# **MANUSCRIPT - TITLE PAGE**

#### Title

Bariatric Surgery or Lifestyle Intervention? An Exploratory Study of Severely Obese Patients'

Motivation for Two Different Treatments

## **Running Head**

Reasons for Choice of Treatment

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## **Disclosure**

No conflict of interest to declare.

# **ABSTRACT**

## Background

In the complex field of treating severe obesity, motivation is receiving increased attention.

This explorative study aims to highlight what influences the preferences of severely obese patients deciding for either gastric bypass surgery or lifestyle treatment.

#### Methods

Patients awaiting laparoscopic gastric bypass were presented with an 18 week inpatient lifestyle programme alternative to gastric bypass. Questionnaires provided qualitative data (reasons for choosing one treatment over another) and quantitative data (mental health assessment using the Hospital Anxiety and Depression Scale). The material was analysed according to a sequential exploratory design involving thematic analysis of patients' arguments, validation using HADS, and statistical computations (hypothesis testing) with one-way ANOVA followed by Dunnett's post-hoc test.

#### **Results**

159 participants (mean BMI 47.2 kg/m²) returned questionnaires of which 32% wanted the lifestyle treatment alternative to surgery. Reasons for choosing the two treatments varied widely as did also the corresponding data on mental health. Two subgroups stood out with particularly high mental symptom scores, namely patients choosing surgery due to reluctance to engage in social interaction in lifestyle treatment, and patients preferring lifestyle treatment due to the fear of dying during general anaesthesia. These two subgroups showed significantly higher symptom scores than other subgroups within their therapy-of-choice group. The number of comorbid diseases was also found to impact upon motivation.

## **Conclusions**

Patients carry different incentives for choosing the same type of treatment. On a subgroup level, psychopathological symptoms seem to follow motivational patterns. Analysing motivation and mental health may provide measures for identifying subgroups with various prospects for therapy outcome.

# Keywords

Overweight; Obesity; Gastric Bypass; Lifestyle Intervention; Mental Health; Mixed Methods

Research; Sequential Exploratory Design

# INTRODUCTION

Dental anxiety is known to limit or even prevent the utilisation of oral health care services [1], often entailing severe consequences for both oral health and quality of life [2]. While dental anxiety is a well recognised problem within the dental profession, little has been done to document similar anxiety mechanisms among patients in need of bariatric treatment. Over the years, we have occasionally met patients who are reluctant to accept or even turn down bariatric procedures, however we have never approached these cases in a systematic fashion with the express objective of trying to understand the impact of anxiety on patient decisions. Paradoxically the potential consequences of morbid obesity are more detrimental to the patients' health than neglected oral health care.

We located only one study looking into reasons why obese patients turn down treatment. Sadhasivam et al found that the most frequent cause for not undergoing bariatric surgery was related to patients' financial coverage [3]. Consequently, this does not explain withdrawals experienced within our public health service where treatment is free of charge. Also, as this study was based on participants recruited from a bariatric clinic, it is likely that patients reluctant to undergo surgery were not referred to the clinic in the first place.

Although bariatric surgery is the recommended treatment for the most severely obese [4, 5], Norwegian health authorities have instructed public hospitals with bariatric units also to provide non-surgical alternatives (i.e. lifestyle alteration). In our process of organising a comprehensive alternative to try to match gastric bypass, we found it necessary to learn more about patients' motivation for treatment. Recent research reveals an increased interest for obese patients' motivation with publications on topics including patients' expectations to and

how patients value different treatment outcomes [6]; patients' reasons for wanting to loose weight [7-9]; and the possible link between motivation and treatment outcome [10]. However, literature provide only limited insight into why obese patients refuse treatment [3], and none at all on why they choose one treatment rather than another.

To shed light upon how patients' make their choices of therapy, we set an explorative study asking referred patients hypothetically to choose between these two very different, yet none the less comprehensive, treatments. The first alternative was the laparoscopic gastric bypass procedure. Alternatively, they were offered an extensive non-surgical lifestyle modification programme involving an 18-week stay at a clinic. Financially, the gastric bypass procedure and the 18-week stay at the clinic cost approximately the same. However, patients were not presented with these costs as inpatient medical treatment in Norway is largely free of charge.

Due to fundamental differences between these two treatments, we anticipated that patients opting for one treatment rather than another would show characteristic differences in motivation. Due to our occasional experience with patients reporting anxiety about the bariatric procedure, we also anticipated to find differences in psychological functioning. Accordingly, the research questions in this explorative study were: A) Do patients choosing the same treatment share mutual rationales?, and B) If not, do patients differ in outcomes on psychological measures according to different rationales?

## MATERIAL AND METHODS

## Setting and Participants

In March 2005, 209 patients in Central Norway referred to the Obesity Clinic at Trondheim University Hospital were asked to fill in a questionnaire sent to them by post. One reminder was sent to non-responders. In all, 159 forms were returned yielding a response rate of 76%. Sample characteristics are summarised in Table 1. Nine participants were excluded, leaving a total of 150 participants. Reasons for exclusion from the study were 1) failure to express which treatment was wanted, 2) contradictory arguments (arguments favouring one treatment but choosing the other), or 3) prior history of bariatric surgery that might cause them to be biased. The study was approved by the Regional Committee for Research Ethics.

## Measures

Participants were presented with information about gastric bypass surgery and an 18-week inpatient lifestyle programme. They were then asked, hypothetically, in a questionnaire to choose between ILP (Inpatient Lifestyle Programme) and LGB (Laparoscopic Gastric Bypass), as well as to list the grounds for their choice in an open-ended question. In addition, they also gave self-reported data on anthropometry (height, weight), sociodemography (educational level, marital status), comorbidity (checking for a list of diseases associated with obesity) and mental health applying HADS (the Hospital Anxiety and Depression Scale).

#### **HADS**

The Norwegian version of HADS has demonstrated good psychometric properties [11] and was used for assessing mental health. The instrument consists of fourteen questions sensitive for anxiety and depression [12]. Each question is followed by four possible responses which

are summed according to Likert-scoring (0123). For our purpose we calculated the total-score, indicating global emotional distress. Using HADS for screening purposes, there is reported good positive predictive value for any mental disorder using a cut-off of 17 or more [13].

## **Analysis**

The study has a sequential exploratory design [14] combining qualitative and quantitative data. More specifically, the qualitative material was analysed thematically [15]. The quantitative data served as a basis for validation as well as giving grounds for hypothesis generation. Finally, the material from different data sources was integrated to make statistical computations possible (hypothesis testing). The process is schematically accounted for in Table 1.

#### Qualitative Analysis

The participants' answers to the open-ended question about why they would choose LGB or ILP represented an extensive textual material, ranging from scant, concise answers consisting of only three words, up to long explanations of more than 150 words. The thematic analysis was performed by the first author and was initially aimed at identifying all reasons behind treatment choice. Among the reasons, some common themes emerged. As some participants gave several reasons for their choice of treatment and the intention was to classify each participant according to his or her main argument, the authors set up a protocol for how this reduction should take place. According to this protocol the first reason listed was decisive unless another reason clearly stood out as more important. The list of reasons served as basis for classification. Finally, the material was quantitised [16] i.e. coded numerically to enable statistical computations.

#### Statistical Analysis

We conducted a contingency table test to see if men and women differed in choice of treatment. One-way ANOVA followed by Dunnett's post hoc tests were applied for multiple comparisons of mental symptom intensity between subgroups of participants to one control group, yet maintaining the family-wise error rate. Finally a contingency test followed by a test for trend was conducted to see if the number of diseases influenced patient motivation. Statistical analyses were performed using software (SPSS for Windows, Rel. 13.0. 2004. Chicago: SPSS Inc.). All statistical tests were two-tailed, with significance set at an  $\alpha$ -level of 0.05.

## **RESULTS**

Sample characteristics are presented in Table 2. Thirty-two percent of the patients preferred lifestyle treatment over gastric bypass. There was no significant difference in choice of treatment between men and women ( $\chi^2$ =0.078, p=0.78).

The qualitative material condensed into a total of nine different categories of arguments for treatment. Five of these were arguments for surgical treatment; denominated *Social Reluctance, A Permanent Solution, Familial Considerations, Work Situation,* and *Being Physically Disabled,* whereas four arguments promoted lifestyle therapy; *Fear of Anaesthesia, Fear of Complications, Desire for Normality,* and *Desire for Follow Up.* The participants were divided into subgroups according to these arguments. However, the five participants choosing surgery due to physical handicaps were not included in the further analysis since their treatment decision did not reflect motivational issues as much as physical functionality.

Rationales as well as typical quotations for pro-surgery and pro-lifestyle participants are presented in Table 3 and 4, respectively.

The qualitative analysis revealed two subgroups giving reasons for their choice of therapy which placed their mental health in question. In the pro-lifestyle category, this was the subgroup reporting death anxiety related to the surgical procedure, while in the pro-surgery category those strongly wanting to avoid social intimacy with other patients stood out. HADS-total, as an indicator of global emotional distress, was calculated for each sub-group to see if the score validated our interpretation of the qualitative data. In Table 3 and 4, subgroups with their representative quotations are listed according to decreasing symptom intensity. In addition, the tables present data on probable caseness (in terms of any mental disorder) according to a cut-off score of 17 and higher.

In the case of participants oriented towards surgical treatment, statistical analysis showed symptom intensity to differ significantly between the subgroups (one-way ANOVA:  $F_{3,95}$ =2.70, p=0.050). Dunnett's test found significantly higher symptom scores among participants with social reluctance when compared to all other subgroups (Table 3). Concerning participants preferring lifestyle therapy, the analysis also showed these subgroups to differ significantly (one-way ANOVA:  $F_{3,28}$ =3.31, p=0.034), although here the subgroup fearing for complications from surgery did not differ statistically significantly from those afraid of dying during the procedure (Table 4). Three outliers were excluded from the lifestyle group before running the analysis.

Another finding in the qualitative data was that some patients reported positive motivation (i.e. choosing treatment A because they regarded treatment A as good for them) while others carried negative motivation (i.e. choosing treatment A to avoid treatment B). Typically,

negatively motivated patients seeking lifestyle treatment often referred to how their disease would increase the risk of complications during surgery. On the other hand, negatively motivated patients seeking surgery often explained how diseases had made exercising difficult and consequently impaired their physical functionality. Finally, we did a statistical test to see if the number of diseases increased the risk of being negatively motivated and found a significant linear trend of medium association ( $\chi^2$ =5.88, p=0.015; Cramer's V=0.22, p=0.041).

# **DISCUSSION**

Participants reported significantly different rationales for choosing the same type of treatment. The mental symptom scores varied according to rationale, supporting the view that the diverse rationales reflected distinctly different subgroups within which some have particular psychological problems that influence choice of treatment.

Thirty-two percent of the participants preferred a lifestyle alternative to bariatric surgery. There is reason to believe that the demand for treatments varies according to the specific therapy and how it is presented. It is worth noting that at the time of this study, bariatric surgery was the standard treatment offered by the Norwegian public healthcare system. Thus, the participants may have been in a process of mental preparedness, making an alternative choice to surgery less likely. This may bias the material in favour of bariatric surgery. However, this should not influence the described motivational traits which were the focus of this study.

#### Different Reasons for Same Type of Treatment

To our knowledge, no one has yet explored how motivation differs between obese people opting for different obesity treatments. Consequently, we had no basis for incorporating pre-

defined response categories in a questionnaire. As to the different reasons reported (Table 3 and 4), arguments varied widely. This suggests that a crude dichotomisation of the material into pro-lifestyle and pro-surgical treatment could conceal important patient characteristics. The sample's moderate size, later divided into no less than eight subgroups according to therapy rationale, produced some groups of very few participants. Nevertheless, as this was an explorative study, we chose to keep data divided into subgroups, although aware that this led to an unbalanced study design.

#### Mental Health and its Influence upon Motivation for Treatment

HADS is primarily a mental health screening instrument made for detecting possible/probable cases as well as assessing change in emotional state [12]. Thus, HADS is insufficient for diagnostic purposes. In our material, 40 percent were labelled 'possible cases' of mental disorder. Bearing in mind the general tendency of not seeking professional help for mental problems [17], the fact that 36 percent of the participants reported having at some time been diagnosed with mental disorder (Table 2) support the high HADS-scores.

When comparing symptom intensity of the two subgroups carrying highest scores to that of the other subgroups within their respective choice of treatment, most differences reached statistical significance (Table 3 and 4). Accompanied by the qualitative data, this suggests that motivation for treatment can be a way to identify qualitatively different subgroups of obese patients. An earlier study investigating psychological underpinnings of the choice of therapy found no differences in psychopathology between patients seeking bariatric surgery and patients seeking a non-surgical treatment [18]. Our study has shown that mental health does vary according to choice of treatment, but requires analysis on a subgroup level.

Physical disease is in general correlated to impaired mental health [19], with severe obesity specially associated with increased risk of depression [20, 21]. Based upon the degree of obesity as well as the number of comorbidities reported in this material, we expected high symptom scores. Participants reporting fear of dying during surgery (denominated *Fear of Anaesthesia*) scored considerably, yet statistically non-significantly, higher on symptom intensity than participants mainly afraid of complications from the procedure. Although the finding is statistically non-significant, we chose to include a comment as the qualitative data validated by the HADS clearly suggest two subgroups experiencing rather different types of worries about bariatric surgery: Feeling some concern about possible complications from surgery may be a sign of soundness. However, when the fear of dying in the operating room excludes surgery as a potential treatment, the magnitude of this worry may be of a pathological character. By turning down obesity treatment, the patient is at high risk of serious comorbidities and decreased longevity. While fear of surgery and anaesthesia in general has been known for a long time [22], our findings suggest that in the field of bariatric surgery, this fear actually make patients refuse treatment.

In general, when assessing subgroups according to decreasing symptom intensity, a shift in motivation occurs from mainly psychological aspects (anxiety, fear, reluctance) to more social issues (working situation, family, follow up-services). It also illustrates that if anxiety is present, this may influence choice of therapy. However, in such cases, what therapy actually is preferred is determined by what triggers the anxiety.

In a recent study by Adams et al. [23], cause-specific mortality related to accidents and suicide were 58% higher among gastric bypass patients than among matched obese controls. While some psychological distress is expected to follow from the severe physical and

psychosocial limitations of being obese, mental health and quality of life is found to improve with weight loss [24, 25]. Even though Adams' findings probably reflect a subset of patients with more grave mental problems, it is clear that there is more to treating obesity than reducing weight. Psychological screening may help identifying both patients of poor mental health as well as those who need more guidance before entering a treatment programme. Today, there are no uniform guidelines for optimal psychological screening. Consequently, this is implemented differently across clinics [26]. Based upon the finding from our study, the bariatric nurses at our clinic systematically ask new patients about their feelings on general anaesthesia as well as intimacy in group settings. Patients with such issues are referred to our psychologist.

#### Physical Health and its Influence upon Motivation for Treatment

In the qualitative material we also see the contours of a more superior trait, namely sign of motivation. The reported reasons appeared to be *either* positively or negatively oriented. By positive motivation we mean the wish to achieve something desirable based on the chosen treatment. This is self-evident and will not be exemplified. The opposite, denominated negative motivation, is primarily fuelled by the wish to avoid an undesirable treatment. The two subgroups that stood out with respect to poor mental health, i.e., participants with anxiety of the surgical procedure, and participants with a high level of social reluctance, are examples of carriers of negative motivation: They pick the lesser of two evils. Keeping in mind that all patients, independently of type of obesity treatment, sooner or later face challenges that threaten to reverse the modified behaviour, this particular subset of patients may be questioned as to their readiness to participate in treatment. Their motivation for treatment reveals a rather limited view on therapies that potentially provide life-long effects. Also, their

strikingly high symptom scores underline the need to examine their motivation more thoroughly as it may express a more profound and possibly undetected mental health problem.

As negatively motivated patients often based their argument on obstacles caused by comorbidities, we found statistical evidence supportive of such a dichotomisation into positively or negatively motivation when testing whether the number of diseases influenced motivation. The psychological mechanism behind this could be that patients suffering from different diseases experience a shift in focus away from possibilities and over to disease driven limitations. Whether *negatively motivated* patients have poorer prospects in terms of weight loss, is yet to be determined. It is likely, however, that individual motivation is a key mechanism for maintaining the necessary alterations in diet and activity.

#### Consequence for Trials Comparing Different Treatments

Participants' reasons for choice of treatment were characterised by unambiguous rationales. Few participants showed signs of doubt, indicating that most were convinced as to what type of therapy would be best in their case. Such absolute certainty has implications for research designs when evaluating effects of lifestyle therapy compared to bariatric surgery. Unless there is a sufficient pool of patients indifferent to type of treatment, making a patient preference trial design possible [27], two considerations point against randomisation in comparative studies.

Firstly, as both bariatric surgery and lifestyle modification programmes require great personal efforts, randomising patients against their preferred choice increases the risk of non-compliance. Then, there is also an important ethical consideration: In general, patients should not be randomised to treatment they do not want when this therapy involves considerably

higher risk of complications than other alternatives. In this case, gastric bypass clearly means a higher risk both for morbidity and mortality. This dilemma is recently also raised by Sjöström et al [5]. Thus, in cases where patients already have made up their mind about what treatment they want, both methodical and ethical considerations point toward selection based on preferred choice rather than randomisation.

# **DISCLOSURE**

No conflict of interest to declare.

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Table 1: Process of analysis – a sequential exploratory study to investigate severely obese patients' motivation for either bariatric surgery or lifestyle intervention.

Step	Analysis	Description	Methodical strengths/weaknesses
LYSIS	Thematic analysis Mapping all different reasons for choice of treatment.	The qualitative material consisted of participants' answers to an open ended question. The material was read repeatedly noting all aspects of motivation emerging from the data.	This trial combines qualitative and quantitative data from the same sample. The sample was bigger than normal for qualitative studies. As the field of interest was unexplored, this increases the chance of
ANA	Reduction Classification and condensation,	The reduction process involved disclosing the common themes in the reported aspects. While	achieving thematic saturation.
ATIVE A	leaving only one reason per participant	some participants reported only one reason, others reported several. Only one reason was kept per participant.	Reducing the complexity of motivation to only one reason per participant is oversimplifying human nature, yet it eases statistical inferences.
QUALITA	Quantitising Numerical representation	Themes emerging from the qualitative material were coded and entered into the statistical software.	As only one researcher analysed the qualitative data, inter-rater reliability tests and consensus making were not possible. Instead authors developed a protocol for theme selection.

VALIDATION	Comparison Does other data support the classifications of the qualitative material?	As some subgroups' motivation seemed to reflect symptoms of psychopathology, we calculated mean symptom scores for each subgroup using HADS. When ranging subgroups according to symptom intensity, a pattern emerged with higher scores for subgroups reporting psychological reasons for their choice, and lower scores for patients reporting mostly social reasons.	The quantitative material contained HADS. Bringing in a validated tool for psychometric measurement provided objective data as grounds for validations of the qualitative analysis.
ESIS	Generating hypothesis	The hypothesis <i>Symptoms of psychopathology influence upon choice of treatment</i> followed the validated qualitative analysis.	In this study there was no basis for making a questionnaire with predefined categories. The relatively large sample size and combination of qualitative and quantitative
HYPOTHESIS	Testing hypothesis	The null hypothesis No significant differences in psychopathology between the subgroups was rejected.	data, proved fruitful for completing an explorative study. The findings may give direction to an interview guide for in depth analysis of patients' reasoning as well as incorporating categories into a questionnaire allowing a better quantitative research design.

Table 2: Sample characteristics of participants (N=150).

	N	Mean (SD)	%
Age		41.2 (10.5)	
Gender			
Female	111		74
BMI		47.2 (5.8)	
Obesity onset			
In childhood	105		70
In adulthood	40		27
Diet attempts (last 5 y)			
None	6		4
1-5 diets	68		45
6-10 diets	47		31
11 diets or more	21		14
Wanted EWL <sup>a</sup>			
Less than 50%	5		3
50 – 100%	103		69
More than 100%	29		19
Family			
Living alone/single	56		37
One or more children	108		72
Level of education			
Primary school	30		20
College/vocational training	84		56
University-level 1-3 years	26		17
University-level $\geq$ 4 years	10		7
Comorbidity history <sup>b</sup>			
Asthma	54		36
Arthritis	29		19
Diabetes	41		27
Heart disease	12		8
Hypertension	61		41
Sleep apnoea	24		16
Gall disease	26		17
Mental disorder	54		36
HADS <sup>c</sup>			
Anxiety, possible cases <sup>d</sup>	72		48
Depression, possible cases <sup>e</sup>	62		41
Total symptom intensity <sup>f</sup>		14.9 (7.7)	

<sup>&</sup>lt;sup>a</sup> Excess weight loss; referring to a BMI of 25. Formula: [(weight-wished weight)/25(height)<sup>2</sup>]100

<sup>&</sup>lt;sup>b</sup> Self-reported: "Has a physician ever told you that you have any of these diseases?"

<sup>&</sup>lt;sup>c</sup> Hospital Anxiety and Depression Scale

<sup>&</sup>lt;sup>d</sup> HADS anxiety score  $\geq 8$ 

<sup>&</sup>lt;sup>e</sup> HADS depression score ≥ 8

<sup>&</sup>lt;sup>f</sup> HADS total symptom score, HADS-T

Table 3: Treatment rationales with corresponding levels of psychological distress among participants preferring gastric bypass (N=102), sorted by descending symptom scores.

Subgroup rationale with representative quotation	Caseness HADS-T <sup>a</sup> ≥ 17	Comparisons <sup>b</sup> HADS-T <sup>c</sup> , mean (SD)	p
RATIONALE 1 – Social Reluctance (n=4)			
"I've got difficulties coping in groups of people. I also	100%	23.8 (2.5)	
find it hard to deal without my wife and don't want to			
leave her."			
RATIONALE 2 – The Permanent Solution (n=65)			
"I loose weight easily. But I also gain it just that easy.	36%	14.7 (7.5)	0.041
I've tried every diet there is and consider surgery to be			
a better solution for me."			
"The gastric bypass creates a physical constriction			
which prevents over eating."			
RATIONALE 3 – Familial Considerations (n=28)			
"I'm a single parent for four small children. Some of	36%	14.2 (7.2)	0.037
them are ill. Their situation is too complex for leaving			
them into someone else's care."			
RATIONALE 4 – Work (n=5)			
"Autumn is high season for me at work. Participation	20%	10.0 (9.2)	0.015
in the lifestyle programme would cause a great			
economical loss that I cannot afford."			

<sup>&</sup>lt;sup>a</sup> HADS-A, Hospital Anxiety and Depression Scale, anxiety subscale

<sup>&</sup>lt;sup>b</sup> Pairwise comparisons of mean scores using the subgroup with social reluctance as control. Method: Dunnett's test following one-way ANOVA: F<sub>3,95</sub>=2.70, p=0.050

<sup>&</sup>lt;sup>c</sup> HADS-T, Hospital Anxiety and Depression Scale, total symptom score

Table 4: Treatment rationales with corresponding levels of psychological distress among participants preferring lifestyle treatment (N=36), sorted by descending symptom scores.

Subgroup rationale	Caseness HADS-T <sup>a</sup> ≥ 17	Comparisons <sup>b</sup> HADS-T <sup>c</sup> , mean (SD)	p
RATIONALE 1 – Fear of Anaeshesia (n=4)			
"I'm terrified of the surgery. I'm so obese that I'm	100%	23.0 (3.4)	
afraid of dying during the procedure."			
RATIONALE 2 – Fear of Complications (n=11)			
"I fear that other diseases I have make the surgical	46%	15.2 (7.2)	NS
procedure risky."			
RATIONALE 3 – Normality (n=14)			
"I don't have any weight related physical afflictions,	23%	13.1 (5.7)	0.014
so I think it's possible for me to loose weight without			
surgery. But I lack the right attitude."			
"I find surgery to be an excuse for doing nothing and			
should be the last resource if nothing else works."			
RATIONALE 4 – Follow Up (n=7)			
"Long term support is necessary to adapt a new	14%	12.8 (1.8)	0.030
lifestyle."			

<sup>&</sup>lt;sup>a</sup> HADS-T, Hospital Anxiety and Depression Scale, total score

<sup>&</sup>lt;sup>b</sup> Pairwise comparisons using the subgroup with procedure related anxiety as control. Method: Dunnett's test following one-way ANOVA:  $F_{3,28}=3.31$ , p=0.034

<sup>&</sup>lt;sup>c</sup> HADS-T, Hospital Anxiety and Depression Scale, total symptom score