Changes in BMI are associated with changes in physical functioning as measured by IWQOL-Lite-CT and SF-36 in individuals with obesity: results from the SCALE IBT trial

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Introduction

- Physical functioning (PF) is an important aspect of health-related quality of life in obesity. It can be assessed via self-reporting using either obesity-specific patient-reported outcome measures or generic measures.
- The Impact of Weight on Quality of Life-Lite Clinical Trial version (IWQOL-Lite-CT) is a recently developed and validated version of the existing IWQOL-Lite questionnaire, an obesity-specific measure.[1] In contrast, the Short Form-36v2® Health Survey, Acute Version (SF-36) is a widely used and recognized generic measure that has been validated extensively in different populations.[2]
- Thus far, no study has examined the ability of these two measures to detect PF changes in individuals with obesity.
- In this study, self-reported PF was assessed using both the IWQOL-Lite-CT and the SF-36 in individuals with obesity participating in a weight-loss trial.[3] We examined the associations between the PF scores captured with each measure, and the associations between PF scores and body mass index (BMI).

Methods

- This study used data from individuals in the USA enrolled in the SCALE IBT trial (NCT02963935), a 56-week, phase 3b, double-blind, randomized controlled trial investigating the efficacy and safety of liraglutide 3.0 mg versus placebo as adjunct to intensive behaviour therapy (IBT) in individuals with obesity (BMI ≥ 30 kg/m^2).[3]
  - All study participants received IBT, which consisted of a weight-based reduction in calorie intake, increased physical activity (with a maximum target of 250 minutes per week), and 23 counselling sessions.
- Participants completed both questionnaires in English at baseline and at week 56.
- The IWQOL-Lite-CT PF scale consists of five items (**Table 1**). The range for the PF score is 0–100, with higher scores indicating better PF.[1]
- The SF-36 PF scale consists of ten items (**Table 1**). The scale was calibrated in a US population in 2009. The score range is 19.3–57.5, with higher scores indicating better PF.[2] The expected score for the general population is 50.

Table 1 IWQOL-Lite-CT PF items and SF-36 PF items

IWQOL-Lite-CT PF items	SF-36 PF items
• Trouble bending over	• Vigorous activities
• Get tired/winded	• Moderate activities
• Unable to stand comfortably	• Lift or carry groceries
• Not physically active	• Climb several flights of stairs
• Unable to walk far/quickly	• Climb one flight of stairs
	• Bend/kneel
	• Walk a mile
	• Walk one hundred yards
	• Walk several hundred yards
	• Bathe/dress yourself

Response choices for the IWQOL-Lite-CT are: never; rarely; sometimes; usually; always; or not at all true; a little true; moderately true; mostly true; completely true

Response choices for the SF-36 are: no, not limited; yes, limited a little; yes, limited a lot

IWQOL-Lite-CT: Impact of Weight on Quality of Life-Lite Clinical Trial version; PF: physical functioning; SF-36: Short Form-36v2® Health Survey, Acute Version

- The data for this analysis were pooled across the liraglutide 3.0 mg and placebo groups.
- Associations between IWQOL-Lite-CT PF score, SF-36 PF score, and BMI were examined using polychoric correlations for ordinal variables.[4] Correlations were calculated for baseline scores and for changes in PF scores and BMI from baseline to week 56.
- The statistical significance of each correlation was assessed by Wald chi-square tests, using SAS version 9.4M5.

Results

- Baseline characteristics for the study population are shown in **Table 2**.
- The mean baseline IWQOL-Lite-CT PF score was 63.1 (standard deviation [SD]: 26.2) and the mean baseline SF-36 PF score was 48.3 (SD: 8.1).

Table 2 Baseline characteristics of individuals included in the study

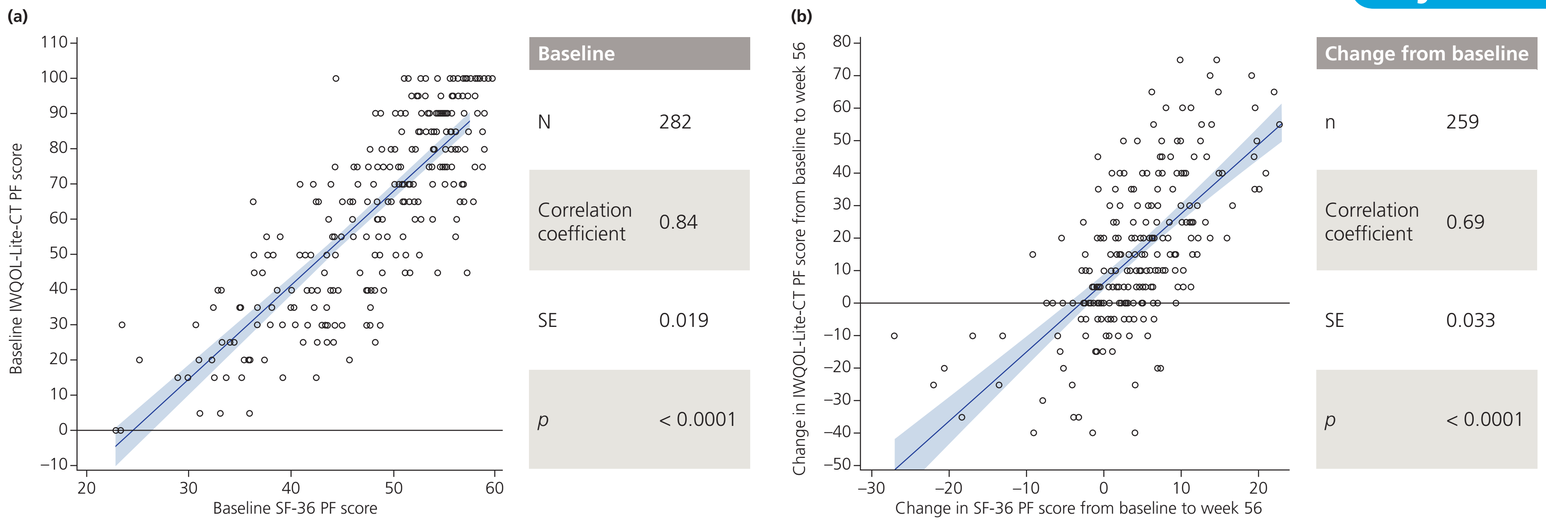
	Study population
Number of individuals, N	282
Sex, % men	16.7
Age, years, mean (SD)	47.2 (11.5)
Body weight, kg, mean (SD)	107.6 (22.0)
BMI, kg/m^2, mean (SD)	39.0 (7.0)
IWQOL-Lite-CT PF score, mean (SD)	63.1 (26.2)
SF-36 PF score, mean (SD)	48.3 (8.1)

Data were from a US population

BMI: body mass index; IWQOL-Lite-CT: Impact of Weight on Quality of Life-Lite Clinical Trial version; PF: physical functioning; SD: standard deviation; SF-36: SF-36v2® Health Survey, Acute Version

Figure 1 Scatter plots for (**a**) baseline SF-36 PF and IWQOL-Lite-CT PF scores and (**b**) changes from baseline to week 56

Key result



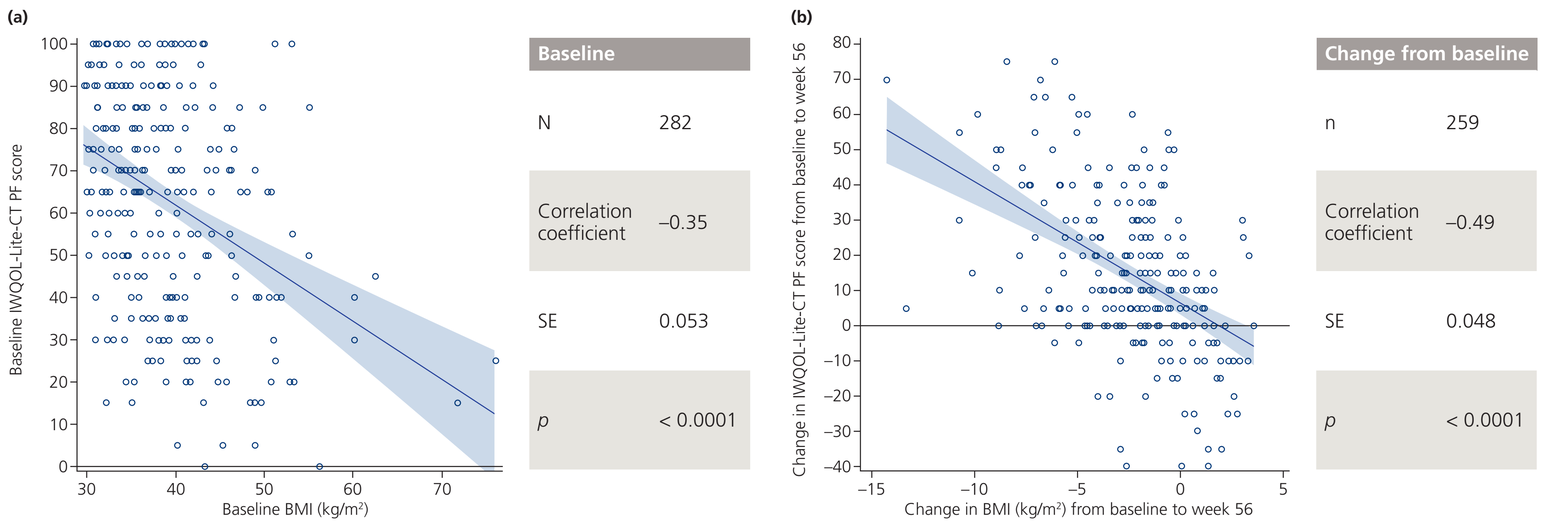
Baseline	
N	282
Correlation coefficient	0.84
SE	0.019
p	< 0.0001

Change from baseline	
n	259
Correlation coefficient	0.69
SE	0.033
p	< 0.0001

Scatter plots show individuals' SF-36 PF and IWQOL-Lite-CT PF scores (baseline and change from baseline), with simple regression lines calculated using these values. Polychoric correlation coefficients, SEs and *p* values were calculated separately. Overlapping points indicate multiple patients with the same score; white noise has been added to the SF-36 scores to allow differentiation between the data points. Regression lines were calculated on actual values

IWQOL-Lite-CT: Impact of Weight on Quality of Life-Lite Clinical Trial version; PF: physical functioning; SE: standard error; SF-36: SF-36v2® Health Survey, Acute Version

Figure 2 Scatter plots for (**a**) baseline BMI and IWQOL-Lite-CT PF scores and (**b**) changes from baseline to week 56



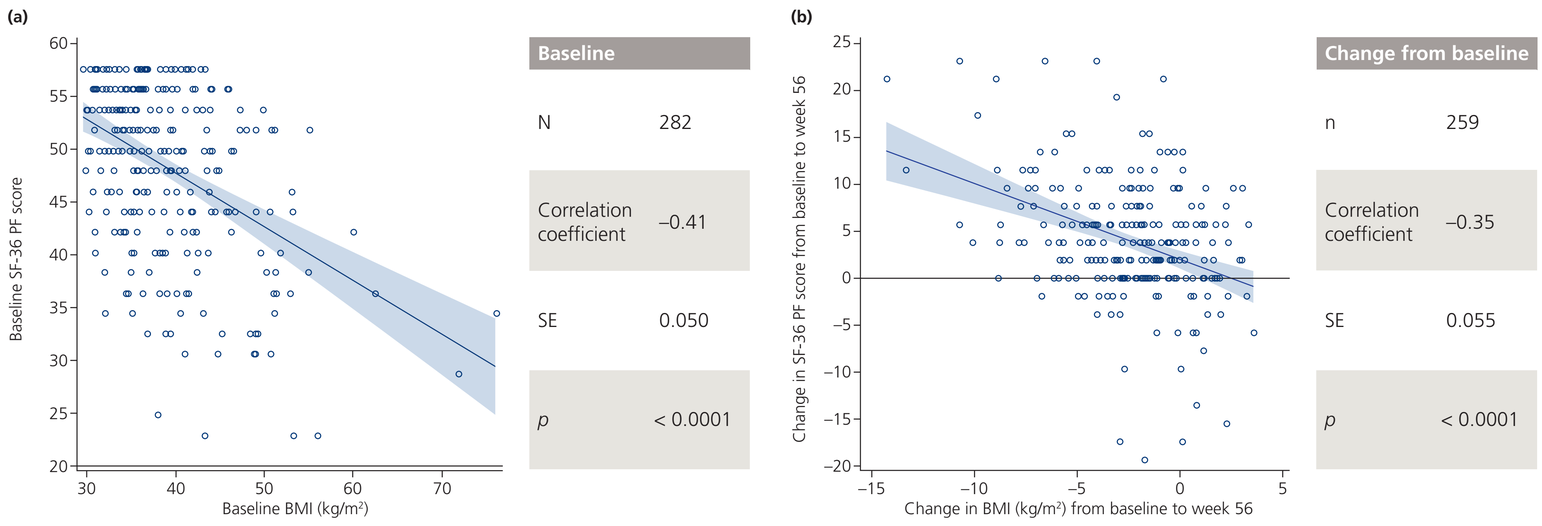
Baseline	
N	282
Correlation coefficient	–0.35
SE	0.053
p	< 0.0001

Change from baseline	
n	259
Correlation coefficient	–0.49
SE	0.048
p	< 0.0001

Scatter plots show individuals' BMI and IWQOL-Lite-CT PF scores (baseline and change from baseline), with simple regression lines calculated using these values. Polychoric correlation coefficients, SEs and *p* values were calculated separately. Overlapping points indicate multiple patients with the same score. Regression lines were calculated on actual values

BMI: body mass index; IWQOL-Lite-CT: Impact of Weight on Quality of Life-Lite Clinical Trial version; PF: physical functioning; SE: standard error

Figure 3 Scatter plots for (**a**) baseline BMI and SF-36 PF scores and (**b**) changes from baseline to week 56



Baseline	
N	282
Correlation coefficient	–0.41
SE	0.050
p	< 0.0001

Change from baseline	
n	259
Correlation coefficient	–0.35
SE	0.055
p	< 0.0001

Scatter plots show individuals' BMI and SF-36 PF scores (baseline and change from baseline), with simple regression lines calculated using these values. Polychoric correlation coefficients, SEs and *p* values were calculated separately. Overlapping points indicate multiple patients with the same score; white noise has been added to the SF-36 scores to allow differentiation between the data points. Regression lines were calculated on actual values

BMI: body mass index; PF: physical functioning; SE: standard error; SF-36: SF-36v2® Health Survey, Acute Version

- In total, 259 individuals finished the study and completed questionnaires at week 56. The liraglutide 3.0 mg and placebo groups displayed similar mean improvements from baseline to week 56 in IWQOL-Lite-CT PF scores and SF-36 PF scores.[5] This supported the approach of pooling the data across treatment groups.
- SF-36 PF and IWQOL-Lite-CT PF scores were strongly correlated at baseline and in terms of change from baseline (**Figure 1**).
- BMI was moderately inversely correlated with IWQOL-Lite-CT PF score at baseline and in terms of change from baseline (**Figure 2**).
- Similarly, BMI was moderately inversely correlated with SF-36 PF score at baseline and in terms of change from baseline (**Figure 3**).
- All correlations were statistically significant ($p < 0.0001$).

Study limitations

- Both the SCALE IBT physical activity programme and participants' weight loss are likely to have contributed to changes in PF in this study, meaning that the PF improvements observed are not solely attributable to reductions in individuals' BMI.
- All individuals included in our study were from the USA, and therefore our findings are most applicable to a non-specialist US setting.

Conclusions

- The correlations between scores on an obesity-specific measure of physical functioning (IWQOL-Lite-CT PF scale) and a generic measure of physical functioning (SF-36 PF scale) at both baseline and 56 weeks suggest that both measures capture a common domain of physical functioning in individuals with obesity.
- Improvements from baseline to week 56 were moderately associated with BMI reduction for both measures, suggesting that both the IWQOL-Lite-CT and the SF-36 may be sensitive to changes in physical functioning related to weight loss.

JBB is an employee of Optum Patient Insights, which distributes the SF-36. Optum Patient Insights performs consulting services for Novo Nordisk A/S outside of the submitted work. PA, LE and LvHS are all employees of Novo Nordisk A/S. RLK has received consulting fees from Novo Nordisk A/S outside of the submitted work. VW has received research funding from Novo Nordisk A/S and other pharmaceutical and biotechnology companies outside of the submitted work.

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References: (**1**) Kolotkin RL et al. Poster presented at Obesity Week, 11–15 November 2018, Nashville, TN, USA; (**2**) Maruish M et al. User's Manual for the SF-36v2 Health Survey, Third edition, 2011; (**3**) Wadden TA et al. Poster SAT-099 presented at ENDO 2019, 23–26 March, New Orleans, LA, USA; (**4**) Drasgow F et al. Polychoric and polyserial correlations. Encyclopedia of Statistical Sciences 9, 2004; (**5**) Wadden TA et al. Oral presentation OS7.02 at the 26th European Congress on Obesity, 28 April–1 May 2019, Glasgow, Scotland, UK