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

ClinicalTrials.gov Identifier:

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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

Protocol BI0-1607 (MED 019)

Sponsor:
Jason Pharmaceuticals, Inc.
(a wholly owned subsidiary of Medifast, Inc.)
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CONFIDENTIAL

INVESTIGATOR PROTOCOL SIGNATURE SHEET

Protocol BI0-1607 (MED 019)

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**

By my signature below, I attest that I have read, understood, and agree to abide by all conditions, instructions, and restrictions contained in this protocol (including appendices). I will not initiate this study without approval from the appropriate Institutional Review Board (IRB) and I understand that any changes to the protocol must be approved in writing by the Sponsor and the IRB before they can be implemented, except where necessary to eliminate immediate hazards to the participant.

Approval Signatures:

22 June 2016

Investigator Signature **Date**

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SPONSOR PROTOCOL SIGNATURE SHEET

Protocol BI0-1607 (MED 019)

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By my signature below, I approve of this protocol.

Sponsor Company:  Signature

 Date

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1. List of Abbreviations

AE	adverse event alkaline
ALP	phosphatase alanine
ALT	aminotransferase analysis
ANCOVA	of covariance analysis of
ANOVA	variance aspartate
AST	aminotransferase body
BMI	mass index
BUN	blood urea nitrogen
C02	carbon dioxide
CFR	Code of Federal Regulations
DXA	dual energy x-ray absorptiometry
cCRF	electronic case report form
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
hs-CRP	high-sensitivity C-reactive protein
ITT	intent-to-treat
ICH	International Conference on Harmonization
IWQOL	Impact of Weight on Quality of Life
IRB kg	Institutional Review Board
LOCF	kilogram
MEDD	last observation carried forward
m	Medifast Direct
m2	meter
mg mL	meter squared
mmHg	milligram
PAL	milliliter
QoL	millimeters of mercury
SEM	physical activity level
SOP	quality of life
TSFL	standard error of the mean
tel	standard operating procedure
us	Take Shape For Life
USDA	telephone
VAS	United States
	United States Department of Agriculture
	visual analog scale

2. Key Roles and Contact Information

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3. Background/Rationale

Recent advances in the understanding of the etiology of obesity, along with development of novel pharmaceutical and surgical treatment options have yet to contribute to a reduction in the obesity prevalence in the US population. Improving diet and physical activity are still the foundation of current obesity treatments. One approach shown to be useful in modulating energy intake to support weight loss in overweight/obese individuals is provision of pre-portioned foods and beverages (i.e., meal replacements; Cheskin 2008, Hannum 2004 and 2006, 1-Ieymsfield 2003). Indeed, a group of obesity experts has considered the evidence behind this strategy as sufficiently strong and consistent to be considered empirically proven compared to more conventional dietary advice, such as food choices based on general concepts like balance, variety, and moderation (Casazza 2013). Some commercially available weight loss programs utilize this approach; however, data from randomized clinical trials documenting the degree of weight loss achievable with these programs is often lacking.

In this context, the role of commercially-available weight loss programs has received increased attention by the scientific community (Gudzune 2015, Jensen 2014). In 2013, joint guidelines issued by the American Heart Association, the American College of Cardiology and The Obesity Society for the management of overweight and obesity in adults (Jensen 2014) examined the use of some commercial programs. The general recommendation was that some commercially available programs that promote a comprehensive lifestyle intervention can be prescribed as an option for weight loss provided there is peer-reviewed published evidence of their safety and efficacy. Yet, well designed, randomized, controlled trials directly testing efficacy of many programs have not been conducted. Thus, a need exists to identify evidence-based, commercially available weight management programs.

Two such commercially available weight loss programs are the Take Shape For Life (TSFL) Optimal Weight 5 & 1 Plan™ and the Medifast Achieve™ Plan (also known as the 4 & 2 & 1 Plan® offered by Medifast Direct). Both programs utilize portion-controlled, nutritionally balanced meal plans combined with various levels of programmatic support. The meal plans consist of either four or five Medifast meal replacements per day supplemented with purchased healthy foods (lean protein, vegetables and healthy fats) to create self-prepared lean and green meals (one or two per day, depending on the specific plan). Preparation of the lean and green meals helps teach portion control and life-long healthy eating habits. The Medifast meal replacements are nutrient dense and fortified with 24 vitamins and minerals to ensure adequate micronutrient nutrition while on a calorie restricted, reduced energy meal plan.

Both programs offer programmatic support, with varying degrees of personal support. TSFL takes a holistic approach to optimal health (and weight loss for those who need it) and provides a skilled and caring personal TSFL coach to help people restore their health and improve their quality of life (QoL). TSFL is based on the Habits of Health system (Andersen 2008) which emphasizes the importance of being physically healthy, free of stress, and poised for a more fulfilling life.

MediJ'ast Direct (MEDD) focuses on individuals who want less support with a self-guided program that offers a variety of tools to assist in weight loss, including written and online resources, program guides, and a self-help workbook, among other items. MEDD users also have access to the optional services of the Medifast Nutrition Support Team, a group of professionals with expertise in the Medifast programs, products, and more generally, in nutrition, exercise and behavioral change. This team is available by phone or e-mail to answer programmatic, weight loss and exercise questions for both MEDD and TSFL users, as well as TSFL coaches.

The interventions in this study are designed to mimic the TSFL and MEDD user experiences and will utilize the meal plans, Medifast products, and support options available for each of these programs. The TSFL and MEDD groups will be compared to a control group following a self-directed, food-based, reduced-calorie diet consistent with the 2015 Dietary Guidelines for Americans and based on the United States Department of Agriculture (USDA) ChooseMyPlate program.

4. Objectives

The primary objective of this study is to evaluate the effects of two commercially available weight loss programs, the TSFL and the MEDD programs, each compared to a self-directed control diet, on changes in body weight over a 16-week weight loss phase, in apparently healthy overweight and obese men and women.

Secondary objectives include, examining effects of each weight loss program compared to the seli directed control diet on changes in body composition, body circumference parameters, QoL, and biomarkers of inflammation over a 16-week weight loss phase. Relationships between changes in body weight with self-reported adherence and QoL assessments will also be examined. Additionally, participant perspectives on program satisfaction and sense of health/well-being will be assessed at the end of the study.

5. Study Sample

Participants will be apparently healthy men and women, 18-65 years of age, inclusive, each with a body mass index (BMI) of27.0 to 42.0 kg/m^2, inclusive. No more than 10% of participants will be enrolled with a BMI 27.0 kg/m^2 and <30.0 kg/nl and no more than 25% of participants will be males.

6. Study Design and Procedures

6.1. Study Design

The study will utilize a randomized, controlled, 16-week parallel study design with one screening visit (Visit I; week -I); 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).

Screening {Visit 1; week -1)

At the screening visit (Visit I; week -I), after providing informed consent, participants will undergo screening visit procedures (evaluations of demographics, medical history, inclusion and exclusion criteria, prior and current medication/supplement use, height, vital signs, and BMI

calculation). Additionally, a gown body weight (fasted 12 ± 2 h, water only, anchored to the time of gown body weight measurement) will be measured. Fasting blood samples will be collected for a chemistry profile and hematology panel. Female participants <60 years of age will also undergo an in-clinic urine pregnancy test.

Baseline (Visit 2; week 0)

At Visit 2 (week 0), participants will arrive at the clinic fasted (12 ± 2 h, water only, anchored to time of gown body weight measurement) to undergo clinic visit procedures [evaluations of inclusion/exclusion criteria, concomitant medication/supplement use, vital signs, BMI calculation, and adverse events (AE)]. Gown body weight and body circumferences [waist, hip, chest, upper arm (dominant arm), and thigh (dominant leg)] will be measured. Additionally, female participants <60 years of age will undergo an in-clinic urine pregnancy test. Blood samples will be collected for analysis of high-sensitivity C-rcactive protein (hs-CRP), with additional blood samples collected and archived for possible future analysis of non-genetic indicators of inflammation and metabolism. A dual energy x-ray absorptiometry (DXA) scan will be performed (female participants <60 years of age must have a negative pregnancy test before the DXA scan is initiated). Participants will then be administered the Impact of Weight on Quality of Life (IWQOL)-Lite and the RAND-36 Questionnaires (Appendices 3 and 4). Additionally, all participants will be administered the Program Questionnaire (questions I and 2 only; Appendix 5). Participants that complete all baseline testing will be randomized before 12:00 h to one of three study groups (Control, TSFL, or MEDD), as follows:

Control Group

The Control group will follow a self-directed diet, which is a food-based, reduced-caloric diet, consistent with the 2015 Dietary Guidelines for Americans (See Supplementary Materials). The Control 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. A personalized daily energy intake level will be determined for each participant based on a targeted weight loss goal of 7% over the 16-week weight loss phase. Participants will receive publicly available information from the USDA Choose MyPlate program. Participants will be instructed to start their weight loss program the day following randomization (day I). No weekly check-ins will occur. More details on the self-directed control diet can be found in Section 6.4.1.

TSFL Group

Participants randomized to the TSFL group will follow Medifast's TSFL Optimal Weight 5 & I Plan'". At Visit 2 (week 0), participants will be dispensed study-specific printed materials (including the "Getting Started Instructions"), along with a starter meal kit containing approximately one week's worth of study foods (see Supplementary Materials). Participants will place an order for the following four weeks' worth of study foods with additional study foods ordered throughout the study. Following Visit 2 (week 0), participants randomized to this group will receive TSFL coaching with an assigned research assistant trained to function as a TSFL coach. Coaching, for the purpose of this study, will take place via telephone. The initial 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 I). Coaching sessions (i.e., phone consults) will occur at additional times throughout the 16 weeks.

Participants in the TSFL group will be encouraged to track weight and food intake, discuss their

progress with their coach during the coaching sessions, and access TSFL written, online, and virtual support tools, to use at their discretion. To be consistent with the commercially available program, participants with questions that the TSFL coach cannot address will be referred to the Medifast Nutrition Support Team. More details on the TSFL program can be found in Section 6.4.1.

MEDDGroup

Participants randomized to the MEDD group will be assigned to the Medifast AchieveTM Plan (4 & 2 & 1 Plan"') for weight loss. Study-specific printed materials (including the "Getting Started Instructions"), will be dispensed at Visit 2 (week 0) along with a starter meal kit containing approximately one week's worth of study foods (see Supplementary Materials). Participants will place an order for the following four weeks' worth of study foods with additional study foods ordered throughout the study. Following the clinic visit, participants randomized to this group will be instructed to contact the Medifast Nutrition Support Team by telephone prior to 17:00 h EST to receive an overview of the weight loss program. This telephone call (l0-15 min in length) will take place 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). Participants will also have telephone and e-mail access to the Medifast Nutrition Support Team (at the participants' discretion) 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. More details on the MEDD program can be found in Section 6.4.1.

Clinic Visits (Visit 3, 4, 5, 6 and 7; weeks 2, 4, 8, 12, and 16)

At Visit 3 (week 2), participants will arrive at the clinic fasted (12 ± 2 h, water only, anchored to time of gown body weight measurement) to undergo clinic visit procedures (evaluations of inclusion/exclusion criteria, concomitant medication/supplement use, vital signs, and AEs). Gown body weight will be measured.

At Visit 4 (week 4), participants will arrive at the clinic fasted (12 ± 2 h, water only, anchored to time of gown body weight measurement) to undergo clinic visit procedures (evaluations of inclusion/exclusion criteria, concomitant medication/supplement use, vital signs, and AEs). Gown body weight and body circumferences [waist, hip, chest, upper arm (dominant arm), and thigh (dominant leg)] will be measured. Additionally, female participants <60 years of age will undergo an in-clinic urine pregnancy test. A DXA scan will be performed (female participants <60 years of age must have a negative pregnancy test before the DXA scan is initiated). All participants will then be administered the Program Questionnaire (Appendix 5), and TSFL and MEDD participants will place an order for the following four weeks' worth of study foods.

At Visit 5 (week 8), participants will arrive at the clinic fasted (12 ± 2 h, water only, anchored to time of gown body weight measurement) to undergo clinic visit procedures (evaluations of inclusion/exclusion criteria, concomitant medication/supplement use, vital signs, and AEs). Gown body weight and body circumferences [waist, hip, chest, upper arm (dominant arm), and thigh (dominant leg)] will be measured. Additionally, female participants <60 years of age will undergo an in-clinic urine pregnancy test. A DXA scan will be performed (female participants <60 years of age must have a negative pregnancy test before the DXA scan is initiated). Participants will then be administered the IWQOL-Lite and the RAND-36 Questionnaires. All

participants will then be administered the Program Questionnaire, and TSFL and MEDD participants will place an order for the following four weeks' worth of study foods.

At Visit 6 (week 12), participants will arrive at the clinic fasted (12 ± 2 h, water only, anchored to time of gown body weight measurement) to undergo clinic visit procedures (evaluations of inclusion/exclusion criteria, concomitant medication/supplement use, vital signs, and AEs). Gown body weight and body circumferences [waist, hip, chest, upper arm (dominant arm), and thigh (dominant leg)] will be measured. Additionally, female participants <60 years of age will undergo an in-clinic urine pregnancy test. A DXA scan will be performed (female participants <60 years of age must have a negative pregnancy test before the DXA scan is initiated). All participants will then be administered the Program Questionnaire, and TSFL and MEDD participants will place an order for the following four weeks' worth of study foods.

At Visit 7 (week 16), participants will arrive at the clinic fasted (12 ± 2 h, water only, anchored to time of gown body weight measurement) to undergo clinic visit procedures (evaluations of inclusion/exclusion criteria, concomitant medication/supplement use, vital signs, and AEs). Blood samples will be collected for analysis ofhs-CRP, with additional blood samples collected and archived for possible future analysis of non-genetic indicators of inflammation and metabolism. Gown body weight and body circumferences [waist, hip, chest, upper arm (dominant arm), and thigh (dominant leg)] will be measured. Additionally, female participants <60 years of age will undergo an in-clinic urine pregnancy test. A DXA scan will be performed (female participants <60 years of age must have a negative pregnancy test before the DXA scan is initiated). Participants will then be administered the IWQOL-Lite, the RAND-36, the Program Questionnaire, and the Satisfaction and Health/Well-being Questionnaire (Appendices 3, 4, 5, and 6). All study participants will be dispensed maintenance handouts and guides prior to discharge from the clinic (see Supplementary Materials). Additionally, eligible Control group participants will be given instructions for placing orders for study food upon completion of all study visits.

6.2. **Flow Chart**

	Screening/ Baseline	**Clinic** Visits					
lvisit'	1	2	3	4	5	6	7
Week	**-1**	0	2	4	8	**12**	**16**
Infon; ed Consent/I-iiPAA[2]	X						
Demographics/Medical History	X						
Clinic Visit'	X	X	X	X	X	X	X
Gown Body Weight	X	X	X	X	X	X	X
Anthropometries'		X		X	X	X	X
In-clinic Urine Pregnancy T st[5]	X	X		X	X	X	X
Chemistry Profile[6]	X						
Hematology Pane1[7]	X						
-h,;-:CRP[8]		X					X
Archive Blood Samples[9]		X					X
Randomization		X					
Dual Energy X-ray Absorptiometry		X		X	X	X	X
IWQOL-Lite Questionnaire'"		X			X		X
-RAND-36"		X			X		X
)iet Education"		X					
Dispense Educational Material "		X					
Dispense Study Food [14]		X					
Order Study Food [15]		X		X	X	X	X
Program QuestJOnnatre[16]		X		X	X	X	X
Dispense Maintenance Guidc [17]							X
Satisfaction and Health/Well-being Questionnaire"							X

Footnotes:

[1]A window of 1-14 d will be allowed between Visits l and 2. A window of± 2 d will be allowed between clinic visits 2 and 3. All other clinic visits will have a± 3 day window (Visit 3 through 7).

'Health Insurance Portability and Accountability Act (HIPAA). The signed document authorizes the use and disclosure of the participant's Protected Health Information by the Clinical Investigator and staff solely for the purposes of the study.

[3] Clinic visit procedures include evaluations of height (Visit I, week -I only), BMI calculation (Visit l and 2, weeks -1 and 0 only), vital signs, inclusion/exclusion criteria (for eligibility at Visit l and for potential protocol deviations at subsequent visits), concomitant medication/supplement use, and AEs, where appropriate.

[4]Body circumference measurements (waist, hip, chest, dominant thigh, and dominant upper arm; Appendix 2).

[5]Urine pregnancy tests will be completed for all women< 60 years of age.

[6]The following will be performed as a part of the fasting (12 h ± 2 h, water only) chemistry panel: glucose, calcium, albumin, total protein, sodium, potassium, carbon dioxide (CO_2), chloride, blood urea

nitrogen (BUN), creatinine, alkaline phosphatase (ALP), aminotransferase (AST), alanine aminotransferase (ALT), total bilirubin, and osmolality.
[7]The following will be performed as part of the fasting (12 h ± 2 h, water only) hematology measurements: white blood cell count/automated differential, red blood cell count, hemoglobin, hematocrit, platelet count, mean corpuscular volume, mean corpuscular hemoglobin, and mean corpuscular hemoglobin concentration.
[8]Blood will be collected for analysisofhs-CRP.
[9]Blood will be collected and archived for possible future analysis of non-genetic indicators of inflammation and metabolism.
[10]Appendix 3.
"Appendix 4.
[12]AII three groups will receive diet instructions at Visit 2 (week 0). See Section 6.4.1 for details.
JJAII three groups will receive educational materials at Visit 2 (week 0). See Section 6.4.1 for details.
[14]The TSFL group and the MEDD group will receive study food as part of the study program. See Section 6.4.1 for details.
[15]The TSFL group and the MEDD group will place orders for additional study foods with the study staff at visits 2, 4, 5, and 6 (weeks 0, 4, 8, and 12); these will be shipped directly from Medifast. Orders must be submitted on the visit days. Participants who are assigned to the Control group and complete all study visits will be provided instructions for placing orders for study food at Visit 7 (week 16).
"'Appendix 5.
[17]All study groups will receive handouts with guidance for weight maintenance.
[18]Appendix 6.

6.3. Study Sample

Each participant must meet all of the following inclusion criteria and none of the exclusion criteria at baseline (Visit 2, week 0) in order to participate in this study.

6.3.1. Inclusion Criteria

I. Participant is judged by the Clinical Investigator to be in good health on the basis of medical history and screening laboratory assessments.
2. Participant is male or female, 18-65 years, inclusive
3. Participant has a BMI of27.0 to 42.0 kg/m^2 at Visit 2 (week 0).
4. Participant has no plans to change smoking habits during the study period.
5. Participant is willing and able to comply with the visit schedule.
6. Participant is willing to modify their physical activity level in accordance with recommendations provided with each group.
7. In the Clinical Investigator's opinion, participant has interest in losing weight, and is ready and willing to do so.
8. Participant is willing/able to follow assigned plan and adhere to food and beverage consumption guidelines for the duration of the study period.
9. Participant has access to the internet via a computer, tablet, and/or smart phone.
10. Participant understands the study procedures and signs forms providing informed consent to participate in the study and authorization for release of relevant protected health information to the study Clinical Investigators.

6.3.2. Exclusion Criteria

1. Participant has an abnormal laboratory test result of clinical significance, at Visit 1 (week **-1),** at the discretion of the Clinical Investigator. One re-test will be allowed on a separate day prior to Visit 2 (week 0), for participants with abnormal laboratory test results.
2. Participant has had a weight loss or gain >5% in the 6 months prior to the screening visit (Visit 1; week -1) except in the case of post-partum weight loss.
3. Participant has extreme dietary habits, including vegetarianism, in the judgment of the Clinical Investigator.
4. Participant has used medications, products, supplements, and/or programs/diets intended to alter body weight within 6months of Visit I (week -I).
5. Participant has used medications which are known to stimulate or suppress appetite, and/or alter body weight but which are taken for other indications, will be allowed as long as the dose has remained stable for the past 6 months.
6. Participant has used thyroid hormones, except stable-dose replacement therapy for ::0:2 months prim· to Visit I (week -I).
7. Participant has used Coumadin@ (warfarin), and/or medications that may influence lipids and/or blood pressure, except stable-dose medications for 1 month prior to Visit I (week -I).
8. Participant has used medications that may influence carbohydrate metabolism, including but not limited to hypoglycemic medications and systemic (intravenous, intramuscular, or oral) corticosteroids within ▌month of Visit ▌(week -1).
9. Participant has used lithium within ▌month of Visit **1** (week **-1).**
10. Participant has a history of any surgery or liposuction for weight reducing purposes.
11. Participant has a history or presence of clinically important gout, cardiac, renal, hepatic, endocrine (type **1** diabetes mellitus or type 2 diabetes mellitus that requires medication), pulmonary, biliary, pancreatic, or neurologic disorders.
12. Participant has a history of an eating disorder (e.g., anorexia nervosa, bulimia nervosa or binge eating) diagnosed by a health professional.
13. Participant has uncontrolled hypertension (systolic blood pressure ::0:160 mm Hg or diastolic blood pressure ::0:100 mm 1-Ig) as defined by the blood pressure measured at Visit **1.** Onere-test will be allowed on a separate day prior to Visit 2 (week 0) for participants whose blood pressure exceeds either ofthese cut points at Visit 1 (week -1).
14. Participant has a history or presence of cancer in the prior 2 years, except for non-melanoma skin cancer.
15. Participant has elective hospitalizations planned (e.g., elective cosmetic procedures) during the study period.
16. Participant is a female who is pregnant, planning to be pregnant during the study period, lactating, or is of childbearing potential and is unwilling to commit to the use of a medically approved form of contraception throughout the study period.
17. Participant has a recent history of (within 12 months of Visit 1; week **-1)** or strong potential for alcohol or substance abuse. Alcohol abuse defined as>14 drinks/week **(1** drink= 12 oz beer, 5 oz wine, or 1 *y,* oz distilled spirits).
18. Participant has a known allergy, sensitivity, or intolerance to the study foods or any ingredient(s) of the study diets (e.g., soy, gluten, wheat, lactose).
19. Exposure to any non-registered drug product within 1 month prior to the screening visit (Visit 1; week -1).

20. Participant has a condition the Clinical Investigator believes would interfere with his or her ability to provide informed consent, comply with the study protocol, or which might confound the interpretation of the study results or put the person at undue risk.

6.3.3. Excluded Medications and Products

Medications which are known to stimulate or suppress appetite, but which are taken for other indications, will be allowed as long as the dose has remained stable for the past six months prior to Visit I (week -1). Use of medications, products, supplements, and/or programs/diets intended to alter body weight are not allowed within six months prior to Visit I (week -1). Unstable use of thyroid hormones within 2 months of Visit I (week -I) is not allowed. The use of other medications that may affect carbohydrate metabolism, including but not limited to hypoglycemic medications and systemic (intravenous, intramuscular, or oral) corticosteroids is not allowed within one month of Visit 1 (week -I). Use ofCoumadin (warfarin) and/or medications known to influence lipids and/or blood pressure, except stable-dose medications within one month of Visit 1 (week **-1),** is not allowed. Additionally, lithium is excluded within one month of Visit I (week **-1).** A list of exclusionary medications/supplements and products can be found in Appendix I.

Should a participant require any of these medications or supplements, the study staff should consult with the Project Manager or Principal Scientific Investigator to discuss the participant's participation in the trial.

6.3.4. Randomization Procedures

Stratified block randomization will be utilized. Participants will be randomized to one of three groups (1:I: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 :SI 0% of participants with a BMI between 2:27.0 and <30.0 kg/m2, but randomization will not be stratified by BMI.

If a participant meets all inclusion and none of the exclusion criteria, a staff member will select the next sealed sequential randomization envelope, derived fi·om a computer generated randomization list, containing randomization number and group assignment for the participant. The randomization number will be recorded with the participant's source documentation. The participant randomization envelope should be maintained with the participant's source documents.

6.4. Study]>mgrams and Foods

6.4.1. Description of Study Programs

Control Group: 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.

Control Group-Specific Procedures

	Weight Los_s_Phase															
[week	[0	1		3	4	5	6	7	8	9	10	11	12	13	14	15	16
Dispense Educational Materialsa	X																X
In-Clinic Instruction Session"	X																
Provide Instructions for Ordering Study Fo()dc																	X

Footnotes:
'At Visit 2 (week 0), participants will receive a SuperTracker Profile, SuperTracker handouts, and meal plan handouts specific to their targeted calorie level (see Supplementary Materials). Participants will be instructed to set up and use the Super Tracker profile at home. At Visit 7 (week 16), participants will receive maintenance handouts and guides tailored to this control group (see Supplementary Materials).
bThe instruction session will be conducted in-clinic by a trained study staff member in a one-on-one format.
'Participants who are assigned to the control group and complete all study visits are eligible to receive study food and will receive instructions on how to place orders at Visit 7 (week 16).

Take Shape For Life Group: The TSFL Program group will be assigned to the Optimal Weight 5 & I Plan'M for weight loss. This is a portion-controlled, nutritionally balanced, low calorie weight loss meal plan (800-1 000 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 Medifasl snacks which can serve as a portable, pre-portioned, ready-to-eat alternate snack option.

This TSFL group will have regularly scheduled coaching sessions starling 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 I). If the coaching session does not take place, participants will be instructed to start their weight loss program on day I 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.

TSFL Group-Specific t>roccdm·cs

	Weight Loss Phase																
''''Ck	**0**	**1**	**2**	3	**4**	5	6	7	**8**	9	**10**	**11**	**12**	**13**	**14**	IS	**16**
⌊.opense Educational Materials"	X																X
""felephone Coaching'	X	X4	XZ	XZ	XZ	X	X	X	X	X	X	X	X	X	X	X	X
TSFL Monthly eNewsletter'			X				X				X				X		
Dispense Study Fooda	X																
Order Study Foodc	X				X				X				X				

Footnotes:
"At Visit 2 (week 0), participants will receive a packet of study-specific TSFL printed materials [includes one of each of the following: The Optimal Weight 5 & I Plan™ Quick Start guide; Dining Out guide; Healthy Celebrations guide; TSFL Optimal Weight 5 & I Plan™ food journal; Dr. A's Habits of Health book; Living a Longer, Healthier Life: The Companion Guide to Dr. A's Habits of Health; Dr. A's Discover Your Optimal Health book; Fit & Festive recipe cards (5 sets); Condiment Recommendations handout; TSFL shaker jar] and the "Getting Started Instructions" for the TSFL Group; see Supplementary Materials) during the clinic visit. The TSFL coach will review key concepts during the initial coaching contact. At Visit 7 (week 16), participants will receive TSFL maintenance handouts and guides (see Supplementary Materials).
"Coaching sessions will be conducted one-on-one by telephone with an assigned TSFL coach trained in the TSFL Habits of Health coaching model. Coaching sessions will take place at baseline and 4 times

during the first week, twice in each of weeks 2, 3 and 4, and weekly thereafter through week 16. Week I coaching will occur Monday through Friday (i.e., no weekend calls), with subsequent sessions taking place at any point during those weeks. The initial intake session at baseline will be approximately 45 min in length. Subsequent check-ins will be approximately 5-10 min, and the final session will be approximately 30 min. Pmticipants in the TSFL group will be encouraged to track weight and food intake, discuss their progress with their coach during the coaching sessions, and access TSFL written, online, and virtual support tools to use at their discretion. These participants will also have limited access to the Medifast Nutrition Support Team.

'The TSFL group will receive monthly newsletters (each calendar month) via email that contain general health information and links to the TSFL Stop, Challenge, Choose e-book, and archived TSFL support calls (doctors and nurse support calls).

d At baseline (Visit 2, week 0), the TSFL group will be dispensed a starter meal kit containing a I0-d supply of study foods for the assigned meal plan (i.e., the 5 & I Plan) to ensure they have adequate study foods until they receive their first order. This kit will contain 7 boxes of Medifast meal replacements (i.e., 49 individual meal replacements). Participants will start the Optimal Weight 5 & 1 Plan™, including consumption of the assigned study food, the day following the randomization visit (day 1), regardless of whether the coaching session has occurred (a protocol deviation form must be submitted).

'Participants will order enough study food to ensure their supply will last until the next food ordering timepoint: each order will include 20 boxes ofMedifast meal replacements (i.e., 140 individual meal replacements), and up to 2 boxes ofMedifast Snacks (i.e., 14 individual snacks), and up to 6 individual Flavors of Home products. The study foods will be participant-selected from among those offered on the TSFL order form (see Supplementary Materials), and the orders will be placed with study staff during clinic visits.

Medifast Direct (MEDD) Program Group: Participants randomized to the MEDD group will be assigned to the Medifast Achieve™ Plan (4 & 2 & I Plan@) for weight loss. The Achieve Plan is a portion-controlled, nutritionally balanced, reduced energy (II 00-1300 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 ofMedifast'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) ofMedifast 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 I). If the telephone call does not take

place, participants will be instructed to start their weight loss program on day I 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.

MEDD-Spccific Procedures

-Week-	Weight Loss Phase																
	0	I	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Dispense Educational Materialsa	X																X
Program Instruction Session"	X																
Dispense Study Foodc	X																
Order Study Food"	X				X				X				X				

Footnotes:

'At Visit 2 (week 0), participants will receive a packet of study-specific MEDD printed materials [includes one of each of the following: The Medifast AchieveTM Plan guide; The Dining Out guide; the 4 & 2 &I Plan"' food journal; Healthy Celebrations guide; Your Self-Directed Healthy Living workbook; Simply Well: An Everyday, Healthy Cookbook; Fit & Festive recipe cards (5 sets); Condiment Recommendations handout; Medifast shaker jar] and the "Getting Started Instructions" for the MEDD Group. At Visit 7 (week I6), participants will receive MEDD group maintenance handouts and guides (see Supplementary Materials).

bThe MEDD group will be instructed to call the Medifast Nutrition Support Team to receive a one-on-one introduction to their assigned weight loss program with a Nutrition Support Team member prior to I7:00 h EST. This telephone call (I 0-15 min in length) will take place the day of Visit 2 (week 0) as participants will be instructed to start their weight Joss program the day following the randomization visit (day I). If the telephone call does not take place, participants will be instructed to start their weight Joss program on day I (a protocol deviation form must be submitted). These participants will also have access to the Nutrition Suppmi Team (to use at their discretion) and all online and written Medifast Direct materials throughout the study.

'At baseline (Visit 2, week 0), the MEDD group will be dispensed a Starter Meal Kit containing a I0-d supply of study foods for the assigned meal plan (i.e., the 4 & 2 & I Plan) to ensure participants have an adequate supply of study food until they receive their first order. This kit will contain 6 boxes of Medifast meal replacements (i.e., 42 individual meal replacements). Participants will stmt the 4 & 2 & I Plan"', including consuming the assigned study food the day following randomization (day I), regardless of whether the telephone call with the Medifast Nutrition Support Team member has occurred.

'Participants will order enough study food to ensure their supply will last until the next food ordering timepoint: each order will include 16 boxes ofMedifast meal replacements (i.e., I12 individual meal replacements), and up to 2 boxes ofMedifast Snacks (i.e., 14 individual snacks), and up to 12 individual Flavors ofl·Iome products. The study foods will be participant-selected from among those offered on the MEDD order form (see Supplementary Materials), and the orders will be placed with study staff during **clinic visits.**

6.4.2. Labeling and Packaging of Study Foods

The Sponsor will provide a total of approximately 17 weeks' worth of study foods for each participant in the TSFL and MEDD groups to cover the 16-week weight loss phase and additional study food to account for shipping time and ensure participants do not run out of food between orders. Foods dispensed at the clinic (Visit 2; week 0) will be supplied in pre-packaged kits (starter meal kits) containing multiple boxes of pre-selected study foods packaged in their original commercial packaging. The outer box of each starter meal kit will list the group kit type (TSFL or MEDD) and will have a space to write the participant's randomization number. Subsequent study foods will be home-delivered to participants, consistent with Medifast's commercial programs. Study foods will be supplied in their original commercial packaging. Medifast meal replacements and Medifast snacks come in boxes of 7 meals or snacks each; Flavors ofl-Iome are individually packaged.

6.4.3. Storage and Usc of Study Foods

The site will maintain an inventory of study foods to include (I) pre-packaged starter meal kits for the TSFL and MEDD groups, and (2) an inventory of individual boxes ofMedifast meal replacements for participant foods that might need to be exchanged (e.g., the participant does not like a food or particular flavor supplied in the starter meal kit). The Site will complete a Master Study Food Log, which is a list of all study Starter Meal Kits received at the site, as well as any individual boxes of study food items received. A Study Food Accountability Log for study Starter Meal Kits and any individual boxes of food items dispensed by the clinic should also be completed individually for each participant and maintained with the participant's chart. The date, participant's initials, randomization number should be recorded on this log.

The study foods will be stored in a dry secure location at ambient temperature. Study foods are to be used only in accordance with this protocol and under the supervision of the Clinical Investigator. All records must be available for inspection by the Sponsor and for regulatory agency inspection at any time. Copies of the records will be provided to the Sponsor at the conclusion of the study. A written explanation from the study staff will be required for any missing study food.

6.5. Clinical Measurements

6.5.1. Clinic Visits

Clinic visits will include evaluations of height (Visit I only), BMI calculation (Visit I and 2 only), vital signs, prior and concomitant medication/supplement use, and inclusion/exclusion criteria (for eligibility at visit I and for potential protocol deviations at subsequent visits). In order to calculate BMI, height will be measured at the screening visit (Visit I, week -I) using a wall-mounted stadiometer. Participants will remove shoes prior to height measurement.

Standardized vital signs measurements will include resting blood pressure and heart rate measured using an automated blood pressure measurement device. Blood pressure will be obtained after the participant has been sitting for at least five min. Systolic and diastolic pressures will be measured once using an appropriate sized cuff (bladder within the cuff must encircle 2:80% of the arm). Clinic staff may take a second blood pressure and heart rate, if warranted. In the event a second measure is assessed, the second measurement will be recorded

in the eCRF. Should elevated blood pressure (see Section 6.3.2, criterion 13) be present at the screening visit (Visit 1, week -1), one retest will be allowed on a separate day, prior to Visit 2 (week 0).

Additionally, AEs will be assessed at each post-randomization visit (Visits 2, 3, 4, 5, 6, and 7; weeks 0, 2, 4, 8, 12, and 16). Inquiring about AEs will occur with an open-ended question. This study is a dietary intervention and does not include an investigational study drug or product. However, for safety purposes, assessment of AEs will be conducted in a manner consistent with clinical trials on investigational study drugs or products. Participants will be asked an open-ended question (e.g. "Have there been in any changes in your health or medications since you were last asked?").

6.5.2. Laboratory Measurements

The procedures for all clinical laboratory measurements will be described in detail in a laboratory manual. Laboratory parameters that are missing or have not been obtained must be entered in the eCRF as "not done."

The following will be performed as a part of the fasting (12 ± 2 h) chemistry profile at Visit I (week -I): glucose, calcium, albumin, total protein, sodium, potassium, C02, chloride, BUN, creatinine, ALP, AST, ALT, total bilirubin, and osmolality. Analytes will be assessed by Elmhurst Memorial Reference Laboratory (Elmhurst, IL).

The following will be performed as part of the fasting (12 ± 2 h) hematology measurements at Visit I (week **-1):** white blood cell count/automated differential, red blood cell count, hemoglobin, hematocrit, platelet count, mean corpuscular volume, mean corpuscular hemoglobin, and mean corpuscular hemoglobin concentration. Analytes will be assessed by Elmhurst Memorial Reference Laboratory (Elmhurst, IL).

At Visits 2 and 7 (weeks 0 and 16) samples will be collected for the assessment ofhs-CRP. hs-CRP will be assessed by Elmhurst Memorial Reference Laboratory (Elmhurst, IL). Additional samples will be collected and stored and archived for possible future analysis of non-genetic indicators of inflammation and metabolism.

An in-clinic urine pregnancy test will be performed at Visits I, 2, 4, 5, 6, and 7 (weeks -1, 0, 4, 8, 12, and 16) for females < 60 years of age.

6.5.3. Gown Body Weight Assessment

Body weight will be measured at all visits (Visits I through 7; weeks -1 through 16) following a fast (12 ± 2 h, water only). Participants will be asked to change into a gown and remove their shoes before their weight is obtained. Weight will be recorded on a medical quality digital scale (Health **O** Meter 349KLX) to the nearest tenth pound (one decimal place). The same digital scale will be used to measure body weight at each clinic visit. The scale will be calibrated at least yearly to assess accuracy.

6.5.4. Anthropometric Measurements

Measurements of waist, hip, chest, dominant upper arm, and dominant thigh circumferences will be conducted at Visits 2, 4, 5, 6, and 7 (weeks 0, 4, 8, 12, and 16; Appendix 2). A stretch- resistant anthropometric tape (Gulick 11 model #67020, Gays Mills, WI) with an indicator buckle to denote proper amount of tension applied to the tape will be used for body circumference measurements. These measurements will be used for calculation of total body circumference and waist-to-hip ratio.

6.5.5. Dual-Energy X-ray Absorptiometry

DXA scans (GE Lunar Prodigy, enCORE software version 16, Madison, WI) will be performed on Visits 2, 4, 5, 6, and 7 (weeks 0, 4, 8, 12, and 16) to assess body composition. The DXA scan will provide estimates of total body fat mass, total body fat-free mass, trunk fat, and non-trunk fat. Female participants <60 years of age must have a negative pregnancy test before the DXA scan is initiated.

6.5.6. Impact of Weight on Quality of Life-Lite Questionnaire

Participants will be administered the electronic IWQOL-Lite Questionnaire at Visits 2, 5, and 7 (weeks 0, 8, and 16; Appendix 3) to assess obesity specific QoL domains (physical function, selt esteem, sexual life, public distress and work).

6.5.7. RAND-36 Questionnaire

Participants will be administered the electronic RAND-36 Questionnaire at Visits 2, 5, and 7 (weeks 0, 8, and 16; Appendix 4). This widely used 36-item test requires participants to assess eight health concepts: physical functioning, role limitations caused by physical health problems, role limitations caused by emotional problems, social functioning, emotional well-being, energy/fatigue, pain, and general health perceptions.

6.5.8. l'rogram Questionnaire

Participants will be administered the electronic Program Questionnaire at Visits 2, 4, 5, 6, and 7 (weeks 0, 4, 8, 12, and 16; Appendix 5). The questionnaire will include questions about activity level only (Question ▌and 2) at Visit 2 (week 0).

Based on the answers to ▌and 2, the Physical Activity Level (PAL = ratio of total energy expenditure / resting metabolic rate) can be determined as shown in each cell for each combination of work/school and leisure time activity estimates. This value can then be recorded for each participant at each time point during the study to track physical activity.

		Leisure Time Activity				
		Very Light	Light	Moderate	Active	Very Active
	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

At Visits 4, 5, 6, and 7 (weeks 4, 8, 12, and 16), participants in all groups will be asked to document their adherence to the weight loss plan and activity level over the previous 4-week period (Questions 3, 4 and 5), and participants in the TSFL and MEDD groups will also be asked to assess their adherence to study meal replacement intake (Question 6).

6.5.9. Satisfaction and Health/Well-being Questionnaire

Participants will complete the electronic Satisfaction and Health/Well-Being Questionnaire at Visit 7 (week 16; Appendix 6). The Satisfaction and Health/Well-Being Questionnaire is a 20-item questionnaire assessing participant satisfaction with the assigned diet program and general health/well-being. Question order will be randomized.

6.6. Procedures at Each Clinic Visit

6.6.1. **Screening (Visit I, week -1)** (-2 weeks to -1 day)

- Informed consent/HIPAA
- Demographics/medical history
- Clinic visit
  - Height
  - BMI calculation
  - Vital signs
  - Review inclusion/exclusion criteria
  - Assess prior and current medication/supplement use
- Gown body weight
- In-clinic urine pregnancy test, where applicable
- Chemistry profile
- Hematology panel

6.6.2. Baseline (Visit 2, week 0) (1 to 14 days alter Visit 1)

- Clinic visit
  - BMI Calculation
  - Vital signs
  - **Assess AEs**
  - Review inclusion/exclusion criteria

    - Assess concomitant medication/supplement use
- Randomization
- hs-CRP
- Archived blood samples
- Gown body weight
- Anthropometric measurements
- In-clinic urine pregnancy test, where applicable
- DXA
- Program Questionnaire
- IWQOL-Lite Questionnaire
- RAND-36 Questionnaire
- Diet education and handouts (Control group)
- Dispense packet of educational materials (TSFL and MEDD groups)
- Dispense starter meal kits (TSFL and MEDD groups)
- Schedule initial TSFL coaching session (TSFL group only)
- Reminder to call Nutrition Support Team (MEDD group only)
- Order study foods (TSFL and MEDD groups)

6.6.3. Clinic visit (Visit 3, week 2 ± 2 d)

- Clinic visit
    - Vital signs
    - Assess AEs
    - Review inclusion/exclusion criteria
    - Assess concomitant medication/supplement use
- Gown body weight

6.6.4. Clinic visit (Visit 4, week 4 ± 3 d)

- Clinic visit
    - Vital signs
    - Assess AEs
    - Review inclusion/exclusion criteria
    - Assess concomitant medication/supplement use
- Gown body weight
- Anthropometric measurements
- In-clinic urine pregnancy test, where applicable
- DXA
- Program Questionnaire
- Order study foods (TSFL and MEDD groups)

6.6.5. Clinic visit (Visit 5, week 8 ± 3 d)

- Clinic visit
    - Vital signs
    - Assess AEs
    - Review inclusion/exclusion criteria
    - Assess concomitant medication/supplement use

- Gown body weight
- Anthropometric measurements
- In-clinic urine pregnancy test, where applicable
- DXA
- Program Questionnaire
- IWQOL-Lite Questionnaire
- RAND-36 Questionnaire
- Order study foods (TSFL and MEDD groups)

6.6.6. Clinic visit (Visit 6, week 12 ± 3 d)

- Clinic visit
  - Vital signs
  - Assess AEs
  - Review inclusion/exclusion criteria
  - Assess concomitant medication/supplement usc
- Gown body weight
- Anthropometric measurements
- In-clinic urine pregnancy test, where applicable
- DXA
- Program Questionnaire
- Order study foods (TSFL and MEDD groups)

6.6.7. Clinic visit (Visit 7, week 16 ±3d)

- Clinic visit
  - Vital signs
  - Assess AEs
  - Review inclusion/exclusion criteria
  - Assess concomitant medication/supplement use
- Gown body weight
- Anthropometric measurements
- In-clinic urine pregnancy test, where applicable
- hs-CRP
- Archived blood samples
- DXA
- Program Questionnaire
- IWQOL-Lite Questionnaire
- RAND-36 Questionnaire
- Satisfaction and Health/Well-being Questionnaire
- Provide instructions for placing study food orders (control group completers only)
- Dispense Group-specific Maintenance Materials and Guides

In addition to (and outside o1) the regularly scheduled clinic visits described above, the TSFL Group will receive telephone coaching sessions per the schedule outlined in the TSFL Group-Specific Procedures (see page 18).

6.7. Early Termination Procedures

The term "Early Termination" refers to a participant's non-completion of the study. Should a participant decide to withdraw, all efforts will be made to complete and report observations as thoroughly as possible. In the event that a participant is withdrawn from the study, the reason for the withdrawal and the party who initiated the withdrawal (participant or Clinical Investigator) will be documented. Should the participant decide to withdraw, documentation of the early termination will be made and an attempt to conduct an early termination visit (which will occur at week 16 and include the clinic visit procedures for Visit 7).

The primary reason for a participant withdrawing prematurely should be selected fi·om the following standard categories:

Adverse Event- event which results in discontinuation of the study food by the participant or that in the judgment of the Clinical Investigator for the best interest of the participant requires discontinuation of study food (includes all categories of study food relatedness; Not Related, Unlikely, Possibly, Probably, and Definitely).

Death -death of the participant.

Withdrawal of Consent- participant desires to withdraw from further participation in the study in the absence of a medical need to withdraw determined by the Clinical Investigator.

Lost to Follow-Up- participant did not return for one or more follow-up visit(s) following dispensing of test product and could not be contacted thereafter. The reason for withdrawal was unknown and could not be documented.

Other- causes of premature termination from the study other than the above, such as theft or loss of study foods, pregnancy, termination of study by Sponsor, etc.

6.8. Procedure for Participants that Reach a Low BMI

Participants who achieve a BMI of 19.0 kg/m^2 or below will discontinue their assigned weight loss diet and this will be noted in source documents. Participants will receive maintenance materials and guides (appropriate to their assigned study group) and will be asked to follow a weight maintenance plan for the duration of the study. The participant will continue in the study and be asked to return for remaining clinic visits.

7. Assessment of Outcomes

7.1. Primary Outcome Variable

The primary endpoint is body weight and the primary outcome is change (percent 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.

7.2. **Secondary Outcome Variables**

Secondary outcome variables will include the following:

- Proportion of participants achieving 2:5% and 2:10% loss of baseline body weight at each post-randomization visit (Visits 3, 4, 5, 6, and 7; weeks 2, 4, 8, 12, and 16)
- Percent and absolute change in body composition parameters (measured via DXA) from baseline to Visits 4, 5, 6, and 7 (weeks 4, 8, 12, and 16).
    - o Total fat mass
    - o Total lean mass (non-bone fat free mass)
    - o Percent body fat (expressed as a percentage of total body mass)
    - o Percent lean mass (expressed as a percentage of total body mass)
    - o Android fat and lean mass
    - o Gynoid fat and lean mass
    - o Abdominal visceral fat mass and volume
- Absolute change in body circumference parameters from baseline to Visits 4, 5, 6, and 7 (weeks 4, 8, 12, and 16).
    - o Waist circumference
    - o Hip circumference
    - o Chest circumference
    - o Dominant upper ann circumference
    - o Dominant thigh circumference
    - o Total body circumference (sum of all 5 measures)
    - o Waist:hip ratio
- Absolute change in QoL questionnaire outcomes (total and domain scores) from baseline to Visits 5 and 7 (weeks 8 and 16). QoL will be measured using both the RAND-36 Questionnaire [which uses the same questions as the Short Form (36) Health Survey Questionnaire (Ware JE, eta!. 1992)] and the IWQOL-Lite Questionnaire.
    - o The IWQOL-Lite Questionnaire (Kolotkin RL, eta!. 2001) is a 31-question self-report instrument to assess obesity specific quality of life and consists of five domains: Physical Function (11 questions), SelfEsteem (7 questions), Sexual Life (4 questions), Public Distress (5 questions), and Work (4 questions).
    - o The RAND 36-ltem Health Survey Questionnaire assesses eight health domains: physical functioning (10 questions), role limitations due to physical health problems (4 questions), bodily pain (2 questions), general health perceptions (5 questions), vitality (4 questions), social functioning (2 questions), role limitations due to emotional problems (3 questions), and emotional well-being (5 questions) (RAND HEALTH, 2009).
- Weight loss program adherence assessed at Visits 4, 5, 6, and 7 (weeks 4, 8, 12, and 16) based on the Program Questionnaire.
    - o Adherence will be calculated based on self-reported TSFL/MEDD meal replacement product consumption, participation at assigned coaching sessions (TSFL only), utilization of Nutrition Support (TSFL/MEDD), and a single question VAS rating adherence to their assigned weight loss program (all groups).
- Participant satisfaction and health/well-being assessed via the Satisfaction and Health/Well-being Questionnaire at Visit 7 (week 16).
- Absolute change in hs-CRP from baseline (Visit 2; week 0) to Visit 7 (week 16).

8. Data Analysis and Statistical Methods

8.1. Sample Size

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 timefi'ame, 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 sized of 0.60). This assumes a nominal $a = 0.025$ (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 $a = 0.05$. To account for possible attrition, a total sample of 198 participants (n = 66 / group) will be randomized.

8.2. Statistical Analysis

8.2.1. 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.

All decisions regarding exclusion from the outcome populations will be documented prior to database lock.

8.2.2. Outcome Analysis

Descriptive statistics [number of participants, mean, standard error of the mean (SEM), standard deviation, median, interquartile limits, minimum and maximum] will be presented for continuous variables. Ratings for categorical variables will be presented as counts and percentages.

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

A mixed model repeated measures analysis of covariance (ANCOVA) will be used to assess differences between study groups in continuous outcome variables. Initial ANCOVA models will contain terms for intervention, week, intervention by week interaction, and sex, with baseline measures (where applicable) as covariatcs. Models will be reduced using a backward selection method until only significant terms and/or intervention and baseline measures (where applicable) remain in the model. Pairwise comparisons between groups at each post-randomization visit will be conducted from the final ANCOVA model, with Dunnett's correction for multiple comparisons between each Medifast group vs. control. Assumptions of normality of residuals will be investigated for each response measurement. If the normality assumption is rejected at the I% level with the Shapiro-Wilk test (Shapiro 1965), then an analysis using ranks or other transformation will be performed.

Counts and percentages of participants who experience weight loss of :0:5% or :0:10% between baseline and each post-randomization visit will be presented. Differences between control and each active group participants with weight loss :0:5% or :0:10% will be assessed using a generalized linear model with a logit link and binomial distribution specified. Initial repeated measures models will contain terms for intervention, week, intervention by week interaction, and sex. Models will be reduced using a backward selection method until only significant terms or intervention remains in the model. Pairwise comparisons at each post-randomization visit will be conducted using Dunnett's correction for multiple comparisons between each Medifast group vs. control.

Counts and percentages for questionnaire responses will be presented by intervention group for ordinal outcomes (e.g. Likert scales). Differences between control and each active group will be assessed using a generalized linear model with a cumulative logit link and multinomial distribution specified. Initial repeated measures models will contain terms for intervention, week, intervention by week interaction, and sex. Models will be reduced using a backward selection method until only significant terms or intervention remains in the model. Pairwise comparisons between control and each active group at each post-randomization visit will be conducted using Dunnett's correction for multiple comparisons between each Medifast group vs. control.

8.2.3. Safety and Tolerability 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.

8.2.4. 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).

9. Study Monitoring

9.1. Concomitant Medications/Supplements

All concomitant medications/supplements used for six months prior to Visit 1 and during the study will be reported to the study personnel for assessment and recorded in the participant's cCRF.

Use of the medications/supplements described in the "Exclusion Criteria" section and Appendix 1 is not allowed during this study. If a participant requires any ofthese medications, the participant may not enter the study.

9.2. Adverse Event Monitoring

In a consensus view of guidelines for the design, conduct and reporting of human intervention studies to evaluate the health benefits of foods, an International Life Sciences Institute Europe Expert Group defines an AE as *"any untoward medical occurrence or undesirable clinical experience in a participant in a clinical trial, whether or not considered related to the intervention"* (Welch 2011). This includes any occurrence that is new in onset or aggravated in severity or frequency from the baseline condition, or abnormal results of diagnostic procedures (including laboratory test abnormalities where applicable). Therefore, clinical observations, including responses to the question, "Have there been in any changes in your health or medications since you were last asked?" will be collected post randomization. These observations will be reviewed for assessment of AE, including severity and potential relationship to the dietary intervention as determined by the study physician.

Events should be considered AEs if they:

- Result in discontinuation from the study,
- Require treatment or any other therapeutic intervention,
- Require further diagnostic evaluation (excluding a repetition of the same procedure to confirm the abnormality),
- Are associated with clinical signs or symptoms judged by the Clinical Investigator to have a significant clinical impact.

9.2.1. Grading and Severity

The Clinicallnvestigator will evaluate all AEs with respect to their severity, and record the outcome and action taken on the AE eCRF. AEs will be graded as:

Mild:	Awareness of symptoms but easily tolerated
Moderate:	Discomfort enough to interfere with but not prevent daily activity
Severe:	Unable to perform usual activity

9.2.2. Relationship

The Clinical Investigator will also judge the likelihood that the AE was related to the diet plan administered and document this on the appropriate eCRF as:

NOT RELATED	**This category applies to those adverse experiences which, after careful consideration, are clearly and incontrovertibly due to extraneous causes (disease, environment, etc.).**
UNLIKELY	**In general, this category can be considered applicable to those experiences that after careful medical consideration at the time they are evaluated, arc judged to be, unlikely** rclated to the study foods administered.
POSSIBLY	**This category applies to those adverse experiences for which, after careful medical consideration at the time they are evaluated, a connection with the study foods administration appears possible but cannot be ruled out with certainty.**
PROBABLY	**This category applies to those adverse experiences that, after careful medical consideration at the time they are evaluated, are felt with a high degree of certainty to** be related to the study foods.
DEFINITELY	This category applies to those adverse experiences which, the Clinical Investigator feels are incontrovertibly related to the study foods.

Appropriate therapeutic action and follow-up measures will be performed by the Clinical Investigator in accordance with good medical practice.

9.2.3. Serious Adverse Event Definition/Qualification

A SAE is defined as an AE that results in any of the following outcomes:

- Death (note that death is the outcome of a SAE and the cause of death should be listed as the AE)
- Life-threatening event
- In-patient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- Congenital anomaly or birth defect
- Any other important medical event that may not result in death, be life-threatening, or require hospitalization, may be considered a SAE when, based upon appropriate medical judgment, the event may jeopardize the pm1icipant and may require medical or surgical intervention to prevent one of the outcomes listed above. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in in-patient hospitalization, or the development of drug dependency or drug abuse.

In the event of a SAE, the participant may be dropped from the study if the Clinical Investigator deems it necessary.

9.2.4. Serious Adverse Event Reporting Instructions

If in the opinion of the Clinical Investigator the event meets the criteria of a SAE the following procedures will be followed:

- The Clinical Investigator will report the SAE by telephone to Biofortis Innovation Services immediately upon becoming aware of the event.

- In addition, the initial SAE report should be submitted with other applicable information (such as medical history, concomitant medications, AEs) to Biofortis Innovation Services within 24 h of reporting the event to the attention of the Project Manager.
- The Clinical Investigator will also notify the Institutional Review Board (IRB) of the event within the parameters and timeframe specified under the IRB Standard Operating Procedures (SOP) after becoming aware of the SAE. An initial report followed promptly by a complete report will be forwarded to the IRB.
- Follow-up information relating to a SAE must be submitted to Biofortis Innovation Services by telephone, fax, or overnight courier as soon as additional data related to the event are available.
- If a subject is hospitalized or hospitalization is prolonged due to the SAE, the hospital discharge summary will be obtained if possible when it becomes available.
- If a death occurs and an autopsy is performed, a copy of the autopsy report will be obtained if possible when it becomes available. All efforts must be undertaken to obtain follow-up information promptly.
- Biofortis Innovation Services will report SAEs to the Sponsor per the terms of the Master Service Agreement.

9.2.5. Electronic CRF Recording of Adverse Events

All AEs will be recorded on the AE eCRF page. For participants who have an ongoing AE at their final study visit, a follow-up AE eCRF page will be collected after 30 d. Participants will be instructed to notify Biofortis Innovation Services immediately should new AEs emerge for an additional 30 d following their last day on the study diet. All SAEs must be recorded on the AE and SAE eCRF page.

9.2.6. Serious Adverse Event Follow-Up

For all SAEs occurring during the study or within 30 d of the study diet, the Clinical Investigator must submit follow-up reports to Biofortis Innovation Services regarding the participant's subsequent course. All SAEs that are ongoing at the end of the study or upon discontinuation of the participant's participation must be followed until either:

- The event resolves, or
- The event/condition has stabilized (e.g., in the case of persistent impairment), or
- The event returns to baseline, if a baseline value is available, or
- The participant dies, or
- The event can be attributed to other than the study treatment, or to other than the study conduct.

9.2.7. Pregnancy

The study foods being dispensed for consumption in this study are commercially available ingredients, safe for consumption by pregnant or lactating women. However, the outcome variables measured would be expected to be affected by pregnancy and lactation, and the caloric levels of the study meal plans are not appropriate for pregnant women. Additionally, the DXA scan involves a very small dose of radiation, which makes the test unsuitable for women who arc, or might be, pregnant. All female participants <60 years of age will undergo in-clinic urine pregnancy testing prior to every DXA scan. Pregnant or lactating women will be excluded from

the study and women of childbearing potential will be required to use appropriate contraceptive methods to avoid pregnancy. Documentation of contraception method must be recorded in the source chart.

Although pregnancy is not a SAE, all pregnancies occurring in mndomized participants will be reported within 24 h of notification. The Clinical Investigator will immediately notify the Principal Scientific Investigator and the IRB about the pregnancy. Should a female participant become pregnant at any time after randomization, the participant should be withdrawn from the study, and the Clinical Investigator will be required to follow the participant through the pregnancy term and report to Biofortis Innovation Services the course of the pregnancy including perinatal and neonatal outcomes.

10. Conduct of the Study

10.1. Ethics and Regulatory Considerations

This study will be conducted according to Good Clinical Practice Guidelines, the Declaration of Helsinki (2000), and US 21 CFR. Signed written informed consent for participation in the study will be obtained from all participants before protocol-specific procedures are carried out. Participants will be informed of their right to withdraw from the study at any time.

10.2. Institutional Review Board

The Clinical Investigator will ensure that an appropriately constituted IRB, in compliance with the requirements of21 CFR 56, reviews and approves the clinical study. Before the study is started, the Clinical Investigator will forward copies of the protocol and consent form for this study to the IRB for review and approval. IRB approval must refer to the study by exact protocol title and number, identify the documents reviewed, and state the date of review. The IRB must be informed of all subsequent protocol amendments. No alterations, modifications to IRB-approved documents, including the protocol, protocol summary, consent form, recruitment materials and questionnaires will be allowed. The IRB must also be informed of all SAEs and of unexpected AEs that meet the IRB's reporting guidelines as outlined in the IRB's SOPs. In addition, the Clinical Investigator will immediately forward copies of all correspondence with the IRB to Biofortis Innovation Services.

10.3. Informed Consent and Protected Health Information

The study will be explained verbally as well as on the informed consent document. Each participant will be given ample opportunity to inquire about details of the study and to read and understand the consent form before signing it.

Consent must be documented by the dated signature of the participant. Each participant's signed informed consent document must be kept on file by the Clinical Investigator for possible inspection by regulatory authorities or by the Sponsor. The participant should receive a copy of the written informed consent document once he/she bas signed it.

The Sponsor recognizes the importance of protecting the privacy of participant data. Therefore, for study sites within the United States, the informed consent form will incorporate, or be accompanied by, a separate document incorporating HIPAA-compliant wording, by which

participants authorize the usc and disclosure of their Protected Health Information by the Clinical Investigator and by those persons who need that information for the purposes of this study.

A participant may not be admitted to the study unless informed consent of the participant (or her legally authorized representative) has been obtained.

10.4. Participant Confidentiality

The Clinical Investigator is responsible for ensuring that participants' anonymity will be maintained. Electronic CRFs or other documents will identify participants by initials, number, or code, and not by name. The Clinical Investigator will keep a separate log showing codes, names, and addresses. All documents showing the participants' identity will be kept in strict confidence by the Clinical Investigator. However, the Clinical Investigator agrees that the Sponsor, its employees or agents, the IRB, as well as representatives of the FDA, will have the right to audit and review pertinent medical records relating to this clinical trial and that the participants will provide written informed consent to this effect. Sponsor will also receive name and contact information for participants for the purpose of fulfilling study food orders (which are sent directly to the homes of participants) and for interactions with the Medifast Nutrition Support Team. Sponsor will ensure that participant information will be kept confidential and will not be used for any commercial purposes.

10.5. Withdrawal of Participants from the Study

Participants may be removed from the study for any of the following reasons:

- A participant requests discontinuation;
- The Clinical Investigator initiates removal for medical or compliance reasons;
- Occurrence of any AE or condition that could, in the Clinical Investigator's opinion, interfere with the evaluation of the treatment effect of the study food or put the participant at undue risk.

It is understood by all concerned that an excessive rate of withdrawals can render the study uninterpretablc, therefore, unnecessary withdrawal of participants should be avoided. Should a participant decide to withdraw, all efforts will be made to complete and report observations as thoroughly as possible. In the event that a participant is withdrawn from the study, the reason for the withdrawal will be documented in the eCRF. Prior to a participant's withdrawal from the study, an attempt will be made to conduct an early termination visit, which will occur at week 16 and include the clinic visit procedures for Visit 7.

Note that any participant who achieves a BMI of <:19 kg/m^2 will be placed on a weight maintenance diet and should not be withdrawn from the study.

11. Administrative Matters

All references to the Sponsor in this section include all designees e.g., Contract Research Organizations or Consultants acting on behalf of the Sponsor.

11.1. Changes to the Protocol

All changes to the protocol must be documented by amendments to the protocol signed by the Sponsor and the Clinical Investigator. The amended protocol and a revised informed consent form will be submitted for approval to the lRB. A copy of the approval will be provided to Biofortis Innovation Services. Where the local IRB regulations regarding protocol amendments differ from this policy, the local regulations will apply.

The above-mentioned requirements do not preclude any immediate action from being taken in the interests of participants' safety.

11.2. Protocol Deviations and Violations

A protocol deviation is a minor departure from the protocol that is approved by the Principal Scientific Investigator or authorized designee prior to implementation and does not compromise participant safety or the integrity of the data. Any deviation from the inclusion/exclusion criteria requires an approved waiver from the Principal Scientific Investigator or designee prior to randomization in order to enroll that participant into the study. The site should accurately document the deviation and approval in the source document and complete the protocol deviation/violation eCRF.

A protocol violation is a divergence from the IRB-approved protocol that is not approved by the Principal Scientific Investigator or authorized designee prior to implementation. A violation can be classified as major or minor. A major violation compromises the safety of the participant or the integrity of the data collected. A minor violation is a less-significant departure from the protocol that, though not pre-approved, does not compromise the safety of the participant or the integrity of the data collected. The site should accurately document the violation in the source document. Violations that could significantly influence participant safety will be reported to the IRB.

11.3. Electronic Case Report Forms

Data collected in the eCRF will be documented in an anonymous fashion (e.g., the participant will be identified only by a stndy number and their initials). Each evaluation recorded in the eCRF will be performed at the time specified in the protocol.

All information required by the protocol should be documented in the source records and provided in the eCRF. The Clinical Investigator must agree to complete and maintain source documents for each participant in the study. An explanation must be given for any omissions. All eCRFs must be completed as soon as possible after the participant's visit, in order that the monitor may verify the validity and completeness of the data. The Clinical Investigator should review and sign (as required) all eCRFs for completeness and accuracy prior to and during monitoring visits, as changes to the eCRF may be made during the monitoring visits by the site staff. All information on the eCRFs must be traceable back to the source documents.

11.4. Clinical Monitoring

An initiation meeting will be conducted by the Sponsor or an approved representative. At this meeting the protocol, eCRFs, and pertinent aspects of the CFR will be reviewed with the Clinical Investigator and all study staff.

Remote and on-site monitoring visits will be conducted during the study, focusing on human participant protection and data integrity risks of the trial. A clinical monitoring plan will be developed which identifies specific risk-based monitoring focal points. These may include:

- Informed consent
- Eligibility criteria
- Randomization/blinding
- SAEs
- Serious protocol violations
- Endpoints
- Test article administration
- Accountability

No data disclosing the identity of participants will leave the study center, except, as described in section 10.4, to the Sponsor for the purposes of food ordering and Medifast Nutrition Support Team interactions. Biofortis Innovation Services and any designees will maintain confidentiality of all participant records.

The Clinical Investigator must ensure that access to the CRF is secured and that other study documentation is stored in a secure location. During the conrsc of the study, the responsible Biofortis Innovation Services staff will be available to discuss any matters relating to the conduct of the study.

11.5. Auditing J>rocedures

In addition to the monitoring visits outlined above, an investigational site may undergo a quality assurance audit. The Sponsor representatives or a regulatory agency such as the FDA may conduct the audit. If a regulatory agency requests an audit of the study site, the Clinical Investigator is required to inform the Sponsor and Biofortis Innovation Services immediately.

11.6. Records Retention

All study documentation generated in connection with this study will be retained for at least five years after the last approval of a marketing application in an International Conference on Harmonization (ICI-1)-region and until there arc no pending or contemplated marketing applications in an ICH-region or at least 5 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the Sponsor. It is the responsibility of the Sponsor to inform the Clinical Investigator/institution as to when these documents no longer need be retained. The study documents include IRB approvals for the study protocol and all amendments, all source documents and laboratory records, eCRF records, signed participant informed consent forms, and any other pertinent study document. The Clinical Investigator agrees to supply Biofortis Innovation Services with a written confirmation that these procedures are in place and will be adhered to.

11.7. Termination of Study

The Sponsor and the Clinical Investigator reserve the right to terminate the study at any time. In terminating the study, the Sponsor and the Clinical Investigator will assure that adequate consideration is given to the protection of each participant's interest.

11.8. Final Rcportfl>ublications

Any formal presentation or publication of data collected as a direct or indirect result of this trial will be considered as a joint publication by the Clinical lnvestigator(s), where applicable, and the Sponsor.

12. Study Foods

All study foods will be supplied to the Clinical Investigator. Product supplies must be kept in an appropriate, secure area (see Section 6.4.3) and maintained under the storage conditions specified in the protocol.

The Clinical Investigator will oversee that an accurate record regarding the shipment and dispensing of the study food is maintained, using a product accountability log. An accurate product disposition record will be kept specifying the date and amount dispensed to each participant and any supplies either destroyed or returned to the Sponsor. This inventory record must be available for inspection by and is subject to regulatory inspection at any time. Copies of this record will be provided to the Sponsor by the Clinical Investigator at the conclusion of the study.

Product supplies are to be used only in accordance with this protocol and under the supervision of the Clinical Investigator. The Clinical Investigator agrees not to destroy any unused product supply.

At the conclusion of the study, and, if appropriate, during the course of the study, the Clinical Investigator will ship all unused product containers and a copy of the completed Master Study Food Log to the Sponsor.

13. Disclosure

By conducting this study, the Clinical lnvestigator(s) agrees that all information provided will be maintained by the Clinical Investigator and his/her staff in strict confidence. Such information may be communicated to the Scientific Committee and/or IRB/Ethics Committee under a similar, appropriate understanding of the confidential nature of the information. Study documents provided (protocols, investigators' brochures, and other material) will be stored appropriately to ensure their confidentiality. It is understood that the confidential information provided to the Clinical Investigator will not be disclosed to others without written authorization, except to the extent necessary to obtain informed consent from those participants who are eligible and choose to participate in the study. Such information will not be provided to potential participants or participants by telephone or to any other individual.

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Appendix 1: Exclusionary Medications/Supplements

This list is not intended to be comprehensive.

CLASS OF DRUG/PRODUCT	GENERIC/BRAND NAME	
Unstable use ofthefollowihg within 6tttontbs of Visit 1 (week -1; "unstable" indicat!'sa changin dose/regimen)		
Medications known to stimulate or suppress appetite, but which are taken for other indications (including, but not limited to: benzod iazepenes, anti-anxiety, antidepressants, anti-psychotics)	Alprazolam (Niravam, Xanax, Xanax XR) Amitriptyline (Eiavil, Endcp) Amoxapine (Asendin) Amphetamine (Adderall) Aripiprazole (Abilify) Buproprion (Wellbutrin) Buspirone (BuS par) Carbamazepine (Tcgretol) Chlordiazepoxide (Librium) Chlorpromazine (Thorazine) Citalopram hydrobromide (Celexa) Clomipramine (Anafranil) Clonazepam (Kionopin) Clorazepatc (Tranxene) Cloazpine (Clorazil) Desipramine (Norpramin) Dextroamphetamine (Adderall, Dexedrine) Diazepam (Valium) Divalproex sodium (Depakote) Doxepin (Adapin, Sinequan) Duloxetine (Cymbalta) Escitalopram (Lexapro) Fluoxetine (Prozac) Fluphenazine (Prolixin) Fluvoxamine (Luvox, Luvox CR) Haloperidol (Haldol) Hydroxyzine pamoatc (Vistaril) Imipramine (Tofranil)	Lithium citrate (Cibalith S) Lorazepam (Ativan) Loxapine (Loxitane) Maprotiline (Ludiomil) Mesoridazine (Serentil) Methylphenidate (Ritalin) Mirtazapine (Remeron) Molindone (Moban) Nefazodone (Serzone) Nortriptyline (Pamelor) Olanzapine (Zyprexa) Oxazepam (Serax) Paroxetine (Paxil, Paxil CR) Pemoline (Cylert) Perphenazine (Trilafon) Phenelzine (Nardi!) Prazepam (Centrax) Prochlorperazine (Compazine) Protriptylinc (Vivactil) Quetiapine (Seroquel) Risperidone (Risperdal) Sertraline (Zoloft) Thioridazine (Mellaril) Thiothixene (Navane) Tranylcypromine sulfate (Prarnate) Trazodone (Desyrel) Trifluoperazine (Stelazine, Vesprin) 'l'rimipramine (Surmontil) Valproic acid (Depakcnc) Venlafaxine (Effexor, Effexor XR)

Excluded within 6montbs prior to Visit l(week -1) and thronghouttltestudy period		
Weight loss medications, products, supplements taken by the participant with the explicit intent to alter body weight, appetite, and/or satiety, and/or programs/diets	Bcnzphetamine HCI (Didrex) Naltrexone and bupropion (Contrave) Diethylpropion HCl (Tenuate,Tenuate Dospan) Mazindol (Sanorex) Orlistat (Xenical, Alii) Phendimetrazine tartrate (Adipost, Anorex-SR, Appecon, Bontril, Bontril SR, Melfiat, Obesine, Phendiet, Plegine, Prelu-2, Statobex) Phentermine (Adipex-P, lonamin, Obenix, Oby-Cap, Pro Fast-SA, Teramine, Zantryl) Sibutramine (Meridia) Phentermine and topiramate (Qsymia) Lorcaserin (Belviq) SlimFast (or similar product) meal replacement bars, shakes, and snacks Any over-the-counter weight loss medications/products Programs (such as Weight Watchers, NutriSystem, Jenny Craig)	Any dietary supplement, including, but not limited to: Chromium picolinate Cinnamon (as a supplement) **Ginseng** Bitter orange Chitosan Chromium Conjugated linoleic acid (CLA) Country mallow Fiber supplements Green tea extract, kola nut, guarana, **guaranine, or yerba mate** 5-Hydroxytryptophan Starch blockers (or similar products such as Carb Away, Carb Cutter, Carb Eliminator, CarboLock, Ultimate Carb Phaser 1000, Ultra Carb Blocker, Detrine, Trimspa) Guggul Lipid Guar gum Gymnema Glucomannan Hoodia Pyruvate Any other weight loss supplement
JJilstabluse or the following withi112 months orvisit.l(weell. -t; "u stabte" indicates a chang" dose/regtml'n)		
Thyroid hormones	Levothyroxine (Leva-T, Levothroid, Levoxyl Synthroid, Unithroid) Liothyronine (Cytomel, Triostat) Liotrix (Thyrolar) Thyroglobulin Thyroid (Armour Thyroid, Thyrar, Thyroid Strong, Westhroid)	
Excluded within 1 month prior to Visit 1 (week -1) and.throughoutthestudy period		
Psychoactive drugs	Lithium	
Alpha-glucosidase Inhibitors	Glyset (Miglitol)	Precosc {Acarbose)
Biguanidcs and Biguanide combinations	Actoplus Met (Pioglitazone + metform in)	Glucovancc (Glyburide + metformin)

	Avandamet (Roziglitazone + metformin) Fortamet (Metformin) Glumetza,G Jucophage, Glucophage XR (Metformin)	Janumct (Sitagliptin + metformin) Metaglip (Giipizide + metformin) Prandimet (Repaglinide + metformin)
Bile acid sequestrant	Welchol (Colescvelam) as hypoglycemic	
Thiazolidinedioncs	Actos (Pioglitazone)	Avandia (Rosiglitazone)
Dipeptidyl Pcptidase-4 Inhibitors	Januvia (Sitagliptin)	Onglyza (Sexagliptin)
Injectable hypoglycemic medications	Apidra, Exubera, Humalog, Humolog Mix, 1-lumulin N, Humulin R, Lantus, Levemir, Novolin, Novo log, Novolog Mix (Insulin) Byetta (Exenatide) Symlin (Pramlintide acetate) Victoza (Liraglutide)	
Meglitinides	Prandimct (Repaglinide + metformin)	Prandin (Repaglinide) Starlix (Nateglinide)
Sulfonylurcas and Combination Sulfonylureas	Amaryl (Glimepiride) Avandaryl (Posiglitazone + glimepiridc) Diabinese (Chlorpropamide) DiaBeta (Giyburide) Duetact (Pioglitazone + glimepiride) Dymelor (Acetohexamide) Glucotrol, Glucotrol XL (Giipizide)	Glynase PresTab (Giipizide) Glucovance (Giyburide + metfonnin) Metaglip (Glipizide + mctfomin) Micronase (Giyburide) Orinase (Tolbutamide) Tolinase (Tolazamide)
Corticosteroids	Oral or systemic use of: Betamethasone Budcsonide Cortisone Dexamethasone Hydrocortisone Methylprednisolone	Prednisolone Prednisone **Triamcinolone** Systemic use of: Fludrocortisone acetate (Florinef)
Unstable use oftheJoii \Ving within 1 month ofVisifl-(week -l; "un t ble" indicates aeltange in dose/•·egimen)		
Lipid-altering medications	Atorvastatin calcium (Lipitor) Dual amlodipinc/atorvastatin (Caduct) Cholestyramine (Prevalite, Questran or Ques!ran Light) Clofibrate (Atromid-S) Colesevelam HCI (WelChol) Colestipol HCJ (Colestid)	Fluvastatin (Lescol) Gemfibrozil (Lopid) Lovastatin (Advicor, Mevacor, Altoprev) Niacin (Niaspan, Advicor, Simcor) Pravastatin sodium (Pravachol) Aspirin + pravastatin (Pravigard PAC)

	Ezetimibe (Zelia) Fenoftbrate (Tricor, Antm·a, Lofibra, Triglide, Fenoglide and Trilipix)	Rosuvastatin Calcium (Crestor) Simvastatin (Simcor, Vytorin, Zocor)
Antihypertensive medications		
Aldosterone antagonists	lnspra (Eplerenone) Spironolactone	
Alpha Adrenergic blockers	Cm·dura (Doxazosin) Flomaxtra/Flomax (Tamsulosin) Hytrin (Terazosin) Minipress (Prazosin)	Phenoxybenzamine Phentolamine (Rogitine) Uroxatral (Aifuzosin)
Alpha-2 agonists	Catapres, Catapres TTS (clonidine)	
Angiotensin-converting enzyme inhibitors	Accupril (Quinipril) Accuretic (Quinipril + hydrocholorothiazide) Aceon (Perinodopril erbumine) Altace(Ramapril) Capoten (Captopril) Capozide (Captopril + hydrocholorthiazide) Lotensin (Benazapril) Lotensin HCT (Benazapril + hydrochlorothiazide) Mavik (Trandolapril) Monopril (Fosinopril)	Prinivil (Lisinopril) Prinzide (Lisinopril + hydrocholorothiazide) Tarim (Trandolapril + verapamil) Uniretic (Moexipril + hydrocholoroth iazide) Univasc (Moexipril) Vaseretic (Enalopril + hydorcholorithiazide) Vasotec (Enalopril) Zestoretic (Lisinopril + hydrocholorothiazide) Zestril (Lisinopril)
Angiotensin II receptor antagonists	Atacand, Atacand HCT (Candesattan) Aval ide (Irbesartan + hydrocholorthiazide) Avapro (Irbesartan) Benicar (Oimesmtan) Beniear HCT (Olmesmtan + hydrocholorothiazide) Cozaar (Losartan) Diovan, Diovan HCT (Valsartan) Edarbi (Azilsartanmedoxomil)	Hyzaar (Losartan + hydrocholothiazide) Micardis, Micardis HCT (Telmisartan) Teveten (Eprosartan) Teveten HCT (Eprosartan + hydrocholorothiazide) Tribenzor (Olmesartan + amlodipine +thiazide diuretic) Twynsta (Telmisartan + amlodipine) Valturna (Valsartan + aliskiren)
Beta-adrenergic blockers	Betapace (Sotalol) Brevibloc (Esmolol) Blocadren (Timolol) Systolic (Nebivolol)	Lopressor HCT (Metroprolol + hydrocholorothiazide) Normodyne (Labetalol) Sectral (Acebutolol)

	Cartrol (Carteolol) Corgard (Nadolol) Corcg CR (Carvedilol) lnderal, lnnopran XL (Propranolol) lnderide (Propranolol + hydrochlorothiazide) Kerlone (Betaxolol) Levatol (Penbutolol) Lopressor (Metoprolol)	Tenoretic (Atenolol + chlorthialidone) Tenormin (Atenolol) Timololmaleate Toprol XL (Metoprolol) Trandate (Labetalol) Viskcn (Pindolol) Zebeta (Bisoprolol) Ziac (Bisoprolol + hydrochl01ihiazide)
Calcium Channel Blockers	Adalat CC (Nifedipinc) Afeditab CR (Nifedipine) Amturnide (Aliskiren, amlodipine and hydrochlorothiazide) Azor (Amlodipine + olmesartan) Calan, Calan SR (Verapamil) Jsoptin, lsoptin SR (Verapamil) Exforge (Amlodipine + valsartan) Lotrel (Amlodipine + benazcpril) Nicardipine Nifcdiac CC, Nifedical XL, Nifedical XR (Nifedipinc)	Nimotop (Nimodipine)Norvasc (Amlodipine) Plendil (Felodipine) Procardia, Procardia XL (Nifedipinc) Sular (Nisoldipine) Tekamlo (Aliskiren +amlodipine) Tiazac (Diltiazem) Tribenzor (Oimesartan + amlodipine +thiazide diuretic) Twynsta (Telmisartan + amlodipine) Vascor (Bepridil) Verelan PM (Verapamil)
Central Alpha-Agonist	Aldoril (Methyldopa+ hydrocholorthiazide) Catapres (Cionidine) Tenex (Guanfacine)	
Direct Renin Inhibitor	Tekamlo (Aiiskiren +amlodipine) Tekturna (Aiiskiren) Tekturna **HCT** (Aiiskerin + hydrocholorthiazide)	
Aldosterone antagonists	Inspra (Eplerenone) Spironolactone (See Diuretics for trade names)	
Alpha Adrenergic blockers	Cm-dura (Doxazosin) Flomaxtra/Fiomax (Tamsulosin) Hytrin (Terazosin) Minipress (Prazosin)	Phenoxybenzamine Phentolamine (Rogitine) Uroxatral (Aifuzosin)

Appendix 2: Body Circumference Measurements

Measurements of waist, hip, chest, upper arm, and thigh circumferences will be performed using a stretch-resistant anthropometric tape. To ensure accuracy and reliability, each site will be carefully determined as explained below:

- Participants should sJand straight with weight equally distributed over both legs and breathe normally.

- All measurements will be taken in order as listed below. For all measurements, a *stretch-resistant tape* that *provides* a constant *amount of tension and* a *special indicator buckle* to identify the proper amount of tension applied will be used.

- Two measurements will be obtained for each site with the measuring tape removed between measurements. All measurements will be recorded to the nearest 0.1 em. If the two measurements are different by>1.0 em, a third measurement will be obtained and recorded.

1st measurement- mid-upper arm (dominant arm) circumference
The upper arm is measured at the midpoint between the shoulder and the elbow, with the ann hanging down the side of the body in a relaxed position. The upper arm measurement should be made without any clothing between the measuring tape and the skin.

2"d measurement - chest circumference
The chest is measured over light clothing worn at each visit with the tape measure wrapped around the upper body on a horizontal plan at the level of the nipples. The measurement should be obtained between the center of both nipples at the end of a normal expiration with the arms down at the participant's sides.

3rd measurement -waist circumference
The iliac crest will be palpated and the waist measured on a horizontal plane at the level of the iliac crest at the end of a normal expiration. The waist circumference measurement should be made without any clothing between the measuring tape and the skin.

4th measurement- hip circumference
The hip is measured on a horizontal plane at the widest portion of the buttocks over light clothing worn at each visit.

5lll measurement- thigh (dominant leg) circumference
The thigh is measured on a horizontal plane at the widest portion of the thigh, which is typically the midpoint between the lower buttocks and the back of the knee. The thigh measurement may be taken over the same light clothing worn at each visit.

Appendix 3. Impact of Weight on Quality of Life (JWQOL)-Lite Questionnaire

Participant Initials -

Visit No. --

Participant Randomization No.--- -

Date _____

Impact of Weight on Quallty of Lifo Questlonnaire-Uto Version (IWQOL-Llto}

Please answet the following staternents by circling the number that best applies to you in the past \>\\eek Be as open as possible. There are no right or wrong answers.

Physical F!tDctjon		A'..WAYS TRL'E	USlU\LLY TRUE	S.O\ILTU/..f'S lR!J£	RARELY iRUE	MCVER HHJG
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▼	f!ecavse of rr.y WJ?lght I ha« dirficclty· get1lng u;;:- !Jo.-'l1 chairs.	5	●	3	2	
4.	Becau5e c.f roy weight I have ll&lli::42- us;,ng slmrs.	5	●	II	2	
5.	Bec.<hr:;e of my weigh! I hB\l"e' dif11ccliy pul:1ing oo or taldng oilrTPf clolhfng.	5	●	3	2	
6.	Becac;;se of my •Ne-lgh! I hiW€ lro<>t"M;- \W1h mf>l'.Y.M\c	5	,,	:;	2	
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9.	t am truJNe<f by painful or eWt joints.	5	●	:I	2	
\0.	f,fy SJJ; ;les and low€r legs. are S<.\Xl!ier,al end ofille day.	-5	●	3	2	
H.	I am .....ort.,;;-0 about my· heallll.	5	●	II	2	
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!.	Because ol my weigh! I am sel-ronsC\0'--"!>.	5	●	:;	2	1
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3.	Becae o!my \".'eight! feel uns:ure o! /Y(,•S2ff.	5	4	3	2	
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6.	Secss:.e of m· weight I avoid loo k'?-J In rrt\rrors m s.eeffig myself In photographs.	5	●	3	2	
7.	Seca;:,;.e ol my weight! am erno-auassed to be seen b public places.	5	●	3	▼	

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Participant's Initials---·-·····---- Date _____

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4.	Becs<.t:;e cf my w ghl! ava;.j sexual enc:x,.;niers ;,<Jhenever possible.	5	⬮	3	2	

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	(Note: For homemakers and retirees. anS\'1er with respect to your dally activities.)	AL".VAYS lRUL	U:SIJ.<\LLY TRUE	SO\iETJil£S lRUL	R..\RELY "TRUE	1-;'£\ICH THUC
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Appendix 4. RAND-36 Questionnaire

Participant Initials _____ Participant Randomization No. — —

Visit No. Date _____

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. **Compared to one year ago,** how would you rate your health in general **now?**	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

Participant's Initials _____ Date _____

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All
3. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing **several** flights of stairs	[1]	[2]	[3]
7. Climbing **one** flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking **more than a mile**	[1]	[2]	[3]
10. Walking **several blocks**	[1]	[2]	[3]
11. Walking **one block**	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

Participant's Initials--- Date _____

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2
14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(Circle One Number)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

21. How much **bodily** pain have you had during the **past 4 weeks?**

(Circle One Number)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

22. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks . . .**

Participant's Initials Date _____

(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?				4	5	6
27. Did you have a lot of energy?				4	5	6
28. Have you felt downhearted and blue?				4	5	6
29. Did you feel worn out?				4	5	6
30. Have you been a happy person?				4	5	6
31. Did you feel tired?	1	2	3	4	5	6

Participant's Initials _____ Dale _____

32. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

How TRUE or FALSE is each of the following statements for you.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Adapted fi·om: Ware JE Jrl, Sherbourne CD. The MOS 36-item short-form health survey (SF-36).!. Conceptual framework and item selection. *Med Care.* 1992; 30:473-83.

Appendix 5. l'rogram Questionnaire

Participant's Initials Date _____

Randomization no_____

Circle Visit number:

Visit 2 **Visit 4** **Visit 5** **Visit 6** **Visit** 7

Questions 1 and 2 for All Groups at Visit 2 only:

I. Describe your physical activity at work or school, on average, over the last 4 weeks?

- O Very Light (sitting at your computer or desk most of the day)
- O Light (light industrial work, sales or office work that comprises light activity)
- O Moderate (cleaning, kitchen stan:or delivering mail on foot or by bicycle)
- O Heavy (heavy industrial work, construction work or farming)

2. Describe your physical activity at leisure time, on average, over the last 4 weeks?

- O Very Light (almost no activity at all)
- O Light (walking, non-strenuous cycling or gardening approximately once a week)
- O Moderate (regular activity at least once a week, e.g., walking, bicycling (including to work) or gardening)
- O Active (regular activities more than once a week, e.g., intense walking, bicycling or sports)
- O Very Active (strenuous activities several times a week)

Questions 3, 4, and 5 for All Groups to be answered at Visits 4, 5, 6, and 7:

DIRECTIONS: Please draw a single, verticaL straight, mark along the line to indicate your response. The vetiiealline must intersect with the horizontal line. Please do not circle any words. Your response should indicate how you are feeling at this moment.

3. Over the last 4 weeks, how well did you follow your assigned weight loss plan?

Not at all _____ _____ Perfectly

VAS measurement (mm): _____

4. Describe your physical activity at work or school, on average, over the last 4 weeks?
   - O Very Light (sitting at your computer or desk most of the day)
   - O Light (light industrial work, sales or office work that comprises light activity)
   - O Moderate (cleaning, kitchen staff, or delivering mail on foot or by bicycle)
   - O Heavy (heavy industrial work, construction work or farming)

5. Describe your physical activity at leisure time, on average, over the last 4 weeks?
   - O Very Light (almost no activity at all)
   - O Light (walking, non-strenuous cycling or gardening approximately once a week)
   - O Moderate (regular activity at least once a week, e.g., walking, bicycling (including to work) or gardening)
   - O Active (regular activities more than once a week, e.g., intense walking, bicycling or sports)
   - O Very Active (strenuous activities several times a week)

Question 6: MEDD and TSFL groups only to be answered at Visits 4, 5, 6, and 7:

6. Over the last 4 weeks, how many Medifast meal replacement products did you consume on **MOST DAYS?** (Do not count Flavors of Home meals or Medifast Snacks in your count.)

Please circle response (limit to one answer).

- 0
-
- 2
- 3
- 4
- 5
- 6
- >6

Appendix 6. Satisfaction and Health/Well-being Questionnaire*

Based on your experience throughout the study with the weight loss plan you were assigned, how much would you agree/disagree with the following statements?

	1 = Strongly Disagree	2 = Disagree	3 = Neither Agree or Disagree	4 = Agree	5 = Strongly Agree
1. I would recommend this weight loss plan.	O	O	O	O	O
2. The weight loss plan was easy to follow.	O	O	O	O	O
3. I feel my sleep has improved.	O	O	O	O	O
4. The weight loss plan was convenient.	O	O	O	O	O
5. The weight loss plan fit my lifestyle.	O	O	O	O	O
6. I feel my overall health has improved.	O	O	O	O	O
7. My clothes fit better.	O	O	O	O	O

	1 = Strongly Disagree	2 = Disagree	3 = Neither Agree or Disagree	4 = Agree	5 = Strongly Agree
8. I have more energy	O	O	O	O	O
9. I believe the support provided was the key to my success on the weight loss plan.	O	O	O	O	O
10. I felt my hunger was under control on the weight loss plan.	O	O	O	O	O
11. I feel I achieved real success.	O	O	O	O	O
12. I believe my experience with this weight loss plan will help me to sustain a healthy lifestyle.	O	O	O	O	O
The weight loss plan was effective for me.	O	O	O	O	O
14. I feel better about myself.	O	O	O	O	O
15. I feel the weight loss plan was a healthy way to lose weight.	O	O	O	O	O

	1 = Strongly Disagree	2 = Disagree	3 = Neither Agree or Disagree	4 = Agree	5 = Strongly Agree
16. I feel more confident	O	O	O	O	O
17. I learned habits for a healthier lifestyle.	O	O	O	O	O
18. The program tools were easy to use.	O	O	O	O	O
19. I feel better physically.	O	O	O	O	O
20. I feel my overall wellbeing has improved.	O	O	O	O	O

*The order of the above questions will be randomly presented to the participants.