Validation of a New Measure of Quality of Life in Obesity Trials: IWQOL-Lite Clinical Trials Version

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Background

• Reliability and validity of the IWQOL-Lite and patient functioning in important domains were assessed using a 6-month follow-up for weight loss trials (Study 1) and a 12-month follow-up for weight maintenance trials (Study 2). Patients' IWQOL-Lite and functioning in maintenance of stable weight were assessed.

• Within the IWQOL-Lite was developed using rigorous qualitative research methods and a clinical trial of group-counseling intervention, the current study evaluated the psychometric properties of the IWQOL-Lite for weight loss and weight maintenance trials.

• For the second trial, results in change in weight and BMI and the IWQOL-Lite composite scores were evaluated.

Objective

The objective of this study was to validate the IWQOL-Lite-CT in its entirety with the FDA patient reported outcomes (PRO) guidance.

Methods

Study Population

• Psychometric analyses of the IWQOL-Lite-CT were conducted in the context of a phase 3a clinical trial (Study 1) and a phase 4, double-blind, placebo-controlled clinical trial of treatment with oral semaglutide (Study 2).

• In Study 1, patients were ≥18 years of age, had a BMI ≥30 kg/m², and were randomly assigned to receive placebo or active treatment for 48 weeks.

• In Study 2, patients were ≥18 years of age, had a BMI ≥30 kg/m², and were randomly assigned to receive placebo or active treatment for 96 weeks.

Analytic Method

• Figure 1 describes the psychometric analysis methods used to evaluate the reliability and validity of each IWQOL-Lite-CT item, with an introduction to the methodology used to evaluate the data and an overview of the results.

• Figure 2 shows the structure of the IWQOL-Lite-CT, with an introduction to the role of the IWQOL-Lite-CT in the analysis of clinical trials.

Results

• A number of key findings emerged from the IWQOL-Lite-CT, including the following: (a) the IWQOL-Lite-CT is a reliable and valid measure of quality of life in obesity trials; (b) the IWQOL-Lite-CT is sensitive to change in weight and BMI; and (c) the IWQOL-Lite-CT is a valid measure of quality of life in obesity trials.

• As a result of these findings, the IWQOL-Lite-CT has been incorporated into the PRO guidance for obesity trials.

• The IWQOL-Lite-CT is recommended for use in obesity trials to assess the impact of weight loss and weight maintenance interventions on quality of life.

• Findings from this study suggest that the IWQOL-Lite-CT is a reliable and valid measure of quality of life in obesity trials, and its use is recommended in future trials.