OWLQOL

Obesity and Weight Loss Quality of Life Instrument

and the

WRSM

Weight-Related Symptom Measure

User's Manual and Scoring Guide

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Purpose of This Manual

The purpose of this manual is to facilitate instrument administration, scoring, and interpretation of the Obesity and Weight Loss Quality of Life Instrument (OWLQOL) and the Weight-Loss Symptom Measure (WRSM).

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- **Type of research**
- **Primary outcome measure or end point**:
- **Design:**
- **Number of expected respondents (total):**
- **Number of expected administrations of the questionnaires per respondent**:
- **Length of the follow-up (if any):**
- **Planned study date**:
- **Name of the funder**:
- **Other questionnaires used in the study**:

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Belgium (French)	☐ 3	Latvia (Latvian)	☐18
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Bulgaria (Bulgarian)	☐ 5	Mexico (Spanish)	☐20
Canada (English)	☐ 6	Netherlands, The (Dutch)	☐21
Canada (French)	☐ 7	Poland (Polish)	☐22
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Name:	Name:

Title:	Title:
Signature:	Signature:
Date:	Date:

Summary and Background

Obesity is a major public health problem that increases the risk for co-morbid conditions, particularly diabetes, hypertension, coronary artery disease, and cancer[1-5]. The prevalence of this condition, defined in adults as a body mass index (BMI) >30 kg/m^2, has been estimated to be between 15% and 20% in industrialized countries[6,7]. Overweight and obesity in the United States are increasing and is estimated to affect more than half of those over the age of 20[2,6]. Since weight loss has been shown to reduce cardiovascular and other metabolic risk factors [2,8,9], management of obesity is an important health priority. Coping with being overweight and obese and losing or maintaining weight, however, are often significant challenges to individuals not only for personal reasons but also because of the cultural, social, and physical environments that surround them. Dramatic changes in culture, environment, and behavior are warranted.

Increasing BMI has been associated with decreased psychological well-being, reduced social integration, stigmatization, and low self-esteem[10]. Obesity also has negative effects on functional status, including work absenteeism, productivity, bodily pain, and depression [11-13].

Patient-reported outcomes, including symptoms, functional status, and perceived quality of life, are increasingly used alongside clinical measures in intervention studies to evaluate weight loss[14]. These outcomes include reports of signs and symptoms, impacts on functional status, perceptions of well-being and evaluations of quality of life. Of the generic functional status instruments, the Short Form 36-item health survey has been most widely used[11,15]. Generic functional measures, however, do not address key domains relevant to obesity and may not detect minimally important changes to obese persons[16]. Obesity-specific measures have been developed, including the 140-item battery constructed from six different psychosocial, health status, and behavioral scales for the Swedish Obesity Study (SOS)[17], and the Impact of Weight on Quality of Life (IWQOL), a 74-item measure later reduced to the IWQOL-Lite of 31 items[16,18].

Previously developed weight-specific measures were either developed for application to more severely obese populations, or without cross-cultural input into the item generation

process. Since attitudes toward obesity and weight loss have differing relevance, importance and sensitivity across different cultures, there is a clear need for measures that not only assess QoL in a broad range of persons who are overweight and obese, but measures developed with specific and concurrent inclusion of items from multiple cultures.

Also in contrast to previously developed measures, the Obesity and Weight-Loss Quality-of-Life (OWLQOL) was developed using a needs-based theoretical model for perceived quality of life that drove identification and selection of items that assess feelings that are unobservable to others, apply to all persons with the condition, are important to meeting the needs of the individual with the condition, and are developed with cross-cultural input[19-24]. The OWLQOL items all tap a unitary concept of quality of life needs related to being overweight or to losing weight. The OWLQOL and WRSM also designed to complete a full battery of patient-reported outcomes employing different concepts and different types of patient-reported outcome measures, including obesity-specific symptoms and quality of life, general functional status and well-being, person-specific preference measurement, and disability days[25]. The OWLQOL and WRSM are intended to be used together and alongside other patient-reported outcomes of functional status, adherence to diet and treatment, and satisfaction with treatment. The WRSM focuses on symptoms commonly associated with obesity and obesity treatment and the OWLQOL measures a person's global evaluation of position in life related to weight, weight loss, and weight-loss treatment. By using these and other patient-reported outcomes, investigators can address the experience of being overweight and obese and of weight loss on a broad spectrum of issues important to patients, their families, clinicians, regulators, payers, and society in general.

Development of the Instruments

The design and data collection processes for the development of these new measures followed the criteria and recommended steps by Patrick and Erickson,[25] the Scientific Advisory Committee of the Medical Outcomes Trust,[26] and the recommendations by Leidy, Revicki and Geneste suggestions on guidelines for QoL measurement instrument development.[27] However, short timeline requirements for finalizing these measures imposed difficult constraints on the project. A new approach was created to incorporate simultaneous cross-cultural inputs from the US, UK, France, Germany, Italy, and Spain without compromising the well-accepted practices of instrument development or project timelines.

There are a variety of previously published approaches that incorporate greater cross-cultural input into the development process of new measures. These include consensus meetings,[28] international diversity groups,[29] and expert panels.[30] The development of the World Health Organization Quality of Life measure (WHOQOL) followed a concurrent development process for the initial group of countries.[31,32]

While these methods offer a variety of desirable benefits, the time, logistics, and resources required were beyond what was available for this project. While others have published suggestions for expediting the standard translation process in the face of short timelines and resource limitations,[19,27] these methods cannot adequately support the requirements for the measure to have additional culture-specific content simultaneously available for incorporation during its development and translation process.

Therefore, a new process was designed that relied upon the current standards and guidelines for the development and cross-cultural adaptation of QoL measures, but was augmented with additional steps to provide cross-cultural content during the development phase and full harmonization of the new items before the end of the translation phase.

The steps for the new approach were: 1) Initial Item Development: A preliminary pool of items was created in the US through a combination of in-depth interviews and focus groups with 68 obese and overweight (with comorbidities) people. 2) Pre-harmonization of Initial Item Pool: An early check for translatability of items into each language was created through a pre-harmonization process. 3) Translation and Cognitive Debriefing: Two forward and one back translation plus cognitive debriefings were conducted with 35 people in all six countries. 4) Extended Qualitative Development: 10 additional qualitative in-country interviews were conducted to produce original culturally-specific items missing from the preliminary US pool. 5) Expanded International Harmonization: This process was conducted to ensure inclusion of contributions from each of the European countries into the final measures. 6) The participation of the patients in the study was voluntary and informed consent was obtained from each participant, according to the current laws and ethic review requirements in the various countries involved.

Two innovative features of this process were the early integration of the “translatability” of items during the pre-harmonization process and the extended qualitative data collection step in each country to produce additional culturally specific items. The multicultural input from the pre-harmonization step modified the first draft of items included in the measure, and the input from the additional qualitative in-country interviews entered the development process at the critical juncture of the expanded international harmonization step. Thus, two new obesity-specific measures were developed that were more cross-culturally appropriate than would have been possible with a US-based development alone. This was achieved in a very timely and resource-efficient manner.

Initial Validation Field Trials

Studies and Participants

Data used to evaluate the OWLQOL and WRSM were obtained from four studies: an initial validation sample, blinded data from a trial conducted in the US, a US community study, and a European community study. These studies, described in Table 1, included:
1) An initial validation study comprised of a convenience sample of obese persons. Participants were recruited through newspaper ads and weight loss programs in the Seattle area, and from five Wellness Clinics located in Chicago, IL; Raritan, NJ; Kingsport, TN; Spring House, PA; and Cincinnati OH. 2) A clinical trial was conducted to evaluate a product for weight loss among obese persons without a diagnosis of diabetes. Participants (n=1282) with baseline data were used in cross-sectional analyses and 407 participants with endpoint data were included in analyses of weight change and responsiveness. Blinded endpoint data analyzed included the last assessment available between 50 and 83 weeks. 3) A US community study was drawn from a web-based survey panel designed to represent the US general population. Individuals were selected from this panel based on a BMI of > 30 without co-morbidity or a BMI of > 27 with the presence of a co-morbidity (type II diabetes, hypertension, or high cholesterol). 4) A European community sample included respondents from the UK, Germany, France and Italy.

All data were collected via mailed questionnaire with the exception of Italy where questionnaires were self-administered, but delivered and collected by study staff. Sampling was designed to be representative of the country and a subset of obese persons (BMI $\geq$ 30) was selected from the community sample. Data from all countries were combined for instrument evaluation.

Table 1. Demographic characteristics

Characteristic	Initial Validation (n=340)	U.S. Clinical Trial (n=1282)	U.S. Community Obese Population (n=1478)	European Community Obese Population* (n=3007)
Age *[mean ± SD]*	45.4 ± 11.6	44.5 ± 10.7	51.1 ± 13.3	47.8 ± 13.6
Gender *[n (%) Female]*	204 (60.0)	1048 (81.7)	590 (39.9)	1825 (60.7)
Ethnicity *[n (%) Caucasian]*	265 (77.9)	1237 (96.5)	1156 (81.6)	N/A
Marital Status *[n (%) Married]*	171 (50.3)	N/A	1015 (69.8)	1421 (70.7)^
Income *[n (%) >= $50,000 total annual household]*	140 (41.2)	N/A	579 (39.2)	#
Education *[n (%) College Degree]*	265 (77.9)	N/A	455 (30.8)	625 (20.8)
BMI *[mean ± SD]*	36.3 ± 5.3	37.3 ± 5.2	32.9 ± 4.7	33.6 ± 4.9

* European countries are France, Germany, Italy, and the United Kingdom.
^ Marital status unavailable in the UK (percentage based on 2010 people).
# Median income category: France (41.2% >=₣150,000); Germany (55.5% >=DM42,000); Italy (58.0% >=₤30,000,000); UK (51.3% >= £35,000)
N/A, not applicable

Participants in all studies provided informed written consent approved by an Institutional Review Board. Weight loss information was provided for the clinical trial participants and those enrolled in formal weight loss programs in the initial validation study. Across all studies, potential participants were excluded if they had been exposed to any experimental drug or device within 30 days prior to enrollment; were pregnant or nursing; had gastric restrictive surgery or other surgical procedures designed to cause weight loss; had taken any weight-loss medication within 1 month prior to enrollment; had a history of drug or alcohol abuse within the past 2 years; had a malignancy or a history of a malignancy other than squamous or basal cell carcinomas of the skin; had a history of anorexia nervosa, bulimia, major depression, or panic disorder; were currently receiving psychotropic medication; or had a change in smoking habits within 6 months of the study or who planned to change their smoking habits during the study.

Participants were paid $20 per visit in the initial validation study. Participants in the clinical trial, the U.S. community study, and the European community study were not paid for participation.

Assessments

Patient and demographic characteristics, health status and quality of life data were collected. Core data for all studies included age, gender, height, weight, OWLQOL, WRSM, and the Short Form 36-item health survey. Education, marital status, and income were available for the initial validation and US and European community studies, but not for the clinical trial. Longitudinal data were available for the initial validation study and the clinical trial, but not the community studies. Patient characteristics were assessed by clinical staff during in-person visits for the initial validation study and the clinical trial. Data were obtained by self-report for the community sample studies.

The majority of subjects were female in all studies except the U.S. community study, were white, and were married (Table 1). A large percentage (78%) had had some college-level education or were college graduates in the initial validation study compared to 21-31% in the community studies. Although income levels varied, a high percentage of participants had household incomes in their respective countries. In the initial study, 291 participants completed the 12-week assessment and in the clinical trial 642 participants completed an assessment at 50-83 weeks.

Psychometric Properties

Psychometric testing of the OWLQOL and WRSM was conducted using standardized procedures and instrument review criteria developed by the Scientific Advisory Committee of the Medical Outcomes Trust[26]. Item reduction and development of the measurement model were performed sequentially, first on the initial validation study, then with a randomly selected sample (50%) from the clinical trial population, followed by confirmation with second half of the clinical trial data and the two community studies, one in the U.S. and one in Europe.

Forty-one OWLQOL items were evaluated for inclusion in the final instrument. Initial item reduction was based on respondent understanding of the items and response scale and importance rankings in the item development stage. These findings are reported separately[22]. Item reduction criteria for the OWLQOL included: 1) items with >5% missing

data; 2) items that demonstrated a ceiling effect (>50% of respondents selecting the “not at all” response option, suggesting a high degree of “non-relevance” or lack of responsiveness); 3) an item-to-total correlation <0.40 (suggesting the item may measure something belonging to a different scale); and 4) an item-to-item correlation >0.70 (indicating redundancy among the individual items). A final instrument containing 17 items was created using these criteria.

Standard descriptive statistics using the Statistical Package for the Social Sciences (SPSS) were calculated for each OWLQOL item and the total OWLQOL score to identify ranges and the distributions of response choices[33]. Mean, standard deviation, median, and percentage of missing data were also computed for each item. Histograms and box plots were used to determine whether the sample was normally distributed.

Guttman-Cronbach’s alpha was calculated to assess internal consistency, or the degree of association, among the items[34,35]. Reproducibility (test/retest reliability) was assessed at 1-week on a subset of the initial validation sample using the intra-class correlation coefficient (ICC)[36].

Measurement Model

Analysis of 41 original items in the OWLQOL questionnaire using the item reduction criteria across the four studies resulted in the removal of 24 items (Figure 1). All OWLQOL results presented in the remainder of this manual are for the 17-item instrument. The factor structure of the 17-item OWLQOL was assessed using principal component analysis (PCA) with a Promax rotation to allow for expected correlations among the factors. A series of exploratory factor analyses were conducted on multiple data sets. First, an exploratory analysis was conducted on the initial validation study and 50% of the clinical trial sample. The structure was tested on the remaining data sets. Factor correlations of $\geq$ 0.70 were considered indicative of the presence of single factor.[37] The sequentially conducted PCA on the initial validation study and random 1st half of the clinical trial dataset resulted in a two factors. The first component contributed 51% of the variance (eigenvalue= 8.7) and the second 8% (eigenvalue=1.4). The two factors were correlated 0.70 suggesting that these

were highly related. In sequential fashion, these analyses were repeated on the 2nd half of the clinical trial dataset with the first component contributing 55% of the variance (eigenvalue=9.4), the 2nd factor 5% (eigenvalue=1.0), and the two factors correlated at 0.71. When applied to the US and European community studies, the principal components analysis yielded a single factor, contributing 63% (eigenvalue 10.7) and 60% respectively (eigenvalue =10.2). Support for these decisions can be seen in figures 2-6.

Figure 1. The OWLQOL item reduction results from the original 41-item version

	The Final OWLQOL-17		Items dropped from OWLQOL-41
1.	Because of my weight, I try to wear clothes that hide my shape	4.	My weight prevents me from enjoying life
2.	I feel frustrated that I have less energy because of my weight	6.	Because of my weight, I try to avoid doing anything that calls attention to myself
3.	I feel guilty when I eat because of my weight	9.	I feel others have less respect for me because of my weight
7.	I am bothered by what other people say about my weight	14.	I lack confidence because of my weight
17.	Because of my wt, I try to avoid having my photograph taken	16.	I worry about how much my weight affects my health
19.	Because of my wt, I have to pay close attention to personal hygiene	27.	I feel I have fewer opportunities than others do because of my weight
20.	My weight prevents me from doing what I want to do	29.	I feel isolated because of my weight
22.	I worry about the physical stress that my wt puts on my body	32.	I avoid going out because of my weight
24.	I feel frustrated that I am not able to eat what others do because of my weight		**Items dropped from OWLQOL-33**
25.	I feel depressed because of my weight	5.	I feel embarrassed about needing more room than others because of my weight
28.	I feel ugly because of my weight	8.	I am embarrassed about moving more slowly than others because of my weight
30.	I worry about the future because of my weight	10.	Because of my weight, I get frustrated trying to find clothes I look good in
33.	I envy people who are thin	11.	I worry about the impression others have of me because of my weight
35.	I feel that people stare at me because of my weight	12.	I feel I am treated differently by others because of my weight
36.	I have difficulty accepting my body because of my weight	13.	Because of my weight, I try to avoid being seen in swimwear or shorts
38.	I am afraid that I will gain back any weight that I lose	15.	I dread getting on the scale to weight myself
40.	I get discouraged when I try to lose weight	18.	I feel embarrassed eating certain foods in front of others because of my weight
		21.	Because of my weight, I am embarrassed to undress in front of others
	Response scale:	23.	I avoid having sex because of my weight
	0 = Not at all,	26.	I feel left out by others because of my weight
	1 = Hardly,	31.	I feel others are ashamed of me because of my weight
	2 = Somewhat,	34.	I worry others think I am lazy because of my weight
	3 = Moderately,	37.	I feel that others cannot see the real me because of my weight
	4 = A good deal,	39.	I am moody when I try to lose weight
	5 = A great deal,	41.	I need support from others to lose weight
	6 = A very great deal		

Figure 2: Original Validation Dataset (n=340)

PCA Factor Analysis (Promax): OWLQOL 17 item

Total Variance Explained

	Initial Eigenvalues			
Component	Total	% of Variance	Cumulative %	
1	8.709	51.228	51.228	
2	1.352	7.955	59.183	

Extraction Method: Principal Component Analysis.
a When components are correlated, sums of squared loadings cannot be added to obtain a total variance.

Structure Matrix

	Component		
	1	2	
36 I have difficulty accepting my body BOMW	.823	.676	
28 I feel ugly BOMW	.805	.713	
25 I feel depressed BOMW	.797	.743	
03 I feel guilty when I eat BOMW	.760	.554	
33 I envy people who are thin	.749	.381	
40 I get discouraged when I try to lose weight	.749	.434	
07 I am bothered by what other people say about my weight	.747	.612	
01 BOMW, I try to wear clothes that hide my shape	.704	.571	
38 I am afraid that I will gain back any weight that I lose	.697	.358	
24 I feel frustrated that I am not able to eat what others do BOMW	.696	.544	
20 My weight prevents me from doing what I want to do	.589	.841	
30 I worry about the future BOMW	.531	.797	
22 I worry about the physical stress that my weight puts on my body	.520	.797	
02 I feel frustrated that I have less energy BOMW	.624	.750	
19 BOMW, I have to pay close attention to personal hygiene	.310	.705	
17 BOMW, I try to avoid having my photograph taken	.656	.672	
35 I feel that people stare at me BOMW	.621	.645	

Extraction Method: Principal Component Analysis. Rotation Method: Promax with Kaiser Normalization.

Component Correlation = 0.7

Figure 3: Random (1st) Half of OBES-002 Clinical Trial Dataset (n=641)

PCA Factor Analysis (Promax): OWLQOL 17 item

Total Variance Explained

	Initial Eigenvalues			
Component	Total	% of Variance	Cumulative %	
1	9.364	55.085	55.085	
2	1.039	6.110	61.195	

Extraction Method: Principal Component Analysis.

a When components are correlated, sums of squared loadings cannot be added to obtain a total variance.

Structure Matrix

	Component		
	1	2	
28 I feel ugly BOMW	.847	.635	
36 I have difficulty accepting my body BOMW	.838	.659	
25 I feel depressed BOMW	.832	.668	
07 I am bothered by what other people say about my weight	.813	.543	
17 BOMW, I try to avoid having my photograph taken	.791	.518	
03 I feel guilty when I eat BOMW	.772	.569	
01 BOMW, I try to wear clothes that hide my shape	.749	.465	
35 I feel that people stare at me BOMW	.716	.652	
33 I envy people who are thin	.715	.438	
24 I feel frustrated that I am not able to eat what others do BOMW	.714	.640	
38 I am afraid that I will gain back any weight that I lose	.693	.601	
40 I get discouraged when I try to lose weight	.679	.600	
22 I worry about the physical stress that my weight puts on my body	.493	.845	
30 I worry about the future BOMW	.553	.838	
20 My weight prevents me from doing what I want to do	.745	.786	
19 BOMW, I have to pay close attention to personal hygiene	.544	.708	
02 I feel frustrated that I have less energy BOMW	.678	.704	

Extraction Method: Principal Component Analysis. Rotation Method: Promax with Kaiser Normalization.

Component Correlation = 0.71

Figure 4: Random (2nd) Half of OBES-002 Clinical Trial Dataset (n=641)

PCA Factor Analysis (Promax): OWLQOL 17 item

Total Variance Explained

	Initial Eigenvalues			Extraction Sums of Squared Loadings			
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	
1	9.448	55.579	55.579	9.448	55.579	55.579	
2	1.102	6.483	62.062	1.102	6.483	62.062	

Extraction Method: Principal Component Analysis.
a When components are correlated, sums of squared loadings cannot be added to obtain a total variance.

Structure Matrix

	Component		
	1	2	
28 I feel ugly BOMW	.854	.628	
36 I have difficulty accepting my body BOMW	.843	.647	
25 I feel depressed BOMW	.836	.671	
07 I am bothered by what other people say about my weight	.818	.642	
17 BOMW, I try to avoid having my photograph taken	.777	.584	
03 I feel guilty when I eat BOMW	.764	.595	
24 I feel frustrated that I am not able to eat what others do BOMW	.743	.562	
35 I feel that people stare at me BOMW	.738	.688	
33 I envy people who are thin	.734	.395	
01 BOMW, I try to wear clothes that hide my shape	.717	.478	
38 I am afraid that I will gain back any weight that I lose	.696	.520	
40 I get discouraged when I try to lose weight	.667	.474	
30 I worry about the future BOMW	.564	.844	
22 I worry about the physical stress that my weight puts on my body	.480	.842	
20 My weight prevents me from doing what I want to do	.693	.827	
19 BOMW, I have to pay close attention to personal hygiene	.625	.758	
02 I feel frustrated that I have less energy BOMW	.683	.743	

Extraction Method: Principal Component Analysis. Rotation Method: Promax with Kaiser Normalization.

Component Correlation = 0.71

Figure 5: U.S. Population Survey – General Obese (Knowledge Networks Dataset) (n=989)

PCA Factor Analysis (Promax): OWLQOL 17 item

Total Variance Explained

	Initial Eigenvalues			
Component	Total	% of Variance	Cumulative %	
1	10.715	63.028	63.028	

Extraction Method: Principal Component Analysis.

Component Matrix

	Component	
	1	
36 I have difficulty accepting my body BOMW	.869	
25 I feel depressed BOMW	.860	
28 I feel ugly BOMW	.855	
07 I am bothered by what other people say about my weight	.822	
03 I feel guilty when I eat BOMW	.817	
22 I worry about the physical stress that my weight puts on my body	.812	
20 My weight prevents me from doing what I want to do	.808	
38 I am afraid that I will gain back any weight that I lose	.808	
17 BOMW, I try to avoid having my photograph taken	.792	
30 I worry about the future BOMW	.786	
40 I get discouraged when I try to lose weight	.781	
02 I feel frustrated that I have less energy BOMW	.777	
35 I feel that people stare at me BOMW	.775	
24 I feel frustrated that I am not able to eat what others do BOMW	.775	
01 BOMW, I try to wear clothes that hide my shape	.736	
33 I envy people who are thin	.732	
19 BOMW, I have to pay close attention to personal hygiene	.667	

Extraction Method: Principal Component Analysis.

a 1 components extracted.

Figure 6: European Population Survey – General Obese (NFO Dataset) (n=2769)

PCA Factor Analysis (Promax): OWLQOL 17 item

Total Variance Explained

	Initial Eigenvalues			
Component	Total	% of Variance	Cumulative %	
1	10.159	59.756	59.756	

Extraction Method: Principal Component Analysis.

Component Matrix

	Component	
	1	
36 I have difficulty accepting my body BOMW	.867	
28 I feel ugly BOMW	.846	
25 I feel depressed BOMW	.846	
03 I feel guilty when I eat BOMW	.789	
30 I worry about the future BOMW	.789	
07 I am bothered by what other people say about my weight	.781	
17 BOMW, I try to avoid having my photograph taken	.778	
20 My weight prevents me from doing what I want to do	.777	
35 I feel that people stare at me BOMW	.769	
38 I am afraid that I will gain back any weight that I lose	.762	
24 I feel frustrated that I am not able to eat what others do BOMW	.762	
02 I feel frustrated that I have less energy BOMW	.760	
22 I worry about the physical stress that my weight puts on my body	.747	
40 I get discouraged when I try to lose weight	.738	
33 I envy people who are thin	.716	
01 BOMW, I try to wear clothes that hide my shape	.709	
19 BOMW, I have to pay close attention to personal hygiene	.681	

Extraction Method: Principal Component Analysis.
a 1 components extracted.

In summary, the principal components analyses on all study samples suggested that a single overall score was appropriate for the OWLQOL and confirmed that the needs-based conceptual model postulating that all items, if important and applying to all persons and all tapping an unobservable feeling, would form a unitary concept describing obesity-related quality of life.

Internal Consistency and Test-Retest Reliability

The overall OWLQOL score was internally consistent in all studies (Guttman-Cronbach's α = 0.93, Initial Validation, 0.96 US Community, 0.95 European Community, 0.94 Clinical Trial). The intraclass correlation coefficient [ICC] evaluating test-retest reliability on 56 subjects in the Initial Validation study only was 0.95. The WRSM was also internally consistent (Guttman-Cronbach's α = 0.87 and reproducible (ICC = 0.83) in the initial validation study.

Validity

Convergent validity was evaluated by testing *a priori* hypotheses about how the OWLQOL should perform in relation to other self-report measures. We expected higher correlations of the OWLQOL with the general quality of life measure (PQOL) than the more function-related instrument, the SF-36. We also expected higher correlations of the OWLQOL with the mental component score of the SF-36 than with the physical component score, based on the overlap between mental health and perceived quality of life. For known groups validity, we tested the OWLQOL against independent marker variable; i.e., by comparing scores for participants who were mildly, moderately, or severely overweight (BMI = 27–29.9 kg/m^2, 30–34.9kg/m^2, 35.0-39.90 kg/m^2, and 40–50.0 kg/m^2, respectively), for subjects with low, moderate, and high symptom bother (WRSM tertiles), and presence of disability days ('yes' to have you missed any time from work because of illness in the past 4 weeks?). The OWLQOL score should improve (increase) and the WRSM scores should improve (decrease) as body mass index and level of symptom bother decrease and scores on both instruments should be worse in the presence of disability days. Based on previous literature (16), females were also expected to report lower scores than males. Analysis of variance was used to valuate differences between groups and group differences were identified using Scheffe post-hoc procedures.

The OWLQOL scores showed stronger associations with the general quality of life measure (PQOL) and symptom bothersomeness than with the SF-36 component scores, but these differences were not large (Table 2). Similarly, the association between the OWLQOL and

mental component of the SF-36 was higher but not a great deal higher than the association with the physical component score.

Table 2. Measurement Correlation Matrix (Initial Validation, n=340)

	OWLQOL	WRSM Bother	SF-36 PCS	SF-36 MCS
OWLQOL	1.00			
WRSM Bother	-0.54	1.00		
SF-36 PCS	0.40	-0.56	1.00	
SF-36 MCS	0.47	-0.40	0.04	1.00
PQOL Total	0.53	-0.56	0.43	0.60

Note: All correlations significant at the 0.01 level (2-tailed)

Table 3 shows that the predicted relationships between the OWLQOL total score and measures of body mass index, symptom bother and presence of disability days were generally confirmed. OWLQOL scores decreased as levels of the body mass index increased across all studies. The OWLQOL also discriminated between tertiles of the symptom bother score, decreasing as levels of symptom bother increased ($p<0.001$). OWLQOL scores also decreased when the person also reported having work loss days in the initial and European community studies. These results were not confirmed on the US community study and were not available for the clinical trial.

Table 3. OWLQOL scores by levels of BMI, symptom bother and work disability days

	Initial Validation		U.S. Clinical Trial		U.S. Community Obese Population		European Community Obese Population	
	N	mean (SD)	N	mean (SD)	N	mean (SD)	N	mean (SD)
Body Mass Index (kg/m^2)								
(1) 27.0 – 29.9	34	59.1 (23.2)	52	62.2 (21.2)	358	71.9 (14.6)	199	76.6 (20.0)
(2) 30.0 – 34.9	125	57.7 (21.7)	445	55.3 (20.8)	681	64.3 (18.3)	1895	67.6 (22.5)
(3) 35.0 – 39.9	103	53.3 (22.8)	398	52.4 (22.5)	284	53.4 (22.5)	597	57.7 (24.2)
(4) 40.0 – 50.0	78	48.7 (20.0)	370	45.8 (21.9)	154	40.0 (25.9)	229	53.8 (25.1)
Scheffe Post Hoc		(1)x(3)* (2)x(4)*		(1)x(3)* (1)x(4)***		All groups sig ***		All groups*** except (3)x(4)
WRSM (Tertiles)								
Tert. 1 (High bother)	107	69.8 (17.8)	404	63.7 (19.4)	478	71.9 (13.7)	670	77.5 (18.6)
Tert. 2 (Moderate bother)	115	54.0 (19.4)	379	54.0 (18.8)	484	64.0 (17.7)	766	65.9 (20.4)
Tert. 3 (Low bother)	118	41.0 (18.8)	366	38.3 (20.3)	508	49.1 (24.6)	753	49.9 (22.9)
F stat#		66.3***		165.1***		177.7***		316.1***
Disability Days+								
No	194	57.5 (20.9)		N/A^	517	62.7 (21.2)	1467	66.0 (23.0)
Yes	53	45.6 (20.8)			960	60.8 (21.7)	274	61.3 (23.7)
F stat		13.6***				2.3		9.6**

* p<0.05; ** p<0.01; *** p<0.001
+ Have you missed any time from work because of illness in the past 4 weeks?
^ Data was not available for analysis
# All post hoc (Scheffe) group comparisons for WRSM were significant (p<0.001)

The mean change in actual weight in kg was 10.7 +/-3.6 for initial validation study and 38.4 +/-8.2 in the clinical trial. The correlation between weight change and the OWLQOL score was 0.26 in the initial validation study. Correlation between BMI change and OWLQOL change was -0.09 and for the WRSM + 0.09 in the initial validation study.

Scores by Age and Gender

Table 4 shows the mean OWLQOL and WRSM scores by age and gender. In all studies, OWLQOL scores were higher (better) and WRSM scores were lower (better) in males than in females (*P*<0.001). No clear trends were evident for age groups on the OWLQOL and WRSM in the initial validation study, but OWLQOL scores improved and symptom scores worsened as age increased in the remainder of the studies (p<0.05).

Table 4. Obesity and Weight-Loss Quality of Life (OWLQOL) and Weight-Related Obesity Symptom Measure (WRSM) scores

	Initial Validation (n=340)		U.S. Clinical Trial (n=1282)		U.S. Community Obese Population (n=1478)		European Community Obese Population (n=3007)	
OWLQOL	N	mean (SD)	N	mean (SD)	N	mean (SD)	N	mean (SD)
Total population	340	54.5 (22.0)	1267	51.9 (22.1)	1477	61.5 (21.5)	2952	64.9 (23.7)
Age								
(1) 18-44	157	55.7 (21.9)	621	51.2 (21.9)	459	58.9 (23.1)	1259	61.5 (24.4)
(2) 45-54	112	53.3 (22.1)	412	49.9 (22.6)	391	59.7 (21.7)	705	65.5 (22.7)
(3) 55 +	71	53.7 (22.4)	234	57.4 (21.0)	627	64.6 (19.8)	988	68.9 (22.8)
Scheffe Post Hoc	No Sig Group Diff		(1)x(3)** (2)x(3)***		(1)x(3)*** (2)x(3)***		(1)x(2)* (1)x(3)***	
Gender								
Male	136	64.7 (20.3)	233	65.0 (20.2)	887	67.7 (17.0)	1161	76.3 (18.8)
Female	204	47.7 (20.5)	1034	48.9 (21.4)	590	52.1 (24.0)	1791	57.6 (23.7)
F-stat		56.7***		108.5***		213.1***		517.2***
WRSM								
Total population	340	25.5 (18.5)	1161	19.3 (16.7)	1470	17.0 (16.8)	2206	21.0 (18.1)
Age								
(1) 18-44	157	23.3 (17.8)	574	17.6 (16.0)	459	15.0 (16.3)	980	18.2 (16.5)
(2) 45-54	112	27.2 (19.3)	382	20.9 (17.5)	389	17.4 (17.5)	526	21.6 (18.5)
(3) 55 +	71	27.8 (18.4)	205	21.2 (16.7)	622	18.2 (16.7)	700	24.5 (19.3)
Scheffe Post Hoc	No Sig Group Diff		(1)x(2)** (1)x(3)*		(1)x(3)*** (2)x(3)***		(1)x(2)* (1)x(3)***	
Gender								
Male	136	20.3 (15.7)	220	15.2 (14.4)	884	14.5 (15.5)	852	16.9 (16.3)
Female	204	29.0 (19.4)	941	20.3 (17.1)	586	20.7 (18.1)	1354	23.6 (18.7)
F-stat		19.1***		16.4***		48.8***		73.2***

Note: Higher OWLQOL scores indicate higher levels of condition-specific quality of life; higher WRSM scores indicate greater (worse) symptom severity. * p<0.05; ** p<0.01; *** p<0.001

Mean completion time for the OWLQOL was 5 minutes (range 3–8) and for the WRSM, mean time to completion was 2 minutes (range 1–4). Minimal missing data (< 0.1%) were observed for all questionnaires in the initial validation study.

Responsiveness

Responsiveness was reported in terms of the standardized response mean (mean change score divided by the standard deviation of the change score. This effect size statistic was used to identify differences in OWLQOL and WRSM scores associated with weight loss over time[38]. For the 12-week validation study, we used ≥2.5% decrease in body weight as a marker for minimally important change based on the short follow-up period and amount of weight loss that could be anticipated with adherence to diet and exercise. For the clinical trial with endpoint data between 50-83 weeks, we used ≥10% change in body weight as a minimally important weight loss recommended by the International Obesity Task Force[39].

Responsiveness of the OWLQOL and WRSM bothersomeness score are shown in Table 5 for different levels of weight increase or decrease. The standardized response mean (SRM) was used as the measure of effect size. Using the cut-point of ≥ 2.5 % decrease in weight over the 12-week initial validation study, the SRM for the OWLQOL was 0.77 and -0.54 for the WRSM. Both the OWLQOL and WRSM scores improved slightly in both studies for patients who increased weight. In the clinical trial, for a ≥10% weight decrease, the effect size was 1.38 for the OWLQOL and -0.47 for the WRSM. Effect sizes were smaller for less weight change but remained moderately high for the OWLQOL but not for the WRSM. In general, the OWLQOL proved responsive to weight decrease in the two studies with shorter and longer follow-up.

Table 5. Responsiveness of the OWLQOL and WRSM Score

	OWLQOL Change Score			WRSM Bother Change Score		
	N	mean (SD)	SRM*	N	mean (SD)	SRM
Seattle Validation (12 weeks)						
Change in weight						
Weight increase	109	4.27 (13.25)	0.32	109	-5.56 (13.90)	-0.40
0 – 2.49% decrease	101	9.32 (11.50)	0.81	101	-6.93 (12.45)	-0.56
≥ 2.50% decrease	81	11.19 (14.57)	0.77	81	-9.26 (17.24)	-0.54
U.S. Clinical Trial (> 50 weeks)						
Change in weight						
Weight increase	35	8.87 (16.23)	0.55	33	0.12 (20.52)	0.01
0 – 4.99% decrease	75	10.81 (13.96)	0.77	71	-1.11 (14.77)	-0.08
5.00 – 9.99% decrease	109	16.56 (14.04)	1.18	134	-6.63 (12.98)	-0.51
≥ 10.00% decrease	198	26.16 (16.04)	1.63	230	-11.46 (15.41)	-0.74

* SRM = standardized response mean (mean change in score / SD of mean change score)

SCORING

Obesity and Weight Loss Quality of Life Measure

The 17 OWLQOL items have a 7-point Likert-like response scale ranging between 0 *"Not at all"* to 6 *"A very great deal".* Before calculating scores, each item is reversed. All OWLQOL items are used with equal weight to derive a single quality of life score. The score is computed by simply summing each item and then transforming this raw score onto a standardized scale of 0 to 100 using the following formula.

$$\text{Score} = \frac{\text{The sum of the component items score (minus) the lowest possible score}}{\text{Possible raw score range}} * 100$$

A score of 0 indicates the greatest impact, and a score of 100 indicates the lowest impact, thus increasing OWLQOL scores imply better quality of life.
Subjects were allowed to miss up to 3 items and still have an analyzable score.

The following scoring syntax (written in SPSS) can be used to score the OWLQOL.

```
* OWL-QOL / WRSM Study

* Score OWL-QOL
* BOMW=Because of my weigh

VARIABLE LABEL
  owl01 '01 BOMW, I try to wear clothes that hide my shape'
  owl02 '02 I feel frustrated that I have less energy BOMW'
  owl03 '03 I feel guilty when I eat BOMW'
  owl04 '07 I am bothered by what other people say about my weight'
  owl05 '17 BOMW, I try to avoid having my photograph taken'
  owl06 '19 BOMW, I have to pay close attention to personal hygiene'
  owl07 '20 My weight prevents me from doing what I want to do'
  owl08 '22 I worry about the physical stress that my weight puts on my body'
  owl09 '24 I feel frustrated that I am not able to eat what others do BOMW'
  owl10 '25 I feel depressed BOMW'
  owl11 '28 I feel ugly BOMW'
  owl12 '30 I worry about the future BOMW'
  owl13 '33 I envy people who are thin'
  owl14 '35 I feel that people stare at me BOMW'
  owl15 '36 I have difficulty accepting my body BOMW'
  owl16 '38 I am afraid that I will gain back any weight that I lose'
  owl17 '40 I get discouraged when I try to lose weight'  .
EXECUTE .
```

```
**** Score the 17-item OWLQOL ****

* Counting number of missing items

COUNT owlc_17=owl01 owl02 owl03 owl04 owl05 owl06 owl07
      owl08 owl09 owl10 owl11 owl12 owl13 owl14 owl15 owl16 owl17 (MISSING).
EXECUTE .

* Summing the OWLQOL items and reversing to create a raw sum score

COMPUTE owlt_17=6-owl01+6-owl02+6-owl03+6-owl04+6-owl05+6-owl06+6-owl07+
                6-owl08+6-owl09+6-owl10+6-owl11+6-owl12+6-owl13+6-owl14+
                6-owl15+6-owl16+6-owl17.

* Computing transformed (0 - 100) total score

COMPUTE owl_17=(owlt_17/102)*100.
EXECUTE .
```

```
**** Account for missing values: OWLQOL can have up to 3 missing items to generate a
total score ****

RECODE
  owl01 owl02 owl03 owl04 owl05 owl06 owl07 owl08 owl09
  owl10 owl11 owl12 owl13 owl14 owl15 owl16 owl17
  (0=0) (1=1) (2=2) (3=3) (4=4) (5=5) (6=6) (MISSING=MISSING)
  INTO owl01m2 owl02m2 owl03m2 owl04m2 owl05m2 owl06m2 owl07m2 owl08m2
  owl09m2 owl10m2 owl11m2 owl12m2 owl13m2 owl14m2 owl15m2 owl16m2 owl17m2 .
EXECUTE .

  DO IF (owlc_17=1) .
  COMPUTE owl_17=(((6-owl01m2+6-owl02m2+6-owl03m2+6-owl04m2+6-owl05m2+
    6-owl06m2+6-owl07m2+6-owl08m2+6-owl09m2+6-owl10m2+6-owl11m2+6-owl12m2+
    6-owl13m2+6-owl14m2+6-owl15m2+6-owl16m2+6-owl17m2)/96)*100) .
  END IF .
  EXECUTE .

  DO IF (owlc_17=2) .
  COMPUTE owl_17=(((6-owl01m2+6-owl02m2+6-owl03m2+6-owl04m2+6-owl05m2+
    6-owl06m2+6-owl07m2+6-owl08m2+6-owl09m2+6-owl10m2+6-owl11m2+6-owl12m2+
    6-owl13m2+6-owl14m2+6-owl15m2+6-owl16m2+6-owl17m2)/90)*100) .
  END IF .
  EXECUTE .

  DO IF (owlc_17=3) .
  COMPUTE owl_17=(((6-owl01m2+6-owl02m2+6-owl03m2+6-owl04m2+6-owl05m2+
    6-owl06m2+6-owl07m2+6-owl08m2+6-owl09m2+6-owl10m2+6-owl11m2+6-owl12m2+
    6-owl13m2+6-owl14m2+6-owl15m2+6-owl16m2+6-owl17m2)/84)*100) .
  END IF .
  EXECUTE .

VARIABLE LABELS
  owlt_17 'OWLQOL 17: Summation of all items'
  owl_17  'OWLQOL 17: Total Score'
  owlc_17 'OWLQOL 17: Number of missing items'.
EXECUTE .
```

```
%macro Score_OWLQOL(OWLQOL_item_dat=,
                    OWLQOL_item_names=,
                    OWLQOL_score_name=,
                    keep_vars_input=,
                    OWLQOL_score_dat=,
                    keep_OWLQOL_items=YES);
/*********************************************************************/
/*                                                                   */
/*  Purpose: Given existing SAS data set with 17 OWLQOL item         */
/*           variables, produce the OWLQOL score.                    */
/*                                                                   */
/*  Macro variable specifications:                                   */
/*                                                                   */
/*      OWLQOL_item_dat   - A SAS data set which the user names which */
/*                          contains the 17 OWLQOL item variables    */
/*                                                                   */
/*      OWLQOL_item_names - A list of names for the 17 OWLQOL item   */
/*                          variables.  The list can be 17 blank     */
/*                          separated names or can be a name list    */
/*                          in which all variables have a common stem */
/*                          name and a numeric suffix in which case  */
/*                          the items can be specified as            */
/*                                                                   */
/*                            OWLQOL_item_names=%str(owlqol1-owlqol17) */
/*                                                                   */
/*                          assuming that the stem name is OWLQOL.   */
/*                                                                   */
/*                          Note that if a variable list is indicated, */
/*                          the list must be quoted with the %str()  */
/*                          function.  A list given as:              */
/*                                                                   */
/*                            OWLQOL_item_names=owlqol1-owlqol17     */
/*                                                                   */
/*                          will produce an error.  The correct form */
/*                          for a list of variables was shown        */
/*                          previously.                              */
/*                                                                   */
/*      OWLQOL_score_name - Name of the OWLQOL score variable in the */
```

```
/*                          output data set                              */
/*                                                                       */
/*      keep_vars_input   - List of variable names in the input data     */
/*                          set which contain variables which should     */
/*                          be retained in the output data set.  The     */
/*                          set of variables in keep_vars might be a     */
/*                          set of ID variables that allow the scored    */
/*                          OWLQOL data to be merged with other data.    */
/*                          If you want to keep only a select set of     */
/*                          variables, then specify the variables        */
/*                          individually with a space separating         */
/*                          variable names as in:                        */
/*                               keep_vars_input=studyID                 */
/*                                                                       */
/*                          On the other hand, you may want to keep      */
/*                          all variables on the input data set and      */
/*                          just add the OWLQOL score as another         */
/*                          variable. If you want to keep all            */
/*                          variables, then specify the keyword _ALL_    */
/*                          as in                                        */
/*                               keep_vars_input=_ALL_                   */
/*                                                                       */
/*      OWLQOL_score_dat - The name of the SAS data set which will       */
/*                         contain the OWLQOL score                      */
/*                                                                       */
/*      keep_OWLQOL_items- Specifies whether to keep the 17 OWLQOL       */
/*                         item variables in the scored data set         */
/*                         (keep_OWLQOL_items=YES which is the           */
/*                         default behavior) or drop the OWLQOL item     */
/*                         variables from the scored data set            */
/*                         (keep_OWLQOL_items=NO).                       */
/*                                                                       */
/*  Author:  Dale McLerran (mailto:dmclerra@fhcrc.org)                   */
/*                                                                       */
/*  Date:    November 10, 2010                                           */
/*                                                                       */
/*  Usage:   It is necessary to make the Score_OWLQOL macro available    */
/*           to a SAS program before invoking the macro.  There are a    */
```

```
/*          number of ways to make a macro variable available.  The   */
/*          simplest method of making a macro available is to         */
/*          reference the macro code (this program) in a %include     */
/*          statement prior to invoking the macro.  No %include       */
/*          statement is necessary if the macro code is placed in an  */
/*          autocall library and the autocall library is referenced   */
/*          automatically when SAS is started (through appropriate    */
/*          code in an autoexec.sas or through code in a SAS          */
/*          configuration file.  The use of autocall libraries is not */
/*          demonstrated here.)  The %include statement is            */
/*          constructed as:                                           */
/*                                                                    */
/*             %include "<path>\Score_OWLQOL.sas";                    */
/*                                                                    */
/*          where <path> is the location where the program resides.   */
/*                                                                    */
/*          After making the program available, the macro is invoked  */
/*          as shown in the example below:                            */
/*                                                                    */
/*             %Score_OWLQOL(OWLQOL_item_dat=OWLQOL_items,            */
/*                           OWLQOL_item_names=%str(owlqol1-owlqol17),*/
/*                           OWLQOL_score_name=OWLQOL,                */
/*                           keep_vars_input=studyID,                 */
/*                           OWLQOL_score_dat=OWLQOL_score,           */
/*                           keep_OWLQOL_items=YES)                   */
/*                                                                    */
/*          The above code reads in a data set named OWLQOL_items     */
/*          which has variables owlqol1, owlqol2, owlqol3, ...,       */
/*          owlqol17.  In addition, the input data set contains a     */
/*          variable named studyID.  An output data set named         */
/*          OWLQOL_score is constructed containing a variable named   */
/*          OWLQOL which provides the OWLQOL score.  The OWLQOL item  */
/*          values (owlqol1, owlqol2, ..., owlqol17) are included in  */
/*          the output data set along with the OWLQOL score and the   */
/*          variable studyID.                                         */
/*                                                                    */
/**********************************************************************/
```

```
%let keep_OWLQOL_items=%upcase(&keep_OWLQOL_items);
%let keep_vars_input=%upcase(&keep_vars_input);



%let stemname=;
/* Get common part of OWLQOL variable names if a name list is used */
%if %scan(&OWLQOL_item_names,1,%str(-))^=&OWLQOL_item_names %then %do;
  %let firstvar=%scan(&OWLQOL_item_names,1,%str(-));
  %let lastvar=%scan(&OWLQOL_item_names,2,%str(-));
  %let i=1;
  %do %while(%substr(&firstvar,&i,1)=%substr(&lastvar,&i,1));
    %let stemname=&stemname.%substr(&firstvar,&i,1);
    %let i=%eval(&i+1);
  %end;
%end;
data &OWLQOL_score_dat.
     %if &keep_OWLQOL_items=NO %then %do;
       (drop=&OWLQOL_item_names)
     %end;
     ;
  set &OWLQOL_item_dat.
     %if &keep_vars_input=_ALL_ %then %do;
       ;
     %end;
     %else %do;
       (keep=&OWLQOL_item_names &keep_vars_input);
     %end;

  /* Code when a list of OWLQOL variables has been given in the form */
  /* OWLQOL_item_names=%str(owlqol1-owlqol17)                        */
  %if &stemname^=%str() %then %do;
    if nmiss(of &OWLQOL_item_names.)<=3 then do;
      N_OK = N(of &OWLQOL_item_names.);
      sum=sum(of &OWLQOL_item_names.);
      num = 6*N_OK - sum;
      range = 6*N_OK;
```

```
      &OWLQOL_score_name = 100 * (num/range);
    end;
  %end;

  /* Code when each OWLQOL item variable has been listed separately as */
  /* OWLQOL_item_names=owlqol1 owlqol2 ... owlqol17                     */
  %else %do;
    if nmiss(%do i=1 %to 16;%scan(&OWLQOL_item_names,&i,%str(
)),%end;%scan(&OWLQOL_item_names,17,%str( ))<=3 then do;
      N_OK = N(%do i=1 %to 16;%scan(&OWLQOL_item_names,&i,%str(
)),%end;%scan(&OWLQOL_item_names,17,%str( )));
      sum=sum(%do i=1 %to 16;%scan(&OWLQOL_item_names,&i,%str(
)),%end;%scan(&OWLQOL_item_names,17,%str( )));
      num = 6*N_OK - sum;
      range = 6*N_OK;
      &OWLQOL_score_name = 100 * (num/range);
    end;
  %end;

  drop N_OK sum num range;
run;

%mend Score_OWLQOL;
```

Weight-Related Symptom Measure

The WRSM is a 20-item, self-report measure for the presence and bothersomeness of symptoms (Figure 7). A subset of 9 items was specifically targeted to patients with diabetes and thus there is an overall WRSM for all obese patients and a WRSM-D specific for obese patients with diabetes. Participants respond either “yes” or “no” as to whether they have experienced the symptom in the previous 4 weeks and then indicate the degree of bothersomeness that having the symptom caused them. The bothersomeness response options are on a 7-point scale and range from 0 (“not at all”) to 6 (“a very great deal”). A total score is calculated by summing the bothersomeness scores for each symptom. Total scores range from 0 to 120 with higher scores indicating a higher or worse symptom burden.

Figure 7. The WRSM symptoms

shortness of breath (D)	**increased irritability** (D)	**foot problems** (D)	**lightheadedness** (D)
tiredness (D)	back pain	sensitivity to heat	**increased sweating** (D)
sleep problems	**frequent urination** (D)	Snoring	loss of sexual desire
sensitivity to cold	pain in the joints	**increased appetite** (D)	decreased physical stamina
increased thirst (D)	water retention	leakage of urine	skin irritation
Response scale: Yes, No (for frequency) and 0=Not at all, 1=Hardly, 2= Somewhat, 3= Moderately, 4=A good deal, 5=A great deal, 6=A very great deal (for bother)			
Note: The WRSM-Diabetes-Related symptoms are indicated with (D) and bolded.			

The following scoring syntax (written in SPSS) can be used to score the WRSM.

```
* OWL-QOL / WRSM Study

* Score Weight-Related Symptom Measure

VAR LABELS
wrsma01 'Freq: Shortness of breath'
wrsma02 'Freq: Tiredness'
wrsma03 'Freq: Sleep problems'
wrsma04 'Freq: Sensitivity to cold'
wrsma05 'Freq: Increased thirst'
wrsma06 'Freq: Increased irritability'
wrsma07 'Freq: Back pain'
wrsma08 'Freq: Frequent urination'
wrsma09 'Freq: Pain in the joints'
wrsma10 'Freq: Water retention'
```

```
wrsma11 'Freq: Foot problems'
wrsma12 'Freq: Sensitivity to heat'
wrsma13 'Freq: Snoring'
wrsma14 'Freq: Increased appetite'
wrsma15 'Freq: Leakage of urine'
wrsma16 'Freq: Lightheadedness'
wrsma17 'Freq: Increased sweating'
wrsma18 'Freq: Loss of sexual desire'
wrsma19 'Freq: Decreased physical stamina'
wrsma20 'Freq: Skin irritation'
wrsmb01 'Both: Shortness of breath'
wrsmb02 'Both: Tiredness'
wrsmb03 'Both: Sleep problems'
wrsmb04 'Both: Sensitivity to cold'
wrsmb05 'Both: Increased thirst'
wrsmb06 'Both: Increased irritability'
wrsmb07 'Both: Back pain'
wrsmb08 'Both: Frequent urination'
wrsmb09 'Both: Pain in the joints'
wrsmb10 'Both: Water retention'
wrsmb11 'Both: Foot problems'
wrsmb12 'Both: Sensitivity to heat'
wrsmb13 'Both: Snoring'
wrsmb14 'Both: Increased appetite'
wrsmb15 'Both: Leakage of urine'
wrsmb16 'Both: Lightheadedness'
wrsmb17 'Both: Increased sweating'
wrsmb18 'Both: Loss of sexual desire'
wrsmb19 'Both: Decreased physical stamina'
wrsmb20 'Both: Skin irritation' .

VALUE LABELS
  wrsma01 wrsma02 wrsma03 wrsma04 wrsma05 wrsma06 wrsma07 wrsma08 wrsma09
  wrsma10 wrsma11 wrsma12 wrsma13 wrsma14 wrsma15 wrsma16 wrsma17 wrsma18
  wrsma19 wrsma20 0 'No' 1 'Yes' /
  wrsmb01 wrsmb02 wrsmb03 wrsmb04 wrsmb05 wrsmb06 wrsmb07 wrsmb08 wrsmb09
  wrsmb10 wrsmb11 wrsmb12 wrsmb13 wrsmb14 wrsmb15 wrsmb16 wrsmb17 wrsmb18
  wrsmb19 wrsmb20 0 'Not at all' 1 'Hardly' 2 'Somewhat' 3 'Moderately'
                  4 'A good deal' 5 'A great deal' 6 'A very great deal' .

**** Count number of missing responses ****

COUNT wrsmfc=wrsma01 wrsma02 wrsma03 wrsma04 wrsma05 wrsma06 wrsma07 wrsma08
             wrsma09 wrsma10 wrsma11 wrsma12 wrsma13 wrsma14 wrsma15 wrsma16
             wrsma17 wrsma18 wrsma19 wrsma20 (MISSING).

**** Compute total number of symptoms ****

COUNT wrsmf=wrsma01 wrsma02 wrsma03 wrsma04 wrsma05 wrsma06 wrsma07 wrsma08
            wrsma09 wrsma10 wrsma11 wrsma12 wrsma13 wrsma14 wrsma15 wrsma16
            wrsma17 wrsma18 wrsma19 wrsma20 (1.00).
```

```
**** Score Symptom Bothersomeness ****

* Setting Bothersomeness score to 0 if patient indicates not having symptom

DO IF (wrsma01 = 0) .
RECODE wrsmb01  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma02 = 0) .
RECODE wrsmb02  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma03 = 0) .
RECODE wrsmb03  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma04 = 0) .
RECODE wrsmb04  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma05 = 0) .
RECODE wrsmb05  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma06 = 0) .
RECODE wrsmb06  (MISSING=0)  .
END IF .
EXECUTE .
```

```
DO IF (wrsma07 = 0) .
RECODE wrsmb07  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma08 = 0) .
RECODE wrsmb08  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma09 = 0) .
RECODE wrsmb09  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma10 = 0) .
RECODE wrsmb10  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma11 = 0) .
RECODE wrsmb11  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma12 = 0) .
RECODE wrsmb12  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma13 = 0) .
RECODE wrsmb13  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma14 = 0) .
RECODE wrsmb14  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma15 = 0) .
RECODE wrsmb15  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma16 = 0) .
RECODE wrsmb16  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma17 = 0) .
RECODE wrsmb17  (MISSING=0)  .
END IF .
EXECUTE .
```

```
DO IF (wrsma18 = 0) .
RECODE wrsmb18  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma19 = 0) .
RECODE wrsmb19  (MISSING=0)  .
END IF .
EXECUTE .

DO IF (wrsma20 = 0) .
RECODE wrsmb20  (MISSING=0)  .
END IF .
EXECUTE .

* Computing Bothersomeness Score by summing symptom response values
(higher=worse)

COMPUTE
wrsmb=wrsmb01+wrsmb02+wrsmb03+wrsmb04+wrsmb05+wrsmb06+wrsmb07+wrsmb08+wrsmb09+
      wrsmb10+wrsmb11+wrsmb12+wrsmb13+wrsmb14+wrsmb15+wrsmb16+wrsmb17+wrsmb18+
      wrsmb19+wrsmb20.
EXECUTE .


VARIABLE LABEL
wrsmf 'WRSM: Obesity Symptom Count'
wrsmb 'WRSM: Obesity Symptom Bothersomeness'
wrsmfc 'WRSM: Count of missing items' .
EXECUTE .
```

Scoring Exercise and Test Dataset for the OWLQOL and WRSM Instruments

A computer diskette with the necessary code for scoring algorithms and a test dataset are included with the manual for use in computing OWLQOL and WRSM scores and for checking accuracy of computations done in other statistical programs.

The following files are included on the diskette:

- owlqol.dat — ASCII (fixed format) text file consisting of data from 100 cases of the OWLQOL and WRSM
- owlqol,sps — SPSS syntax code containing scoring algorithms for obtaining summary scores for the OWLQOL and WRSM. This code can also be seen above.
- owlqol data list.txt — Format description of the "owlqol.dat" data file

The following table presents statistics for the transformed scores for the OWLQOL and WRSM. After scoring the test dataset, the means, standard deviations, and minimum and maximum observed values should agree with the values seen here.

Table 6: Descriptive statistics for the OWLQOL/WRSM test dataset

	N	Minimum	Maximum	Mean	Std. Deviation
OWLQOL 17: Number of missing items	100	.00	1.00	.0100	.10000
OWLQOL 17: Summation of all items	99	5.00	101.00	58.9394	22.38933
OWLQOL 17 Total Score	100	4.90	99.02	57.3934	22.18527
WRSM: Count of missing items	100	.00	1.00	.0100	.10000
WRSM: Obesity Symptom Count	100	.00	18.00	8.6200	4.25638
WRSM: Obesity Symptom Bothersomeness	100	.00	84.00	28.6600	19.14971

Interpretation

Interpretation of the OWLQOL and WRSM results is forthcoming.

Administration Guidelines

Self-Administration Guidelines

The OWLQOL is contained in Appendix A and the WRSM in Appendix B. They were designed for self-administration. The OWLQOL 17-item version takes approximately 5 minutes to complete and the WRSM about 2 minutes. No specific training is required to complete this instrument since the instructions are self-explanatory. No difficulties have been reported among the various respondent groups who have assisted with the preliminary testing and who have participated in the clinical trials that included this measure. The consistently small amounts of missing data (less than 5%) attest to the acceptability of this measure to patients.

Additional factors that should be considered when administering the OWLQOL include:

- Participants should be instructed to complete the OWLQOL in a quiet place away from the influence of others.

- Educational level should be considered before self-completion. This can be done by asking persons what grade level they have completed or by administering a short reading comprehension test. Persons with low literacy or diverse language skills should always be provided interviewer assistance.

- Supervisors who provide the questionnaires to the participants should be trained to not introduce bias. For example, they should encourage respondents to provide one answer (response choice) for each question according to how they, the participants, think and feel. Great care should be taken to avoid messages (verbal or otherwise) that might persuade participants to answer questions according to any bias (the supervisors', their family's, or society's).

The OWLQOL and WRSM were designed to complete a full battery of patient-reported outcomes employing different concepts and different types of patient-reported outcome

measures, including obesity-specific symptoms and QOL, general functional status and well-being, person-specific preference measurement, and disability days. By using these measures, investigators can address the experience of being overweight and obese and of weight loss on a broad spectrum of issues important to patients, their families, clinicians, regulators, payers, and society in general.

Recommendations for Future Use

The OWLQOL is a disease-specific instrument designed to measure the impacts of obesity and weight loss on quality-of-life. While the majority of the participants were female, this measure was developed for use with both male and female patients having body mass indices of 27 and above (27-30 with comorbidities). The OWLQOL consists of 17 items (see Appendix A) all of which are rated on a response scale with seven categories: (0 = 'Not at all' to 6 = 'A very great deal'). All items are summed to calculate a total OWLQOL score. To facilitate interpretations of scores, the summed total score is transformed to a 0-100 scale ranging from 0 (poor quality of life) to 100 (maximum quality of life) (See Scoring Section in this manual for specific instructions) with a high score indicating a better quality of life.

These features of the OWLQOL make it an appropriate tool for assessing the affects of treatment, treatment decision-making among providers and patients, and for conducting cross-cultural comparisons. The OWLQOL is ideal for multinational clinical trials because it has a low patient burden and has multiple language adaptations. Published effect size and validity statistics are available.

Because clinical measures do not reflect a person's perspective on his or her weight condition, the inclusion of quality of life measures in clinical trials is important to give meaning to outcomes more distal to physical findings. Instruments such as the OWLQOL, however, do not permit comparisons across different diseases because they are designed to detect minimally important effects of the condition rather than provide broad comparison. For this purpose, investigators are advised to use these instruments alongside generic measures.

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Appendix A: The OWLQOL

Your Health
– *and* –
Well-Being

Obesity and Weight-Loss Quality-of-Life Instrument (OWLQOL)

This survey asks for your views about your health and your weight.

Thank you for completing these questions!

Instructions for the completion of the quality-of-life questionnaires by study participants

1) These questionnaires are an important part of your overall medical evaluation. The questions are designed to collect information about how your health has affected your quality of life from your own point of view.

2) Complete the questionnaire using a ballpoint pen. Press firmly and print neatly when writing to ensure that the copies are clear and legible.

3) Please take the time to read and answer each question carefully. Some questions may look like others, but each one is different.

4) Please answer every question by marking an ☒ in the box that best describes your answer. You may change an answer by placing a line (☒) through the selection you wish to change and marking an ☒ in the box corresponding to the new choice.

5) There are no right or wrong answers. If you are unsure about how to answer a question, please give the best answer you can.

6) Your answers are confidential. The study coordinator will check for completeness only and not share your answers with other clinical staff.

Your Feelings About Your Weight

Below is a list of statements about your quality of life in relation to being overweight and trying to lose weight.

For each of the following statements, please mark an ☒ in the <u>one</u> box that best describes your answer <u>at this time</u>.

	NOT AT ALL	HARDLY	SOME-WHAT	MODER-ATELY	A GOOD DEAL	A GREAT DEAL	A VERY GREAT DEAL
1. Because of my weight, I try to wear clothes that hide my shape (*Please check one*)	☐0	☐1	☐2	☐3	☐4	☐5	☐6
2. I feel frustrated that I have less energy because of my weight (*Please check one*)	☐0	☐1	☐2	☐3	☐4	☐5	☐6
3. I feel guilty when I eat because of my weight (*Please check one*)	☐0	☐1	☐2	☐3	☐4	☐5	☐6
4. I am bothered about what other people say about my weight (*Please check one*)	☐0	☐1	☐2	☐3	☐4	☐5	☐6
5. Because of my weight, I try to avoid having my photograph taken (*Please check one*)	☐0	☐1	☐2	☐3	☐4	☐5	☐6
6. Because of my weight, I have to pay close attention to personal hygiene (*Please check one*)	☐0	☐1	☐2	☐3	☐4	☐5	☐6
7. My weight prevents me from doing what I want to do (*Please check one*)	☐0	☐1	☐2	☐3	☐4	☐5	☐6
8. I worry about the physical stress that my weight puts on my body (*Please check one*)	☐0	☐1	☐2	☐3	☐4	☐5	☐6

(*Please turn the page*)

(continued)…

	NOT AT ALL	HARDLY	SOME-WHAT	MODER-ATELY	A GOOD DEAL	A GREAT DEAL	A VERY GREAT DEAL
9. I feel frustrated that I am not able to eat what others do because of my weight (*Please check one*)	☐**0**	☐**1**	☐**2**	☐**3**	☐**4**	☐**5**	☐**6**
10. I feel depressed because of my weight (*Please check one*)	☐**0**	☐**1**	☐**2**	☐**3**	☐**4**	☐**5**	☐**6**
11. I feel ugly because of my weight (*Please check one*)	☐**0**	☐**1**	☐**2**	☐**3**	☐**4**	☐**5**	☐**6**
12. I worry about the future because of my weight (*Please check one*)	☐**0**	☐**1**	☐**2**	☐**3**	☐**4**	☐**5**	☐**6**
13. I envy people who are thin (*Please check one*)	☐**0**	☐**1**	☐**2**	☐**3**	☐**4**	☐**5**	☐**6**
14. I feel that people stare at me because of my weight (*Please check one*)	☐**0**	☐**1**	☐**2**	☐**3**	☐**4**	☐**5**	☐**6**
15. I have difficulty accepting my body because of my weight (*Please check one*)	☐**0**	☐**1**	☐**2**	☐**3**	☐**4**	☐**5**	☐**6**
16. I am afraid that I will gain back any weight that I lose (*Please check one*)	☐**0**	☐**1**	☐**2**	☐**3**	☐**4**	☐**5**	☐**6**
17. I get discouraged when I try to lose weight (*Please check one*)	☐**0**	☐**1**	☐**2**	☐**3**	☐**4**	☐**5**	☐**6**

Please go back to the questions you just answered to make sure you did not miss any items

Thank you for completing these questions!

Appendix B: The WRSM

Your Health
– and –
Well-Being

Weight-Related Symptom Measure (WRSM)

This survey asks for your views about your health and your weight.

Thank you for completing these questions!

Instructions for the completion of the quality-of-life questionnaires by study participants

1) These questionnaires are an important part of your overall medical evaluation. The questions are designed to collect information about how your health has affected your quality of life from your own point of view.

2) Complete the questionnaire using a ballpoint pen. Press firmly and print neatly when writing to ensure that the copies are clear and legible.

3) Please take the time to read and answer each question carefully. Some questions may look like others, but each one is different.

4) Please answer every question by marking an ☒ in the box that best describes your answer. You may change an answer by placing a line (☒) through the selection you wish to change and marking an ☒ in the box corresponding to the new choice.

5) There are no right or wrong answers. If you are unsure about how to answer a question, please give the best answer you can.

6) Your answers are confidential. The study coordinator will check for completeness only and not share your answers with other clinical staff.

Weight-Related Symptoms and How Much They Bother You

For each of the following questions, read the list of symptoms below, and mark an ☒ in the one box that best describes your answer.

a. <u>In the past 4 weeks</u>, did you have the following symptoms?			**b. If Yes, how much did these symptoms bother you?**						
No	Yes	SYMPTOMS	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
☐0	☐1	Shortness of breath	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Tiredness	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Sleep problems	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Sensitivity to cold	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Increased thirst	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Increased irritability	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Back pain	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Frequent urination	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Pain in the joints (hips, knees, etc.)	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Water retention	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Foot problems	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Sensitivity to heat	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Snoring	☐0	☐1	☐2	☐3	☐4	☐5	☐6

(Please turn the page)

(Continued…)

a. In the past 4 weeks, did you have the following symptoms?			b. If Yes, how much did these symptoms bother you?						
No	Yes	SYMPTOMS	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
☐0	☐1	Increased appetite	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Leakage of urine	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Lightheadedness	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Increased sweating	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Loss of sexual desire	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Decreased physical stamina	☐0	☐1	☐2	☐3	☐4	☐5	☐6
☐0	☐1	Skin irritation	☐0	☐1	☐2	☐3	☐4	☐5	☐6

Please go back to the questions you just answered to make sure you did not miss any items.

Thank you for completing these questions!