The Relationship between Health-Related Quality of Life and Weight Loss

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Abstract

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Objective: This is a report of health-related quality of life (HRQOL) changes in obese patients completing at least 1 year of outpatient treatment in a weight reduction program combining phentermine-fenfluramine and dietary counseling.

Research Methods and Procedures: Participants were 141 women (87.6%) and 20 men (12.4%) who had an average body mass index at intake of 41.1 kg/m^2 (SD = 7.0, range = 29.5 to 67.0 kg/m^2) and an average age of 44.9 years (SD = 9.3, range = 23 to 65 years). HRQOL was assessed at intake and at 1-year follow-up using the Impact of Weight on Quality of Life (IWQOL)-Lite questionnaire. The relationship between HRQOL changes and weight loss was examined using Pearson correlations. Clinically meaningful change in HRQOL was defined as a 1.96 SEM reduction in IWQOL-Lite total score.

Results: On average, participants lost 20.2 kg or 17.6% of their weight over the 1-year period. Of the participants, 15.5% lost <10% of their weight, 24.2% lost 10% to 14.9%, 23.6% lost 15% to 19.9%, and 36.6% lost 20% or more. All five IWQOL-Lite scales and total score showed statistically significant improvement over the 1-year period. Changes in IWQOL-Lite scores from intake to 1 year showed statistically significant correlations with percentage of weight loss for all subscales and total score. Subscale correlations with weight loss ranged from 0.166 (Public Distress) to 0.396 (Physical Function) and was 0.370 for the total score. Forty-four percent of participants losing <10% met the criterion of clinically meaningful change, compared with 51.3% losing 10% to 14.9%, 55.3% losing 15% to 19.95%, and 76.3% losing >20%. For total score and for three of the five IWQOL-Lite scales (Physical Function, Self-Esteem, and Sexual Life), the relationship between weight loss and clinically meaningful change was linear and was significant at $p < 0.05$. Physical Function and Self-Esteem were most strongly affected by weight loss.

Discussion: HRQOL changes, as measured by an obesity-specific instrument (IWQOL-Lite), are strongly related to weight reduction.

Key words: quality of life, health-related quality of life, Impact of Weight on Quality of Life-Lite questionnaire, weight loss, clinically meaningful change

Introduction

It has been shown consistently that obesity may impact important aspects of health-related quality of life (HRQOL), such as physical health, emotional well-being, and psychosocial functioning (1–4). Recently, researchers have become interested in using standardized assessment instruments to directly assess the effects of obesity on health-related quality of life. Using a well-known generic measure of HRQOL, the Short Form of the Medical Outcomes Study (SF-36) (5), researchers have shown that HRQOL varies directly with the severity of obesity among individuals seeking weight loss treatment; the most obese individuals have the poorest quality of life (6). Furthermore, it has been found that obese persons reporting pain show the greatest impairments in HRQOL (7) and that obese persons seeking treatment are significantly more physically impaired than those who are not trying to lose weight (8). In addition, increasing overweight has been associated with poor physical, but not emotional, well-being (9,10).

The relationship between weight loss and HRQOL has been investigated recently in several treatment outcome studies using the SF-36. HRQOL has been shown to improve after weight reduction treatment (11,12) and after cardiac rehabilitation for obese cardiac patients (13).

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Weight loss has also been associated with improved physical, rather than mental, HRQOL as measured by the SF-36 in a prospective study of weight change and HRQOL in women (10). In an analysis of data from four randomized trials of sibutramine vs. placebo, weight loss was associated with improvements in HRQOL as measured by the SF-36, as well as with improvements on an obesity-specific quality of life instrument (14).

Whereas generic instruments such as the SF-36 provide useful information on broad aspects of quality of life, they are not designed to assess the specific range of health-related problems experienced by individuals with a specific disease. Disease-specific instruments are designed to focus on the domains, characteristics, and complaints most relevant to a particular disease. Disease-specific instruments are usually more sensitive to changes in quality of life that result from treatment (15). To our knowledge, only two studies to date have investigated HRQOL changes after weight loss using a disease-specific instrument. In one study (16), a group of obese persons who had lost 5% or more of their weight was compared with a group who had gained weight and also with a weight-stable group. Subjects in the weight loss group reported improved functioning on the obesity-specific measure, those in the weight gain group reported decreased functioning, and those in the weight-stable group reported inconsistent results. In another study that used an obesity-specific HRQOL instrument, the Impact of Weight on Quality of Life (IWQOL) questionnaire, weight loss was associated with improvements on several of the domains being assessed (14).

Researchers have sought to determine what constitutes a clinically meaningful change in their disease-specific HRQOL measures (e.g., 17,18). However, a definitive definition of clinically meaningful change has not yet been established. A number of different procedures have been described for defining and evaluating clinically relevant change in quality of life research. Anchor-based methods measure change in quality of life in relationship to some clinically relevant external standard and are especially suited for assessing perception of change from the individual patient's perspective (19,20). A recent example of an anchor-based method is provided by Osoba et al. (17), who compared changes in quality of life scores with global ratings of improvement in cancer patients. Another example of an anchor-based approach is the study reported by Ward et al. (21), who used receiver-operating characteristic curves to identify the amount of change in patient global assessment that best differentiated improvement from no change. In contrast, distribution-based approaches are based on the statistical characteristics of the obtained sample. Distribution-based methods are particularly well-suited for defining clinically meaningful change from the clinical perspective (i.e., the degree of change necessary to warrant changes in therapeutic intervention), where information about the distribution of patient populations is known. Examples of distribution-based approaches include the use of effect size (22,23) and SEM (24). Distribution-based methods for defining clinically meaningful change may not correspond to anchor-based methods and are not a substitute for anchor-based methods of defining clinically meaningful change. Another method of determining clinically meaningful differences is the population-based method that relates changes on a quality of life measure to known population norms (25). However, it is rare that such population-based information is available. Therefore, population-based methods have limited applicability.

One advantage of the SEM is that it is, at least theoretically, a fixed characteristic of the measure, regardless of the sample being studied (26). Whereas the SD and the reliability of a measure (which are used to calculate SEM) are sample-dependent, their relationship (and, hence, the SEM) remains constant across samples. However, in practical application, the SEM for a given measure is likely to vary considerably across samples depending on the method used to estimate reliability and the presence of extreme scores.

The goals of the present study were 2-fold: to assess obesity-specific quality of life changes using the IWQOL-Lite (27) over a 1-year period in patients who participated in a weight-reduction program combining phentermine-fenfluramine and dietary counseling and to quantify the relationship between amount of weight loss and amount of change in obesity-specific quality of life.

Research Methods and Procedures

Participants

Participants were 199 persons over the age of 18 years (170 women and 29 men) undergoing treatment for obesity in a primary care setting or a subspecialty endocrinology clinic. Individuals were eligible for participation in this study if their weight was ≥130% of ideal weight and if they met stringent medical and psychological exclusion criteria as defined below. Data in this report are based on 161 participants (141 women and 20 men) who completed a minimum of 12 months in the program and provided IWQOL-Lite data at both baseline and 1-year follow-up. The 38 participants that were dropped from the analyses included 22 subjects who failed to complete 12 months of the program, 6 who did not provide baseline IWQOL-Lite data, 5 who did not provide 12-month IWQOL-Lite data, and 5 who failed to report for a 12-month visit but who did complete subsequent visits. These 38 participants did not differ significantly from the 161 participants included in this report in terms of gender (76.3% women vs. 87.6% men, Fishers exact $p = 0.121$), age (45.6 ± 9.9 vs. 44.9 ± 9.3 years, $t = -0.42$, $df = 197$, $p = 0.675$), baseline body mass index (BMI; 40.0 ± 8.5 vs. 41.1 ± 7.0 kg/m^2, $t = 0.82$, $df = 196$, $p = 0.411$), or baseline IWQOL-Lite total score (58.5 ± 18.7 vs. 63.1 ± 19.5, $t = 1.19$, $df = 189$, $p = 0.236$).

Baseline BMI averaged 41.1 kg/m^2 for the sample of 161 persons (SD = 7.0; range = 29.5 to 67.0 kg/m^2). The mean baseline BMI for men was 44.4 kg/m^2 (SD = 9.0) compared with 40.6 kg/m^2 (SD = 6.6) for women ($t = 2.28$, $df = 159$, $p = 0.024$). The average age of participants was 44.9 years (SD = 9.3; range = 23 to 65 years).

Pretreatment evaluation for inclusion in this study consisted of the following: a thorough medical history and physical examination conducted by a study internist, a psychological assessment and structured psychological diagnostic interview conducted by a study psychologist, a nutritional assessment with a registered dietitian, and an extensive laboratory examination. The following exclusion criteria were used: pregnancy; uncontrolled hypertension (≥140/90); any lifetime history of pulmonary hypertension, glaucoma, or symptomatic cardiovascular disease; or any lifetime history of serious psychiatric illness (schizophrenia, schizoaffective disorder, bipolar disorder, panic disorder, dementia/organic brain syndrome, chemical dependency/abuse, anorexia nervosa, bulimia nervosa if purging was engaged in for more than a brief period of experimentation, or suicide attempts/serious self-injurious behavior). Individuals with current major depressive disorder were excluded from the study, but those with a past history of major depressive disorder were not excluded.

Assessment Instruments

Participants completed a set of self-administered psychological instruments including the IWQOL (28,29). The IWQOL was administered in the original 74-item version but was scored using the newer, more psychometrically sound 31-item version (IWQOL-Lite). (27) The IWQOL-Lite assesses the impact of weight on quality of life in five areas: Physical Function (11 items), Self-Esteem (7 items), Sexual Life (4 items), Public Distress (5 items), and Work (4 items). The IWQOL-Lite has been translated into 14 languages and seems to be a clinically sensitive and valid instrument with strong psychometric properties (27).

Treatment Program

Treatment consisted of regular meetings with a registered dietitian, individualized diets, exercise recommendations, and medication. Medication was *d,l*-fenfluramine HCl (20 mg orally three times a day up to a maximum of 120 mg/d) combined with phentermine HCl (30 mg orally daily).

Statistical Analysis

Comparisons between women and men on baseline IWQOL-Lite scores were performed controlling for baseline BMI using analysis of covariance. Changes in IWQOL-Lite scores from baseline to 1-year were analyzed using a paired *t* test. Correlations between changes in IWQOL-Lite scores and percentage of weight loss were analyzed using Pearson correlation. Reliability at baseline was calculated using Cronbach's α coefficient.

We defined clinically relevant improvement for each IWQOL-Lite score as a reduction of at least 1.96 SEM, reflecting a two-tailed 95% confidence interval. SEMs were then calculated for IWQOL-Lite scales and total score by multiplying the SD at baseline by the square root of one minus the reliability coefficient at baseline (30). Clinically significant improvement in IWQOL-Lite scores (i.e., improvement of at least 1.96 SEM) was then assessed across weight loss groups using the Mantel–Haenszel test for linear association (31).

Results

Weight Changes

On average, participants lost 20.2 kg or 17.6% of their weight during the 1-year period (range = −1.6% to 43.0%). A total of 25 participants (15.5%) lost <10% of their weight, 39 (24.2%) lost 10% to 14.9%, 38 (23.6%) lost 15% to 19.9%, and 59 (36.6%) lost 20% or more.

Obesity-Specific Quality of Life Changes

Table 1 presents IWQOL-Lite scores at baseline and 1 year separately by gender. After controlling for baseline differences in BMI using analysis of covariance, women scored significantly higher ($F = 8.18$, $df = 1158$, $p = 0.005$) at baseline on Self-Esteem (i.e., worse HRQOL). All five subscales and the total score on the IWQOL-Lite demonstrated significant ($p < 0.001$) improvements in quality of life over the 1-year period. Women improved significantly on all five scales and total score, whereas males improved significantly on Physical Function, Self-Esteem, Public Distress, and total score.

Relationship between Changes in Weight and Quality of Life

The correlation between 1-year change in IWQOL-Lite scores and percentage of weight loss over the 1-year period were Physical Function = 0.396 ($p < 0.001$), Self-Esteem = 0.242 ($p = 0.002$), Sexual Life = 0.294 ($p < 0.001$), Public Distress = 0.166 ($p = 0.003$), Work = 0.169 ($p = 0.032$), and IWQOL-Lite total = 0.370 ($p < 0.001$). Consequently, ~14% of the variance in IWQOL-Lite total score can be accounted for by weight loss.

Figure 1 shows the relationship between amount of weight loss and IWQOL-Lite score changes over the 1-year period. Because scales differ considerably in terms of number of items (Physical Function = 11, Self-Esteem = 7, Sexual Life = 4, Public Distress = 5, Work = 4, and total score = 31), the graph reflects the average change per item for each of the four weight loss groups. This allows a direct comparison of the impact of weight loss on quality of life changes across scales. For example, the 20% + Weight

Table 1. IWQOL-Lite scores at baseline and 1-year by gender

IWQOL-Lite scale	Baseline	1-Year	Significance
Physical function			
Women (n = 141)	24.4 ± 8.0	17.9 ± 6.1	
Men (n = 20)	29.1 ± 12.3	18.0 ± 5.5	
Total	25.0 ± 8.8	17.9 ± 6.0	$t_{(160)} = 11.15$, $p < 0.001$
Self-esteem			
Women (n = 141)	15.5 ± 5.2	11.5 ± 5.3	
Men (n = 20)	13.0 ± 5.8	10.4 ± 3.6	
Total	15.2 ± 5.3	11.3 ± 5.1	$t_{(160)} = 9.67$, $p < 0.001$
Sexual life			
Women (n = 141)	8.2 ± 3.9	6.3 ± 3.0	
Men (n = 20)	6.8 ± 2.9	6.1 ± 2.6	
Total	8.0 ± 3.8	6.3 ± 3.0	$t_{(160)} = 6.07$, $p < 0.001$
Public distress			
Women (n = 141)	8.8 ± 3.8	6.9 ± 2.9	
Men (n = 20)	9.2 ± 5.2	7.0 ± 2.4	
Total	8.9 ± 4.0	6.9 ± 2.8	$t_{(160)} = 8.10$, $p < 0.001$
Work			
Women (n = 141)	5.9 ± 2.5	5.1 ± 2.0	
Men (n = 20)	7.0 ± 3.7	6.3 ± 2.8	
Total	6.0 ± 2.7	5.3 ± 2.1	$t_{(160)} = 3.84$, $p < 0.001$
IWQOL-Lite total			
Women (n = 141)	62.8 ± 18.7	47.6 ± 16.5	
Men (n = 20)	65.1 ± 25.1	47.7 ± 13.3	
Total	63.1 ± 19.5	47.6 ± 16.1	$t_{(160)} = 11.40$, $p < 0.001$

Cell entries represent means ± SD. Lower scores represent better quality of life.

Loss group averaged a 0.94-point decrease per item (of a possible five points) on the Physical Function scale, or 10.34 (0.94 × 11 items) total points. In contrast, the 20% + Weight Loss group averaged only a 0.30-point decrease per item on the Work scale, or 1.2 (0.30 × 4 items) total points. In general, Figure 1 shows a relatively orderly pattern of the relationship between weight loss category and change in IWQOL-Lite score, with greater amounts of weight loss associated with greater improvements in IWQOL-Lite scores. The figure also suggests that Physical Function and Self-Esteem are most strongly affected by weight loss, whereas Work is least affected by weight loss.

SEM information for IWQOL-Lite scales is presented in Table 2. α-Reliability coefficients at baseline ranged from 0.761 (Work) to 0.890 (Physical Function), and was 0.928 for the total score. The third column (labeled SEM) represents the SE of measurement at baseline, calculated by multiplying the SD by the square root of one minus the α-coefficient. The final column in Table 2 (labeled 1.96 SEM) represents the minimum reduction (i.e., improvement) in IWQOL-Lite scores over the 1-year period required to be considered clinically meaningful. For example, the IWQOL-Lite total score would need to decrease by ~10 points to be a clinically meaningful reduction in score.

Table 3 presents the percentage of participants in each weight loss group meeting clinically meaningful IWQOL-Lite reduction criteria as described above. With the exception of the Work scale, all IWQOL-Lite scales and total score show an increasing percentage of participants with a clinically meaningful reduction in IWQOL-Lite scores as weight loss increases. For three of the five IWQOL-Lite scales (Physical Function, Self-Esteem, and Sexual Life) and total score, this increase across weight loss group demonstrates a significant linear increase (based on the Mantel–Haenszel test).

Discussion

We assessed changes in obesity-specific quality of life over a 1-year period in patients undergoing weight reduc-

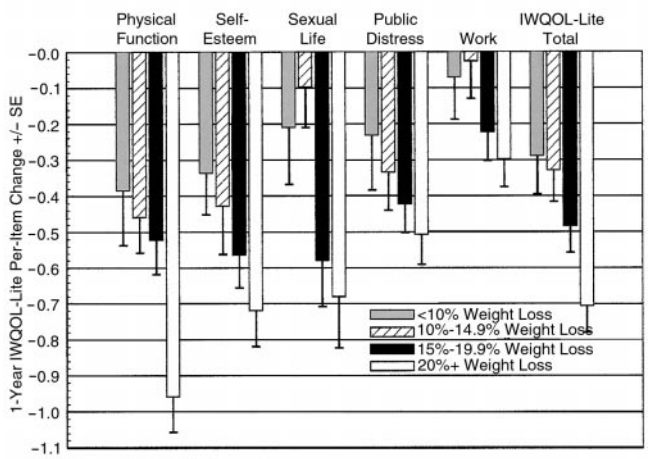

Figure 1: Relationship between weight loss and IWQOL-Lite scores.

tion treatment. Significant improvements were found on all five scales of the IWQOL-Lite questionnaire, as well as on total score. Correlations between percent change in IWQOL-Lite scores and percentage of weight loss over the 1-year period were significant for all scales, and ~14% of the variance in IWQOL-Lite total score could be accounted for by weight loss.

To determine the extent to which weight loss was associated with clinically meaningful improvement in quality of life as measured by the IWQOL-Lite, we used the SEM of the IWQOL-Lite scores. The SEM was chosen instead of effect size because the SEM is a fixed characteristic of the instrument, although estimates of the SEM may vary across samples. As weight loss increased, IWQOL-Lite total score and all scales except the Work scale showed an increasing percentage of participants with a clinically meaningful change in IWQOL-Lite score. For total score and for three of the five IWQOL-Lite scales (Physical Function, Self-Esteem, and Sexual Life), the linear relationship between weight loss and clinically meaningful change was significant. The analyses presented above suggest that there is considerable variability among different facets of HRQOL in terms of response to weight loss. Among those dimensions measured by the IWQOL-Lite, Physical Function showed the most improvement with weight loss, followed by Self-Esteem. Over one-third of participants losing <10% of their body weight demonstrated clinically meaningful improvements in Physical Function and in Self-Esteem. Nearly three-fourths of individuals losing 20% or more of their weight demonstrated clinically meaningful improvements in Physical Function, followed by 61% demonstrating clinically meaningful change on Self-Esteem. Sexual Life and Public Distress also showed some improvements with weight loss, although to a lesser degree. In contrast, work-related HRQOL showed only minimal improvements with weight loss.

Table 2. SEM information for IWQOL-Lite scores at baseline

IWQOL-Lite scale	SD	α Coefficient	SEM	1.96 SEM
Physical Function	8.77	0.890	2.91	5.71
Self-Esteem	5.32	0.865	1.96	3.83
Sexual Life	3.82	0.869	1.39	2.71
Public Distress	4.01	0.879	1.40	2.74
Work	2.70	0.761	1.32	2.59
IWQOL-Lite total	19.52	0.928	5.22	10.24

There is a small body of literature examining changes in HRQOL occurring after weight loss. In some of these studies, weight loss was associated with improvements in the physical, rather than psychological, aspects of HRQOL (12,10). In other studies weight loss was associated with improvements on both the physical and psychological aspects of HRQOL (11,13,14). Results of the present study are consistent with these latter studies in that we found improvements in both the physical and psychological aspects of HRQOL associated with weight loss. However, there are many differences between the present study and previous studies of HRQOL and weight loss. In other studies, a generic measure of HRQOL was used (10–13), the amount of weight loss was considerably less (11–13), only women were used as subjects (10,11), and one study did not differentiate between intentional and unintentional weight loss because it was a prospective study and not a treatment outcome study (10).

As in previous research on the IWQOL-Lite (27), significant differences were found between men and women on the Self-Esteem scale at baseline, indicating poorer quality of life in this area for women. Unlike previous research on the IWQOL-Lite (27), the present study did not find baseline gender differences on the Sexual Life scale or on total score. This failure to find significant gender differences at baseline on Sexual Life and total score in the present study is likely due to the small sample size of men ($n = 20$). Other studies of HRQOL in obese individuals reported baseline quality of life differences between men and women, with women exhibiting poorer quality of life. Women showed poorer quality of life than men on the ORWELL, an obesity-specific instrument (32). Similarly, obese women perceived markedly more psychosocial problems on a variety of HRQOL measures than did men in the Swedish Obese Subjects study (33). These differences between men and women on HRQOL are consistent with our clinical experi-

Table 3. Percent of participants experiencing clinically meaningful reduction (≥1.96 SEM) in IWQOL-Lite score by BMI group

	Percent 1-year weight loss				
IWQOL-Lite scale	**<10%**	**10% to 14.9%**	**15% to 19.9%**	**20%+**	**Significance**
Physical Function	36.0%	43.6%	44.7%	72.9%	$\chi^2_{(1)} = 12.5$, $p = 0.001$
Self-Esteem	36.0%	43.6%	44.7%	61.0%	$\chi^2_{(1)} = 5.1$, $p = 0.024$
Sexual Life	20.0%	21.1%	37.8%	43.9%	$\chi^2_{(1)} = 7.1$, $p = 0.008$
Public Distress	24.0%	35.9%	36.8%	39.0%	$\chi^2_{(1)} = 1.3$, $p = 0.252$
Work	12.0%	12.8%	10.5%	23.7%	$\chi^2_{(1)} = 2.3$, $p = 0.126$
IWQOL-Lite total	44.0%	51.3%	55.3%	76.3%	$\chi^2_{(1)} = 9.6$, $p = 0.002$

ence of patients in treatment for obesity, as well as consistent with what is known about gender differences and body image (34).

When analyzed separately, women improved significantly at 1-year follow-up on all five scales plus total score of the IWQOL-Lite, whereas men improved significantly on three of the five scales (Physical Function, Self-Esteem, and Public Distress). The small sample size for men in this study probably accounts for our inability to find significant pre-post-treatment changes on the other IWQOL-Lite scales for men. Other researchers exploring gender differences in HRQOL after weight loss have found mixed results: either no gender differences (35–37), gender differences in favor of men (38), or gender differences in favor of women (39). Given that gender differences seem to exist on the IWQOL-Lite, ideally we would compute SEM for women and men separately and develop separate values for clinically meaningful change in men and women. However, in the present sample, sample sizes for men were too small to justify performing these calculations.

A limitation of the present study is that subjects completed the original, 74-item IWQOL, rather than the newly developed 31-item version. Therefore, we are making an assumption that subjects' responses to the 31 items embedded in the 74-item questionnaire are equivalent to their responses had they taken the 31-item version. Another limitation is that the sample size for men was too small to compute separate SEMs for each gender. A third limitation is that because no placebo control group was used in this study, we do not know whether the change in quality of life experienced by subjects was due to weight loss itself or to the psychopharmacological effects of phentermine and fenfluramine on the nervous system. Finally, subjects with a lifetime history of a serious psychiatric illness or current major depression were excluded from the study. This procedure may have served to screen out a disproportionate number of individuals with severe impairments in HRQOL at baseline. By excluding these individuals, it is likely that the magnitude of change in HRQOL was artificially lowered (because individuals with higher baseline scores have more of an opportunity to change than those with lower baseline scores), thereby providing us with a conservative estimate of change in HRQOL.

This study used a criterion of 1.96 SEM for assessing clinically meaningful change (corresponding to a two-tailed 95% confidence interval). This criterion was conservative because all but one patient in this study lost at least some weight. The use of a more liberal criterion of 1.58 SEM (based on a one-tailed test) would have resulted in a larger number of patients meeting the definition of clinically meaningful change.

This study determined clinically meaningful changes on the IWQOL-Lite using a distribution-based method, the SEM. Other researchers have recommended using anchor-based methods that rely on an external standard (17,18). Our future research plans include an exploration of clinically meaningful change on the IWQOL-Lite using anchor-based methods. Ideally, results from anchor-based methods and distribution-based methods would converge. Identifying clinically meaningful differences on the IWQOL-Lite would also enable researchers to conduct power calculations for obesity quality of life studies.

Another direction for future research is the administration of obesity-specific instruments, such as the IWQOL-Lite, simultaneously with generic instruments, such as the SF-36, at baseline and at follow-ups in treatment outcome studies. This would allow us to see the ways in which findings from these two types of measures differ or are the same. We would expect obesity-specific instruments to be more sensitive to change than generic instruments (15). We may also want to assess HRQOL changes that occur after small, medium, and large weight losses.

Another direction for future research is to examine the baseline and change scores on the IWQOL-Lite in other cultures. The IWQOL-Lite has been translated and pilot-tested for use in 23 countries, which will allow for cross-cultural comparisons.

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