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Changes in Health-Related Quality of Life among African-Americans in a lifestyle weight loss program

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Abstract

Purpose—Changes in health-related quality of life (HRQoL) were assessed in clinically obese, African-American adults after completion of a weight loss program that resulted in modest average weight loss.

Methods—Data were analyzed for 87 men and women who provided weight measurements after an initial 10-week weight loss program (Phase 1) and a subsequent clinical trial to evaluate three weight maintenance approaches (Phase 2) over an additional 8 to 18 months. HRQoL was assessed using the Short Form SF-36 questionnaire. Intra-person changes in HRQoL were assessed and analyzed for associations with weight change within each phase. Non-parametric bivariable analyses and multivariable linear regression were used in statistical analyses.

Results—Changes in HRQoL were modest; clinically significant intra-subject improvements in SF-36 domains of general health and vitality and in the mental component summary score were observed after Phase 1 but were attenuated during Phase 2. Improvements in vitality were significantly associated with greater weight loss in Phase 1, but no HRQoL change scores during Phase 2 were associated with weight change.

Conclusions—Short-term improvements in general health and vitality were observed. The vitality domain of the SF-36 appeared to be the domain of HRQoL most responsive to modest weight change.

Keywords

Health-related quality of life; Ethnic groups; Obesity; Health promotion; Weight loss; Intervention studies; African Americans

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Introduction

The high prevalence of obesity, with its risks of medical comorbidities and premature mortality, is an important public health concern [1–5]. In multiple cross-sectional studies, obese persons report a lower health-related quality of life (HRQoL) than non-obese persons [6,7]. Clinically significant weight loss, whether achieved by bariatric surgery, prescription drugs or lifestyle changes, is associated with improvements in HRQoL for obese individuals [8–12]. Lifestyle behavioral interventions have produced short-term improvements in HRQoL [11,13,14]. The long-term effects of such interventions are less clear, especially since the initial weight loss is often not sustained [12,13]. In addition, whether improvements in HRQoL observed in lifestyle change programs are mediated primarily by the amount of weight loss is uncertain given that the amount of weight loss often does not correlate with the magnitude of HRQoL improvement [13].

The prevalence of obesity in African-Americans is higher than in whites, yet studies investigating the effects of obesity and its treatment in this population are few [15]. Available studies indicate that although lifestyle interventions are generally efficacious for African-Americans, weight losses in African-Americans are less than in their white counterparts [16–18]. HRQoL effects associated with minimal or modest weight loss may be of particular relevance to African-Americans.

We analyzed weight and HRQoL data for African-American women and men who completed the healthy eating and lifestyle program (HELP) study [19]. During the HELP study, we observed modest average weight loss that was well maintained regardless of weight maintenance strategies. A full description and main results of this study have been published elsewhere [19]. The primary study questions here relate to the size and direction of changes in HRQoL after the initial, intensive phase of the program and also after the subsequent, longer weight maintenance phase. Additionally, we sought to determine whether any observed changes in HRQoL were correlated with the amount of weight lost or with weight loss maintenance. We expected that participants with clinically significant weight loss during the intensive phase of the study and those who maintained their weight loss during the second phase would report the largest improvements in HRQoL.

Methods

Study design

The design and main results of the HELP study have been reported previously [19]. Briefly, African-Americans aged 25 to 70 with body mass index (BMI) between 30 and 50 kg/m^2 were recruited through physician referrals and general advertisements. Participants were offered 10 weeks of weight control counseling classes (Phase 1) designed to help them begin the process of weight loss. Interested participants who completed Phase 1 were subsequently enrolled in a randomized trial that compared three approaches to weight maintenance (Phase 2) for an additional 8 to 18 months: continued group counseling classes; a self-help program facilitated by an outreach worker; or usual care (referral back to their primary care provider). Cultural adaptations included: recruiting only African-American participants to create homogeneous groups; having African-American intervention staff; using study materials (printed and video) with African-American actors, images and cultural references; featuring African-American ethnic foods; and including other content and activities designed to appeal to this audience on the basis of theory or published reports [19,20].

Data collection procedures

Informed consent was obtained separately for Phases 1 and 2. All study procedures and protocols were approved by the University of Pennsylvania Institutional Review Board. Participants completed demographic, medical history, weight history and other health and behavior questionnaires before and after each phase.

HRQoL measurements

HRQoL was assessed using the Medical Outcomes Study Short Form Health Survey (SF-36), which was administered at the baseline visit, at the end of Phase 1 and at the end of Phase 2. The SF-36 is a 36-item, generic quality of life measure that assesses 8 domains: (1) physical functioning (PF); (2) role limitations due to physical health (RP); (3) bodily pain (BP); (4) general health perceptions (GH); (5) vitality (VT); (6) social functioning (SF); (7) role limitations due to emotional health problems (RE); and (8) mental health (MH) [21]. Each domain's score can range from 0 to 100, with higher numbers always reflecting better function. The RP and RE domains can also be made into binary variables describing the presence (RP and RE score < 100) or absence (RP and RE score = 100) of any role limitations. These eight domains are weighted and summed to calculate the physical component summary (PCS) and the mental component summary (MCS) scores, which are standardized to a mean of 50, with scores above or below 50 representing better or worse status than the US population average, respectively [22].

Statistical methods

All statistical analyses were done with STATA/SE version 11 [23]. After preliminary analyses revealed no differences in weight change or HRQoL outcomes by randomization assignment, Phase 2 treatment groups were merged for these analyses. Only the participants who completed both phases of the study are included in these analyses. Baseline characteristics were summarized with descriptive statistics. Characteristics of participants who did or did not complete each phase were analyzed using parametric or non-parametric tests where appropriate to explore potential selection biases influencing the composition of the analysis sample relative to those who enrolled initially or at the beginning of Phase 2. The SF-36 domain scores and summary scores were explored graphically, and the normality assumption was assessed via the Shapiro–Wilk test. Medians and interquartile ranges of the baseline SF-36 domains were compared with those of the US population norms. The 95 percent (%) confidence intervals (CI) around the median of each SF-36 domain were calculated using one thousand bootstrap samples with replacement via the normal approximation method [24]; the US population medians were compared with the calculated 95% CI.

The weight change for each phase was calculated as the post-intervention weights minus pre-intervention weights. A binary variable to reflect clinically significant weight loss was created describing those who did or did not lose ≥5% of their body weight during the particular phase of the study [25]. Weight maintainers in Phase 2 were defined as participants who either lost weight or gained ≤+3% during this phase [26].

The change in HRQoL was assessed by calculating the absolute change (post-pre differences) in SF-36 domains, MCS and PCS for each phase of the study. Change scores were explored graphically and, since most were not normally distributed, non-parametric techniques were used to estimate associations between variables. The minimum clinically important difference (MCID) in HRQoL was defined as an intra-subject change of at least 5 points for each SF-36 domain or at least 2 points for the MCS or PCS [21,22]. Bootstrap methodology was used to calculate the 95% CI around the median change scores [24]. Since we had a priori hypotheses for the eight SF-36 domain changes, we considered a Bonferoni adjusted *P*-value of less than 0.006 as statistically significant.

To explore the relationship between weight change and vitality change score adjusted for potential confounders, multiple linear regression analysis was used with the vitality change score as the dependent variable and the weight change variable as the independent variable. Potential confounders included the baseline vitality scores (and where appropriate the vitality scores at the beginning of Phase 2) and the baseline demographic, personal, health status and weight history variables included in Table 1 (see "Results"). Assumptions of the underlying models, including linearity, were tested and verified by using standard regression diagnostics.

Results

Participant characteristics

Two hundred and thirty-seven individuals were enrolled in the study initially. Of these: 134 (57%) completed Phase 1, of whom 128 agreed to be randomized to the Phase 2 weight maintenance strategies; 87 of these 128 (68%) completed the Phase 2 follow-up. Some of characteristics of the 87 participants who completed both phases of the study are shown in Table 1. Participants who completed both phases of the study were similar to those who did not complete on medical, weight history and demographic characteristics except for being older (mean age ± SD of 46.5 ± 9.7 vs. 40.9 ± 10.7 years, respectively, $P = 0.0005$), and more likely to have a professional occupation (57.5 vs. 30.4%, respectively $P < 0.001$). In general, over the entire course of the study, when baseline HRQoL data were compared for the study completers versus non-completers, completers appeared to have similar median baseline SF-36 scores but with higher 25th percentile scores. Only in the PF ($z = -1.65$, $P = 0.09$) and VT, domains ($z = -2.24$, $P = 0.03$) were the differences of borderline significance, with the completers reporting a higher range of scores. Similarly, when Phase 1 completers were compared with baseline enrollees, completers tended to report a higher interquartile range of HRQoL baseline scores compared to those participants who did not complete the phase. In the RP domain, this difference reached statistical significance (binary variable, chi-squared 8.39, $P = 0.004$). Phase 2 completers began the phase with similar median scores but higher interquartile ranges than the non-completers of the phase; in none of the domains or summary scores were the differences statistically significant.

Table 2 shows the baseline HRQoL in our sample and compares these values to US general population norms taken from the SF-36 interpretation guide [23,24]. Our study sample reported lower baseline vitality scores than the US population norms but was similar to the US population norms in the other HRQoL domains and in the summary scores.

Changes in weight

Phase 1 weight change ranged from −18.8 to +4.6 kg, with a median weight change of −1.27 kg. Sixty-three percent of the participants had lost weight during Phase 1: Only 13% of participants lost at least 5% of their baseline weight; 40% lost between 1 and 5% of their baseline weight during Phase 1. Only 5 participants gained more than 3% of their baseline weight during this phase.

In Phase 2, mean weight change ranged from −9.6 kg to +13.4 kg, with a median weight change of +0.36 kg. Seventy-seven percent of the participants either lost or maintained within 3% of their weight from the beginning of Phase 2. Forty-seven percent of the participants lost weight during this phase: 11.5% lost at least 5% of their weight; 24% between 1 and 5%.

HRQoL changes

Table 3 shows the median change score and its calculated 95% CI for the eight SF-36 domains and the two component summary scores over the two phases of the study. Figure 1 shows the

proportion of participants with decreased, stable or improved SF-36 scores after both phases of the study for the eight SF-36 domains.

Phase 1 (weight loss phase)

As shown in Table 3, the median Phase 1 HRQoL change score was zero for five of the eight SF-36 domains. A majority of participants reported no change in RP, SF or RE over Phase 1 (63, 53 and 71%, respectively). A majority reported improvements in the GH, VT and MH domains (57, 64 and 53%, respectively). Of the three domains with median change score higher than zero (GH, VT and MH), only in the VT and GH domains did the 95 percent CI of the median score not include zero. It was in these same two domains (GH, VT) that at least 50% of the study participants reported HRQoL improvements greater than or equal to the MCID of 5 points (data not shown).

The PCS and MCS scores improved for 57 and 69% of participants, respectively. The median change in MCS was about 2 points, and the 95% CI did not include zero. About 40 and 50% of the participants improved greater than the MCID for the PCS and MCS, respectively.

Association of changes in HRQoL and weight change during Phase 1

In general, greater weight loss was associated with more improvements in HRQoL scores ($-0.30 > \rho < -.06$). The correlation between weight change and GH change was weak and not statistically significant (ρ −0.0817, $P = 0.45$). More robust was the correlation between weight change and MH change (ρ −0.22, $P = 0.04$). The strongest correlation was seen between VT change and weight change (ρ −0.30, $P = 0.005$). Participants who lost at least 5% of baseline weight during Phase 1 had a median vitality change score of 30 versus a median change score of 5 in participants who did not lose at least 5% of their baseline weight during Phase 1 ($z = -2.40$, $P = 0.0160$). No other Phase 1 change score was associated with clinically significant weight loss during Phase 1.

Table 4 shows the final regression models testing the association between change in vitality and the change in weight during both phases of the study. Phase 1 vitality change was not changed by adjustment for any of the baseline characteristics in Table 1. Higher baseline vitality score was associated with less change during Phase 1. The final regression model for the vitality change score included the weight change variable with the baseline vitality score.

Phase 2 (weight maintenance phase)

The median Phase 2 HRQoL change score for six of the eight domains was zero. Most participants reported no change in the RP and RE domains (63.4 and 72.8%, respectively). Across all domains, more participants reported declines in HRQoL than improvements. Median change scores were less than zero for the GH and VT domains. Only with the VT change score did the calculated 95% CI not include zero. About 55% of the participants reported a *decrease* in vitality greater than the MCID. The median change scores for both the PCS and the MCS were negative, with the 95% CI including zero. More participants reported declines than improvements in the summary component scores (57 and 51%, respectively, for the PCS and MCS).

Association of changes in HRQoL and weight change during Phase 2

As in Phase 1, Phase 2 weight change was inversely correlated with SF-36 change scores ($-0.25 > \rho < -0.06$, i.e., weight gain was associated with decreasing scores). Only with the VT change score was this correlation of borderline significance (ρ −0.25, $P = 0.024$). In general, there was no consistent relationship between weight maintenance category and direction and magnitude HRQoL changes. In a regression model with VT change score as the dependent variable, the

Phase 2 weight change was *not* an independent predictor of change in vitality after adjusting for baseline VT scores and VT scores at the beginning of Phase 2 (see Table 4).

Discussion

In this sample of obese African-Americans with modest weight change after a 10-week lifestyle intervention, the change in HRQoL was also modest. Although weight loss was associated with improvements in HRQoL and weight gain with decreased HRQoL, the correlations were weak. The VT domain of the SF-36 appeared to be the most responsive to small changes in weight for this study population.

Subjective vitality relates to having positive energy available and within one's control [27]. The fact that our study sample showed clinically significant improvements in VT with weight loss during Phase 1 is consistent with the growing literature on the association between vital exhaustion (the opposite of vitality) and obesity and its related comorbidities [28]. It is possible that weight loss in Phase 1 led to greater energy levels and "pep" during this phase of the intervention and/or that participants' ability to lose weight led them to feel more motivated and in control of their lives. It is worth noting that the VT domain was also the only domain in which the study population appeared to be significantly lower at baseline than the US population norms. The distribution of VT scores in this sample may have allowed more room for improvement compared to other domains whose range of baseline scores were closer to the SF-36 ceiling.

The modest short-term improvements in GH, VT and MCS during Phase 1 of this study are consistent with earlier studies in mostly white populations on the short-term effects of lifestyle intervention for obesity on HRQoL. Rippe et al. [11] investigated the effect of a 12-week weight loss strategy that involved self-selected diet and exercise plans motivated by weekly meetings. At the end of the intervention (mean weight change of −6.1 kg compared with the −1.5 kg seen in our study), there were significant changes in the PF, VT and MH domains when compared to participants who did not receive the intervention. Fontaine et al. [14] showed in an 80% Caucasian population that after 13 weeks of behaviorally oriented treatment (mean weight change −8.6 kg) there were significant changes in the PF, RP, GH, VT and MH domains. In the one study identified that documented short-term effects of a culturally sensitive dietary intervention for obese African-Americans on HRQoL, Ard et al. [29] reported a mean weight change of −6.7 kg and significant improvements in PF, BP, RP, VT and MH domains of the SF-36. When our findings are taken together with those of these prior studies, the impression is that participants are more likely to report improvements in physical health domains of SF-36 (PF, RP, BP, GH) with relatively large weight losses but that improvements in VT and MH may emerge with only modest weight loss.

Phase 2 represents the longer-term effects of a weight loss intervention—a phase that is often associated with recidivism and weight regain. Much of the improvements in VT, GH and MCS that were observed during the first part of the study were lost during the second phase. This tendency to return to baseline in HRQoL is consistent with much of the literature on the long-term effects of weight loss interventions [30]. Blissmer et al. [31] studied the long-term effects of a 6-month intervention and showed that HRQoL effects peaked at the end of the intensive intervention, with almost all domains returning to baseline by the two-year follow-up point (only one-third of the study sample maintained at least 5% weight loss).

The lack of a consistent relationship between HRQoL changes and weight change during either phase of the intervention has several potential explanations. Changes in diet and physical activity known to occur during behavioral interventions might have led to HRQoL changes initially, independent of weight change. Insufficient data for changes in dietary intake [32] or

physical activity adoption during Phase 2 precluded analyses of such effects. It is also possible that the social interaction and support offered during the behavioral intervention was responsible for some of the initial improvements in HRQoL. Our HRQoL measures may also be capturing health attributes other than those identified as part of the SF-36, e.g., the health optimism that is common among participants in behavioral interventions [33]. Assessment of health optimism might be useful in future studies of HRQoL changes.

The infeasibility of exploring, in the available data, diet and physical activity changes that might have explained the observed HRQoL changes is a limitation of this study. Following are other limitations. The drop-out rates for Phase 1 and Phase 2, although not atypical for lifestyle weight control studies [13], were high, and resulted in a relatively small sample size for these analyses. Our sample size may have been too small to detect significant changes in HRQOL. We had no untreated comparison group in Phase 1. However, in Phase 2, some participants had minimal contacts and could be considered similar to a usual care comparison group but there was no difference in HRQoL change in this treatment group compared to the others. We used a generic instrument for measuring HRQoL. While generic measures provide useful information that can be compared across populations, chronic conditions and types of weight loss interventions, they are not designed to measure specific health-related problems experienced by obese individuals. This study might have been enhanced by the complementary information an obesity-specific quality of life measure could have provided. However, to date we are unaware of any obesity-specific quality of life measure that has been validated in an African-American population. Finally, these analyses were restricted to the participants who completed the entire study and so cannot be generalized even to participants with the characteristics of those who enrolled initially. Although we explored the differences between completers and non-completers and found few statistically significant differences, we could not rule out the possibility of a clinically significant difference in HRQoL between our sample and those who enrolled but did not complete the study. Nevertheless, our exploration of these issues in an understudied population, our ability to compare the weight loss and maintenance phases, and our translation of HRQoL changes into clinically meaningful terms are strengths.

Conclusion

A lifestyle weight management program adapted for African-Americans that produced modest weight loss during the intensive phase of the study was associated with short-term improvements in general health and vitality domains. The vitality domain of the SF-36 appeared to be the most responsive HRQoL domain to modest weight change in this population. Future studies should attempt to identify aspects of the intervention other than weight change that might be important in mediating changes in HRQoL.

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Abbreviations

BMI	Body mass index
HELP	Healthy eating and lifestyle program study
HRQoL	Health-related quality of life
MCID	Minimum clinically important difference
SF-36	The short form 36 questionnaire

GH	General health
PF	Physical functioning
MH	Mental health
RP	Role-limitations-physical
RE	Role-limitations-emotional
VT	Vitality
SF	Social functioning
BP	Bodily pain
PCS	Physical component summary
MCS	Mental component summary
CI	Confidence intervals

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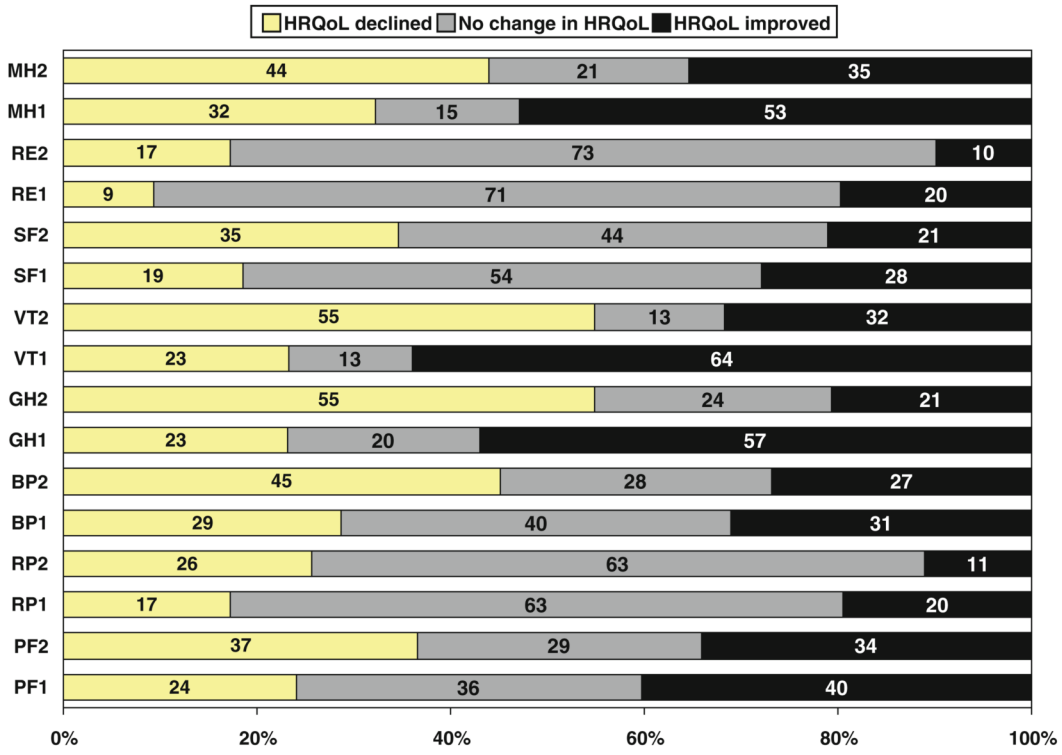

Fig. 1.

shows the percent of participants with decreased (change score < 0), stable (change score = 0) or improved SF-36 (change score > 0) scores after each phase of the study for the eight SF-36 domains. The eight SF-36 domains are: PF—physical functioning; RP—role limitations due physical health; BP—bodily pain; GH—general health; VT—vitality; SF—social functioning; RE –role limitations due to emotional health; MH—mental health. The number after each domain refers to the phase of the study: 1—Phase 1 (the intensive weight loss phase); 2—Phase 2 (the weight maintenance phase). Change scores for Phase 2 refer to changes in HRQoL that occurred after Phase 1, from enrollment in Phase 2 to the end of the study. See text for further details on how the change scores for each phase were calculated. In general, the RP, RE and SF domains appeared minimally responsive; most participants in either phase reported no change in these domain scores. The percentage of participants with improvements in HRQoL was higher in Phase 1 compared to Phase 2 while the percentage of participants with declines was higher in Phase 2 compared to Phase 1

Table 1

Characteristics of 87 completers of the study

Characteristic	Value*
Female	87.4
Age in years, mean (SD)	46.5 (9.7)
Education >12 years[a]	70.2
Professional occupation	57.5
Married	44.8
Children <18 years	54.0
Current smoker	11.8
Current drinker[b]	29.2
Self-rated health	
Excellent or very good	23.0
Good	54.0
Fair or poor	23.0
Obesity-related comorbidities[e]	77.0
Weight in kg, median (IQR)	Men 118.0 (102.4–138.3)
	Women 97.8 (87.0–109.3)
BMI, median (IQR)	Men 36.4 (33.3–43.3)
	Women 36.6 (33.2–40.9)
Age first overweight by 10 + lb in yrs, mean (SD)[c]	26.2 (12.6)
Expected weight loss in the first 3 months in lb, median (IQR)[a]	23.8 (15.9–36.3)
# prior weight loss programs, median (IQR)[d]	1 (0–2)
Phase 1 weight change in kg, median (IQR)	−1.27 (−3.4–0.82)
Phase 2 weight change in kg, median (IQR)	+0.36 (−2.5–3.0)

BMI body mass index, *IQR* interquartile range, *SD* standard deviation

*Data are given as percentages except where noted

[a] $n = 84$;

[b] $n = 72$;

[c] $n = 79$;

[d] $n = 85$

[e] Defined as participants whose medical history information indicated diagnosis of high blood pressure, gallbladder disease, gout or elevated uric acid, obstructive sleep apnea, breathing problems, stroke, angina, heart disease, arthritis, joint pain, diabetes, hypercholesterolemia or high cholesterol

Table 2

Baseline health-related quality of life for study participants compared to the US population norm

	Study sample (*n* = 87)	US population norm
Physical functioning	80 (70–95)	90 (70–100)
Role physical, % ceiling[a]	73.6	70.9
Bodily pain	74 (52–100)	74 (61–100)
General health	72 (57–87)	72 (57–85)
Vitality[b]	50 (40–65)	65 (45–75)
Social functioning	87.5 (75–100)	100 (75–100)
Role emotional,% ceiling[a]	67.8	71.0
Mental health	76 (68–88)	80 (64–88)
Physical component score, mean (SD)[c]	49.1 (7.7)	50.0 (10.0)
Mental component score, mean (SD)[c]	49.4 (9.4)	50.0 (10.0)

% percent, *SD* standard deviation

SF-36 domain scores for the study sample and for the US population norm are presented as median (interquartile range) except where indicated. The component scores are presented as mean (standard deviation). Given the demographics of the study sample (men and women, aged 25–70) we did not use an age-specific norm

[a] % ceiling refers to percent with RP or RE = 100

[b] the bootstrap calculated 95% confidence interval of the median (42.9–57.1) suggests that study population VT is significantly lower than US population norm

[c] Physical component score and mental component score are standardized to a mean of 50 such that above or below 50 represents better or worse than the US population average (see text)

Table 3

Median change score and calculated 95% confidence interval for each SF-36 domain and summary score for phases 1 and 2 of the study

SF-36 domains	Median Phase 1 change score, median (95% CI)	Median Phase 2 change score[a], median (95% CI)
Physical functioning	0 (−1.62, 1.62)	0 (−0.91, 0.91)
Role physical	0 (0, 0)	0 (0, 0)
Bodily pain	0 (0, 0)	0 (−6.44, 6.44)
General health	5 (1.82, 8.18)[b]	−2.5 (−6.33, 1.33)
Vitality[b]	5 (0.11, 9.89)[b]	−5 (−8.82, −1.17)[b]
Social functioning	0 (0, 0)	0 (−1.89, 1.89)
Role emotional	0 (0, 0)	0 (0, 0)
Mental health	4 (−0.13, 8.13)	0 (−2.74, 2.74)
Physical component score	0.77 (−0.30, 1.84)	−0.81 (−1.83, 0.22)
Mental component score	1.9 (0.57, 3.30)[b]	−0.67 (−2.50,1.14)

95% confidence interval (CI) was calculated using 1,000 bootstrap samples with replacement via the normal approximation method

[a] Phase 2 change score uses as baseline the score at the end of Phase 1

[b] 95% confidence interval did not include zero

Table 4

Final regression models showing the relationship between weight change and vitality change for both phases of the study

Variables	Phase 1 vitality change[a]		Phase 2 vitality change[b]	
	Regression coefficient (95% CI)	*P*-value	Regression coefficient (95% CI)	*P*-value
Phase 1 weight change (kg)	−2.05 (−2.93, −1.17)	< 0.001		
Vitality baseline score[c]	−0.50 (−0.65, −0.34)	< 0.001		
Phase 2 weight change (kg)			−0.50 (−1.12, 0.12)	0.11
Vitality baseline score[c]			0.37 (0.20, 0.53)	< 0.001
Vitality score at the beginning of Phase 2			−0.61 (−0.79, −0.43)	< 0.001

The dependent variables were the Phase 1 or Phase 2 vitality change score; the independent variables were the Phase 1 weight change and the Phase 2 weight change, respectively. For both phases, potential confounders tested included age, gender, education, occupation, marital status, self-rated health, presence of obesity-related comorbidities, age when first overweight, expected weight loss, number of prior weight loss programs (see Table 1 and text for more details)

[a] The final model included Phase 1 weight change and vitality baseline score; $N = 86$; R-squared = 0.41

[b] The final model included the vitality score at the beginning of Phase 2 and the vitality baseline score; $N = 81$; R-squared = 0.40

[c] Vitality baseline score refers to the vitality score at the beginning of Phase 1