Study Title:

A Randomized, Controlled, 3-Arm Clinical Trial to Assess Weight Loss using the Take Shape For Life Program or the Medifast Direct Program Versus a Self-Directed Diet

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A Randomized, Controlled, 3-Arm Clinical Trial to Assess Weight Loss using the Take Shape For Life Program or the Medifast Direct Program Versus a Self-Directed Diet

Signature Page

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ABBREVIATIONS

AE	adverse event alkaline
ALP	phosphatase alanine
ALT	aminotransferase
ANCOVA	analysis of covariance
ANOVA	analysis of variance
AST	aspartate aminotransferase
BMI	body mass index
BUN	blood urea nitrogen
CO_2	carbon dioxide
DXA	dual energy x-ray absorptiometry
eCRF	electronic case report form
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
hs-CRP	high-sensitivity C-reactive protein
ICH	International Conference on Harmonization
IQR	Inter-Quartile Range
IRB	Institutional Review Board
ITT	intent to treat
IWQOL	Impact of Weight on Quality of Life
kg	kilogram
LOCF	Last Observation Carried Forward
MEDD	Medifast Direct
m	meter
m^2	meter squared
mg	milligram
mITT	Modified intent to treat
mL	milliliter
mm Hg	millimeters of mercury
PAL	physical activity level
QoL	quality of life
SEM	standard error of the mean
SOP	standard operating procedure
TSFL	Take Shape For Life
tel	telephone
VAS	visual analog scale

TABLE OF CONTENTS

1.0. STUDY OBJECTIVES

The objective of this study is to evaluate the effects of two commercially available weight loss programs, TSFL and MEDD, each compared to a self-directed control diet, on changes in body weight in apparently healthy overweight and obese men and women.

2.0. TRIAL DESIGN AND VISIT STRUCTURE

This randomized, controlled, 16-week parallel study includes one screening visit (Visit 1; week -1), one baseline visit (Visit 2; week 0), and five clinic visits (Visits 3,4,5,6, and 7; weeks 2, 4, 8, 12, and 16). Subjects will be randomly assigned in 1:1:1 ratio to one of the three groups (TSFL Program Group, MEDD Program Group, or Control Group) within which the subjects will receive the following interventions:

- **TSFL Program Group:** The TSFL Program group will be assigned to the Optimal Weight 5 & 1 Plan™ for weight loss. This is a portion-controlled, nutritionally balanced, low calorie weight loss meal plan (800-1000 kcal/day) that consists of five Medifast meal replacements, one lean and green meal, and one optional snack each day. The Medifast meal replacements are nutrient dense and fortified with 24 vitamins and minerals to ensure adequate micronutrient nutrition while on a calorie restricted meal plan. All Medifast meal replacements share a similar nutritional profile, allowing them to be used interchangeably. All Medifast meal replacements required for the meal plan will be provided to the TSFL Group participants throughout the 16-week weight loss period of the study. The lean and green meal is a self-prepared meal consisting of a specified amount of lean protein, non-starchy vegetables, and healthy fats. Participants will purchase and prepare foods used for the lean and green meals on their own. Additionally, the Medifast Flavors of Home® products offer a "heat and serve" alternative to the self-prepared lean and green meal for occasional use. TSFL participants will receive up to six Flavors of Home products per month during the study. TSFL participants will receive a list of self-selected foods (purchased by the participants) that can be used for the optional snack. In addition, participants will also be provided with up to two boxes (i.e., 14 individual packets) of Medifast snacks which can serve as a portable, pre-portioned, ready-to-eat alternate snack option.

  This TSFL group will have regularly scheduled coaching sessions starting at Visit 2 (week 0) with an assigned research assistant trained to function as a TSFL coach (hereinafter referred to as the TSFL Coach) for the duration of the study. The TSFL coach training will take place before the study and will utilize a training protocol mimetic of current training received by new TSFL Coaches. The coaching schedules and content will meet the TSFL coaching standards of practice. Coaching, for the purpose of this study, will take place via telephone. The initial coaching session (45 min in length) will occur the day of Visit 2 (week 0) as participants will be instructed to start their weight loss program on the day following the randomization visit (day 1). If the coaching session does not take place, participants will be instructed to start their weight loss program on day 1 regardless (a protocol deviation form must be submitted). Participants will have access to TSFL written support tools and monthly e-mailed newsletters throughout the study to assist with weight loss. Participants will also have limited

telephone and e-mail access during the study to the Medifast Nutrition Support Team (available when a question exceeds the scope of the TSFL Coach training), which is consistent with the commercially available program.

- **MEDD Program Group:** Participants randomized to the MEDD group will be assigned to the Medifast Achieve™ Plan (4 & 2 & 1 Plan®) for weight loss. The Achieve Plan is a portion-controlled, nutritionally balanced, reduced energy (1100-1300 kcal/day) meal plan that consists of four Medifast meal replacements, two lean and green meals, and one healthy snack. The Medifast meal replacements and the lean and green meals are the same as those described above for the TSFL Group. Briefly, Medifast meal replacements are portion-controlled, nutrient dense, and fortified with 24 vitamins and minerals. All Medifast meal replacements share a similar nutritional profile, allowing them to be used interchangeably. Medifast meal replacements required for the program will be provided to the MEDD Group participants throughout the study. The lean and green meal is a self-prepared meal consisting of a specified amount of lean protein, non-starchy vegetables, and healthy fats. Participants will purchase and prepare foods used for the lean and green meals on their own. Additionally, the Medifast Flavors of Home® products offer a "heat and serve" alternative to the self-prepared lean and green meal for occasional use. MEDD participants will receive up to twelve Flavors of Home products per month during the study. The healthy snack will consist of a self-selected serving of fruit, dairy, or grain purchased by the participant, or one of Medifast's portable, pre-portioned, ready-to-eat Medifast snacks can be used as a healthy snack. Participants will receive up to two boxes (i.e., 14 individual packets) of Medifast snacks per month.

  Participants will be dispensed study-specific printed materials (including the "Getting Started Instructions") at Visit 2 (week 0) and will have one telephone call with a Medifast Nutrition Support Team member prior to 17:00 h EST at Visit 2 (week 0) to receive instruction on the meal plan and support materials as participants will be instructed to start their weight loss program on the day following the randomization visit (day 1). If the telephone call does not take place, participants will be instructed to start their weight loss program on day 1 regardless (a protocol deviation form must be submitted). Participants will also have telephone and e-mail access to the Medifast Nutrition Support Team and Medifast online tools throughout the study. Participants in the MEDD group will be encouraged to track weight and food intake and access MEDD written, online, and virtual support tools to use at their discretion.

- **Control:** The Control group will follow a self-directed diet, which is a food-based, reduced-calorie diet, consistent with the 2015 Dietary Guidelines for Americans (See Supplementary Materials). This group will receive a one-on-one personal instruction session (10-15 min) with a trained member of the study staff at the Visit 2 (week 0) clinic visit. During this session, daily energy intake targets will be determined for each participant using the National Institutes of Health body weight planner (www.niddk.nih.gov/health-information/health-topics/weight-control/body-weight-planner/Pages/bwp.aspx). The personalized daily energy intake level will be specific to each participant's 16-week weight loss goal, targeting 7% weight loss over the 16-week weight loss period, consistent with recent obesity treatment guidelines (Jensen 2014). Participants will receive publicly available information from the USDA Choose MyPlate

program, including a handout with a meal plan from the website to match their target energy intake, as well as instruction to utilize the www.choosemyplate.gov website. Participants with target energy intakes of <1600 kcal per day will be instructed to take a multi-vitamin of their choosing (not marketed to enhance or benefit weight loss, energy, metabolism, etc.) to ensure adequate intake of micronutrients. Participants will be instructed to start their weight loss program on the day following randomization (day 1). In keeping with the self-directed nature of this control group, participants will not receive further instructions or personal support during the weight loss period.

3.0. SIZE OF TRIAL POPULATION

A standard deviation of 15.0 lb for change in body weight over 16 weeks was derived from the largest variability observed in a previous study by Davis et al. (2010) that compared weight loss over 16 weeks on the Medifast 5 & 1 Plan® (-29.8 ± 13.0 lb) vs. a food-based isocaloric control diet (-14.3 ± 15.0 lb). Using this estimate of expected variability and accounting for a more conservative mean difference in weight loss between groups over a similar timeframe, an evaluable sample of 55 participants in each group (165 total) will provide 80% power to detect a difference of 9.0 pounds (an effect size d of 0.60). This assumes a nominal $\alpha = 0.025$ (two-sided) accounting for two primary comparisons, each Medifast group compared to the control group, in order to maintain an overall type I error of $\alpha = 0.05$. To account for possible attrition, a total sample of 198 participants will be randomized.

Subjects will be randomized to one of three groups (1:1:1 ratio) stratified by sex to ensure each group is allocated a maximum of 25% male participants. Additionally, the total study sample will be limited to ≤10% of participants with a BMI between ≥27.0 and <30.0 kg/m^2, but randomization will not be stratified by BMI.

4.0. PERSONNEL RESPONSIBLE FOR DATA ANALYSIS

Data analyses will be carried out by personnel from Biofortis.

5.0. ANALYSIS POPULATIONS

All statistical analyses will be conducted using SAS® software for Windows (version 9.4 or higher, Cary, NC).

An Intent-To-Treat (ITT) population will include all subjects who were randomized into the study. A modified ITT (mITT) population will include all randomized participants that had at least one post-baseline weight measurement. In addition, a Completers population will comprise subjects who were randomized into the study and completed all clinic visits during the entire 16-week study period.

All decisions regarding population assignment will be documented prior to database lock.

6.0. PRESENTATION OF SUBJECT DISPOSITION

Frequency counts and percentages for all subjects who are screened, randomized, complete the study, and discontinue early will be presented. Information will be presented for subjects who withdraw early on the visits at which withdrawal occurred and the intervention condition(s) completed. In addition, frequency counts and percentages of subjects' reported reasons for discontinuation will be summarized.

7.0. PRESENTATION OF SCREENING/BASELINE VARIABLES

Variables collected at screening (Visit 1) will be summarized and presented. In addition, vital signs measurements collected from Visits 1 to 7 will also be summarized and presented. Descriptive statistics (number of subjects, mean, standard error of the mean (SEM), median, inter-quartile limits, minimum, and maximum values) will be presented for the continuous variables. Frequency counts and percentages will be presented for the categorical variables. The following variables will be presented:

- Demographic characteristics: *(Visit 1)*
  - Gender (male, female)
  - Age (years)
  - Race (White, Black/African American, American Indian or Alaskan Native, Asian or Pacific Islander, Multiracial Origin, or Other)
  - Ethnicity (Hispanic/Latino or Not Hispanic/Latino)
  - Weight (kg)
  - Height (cm)
  - BMI (kg/m^2) as continuous and categorical variables (frequency counts and percentages of subjects randomized to each BMI strata for each group)
  - Smoking status
  - Education
  - Fasting glucose (mg/dL)

- Vital signs measurements: *(Visits 1 to 7)*
  - Systolic blood pressure (mmHg)
  - Diastolic blood pressure (mmHg)
  - Heart rate (bpm)

The chemistry and hematology profiles for each subject at screening visit (Visit 1) will be reviewed by the clinical investigators (MD) and any findings of clinical significance will be documented. No descriptive statistics will be generated.

8.0. OUTCOME ANALYSIS

8.1. Primary Outcome Variable

The primary outcome variable will be change (absolute and percent change) in body weight from baseline (Visit 2; week 0) to end of study (Visit 7; week 16)

8.2. Secondary Outcome Variables

Secondary outcome variables include values of the following variables at post-randomization visits as stated:

- Change (absolute and percent change) in body weight from baseline (Visit 2; week 0) to Visits 3, 4, 5, and 6 (weeks 2, 4, 8, and 12)
- Proportion of participants achieving ≥5% and ≥10% loss of baseline body weight at each post-randomization visit Visits 3, 4, 5, 6, and 7 (weeks 2, 4, 8, 12, and 16)

- Change (absolute and percent change) in the following body composition parameters (measured via DXA) from baseline (Visit 2; week 0) to Visits 4, 5, 6, and 7 (weeks 4, 8, 12, and 16)
    - Total fat mass (kg)
    - Total lean mass (non-bone fat free mass) (kg)
    - Percent body fat (expressed as percentage of total body mass)
    - Android fat and lean mass (g)
    - Gynoid fat and lean mass (g)
    - Abdominal visceral fat mass (g) and volume (cm^3)
- Absolute change in body circumference parameters from baseline (Visit 2; week 0) to Visits 4, 5, 6, and 7 (weeks 4, 8, 12, and 16)
    - Waist circumference (cm)
    - Hip circumference (cm)
    - Chest circumference (cm)
    - Dominant upper arm circumference (cm)
    - Dominant thigh circumference (cm)
    - Total body circumference (sum of all five measures) (cm)
    - Waist to hip ratio
- Absolute change in QoL questionnaire outcomes (domain and/or total scores) from baseline (Visit 2; week 0) to Visits 5 and 7 (weeks 8 and 16). QoL will be measured using both RAND-36 Questionnaire (uses same questions as the Short Fom (36) Health Survey Questionnaire (Ware JE, et al. 1992)) and IWQOL-Lite Questionnaire.
    - RAND 36-item Health Survey Questionnaire assesses the eight health scales: physical functioning (10 questions), role limitations due to physical health problems (4 questions), role limitations due to emotional problems (3 questions), energy/fatigue (4 questions), emotional well-being (5 questions), social functioning (2 questions), pain (2 questions), and general health (5 questions). The scales' scores will be calculated as described on the RAND website (http://www.rand.org/health/surveys_tools/mos/36-item-short-form/scoring.html).
    - IWQOL-Lite Questionnaire (Kolotkin RL, et al. 2001) is a 31-question self report instrument to assess obesity specific quality of life and consists of five domains: Physical Function (11 questions), Self-Esteem (7 questions), Sexual Life (4 questions), Public Distress (5 questions), and Work (4 questions). The domain scores will be the sum of the ratings on questions that correspond to the specific domain. A total score (all 31 questions) will also be presented.
- Participant satisfaction and health/well-being assessed using the Satisfaction and Health/Well-Being Questionnaire at Visit 7 (week 16). Responses will be coded as follows: "1" and "2" = "Disagree", "3"= "Neither agree nor disagree", and "4" and "5"= Agree.
- Absolute change in hs-CRP from baseline (Visit 2; week 0) to Visit 7 (week 16)
- Weight loss program adherence assessed at Visits 4, 5, 6, and 7 (weeks 4, 8, 12, and 16) based on the Program Questionnaire. Adherence will be calculated based on self-reported TSFL/MEDD meal replacement product consumption (active groups only) and a single question VAS rating adherence to their assigned weight loss program (all groups). For the self-reported TSFL/MEDD meal replacement product consumption, if the subject encircled ">6", it will be coded as "7". Also, questions (1,2) and (4,5) of the Program Questionnaire will be scored as:

		Leisure Time Activity				
		Very Light	Light	Moderate	Active	Very Active
Work/School Activity	Very Light	1.4	1.5	1.6	1.7	1.9
	Light	1.5	1.6	1.7	1.8	2.0
	Moderate	1.6	1.7	1.8	1.9	2.2
	Heavy	1.7	1.8	1.9	2.1	2.3

- Participation at assigned coaching sessions as a measure of adherence for the TSFL group.
- Utilization of Nutrition Support for the TSFL and MEDD group.

9.0. STATISTICAL METHODS

Descriptive statistics (number of subjects, mean, SEM, median, interquartile limits, minimum and maximum) will be presented for quantitative variables. Ratings for categorical variables will be presented as counts and percentages. All tests of significance, unless otherwise stated, will be performed at alpha=0.05, two-sided.

Baseline comparisons for demographic characteristics between control and intervention groups will be completed with the Chi-square test, Fisher's exact (two-tail) test, or analysis of variance (ANOVA), as appropriate.

Analysis of covariance (ANCOVA) will be used to assess differences among intervention groups in the primary and continuous secondary outcome variables at each post-randomization visit. The ANCOVA model will contain a term for intervention, with sex and baseline measures as covariates. Least squares mean values and corresponding SEM will be derived from the final ANCOVA model for each intervention group.

Counts and percentages of subjects who experience weight loss of ≥5% and ≥10% between baseline (Visit 2) and each post-randomization visit (visits 3, 4, 5, 6, and 7) will be presented. Differences among intervention groups in subjects with weight loss of ≥5% and ≥10% will be assessed using a generalized linear model with a logit link and binomial distribution specified. The model will contain a term for intervention, with sex as a covariate.

Differences among intervention groups in individual Satisfaction and Health/Well-being questionnaire scores will be assessed using a generalized linear model with a cumulative logit link and multinomial distribution specified. The model will contain a term for intervention, with sex and absolute change in weight as covariates.

For the analyses of body weight, body composition parameters, and body circumference parameters, each active group will be compared to the control group using a step-down Dunnett adjustment for multiple comparisons when a significant treatment effect is observed. Meanwhile,

no adjustments will be done on control vs. active comparisons on the remaining outcome variables.

Descriptive statistics will be provided for the Program Questionnaire outcomes. Also, linear association between change (absolute) in body weight from baseline (Visit 2; week 0) to end of study (Visit 7; week 16) and average meal replacements [averaged across Visits 4 to7 (weeks 4-16)] will be obtained (spearman's rank-order correlation) for the MEDD and TSFL groups. Additionally, for the TSFL group, linear association between change (absolute) in body weight from baseline (Visit 2; week 0) to end of study (Visit 7; week 16) and number of coaching contacts will be obtained (spearman's rank-order correlation). Lastly, for the MEDD group, association between whether subjects made discretionary Nutrition Support contact(s) or not and weight loss of ≥5% will be assessed using a Fisher's exact test.

Assumption of normality of residuals will be investigated for each outcome variable at the 5% level of significance with the Shapiro-Wilk test (Shapiro 1965). If the normality assumption is not satisfied, then an analysis based on ranks will be performed.

10.0. MISSING OR INCOMPLETE DATA

For the ITT population, a multiple imputation method will be implemented if the missing data mechanism is at least missing at random (MAR). Meanwhile, for the modified ITT population, analyses with and without imputation will be conducted. For this imputation, the method of Last Observation Carried Forward (LOCF) will be used as a single imputation approach (Elobeid MA et al, 2009). In this approach, if a subject's measurement is missing at a post-randomization visit, the value from the most proximal prior visit will be used for all missing visits afterwards. The imputation methods will only be applied to body weight. No imputations will be performed for other variables.

11.0. SAFETY ANALYSIS

Safety assessments will be determined from intervention-emergent AEs that occur after randomization at Visit 2 (week 0). Possible differences in the number of participants with at least one AE will be assessed with Chi-Square or Fisher's exact test.

Participants who achieve a BMI of 19.0 kg/m^2 or below will discontinue the weight loss diet and begin a maintenance diet and will be asked to return for remaining clinic visits. These participants will be noted in the safety analysis.

Vitals (blood pressure, pulse rate) will be summarized by group with descriptive statistics.

12.0 OUTLIERS

Individual values for the key outcome parameters (body weight, waist circumference, and body composition) at each time point across intervention groups will be examined. Subjects who have values outside +/-1.5*IQR will be discussed and decisions about how to handle these data will be agreed upon and documented in writing.

13.0. DEVIATIONS FROM STATISTICAL PLAN AND OTHER ISSUES

During the analysis and reporting process, any deviations from the statistical plan designed for this protocol will be described and justified in the clinical study report.

14.0. CHANGES FROM THE PROTOCOL

1. Analysis populations

An intent-to-treat (ITT) population will include all participants who were randomized into the study. A complete case population (i.e., completers) will include the subset of participants that completed the study on their assigned intervention. A modified ITT population will include all randomized participants that had a least one post-baseline weight measurement.

Changed to

An Intent-To-Treat (ITT) population will include all subjects who were randomized into the study. A modified ITT population will include all randomized participants that had at least one post-baseline weight measurement. In addition, a Completers population will comprise subjects who were randomized into the study and completed all the clinic visits of the whole 16 weeks of the study.

2. Primary outcome variables

The primary endpoint is change (percent change and absolute change) from baseline (Visit 2; week 0) body weight to Visit 7 (week 16). Body weight change (percent and absolute change) at Visits 3, 4, 5, and 6 (weeks 2, 4, 8, and 12) will also be evaluated.

Changed to

The primary outcome variable will be change (absolute and percent change) in body weight from baseline (Visit 2; week 0) to end of study (Visit 7; week 16)

3. Secondary outcome variables

Added

Change (absolute and percent change) in body weight from baseline (Visit 2; week 0) to Visits 3, 4, 5, and 6 (weeks 2, 4, 8, and 12)

Participation at assigned coaching sessions as a measure of adherence for the TSFL group.

Utilization of Nutrition Support for the TSFL and MEDD group.

4. Missing or Incomplete Data

Analysis with and without imputation will be conducted in the ITT population. For the analysis with imputation, single [e.g., last observation carried forward (LOCF)], and/or

multiple imputation will be considered, as appropriate (Elobeid, 2009; Peng 2015; George 2016).

Changed to

For the ITT population, a multiple imputation method will be implemented if the missing data mechanism is at least missing at random (MAR). Meanwhile, for the modified ITT population, analyses with and without imputation will be conducted. For this imputation, the method of Last Observation Carried Forward (LOCF) will be used as a single imputation approach (Elobeid MA et al, 2009). In this approach, if a subject's measurement is missing at a post-randomization visit, the value from the most proximal prior visit will be used for all missing visits afterwards. The imputation methods will only be applied to body weights. No imputations will be performed for other variables.

5. Outliers

Individual values for the key outcome parameters (body weight and waist circumference) at each time point across intervention groups will be examined. Subjects who have values outside +/-1.5*IQR will be discussed and decisions about how to handle these data will be agreed upon and documented in writing.

Changed to

*Individual values for the key outcome parameters (body weight, waist circumference, and body composition) at each time point across intervention groups will be examined. Subjects who have values outside +/-1.5*IQR will be discussed and decisions about how to handle these data will be agreed upon and documented in writing.*

15.0. REFERENCES

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16.0. PLANNED TABLES

The following tables will be produced for the ITT, mITT and Completers populations as appropriate.

Population(s)		
	Table 1	Subject Disposition
ITT	Table 2.1	Demographic Characteristics
ITT	Table 2.2	Vitals
ITT, mITT, Completers	Table 3	Primary Outcome Variable: Body Weight (Visit 7)
ITT, mITT, Completers	Table 4.1	Secondary Outcome Variables: Body Weight (Visits 3, 4, 5, 6)
ITT, mITT, Completers	Table 4.2	Secondary Outcome Variables: Weight Loss ≥ 5% and≥ 10%
mITT, Completers	Table 4.3	Secondary Outcome Variables: Body Composition
mITT, Completers	Table 4.4	Secondary Outcome Variables: Body Circumference Parameters
mITT, Completers	Table 4.5	Secondary Outcome Variables: hs-CRP
mITT, Completers	Table 4.6	Secondary Outcome Variable: IWQOL-Lite Questionnaire Outcomes
mITT, Completers	Table 4.7	Secondary Outcome Variable: RAND Health Survey Questionnaire Outcomes
mITT, Completers	Table 4.8.1	Secondary Outcome Variables: Satisfaction and Health/Well-being Questionnaire
mITT, Completers	Table 4.8.2	Secondary Outcome Variables: Satisfaction and Health/Well-being Questionnaire (Recoded)
mITT, Completers	Table 4.9	Secondary Outcome Variables: Program Questionnaire

mITT, Completers	Table 4.10	Secondary Outcome Variable: Weight Loss Program Adherence
mITT, Completers	Table 4.11	Secondary Outcome Variable: Nutrition Support Contact
mITT	Table 5	Summary of Subjects with at Least One Intervention-Emergent Adverse Event

Note: Tables 3, 4.1, and 4.2 will be generated for Completers, ITT population with multiple imputation applied for the missing data and for the mITT population, both with and without imputation. For the mITT population with imputation, LOCF imputation method applied for missing data will be reflected in footnotes of relevant tables. All other tables generated for the mITT population will be without imputation.

Table 1
Subject Disposition

17.0. APPENDIX: TABLE SHELLS

Number of Subjects	Control	TSFL	MEDD	Overall
Screened				N (%)
Randomized	N (%)	N (%)	N (%)	N (%)
Completed Study	N (%)	N (%)	N (%)	N (%)
Did Not Complete Study	N (%)	N (%)	N (%)	N (%)
Included in:				
m ITT Population	N (%)	N (%)	N (%)	N (%)
Completers Population	N (%)	N (%)	N (%)	N (%)
Discontinued due to:				
Adverse Event	N (%)	N (%)	N (%)	N (%)
Death	N (%)	N (%)	N (%)	N (%)
Withdrawal of Consent	N (%)	N (%)	N (%)	N (%)
Lost to Follow-up	N (%)	N (%)	N (%)	N (%)
Other	N (%)	N (%)	N (%)	N (%)

Table 2.1
Demographic Characteristics

Characteristic		Control (N =)	TSFL (N=)	MEDD (N=)	Overall (N=)	p-value*
Gender	**Female**	N (%)	N (%)	N (%)	N (%)	x.xxx
	Male	N (%)	N (%)	N (%)	N (%)	
	Total	N (%)	N (%)	N (%)	N (%)	
Age (years)	**N**	N	N	N	N	x.xxx
	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
	Median	Median	Median	Median	Median	
	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
	Min, Max	Min, Max	Min, Max	Min, Max	Min, Max	
Race	**White**	N (%)	N (%)	N (%)	N (%)	x.xxx
	Black/African American	N (%)	N (%)	N (%)	N (%)	
	American Indian or Pacific Islander	N (%)	N (%)	N (%)	N (%)	
	Multiracial Origin	N (%)	N (%)	N (%)	N (%)	
	Other	N (%)	N (%)	N (%)	N (%)	
	Total	N (%)	N (%)	N (%)	N (%)	
Ethnicity	**Non-Hispanic/Latino**	N (%)	N (%)	N (%)	N (%)	x.xxx
	Hispanic/Latino	N (%)	N (%)	N (%)	N (%)	
	Total	N (%)	N (%)	N (%)	N (%)	
Weight (kg)	**N**	N	N	N	N	x.xxx
	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
	Median	Median	Median	Median	Median	
	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
	Min, Max	Min, Max	Min, Max	Min, Max	Min, Max	
Height (cm)	**N**	N	N	N	N	x.xxx
	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
	Median	Median	Median	Median	Median	
	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	

Table 2.1
Demographic Characteristics

Characteristic		Control (N =)	TSFL (N=)	MEDD (N=)	Overall (N=)	p-value*
	Min, Max	Min, Max	Min, Max	Min, Max	Min, Max	
BMI (kg/m²)	**N**	N	N	N	N	x.xxx
	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
	Median	Median	Median	Median	Median	
	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
	Min, Max	Min, Max	Min, Max	Min, Max	Min, Max	
BMI (kg/m²)	**Overweight (27.00 to 30.00)**	N (%)	N (%)	N (%)	N (%)	x.xxx
	Obese (>30.00)	N (%)	N (%)	N (%)	N (%)	
Systolic Blood	**N**	N	N	N	N	x.xxx
Pressure (mmHg)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
	Median	Median	Median	Median	Median	
	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
	Min, Max	Min, Max	Min, Max	Min, Max	Min, Max	
Diastolic Blood	**N**	N	N	N	N	x.xxx
Pressure (mmHg)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
	Median	Median	Median	Median	Median	
	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
	Min, Max	Min, Max	Min, Max	Min, Max	Min, Max	
Heart Rate (bpm)	**N**	N	N	N	N	x.xxx
	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
	Median	Median	Median	Median	Median	
	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
	Min, Max	Min, Max	Min, Max	Min, Max	Min, Max	
Fasting glucose (mg/dL)	**N**	N	N	N	N	x.xxx
	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
	Median	Median	Median	Median	Median	

Table 2.1
Demographic Characteristics

Characteristic		Control (N =)	TSFL (N=)	MEDD (N=)	Overall (N=)	p-value*
	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
	Min, Max	Min, Max	Min, Max	Min, Max	Min, Max	
Smoking Status	**Non-Smoker**	N (%)	N (%)	N (%)	N (%)	x.xxx
	Current Smoker	N (%)	N (%)	N (%)	N (%)	
	Past Smoker	N (%)	N (%)	N (%)	N (%)	
	Total	N (%)	N (%)	N (%)	N (%)	
Education	**Some High School, no diploma**	N (%)	N (%)	N (%)	N (%)	x.xxx
	High School diploma or equivalent (GED)	N (%)	N (%)	N (%)	N (%)	
	Trade/Technical/Vocational Training	N (%)	N (%)	N (%)	N (%)	
	Some College, no degree	N (%)	N (%)	N (%)	N (%)	
	College Degree (Associate or Bachelor)	N (%)	N (%)	N (%)	N (%)	
	Graduate/Professional Degree	N (%)	N (%)	N (%)	N (%)	
	Total	N (%)	N (%)	N (%)	N (%)	

*p-values shown are generated from Chi-Square test, Fisher's exact test, or ANOVA, as appropriate

Table 2.2
Vitals

Parameter	Week		Control (N =)	TSFL (N=)	MEDD (N=)	Overall (N=)
Systolic Blood	**Screening (Week -1)**	**N**	N	N	N	N
Pressure (mmHg)	**(Visit 1)**	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Baseline (Week 0)	**N**	N	N	N	N
	(Visit 2)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 2	**N**	N	N	N	N
	(Visit 3)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 4	**N**	N	N	N	N
	(Visit 4)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 8	**N**	N	N	N	N
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 12	**N**	N	N	N	N
	(Visit 6)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)

Table 2.2
Vitals

Parameter	Week		Control (N =)	TSFL (N=)	MEDD (N=)	Overall (N=)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 16	**N**	N	N	N	N
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
Diastolic Blood	**Screening (Week -1)**	**N**	N	N	N	N
Pressure (mmHg)	**(Visit 1)**	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Baseline (Week 0)	**N**	N	N	N	N
	(Visit 2)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 2	**N**	N	N	N	N
	(Visit 3)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 4	**N**	N	N	N	N
	(Visit 4)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max

Table 2.2
Vitals

Parameter	Week		Control (N =)	TSFL (N=)	MEDD (N=)	Overall (N=)
	Week 8	**N**	N	N	N	N
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 12	**N**	N	N	N	N
	(Visit 6)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 16	**N**	N	N	N	N
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
Heart Rate (bpm)	**Screening (Week -1)**	**N**	N	N	N	N
	(Visit 1)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Baseline (Week 0)	**N**	N	N	N	N
	(Visit 2)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 2	**N**	N	N	N	N
	(Visit 3)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median

Table 2.2
Vitals

Parameter	Week		Control (N =)	TSFL (N=)	MEDD (N=)	Overall (N=)
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 4	**N**	N	N	N	N
	(Visit 4)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 8	**N**	N	N	N	N
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 12	**N**	N	N	N	N
	(Visit 6)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max
	Week 16	**N**	N	N	N	N
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max	Min, Max

Table 3
Primary Outcome Variable: Body Weight (Visit 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
Body Weight	**Baseline (Week 0)**	**N**	N	N	N	
(kg)	**(Visit 2)**	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Week 16	**N**	N	N	N	
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change (Week 16)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	% Change (Week 16)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	

^ p-values are from ANCOVA models, adjusted for sex and baseline values at Visit 2
(r) indicates rank transformation was employed.
* p-values are adjusted for multiple comparisons (each active group vs. control group)

Table 3
Primary Outcome Variable: Body Weight (Visit 7) Descriptive Statistics and P-values

+ p-values are generated from paired t-test or sign-rank test, as appropriate

Table 4.1
Secondary Outcome Variable: Body Weight (Visit 3, 4, 5, 6) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
Body Weight	**Baseline (Week 0)**	**N**	N	N	N	
(kg)	**(Visit 2)**	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Week 2	**N**	N	N	N	
	(Visit 3)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change (Week 2)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	% Change (Week 2)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 4	**N**	N	N	N	
	(Visit 4)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	

Table 4.1
Secondary Outcome Variable: Body Weight (Visit 3, 4, 5, 6) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change (Week 4)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	% Change (Week 4)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 8	**N**	N	N	N	
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change (Week 8)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	

Table 4.1
Secondary Outcome Variable: Body Weight (Visit 3, 4, 5, 6) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	% Change (Week 8)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 12	**N**	N	N	N	
	(Visit 6)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change (Week 12)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	% Change (Week 12)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	

Table 4.1
Secondary Outcome Variable: Body Weight (Visit 3, 4, 5, 6) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	

^ p-values are from ANCOVA models, adjusted for sex and baseline values at Visit 2
(r) indicates rank transformation was employed.
* p-values are adjusted for multiple comparisons (each active group vs. control group)
+ p-values are generated from paired t-test or sign-rank test, as appropriate

Table 4.2
Secondary Outcome Variables: Weight Loss ≥5% and ≥10% (Visits 3, 4, 5, 6, 7)

Parameter		Week	Control	TSFL	MEDD	Intervention p-value^
Weight Loss responders	**(% change ≥5%)**	**% Change Week 2 (Visit 3)**	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	
		% Change Week 4 (Visit 4)	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	
		% Change Week 8 (Visit 5)	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	
		% Change Week 12 (Visit 6)	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	
		% Change Week 16 (Visit 7)	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	
Weight Loss responders	**(% change ≥10%)**	**% Change Week 2 (Visit 3)**	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	
		% Change Week 4 (Visit 4)	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	
		% Change Week 8 (Visit 5)	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	
		% Change Week 12 (Visit 6)	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	
		% Change Week 16 (Visit 7)	N (%)	N (%)	N (%)	x.xxx
		Group comparison p-value*		x.xxx	x.xxx	

^ p-values are from GLM models with a logit link and binomial distribution specified and sex as a covariate
* p-values are adjusted for multiple comparisons (each active group vs. control group)

Table 4.3
Secondary Outcome Variable: Body Composition (Visits 4, 5, 6, 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
Total Fat Mass (kg)	**Baseline (Week 0)**	**N**	N	N	N	
	(Visit 2)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Week 4	**N**	N	N	N	
	(Visit 4)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 4	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	% Change (Week 4)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 8	**N**	N	N	N	
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	

Table 4.3
Secondary Outcome Variable: Body Composition (Visits 4, 5, 6, 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 8	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	% Change (Week 8)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 12	**N**	N	N	N	
	(Visit 6)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 12	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	

Table 4.3
Secondary Outcome Variable: Body Composition (Visits 4, 5, 6, 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	% Change (Week 12)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 16	**N**	N	N	N	
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 16	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	% Change (Week 16)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	

Table 4.3
Secondary Outcome Variable: Body Composition (Visits 4, 5, 6, 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	

^ p-values are from ANCOVA models, adjusted for sex and baseline values at Visit 2.
(r) indicates rank transformation was employed.
* p-values are adjusted for multiple comparisons (each active group vs. control group)
+ p-values are generated from paired t-test or sign-rank test, as appropriate

NOTE: This table will be presented for body composition measures: total fat mass, total lean mass, percent body fat, android fat and lean mass, gynoid fat and lean mass, and abdominal visceral fat mass and volume.

Table 4.4
Secondary Outcome Variables: Body Circumference Parameters (Visits 4, 5, 6, 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
Waist Circumference (cm)	**Baseline (Week 0)**	**N**	N	N	N	
	(Visit 2)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Week 4	**N**	N	N	N	
	(Visit 4)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 4	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 8	**N**	N	N	N	
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 8	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	

Table 4.4
Secondary Outcome Variables: Body Circumference Parameters (Visits 4, 5, 6, 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 12	**N**	N	N	N	
	(Visit 6)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 12	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 16	**N**	N	N	N	
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 16	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	

^ p-values are from ANCOVA models, adjusted for sex and baseline values at Visit 2.

Table 4.4
Secondary Outcome Variables: Body Circumference Parameters (Visits 4, 5, 6, 7) Descriptive Statistics and P-values

(r) indicates rank transformation was employed.
* p-values are NOT adjusted for multiple comparisons
+ p-values are generated from paired t-test or sign-rank test, as appropriate

NOTE: This table will be presented for body circumference parameters: waist circumference, hip circumference, chest circumference, dominant upper arm circumference, dominant thigh circumference, total body circumference (sum of all five measures), and waist to hip ratio.

Table 4.5
Secondary Outcome Variable: hs-CRP (Visit 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
hs-CRP (mg/L)	**Baseline (Week 0)**	**N**	N	N	N	
	(Visit 2)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Week 16	**N**	N	N	N	
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change (Week 16)	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	

^ p-values are from ANCOVA models, adjusted for sex and baseline values at Visit 2
(r) indicates rank transformation was employed.
* p-values are NOT adjusted for multiple comparisons
+ p-values are generated from paired t-test or sign-rank test, as appropriate

Table 4.6
Secondary Outcome Variable: IWQoL-Lite Questionnaire Outcomes (Visits 5 and 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
IWQoL Total Score	**Baseline (Week 0)**	**N**	N	N	N	
	(Visit 2)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Week 8	**N**	N	N	N	
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 8	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 16	**N**	N	N	N	
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 16	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	

Table 4.6
Secondary Outcome Variable: IWQoL-Lite Questionnaire Outcomes (Visits 5 and 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	

^ p-values are from ANCOVA models, adjusted for sex and baseline values at Visit 2.
(r) indicates rank transformation was employed.
* p-values are NOT adjusted for multiple comparisons (each active group vs. control group)
+ p-values are generated from paired t-test or sign-rank test, as appropriate

NOTE: This table will be presented for IWQOL-Lite total score and five scale scores (Physical Function, Self-Esteem, Sexual Life, Public Distress, and Work).

Table 4.7
Secondary Outcome Variable: RAND Questionnaire Outcomes (Visits 5 and 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
Physical Functioning	**Baseline (Week 0)**	**N**	N	N	N	
	(Visit 2)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Week 8	**N**	N	N	N	
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 8	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	
	Week 16	**N**	N	N	N	
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
	Change Week 16	**N**	N	N	N	
		Mean (SEM)	Mean (SEM)	Mean (SEM)	Mean (SEM)	
		Median	Median	Median	Median	
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3	
		Min, Max	Min, Max	Min, Max	Min, Max	
		Within group p-value+	x.xxx(r)	x.xxx(r)	x.xxx(r)	

Table 4.7
Secondary Outcome Variable: RAND Questionnaire Outcomes (Visits 5 and 7) Descriptive Statistics and P-values

Parameter	Week		Control	TSFL	MEDD	Intervention p-value^
		LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	LS Mean (SEM)	x.xxx(r)
		Group comparison p-value*		x.xxx(r)	x.xxx(r)	

^ p-values are from ANCOVA models, adjusted for sex and baseline values at Visit 2.
(r) indicates rank transformation was employed.
* p-values are NOT adjusted for multiple comparisons (each active group vs. control group)
+ p-values are generated from paired t-test or sign-rank test, as appropriate

NOTE: This table will be presented for the eight scale scores of the RAND questionnaire (Physical functioning, Role limitations due to physical health, Role limitations due to emotional Problems, Energy/fatigue, Emotional well-being, Social functioning, Pain, General health).

Table 4.8.1
Secondary Outcome Variable: Satisfaction and Health/Well-being Questionnaire Descriptive Statistics

Parameter	Week	Rating	Control	TSFL	MEDD
Recommend Weight Loss Plan	**Week 16**	**Strongly Disagree**	N (%)	N (%)	N (%)
	(Visit 7)	**Disagree**	N (%)	N (%)	N (%)
		Neither Agree or Disagree	N (%)	N (%)	N (%)
		Agree	N (%)	N (%)	N (%)
		Strongly Agree	N (%)	N (%)	N (%)

NOTE: This table will be presented for ratings for each question of the Satisfaction and Health/Well-being questionnaire.

Table 4.8.2
Secondary Outcome Variable: Satisfaction and Health/Well-being Questionnaire (Recoded) Descriptive Statistics and P-values

Parameter	Week	Rating	Control	TSFL	MEDD	Intervention p-value
Recommend Weight Loss Plan	**Week 16**	**Disagree**	N (%)	N (%)	N (%)	x.xxx
	(Visit 7)	**Neither Agree or Disagree**	N (%)	N (%)	N (%)	
		Agree	N (%)	N (%)	N (%)	
		Group comparison p-value*		x.xxx	x.xxx	

* p-values are NOT adjusted for multiple comparisons

NOTE: This table will be presented for ratings for each question of the Satisfaction and Health/Well-being questionnaire.

Table 4.9
Secondary Outcome Variable: Program Questionnaire (Visits 4, 5, 6, 7) Descriptive Statistics

Parameter	Week		Control	TSFL	MEDD
Physical Activity Level	**Baseline (Week 0)**	**N**	N	N	N
	(Visit 2)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max
	Week 4	**N**	N	N	N
	(Visit 4)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max
	Week 8	**N**	N	N	N
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max
	Week 12	**N**	N	N	N
	(Visit 6)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max
	Week 16	**N**	N	N	N
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max
VAS	**Week 4**	**N**	N	N	N
	(Visit 4)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3

Table 4.9
Secondary Outcome Variable: Program Questionnaire (Visits 4, 5, 6, 7) Descriptive Statistics

Parameter	Week		Control	TSFL	MEDD
		Min, Max	Min, Max	Min, Max	Min, Max
	Week 8	**N**	N	N	N
	(Visit 5)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max
	Week 12	**N**	N	N	N
	(Visit 6)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max
	Week 16	**N**	N	N	N
	(Visit 7)	**Mean (SEM)**	Mean (SEM)	Mean (SEM)	Mean (SEM)
		Median	Median	Median	Median
		Q1, Q3	Q1, Q3	Q1, Q3	Q1, Q3
		Min, Max	Min, Max	Min, Max	Min, Max
Meal Replacement	**Week 4**	**N**		N	N
	(Visit 4)	**Mean (SEM)**		Mean (SEM)	Mean (SEM)
		Median		Median	Median
		Q1, Q3		Q1, Q3	Q1, Q3
		Min, Max		Min, Max	Min, Max
	Week 8	**N**		N	N
	(Visit 5)	**Mean (SEM)**		Mean (SEM)	Mean (SEM)
		Median		Median	Median
		Q1, Q3		Q1, Q3	Q1, Q3
		Min, Max		Min, Max	Min, Max
	Week 12	**N**		N	N
	(Visit 6)	**Mean (SEM)**		Mean (SEM)	Mean (SEM)
		Median		Median	Median

Table 4.9
Secondary Outcome Variable: Program Questionnaire (Visits 4, 5, 6, 7) Descriptive Statistics

Parameter	**Week**		**Control**	**TSFL**	**MEDD**
		Q1, Q3		Q1, Q3	Q1, Q3
		Min, Max		Min, Max	Min, Max
	Week 16	**N**		N	N
	(Visit 7)	**Mean (SEM)**		Mean (SEM)	Mean (SEM)
		Median		Median	Median
		Q1, Q3		Q1, Q3	Q1, Q3
		Min, Max		Min, Max	Min, Max

Table 4.10
Secondary Outcome Variable: Weight Loss Program Adherence Descriptive Statistics and P-values

Parameter		**TSFL**	**MEDD**
Meal Replacement^	**Mean (SEM)**	Mean (SEM)	Mean (SEM)
	Median	Median	Median
	Q1, Q3	Q1, Q3	Q1, Q3
	Min, Max	Min, Max	Min, Max
	Corr (p-value)+	0.xxx (x.xxx)	0.xxx (x.xxx)
Nutrition Support Contact	**Mean (SEM)**	Mean (SEM)	Mean (SEM)
	Median	Median	Median
	Q1, Q3	Q1, Q3	Q1, Q3
	Min, Max	Min, Max	Min, Max
Coaching Contact	**Mean (SEM)**	Mean (SEM)	
	Median	Median	
	Q1, Q3	Q1, Q3	
	Min, Max	Min, Max	
	Corr (p-value)+	0.xxx (x.xxx)	

^average meal replacement (per day) across the 16-weeks of the study
+spearman's rank-order correlation between the corresponding parameter and absolute change in body weight from baseline (Visit 2; week 0) to end of study (Visit 7; week 16)

Table 4.11
Secondary Outcome Variable: Nutrition Support Contact P-values

Group	Parameter		Initial & Discretionary NS contact*	Initial NS contact or None**	p-value^
MEDD	**% weight loss >= 5%**	**N (%)**	N (%)	N (%)	x.xxx
TSFL	**% weight loss >= 5%**	**N (%)**	N (%)	N (%)	x.xxx

^p-values shown are generated from Fisher's exact test
*at least two NS contacts for MEDD or at least one NS contact for TSFL
**at most one NS contact for MEDD or none for TSFL

Table 5
Summary of Subjects with at Least One Intervention-emergent Adverse Events

	Control	TSFL	MEDD	Intervention p-value[+]
Any Adverse Event	N (%)	N (%)	N (%)	x.xxx
Serious	N (%)	N (%)	N (%)	x.xxx
Severe	N (%)	N (%)	N (%)	x.xxx
Related to Study Treatment*	N (%)	N (%)	N (%)	x.xxx

[+]p-values shown are generated from Chi-Square or Fisher's exact test, as appropriate
* Probably or Definitely Related to Study Treatment.