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The effect of weight loss on changes in health-related quality of life among overweight and obese women with urinary incontinence

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Abstract

OBJECTIVE—To estimate the effect of change in weight and change in urinary incontinence (UI) frequency on changes in preference-based measures of health-related quality of life (HRQL) among overweight and obese women with UI participating in a weight loss trial.

METHODS—We conducted a longitudinal cohort analysis of 338 overweight and obese women with UI enrolled in a randomized clinical trial comparing a behavioral weight loss intervention to an educational control condition. At baseline, 6, and 18 months, health utilities were estimated using the Health Utilities Index Mark 3 (HUI3), a transformation of the SF-36 to the preference-based SF-6D, and the estimated Quality of Well-Being (eQWB) score (a summary calculated from the SF-36 physical functioning, mental health, bodily pain, general health perceptions, and role limitations-physical subscale scores). Potential predictors of changes in these outcomes were examined using generalized estimating equations.

RESULTS—In adjusted multivariable models, weight loss was associated with improvement in HUI3, SF-6D, and eQWB at 6 and 18 months ($p < .05$). Increases in physical activity also were independently associated with improvement in HUI3 ($p = .01$) and SF-6D ($p = .006$) scores at 18

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DISCLOSURE

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months. In contrast, reduction in UI frequency did not predict improvements in HRQL at 6 or 18 months.

CONCLUSION—Weight loss and increased physical activity, but not reduction in UI frequency, were strongly associated with improvements in health utilities measured by the HUI3, SF-6D, and eQWB. These findings provide important information that can be used to inform cost-utility analyses of weight loss interventions.

Keywords

quality of life; weight loss; urinary incontinence; HUI; eQWB; SF-6D

Obesity and urinary incontinence (UI) are prevalent and chronic conditions that negatively affect health-related quality of life (HRQL) [1–4]. Among overweight and obese women with UI, weight loss results in reduced prevalence of UI, reduced frequency of incontinent episodes, and/or improvements in UI-specific HRQL [5–10]. Surgical weight loss studies have demonstrated these effects following large weight losses and studies of lifestyle interventions have shown that even modest weight reduction results in UI-related benefits [9]. Typically, weight losses of 5% or more among overweight and obese women with UI are associated with improvements in both incontinence episode frequency and UI-specific HRQL [9].

Large weight loss trials (not specifically targeting incontinence) have shown that weight loss is associated with improvements in obesity-specific and generic HRQL [11–15] although there are inconsistencies across studies and measures. For example, a review of randomized weight loss trials [14] reported variable improvement in HRQL assessed via generic measures such as the Medical Outcomes Study Short Form 36 (SF-36) as well as obesity-specific instruments (e.g., Impact of Weight on Quality of Life (IWQOL) scale) and non-obesity-specific instruments (e.g., Beck Depression Inventory (BDI)). Studies have typically evaluated changes in *non-preference-based* measures of HRQL (such as the SF-36) that assign scores based on the level of functioning in various domains of health. Fewer investigations have reported on *preference-based* measures of HRQL such as the Health Utilities Index (HUI) [16,17], Quality of Well-Being Scale (QWB) [18,19], Short Form 6D [20,21] (SF-6D, derived from the SF-36 [22]), and EuroQol 5D (EQ-5D) [23,24] that also incorporate how health states are valued by patients or the general public. These measures are important because they estimate utilities, which, when combined with life-expectancy estimates, can be used to calculate quality adjusted life years (QALYs) for cost-utility analyses.

In the Diabetes Prevention Program (DPP), a large multisite randomized clinical trial designed to assess the impact of an intensive lifestyle intervention vs. metformin vs. placebo on the development of type 2 diabetes in overweight and obese adults with impaired glucose tolerance, weight loss was independently associated with improvement in health state utilities measured by the SF-6D at 1-year and 2-year follow-up when controlling for potential confounders [25]. Another study evaluating the cost-effectiveness of sibutramine in the treatment of obesity showed that weight loss was associated with utility gains measured by the SF-6D [26]. Finally, using the EQ-5D, Kolotkin and colleagues [27] showed that scores increased with weight loss in a large sample of obese adults (84% women) enrolled in a placebo-controlled weight loss medication trial. These studies suggest that the SF-6D and EQ-5D appear to be sensitive to changes in HRQL associated with weight loss. However, additional research is needed to further examine this relationship in other weight loss treatment seeking samples using other preference-based measures of HRQL.

There is limited information on how weight loss or changes in UI affect preference-based measures of HRQL. Further, for overweight and obese incontinent women, the relative impact of weight loss and reductions in UI frequency on changes in these outcomes is not known. Thus, the purpose of the current study was to examine the effect of change in weight and change in UI frequency on changes in preference-based measures of HRQL (HUI3, SF-6D, and estimated QWB (eQWB)) at 6- and 18-months among overweight and obese women with UI enrolled in a clinical trial of a lifestyle weight loss intervention.

METHODS

Participants

Participants were 338 women recruited from Providence, Rhode Island and Birmingham, Alabama between July 2004 and April 2006 and enrolled in the Program to Reduce Incontinence by Diet and Exercise (PRIDE) randomized clinical trial. A prior report [8] provides characteristics of the study sample and inclusion and exclusion criteria. Briefly, eligible participants were women at least 30 years of age with a BMI of 25–50 kg/m² who reported 10 or more urinary incontinence episodes on a 7-day voiding diary at baseline. Exclusion criteria included use of medical therapy for incontinence or weight loss within the past month, major medical or genitourinary tract conditions, pregnancy or having given birth in the previous 6 months, type 1 or type 2 diabetes requiring medical therapy that increases the risk of hypoglycemia, and uncontrolled hypertension. The study received institutional review board approval at each site and written informed consent was obtained from all participants before enrollment.

Study Design

The PRIDE was an 18-month two-site randomized clinical trial which examined whether a behavioral weight loss intervention for overweight and obese women with incontinence produces greater reductions in frequency of incontinence episodes compared to a control condition at 6- and 18-months. Eligible participants were randomly assigned to receive either a behavioral weight loss intervention (n=226) or a structured education program (Control; n=112). After 6 months, participants in the weight loss intervention were re-randomized to either a skills-based maintenance program (n=113) or a motivation-based approach (n=113) for an additional 12 months.

Interventions

Structured education program (control group)—The control group included 7 one-hour group education sessions at months 1, 2, 3, 4, 6, 9, and 15. Sessions provided general information about weight loss, physical activity, and healthy eating and followed a structured protocol.

Behavioral weight loss program—Participants randomized to the behavioral weight loss program met in groups of 10 to 15 for 1-hour sessions weekly for six months and every other week for 12 months.[8] Groups followed a structured protocol and were modeled after the programs used in the DPP [28] and Look AHEAD (Action for Health in Diabetes) [29,30]. Participants were instructed to follow a calorie and fat restricted diet of 1200 to 1800 kcal per day (depending on initial weight), and to consume less than 30% of calories from fat. Sample meal plans and vouchers for Slim-Fast™ meal replacement products were provided to increase adherence. Physical activity such as brisk walking was strongly encouraged and participants were instructed to gradually increase their activity level to 200 minutes per week. In addition to the dietary and physical activity components, the program also emphasized behavioral skills, such as self-monitoring of diet and exercise. The program

was designed to achieve an average weight loss of 7% to 9% of starting weight during the first six months.

Participants in both the control group and behavioral weight loss group received a self-help behavioral treatment booklet with instructions for improving bladder control [31] but no further information about incontinence was provided throughout either program.

Measures

Body weight, UI frequency, physical activity, and preference-based measures of HRQL were assessed at baseline, 6-months, and 18-months. Other measures were taken at baseline only. Demographic characteristics and medical, behavioral, and incontinence histories were obtained using self-report questionnaires. Participants were weighed in street clothes without shoes, using a calibrated digital scale (Tanita BWB 800) that recorded weight to the nearest 0.5 kg. Height was measured to the nearest centimeter using a calibrated wall-mounted stadiometer and a horizontal measuring block. Body mass index (BMI) was computed as kg/m².

Participants recorded incontinence episodes in a 7-day voiding diary and identified each episode as stress (involuntary loss of urine with coughing, sneezing, straining, or exercise), urge (loss of urine associated with a strong need or urge to void) or other, using the instructions provided. Incontinence type was then classified as stress only; stress predominant (stress episodes comprised at least 2/3 of the total); urge only; urge predominant (urge episodes comprised at least 2/3 of the total); or mixed incontinence, if at least two types were reported but no type comprised at least 2/3 of the total. Physical activity was assessed using the participant-completed Paffenbarger Activity Questionnaire [32] which yields estimates of calories expended in overall leisure activity (e.g., number of stairs climbed, blocks walked) and in light (5 kcal/min), medium (7.5 kcal/min), and high (10 kcal/min) intensity activity.

Health-related quality of life was measured using the HUI3 and SF-36 [33]. The HUI3 [16,17] is a 15-item generic measure of health status and HRQL that has been used in clinical and population health studies. Items of the HUI3 assess eight attributes (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain) and participants rate each attribute based on 5 to 6 levels of functioning. Using preference weights obtained from a community sample, data are converted into a multiattribute utility score that reflects global HRQL on a scale of -0.36 to 1.0, where -0.36 indicates the worst possible state, 0 is associated with death, and 1.0 is perfect health. On the HUI3, a difference of 0.03 is considered clinically important [34–36]. The SF-36 [22] is a 36-item generic self-report health survey that assesses the following eight dimensions of health and well-being: physical functioning, role limitations-physical, bodily pain, general health, vitality, social functioning, role limitations-emotional, and mental health. The SF-36 has been used to measure health status in population studies and health outcomes in clinical research [22]. In this study, the SF-36 was used to generate two preference-based HRQL scores: the SF-6D and an estimated QWB score (eQWB). The SF-6D [20,21] is a single index measure of health which is based on 11 items from the SF-36 that comprise six dimensions (physical functioning, role limitations, social functioning, pain, mental health, and vitality). The SF-6D was developed in the UK general population and scores range from .30 to 1.00 (where 1.00 indicates “full health”). The mean minimal important difference for the SF-6D has been reported as 0.03–0.04 [37,38]. The eQWB scores [39], which range from 0.45 to 0.84, are calculated from five SF-36 subscale scores (physical functioning, mental health, bodily pain, general health perceptions, and role limitations-physical), using a regression equation developed by Fryback et al. [40]. This estimation has been used in prior studies

[39,41]. We did not find published reports of a clinically important difference for the eQWB, however, the minimal important difference for the QWB is 0.03 [42].

Predictor variables were operationalized as follows: 1) change in weight (per 5% decrements) from baseline to follow-up; 2) achievement of at least 70% reduction in total UI frequency from baseline to follow-up; and 3) changes in kilocalories expended per day through physical activity from baseline to follow-up. A priori selected potential covariates tested in univariable models included baseline weight (per 5 kg increments), total weekly UI frequency at baseline (per 10% increments), kilocalories expended per day through physical activity at baseline, annual household income (<\$40,000, \$40,000–\$99,999, \$100,000), relationship status (married/partnered, single/widowed/divorced), education level, alcohol use, current smoking, ever smoked >100 cigarettes, number of live births, menopausal status, and monthly or greater fecal incontinence.

Statistical Analyses

Generalized estimating equation (GEE) models for repeated outcomes were used to assess the effects of treatment and other factors on changes in HUI3, SF-6D, and eQWB from baseline to 6 and 18 months. These models used robust standard errors to account for clustering of outcomes within groups of 10–15 women to which the intervention was delivered. Because no statistically significant treatment effects on change in HRQL were observed, we combined the weight loss and control groups to examine factors related to change in HRQL. To meet normality assumptions, HUI3 was log-transformed. We also log-transformed baseline measures of weekly UI frequency and kilocalories expended in physical activity to meet linearity assumptions and to avoid influential points. We first used unadjusted models with a retention criterion of $p < 0.20$ to screen a set of candidate predictors selected *a priori*, then used backward elimination with a retention criterion of $p < 0.20$ to remove some unimportant variables from the final adjusted models. In developing these models, we considered both main effects and interactions with time for fixed predictors, and both baseline values and changes from baseline for time-varying predictors. For both classes of predictors, between-person effects are captured by the first variable and within-person effects by the second. In general, these paired variables were both retained if the effect of interactions with time had a p -value < 0.20 , or if either the baseline or change effect had a p -value < 0.20 ; main effects of age, race (white/non-white), and clinical site (Providence/Birmingham) were retained in all models. Missing data were handled using multiple imputation, an imputation procedure ensuring that standard errors and confidence intervals properly reflect the uncertainty of the imputed values. Provided the data are “missing at random” [43], given the data that are observed, multiple imputation reduces bias and is more efficient than standard complete-case analysis. Twenty imputed data sets were created and the results combined using standard techniques, as implemented in SAS Proc MI and Proc MIAnalyze. A p -value of < 0.05 was considered statistically significant. All analyses were implemented in SAS Version 9.2 (SAS Institute, Cary, NC).

RESULTS

At baseline, mean $\pm$ standard deviation (SD) age was 53 ± 11 years, weight was 97 ± 17 kg, body mass index (BMI) was 36 ± 6 kg/m², and incontinence episode frequency was 24 ± 18 episodes per week (Table 1). Forty five percent of women classified their health as “excellent” or “very good”. Data on weight loss and changes in UI frequency over time have been reported previously [8,44]. Briefly, weight loss from baseline was greater in the weight loss group compared to the control group at 6 months (-8.0% vs. -1.6% , $p < .001$) and 18 months (-5.5% vs. -1.6% , $p < .001$). Decrease in the frequency of total UI episodes from baseline was greater in the weight loss group compared to the control group at 6 months (-47% vs. -28% , $p = .01$) but not at 18 months (-62% vs. -55% , $p = .3$).

We did not find a significant effect of treatment group assignment on change in HUI3, SF-6D, or eQWB scores from baseline to 6 or 18 months. In the overall cohort including both treatment groups, mean scores on the eQWB increased from baseline to both 6 months ($p<0.001$) and 18 months ($p=0.02$; Table 2). However, we found no significant change in HUI3 or SF-6D scores over time.

Results of prediction models showed that neither baseline weight nor baseline UI frequency was related to *changes* in HRQL. After adjusting for covariates, weight loss predicted improvement in HUI3, SF-6D, and eQWB at 6 and 18 months ($p<.05$; Tables 3–5), but reduction in UI frequency did not. The effect of weight loss on change in HRQL did not vary by baseline weight; similarly, the effect of reductions in UI frequency on change in HRQL did not vary by baseline UI frequency. Increases in physical activity from baseline to 18 months were independently associated with improvement in HUI3 ($p=0.01$) and SF-6D scores ($p=0.006$) at 18 months after controlling for covariates. Finally, compared to women who were premenopausal, being postmenopausal was associated with less improvement on the HUI3 ($p<.001$) and eQWB ($p=.04$) at 18 months and the SF-6D at both 6 months ($p=.04$) and 18 months ($p=.001$).

DISCUSSION

Results of the current study show that after adjusting for covariates, weight loss was independently associated with improvement in HUI3, SF-6D, and estimated QWB (eQWB) scores in both the shorter term (6 months) and longer term (18 months) among overweight and obese women with UI enrolled in a clinical trial of a lifestyle weight loss intervention. Improvement in HRQL was independent of baseline weight, indicating that HRQL-related benefits of weight loss were observed across a range of starting weights. Further, we did not find a significant effect of treatment group assignment on change in HRQL, which suggests that weight loss predicted improvement in HRQL regardless of treatment group. Failure to find a significant treatment group $\times$ time interaction for the HUI3 despite large differences between weight loss and control participants in change from baseline to follow-up on this measure may be due to the substantial variability observed in the HUI3. On the eQWB, there were significant increases over time among weight loss participants but not control participants; however, the group difference was not large enough to result in a significant treatment group $\times$ time interaction.

Recent findings from the DPP showed that weight loss among overweight and obese men and women with impaired glucose tolerance was independently associated with improvement on the SF-6D [25]. In that study, weight losses of 5 kg were associated with a 0.007 increase in SF-6D score from baseline to year 1. Results from our study show that for a woman at the average baseline weight, a weight loss of 5% was associated with improvements in SF-6D scores of 0.023 at 6 months and 0.015 at 18 months. These findings suggest that weight losses of 6% and 10% would predict a clinically meaningful increase of 0.03 on SF-6D score in the shorter-term and longer-term, respectively.

To our knowledge, no prior studies have examined the impact of weight loss on changes in HRQL using the HUI3 or eQWB. Our results indicate that weight loss is associated with significant improvements in both measures. Specifically, reductions in weight of 5% from baseline were associated with a 0.015 increase in eQWB score at 6 months and a 0.012 increase at 18 months. This suggests that weight losses of 10% at 6 months and 12% at 18 months would produce clinically meaningful changes on this measure. For the HUI3, the impact of weight loss on change in utilities was smaller. A 5% weight loss predicted improvements of 0.008 at 6 months and 0.004 at 18 months. Thus, to achieve a clinically meaningful increase of 0.03 in HUI3 score, a large weight loss of 19% would be needed at 6

months and a very large weight loss of 35% would be needed at 18 months. The substantial variability of HUI3 scores within participants over time in this cohort may have contributed to the large estimated change in weight needed for clinically meaningful improvement on the HUI3. Variability in the responsiveness of the HUI3, SF-6D, and eQWB to weight loss may also reflect differences in the health domains assessed by these HRQL instruments and how sensitive the health domains are to changes in weight. In a prior study of this cohort, we examined the association of BMI and HRQL at baseline and showed that small differences in BMI across participants were associated with clinically significant differences in HUI3 scores while much larger differences in BMI across participants were needed to demonstrate clinically significant differences on the eQWB, and BMI was not significantly related to the SF-6D [33]. These results suggest that certain measures may be more sensitive to changes in HRQL produced by weight loss (i.e., within respondents) while other measures may better capture differences in HRQL associated with body weight in a cross-sectional analysis (i.e., between respondents). Thus, researchers may need to consider issues of study design when selecting preference-based measures of HRQL and use caution when interpreting findings.

In the current study, there was an independent effect of increasing physical activity on improvement in HRQL as assessed by the HUI3 and SF-6D at 18 months. This is consistent with other prospective reports [45,46] and may reflect the many benefits of being active, such as improved fitness and musculoskeletal health, increased functional ability, and improved mental health [47]. Further, the finding that increasing physical activity contributes to improvement in HRQL independent of weight loss may offer additional incentives for individuals to adopt a more active lifestyle.

Interestingly, reduction in total UI frequency was not significantly related to improvement in HUI3, SF-6D, or eQWB scores in this study. A unique feature of the current study is that we directly assessed the relative impact of changes in weight and UI frequency on change in these preference-based measures of HRQL. Our results provide strong support for an effect of weight loss on these outcomes, but no evidence for an effect of reduction in incontinence. Prior studies have examined changes in quality of life with improvement in UI, however, few of these included preference-based measures of HRQL, and our search of the literature did not reveal any that use the HUI3, SF-6D, or eQWB. Findings from a trial of surgical treatment for UI that assessed health utilities using the EQ-5D [48] showed that scores improved significantly following surgery while a trial of physiotherapy for UI [49] revealed that EQ-5D scores changed minimally after treatment compared to scores on the Urinary Incontinence-Specific Quality of Life Instrument (I-QoL). Other treatment studies examining incontinence-specific measures of quality of life also have shown that reductions in UI are associated with improvements in these instruments [50,51]. Given the limited data in this area, additional research examining the sensitivity of the HUI3, SF-6D, and eQWB to health-related changes associated with improvement in UI is warranted.

After adjusting for age, women who were postmenopausal reported less improvement in HRQL over time compared to their premenopausal counterparts. This finding may reflect changes in HRQL associated with symptoms of menopause [52,53].

Results of the current study document the effect of weight loss and improvement in UI on three preference-based measures of HRQL (HUI3, SF-6D, and an SF-36-derived, estimated QWB score (eQWB)) and provide utility estimates that can be used to calculate QALYs in cost-utility analyses. While weight loss was associated with significant improvement in all three measures of HRQL, we found variability in the magnitude of change in utilities across these instruments with the SF-6D being more sensitive to weight loss than the HUI3 or eQWB. Others have also noted variability in how responsive preference-based HRQL measures are to change in different patient groups [54]. Such differences in utility values

may impact the calculation of QALYs for economic evaluations; thus researchers should consider that choice of instrument can affect their results.

Strengths of the current study are its large sample size, observed measures of height and weight, and follow-up period of 18 months. Our study had limitations that should be considered when interpreting the results. First, the study was a secondary analysis of a randomized controlled trial and may not have been adequately powered to detect effects tested on HRQL or changes in HRQL across treatment groups. Second, we included only overweight and obese women with UI who enrolled in a clinical trial of a weight loss intervention for urinary incontinence and thus the findings do not inform the relation between weight loss and changes in utilities for other populations. Finally, this study estimated the QWB (eQWB) using mapping based on a regression equation developed by Fryback and colleagues [40]; thus, these values may differ from those of the directly obtained self-administered version of the QWB.

In conclusion, we found that weight loss and increased physical activity, but not decreased frequency of UI, were associated with improvement in preference-based measures of HRQL among overweight and obese women with UI enrolled in a weight loss intervention trial. Data on changes in HUI3, SF-6D, and eQWB associated with weight loss provide important information that can be used to inform cost-utility analyses of weight loss interventions.

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Table 1

Characteristics of the participants at baseline

	Total (N=338)	Weight Loss (N=226)	Control (N=112)
Age (years)	53 ± 11	53 ± 11	53 ± 10
Race – no. (%)			
White	262 (77.5)	171 (75.7)	91 (81.2)
Black	64 (18.9)	47 (20.8)	17 (15.2)
Other	12 (3.6)	8 (3.5)	4 (3.5)
Education beyond high school–no. (%)	293 (86.7)	200 (88.5)	93 (83.0)
Relationship Status – no. (%)			
Married or living with partner	256 (75.7)	166 (73.5)	90 (80.4)
Single, widowed, or divorced	82 (24.3)	60 (26.5)	22 (19.6)
Body mass index (BMI; kg/m ²)	36±6	36±6	36±5
Weight (kg)	97±17	98±17	95±16
Physical activity (kcal expended/day) ^a	392 (140, 1078)	393 (140, 1235)	350 (140, 798)
Self-reported health status – no. (%)			
Excellent or very good	151 (44.7)	107 (47.3)	44 (39.3)
Good	150 (44.4)	99 (43.8)	51 (45.5)
Fair or poor	37 (10.9)	20 (8.8)	17 (15.2)
Diabetes – no. (%)	10 (3.0)	9 (4.0)	1 (0.9)
Current smoker – no. (%)	18 (5.3)	14 (6.2)	4 (3.6)
Current alcohol use – no. (%)	228 (67.5)	154 (68.1)	74 (66.1)
Postmenopausal – no./total no. (%)	177/316 (56.0)	115/209 (55.0)	62/107 (57.9)
Type of urinary incontinence – no. (%) ^b			
Stress only/stress predominant	75 (22.2)	44 (19.5)	31 (27.7)
Urge only/urge predominant	149 (44.1)	104 (46.0)	45 (40.2)
Mixed	114 (33.7)	78 (34.5)	36 (32.1)
Urinary incontinence episodes per week	24 ± 18	24 ± 18	24 ± 18
HUI3	0.81 ± 0.18	0.81 ± 0.16	0.80 ± 0.20
SF-6D *	0.75 ± 0.10	0.76 ± 0.10	0.73 ± 0.10
eQWB	0.71 ± 0.06	0.71 ± 0.06	0.70 ± 0.06

Data are presented as mean ± standard deviation or number (percent) unless otherwise noted. HUI3 = Health Utilities Index Mark 3; SF-6D = Short Form 6D; eQWB = estimated Quality of Well Being

^aData presented as median (IQR)

^bType of UI was classified according to the participant's designation of each incontinence episode in a 7-day voiding diary.

* p<0.05 for the comparison between weight loss and control groups

Table 2

Percent change from baseline in HUI3, SF-6D, eQWB scores

	Total (N=338)	Weight Loss (N=226)	Control (N=112)	Between Group Difference
	Estimate (95% CI) ^a	Estimate (95% CI) ^a	Estimate (95% CI) ^a	Estimate (95% CI) ^a
HUI3^b				
6 months	-2.4 (-13.3, 10.0)	2.7 (-9.9, 17.0)	-11.8 (-30.5, 12.0)	16.4 (-11.2, 52.7)
18 months	0.7 (-8.4, 10.7)	5.4 (-6.0, 18.2)	- 8.3 (-21.3, 6.9)	14.9 (-5.2, 39.3)
SF-6D				
6 months	1.5 (-0.3, 3.3)	0.8 (-0.9, 2.5)	2.9 (-1.2, 7.0)	- 2.0 (-6.3, 2.4)
18 months	0.3 (-1.4, 2.0)	0.2 (-1.5, 1.9)	0.4 (-3.5, 4.3)	- 0.1 (-4.3, 4.0)
eQWB				
6 months	2.1 (1.1, 3.1) ***	2.2 (1.1, 3.2) ***	1.9 (-0.3, 4.2)	0.2 (-2.2, 2.7)
18 months	1.3 (0.2, 2.5) *	1.9 (0.7, 3.0) **	0.3 (-2.3, 2.8)	1.6 (-1.2, 4.4)

HUI3 = Health Utilities Index Mark 3; SF-6D = Short Form 6D; eQWB = estimated Quality of Well Being

^aEstimate coefficient is presented as a percent change from baseline; negative coefficients indicate decreases in HRQL at follow-up and positive coefficients indicate increases in HRQL at follow-up. Model adjusted for clinic site.^bLog transformation applied.*
p=0.02 compared to baseline;**
p=0.001 compared to baseline;***
p<0.001 compared to baseline

p>0.05 for the comparison between weight loss and control groups for change in HUI3, SF-6D, and eQWB scores at 6 and 18 months.

Table 3Factors associated with change in HUI3 score from baseline in multivariable analyses^a

	HUI3 Baseline to 6 months		HUI3 Baseline to 18 months	
	Estimate (95% CI)	p-value ^b	Estimate (95% CI)	p-value ^c
Baseline variables				
Menopausal status (post) × Time	NA		−38.6 (−51.8, −21.9)	<0.001
Race (non-White) × Time	25.4 (−10.1, 74.8)	0.18	NA	
Change variables				
Change in weight (per 5% decrease)	21.3 (7.9, 36.4)	0.001	10.7 (1.0, 21.4)	0.03
Achieving at least 70% reduction in total weekly UI frequency	10.2 (−14.0, 41.1)	0.44	13.0 (−9.0, 40.3)	0.27
Kcals expended per day in physical activity (per 100 kcal increase)	NA		1.2 (0.3, 2.2)	0.01

HUI3 = Health Utilities Index Mark 3; UI = urinary incontinence; NA indicates that the variable was not included in the final model.

^a Estimate coefficient is presented as percent change from baseline; see *Statistical Analyses* section for a description of the model and predictor selection methods.^b Analysis controlled for age, race, clinic site, baseline weight, and baseline weekly UI frequency^c Analysis controlled for age, race, clinic site, baseline weight, baseline weekly UI frequency, baseline kcals expended per day in physical activity, and menopausal status.

Table 4

Factors associated with change in SF-6D score from baseline in multivariable analyses

	SF-6D Baseline to 6 months		SF-6D Baseline to 18 months	
	Estimate (95%CI)	p-value ^a	Estimate (95% CI)	p-value ^a
Baseline variables				
Menopausal status (post) × Time	−0.025 (−0.05, −0.0008)	0.04	−0.045 (−0.072, −0.017)	0.001
Race (non-White) × Time	0.032 (0.003, 0.062)	0.03	NA	
Change variables				
Change in weight (per 5% decrease)	0.023 (0.011, 0.036)	<0.001	0.015 (0.004, 0.025)	0.005
Achieving at least 70% reduction in total weekly UI frequency	−0.011 (−0.031, 0.01)	0.30	0.01 (−0.02, 0.041)	0.51
Kcals expended per day in physical activity (per 100 kcal increase)	0.0005 (−0.0005, 0.001)	0.37	0.001 (0.0004, 0.002)	0.006

SF-6D = Short Form 6D; UI = urinary incontinence; NA indicates that the variable was not included in the final model.

^aSee *Statistical Analyses* section for a description of the model and predictor selection methods. Analysis controlled for age, race, clinic site, baseline weight, baseline weekly UI frequency, baseline kcals expended per day in physical activity, and menopausal status.

Table 5

Factors associated with change in eQWB score from baseline in multivariable analyses

	eQWB Baseline to 6 months		eQWB Baseline to 18 months	
	Estimate (95%CI)	p-value ^a	Estimate (95% CI)	p-value ^a
Baseline variables				
Menopausal status (post) × Time	−0.012 (−0.027, 0.003)	0.11	−0.02 (−0.039, −0.0009)	0.04
Marital status (single) × Time	−0.018 (−0.034, −0.002)	0.03	−0.017 (−0.035, 0.002)	0.07
Change variables				
Change in weight (per 5% decrease)	0.015 (0.009, 0.021)	<0.001	0.012 (0.006, 0.019)	<0.001
Achieving at least 70% reduction in total weekly UI frequency	−0.0003 (−0.017, 0.016)	0.97	0.009 (−0.008, 0.026)	0.28
Kcals expended per day in physical activity (per 100 kcal increase)	0.0003 (−0.0003, 0.0008)	0.35	0.0006 (−0.0001, 0.001)	0.08

eQWB = estimated Quality of Well Being; UI = urinary incontinence

^aSee *Statistical Analyses* section for a description of the model and predictor selection methods. Analysis controlled for age, race, clinic site, baseline weight, baseline weekly UI frequency, baseline kcals expended per day in physical activity, menopausal status, and marital status.