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Psychometric Evaluation of the Impact of Weight on Quality of Life–Lite Clinical Trials (IWQOL-Lite-CT) Version in Adults Participating in a Pharmacological Clinical Trial for Obesity

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Introduction

The Impact of Weight on Quality of Life-Lite, Clinical Trials version (IWQOL-Lite-CT) is a 20-item, patient-reported measure consisting of 3 composites (Physical, Physical Functioning, and Psychosocial) developed to evaluate weight-related changes in clinical trials among adults with obesity or overweight.

Additional psychometric analysis can help further confirm its reliability, validity, and responsiveness to change in patients with obesity or overweight.

Objective

To evaluate the reliability, validity, and ability to detect change of the IWQOL-Lite-CT.

Method

This analysis used data from 2 clinical trials of glucagon-like peptide 1 receptor agonists lotiglipron (Study 1, NCT05579977), and danuglipron (Study 2, NCT04707313) among adults with obesity.

- Anchor measures included the 36-item Short Form Survey (SF-36), PROMIS Physical Function Custom 13-Item Version, Patient Global Impression of Severity (PGI-S), and Patient Global Impression of Change (PGI-C).
- Reliability:
  - Test-retest reliability was evaluated by estimating intraclass correlation coefficients (ICCs).
  - Internal consistency reliability was determined by using Cronbach alpha coefficient.
- Validity:
  - Known-group validity was evaluated using anchor-based regression analysis where the IWQOL-Lite-CT composite scores were used as the outcome.
  - Convergent validity was determined by examining correlations among IWQOL-Lite-CT composites and relevant outcomes.
- Ability to detect change
  - Applicable anchor measures were used to evaluate the ability to detect change.
- Floor and ceiling effects
  - 15% or more of participants reporting the lowest score (0) or highest score (100) considered indicative of a floor or ceiling effect.

Conclusions

The IWQOL-Lite-CT was found to be reliable, valid, and able to detect change in clinical trial populations of patients with overweight or obesity and is appropriate to evaluate the impact of pharmacological weight loss treatments.

This psychometric evaluation of the IWQOL-Lite-CT provides additional evidence to support the use of this instrument to collect patient perspectives from clinical trials to evaluate functional impacts related to weight management.

Results

Data from 1,015 total participants (Study 1, N=389; Study 2, N=626) were included in this psychometric evaluation

An acceptable test-retest reliability was observed for all composites (i.e., Physical, Physical Function, Psychosocial) of the IWQOL-Lite-CT in both studies (Study 1 and Study 2), with ICCs greater than 0.70.

Table 1. Test-retest reliability: Intraclass Correlation Coefficient (ICC) Estimates of IWQOL-Lite-CT Composites

	STUDY 1	STUDY 2
Number of participants	426[a]	534
Number of observations	819	985
ICC for IWQOL-Lite-CT		
Physical Function composite	0.75	0.77
Physical composite	0.78	0.78
Psychosocial composite	0.81	0.80

a: Analysis included participants during run-in period who may not be randomized.

The IWQOL-Lite-CT Physical, Physical Function, and Psychosocial composites had acceptable internal consistency reliability, with a Cronbach coefficient alpha greater than 0.7 in all analyses.

Table 2. IWQOL-Lite-CT Internal Consistency Reliability Summary

IWQOL-Lite-CT composite	Week	N	Cronbach coefficient alpha (raw)
STUDY 1			
Physical Function	0	394[a]	0.82
	20	299	0.77
Physical	0	394	0.85
	20	299	0.81
Psychosocial	0	394	0.94
	20	299	0.93
STUDY 2			
Physical Function	0	455	0.81
	16	283	0.78
	24	71	0.79
	26	162	0.80
	32	61	0.78
Physical	0	455	0.85
	16	283	0.82
	24	71	0.81
	26	162	0.83
	32	61	0.82
Psychosocial	0	455	0.94
	16	283	0.94
	24	71	0.92

a: Analysis included participants during run-in period who may not be randomized.

Evidence for known-groups validity was supported, with large effect sizes (0.78 to 2.18) for the Physical and Physical Function composites and small-to-medium effect sizes (0.36 to 0.50) for the Psychosocial composite.

These effect sizes represent differences in the composite scores corresponding to a 10-point difference in the corresponding SF-36 domains or between individuals classified as “None” (PGI-S score=0) and “Very severe” (PGI-S score=4) for the PGI-S–based analyses.

Table 3. Known-Group Validity of IWQOL-Lite-CT

Anchor instrument	Domain	Difference	Effect size of the difference	P value
STUDY 1				
PGI-S (none vs. very severe)	Physical Function score	49.11	2.18	<0.0001
PGI-S (none vs. very severe)	Physical score	44.80	2.10	<0.0001
SF-36 Physical Functioning	Physical Function score[a]	17.96	0.80	<0.0001
SF-36 Physical Functioning	Physical score[a]	16.62	0.78	<0.0001
SF-36 Mental Health	Psychosocial score[a]	11.01	0.50	<0.0001
STUDY 2				
SF-36 Physical Functioning	Physical Function score[a]	17.76	0.78	<0.0001
SF-36 Physical Functioning	Physical score[a]	17.12	0.79	<0.0001
SF-36 Mental Health	Psychosocial score[a]	8.06	0.36	<0.0001

Correlations between the composites and corresponding anchor domains provided evidence for convergent validity (nearly all Pearson correlation coefficients ≥0.4).

Table 4. Convergent Validity: Correlations Between Anchor Instrument Score and IWQOL-Lite-CT Physical Function and Physical Composite Scores

Anchor instruments	Week	Correlation with Physical Function composite	Correlation with Physical composite
STUDY 1			
PGI-S (physical limitations)	0	-0.63	-0.63
	20	-0.51	-0.48
SF-36 Physical Functioning domain	0	0.69	0.69
	20	0.75	0.73
SF-36 Physical Component Summary	0	0.72	0.74
	20	0.71	0.73
PROMIS Physical Function	0	0.78	0.79
	20	0.75	0.73
STUDY 2			
SF-36 Physical Functioning domain	0	0.75	0.76
	16	0.68	0.69
	24	0.73	0.73
	26	0.74	0.75
	32	0.76	0.80
SF-36 Physical Component Summary	0	0.71	0.75
	16	0.68	0.71
	24	0.73	0.77
	26	0.71	0.73
	32	0.79	0.83
PROMIS Physical Function	0	0.79	0.80
	16	0.75	0.75
	24	0.81	0.80
	26	0.79	0.77
	32	0.81	0.80

Evidence for the ability of the IWQOL-Lite-CT to detect change was supported by the relationship between changes in the IWQOL-Lite CT composite scores corresponding to 10-point improvements in the corresponding SF-36 domain.

With medium effect sizes (0.45 to 0.50) for the Physical and Physical Function composites and small-to-medium effect sizes (0.24 to 0.34) for the Psychosocial composite.

Table 5. Relationship of Improvement in SF-36 Domain With the Improvements in IWQOL-Lite-CT Composites

10-Point improvement in SF-36 domain (anchor)	IWQOL-Lite-CT composite (outcome)	Improvement in IWQOL-Lite-CT score[a] Effect size of the change P value	
		STUDY 1 (n=298)	STUDY 2 (n=284)
Physical Functioning	Physical Function	10.14 0.45 (medium) <0.0001	11.14 0.49 (medium) <0.0001
Physical Functioning	Physical	9.84 0.46 (medium) <0.0001	10.78 0.5 (medium) <0.0001
Mental Health	Psychosocial	7.59 0.34 (small-to-medium) <0.0001	5.25 0.24 (small-to-medium) <0.0001

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Conflict of Interest

RLK receives royalties for the IWQOL-Lite-CT from Duke University and has previously received consulting fees from Pfizer Inc. AGB, NLP, XL, JCC, JTS, CB and SC are employees of Pfizer and may hold shares and/or stock options in the company. SM is a full-time employee of RTI Health Solutions, an independent nonprofit research organization.

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