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Effect of Allowing Choice of Diet on Weight Loss. A Randomized Trial

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Abstract

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Background—Choosing rather than being prescribed a diet could improve weight loss.

Objective—Examine whether offering choice of diet improves weight loss.

Design—Doubly randomized preference trial of choice between 2 diets (Choice) versus random assignment to diet (Comparator) over 48 weeks, performed from October 2010 to October 2013.

Setting—Outpatient clinic at Durham, NC Veterans Affairs Medical Center.

Patients—Outpatients with BMI ≥30 kg/m^2.

Intervention—Choice participants received information about their food preferences and two diet options (low-carbohydrate diet [LCD] or low-fat, reduced-calorie diet [LFD]) before choosing, and were allowed to switch diets at 12 weeks. Comparator participants were randomly assigned to one diet for 48 weeks. Both arms received group and telephone counseling for 48 weeks.

Measurements—The primary outcome was weight at 48 weeks.

Results—Of 105 Choice participants; 61 (58%) chose the LCD and 44 (42%) chose the LFD, with 5 participants (3 LCD, 2 LFD) switching diets at 12 weeks; 87 (83%) completed measurements at 48 weeks. Of 102 Comparator participants, 53 (52%) were randomly assigned to the LCD and 49 (48%) to the LFD; 88 (86%) completed measurements. At 48 weeks, estimated mean weight loss was 5.7 kg (95% confidence intervals [95%CI] 4.3, 7.0) in the Choice arm and 6.7 kg (95% CI, 5.4, 8.0) in the Comparator arm; mean difference (Choice minus Comparator) −1.1 kg (95%CI, −2.9, 0.8; p=0.26). Secondary outcomes of dietary adherence, physical activity, and weight-related quality of life were similar between arms at 48 weeks.

Limitations—Only two dietary options were provided. Results in this older veteran sample might not generalize to other populations.

Conclusions—Contrary to popular opinion, the opportunity to choose a diet to follow, as opposed to being assigned a diet, did not improve weight loss.

Primary Funding Source—Department of Veterans Affairs

Keywords

obesity; low carbohydrate diet; low fat diet; autonomy; food preference; choice behavior

INTRODUCTION

A variety of dietary approaches have proven effective for weight management, amelioration of risk factors, and/or disease prevention (1-9). Regardless of approach, higher adherence to the dietary recommendations has been the best predictor of weight loss (10). Therefore, new strategies that maximize dietary adherence are needed to help patients experience maximum health benefits.

Allowing individuals to choose among evidence-based dietary strategies intuitively holds promise for improving diet adherence because it is patient-centered, offering the opportunity to select a diet based on food preferences or other factors that patients may value. If allowing choice among diets improves weight outcomes as has been suggested, (11-13) then

various dietary approaches could be made available to those seeking weight loss, and strategies developed to facilitate choice. In this doubly randomized preference trial, we evaluated whether participants allowed the opportunity to choose between two diets would have greater weight loss than participants randomly assigned a diet.

METHODS

Setting and Participants

Details regarding the study protocol have been reported (14). Participants were recruited from clinics of the Veterans Affairs Medical Center (VAMC) in Durham, NC between May 2011 and June 2012. Participants were eligible if they had BMI ≥30 kg/m^2, a regular VAMC provider, access to a telephone, and reliable transportation. Participants were ineligible for the following reasons: ≥75 years old, serum creatinine >132.6 μmol/L (1.5 mg/dL) in men or >114.9 μmol/L (1.3 mg/dL) in women, liver disease, type 1 diabetes, hemoglobin A_{1c} ≥12%, daily insulin use, unstable heart disease, organ transplant, blood pressure ≥160/100 mm Hg, fasting triglycerides ≥6.8 mmol/L (600 mg/dL) or LDL-C ≥4.9 mmol/L (190 mg/dL), pregnant, breastfeeding, lack of birth control if premenopausal, dementia, severe psychiatric illness, recent substance abuse, recent weight loss attempt, pacemaker or defibrillator. Outpatients matching entry criteria for age, BMI, and VAMC provider, and who lived within a 50-mile radius, were mailed a letter inviting them to call if interested in participating. Patients could also self-refer via advertisements posted in clinics or be referred by health care personnel. Research assistants assessed eligibility via the electronic medical record, a phone screen, and an in-person screen, at which written informed consent was obtained. Potential participants who expressed a strong aversion to one of the diets were informed they might be randomly assigned to that diet and should enroll only if that would be acceptable. The institutional review board of the Durham VAMC approved the study.

Randomization

Eligible participants were randomly assigned in parallel fashion to the Choice arm or Comparator arm (1:1 randomization) using a computerized random number generator in blocks <10 stratified by sex, BMI (<40 kg/m^2, ≥40 kg/m^2), and diagnosis of type 2 diabetes. Comparator participants underwent a second randomization (1:1) to either the low-carbohydrate diet (LCD) or low-fat diet (LFD). Only the study statisticians were aware of the randomization sequence. The project coordinator entered final eligibility data into the database, which automatically generated arm assignment for eligible participants. Participants were not made aware of assignment, and thus not considered randomized, until their first group visit.

Interventions

Choice arm procedures—At the first group visit, Choice arm participants received summary results from the Geiselman Food Preference Questionnaire (FPQ), administered during the screening visit, indicating with which of the 2 diet options their preferences aligned (15). The FPQ assesses preferences for 72 foods that are common sources of macronutrients in the typical U.S. diet with a 9-point Likert scale (1=*dislike extremely* to 9=*like extremely*). Participants scoring higher in the Low Carbohydrate/ High Protein

summary category of the FPQ were advised that their food preferences aligned best with the LCD, whereas those scoring higher in the Low Fat/ High Simple Sugar or Low Fat/ High Complex Carbohydrate categories were advised their preferences aligned best with the LFD. Participants then received verbal and printed information about the 2 diets, including foods emphasized and de-emphasized, sample menus, and evidence for safety and efficacy with neither diet having demonstrated superiority. Participants were asked not to discuss their decision with other study participants but advised they could consult with non-participants. Participants were advised they could use all this information to inform their choice of diet. The following week, the study dietitian called participants to elicit their diet choice, with diet counseling starting at the subsequent group visit. At this stage of enrollment, participants in each of 4 cohorts (approximately 50 per cohort) were placed into 4 separate small groups of approximately 12 participants each (Choice-LCD, Choice-LFD, Comparator-LCD, and Comparator-LFD). At week 12, Choice participants had the option of switching to the other diet, in which case they received personal counseling for the new diet and subsequently joined the corresponding Choice diet group.

Comparator arm procedures—At the first group visit, Comparator arm participants learned of their diet assignment and received an overview of the study design and procedures but were advised not to begin the diet until the subsequent study visit in order to parallel the timeline of the Choice arm. Comparator participants then received counseling specific to their randomly assigned diet for the duration of the study.

Procedures common to all participants—Group sessions occurred every 2 weeks for 24 weeks, then every 4 weeks for 24 weeks, with a telephone call from the dietitian between these monthly sessions. In both arms, sessions consisted of measurements followed by group counseling by a single study dietitian. Counseling consisted of dietary and physical activity topics as well as behavioral elements (e.g., mindfulness eating, planning for high-risk situations). A pocket calorie, fat, and carbohydrate counting guide was provided (16). Participants were advised to strive for 30 minutes of moderate-intensity aerobic physical activity 5 days per week (17). A study physician was available as needed for antihypertensive or antiglycemic medication adjustments following an algorithm (Appendix 1, available at www.annals.org).

The telephone counseling focused on individual goal-setting and problem-solving, incorporating principles of motivational interviewing (18). Using a script, the dietitian helped the patient identify and rank possible goals, and then develop and refine action plans (19). The dietitian recorded the goals and action plans electronically so that progress could be assessed during subsequent calls.

Dietary interventions—Participants received a book and printed handouts specific to the diet they were following (20, 21). For the LCD, carbohydrate intake was initially restricted to approximately 20 grams per day, but calories were not restricted (7, 22). Participants were instructed how to increase carbohydrate intake gradually as they neared their weight loss goal or if cravings threatened adherence. For the LFD, intake of total fat was restricted to less than 30% of daily energy intake, saturated fat to less than 10% of daily energy intake,

and cholesterol to less than 300 mg per day (21, 23); calorie intake was restricted by subtracting 500 kcal from the daily maintenance energy requirement (24).

Outcome measures

The primary outcome, body weight, was measured at each of the 19 visits at the same time of day on a standardized digital scale with participants in light clothing and shoes removed. Secondary outcomes were measured every 12 weeks for a total of 5 measurements. Waist circumference was measured with a non-elastic tape measure placed on the skin horizontally at the iliac crest (23).

Dietary adherence was assessed using the Block Brief 2000 Food Frequency Questionnaire (FFQ), which assesses over 70 food items (25). A summary measure of dietary adherence was calculated because the LCD and LFD have different dietary goals. The measure was calculated beginning at 12 weeks because dietary adherence did not apply at baseline. The calculation was percentage deviation from the goal macronutrient intake, with lower values considered to be greater adherence. For the LFD, the goal was ≤30% of daily calories from fat. For the LCD, the goal was ≤10% of daily calories from carbohydrates based on our previous study demonstrating this was the mean percentage intake (SD=12) at 2 weeks (22).

Weight-related quality of life was assessed with the Impact of Weight on Quality of Life-Lite questionnaire (IWQOL-Lite), (26, 27) which has a total score and 5 subscales (Physical Function, Self-Esteem, Sexual Life, Public Distress, and Work); higher scores indicate higher quality of life. Physical activity was assessed with the International Physical Activity Questionnaire (IPAQ) long version (28). We developed a knowledge assessment for each diet consisting of 47 items and scored as percent of total items answered correctly.

Measurements were performed by trained, blinded research personnel or hospital laboratory personnel with the exception of diet-specific knowledge questionnaires, which were administered by unblinded personnel.

Statistical analysis

The primary and secondary analyses were conducted on an intent-to-treat basis with participants analyzed in the group to which they were randomized, regardless of intervention adherence (29). Descriptive statistics of dietary energy and nutrient intake measured by the Block FFQ were calculated to assess diet composition. For continuous longitudinal outcomes, linear mixed effects models (Proc Mixed) were used to test hypotheses of treatment differences over time (30). The final models included the fixed effects linear, quadratic, cubic, and/or quartic time and associated time by arm interaction terms, to account for the fact that weight loss is not a smooth process over time. The randomization stratification variables (sex, BMI <40 or ≥40 kg/m^2 and diabetes status) were also included in the final models as fixed effects. A random effect was fit to account for the clustering of counseling group, and covariance terms were fit for the repeated measures over time. For the IPAQ, change from baseline was used as the outcome due to normality assumptionsLongitudinal models used all available data, including data from participants who had missing observations and/or were lost to attrition, with the estimation procedure implicitly accommodating missingness when related to prior outcome or to other baseline

covariates in the model (i.e., missing at random (MAR)). To assess the primary model's robustness to the missing observations, we multiply imputed missing longitudinal weight measurements using a Markov chain Monte Carlo (MCMC) algorithm incorporating additional variables beyond those in the linear mixed effects models to strengthen the MAR assumption. In a sensitivity analysis, we included diet type and diet type by week interaction terms to examine the impact of inclusion of these terms on treatment effects. We also fit models to explore weight loss for the subgroups of patients that attended <15 or ≥15 (approximately 80%) of the 19 group sessions. Statistical analyses were performed using SAS for Windows (Version 9.2: SAS Institute, Cary, NC) and R (http://www.R-project.org) (Appendix 2, available at www.annals.org).

Based on previous data, a 2-sided type-1 error rate of 0.05 and 80% power, we estimated that 216 patients (113 in each arm) were needed to detect a 4.4 kg mean difference in weight between the Choice and Comparator arms at 48 weeks, an amount (~4%) that is considered clinically significant (13). We used an intraclass correlation coefficient (ICC) and the correlation between repeated weight measurements (ρ) to adjust the variance of a two-sample difference in means test (i.e., the difference in weight at 48 weeks between the Choice and Comparator arms) in order to account for clustering and the longitudinal design, respectively.(32, 33) Sample size calculations assumed a within patient correlation of weight of 0.90, a 25% final dropout rate, and accounted for clustering due to counseling groups using an ICC of 0.005.

The funding source had no role in the design, conduct, or analysis of the study, nor in the decision to submit the manuscript for publication.

RESULTS

Participants, retention and attendance

We received 570 inquiries from 6245 letters sent to potentially eligible patients, and separately received 83 self-referrals and 144 referrals from clinicians (Figure 1). Of these, 207 participants were eligible, provided written informed consent, and attended the first group session: 105 were randomly assigned to the Choice arm and 102 to the Comparator arm. Among these, 87 (83%) Choice participants and 88 (86%) Comparator participants completed weight measurements at 48 weeks. At baseline, the mean age of participants was 55 years and mean BMI was 36 kg/m^2; 51% were African-American, 27% were women, and 23% had type 2 diabetes (Table 1).

In the Choice arm, 61 (58%) participants chose the LCD and 44 (42%) chose the LFD; in the Comparator arm, 53 (52%) participants were randomly assigned to the LCD and 49 (48%) to the LFD. Of Choice arm participants, 71% chose the diet aligning with their food preferences by the FPQ: 54 (89%) of those choosing the LCD had preferences aligning with the LCD and 21 (48%) of those choosing the LFD had preferences aligning with the LFD. (34) At 12 weeks, 3 Choice-LCD participants and 2 Choice-LFD participants switched diets. The mean (SD) number of group sessions attended (of 19) and calls completed (of 6) were 13.5 (5.5) and 2.5 (2.5), respectively, for Choice participants and 14.8 (4.7) and 3.0 (2.5) for

Comparator participants. Proportionally, 55.2% of Choice participants and 67.6% of Comparator participants attended at least 15 of the 19 group sessions.

Weight outcomes

At 48 weeks, estimated mean weight loss was 5.7 kg (95% confidence intervals [95%CI] 4.3, 7.0) in the Choice arm compared with 6.7 kg (95% CI, 5.4, 8.0) in the Comparator arm; mean difference (Choice minus Comparator) was −1.1 kg (95%CI, −2.9, 0.8; p=0.26). The mean weight loss estimates translate to a percentage change in weight from baseline of 5.6% for the Choice arm and 6.2% for the Comparator arm. There was no estimable group clustering random effect for weight. Similar weight loss results were found using the multiply imputed datasets (mean difference = −1.3 kg (95% CI, —3.1, 0.6; p=0.17) as well as in the sensitivity analysis adjusting for diet type (mean difference = −1.1 kg (95% CI, −3.0, 0.7; p=0.23) (Appendix 3, available at www.annals.org). In the exploratory subgroup analysis, the estimated mean weight loss at 48 weeks for participants who attended at least 15 group counseling visits was 7.6 kg for Choice and 8.2 kg for Comparator, and for participants who attended fewer than 15 visits weight loss was 2.7 kg for Choice and 2.8 kg for Comparator. BMI and waist circumference results mirrored the weight loss results (Table 2).

Dietary adherence, physical activity, and quality of life outcomes

Macronutrient composition diverged as expected based on assigned diets (LCD or LFD) in both arms (Appendix 4, available at www.annals.org). Dietary adherence was similar between arms (p=0.66, Table 2). Across time points, participants following the LCD answered correctly a mean of 81-88% of items from the LCD knowledge questionnaire, and LFD participants answered correctly a mean of 63-79% of items from the LFD knowledge questionnaire. We found no differences between arms in change in IPAQ scores or IWQOL-Lite total or subscale scores from baseline (Table 2).

DISCUSSION

It is believed that psychological factors such as motivation, engagement, and compliance may be optimized with a preferred rather than randomized treatment, leading to better outcomes in participants receiving the preferred treatment when participants cannot be blinded to treatment, as is the case in dietary counseling studies (35). The doubly randomized preference trial design allowed us to determine that preference did not meaningfully impact weight loss. Moreover, the range of estimated weight differences between arms in the 95% confidence intervals does not contain a clinically meaningful difference in favor of the Choice arm.

A prior study used a similar design to examine the effects of offering dietary choice. In the Paving the Road to Everlasting Food and Exercise Routine (PREFER) study, 176 participants with at least a moderate preference for either an LFD or a lacto-ovo-vegetarian (LOV) diet were randomized to a choice or no choice condition (36). Participants in the choice condition lost less weight (−3.9% and −5.3% for chosen LFD and LOV diet, respectively), than those assigned a diet (−8.0% and −7.9% for assigned LFD and LOV diet,

respectively; p=0.02 for study arm by time interaction). To aid choice, PREFER participants received a printed summary of the main points of each diet before indicating their preference. In contrast, our procedures mimicked an informed decision-making process by presenting individualized feedback about food preferences using the FPQ followed by verbal and written information about the diets. Our study design additionally offered participants the opportunity to switch diets at 12 weeks. Another distinction regards the diet options; in the PREFER study the LOV diet was chosen substantially less often than the LFD, whereas, in our study, the LCD was chosen more often than the LFD. Because of these design features, our results might better generalize to a clinic setting where commonly desired diet options are offered to patients without a strong preference using a facilitated decision-making approach. Another difference between the two studies was that our sample was primarily men and more racially-mixed, an important distinction because men and minorities are underrepresented in weight loss trials (37, 38).

Another study examined the relationship between diet preference and outcomes in a standard randomized trial comparing the LCD and LFD (39). In this study, participants did not have the opportunity to choose their diet, but rather, their preference was assessed on a Likert-type scale prior to and after random assignment to one of the diets. In analyses, participants who received their baseline preference actually lost statistically significantly less weight (−7.7 kg) than participants who did not receive their baseline preference (−9.7 kg, p=0.04 for comparison) or participants who did not express a preference (−11.2 kg, p<0.001 for comparison).

These results converge to suggest that providing a choice of diets to patients does not enhance weight loss and may actually hinder weight loss. One reason may be that individuals are more likely to overeat when following a diet that emphasizes foods they find palatable. Palatability is a major determinant of food intake and total caloric intake (40-42). Another possible reason may be a ‘personal trainer’ effect in which individuals may be more adherent to a fitness program if directed what exercises to do rather than choosing on their own.

An unexpected finding was that few of the Choice arm participants elected to switch diets at 12 weeks. We chose this time point purposefully so that participants would have ample time to learn and experience the initial diet choice before encountering the opportunity to switch but also would not yet have reached the 4-6 month period when weight loss typically plateaus, which might lead some participants to switch even though the diet was a good fit.

An interesting result was that the FPQ categorized a higher percentage of participants as having food preferences aligned with the LCD than with the LFD. This may have at least partially resulted from participant demographics given that our sample was predominantly men, and prior research shows that men are more likely to prefer foods that are high in fat (40, 43). Nevertheless, the ultimate diet choice breakdown was more balanced, with 58% choosing LCD and 42% choosing LFD, and sensitivity analyses adjusting for diet type mirrored the main results.

Having predominantly men in the sample might limit the generalizability of our results, as could the age of the sample. Having more than 2 dietary options might have had broader appeal to participants but would have been logistically difficult, so we chose the 2 diets we felt had the strongest evidence base and greatest appeal in our patient population yet were diverse in macronutrient content. Advising participants with a strong aversion to one diet not to enroll may have weakened the potential beneficial effect of choice on adherence but occurred rarely (n=2) and was done to minimize differential attrition between the arms. An additional difficulty we faced was analyzing dietary adherence when each arm included 2 diets with very different macronutrient goals. We used the Block Brief FFQ, which is known to underestimate energy and macronutrient intake, and calculated percentage deviation from macronutrient goal, which did not perfectly reflect the carbohydrate goal in the LCD or the energy goal in the LFD; any inaccuracy, however, should exist similarly in both study arms.

Offering choice among diet options did not improve weight loss, dietary adherence, or weight-related quality of life in participants who did not have a strong diet preference at baseline. Given that diverse diets have proven effective for weight loss, future research might examine matching patients to their optimal diet based on other characteristics (e.g., metabolic profile, genetics) instead of their preferences.

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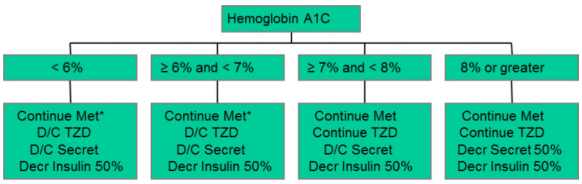
APPENDICES

Appendix 1. Medication Adjustment Algorithms

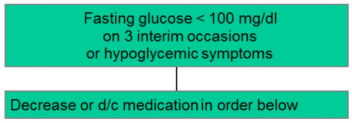
Initial Diabetes Medication Adjustment



D/C = Discontinue, Decr = Decrease
Oral Meds: Met=Metformin, TZD=thiazolidinediones, Secret=Secretagogues
*If monotherapy, then metformin will be decreased 50% for Hgb A1c<7%.
Alpha-glucosidase inhibitors will be stopped for the duration of the study.
Incretin/amylin agonists will not be adjusted initially.

Rationale
1) If glycemic control is only fair, then continue insulin sensitizers
2) Discontinue secretagogues that increase the risk of hypoglycemia
3) Reduce insulin because of reduced dietary carbohydrate and/or energy intake
4) If fair/poor control and on no medication, start without medication and assess at 2 weeks

Medication Adjustment For Follow-up Hypoglycemia
IF TAKING MORE MEDICATION THAN METFORMIN ONLY

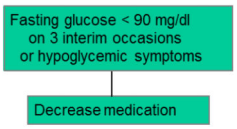


Hypoglycemia defined as >1 "unassisted" episodes or 1 "assisted" episode (requiring emergency medical care) in the previous 2 weeks.

Decrease medications as follows:
Oral agents: 50% reduction in dose
Insulin: 50% reduction in total daily dose

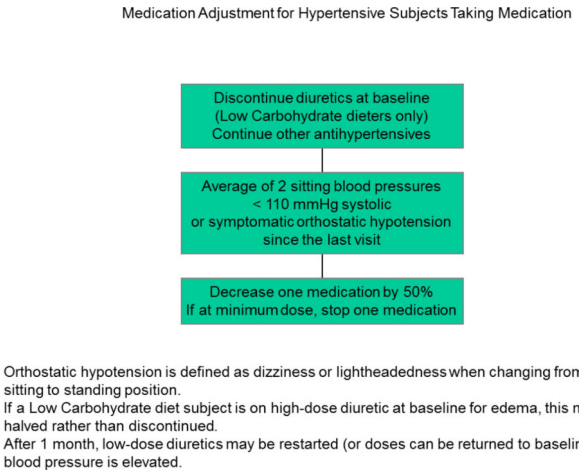
Order of discontinuation of medication:
First removed: insulin or secretagogues based on patient preference
Then: thiazolidinediones
Then: metformin and GLP-1/amylin agonists

Medication Adjustment For Follow-up Hypoglycemia
IF TAKING METFORMIN ONLY



Hypoglycemia defined as >1 "unassisted" episodes, or 1 "assisted" episode (requiring emergency medical care) in the previous 2 weeks.

Decrease Metformin with the following stepwise changes:
Metformin
a) 1000mg am/1000 mg pm
b) 1000mg am/500 mg pm
c) 500 mg bid
d) 500 mg qd
e) discontinue



Appendix 2

Technical Appendix

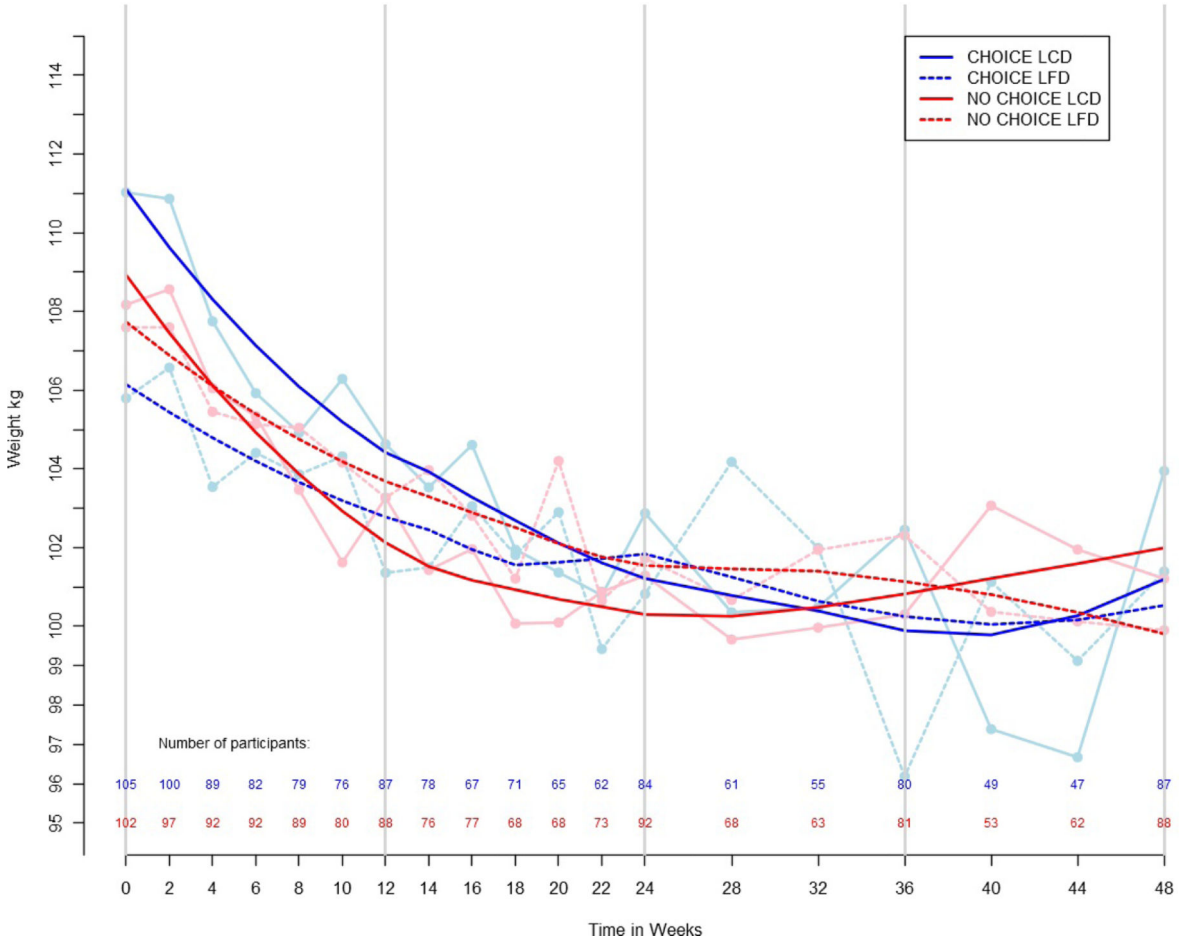
1. Model Selection and Fitting process—The process for selecting the best model for each outcome was a two-step process.

- In the first step we determined the "best" covariance structure by fitting "hybrid" models with a random effect for group and different covariance structures that included CS, AR(1), TOEP, SP(EXP), SP(POW), and UN for the serial correlation between time points and a set of random coefficient models that included 1) random effect for group and random intercept and linear slope for subjects and 2) random effect for group and random intercept, random linear slope and random quadratic slope. These models were fit using REML, and AIC model selection criteria were assessed to determine the best fit model. In the second step, we used the covariance structure identified in step 1 for each outcome to determine the best mean structure. In this step, we fit separate models using linear time, quadratic time, cubic time and quartic time for the fixed effects for each outcome. These models were fit using ML, and AIC model selection criteria were assessed to determine the best fit model.

Following this process for each outcome, we ran the "best fit" model including stratification variables and estimated arm differences at 48 weeks from these models. All the final models were fit using REML. The final model for weight was determined by this process and accounted for the covariance in weight within individual over time using a spatial correlation structure (SP(EXP)(week)). This model was used for all subsequent sensitivity analyses.

2. Multiple Imputation Procedure—We conducted a sensitivity analysis using a multiple imputation (MI) approach that included additional variables beyond those in our random effects models to strengthen the MAR assumption. As a first step, we used t-tests and chi-square tests as appropriate to assess each potential variable's association with missingness at week 48, and any variable with an association p-value of 0.1 or less was included in the imputation model. Variables assessed included age, race, smoking status,

waist size at baseline, education level, systolic and diastolic blood pressure at baseline, diet preference at baseline, a scale of how successful the participant believed they would be at losing weight, whether or not they had attempted weight loss previously, the number of people living in their household, socioeconomic status, employment status, number of minutes spent walking per week, number of minutes spent in moderate exercise per week, which diet they were following (low carbohydrate vs. low fat), and six quality of life scores: physical function, self-esteem, sex life, public distress, work, and total. Of these, the following were associated with missing status at week 48 and therefore included in the imputation model: number of people living in the household, employment status, age, number of minutes in moderate exercise per week, and public distress quality of life score. The imputation model additionally included randomization arm, stratification variables (gender, type 2 diabetes status, BMI category), and all collected weight measurements at the 19 possible time points. Missing weight measurements at any of the 19 time points were imputed using a Markov chain Monte Carlo (MCMC) algorithm with 10 imputations. The imputation provided results that were very similar to the main analysis. Models run on the imputed datasets estimated weight loss to be 1.3kg less (95% CI, −3.1, 0.6; p=0.17) in the Choice arm than the Comparator arm.



Appendix 3. Figure.

Smoothed spline trajectories of weight over 48 weeks by diet type and arm (blue and red solid and dashed lines) and observed mean trajectories of weight over 48 weeks by diet type and arm (light blue and pink solid and dashed lines).

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Appendix 4

Table. Mean (SD) dietary intake and diet knowledge by study arm and time point

Nutrient	Choice Arm		Comparator Arm	
	Low Carbohydrate Diet (n=61)*	Low Fat Diet (n=44)*	Low Carbohydrate Diet (n=53)	Low Fat Diet (n=49)
Energy, kcal/d				
Baseline	2010 (1156)	1631 (736)	1584 (642)	2210 (1695)
12 weeks	1083 (508)	957 (431)	1168 (493)	1307 (741)
24 weeks	1085 (611)	985 (419)	970 (434)	1158 (591)
36 weeks	1158 (602)	968 (353)	998 (391)	1169 (550)
48 weeks	1212 (614)	937 (303)	1042 (431)	1259 (751)
Carbohydrates, g/d				
Baseline	203 (110)	182 (84)	172 (77)	236 (202)
12 weeks	45 (38)	110 (51)	56 (40)	151 (86)
24 weeks	54 (58)	117 (55)	47 (36)	135 (69)
36 weeks	66 (57)	118 (60)	49 (32)	134 (66)
48 weeks	79 (67)	117 (44)	60 (41)	145 (90)
Carbohydrates, % daily kcal				
Baseline	10 (1.8)	11 (2.1)	11 (2.1)	10 (1.6)
12 weeks	4.2 (2.3)	12 (2.6)	4.9 (3.0)	12 (1.9)
24 weeks	4.8 (2.7)	12 (3.0)	5.0 (2.9)	12 (1.9)
36 weeks	5.6 (3.1)	12 (3.0)	5.1 (2.6)	12 (1.9)
48 weeks	6.2 (3.5)	13 (3.1)	5.9 (3.3)	12 (2.1)
Total fat, g/d				
Baseline	97 (66)	72 (37)	72 (32)	103 (77)
12 weeks	73 (35)	38 (20)	75 (32)	54 (34)
24 weeks	70 (36)	39 (21)	63 (28)	48 (26)
36 weeks	71 (36)	37 (13)	64 (28)	48 (24)
48 weeks	74 (40)	35 (16)	65 (31)	53 (34)
Total fat, % daily kcal				
Baseline	4.7 (0.7)	4.3 (0.8)	4.5 (0.8)	4.7 (0.6)

Nutrient	Choice Arm		Comparator Arm	
	Low Carbohydrate Diet (n=61)*	Low Fat Diet (n=44)*	Low Carbohydrate Diet (n=53)	Low Fat Diet (n=49)
12 weeks	6.7 (1.0)	3.9 (1.0)	6.4 (1.2)	4.1 (0.7)
24 weeks	6.5 (1.3)	3.9 (1.0)	6.5 (1.1)	4.1 (0.7)
36 weeks	6.2 (1.3)	3.9 (1.0)	6.4 (0.9)	4.1 (0.6)
48 weeks	6.2 (1.2)	3.6 (0.9)	6.2 (1.3)	4.2 (0.7)
Saturated fat, g/d				
Baseline	32 (22)	24 (12)	24 (11)	34 (26)
12 weeks	25 (13)	12 (6)	25 (13)	17 (10)
24 weeks	23 (12)	13 (7)	21 (10)	15 (8)
36 weeks	24 (13)	12 (4)	22 (10)	15 (9)
48 weeks	25 (14)	12 (5)	21 (10)	17 (12)
Saturated fat, % daily kcal				
Baseline	1.6 (0.3)	1.4 (0.3)	1.5 (0.3)	1.6 (0.2)
12 weeks	2.3 (0.5)	1.3 (0.4)	2.1 (0.5)	1.3 (0.2)
24 weeks	2.2 (0.6)	1.3 (0.3)	2.1 (0.5)	1.3 (0.2)
36 weeks	2.1 (0.5)	1.3 (0.4)	2.1 (0.4)	1.3 (0.3)
48 weeks	2.0 (0.5)	1.2 (0.4)	2.0 (0.4)	1.3 (0.3)
Protein, g/d				
Baseline	81 (48)	66 (30)	63 (26)	88 (60)
12 weeks	62 (33)	43 (22)	67 (34)	61 (34)
24 weeks	59 (34)	46 (23)	53 (27)	51 (27)
36 weeks	62 (36)	44 (15)	55 (25)	54 (28)
48 weeks	61 (34)	43 (20)	53 (27)	55 (31)
Protein, % daily kcal				
Baseline	4.1 (0.6)	4.1 (0.9)	4.0 (0.8)	4.1 (0.7)
12 weeks	5.7 (1.2)	4.5 (0.8)	5.6 (1.4)	4.7 (0.7)
24 weeks	5.5 (1.1)	4.7 (1.4)	5.5 (1.3)	4.5 (0.9)
36 weeks	5.3 (1.2)	4.7 (1.0)	5.4 (1.1)	4.6 (0.9)
48 weeks	5.0 (1.3)	4.5 (1.1)	5.1 (1.4)	4.4 (0.8)

Nutrient	Choice Arm		Comparator Arm	
	Low Carbohydrate Diet (n=61)*	Low Fat Diet (n=44)*	Low Carbohydrate Diet (n=53)	Low Fat Diet (n=49)
Low Carbohydrate Diet knowledge, % correct responses				
12 weeks	84 (9)		85 (10)	
24 weeks	85 (11)		85 (16)	
36 weeks	84 (12)		88 (10)	
48 weeks	82 (17)		81 (18)	
Low Fat Diet knowledge, % correct responses				
12 weeks		63 (21)		73 (18)
24 weeks		77 (12)		75 (11)
36 weeks		79 (7)		78 (12)
48 weeks		77 (11)		78 (10)

*After 12 weeks, the number of Choice arm Low Carbohydrate Diet participants was 60 and the number of Choice arm Low Fat Diet participants was 45.

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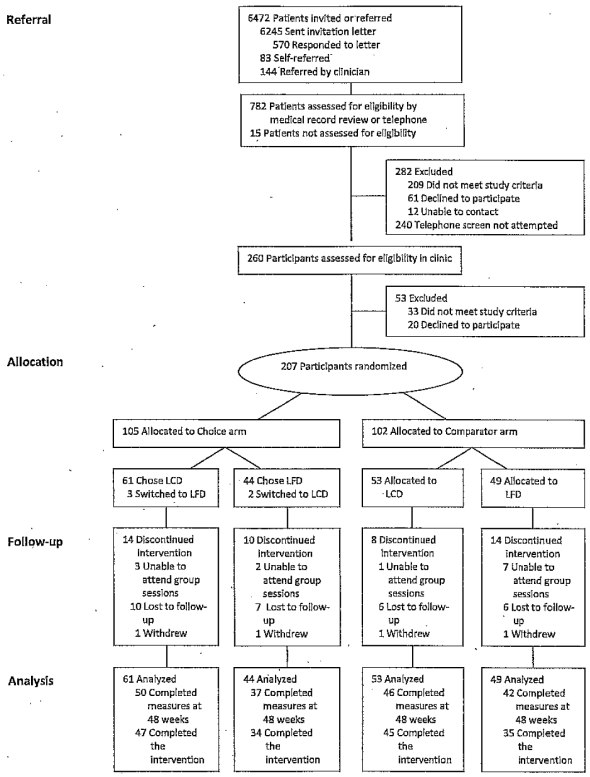

Figure 1.
Participant flow.

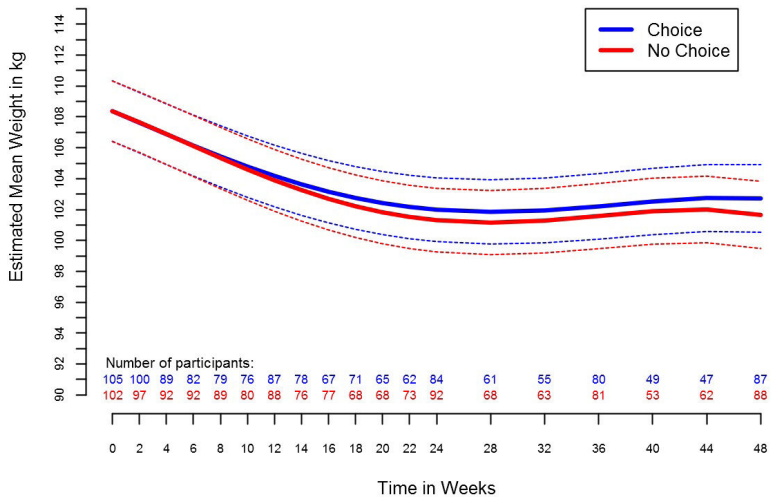

Figure 2.

Estimated mean weight trajectories in kg over 48 weeks for the Choice and Comparator arms from linear mixed models.

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Table 1

Baseline participant characteristics[a]

Characteristic	Both Arms	Choice Arm			Comparator Arm		
	Total (n=207)	Total (n=105)	Completers (n=87)	Non-completers[b] (n=18)	Total (n=102)	Completers (n=88)	Non-completers[b] (n=14)
Demographics							
Age, y	55 (11)	54 (11)	55 (10)	49 (13)	55 (10)	57 (10)	47 (6)
Women, No. (%)	55 (27%)	28 (27%)	25 (29%)	3 (17%)	27 (26%)	25 (28%)	2 (14%)
Race							
African-American, No. (%)	106 (51%)	45 (43%)	39 (45%)	6 (33%)	61 (60%)	49 (56%)	12 (86%)
White, No. (%)	93 (45%)	54 (51%)	45 (52%)	9 (50%)	39 (38%)	37 (42%)	2 (14%)
College degree, No. (%)	73 (35%)	34 (32%)	31 (36%)	3 (17%)	39 (38%)	34 (39%)	5 (36%)
Clinical Measures							
Body weight, kg	108 (20)	109 (21)	109 (22)	108 (16)	108 (19)	107 (19)	112 (22)
Body mass index, kg/m^2	36 (6)	36 (6)	36 (7)	35 (4)	36 (5)	36 (5)	37 (5)
BMI ≥40 kg/m^2	37 (18%)	20 (19%)	17 (20%)	3 (17%)	17 (17%)	14 (16%)	3 (21%)
Waist circumference, cm[c]	46 (5)	46 (6)	46 (6)	46 (5)	46 (5)	46 (5)	45 (7)
Systolic blood pressure, mm Hg[d]	131 (14)	131 (14)	131 (14)	135 (12)	131 (14)	132 (15)	127 (10)
Diastolic blood pressure, mm Hg[d]	85 (9)	86 (9)	85 (9)	89 (10)	84 (8)	85 (8)	84 (8)
Diet Preference by Geiselman FPQ, No. (%)[e]							
Low carbohydrate diet	155 (76%)	77 (73%)	62 (71%)	15 (83%)	78 (80%)	66 (79%)	12 (86%)
Low fat diet	48 (24%)	28 (27%)	25 (29%)	3 (17%)	20 (20%)	18 (21%)	2 (14%)
IWQOL-Lite, Total Score[f]	72 (19)	72 (20)	72 (21)	67 (13)	72 (19)	71 (19)	73 (17)
Physical function	63 (24)	63 (24)	64 (24)	60 (25)	63 (24)	63 (24)	59 (25)
Self-esteem	65 (28)	65 (29)	68 (30)	54 (22)	66(27)	65 (28)	68 (23)
Sexual life[g]	76 (28)	76 (29)	77 (28)	68 (30)	77 (28)	75 (30)	88 (15)
Public distress	87 (19)	87 (20)	86 (22)	91 (11)	88 (17)	87 (17)	94 (13)
Work	82 (21)	82 (20)	83 (21)	78 (12)	81 (22)	81 (22)	83 (21)
Risk Factors							

Characteristic	Both Arms	Choice Arm			Comparator Arm		
	Total (n=207)	Total (n=105)	Completers (n=87)	Non-completers[b] (n=18)	Total (n=102)	Completers (n=88)	Non-completers[b] (n=14)
Smokers, No. (%)[h]	19 (9%)	8 (8%)	7 (8%)	1 (6%)	11 (11%)	8 (9%)	3 (21%)
Physical activity[i], mins/week Median[1st quartile; 3rd quartile]							
Walking	180 [30; 600]	180 [30;630]	180 [25;630]	300 [40;600]	180 [40;600]	178 [45;500]	240 [0;1050]
Moderate activity	360 [90; 720]	290 [15;720]	240 [0;540]	720 [360;1080]	480 [120;840]	390 [120;740]	660 [480;1200]
Diabetes, No. (%)	47 (23%)	23 (22%)	21 (24%)	2 (11%)	24 (24%)	22 (25%)	2 (14%)

FPQ=food preference questionnaire; IWQOL-Lite=Impact of Weight on Quality of Life-Lite questionnaire

[a] Values presented are means (SD) unless otherwise specified.

[b] Non-completers are those participants who did not have their final (week 48) measurements completed.

[c] There were 2 participants from the Choice arm and 2 from the Comparator arm with missing waist circumference data at baseline.

[d] There was 1 participant from the Choice arm and 1 from the Comparator arm with missing BP measurement data at baseline.

[e] There were 4 participants from the Comparator arm missing FPQ data at baseline.

[f] There was 1 participant from the Comparator arm missing IWQOL data at baseline for total, physical function, self-esteem, public distress, and work scales.

[g] There were 2 participants from the Choice arm and 3 from the Comparator arm missing IWQOL data at baseline for the sexual life sub-scale.

[h] There was 1 participant from the Comparator arm missing baseline smoking status.

[i] Physical activity was assessed by the International Physical Activity Questionnaire. There were 3 participants from the Choice arm and 3 from the Comparator arm with missing physical activity data at baseline.

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Table 2

Estimated means and mean differences [95% CI] of outcomes for Choice and Comparator arms by time point[a]

Measurements	Choice Arm	Comparator Arm	Choice Arm – Comparator Arm (95% CI)	P value at 48 weeks
Body weight, kg				
Baseline		108.4		
12 weeks	104.2	103.9	0.3 [−0.6,1.2]	
24 weeks	102.0	101.3	0.7 [−0.6,2.0]	
36 weeks	102.2	101.6	0.6 [−1.0, 2.3]	
48 weeks	102.7	101.7	1.1 [−0.8, 2.9]	0.26
Waist circumference, cm				
Baseline		45.9		
12 weeks	44.0	43.7	0.3 [−0.2, 0.8]	
24 weeks	43.2	43.1	0.2 [−0.4, 0.8]	
36 weeks	43.2	43.1	0.1 [−0.6, 0.8]	
48 weeks	43.5	43.1	0.4 [−0.3, 1.2]	0.28
Diet adherence, % deviation from goal				
12 weeks	7.2	8.6	−1.3 [−4.9, 2.2]	
24 weeks	7.1	8.4	−1.3 [−4.8, 2.3]	
36 weeks	8.4	8.7	−0.3 [−3.9, 3.3]	
48 weeks	9.4	10.3	−0.9 [−4.9, 3.1]	0.66
IWQOL-Lite, total score				
Baseline		71.5		
12 weeks	77.5	78.3	−0.8 [−3.3, 1.7]	
24 weeks	79.3	81.6	−2.3 [−5.1, 0.4]	
36 weeks	79.8	82.7	−2.9 [−6.0, 0.2]	
48 weeks	81.9	82.7	−0.8 [−4.1, 2.6]	0.65
IWQOL-Lite, Physical function				
Baseline		62.7		
12 weeks	69.9	70.7	−0.7 [−4.0, 2.5]	
24 weeks	71.4	75.3	−4.0 [−7.4, −0.5]	
36 weeks	71.6	77.1	−5.6 [−9.6, −1.5]	

Measurements	Choice Arm	Comparator Arm	Choice Arm – Comparator Arm (95% CI)	P value at 48 weeks
48 weeks	75.1	76.6	−1.5 [−5.7, 2.7]	0.49
IWQOL-Lite, Self-esteem				
Baseline		65.5		
12 weeks	72.3	74.8	−2.5 [−6.6, 1.6]	
24 weeks	76.5	78.4	−1.9 [−6.5, 2.7]	
36 weeks	79.0	79.4	−0.4 [−5.3, 4.5]	
48 weeks	80.3	80.5	−0.2 [−5.2, 4.9]	0.95
IWQOL-Lite, Sexual life				
Baseline		76.3		
12 weeks	83.5	81.8	1.7 [−3.5, 6.8]	
24 weeks	84.0	84.1	−0.2 [−5.5, 5.2]	
36 weeks	82.9	84.7	−1.8 [−7.1, 3.5]	
48 weeks	85.3	85.0	0.3 [−5.9, 6.4]	0.93
IWQOL-Lite, Public distress				
Baseline		87.3		
12 weeks	89.4	90.6	−1.2 [−4.3, 1.9]	
24 weeks	91.0	91.6	−0.5 [−3.7, 2.6]	
36 weeks	91.6	91.4	0.2 [−3.1, 3.5]	
48 weeks	90.5	91.3	−0.7 [−4.1, 2.6]	0.67
IWQOL-Lite, Work				
Baseline		81.9		
12 weeks	86.2	87.1	−0.9 [−4.0, 2.2]	
24 weeks	87.4	88.9	−1.5 [−5.0, 2.0]	
36 weeks	87.7	89.3	−1.5 [−5.5, 2.5]	
48 weeks	89.6	90.3	−0.7 [−4.9, 3.5]	0.73
Walking[b], change from baseline, mins/week				
12 weeks	6.0	4.4	1.6 [−37.3, 40.6]	
24 weeks	6.0	2.7	3.2 [−74.6, 81.1]	
36 weeks	5.9	1.1	4.9 [−112.0, 121.7]	
48 weeks	5.9	−0.6	6.5 [−149.3, 162.2]	0.93
Moderate physical activity, change from baseline, mins/week				

Measurements	Choice Arm	Comparator Arm	Choice Arm – Comparator Arm (95% CI)	P value at 48 weeks
12 weeks	21.8	59.4	−37.6 [−101.7, 26.6]	
24 weeks	26.3	67.5	−41.1 [−142.3, 60.0]	
36 weeks	18.5	29.2	−10.7 [−140.0,118.5]	
48 weeks	−1.5	−55.1	53.6 [−124.7, 231.9]	0.55

IWQOL-Lite=Impact of Weight on Quality of Life-Lite questionnaire

[a]Values are estimated means by linear mixed-effects models analysis; missing 48 week outcomes (# Choice arm; # Comparator arm): body weight (18; 14), waist(19; 14), Diet Adherence (26; 21), IWQOL-Lite (26; 18); IWQOL-Lite, Sexual Life (28; 22), IWQOL-Lite, Work (27; 18), Walking and Moderate physical activity (28; 19).

[b]Physical activity was assessed by the International Physical Activity Questionnaire.