAND/SF-36 is a free to use version of SF-36. SF-36 has been found reliable and valid to use in a Swedish context. The instrument consists of 36 items grouped into eight multi-item scales that measure physical function, role function, bodily pain, general health, vitality, social functioning, emotional role and mental health. All scales are scored from 0 to 100, with a higher score indicating better health status. Also, two summary scores are calculated: the physical component summary and the mental component summary; these summaries reflect overall physical and mental health status.^{56 57}

Obesity-related problem scale

The obesity-related problem (OP) scale is a disease-specific scale measuring the impact of obesity on HRQoL. Psychometric testing showed a strong construct validity, high internal consistency with a Cronbach alpha above 90 and exploratory factor analysis (EFA) showed unidimensionality. The OP scale consists of eight questions on common OPs. The scores from each question are summarised to a total score ranging from 0 to 100. A low score represents better psychosocial functioning.⁵⁸

Data collection procedure

Before bariatric surgery the patient answers the three questionnaires (GSE, Swedish FHL scale and Swedish C & C HL scale), with a total of 20 items/questions. Before bariatric surgery the patient also answers SF-36 and OP, which are part of the SOReg data collection. Data from SOReg will be collected 30 days, 1 year and 2 years after bariatric surgery (table 1). Information on educational level (primary school, high school or university) and household income/year (<200 000, 200 000–300 000, 300 000–400 000, 400 000–500 000, 500 000–600 000, >600 000 of Swedish krona [SEK])⁵⁹ will also be collected.

Embedded in the main study will be a qualitative study with an inductive approach.⁴⁴ Twenty persons who participated in the main study will be included in a qualitative phase using an inductive approach. Data will be collected 1 year after bariatric surgery. A purposeful sampling will be conducted. Participants who reported low self-efficacy⁴⁸ will be included and will be selected to ensure maximum variation regarding centre, age and gender.⁶⁰ Individual interviews with a semi-structured interview

Table 1 Data extracted from SOReg

	Before bariatric surgery	During hospital admission	30 days after bariatric surgery	1 year after bariatric surgery	2 years after bariatric surgery
Gender	X				
Age	X				
Weight	X	X	X	X	X
Height	X				
Comorbidity	X			X	X
Body mass index	X		X	X	X
Level of education	X				
Date of surgery		X			
Duration of surgery		X			
Type of surgery		X			
Intraoperative complication		X			
Length of stay		X			
Excess BMI loss			X	X	X
Readmission			X	X	X
Complications*			X	X	X
Obesity-related problem scale			X	X	X
SF-36 RAND	X		X	X	X

*These will be defined as Clavien–Dindo over 3b. X=data extracted from SOReg

guide will be conducted, including open-ended questions: ‘Describe your experiences of the first months after bariatric surgery?’ and ‘How has your everyday life changed since bariatric surgery?’ These will be followed by questions such as ‘What has been hard to handle after bariatric surgery?’ and ‘What has been easy to handle after bariatric surgery?’ Probing questions will be asked when needed to gain a deeper understanding. Interviews will be conducted by the researchers. All interviews will be audio recorded, using Philips, DVT6010. None of the researchers conducting the interviews will be involved in the care of the included participants.

Statistical analysis

Demographic variables will be analysed with descriptive statistics with number, percentage, mean, and SD or median (range), as appropriate. A variety of tests will be used, depending on scale level, or whether the data are normally distributed or not. To test for normal distribution, the Shapiro-Wilk test will be used. For non-normally

distributed data, differences between groups will be analysed with Chi-square test, Mann-Whitney U test and Kruskal-Wallis test, as appropriate. For normally distributed data, *t*-test and one-way ANOVA will be used. To investigate association, the Spearman rank sum test will be used. For the analyses on weight loss and HRQoL, multivariable regression analyses including other factors potentially influencing postoperative weight loss will be performed. As a sensitivity analysis, patients included in the study will be compared in terms of baseline characteristics with those not included in order to identify potential risk for selection bias. Internal consistency will be analysed with Cronbach’s alpha, and to confirm the factors structure extracted in earlier EFA analysis a confirmatory factor analysis will be performed (table 2).

The psychometric analysis will be guided by consensus-based standards for the selection of health measurement instruments manual⁶¹ (table 2).

Table 2 Planned psychometric evaluation

	Construct validity	Discriminant validity	Internal consistency	Confirmatory factor analysis	Floor/ceiling effect
SFHL	X	X	X	X	X
S C & C HL			X	X	X
GSE			X	X	X

GSE, general self-efficacy; S C & C HL, Swedish communicative and critical health literacy; SFHL, Swedish functional health literacy. X=Planned psychometric evaluation

Qualitative analysis

Thematic analysis, described by Braun and Clarke,⁶² will be used to provide in-depth analyses of patients' experience of postoperative recovery after bariatric surgery. To ensure trustworthiness and rigour, analyses will adhere to the quality criteria outlined by Lincoln and Guba (credibility, confirmability, dependability, transferability).⁶³

All interviews will be recorded and transcribed verbatim. Analyses will start with the researchers listening to the recorded interviews and then reading through the transcribed interviews to familiarise themselves with the data. During the analysis the researchers pre-understanding will be taken under consideration. After reading through the interviews, the coding process will be conducted, and the codes will be searched for patterns. Codes will be gathered together in subthemes and themes that respond to the research question. Subthemes and themes will be reviewed and refined by the researchers, as will be headings of the subthemes and themes. During the analysis researchers will move back and forth between the different steps to ensure correspondence with the original data and ensure that subthemes and themes are internally homogeneous and externally heterogeneous.

ETHICS AND DISSEMINATION

The study will follow the principles outlined in the 1964 Helsinki Declaration and its later amendments. The patients will receive both oral and written information about the study. Before participation, written informed consent will be obtained from prospective participants.

Dissemination

The study results will be disseminated through peer-reviewed publications and conference presentations to the scientific community and social media.

Patient and public involvement

Patients were not involved in the design of the study and will not be involved in the recruitment of participants. The results of the project will be disseminated through scientific papers.

DISCUSSION

To our knowledge neither GSE nor HL has been investigated in patients undergoing bariatric surgery, and research questions such as ours have not been reported previously. Also, research available shows disparity in results, which justifies further research.

According to Swedish legislations, the patient should be the centre of attention treating as an individual with dignity and respect,^{64 65} that is, taking a person-centred approach. Patient-centred care, has been defined as healthcare that establishes a partnership among practitioners, patients and their families to ensure that decisions respect patients' wants, needs and preferences and that patients have the education and support they

need to make decisions and participate in their own care. Patient-centred care has been highlighted as an important factor in improving self-care after discharge from the hospital.⁶⁶ Therefore, healthcare providers need to address potential barriers regarding HL or GSE. The results from this study can be hypothesis generating in the sense that if our a priori hypotheses are confirmed, a multidisciplinary intervention study (including peer education) can be planned. If the patients can strengthen in their self-efficacy, they may feel empowered to handle their situation. Also, if information provided is appropriate according to their level of HL, patients may be able to manage their postoperative recovery. Furthermore, perhaps readmissions due to non-specific conditions can, to some extent, be avoided, that is, a cost-effective care can be provided.

Limitations

The study will not be without limitations. All patients meeting the inclusion criteria will be offered inclusion in the study. However, with more women than men undergoing bariatric surgery in Sweden,¹⁰ this gender discrepancy may limit interpretations of the study results to women exclusively. We will address this issue within the quantitative studies by using multivariate regression analyses adjusting for sex. Furthermore, the study group is expected to represent the population of patients undergoing laparoscopic bariatric surgery in Sweden, thus maintaining a high external validity.

The follow-up will include a clinical registry of high quality. The registry collects variables of clinical interest. However, the study will be limited to variables followed within the registry. Thus, information on a few parameters more difficult to assess, such as substance abuse, will be more difficult to ascertain.

In qualitative research the researcher is the instrument in data collection and analysis. It is therefore important to be aware of and reflexive about the researchers pre-understanding. Throughout the analysis process the researchers will discuss the analysis and interpretation of data. To ensure accuracy of the data all interviews will be recorded and transcribed verbatim and the themes and subthemes will be checked against the transcripts. To enhance the participants to speak freely about their experiences none of the researchers conducting the interviews will be involved in the care of the included participants.

Contributors MJ, KD, UN and ES contributed to the study design. ES led the calculation of sample size. KD led the design of the qualitative study. All participants contributed to the preparation of the manuscript and approval of the final version.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The project has been approved by the regional ethical review board in Uppsala, Sweden (number 2018/256).

Provenance and peer review Not commissioned; externally peer reviewed.

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