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Faculty of health science

**Improved quality of life after conservative treatment of obesity
- A retrospective observational study**

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Foreword

After being introduced to the master thesis in medicine, I knew I wanted to write about obesity and health-related quality of life (HRQoL). In the process of finding and defining a project, I reached out to Dr. Maria Arlén Larsen. She proposed to investigate the changes in HRQoL post obesity-treatment, and how that related to changes in weight. During my work on the master thesis, I have been able to investigate this through clinical data from Skibotn Helse og Rehabilitering (SHR – Skibotn Health and Rehabilitation).

The primary supervisor for this master thesis is Dr. Maria Arlén Larsen and secondary Professor Jon R. Florholmen from the research group of Gastroenterology and nutrition, Institute of Clinical Medicine, UiT. Dr. Larsen supervised throughout the whole process of designing the study, collecting the data, data analysis and writing the thesis. I would like to give special thanks to Larsen for excellent support and feedback.

Hammerfest, 30.05.21

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Abstract

Introduction: Obesity is a global and national health challenge. In Norway 23.0% of adults are obese. The clinical treatment for obesity is weight loss, either surgical or conservative. However, there is limited research on health-related quality of life (HRQoL) and conservative treatment of obesity. The primary aim of this study is to investigate changes in HRQoL from baseline to post-treatment for obesity. Secondary aims are what factors of HRQoL weight change potentially affects, and if a significant weight loss improves HRQoL in individuals with obesity.

Material and method: 50 patients that had finished a three-year conservative treatment of obesity at *Skibotn Health and Rehabilitation* were included in this study. The participants were divided into a weight-loss group (WL group) and a weight-gain group (WG group). To measure HRQoL, 36-Item Short Form Health Survey (SF-36) was used. The SF-36 measures HRQoL across eight domains. Data at baseline and post-treatment was analyzed.

Results: Post-treatment the whole group had a 12.5% improvement in bodily pain, and the WG group had a 6.0% improvement in mental health, and a 12.5% improvement in social functioning. The WL group had no significant changes post-treatment, but had several at year two, including improved physical functioning, physical role functioning, vitality, and bodily pain. The WG group had a significantly reduced mental health at year two, with a median change of -4.0%, but a significantly increased mental health at the end of the treatment, with a median change of 6.0% from baseline.

Conclusion: There were some improvements in HRQoL from baseline to post-treatment. The aspects of HRQoL that changed post-treatment were bodily pain, emotional wellbeing, and social functioning. All participants had a 12.5% improvement in bodily pain, and the WG group had a 6.0% improvement in mental health and a 12.5% improvement in social functioning. One can therefore state that weight gain showed positive changes within the mental health aspect of HRQoL.

Abbreviations

QoL	Quality of life
HRQoL	Health-related quality of life
SF-36	36-Item Short Form Health Survey
PF	Physical functioning
BP	Bodily pain
GH	General health perception
RP	Physical role functioning
VT	Vitality
RE	Emotional role functioning
SF	Social functioning
MH	Mental health
SHR	Skibotn Health and Rehabilitation
WL group	Weight-loss group
WG group	Weight-gain group
BMI	Body mass index
T2DM	Type 2 diabetes mellitus
CVD	Cardiovascular disease
REK	Regional Committee for Medical Health and Research Ethics
SD	Standard deviation

1 Background

The prevalence and incidence of overweight and obesity are increasing globally (1, 2). Since 1975, the worldwide prevalence of obesity has almost increased threefold (3). In 2016, 39% of men, and 39% of women worldwide were overweight, and about 13% of the world's adult population were obese (3). Furthermore, in Norway, approximately 1 in 4 men and 1 in 5 women between the age of 40 and 45 years were obese in 2017 (4).

Obesity is classified by body mass index (BMI), defined as bodyweight in kilograms (kg) divided by the height squared (kg/m^2). Overweight is defined as a $\text{BMI} \geq 25$, and obesity is defined as a $\text{BMI} \geq 30$ (table 1) (5).

Table 1: Classification of adults according to BMI (5).

Classification	BMI	Risk of comorbidities
Underweight	< 18.50	Low
Normal range	18.50-24.99	Average
Overweight	≥ 25.00	
Preobese	25.00-29.99	Increased
Obese class I	30.00-34.99	Moderate
Obese class II	35.00-39.99	Severe
Obese class III	≥ 40.00	Very severe

The World Health Organization (WHO) classifies obesity as a chronic disease (6). Chronic diseases progress slowly, have a long duration, and they often need medical treatment (7). All in all, they impact patients' lives negatively. It is well known that obesity is associated with increased risk of type 2 diabetes (T2DM), cardiovascular disease (CVD), sleep apnoea, osteoarthritis of the knees and hips, some types of cancers, mental disorders and unhappiness (4). Furthermore, in a meta-analysis of 15 American and European studies, Luppino et al. (8)

found that there is a reciprocal link between obesity and depression. These factors and other possible health risks affect individuals on different levels, including quality of life (QoL) (9, 10). QoL can be thought upon as a standard of health, comfort, and happiness in one's life. It is a multidimensional construction of different factors that alone or altogether influence one's perception of wellbeing (11). Some of the different factors can be physical health, mental health, sexual life, and occupation. An increased number of chronic conditions, including obesity, has a strong negative effect on health-related quality of life (HRQoL) (12).

It is important to measure HRQoL to inform patient management and policy decisions (13). There are many questionnaires that can be used to measure HRQoL. The 36-Item Short Form Health Survey (SF-36) is a validated survey for measurement of HRQoL. This specific questionnaire has been proved to maintain a robust internal structure in obese outpatients (14). Available research states that SF-36 is a good measurement of HRQoL, as it has a good construct validity, high internal consistency, and high test-retest reliability (15-17).

Preventing and treating obesity is important both globally and nationally to decrease the risk and burden of the disease. It is shown that a weight loss of only 5-10% from baseline bodyweight gives a considerable improvement in physical health, measured by blood pressure, lipids in the blood, insulin resistance and sleep-disordered breathing (18, 19). Long term weight loss however, is difficult to achieve, and relapse is normal (20). This is among other factors due to complex processes in the central nervous system and appetite regulation that favors to maintain a high bodyweight when it is established (20). In Norway, specialized medical and/or surgical treatment for obesity is indicated in patients with a BMI \geq 40, or patients with a BMI \geq 35 with weight-related comorbidities, such as T2DM, sleep apnea, CVD or osteoarthritis (20).

The treatment for obesity is weight loss, and there are two main options: conservative or surgical. The conservative treatment is based up on three principals of lifestyle change: physical activity, nutrition and psychological coping (20). The best result in terms of weight loss is seen with an energy-reduced diet, as it is easier to reduce the energy intake compared

to increase the energy expenditure with physical activity (20). However, physical activity has many other health benefits than weight loss (20). Physical activity reduces weight-related risk of disease, even if the weight does not decrease (21, 22). An energy-reduced diet and physical activity are however better together than separately (23). Patients need to learn new strategies and coping mechanisms that go along with their new lifestyle, and they need to be better able to deal with loss of motivation and potential weight gain (20). In a cross-sectional study, Baumeister and Härter found that there is a strong relationship between obesity and mental disorders (24). The psychological coping and mental aspects are therefore also important in treatment.

There is a limited number of studies that compare HRQoL before and after conservative treatment of obesity (25). Some of the already existing literature suggests investigating the mediators of change in HRQoL, to understand if weight loss itself changes HRQoL, or if there are other causes (26-29). However, to my knowledge there are no Scandinavian studies in a clinical setting that measures HRQoL after conservative treatment of obesity in the tertiary healthcare setting. Further studies are needed to investigate the effect of HRQoL after conservative treatment in a clinical setting.

1.1 Aim of the study

The primary aim of this study is to investigate the treatment of obesity and HRQoL:

1. Is there a change in HRQoL from baseline to post-treatment conservative treatment of obesity?

As secondary aims, this study will investigate HRQoL and change in bodyweight per se:

1. What factors of HRQoL does change in bodyweight potentially affect?
2. Does a significant weight loss improve HRQoL in individuals with obesity?

2 Materials and method

Patients were recruited from *Skibotn Helse og Rehabilitering* (SHR – Skibotn Health and Rehabilitation) where the patients go through a 3-year conservative treatment programme. Inclusion criteria were: patients that had finished the full three-year treatment at SHR since the start (2015), as well as answered the questionnaire SF-36 at year 1, 2 and 3. Exclusion criteria were patients that did not finish the full three-year treatment, patients that had a break in the treatment, patient that did not answer the questionnaire SF-36 at all three years, and patients that had been severely ill during the treatment.

Ethics

All participants signed a written consent form at baseline. All parts of the study were included in the original clinical treatment, and the goal was to evaluate the quality of the treatment. The study was evaluated as a quality safety study by the regional ethics committee (REK Nord) with reference number 1702.

Statistics

For statistical calculations, SPSS Statistics 25 for Windows (SPSS Inc. IBM, Chicago, IL, USA) was used. Parametric tests were used on raw or transformed variables that resembled a normal distribution visually or by skewness/kurtosis. Otherwise, non-parametric tests were performed. The assumption of normality was not satisfied for all group combinations as assessed by Shapiro-Wilk's test. Furthermore, a Wilcoxon signed-rank test was done to determine whether there was a median difference between the paired observations for HRQoL from year one to year two, and from year one to year three. The data was then split in two; a weight-loss group (WL group), and a weight-gain group (WG group). The WL group included only significant weight loss at the end, defined as $\geq 5\%$ weight loss, as that amount of weight loss has been shown to considerably improve physical health (18, 19). Weight gain was defined as any increase in weight ($> 0\%$) at the end. A Wilcoxon signed-rank test was performed on both groups, as well as on the population as a whole, to determine if there was a median change in HRQoL during the three years.

SHR- conservative treatment of obesity in a tertiary setting

During the three-year treatment at SHR, the patients have in total six overnight-stays in SHR. The first stay is three weeks long, and the remaining five are two weeks long. While at the clinic the patients get educated about lifestyle changes, following the guidelines from the Norwegian Directorate of Health (20). The patients are followed up by an interdisciplinary team consisting of a doctor, physiotherapist, clinical dietitian, and nurses, including a psychiatric nurse. Each patient gets one personal contact that follows them up more closely, and the patients are encouraged to keep the contact with their assigned contact person while at home.

Measurement of HRQoL

The SF-36 is a self-reported survey that includes eight domains of HRQoL: physical functioning (PF), bodily pain (BP), general health perceptions (GH), physical role functioning (RP), vitality (VT), emotional role functioning (RE), social functioning (SF) and mental health (MH) (30). These eight domains can be divided in two groups: physical health, including PF, BP, GH and RP, and mental health, including VT, RE, SF and MH. There are 36 questions in the questionnaire, and the answers are rated on a Likert-type scale. They are further summed and transformed into a scale from 0-100, where a higher score indicates a better HRQoL (30). The patients fill out this survey at baseline and every year. The survey is part of the clinic's assessment of the patients and work toward improving the quality of the rehabilitation.

Other clinical measurements

Clinical measurements that were collected during the treatment were bodyweight, fat percentage, BMI, age, sex, occupation, health status, diagnoses, and mental health status. Bodyweight was measured on Tanita scale. All this data was used to assess the descriptive statistics of the group.

3 Results

Since the treatment started in 2015, a total of 50 participants finished the three-year treatment. Not all participants answered all the questions in SF-36 during the three years of treatment. There were 34 participants that answered the questionnaire at year two (16 participants excluded) and 29 participants that answered the questionnaire at year three (21 participants excluded). The descriptive statistics at baseline and at year three is based on all 50 participants that finished the three-year treatment. However, the outcome in HRQoL is based on the participants that answered all the questions in SF-36, at year two and year three respectively. Missing values, from the excluded patients, were not calculated, as it was beyond the scope of this master thesis. Post-treatment, participants were divided into two groups: WL group and WG group. The participants with 0-5% weight loss were not the focus of this study, but they were included in analysis of “all patients”, including both descriptive statistics and HRQoL.

The study population includes 64.0% women and 36.0% men. The age varies from 22-67 (mean 48) years of age at baseline. Descriptive statistics of the 50 participants can be seen in table 2 and table 3. Table 2 also shows BMI, bodyweight, fat percentage and numbers of comorbidities (table 2). Of the 50 participants, 38.0% (19 individuals) had a significant weight loss ($\geq 5.0\%$), 28.0% (14 individuals) lost 0-5% weight, and 34.0% (17 individuals) gained weight. There was not a statistically significant difference in mental illness, T2DM, CVD and other comorbidities between the WG group and the WL group (table 3). The two groups showed some differences in distribution of sex, hypertension, and occupation. The WL group had 36.8% men (7/19), while the WG group had 23.5% men (4/17). In the WL group 52.6% (10/19) had hypertension, whereas only 29.4% (5/17) had hypertension in the WG group. In the WL group 47.4% (9/19) had reduced work or were not working at all, and 35.3% (6/17) had reduced work or did not work at all in the WG group (table 3).

Table 2: Descriptive statistics I. Significant differences between WL- and WG group are shown with yellow highlight.

	All participants	WL group	WG group	Sig. difference
	mean, range, (SD)	mean, range, (SD)	mean, range, (SD)	p-value
Age (years)	48.0 , 22.0-67.0 (11.2)	48.3 , 27.0-65.0 (12.2)	41.6 , 22.0-58.0 (9.8)	0.08
BMI baseline (kg/h ²)	42.6 , 34.3-56.6 (5.1)	42.9 , 34.3-56.6 (5.9)	43.5 , 34.8-51.1 (4.9)	0.74
BMI year 2 (kg/h ²)	40.8 , 26.3-51.8 (5.4)	39.3 , 26.3-51.8 (5.7)	43.5 , 32.3-51.7 (5.3)	0.03
BMI post-treatment (kg/h ²)	41.2 , 27.3-52.2 (5.8)	38.3 , 27.3-47.8 (5.2)	45.9 , 35.9-52.2 (4.9)	0.00
Weight baseline (kg)	125.1 , 82.5-200.1 (23.6)	127.0 , 82.5-200.1 (27.7)	125.7 , 91.9-167.4 (19.9)	0.87
Weight year 2 (kg)	119.9 , 63.2-183.6 (23.6)	116.2 , 63.2-183.1 (25.2)	125.7 , 88.5-169.4 (21.0)	0.23
Weight post-treatment (kg)	120.4 , 65.6-175.1 (22.4)	112.9 , 65.6-156.6 (22.0)	130.6 , 96.5-168.1 (20.1)	0.02
Fat percentage baseline (%)	43.4 , 30.4-51.2 (5.1)	43.4 , 35.4-50.9 (4.5)	44.5 , 32.3-50.6 (4.6)	0.47
Fat percentage year 2 (%)	42.6 , 29.0-51.5 (6.0)	41.2 , 32.3-50.7 (5.5)	45.1 , 29.0-50.6 (5.2)	0.04
Fat percentage post-treatment (%)	42.8 , 30.3-52.7 (6.0)	40.7 , 32.4-49.6 (5.8)	46.7 , 36.9-51.7 (3.8)	0.00
Number of comorbidities (n)	1.8 , 0.0-3.0 (0.9)	1.7 , 0.0-3.0 (0.8)	1.5 , 0.0-3.0 (0.9)	0.59

Table 3: Descriptive statistics II

	All participants	WL group	WG group
Men	36.0% (18/50)	36.8% (7/19)	23.5% (4/17)
Mental illness	32.0% (16/50)	31.6% (6/19)	35.3% (6/17)
T2DM	34.0% (17/50)	31.6% (6/19)	35.3% (6/17)
Hypertension	46.0% (23/50)	52.6% (10/19)	29.4% (5/17)
CVD	16.0% (8/50)	10.5% (2/19)	11.8% (2/17)
Other comorbidities	80.0% (40/50)	73.7% (14/19)	76.5% (13/17)
Reduced work/not working	48.0% (24/50)	47.4% (9/19)	35.3% (6/17)

As demonstrated in Figures 1 and 2, majority of weight loss happened from baseline to year two, and most of weight gain happened from year two to the end of treatment at year three (figures 1-2).

Figure 1: Changes in BMI throughout the treatment. The yellow diamonds indicate a statistically significant change from baseline within the respective groups.

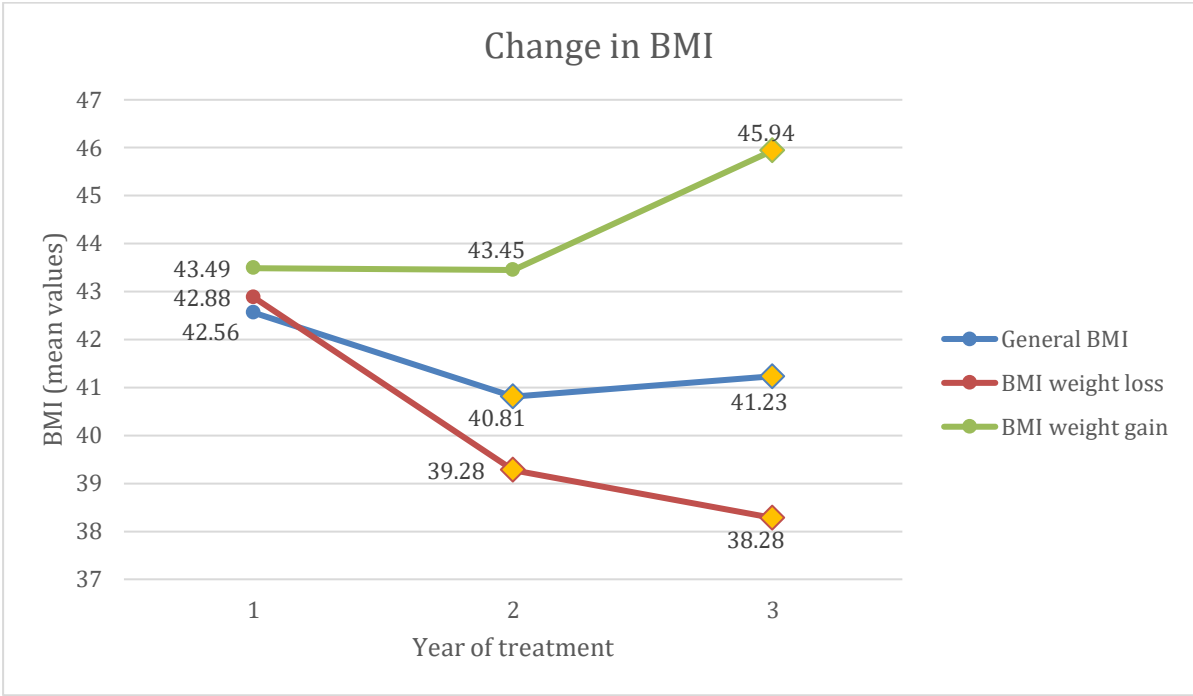
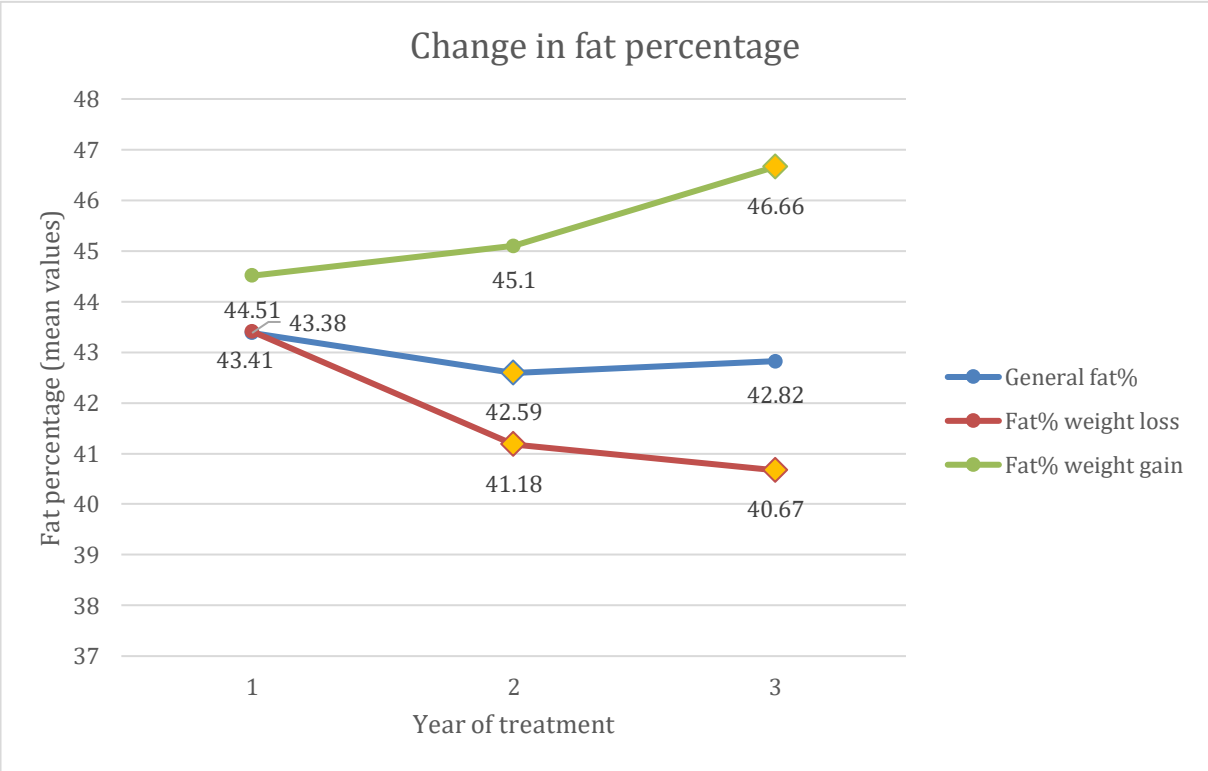


Figure 2: Changes in fat percentage throughout the treatment. The yellow diamonds indicate a statistically significant change from baseline within the respective groups.



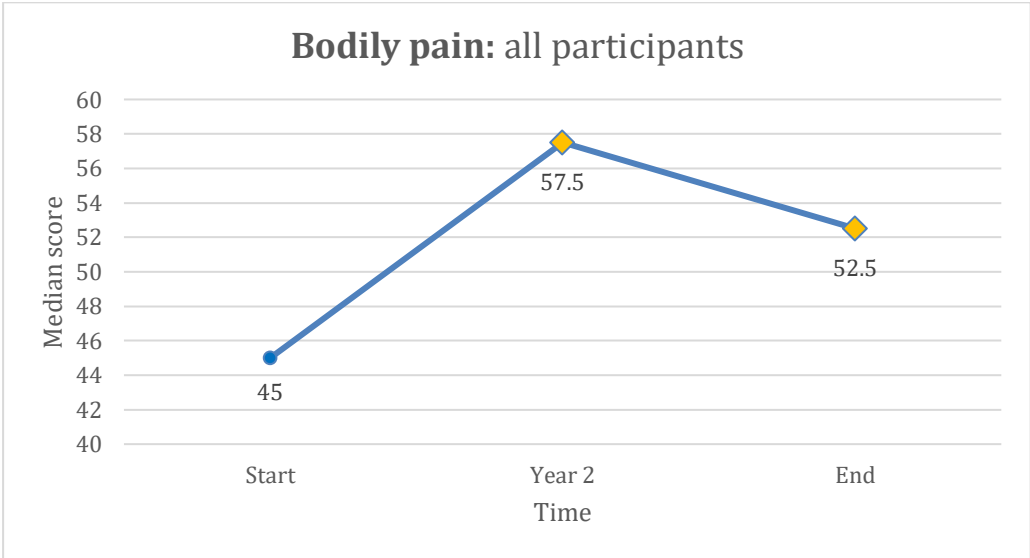
3.1 Significant findings in HRQoL: general population

3.1.1 Bodily pain

A total of 34 participants finished the treatment and answered the questionnaire at baseline and at year two. Of the 34 participants, 58.8% (20/34) had less BP at year two compared to baseline, 26.5% (9 /34) had more BP at year two compared to baseline, and 14.7% (5/34) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in BP (10.0%) from baseline (45.0) to year two (57.5), $z=-2.091$, $p=0.037$. This demonstrates a statistically significant 10.0% improvement in bodily pain perception from baseline to year two (figure 3).

There was a total of 29 participants that answered the questionnaire at the beginning and at the end. Of the 29 participants, 51.7% (15/29) had less BP at the end compared to the beginning, 27.6% (8/29) had more BP at the end compared to the beginning, and 20.7% (6/29) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in BP (12.5%) from the beginning (46.25) to the end (52.5), $z=-1.984$, $p=0.047$. Thus, indicating a statistically significant 12.5% improvement in bodily pain perception from baseline to post-treatment (figure 3).

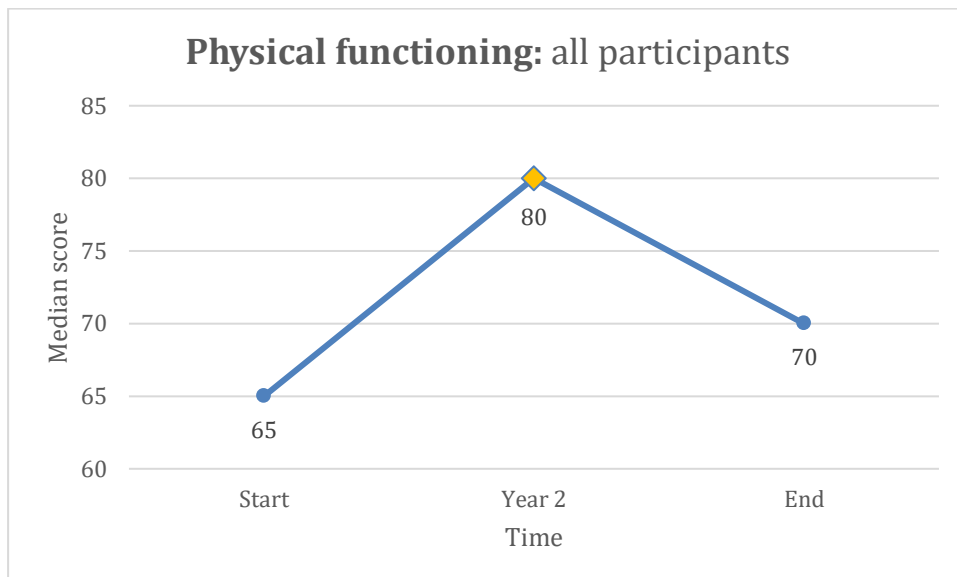
Figure 3: Changes in “bodily pain” for all participants. The yellow diamond indicates a statistically significant change from baseline. Note: a higher score indicates less bodily pain.



3.1.2 Physical functioning

A total of 34 participants finished the treatment and answered the questionnaire at baseline and at year two. Of the 34 participants, 58.8% (20/34) had an increased PF at year two compared to baseline, 29.4% (10/34) had a decreased PF at year two compared to the beginning, and 8.8% (4/34) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in PF (5.0%) from baseline (65.0) to year two (80.0), $z=-2.349$, $p=0.019$. Thus, indicating a statistically significant 5.0% increase in physical functioning from baseline to year two (figure 4).

Figure 4: Changes in “physical functioning” for all participants. The yellow diamond indicates a statistically significant change from baseline.

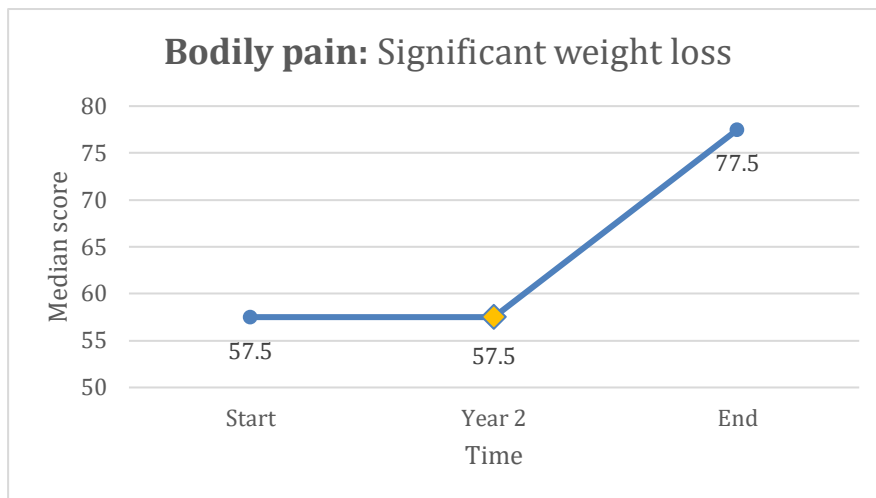


3.2 Significant findings in HRQoL: weight-loss group

3.2.1 Bodily pain

A total of 10 participants with significant weight loss at year three answered the questionnaire at the baseline and at year two. Of the 10 participants, 70.0% (7/10) had less BP at year two compared to the beginning, 10.0% (1/10) had more BP at year two compared to the beginning, and 20.0% (2/10) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in BP (27.5%) from the beginning (57.5) to year two (57.5), $z=-2.252$, $p=0.024$. Meaning there was a statistically significant 27.5% improvement in bodily pain perception from baseline to year two (figure 5).

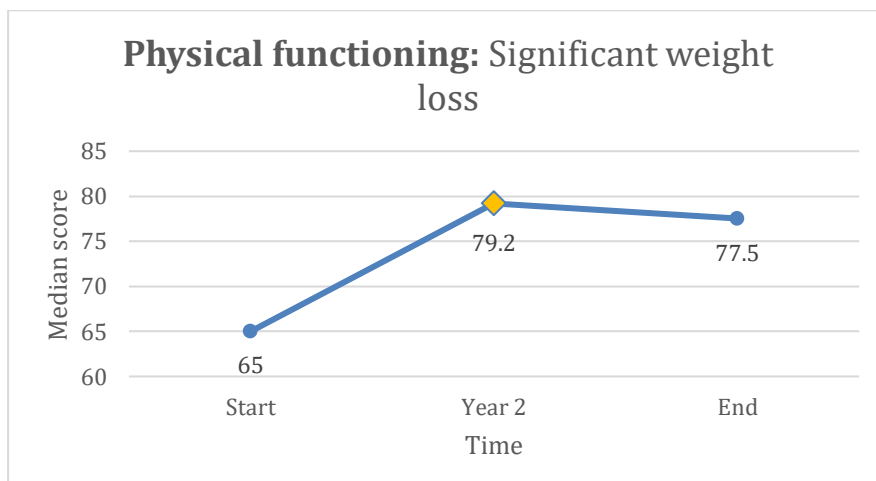
Figure 5: Changes in “bodily pain” for WL group. The yellow diamond indicates a statistically significant change from baseline. Note: a higher score indicates less bodily pain.



3.2.2 Physical functioning

A total of 10 participants with significant weight loss at the end answered the questionnaire at baseline and at year two. Of the 10 participants, 70.0% (7/10) had an increased PF at year two compared to the beginning, 10.0% (1/10) had a decreased PF at year two compared to the beginning, and 20.0% (2/10) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in PF (5.0%) from the beginning (65.0) to year two (79.2), $z=-2.200$, $p=0.028$. Thus, indicating a statistically significant 5.0% increase in physical functioning from baseline to year two (figure 6).

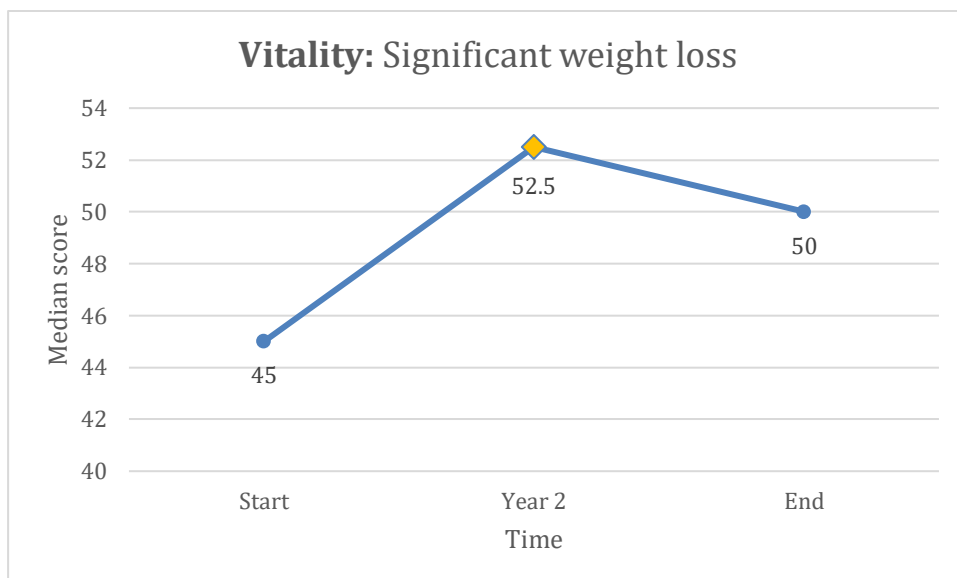
Figure 6: Changes in “physical functioning” for WL group. The yellow diamond indicates a statistically significant change from baseline.



3.2.3 Vitality (energy/fatigue)

A total of 10 participants with significant weight loss post-treatment answered the questionnaire at baseline and at year two. Of the 10 participants, 80.0% (8/10) had an increased VT at year two compared to the beginning, 10.0% (1/10) had a decreased VT at year two compared to the beginning, and 10.0% (1/10) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in VT (17.5%) from the beginning (45.0) to year two (52.5), $z=-2.257$, $p=0.024$. Meaning there was a statistically significant 17.5% increase in vitality from the beginning to year two (figure 7).

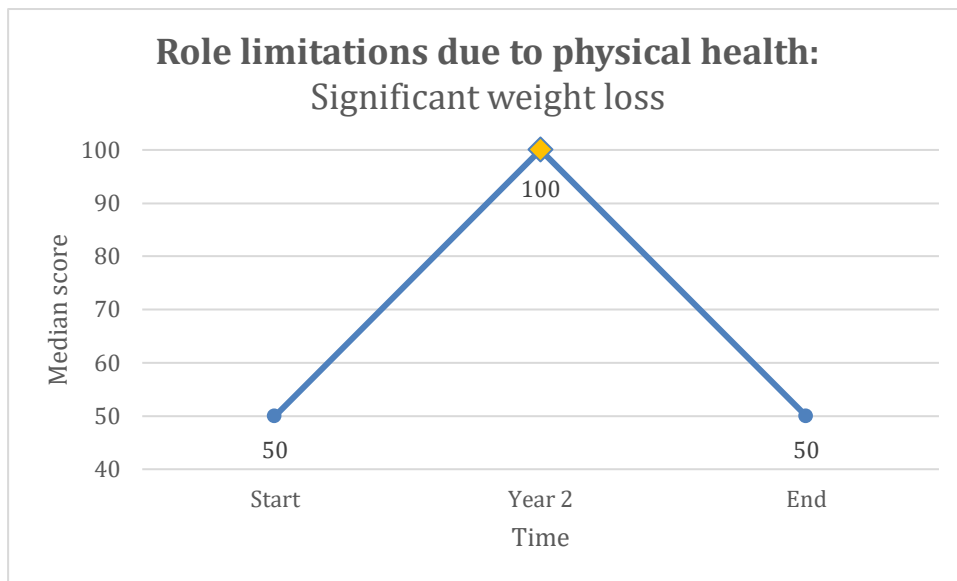
Figure 7: Changes in “vitality” WL group. The yellow diamond indicates a statistically significant change from baseline.



3.2.4 Role limitations due to physical health

A total of 10 participants with significant weight loss at the end answered the questionnaire at baseline and at year two. Of the 10 participants, 50.0% (5/10) had an increased RP at year two compared to the beginning, and 50.0% (5/10) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in RP (12.5%) from the beginning (50.0) to year two (100.0), $z=-2.041$, $p=0.041$. Thus, indicating a statistically significant 12.5% improvement in role limitations due to physical health from baseline to year two (figure 8). As seen in figure 8, at year three, there was no statistically significant change.

Figure 8: Changes in «role limitations due to physical health” WL group. The yellow diamond indicates a statistically significant change from baseline.



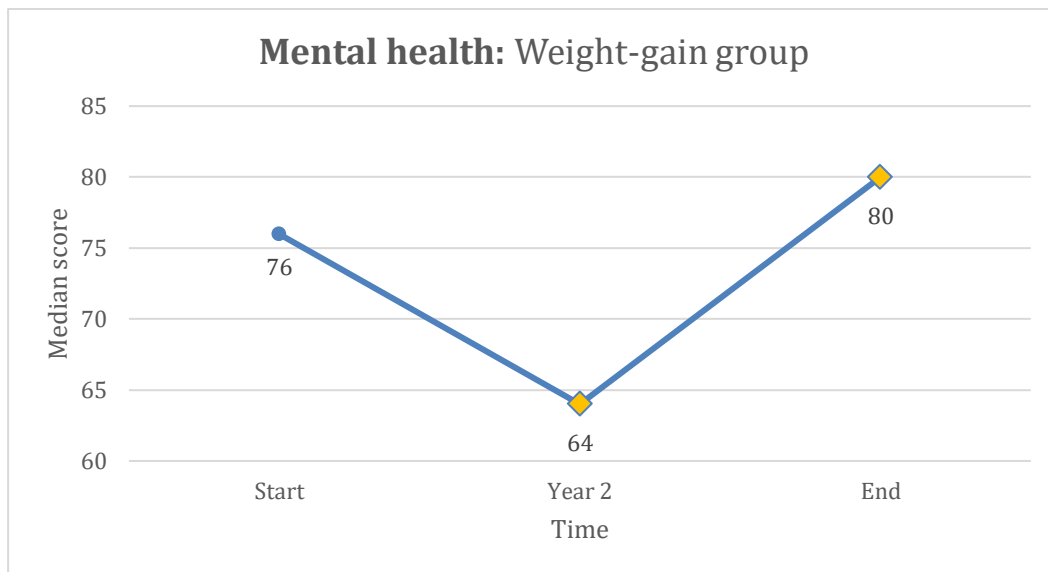
3.3 Significant findings in HRQoL: weight-gain group

3.3.1 Mental health (emotional wellbeing)

A total of 15 participants with weight gain at the end answered the questionnaire baseline and at year two. Of the 15 participants, 13.3% (2/15) had an increased MH at year two compared to baseline, 73.3% (11/15) had a decreased MH at year two compared to baseline, and 13.3% (2/15) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in MH (-4.0%) from baseline (76.0) to year two (64.0), $z=-2.285$, $p=0.022$. Meaning there was a statistically significant 4.0% decrease in mental health (emotional wellbeing) from baseline to year two (figure 9).

A total of 14 participants with weight gain answered the questionnaire at baseline and post-treatment. Of the 14 participants, 78.6% (11/14) had an increased MH at the end compared to the beginning, 14.3% (2/14) had a decrease in MH at the end compared to the beginning, and 7.1% (1/14) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in MH (6.0%) from baseline (76.0) to post-treatment (80.0), $z=-2.150$, $p=0.032$. Thus, indicating a statistically significant 6.0% improvement in mental health (emotional wellbeing) from baseline to post-treatment (figure 9).

Figure 9: Changes in «mental health» in the WG group. The yellow diamonds indicate statistically significant changes from baseline.

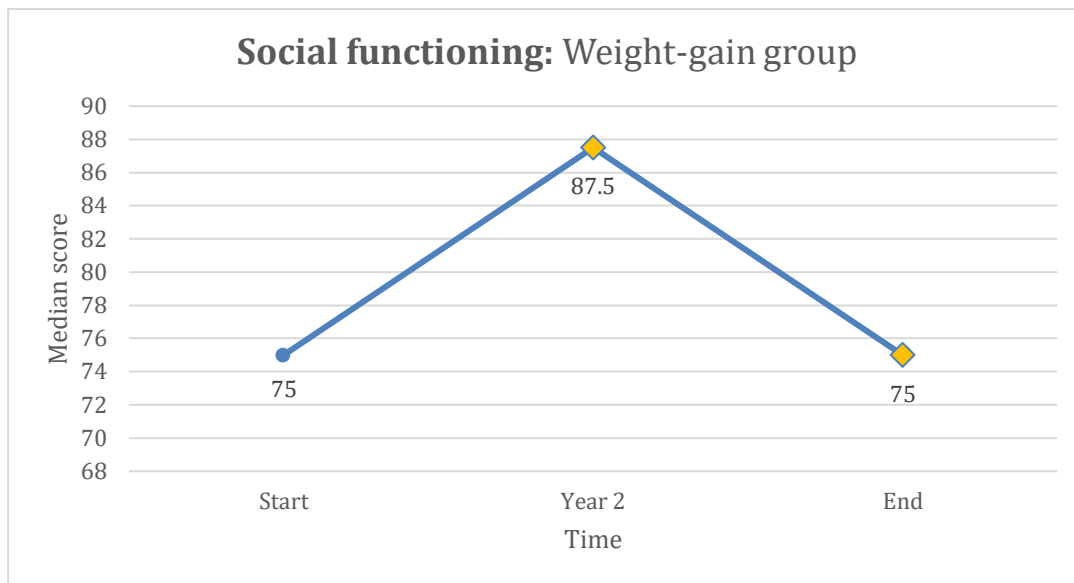


3.3.2 Social functioning

A total of 15 participants with weight gain post-treatment answered the questionnaire at baseline and at year two. Of the 15 participants, 53.3% (8/15) had an increased SF at year two compared to baseline, 13.3% (2/15) had a decreased SF at year two compared to the beginning, and 33.3% (5/15) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in SF (12.5%) from the beginning (75.0) to year two (87.5), $z=-2.235$, $p=0.025$. Meaning there was a statistically significant 12.5% improvement in social functioning from the beginning to year two (figure 10).

A total of 14 participants with weight gain post-treatment answered the questionnaire at baseline and at year three. Of the 14 participants, 57.1% (8/14) had an increased SF at the end compared to the beginning, 21.4% (3/14) had a decreased SF at the end compared to the beginning, and 21.4% (3/14) had no change. A Wilcoxon signed-rank test determined that there was a statistically significant median change in SF (12.5%) from baseline (75.0) to post-treatment (75.0), $z=-2.160$, $p=0.031$. Meaning there was a statistically significant 12.5% improvement in social functioning from the beginning to year three (figure 10).

Figure 10: Changes in «social functioning» in the WG group. The yellow diamonds indicate a statistically significant change from baseline.



3.4 Non-significant findings in HRQoL

There were no statistically significant median changes in RP, RE, VT, MH, SF and GH for all participants from year one to year two. From year one to year three, there were no statistically significant median changes in PF, RP, RE, VT, MH, SF and GH for all participants (table 4).

There were no statistically significant median changes in RE, MH, SF and GH for the WL group from year one to year two. From year one to year three there was no statistically significant median change in any of the eight different domains for the WL group (table 5).

There were no statistically significant median changes in PF, RP, RE, VT, BP, and GH for the WG group from year one to year two. From year one to year three there were no statistically significant median changes in PF, RP, RE, VT, BP, and GH for the WG group (table 6).

Table 4: Non-significant findings in «all participants». Near-significant values are marked with yellow highlights.

Changes from baseline to year two					
	Median value (baseline)	Median value (year 2)	Median change	Z-value	P-value
Role limitations due to physical health (RP)	50.0	50.0	0.0	-1.615	0.106
Role limitations due to emotional problems (RE)	83.3	100.0	0.0	-0.132	0.895
Energy/fatigue (VT)	42.5	50.0	5.0	-1.379	0.168
Emotional wellbeing/mental health (MH)	76.0	70.0	-4.0	-0.957	0.339
Social functioning (SF)	75.0	75.0	0.0	-1.392	0.164
General health (GH)	55.0	55.0	1.25	-0.850	0.395
Changes from baseline to post-treatment					
	Median value (baseline)	Median value (year 3)	Median change	Z-value	P-value
Physical functioning (PF)	67.5	70.0	5.0	-0.905	0.365
Role limitations due to physical health (RP)	25.0	50.0	0.0	-0.723	0.470
Role limitations due to emotional problems (RE)	66.7	83.3	0.0	-0.364	0.716
Energy/fatigue (VT)	40.0	47.5	0.0	-0.352	0.725
Emotional wellbeing/mental health (MH)	72.0	78.0	4.0	-1.278	0.201
Social functioning (SF)	75.0	75.0	0.0	-1.652	0.099
General health (GH)	55.0	58.1	-5.0	-0.138	0.890

Table 5: Non-significant findings in WL group. Near-significant values are marked with yellow highlights.

Changes from baseline to year two					
	Median value (baseline)	Median value (year 2)	Median change	Z-value	P-value
Role limitations due to emotional problems (RE)	50.0	100.0	8.3	-0.768	0.443
Emotional wellbeing/mental health (MH)	76.0	74.0	8.0	-1.177	0.239
Social functioning (SF)	87.5	75.0	6.25	-1.200	0.230
General health (GH)	55.0	70.0	12.5	-1.602	0.109
Changes from baseline to post-treatment					
	Median value (baseline)	Median value (year 3)	Median change	Z-value	P-value
Physical functioning (PF)	65.0	77.5	5.0	-1.357	0.175
Role limitations due to physical health (RP)	50.0	50.0	0.0	-0.552	0.581
Role limitations due to emotional problems (RE)	50.0	66.7	8.3	-0.841	0.400
Energy/fatigue (VT)	45.0	50.0	-5.0	-0.841	0.400
Emotional wellbeing/mental health (MH)	76.0	76.0	0.0	-0.271	0.786
Social functioning (SF)	87.5	87.5	0.0	-0.730	0.465
Bodily pain (BP)	57.5	77.5	27.5	-1.542	0.123
General health (GH)	55.0	60.0	-5.0	-0.298	0.765

Table 6: Non-significant findings in WG group. Near-significant values are marked with yellow highlights.

Changes from baseline to year two					
	Median value (baseline)	Median value (year 2)	Median change	Z-value	P-value
Physical functioning (PF)	75.0	80.0	5.0	-1.387	0.165
Role limitations due to physical health (RP)	75.0	62.5	0.0	-0.660	0.509
Role limitations due to emotional problems (RE)	83.3	66.7	0.0	-0.106	0.915
Energy/fatigue (VT)	40.0	37.5	0.0	-0.140	0.888
Bodily pain (BP)	46.3	51.3	2.5	-0.590	0.555
General health (GH)	62.5	52.5	0.0	-0.424	0.671
Changes from baseline to post-treatment					
	Median value (baseline)	Median value (year 3)	Median change	Z-value	P-value
Physical functioning (PF)	75.0	60.0	2.5	-0.447	0.655
Role limitations due to physical health (RP)	75.0	62.5	0.0	-0.262	0.794
Role limitations due to emotional problems (RE)	100.0	100.0	0.0	-0.850	0.395
Energy/fatigue (VT)	40.0	52.5	0.0	-0.806	0.420
Bodily pain (BP)	57.5	51.3	12.5	-1.298	0.194
General health (GH)	55.0	50.0	-2.5	-0.458	0.647

In the WL group there was a trend for improvement in BP (a median change of +27.5), but it was not significant ($p=0.12$). Furthermore, there was a trend for improvement in RE (a median change of +8.3), but it was not significant ($p=0.40$). In the WG group, there was a trend for improvement in BP (a median change of +12.5), but it was not significant ($p=0.19$).

3.5 Summary of results

After the three-year treatment at SHR the whole group (all participants) had a 12.5% improvement in bodily pain, and the WG group had a 6.0% improvement in mental health (emotional wellbeing), and a 12.5% improvement in social functioning. The WL group had no significant changes post-treatment, but had several at year two, including improved physical functioning, physical role functioning, vitality, and bodily pain. The WG group had a significantly reduced mental health at year two, with a median change of -4.0%, but a significantly increased mental health post-treatment, with a median change of 6.0% from baseline.

4 Discussion

In this retrospective observational study, investigating HRQoL and obesity, the main results were that all participants had less bodily pain post-treatment, and that the WG group had an improved mental health and social functioning post-treatment. At the end of the three-year treatment the group as a whole had less bodily pain. Some studies suggest that change in bodily pain is associated with changes in weight and BMI (31, 32). In the present study, the WL group did not show a significant reduction in bodily pain post-treatment, and neither the WG group showed a significant increase in bodily pain post-treatment, contrary to results of other studies (31, 32). The reason for this might be the sample sizes of the subgroups giving less power to the statistical analysis. On the other hand, through an evidence-based obesity-reduction program, Lemstra and Rogers found that all domains of SF-36 improved from baseline to post-treatment, including bodily pain (33). The study did not include weight or weight-change statistics, but overall, the participants had an absolute decrease (improvement) in pain of 6.2%. These results might explain that it is the treatment itself, rather than the weight change, that improves the perception of pain.

The WL group had no significant changes in HRQoL at the end. This result contrasts with other studies showing an increase in HRQoL with weight loss (34-36). There were however several significant changes in HRQoL at year two, including both physical health aspects of HRQoL (PF, RP and BP) and mental health aspect of HRQoL (VT).

The WG group had an increased MH and SF at the end of the three-year treatment compared to baseline. MH and SF are both part of the mental health aspect of HRQoL, and one can therefore state that the WG group had a positive change in mental health. These results are conflicting with results of similar studies that have found reduced HRQoL with weight gain (32, 34). Some studies show that the majority of change in HRQoL is within physical health, and that there is no significant change or minimal change within mental health (28, 37, 38). Müller-Nordhorn et al. found that the mental HRQoL seemed to increase with increasing BMI over time (39). Similarly, Karlsson et al found that obesity-related psychosocial problems were improved at 10 year follow-up after conventional treatment for obesity, even though the group had gained weight (34).

Many of the studies about weight change and HRQoL do not focus on a “weight-loss lifestyle modification” (40) approach, and rather focus on a calorie reduced diet, exercise, surgery or pharmaceutical treatment, either combined or alone. This leaves out the very important cognitive and psychological part of obesity treatment. In the obese population, anxiety and depression are two psychological disorders that occur frequently (41-44). In contrast, some studies have found that bodyweight does not affect the mental health aspect of HRQoL. De Zwaan et al. found no difference in mental health scores of SF-36 with degree of obesity (45). In addition, Sahle et al. found that an increasing degree of BMI gain is related more strongly to decline in physical rather than mental health domains (31). This might explain why the WG group in the present study had an increase in the mental health domain of HRQoL.

A study by De Zwaan et al. found that the mental health aspect of HRQoL increased with increased age (45). However, this cannot explain the outcome in this study, as there was no statistically significant difference in age between the WL- and WG group (table 2).

Observations in the clinical setting indicate that patients struggling to make lifestyle changes and to lose weight often have mental health problems (46, 47). These mental problems have not been processed and worked through properly, and therefore that becomes the main focus in the treatment of obesity when the patients are in the health care system. One theory of why

the WG group had a positive change in mental health at the end of the treatment is that they worked more on the mental and emotional part of lifestyle change than the WL group did. However, there is no evidence to verify this statement. More research on conservative treatment is needed.

This study was subject to limitations. Firstly, the study had a skewed composition of the sexes, with more women than men. This is common in obesity trials (28, 48) and may be due to the fact that women tend to seek help more often than men (49). The study population includes only people from Northern-Norway and therefore generalizability to global population is uncertain. Secondly, the small sample size leads to less power in the statistical analysis, especially when dividing the population into subgroups. Furthermore, the participants who did not finish the three-year treatment were excluded, in addition to the participants that did not answer some of the questions in SF-36. Calculating missing values to include all participants was beyond the scope of this master thesis. Therefore, there is no data or analysis on drop-out. Moreover, the study design, retrospective observational study, does not allow us to claim causations.

That being said, this study has several strengths as well. Firstly, the study is done in a clinical setting rather than a research setting, as it includes real patients that are in the specialist health care system in Norway. Secondly, it shows results from this specific treatment at SHR and can therefore be used to further improve the treatment. Third, the treatment and follow-up of the participants were three years in total, which is a long duration compared to many other studies. Furthermore, this study is done on a Scandinavian population, which to my knowing has not been done before.

5 Conclusion

In conclusion, there were some positive changes in HRQoL from baseline to post-treatment in patients with obesity. The study population had 12.5% less bodily pain post-treatment compared to baseline, and the WG group had a 6.0% improvement in mental health (emotional wellbeing) and a 12.5% improvement in social functioning. The WL group had no

significant changes in HRQoL from baseline to post-treatment. According to this study significant weight loss does not improve HRQoL in individuals with obesity. These results are in some ways conflicting with other similar studies, and more research is needed to further investigate changes in HRQoL after conservative treatment of obesity, and how that relates to changes in weight. The goal of obesity-treatment should be improved HRQoL, in addition to weight loss. It is a common misconception that weight loss leads to increased HRQoL. That is not always the case. Hopefully this master thesis can start a discussion and further research about what the best treatment is to reach improved HRQoL in individuals with obesity. More studies with more participants and a different study design are needed to further investigate this.

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Appendix

Grade 1

Source: Lemstra ME, Rogers MR. Improving health-related quality of life through an evidence-based obesity reduction program: the Healthy Weights Initiative. *J Multidiscip Healthc.* 2016;9:103-9.

STUDY DESIGN: Cross-sectional study

Grade - quality



Aim of the study	Material and Method	Results	Discussion/comments/checklist																																																						
<p>Determine the impact of a multidisciplinary, community-based obesity reduction program on HRQL and to determine the independent risk factors for lack of improvement from baseline to follow-up.</p>	<p>Population: Obese (BMI >30) adults who were referred by a medical doctor were eligible to participate.</p> <p>Main outcome: HRQL using SF-36</p> <p>Important confounders: sex, age, marital status, employment status, comorbidities, depressed mood, smoking status, program-buddy, self-esteem</p>	<p>Main results 84.5% had improved HRQL as determined by an increase in overall SF-36 score. Improvement was seen in all eight domains:</p> <table border="1" data-bbox="579 555 1201 728"> <caption>Table 1 Healthy Weights Initiative – SF-36 dimensions (N=209)</caption> <thead> <tr> <th></th> <th>Baseline, mean (SD)</th> <th>Follow-up, mean (SD)</th> <th>Absolute change</th> <th>Relative change (%)</th> <th>P-value</th> </tr> </thead> <tbody> <tr> <td>Physical functioning</td> <td>65.9 (22.0)</td> <td>78.0 (17.4)</td> <td>+12.1</td> <td>15.5</td> <td>0.000</td> </tr> <tr> <td>Less role limitations due to physical health</td> <td>61.8 (35.6)</td> <td>74.4 (33.3)</td> <td>+12.6</td> <td>16.9</td> <td>0.000</td> </tr> <tr> <td>Pain</td> <td>63.8 (22.5)</td> <td>70.0 (21.1)</td> <td>+6.2</td> <td>8.9</td> <td>0.000</td> </tr> <tr> <td>General health</td> <td>51.2 (21.3)</td> <td>64.1 (19.6)</td> <td>+12.9</td> <td>20.1</td> <td>0.000</td> </tr> <tr> <td>Vitality</td> <td>43.3 (17.7)</td> <td>61.3 (18.1)</td> <td>+18.0</td> <td>29.4</td> <td>0.000</td> </tr> <tr> <td>Social functioning</td> <td>71.1 (24.1)</td> <td>79.5 (18.2)</td> <td>+8.4</td> <td>10.6</td> <td>0.000</td> </tr> <tr> <td>Less role limitations due to emotional health</td> <td>68.7 (34.9)</td> <td>76.5 (30.4)</td> <td>+7.8</td> <td>10.2</td> <td>0.000</td> </tr> <tr> <td>Emotional well-being</td> <td>64.3 (18.6)</td> <td>73.7 (13.2)</td> <td>+7.6</td> <td>12.8</td> <td>0.000</td> </tr> </tbody> </table> <p><small>Notes: Higher scores indicate improvements on that dimension. SF-36 is the Medical Outcomes Study 36-Item Short-Form Health Survey. Abbreviation: SD, standard deviation.</small></p>		Baseline, mean (SD)	Follow-up, mean (SD)	Absolute change	Relative change (%)	P-value	Physical functioning	65.9 (22.0)	78.0 (17.4)	+12.1	15.5	0.000	Less role limitations due to physical health	61.8 (35.6)	74.4 (33.3)	+12.6	16.9	0.000	Pain	63.8 (22.5)	70.0 (21.1)	+6.2	8.9	0.000	General health	51.2 (21.3)	64.1 (19.6)	+12.9	20.1	0.000	Vitality	43.3 (17.7)	61.3 (18.1)	+18.0	29.4	0.000	Social functioning	71.1 (24.1)	79.5 (18.2)	+8.4	10.6	0.000	Less role limitations due to emotional health	68.7 (34.9)	76.5 (30.4)	+7.8	10.2	0.000	Emotional well-being	64.3 (18.6)	73.7 (13.2)	+7.6	12.8	0.000	<p>Checklist:</p> <ul style="list-style-type: none"> Is the aim well formulated? Yes Are the participants from a specific population? (selection bias) Yes Were measurements done in the same manner, and in a validated way? (Classification bias) ** Yes Was the study prospective? Yes Were enough participants followed up? (Attrition bias/follow-up-bias) Yes Are dropout-analysis done? (Eval. attrition bias) No Was the duration long enough to get positive/negative outcomes? Yes Are confounders taken into consideration in design/implementation/analysis? Yes Do you believe in the results? Yes <ul style="list-style-type: none"> -Bradford Hills criteria (time sequence, dose-response gradient, biological plausibility, consistency....) Are the results generalizable? No, but maybe to the white, obese population outside of Canada. Are there other studies supporting/opposing the results? Yes How are the results important for changes in the clinic? Social support should be implemented in obesity-reduction programs
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<p>Conclusion Obesity reduction programs that target increasing exercise, improving diet, and cognitive behavioral therapy can positively impact HRQL in obese adults. Social support has a strong role to play in improving outcomes.</p>	<p>Statistical methods Using SPSS 22.0, mean scores of each SF-36 dimension were compared before and after the program using paired samples <i>t</i>-tests (<i>P</i>,0.05).</p> <p>Mean changes in weight and body composition were compared between those who had improved in overall HRQL versus those who did not, using one-way analysis of variance.</p>	<p>There were no statistically significant differences in overall SF-36 score improvement and sex, age, marital status, employment status, program attendance (>80% versus <80% attendance), presence of comorbidities, or depressed mood at baseline. Overall improvement in HRQL was associated with smoking status at baseline (only 70% of smokers had improved scores, while 86.9% of nonsmokers had improved scores). Improvement in HRQL was also associated with whether a buddy attended the program; 86.3% of those who had a buddy in the program had improved HRQL versus 70.8% of those who did not have a buddy (<i>P</i>=0.048).</p>	<p>What do the authors discuss as:</p> <p>Strengths Not discussed</p> <p>Limitations The long-term (1-year) results of the study are not yet available. It is possible that adherence to weight loss practices promoted in the program may change over time, and therefore, the physical and mental health outcomes associated with the program may also change.</p>																																																						
<p>Country</p>	<p>Cross-tabulations were then performed to determine significant associations between those who improved in HRQL and those who did not, across demographic variables, presence of comorbidities, program adherence, self-esteem, smoking status, depressed mood, and social support.</p>	<p>After logistic regression, smoking status increased the risk of no improvement on overall SF-36 after the program (odds ratio 3.75; 95% CI 1.44–9.78; <i>P</i>=0.007). Additionally, not having a buddy in the program increased the risk of no improvement on overall SF-36 by 270% (95% CI 1.28–10.68; <i>P</i>=0.015).</p>																																																							
<p>Year(s) of data collection</p>	<p>Canada</p>	<p>Secondary results Although those who improved in HRQL lost more weight and body fat in comparison to those who did not improve, these differences were not statistically significant</p>																																																							
<p>January 2014 to March 2015</p>	<p>Significant differences were determined using chi-square test (<i>P</i>,0.05). The unadjusted effect of each covariate was determined and then entered one step at a time based on changes in the –2 log likelihood and the Wald test. The final results were presented as adjusted odds ratios with 95% confidence intervals (CIs).</p>																																																								

Grade 2

<p>Source: Sahle BW, Slewa-Younan S, Melaku YA, Ling L, Renzaho AMN. A bi-directional association between weight change and health-related quality of life: evidence from the 11-year follow-up of 9916 community-dwelling adults. <i>Qual Life Res.</i> 2020;29(6):1697-706.</p>			<p>STUDY DESIGN: Cross-sectional study</p>					
			Grade - quality	⊕⊕				
Aim of the study	Material and Method	Results	Discussion/comments/checklist					
<p>To examine the prospective association between body mass index (BMI) and health-related quality of life (HRQoL).</p>	<p>Population: A total of 9916 men and women >age 18 from all regions in Australia.</p> <p>Main outcome: BMI (height and weight self-reported) and HRQoL (SF-36)</p> <p>Important confounding factors Chronic disease (CVD, COPD, DM2), physical activity, dietary intake, smoking, alcohol consumption, age, sex, dieting, SEIFA</p> <p>Statistical methods We used linear mixed-effects regression models to investigate the associations between change in BMI (kg/m²) and concurrent changes in HRQoL scores over the 11 years. We repeated the analyses stratifying according to the baseline BMI category (normal weight, obese) because of presumed differences in the association between changes in BMI and HRQoL according to baseline BMI levels. We used the same approach to examine if HRQoL predicted BMI, and if this association varies according to baseline BMI.</p>	<p>Main results BMI gain was associated with deterioration of HRQoL and vice versa. The bi-directional association was stronger for the relationship between BMI and physical domains than mental domains of HRQoL.</p> <p>BMI change associated to PCS varied according to baseline BMI category. Every unit increase in PCS was associated with a decrease of 0.02 ($P < 0.001$), 0.03 ($P < 0.001$) and 0.04 ($P < 0.001$) kg/m² among adults with normal weight, overweight or obesity at baseline, respectively</p> <p>Over the 11-year period, every increase in BMI of 1 kg/m² was associated with a decline of 0.22 ($P < 0.001$), 0.32 ($P < 0.001$) and 0.34 ($P < 0.001$) in PCS units in people with normal weight, over-weight and obesity at baseline, respectively.</p>	<p>Checklist:</p> <ul style="list-style-type: none"> • Is the aim well formulated? Yes • Are the participants recruited from a specific population? (selection bias) No • Were measurements done in the same manner, and in a validated way? (Classification bias) ** Yes • Was the study prospective? Yes • Were enough people followed up? (Attrition bias/follow-up-bias) Yes • Is a dropout-analysis done? (Eval. attrition bias) No • Was the duration long enough to get a positive/negative outcome? Yes • Are important confounders taken into consideration in design/implementation/analysis? Yes • Do you believe in the results? Yes -Bradford Hills criteria (time sequence, dose-response gradient, biological plausibility, consistency....) • Are the results generalizable? Yes • Is there other literature supporting/opposing the results? Yes • How are the results important for changes in the clinic? We need to optimise the impact of existing obesity and overweight prevention initiatives. <p>What do the authors discuss as:</p> <p>Strengths:</p> <ul style="list-style-type: none"> - a large nationally (Australia) representative sample size. - Repeated assessments of both BMI and HRQoL over a long-term follow-up. - Taken confounders into consideration. - Assessment of simultaneous changes in BMI and HRQoL, not just the cross-sectional changes during the study period. <p>Limitations: BMI based on self-reported height and weight. There could be other confounders.</p>					
Conclusion								
Weight gain was not only associated with deterioration of HRQoL, and vice versa. The bi-directional association was stronger for physical than mental domains of HRQoL.								
Country								
Australia								
Year(s) of data collecting								
2006-2016								

Grade 3

Source: Karlsson, J., Taft, C., Rydén, A. <i>et al.</i> Ten-year trends in health-related quality of life after surgical and conventional treatment for severe obesity: the SOS intervention study. <i>Int J Obes</i> 31 , 1248–1261 (2007). https://doi.org/10.1038/sj.ijo.0803573			STUDY DESIGN: Cross-sectional study
			Grade - quality ⊕⊕
Aim of the study	Material and Method	Results	Discussion/comments/checklist
<p>To examine trends and effects of weight loss treatment on health-related quality of life (HRQL) in the severely obese over 10 years.</p> <p>Conclusion</p> <p>Long-lasting weight reduction in the severely obese has a general long-standing positive outcome on HRQL. Bariatric surgery is a favorable option for the treatment of severe obesity, resulting in long-term weight loss and HRQL improvements in a majority of patients. However, difficulties among some surgical patients to control and maintain weight loss over time should not be ignored.</p> <p>Country</p> <p>Sweden</p> <p>Year(s) of data collection</p> <p>1987-1994</p>	<p>Population: 1703 participants in total, where 1276 completed the 10 years. 655 participants in surgical group and 621 participants in conventional group. Swedish, age between 37-60, BMI $\geq 34\text{kg/m}^2$ for males and BMI $\geq 38\text{kg/m}^2$ for females. Mean age was 47.0 y in surgical treatment group, and 48,4 y in conventional treatment group.</p> <p>Cohorts: surgical treatment and conventional treatment</p> <p>Main outcome: HRQL and weight change.</p> <p>Important confounders</p> <p>Age</p> <p>Statistical methods: Significance testing of differences in HRQL between two groups was performed using Fisher's nonparametric permutation test. For comparison of three or more groups, the nonparametric Kruskal–Wallis' ANOVA was used and Tukey's range test was utilized for post hoc testing of differences between mean values. Correlations between variables were tested using Pitman's nonparametric permutation test and Pearson's correlation coefficients were calculated for descriptive purposes. The limit for significance was set at the 5% level. Analysis of longitudinal treatment effects in surgical vs conventional cases was performed using Fisher's nonparametric test. Mantel's pooling technique applied to Fisher's test was used to adjust for baseline differences in the longitudinal analysis.</p> <p>The magnitude of group differences was further analyzed by means of effect sizes (ES). ES of a between-group difference was estimated by calculating the mean difference, divided by the pooled standard deviation. ES of within-group change was calculated as mean change between assessments, divided by the standard deviation of change. ES were judged against standard criteria proposed by Cohen.</p>	<p>Main results</p> <p>Changes in HRQL after surgical treatment followed phases of weight loss, weight regain and weight stability. Maximum weight loss (25%) at 1 year, thereafter a weight regain until year 6. After year 6 the weight regain slowed down, and at year 10 the mean weight loss was 16%.</p> <p>In the conventional group, an average maximum weight loss of 1.2% after 6 months was regained after 2 years and an increase in body weight of 1.5% was noted after 10 years. Changes in HRQL was trivial in most domains, except for small long-term improvements in anxiety and obesity-related psychosocial problems.</p>	<p>Checklist:</p> <ul style="list-style-type: none"> • Is the aim well formulated? Yes • Are the participants recruited from a specific population? (selection bias) Yes • Were measurements done in the same manner, and in a validated way? (Classification bias) ** Yes • Was the study prospective? No • Were enough people followed up? (Attrition bias/follow-up-bias) Yes • Is a dropout-analysis done? (Eval. attrition bias) Yes • Was the duration long enough to get positive/negative outcomes? Yes • Are confounders taken into consideration in design/implementation/analysis? No • Do you believe in the results? Yes <ul style="list-style-type: none"> -Bradford Hills criteria (time sequence, dose-response gradient, biological plausibility, consistency....) • Are the results generalizable? No • Is there other literature supporting/opposing the results? Yes <p>What do the authors discuss as:</p> <p>Strengths</p> <ul style="list-style-type: none"> - Not discussed <p>Limitations</p> <ul style="list-style-type: none"> - Age of population between 47-70 at 10 year follow up – results might be different in younger population. - Conventional treatment not standardized and without extra resources, across 480 different health-care centers. This might explain why the conventional group lost very little weight.

Grade 4

Source: Müller-Nordhorn J, Muckelbauer R, Englert H, Grittner U, Berger H, et al. (2014) Longitudinal Association between Body Mass Index and Health-Related Quality of Life. PLoS ONE 9(3): e93071. doi:10.1371/journal.pone.0093071			STUDY DESIGN: Cross-sectional study
		Grade - quality	⊕⊕
Aim of the study	Material and Method	Results	Discussion/comments/checklist
<p>Assess the association of HRQoL and body mass index (BMI) as an indicator for obesity.</p>	<p>Population: 6682 participants with hypercholesterolemia and an indication for statin therapy. Underweight (BMI <18.5 kg/m²) were excluded.</p>	<p>Main results Of the 7640 participants who completed the baseline questionnaire, 6726 participants (mean age: 61 years) were analyzed. The baseline BMI was inversely associated with physical and mental SF-12 summary scores (b [95% CI] per 1 kg/ m²: 20.36 [20.41; 20.30] and 20.05 [20.11; 20.00], respectively). A significant association between the change in BMI and physical SF-12 summary scores over time was only present in women (20.18 [20.27; 20.09]) and only in obese participants (20.19 [20.29; 20.10]). A change in BMI was directly associated with mental SF-12 summary scores (0.12 [0.06; 0.19]) in the total population.</p>	<p>Checklist:</p> <ul style="list-style-type: none"> Is the aim well formulated? Yes Were the participants recruited from a specific population? (selection bias) Yes Were measurements done in the same manner, and in a validated way? (Classification bias) ** Yes, although they were self-reported Was the study prospective? No Was enough people followed up? (Attrition bias/follow-up-bias) Yes Is dropout-analysis done? (Eval. attrition bias) No Was the duration long enough to get positive/negative outcomes? Yes Are confounders taken into consideration in design/implementation/analysis? Yes Do you believe in the results? Yes <ul style="list-style-type: none"> -Bradford Hills criteria (time sequence, dose-response gradient, biological plausibility, consistency....) Are the results generalizable? No Is there other literature supporting/opposing the results? Yes <p>What do the authors discuss as:</p> <p>Strengths</p> <ul style="list-style-type: none"> - Application of the mixed-effects model which used all available data of the baseline and the six follow-up points by multilevel modeling. Selection bias reduced <p>Limitations</p> <ul style="list-style-type: none"> - BMI and HRQoL were self-reported which may introduce measurement bias. - Study population not representative for the general population - Linear modeling of the associations between BMI and HRQoL
<p>Conclusion</p> <p>Increases in BMI were associated with decreases in physical HRQoL, particularly in obese individuals and in women. In contrast, the mental HRQoL seemed to increase with increasing BMI over time.</p>	<p>Main outcome: HRQoL using SF-12</p> <p>Important confounders age, sex, smoking status, education level, living situation, employment status, comorbidities, time</p> <p>Statistical methods A linear and a linear mixed-effects regression model was used to investigate the association between BMI and SF-12 summary scores at baseline as well as between change in BMI and SF-12 summary scores over 3 years. We adjusted for age, sex, smoking status, and in the longitudinal analysis also for the study arm and its interaction term with time.</p> <ul style="list-style-type: none"> - Spearman correlation coefficient to determine the correlation between the self-reported and physician-reported BMI. - Regression analysis - Descriptive statistics - Linear mixed-effects regression model. 		
<p>Country</p> <p>Germany</p>			
<p>Year(s) of data collecting</p> <p>2002-2004</p>			

Grade 5

Source: de Zwaan M, Petersen I, Kaerber M, Burgmer R, Nolting B, Legenbauer T, et al. Obesity and Quality of Life: A Controlled Study of Normal-Weight and Obese Individuals. *Psychosomatics*. 2009;50(5):474-82.

STUDY DESIGN: Cross-sectional study

Grade - quality



Aim of the study

Material and Method

Results

Discussion/comments/checklist

The authors investigated the associations between health-related quality of life (HRQL) and Body Mass Index (BMI), gender, age, mental and somatic disorders, as well as therapy-seeking status.

Population: 251 obese individuals participating in a conventional weight-loss program; 153 bariatric-surgery patients; and random, population-based, normal-weight (N=174) and obese (N=129) control samples. For this analyses, we collapsed the four subsamples and regrouped them according to BMI ranges.

Main outcome:
- HRQL using SF-36

Important confounders
Age, gender, marital status, employment status, years of education, somatic comorbidities, mental comorbidities, therapy status

Statistical methods: In order to compare group differences between the four weight categories, chi-square tests and analyses of variance (ANOVAs) with Tukey's post-hoc tests were conducted as appropriate. To assess the correlations between the PCS, the MCS, age, BMI, and the number of mental and somatic disorders, we conducted Pearson's product-moment correlation calculations. Student *t*-tests were conducted to compare MCS and PCS scores between participants with and without individual mental disorders (substance abuse, mood disorders, anxiety disorders, eating disorders, somatoform disorders). Finally, we carried out multiple linear-regression analyses for the two outcome variables, namely the SF-36 PCS and SF-36 MCS.

Main results

Higher BMI, higher age, and higher numbers of current somatic and mental disorders negatively predicted the physical dimension of HRQL.

Higher numbers of both mental and somatic disorders as well as female gender and younger age seemed to be independent negative predictors of mental HRQL, whereas BMI was not associated with mental HRQL. Therapy status was not related to mental or physical HRQL.

TABLE 5. Regression Models for the SF-36 PCS and the SF-36 MCS

Response	Explanatory Variables	r ^a	Contribution When Variable(s) Added Last		Parameter Estimates			
			Explanatory Property of Variance, %	df	β ^b	95% Confidence Interval	t	p
SF-36 PCS	Body Mass Index	-0.56***	30.9	1	-0.47	-0.53 to -0.40	-13.94	<0.001
	Somatic Disorders	-0.54***	13.7	1	-2.19	-2.63 to -1.75	-9.72	<0.001
	Age	-0.21***	1.7	1	-0.17	-0.24 to -0.10	-4.68	<0.001
	Mental Disorders	-0.16***	0.3	1	-0.90	-1.78 to -0.01	-1.99	<0.05
	Constant					73.24	69.42 to 77.01	
	Model		R ² =0.466	4, 628			F=136.885	<0.001
Variables not in the equation								
	Therapy Status	-0.39***			0.05		1.19	0.23
SF-36:	Mental Disorders	-0.32***	10.5	1	-2.66	-4.66 to -2.62	-7.02	<0.001
MCS	Age	0.17***	1.8	1	1.89	0.11 to 0.27	4.78	<0.001
	Somatic Disorders	-0.15***	2.7	1	-1.74	-1.53 to -0.59	-4.41	<0.001
	Gender	0.13***	0.6	1	0.07	0.08 to 3.71	2.05	<0.05
	Constant					40.85	37.01 to 44.69	
	Model		R ² =0.155	4, 628			F=28.799	<0.001

^a Bivariate correlation (Pearson); ^b Unstandardized β.
* p<0.05; ** p<0.01; *** p<0.001.

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- Checklist:**
- Is the aim well formulated? **Yes**
 - Are the participants recruited from a specific population? (selection bias) **Yes**
 - Were measurements done in the same manner, and in a validated way? (Classification bias) **** Yes**
 - Was the study prospective? **No**
 - Were enough people followed up? (Attrition bias/follow-up-bias) **Yes**
 - Was the duration long enough to get positive/negative outcomes? **Yes**
 - Were confounders taken into consideration in design/implementation/analysis? **Yes**
 - Do you believe in the results? **Yes**
 - Bradford Hills criteria (time sequence, dose-response gradient, biological plausibility, consistency....)
 - Are the results generalizable? **No, but maybe to the general obese population**
 - Is there other literature supporting/opposing the results? **Yes**
 - How are the results important for changes in the clinic? **It is indicated to consider the somatic and mental health diagnostic status in obesity treatment, especially in individuals with a higher level of obesity.**

What do the authors discuss as:
Strengths
The inclusion of a large sample, the direct weight measurements, and the assessment of mental disorders through face-to-face interviews.

Limitations
- Cross-sectional design means no conclusions regarding causal relationships between obesity, mental or somatic disorders, and impaired HRQL can be drawn.
- Assessment of somatic disorders was done by self-rating
- The regression model for mental HRQL explained only a small percentage of the variance.

