# Psychometric Evaluation of Two Obesity and Weight-Loss Quality-of-Life Instruments: The OWLQOL and WRSM

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## ABSTRACT

The objective of this study was to report U.S. validation of two measures specific to obesity and weight loss: the Obesity and Weight-Loss Quality-of-Life Instrument (OWLQOL) and Weight-Related Symptom Measure (WRSM), including measurement model, psychometric properties and burden. Two groups were recruited: 160 obese enrollees in diet, exercise, and health programs, and 180 obese non-enrollees from the general public. Respondents had a body mass index (BMI) of 27 through 50 and were between the ages of 18 and 75. All completed the OWLQOL, the WRSM, the SF-36, the CES-D (depression), the Perceived QOL scale, and standard demographic items at baseline, 1 week (for test/retest of OWLQOL and WRSM), and again at 12 weeks (for responsiveness based on weight loss and global rating of change). Psychometric testing followed standardized procedures. 340 patients completed baseline assessments: 60.0% female, 77.9% white, and 50.3 married. The overall OWLQOL score was internally consistent (alpha=0.96) and reproducible (ICC=0.90). As predicted, OWLQOL scores had stronger associations with the SF-36 vitality subscale (0.54), the more generic quality of life scale (PQOL, 0.54), weight-related symptom bothersomeness (0.53), and depressive symptomotology (CES-D, 0.49) than the SF-36 physical function subscale (0.40). The overall WRSM was also internally consistent (0.87) and reproducible (0.83). OWLQOL scores were able to discriminate between levels of BMI, levels of symptoms, levels of depressive symptomatology (CES-D), and gender. The total sample (irregardless of being in a program) was evaluated for responsiveness at 12 weeks. Effect size for 2.5% or greater decrease in the patients' weight were 0.76 for the OWLQOL, 0.54 for the WRSM, and ranged from 0.20-0.60 for the eight subscales of the SF-36. In this stand-alone study, the OWLQOL and WRSM proved valid, reproducible, and responsive to weight-loss and global rating of change.

## INTRODUCTION

- Studies evaluating the impact of obesity on health-related quality of life (HRQOL) are in general agreement that increasing body mass index (BMI) has a negative effect.[1]
- Fontaine et al.[2] demonstrated a notable difference in the distress levels of obese patients who were seeking treatment to help them lose weight. This finding suggests that two very different aspects of condition-specific QOL should be addressed in the qualitative data collection supporting development of an obesity-specific QOL measure:
  – those with sufficient QOL impacts to cause obese persons to try and lose weight and to seek treatment to help them change their situation
  – impacts of being obese on general QOL
- The overall aim of this study was to assess the measurement model, internal consistency, test-retest reliability, reproducibility, construct validity, responsiveness (longitudinal validity), and respondent burden of a new obesity-specific QOL measure (OWLQOL) and weight-related symptom measure (WRSM).

## MATERIAL AND METHODS

### Subject Inclusion Criteria

- Informed consent
- 18-65 years of age
- BMI of 30-40 kg/m² or a BMI of 27-29.9 kg/m² with a diagnosis of hypertension, hypercholesterolemia, and/or type 2 diabetes
- Weight stable for at least 3 months prior to enrollment (varying no more than 4 kg)

### Study Procedures

- Baseline visit:
  – informed consent
  – baseline assessments
  – measurement of height and weight, blood pressure, waist and hip measurement
- 1-week retest
- 6- and 12-week visits:
  – reassessment
  – measurement of height and weight, blood pressure, waist and hip measurement

## Measures*

- **Obesity and Weight-Loss Quality-of-Life (OWLQOL):** population-specific measure that addresses the QOL impacts of obesity and of trying to lose weight. It has 33 items with a 7-point response scale that ranges from 0 "not at all" to 6 "a very great deal" (Table 1). The OWLQOL has a single summative score and four domain subscale scores transformed to a 0-100 scale, with higher scores indicating better obesity-specific QOL.

### Table 1. OWLQOL Questionnaire

| | | |
|---|---|---|
| 1 | SI: | Because of my weight, I try to wear clothes that hide my shape |
| 2 | PH: | I feel frustrated that I have less energy because of my weight |
| 3 | SI: | I feel guilty when I eat because of my weight |
| 4 | SS: | I feel embarrassed about needing more room than others because of my weight |
| 5 | SS: | I am bothered by what other people say about my weight |
| 6 | SS: | I am embarrassed about moving more slowly than others because of my weight |
| 7 | SI: | Because of my weight, I get frustrated trying to find clothes I look good in |
| 8 | SI: | I worry about the impression others have of me because of my weight |
| 9 | SS: | I feel I am treated differently by others because of my weight |
| 10 | SI: | Because of my weight, I try to avoid being seen in swimwear or shorts |
| 11 | SI: | I dread getting on the scale to weight myself |
| 12 | SS: | Because of my weight, I try to avoid having my photograph taken |
| 13 | SI: | I feel embarrassed eating certain foods in front of others because of my weight |
| 14 | PH: | My weight prevents me from doing what I want to do |
| 15 | PH: | Because of my weight, I have to pay close attention to personal hygiene |
| 16 | SI: | Because of my weight, I am embarrassed to undress in front of others |
| 17 | PH: | I worry about the physical stress that my weight puts on my body |
| 18 | SI: | I avoid having sex because of my weight |
| 19 | SI: | I feel frustrated that I am not able to eat what others do because of my weight |
| 20 | SI: | I feel depressed because of my weight |
| 21 | SS: | I feel left out by others because of my weight |
| 22 | SI: | I feel ugly because of my weight |
| 23 | PH: | I worry about the future because of my weight |
| 24 | SS: | I feel others are ashamed of me because of my weight |
| 25 | LW: | I envy people who are thin |
| 26 | SS: | I worry others think I am lazy because of my weight |
| 27 | SS: | I feel that people stare at me because of my weight |
| 28 | SI: | I have difficulty accepting my body because of my weight |
| 29 | SS: | I feel that others cannot see the real me because of my weight |
| 30 | LW: | I am afraid that I will gain back any weight that I lose |
| 31 | LW: | I am moody when I try to lose weight |
| 32 | LW: | I get discouraged when I try to lose weight |
| 33 | LW: | I need support from others to lose weight |

Subscales: SI=Self-image; SS=Social Stigma; LW=Trying to lose weight; PH=Physical Health

- **The Weight-Related Symptom Measure (WRSM):** newly developed 20-item, patient-based measure for symptom presence and distress (Table 2). Patients respond either "yes" or "no" to whether they have experienced the symptom in the past 4 weeks and then indicate the degree of bothersomeness that having the symptom has caused them on a 0-6 response scale.

### Table 2. WRSM

| | | |
|---|---|---|
| Shortness of breath | Frequent urination | Leakage of urine |
| Tiredness | Pain in the joints (hips, knees, etc.) | Lightheadedness |
| Sleep problems | Water retention | Increased sweating |
| Sensitivity to cold | Foot problems | Loss of sexual desire |
| Increased thirst | Sensitivity to heat | Decreased physical stamina |
| Increased irritability | Snoring | Skin irritation |
| Back pain | Increased appetite | |

* The OWLQOL and WRSM must not be reproduced or utilized in any manner without prior approval. Requests for permission to utilize the OWLQOL and WRSM should be sent to: Robert Jones, Pharmaceuticals Group Strategic Marketing, c/o R.W. Johnson Pharmaceutical Research Institute, 920 Route 202, PO Box 300, Raritan, NJ  08869-0602 (phone: 908-704-4051; E-mail: rjones17@prius.jnj.com).

- **Disability Days:** 5-item descriptive measure of self-reported disability and loss of work productivity related to a person's health.[3]
- **Center for Epidemiologic Studies – Depression (CES-D):** 20-item scale designed to screen for major depression in community populations and provide a measure of depressive symptomatology.[4]
- **Psychological General Well-being Index:** assessment tool for psychological well-being.[5]
- **Medical Outcomes Study Short Form (SF-36):** 36-item generic measure of functional status and well-being which is used in clinical practice, clinical trials, and research in general population surveys.[6]
- **Patients Global Rating of Change (PGRC):** 2-item measure with a 15-point rating of change in QOL because of weight, ranging from "a very great deal better" to "a very great deal worse."

### Measurement Model and Scoring

- A hypothesized domain structure was developed a priori based on the literature and patient interviews. Principal Components Analyses and Rasch Analyses suggested four domains with an overall score. The four domain and overall scores for the OWLQOL were obtained by summing the scores of the individual items (response scale values) and transforming each score as follows:

$$\text{Scale Score} = \frac{\text{the sum of the items–lowest possible score}}{\text{possible raw score range}} * 100$$

### Psychometric Analysis

- Item reduction statistics assessed for the OWLQOL included:
  – items with greater than 5% missing data
  – items that demonstrated a ceiling effect (more than 50% of respondents selecting the "not at all" response option, which would suggest a high degree of "non-relevance")
  – an item-to-total correlation lower than 0.40 (suggesting the item may measure something belonging to a different scale)
  – an item-to-item correlation of greater than 0.70 (indicating redundancy among the individual items)

### Descriptive Analysis

- Standard descriptive statistics were carried out for all measures and subscales.
- Mean, standard deviations, median, and percentage of missing data were computed for each item. Histograms and box plots were used to determine if the sample was normally distributed.

### Internal Consistency

- Cronbach's alpha was used to assess internal consistency reliability.

### Reliability

- Reproducibility (test/retest reliability) was ascertained using the intraclass correlation coefficient (ICC) to evaluate the relationship between the baseline and 1-week measures.

### Validity

- Convergent validity involved comparing the OWLQOL to logically related measures (i.e., vitality from the SF-36 and general QOL from the perceived QOL).
- Discriminant validity was evaluated by testing various hypotheses about how the OWLQOL should perform in relation to other marker variables, such as disease severity, age, and comorbidity.

### Responsiveness and Interpretation of Change

- Responsiveness (or sensitivity to change) was interpreted in terms of minimally important differences in body weight (i.e., a decrease of 2.5% or more) and PGRC (ranging from minimal to greatest change).
- Responsiveness to change was assessed by calculation of change in OWLQOL scores from baseline to 12 weeks. This was done using three different statistics:
  – effect size – mean change score divided by the standard deviation of baseline scores

- standardized response mean – mean change score divided by the standard deviation of the change score
- responsiveness statistic – mean change in score divided by the standard deviation of the mean change scores for the stable group
- Higher values for the effect size, standardized response mean, and responsiveness statistic indicate a greater sensitivity to change.

## RESULTS

### Subjects Enrolled

- Baseline characteristics for subjects enrolled are summarized in Table 3.

### Table 3. Summary of Subject Characteristics (n=340)

| Characteristic | | n (%) |
|---|---|---|
| Age [mean (SD): 45.4 (11.6)] | <45 | 157 (46.2) |
| | ≥45 | 183 (53.8) |
| Gender | Male | 136 (40.0) |
| | Female | 204 (60.0) |
| Ethnicity | White | 265 (77.9) |
| | Non-white | 75 (22.1) |
| Marital Status | Married | 171 (50.3) |
| | Not married | 169 (49.7) |
| Income | ↓ 15,000 | 56 (16.5) |
| | ↑ 15,000 | 282 (82.9) |
| | Missing | 2 (0.6) |
| Education | ≤High School | 75 (22.1) |
| | >High School | 265 (77.9) |

### Internal Consistency and Reliability

- The overall OWLQOL summary score (n=340) showed high internal consistency (α=0.96), indicating that the 33 items could be summed to form a composite score.
- The ICC (n=50) assessing reproducibility at 1 week was 0.90 for the OWLQOL total score and above 0.80 for all subscales (Table 4). The ICC for symptom bothersomeness was 0.83.

### Table 4. Cronbach's Alpha and ICC for OWLQOL and Subscales

| | OWL QOL-33 | Self-Image | Social Stigma | Trying to Lose Weight | Physical Health |
|---|---|---|---|---|---|
| Cronbach's Alpha | 0.96 | 0.95 | 0.93 | 0.82 | 0.85 |
| ICC | 0.90 | 0.92 | 0.85 | 0.88 | 0.90 |

### Validity

- Correlations between the OWLQOL total scores and the subscales of the SF-36 ranged between 0.35 and 0.54.
- OWLQOL scores were found to be more closely related to vitality (0.54) and social functioning (0.54) and WRSM scores were found to be more closely related to bodily pain (0.59) and physical functioning (0.58)

### OWLQOL and WRSM Scores

- Total scores for the OWLQOL subscale scores and WRSM bothersomeness scores are shown in Figure 1. Scores are generally higher (indicating better QOL) for males than for females on the OWLQOL and lower on the WRSM.
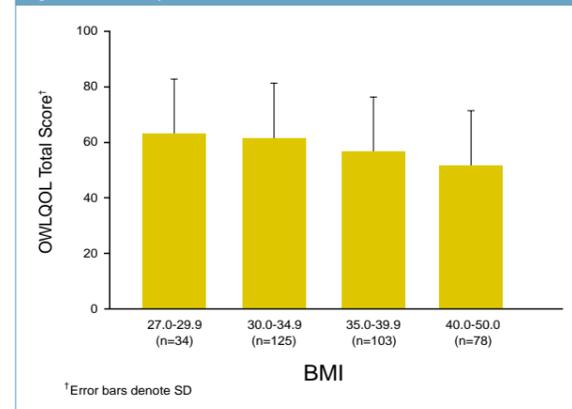
### Figure 1. OWLQOL and WRSM Scores



†Error bars denote SD
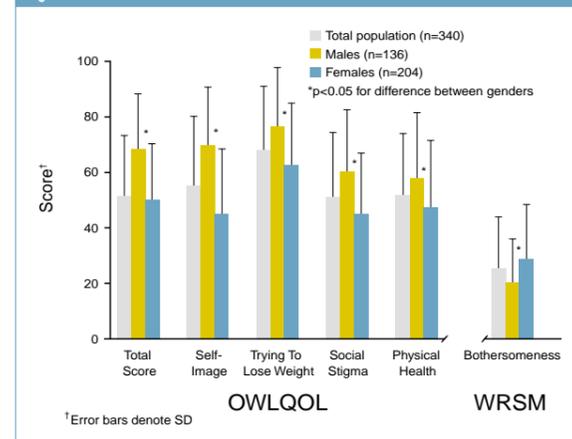
### Relationship Between OWLQOL and WRSM Scores, BMI, Disability Days, and CES-D

- There was a significant inverse relationship between OWLQOL total score and BMI (p<0.01, Figure 2) as well as significant inverse relationships between BMI and the social stigma (p<0.01) and physical health (p<0.001) subscales of the OWLQOL.
- Disability days was significantly related with lower OWLQOL total score, lower scores on all subscales, and higher WRSM bothersomeness (all p≤0.01).
- Higher CES-D scores were significantly related with lower OWLQOL total score, lower scores on all subscales, and higher WRSM bothersomeness (all p<0.001).

### Figure 2. Relationship Between BMI and OWLQOL Total Score



†Error bars denote SD

### Responsiveness of OWLQOL

- Changes in OWLQOL and WRSM over the 12-week study reflected both weight change (Figure 3) and PGRC (Figure 4).

### Figure 3. Relationship Between Changes in OWLQOL Total Score, WRSM Score, and Weight Change Over 12 Weeks
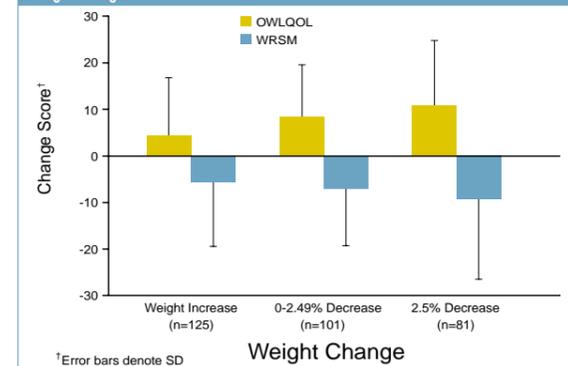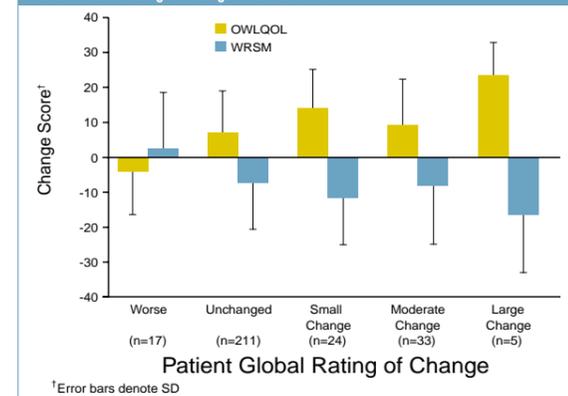


†Error bars denote SD

### Figure 4. Relationship Between Changes in OWLQOL Total Score, WRSM Score, and Patient Global Rating of Change Over 12 Weeks



†Error bars denote SD

## CONCLUSIONS

- In this validation study, the OWLQOL and WRSM met established criteria for measurement model, reliability, validity, and responsiveness. Both measures are easily self-administered with minimal missing data. These weight-related QOL measures are ready for use in clinical trials:
  – valid, reproducible, responsive to weight-loss and global rating of change.
- Completion of WRSM took an average of 2 minutes and OWLQOL took approximately 5 minutes.

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