A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults

FINAL STUDY REPORT

Confidentially Prepared for:

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Date: March 3, 2017

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1. TITLE PAGE

TITLE:	A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults.	
STUDY IDENTIFICATION NUMBER:	16MWHC	
STUDY PERIOD (year):	2016	
DATES OF STUDY:	Date of First Screening: August 17, 2016 Date of First Participant Randomization: September 01, 2016 Date of Last Participant's Last Visit: December 15, 2016	
INVESTIGATIONAL PRODUCT:	Yes You Can! Meal Replacement	
INDICATION(S) STUDIED:	Weight loss	
STUDY PHASE:	Phase II	
STUDY DESIGN:	Randomized, Comparator-Controlled, Parallel Study	
KEYWORDS:	Meal Replacement, Weight Loss, Obesity, Nutrition	
SPONSOR:	Chaban Wellness, LLC 657 South Drive Suite #403 Miami Springs, FL 33166 USA	
SPONSOR CONTACT:	Arlene Semeco Chaban Wellness, LLC arlene@arlenesemeco.com	
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STUDY SITE	KGK USA, Florida Site 114 W Underwood St. Orlando, FL 32806	KGK USA, California Site Progressive Medical Center 26750 Towne Centre Dr. Ste A Foothill Ranch, CA 92610
DATE OF REPORT:	March 3, 2017	
TOTAL PAGES:	82 pages + Appendix	

This study was performed in compliance with ICH Guideline for Good Clinical Practice Current Step 4 Version dated June 10, 1996, including the archiving of essential documents.

2. SYNOPSIS

Name of Sponsor/Company:	**Name of Finished Product:**	**Name of Active Ingredient:**
Chaban Wellness, LLC 657 South Drive Suite #403 Miami Springs, FL 33166 USA	Yes You Can! Meal Replacement	Meal Replacement (Whey protein, Medium Chain Triglycerides, Vitamins, and Mineral mix)

Title of Study:
A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults.

Study Design:
Randomized, Comparator-Controlled, Parallel Study

Medical Directors / Qualified Investigators:
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Foothill Ranch, CA 92610

Studied Period:
Date of First Screening: August 17, 2016
Date of First Participant Randomization: September 01, 2016
Date of Last Participant Exit Visit: December 15, 2016

Objectives:

Primary Objective

- Change in body weight from baseline to day 85 between participants on Yes You Can (YYC!™) meal replacement with minimal physical activity vs participants on the Modified American Heart Association (MAHA) diet with minimal physical activity

Secondary Objectives

- Change in body weight from baseline to day 28 and day 56 between participants on YYC!™ meal replacement with minimal physical activity vs participants on the MAHA Diet with minimal physical activity
- Change in body mass index (BMI) from baseline to day 28, day 56 and day 85 between participants on YYC!™ meal replacement with minimal physical activity vs participants on the MAHA Diet with minimal physical activity
- Change in waist circumference from baseline to day 28, day 56, and day 85 between participants on YYC!™ meal replacement with minimal physical activity vs participants on the MAHA Diet with minimal physical activity
- Change in hip circumference from baseline to day 28, day 56, and day 85 between participants on YYC!™ meal replacement with minimal physical activity vs participants on the MAHA Diet with minimal physical activity
- Change in waist to hip circumference ratio from baseline to day 28, day 56, and day 85 between participants on YYC!™ meal replacement with minimal physical activity vs. participants on the MAHA Diet with minimal physical activity
- Change in thigh circumference from baseline to day 28, day 56, and day 85 between participants on YYC!™ meal replacement with minimal physical activity vs participants on the MAHA Diet with minimal physical activity
- Change in arm circumference from baseline to day 28, day 56, and day 85 between participants on YYC!™ meal replacement with minimal physical activity vs participants on the MAHA Diet with minimal physical activity

Safety Outcomes

- Clinically significant abnormal haematology and clinical chemistry values
- Clinically significant abnormal kidney and liver function values
- Clinically significant abnormal electrolyte values
- Clinically significant abnormal heart rate and blood pressure
- Incidence of adverse events over the course of the study by organ group

Methodology:

This was a multi-center, randomized, comparator-controlled, 2-arm parallel group study conducted at two sites in the USA. This study investigated the effects of YYC!™ meal replacement with minimal physical activity on weight loss in overweight and mildly obese adults over a 12-week intervention period.

Volunteers met with clinic staff to assess eligibility. Eligible volunteers began a 14-day run-in period during which they consumed 1500 Calories/day ± 20% and completed online food records, study diary

and weekly exercise questionnaires. Participants were randomized to either YYC!™ meal replacement diet or on the MAHA Diet at a ratio of 1:1, after completing the run-in period, and passing all eligibility criteria. Participants randomized into the study continued to consume 1500 Calories/day ± 20% and either followed the YYC!™ meal replacement diet or on the MAHA Diet for 85 days. To evaluate the goals of the study, assessments were conducted at day 0, day 28, day 56 and day 85. At all visits, participants' study diaries were reviewed for concomitant therapies, adverse events, rescue medication use, and anthropometric measures were assessed. Laboratory parameters (CBC, electrolytes [Na, K, Cl], creatinine, BUN, AST, ALT, and bilirubin) for safety were assessed at screening and end-of-study, as well as HbA1c at the screening.

Number of Participants (Planned and Analysed):
The planned sample size for this study was 70 overweight and mildly obese adults. Participants were randomized equally to each arm at a ratio of 1:1.

Forty-eight participants completed the study and were analyzed, with 22 participants in the YYC!™ meal replacement group and 26 participants in the MAHA Diet group.

Enrollment Criteria
Participants were enrolled into the study if they met all inclusion criteria and did not meet any of the exclusion criteria.

Inclusion Criteria

1. Males and females 18 - 65 years (inclusive) of age
2. BMI of 25.0 kg/m² - 34.9 kg/m² (± 1.0 kg/m^2)
3. If female, participant was not of child bearing potential, which is defined as females who have had a hysterectomy or oophorectomy, bilateral tubal ligation or are post-menopausal (natural or surgically with > 1 year since last menstruation)
   OR
   Females of childbearing potential must agree to use a medically approved method of birth control and have a negative urine pregnancy test result. Acceptable methods of birth control include:
   - Hormonal contraceptives including oral contraceptives, hormone birth control patch (Ortho Evra), vaginal contraceptive ring (NuvaRing), injectable contraceptives (Depo-Provera, Lunelle), or hormone implant (Norplant System)
   - Double-barrier method
   - Intrauterine devices
   - Non-heterosexual lifestyle or agrees to use contraception if planning on changing to heterosexual partner(s)
   - Vasectomy of partner (shown successful as per appropriate follow-up)
4. Stable weight defined as less than 5.0 kg gained or lost in the past 3 months
5. Healthy as determined by laboratory results, medical history, and physical exam
6. Planned not to change smoking habits during the study period
7. Agreed to follow diet plan and physical activity of 35 min, 3 to 5 times a week during the study

8. Had daily access to internet through the use of a computer, phone or tablet to enter food records online
9. Willing to complete and comply with all study procedures, questionnaires, records, diaries, and dietary restrictions associated with the study and to complete all clinic visits.
10. Had given voluntary, written, informed consent to participate in the study

Exclusion Criteria

1. Women who are pregnant, breastfeeding, or planning to become pregnant during the trial
2. Use of prescription or over the counter products, programs or meal replacement product known to affect weight within 4 weeks of enrollment and during the trial
3. History of surgery for weight loss (including gastric bypass or lap band)
4. History or presence of clinically important renal, hepatic, endocrine, pulmonary, biliary or pancreatic disorders
5. Presence or history of neurological disorders or significant psychiatric illness
6. Type I or Type II Diabetes
7. Any disorder associated with eating behaviour
8. History of or current diagnosis of any cancer (except for successfully treated basal cell carcinoma) diagnosed less than 5 years prior to screening. Cancer in full remission more than 5 years after diagnosis are acceptable
9. Alcohol abuse (>2 standard alcoholic drinks per day) or drug abuse within the past 6 months
10. Use of medicinal marijuana
11. Use of antipsychotic drugs
12. Plan on donating blood during the study or within 30 days of completing the study
13. Known allergy or sensitivity to the test material's active or inactive ingredients
14. Unstable medical conditions
15. Clinically significant abnormal laboratory results at screening
16. Participation in a clinical research trial within 30 days prior to randomization
17. Cognitively impaired and/or unable to give informed consent
18. Any other condition which in the Qualified Investigator's opinion may adversely affect the Individual's ability to complete the study or its measures or which may pose significant risk to the individual

Test Product, Dose and Mode of Administration, Lot Number:

Test Product:
YYC!™ meal replacement

Active ingredients: Protein Matrix (Whey Protein Concentrate, Micellar Casein), Corn Fiber, MCT Powder, and Vitamin Mineral Premix (Tri-magnesium Citrate, Dipotassium Phosphate, Vitamin C (Ascorbic Acid), Ferrous Sulfate, Vitamin E (Alpha-Tocopheryl acetate), Biotin, Vitamin A, Palmitate, Zinc Sulfate, Niacinamide, Vitamin B5 (Calcium Pantothenate), Copper Gluconate, Cyanocobalamin, Vitamin B6 (Pyridoxine), Vitamin D3 (Cholecalciferol), Potassium Iodide, Vitamin B2 (Riboflavin), Vitamin B1 (Thiamine), Chromium Chloride, Vitamin B9 (Folic Acid)).

Other ingredients: Natural and Artificial Flavor, Xanthan Gum, Sucralose, and Sodium Chloride.

Mode of Administration:
Participants mixed one scoop of the YYC!™ meal replacement powder into 16 oz. (2 cups) of water. Participant consumed the product twice daily, substituting any 2 out of the 3 meals (i.e. breakfast, lunch, dinner) for 85 days.

Lot Number: IM454181

Duration of Study: This study consisted of a 12-week study period.

Comparator Control:

Comparator:
MAHA Diet

Mode of Administration:
Participants adhered to the MAHA Diet guideline for the 12-week study duration.

Statistical Methods:

Analytical Population

Completer population consisted of all participants who completed all study visits and procedures connected with the measurement of the primary variable.

Safety population consisted of all participants who received any amount of either product, and on whom any post-randomization safety information is available

Analysis Plan
Efficacy analysis based on the completer population and safety analysis based on the safety population were performed. Variables were tested for normality and log-normality. Log-normally distributed variables were analyzed in the logarithmic domain. The appropriate non-parametric test was used to analyze non-normal variables. Safety analysis was based on the safety population.

All missing values in the efficacy analysis were imputed with the most recent previously-available value (LOCF, or "last-observation-carried-forward" imputation). No imputations were performed for missing values of safety variables.

Data were summarized by visit and by product. Numerical variables were summarized as mean, standard deviation, standard error of the mean, median, and range (minimum and maximum). Changes from baseline to each subsequent visit were summarized similarly, and a *p* value indicating whether the mean change within each group was significantly different from zero (based on the paired Student *t* test, or the non-parametric Wilcoxon Signed-Ranks test). Mean values were displayed as graphs, with a separate line for each product, and error bars indicating ± 1 SEM. Mean changes from baseline were graphed similarly. As the objective of this clinical trial was to assess the change in body weight following supplementation with the product relative to a comparator group and not to assess the final weight

adjusted to baseline, the Student's *t* test was used test the differences between groups with the baseline subtracted.

Demographics at Screening:

Baseline demographics of participants in the YYC!™ meal replacement and MAHA Diet groups were similar for age, gender, BMI, smoking status, and race. Participants with an age range between 19 - 64 years and a BMI between 24.96 – 35.84 kg/m^2 were enrolled in this study. 70% of the participants enrolled in the study were female, 83% were non-smokers, 46% reported occasional alcohol use and 33% reported no use of alcohol. Participants were predominantly Western European White (40%), 20% African-American, 19% Central American, and 7% South American or Eastern European White. All participants were deemed healthy by physical examination and as per their screening laboratory parameters.

Completers Population
Participants who completed all study visits were defined as the Completer population

Product Compliance for the Completers Population
Compliance to YYC!™ meal replacement in the Completers population was > 90%, with an overall mean compliance of approximately 96%.

Diet Compliance for the Completers Population:
The mean dietary consumption for participants in the YYC!™ and MAHA Diet groups was within the required caloric intake of 1500 ± 20% Calories/day. There was no significant difference between groups in overall compliance.

Efficacy Analysis

Completers Population

There was a significant ($p = 0.037$) decrease in body weight in the YYC! ™ meal replacement group vs. the MAHA Diet group at day 28 of the intervention. Participants who incorporated the YYC!™ meal replacement plan lost significantly more body weight (1.10 kg), than those on the MAHA Diet plan (0.18 kg).

Though participants on the YYC!™ meal replacement plan sustained their weight loss from baseline to day 56 (1.36 kg) and day 85 (1.35 kg) it was not significantly different from the MAHA Diet group.

Following 85 days on the YYC!™ meal replacement, participants showed a 1.6% reduction in body weight, compared to participants on the MAHA Diet who lost an average of 1.03 kg, a reduction of 1.2% body weight.

Analysis of sub groups for compliance showed a consistent decrease in body weight that was limited to the YYC!™ meal replacement plan.

BMI and circumference

The decrease in weight loss was mirrored by the significant decrease in BMI of participants in the YYC!™ meal plan at day 28 ($p = 0.045$) *vs.* the MAHA Diet. Participants in the YYC!™ group were on an average classified as mildly obese (30.6 kg/m^2) at baseline but by the end of the study, these participants fell into a overweight category (29.6 kg/m^2). This was a significant decrease ($p < 0.023$) in BMI from baseline to day 85. The MAHA Diet did not affect BMI status significantly as participants, on an average, were at the overweight category throughout the study.

There were no significant differences between the YYC!™ *vs.* MAHA groups in waist, hip, thigh, arm circumferences or waist to hip ratio.

Blood Pressure

The YYC!™ group showed a trend towards significant decrease in systolic blood pressure at day 28 ($p = 0.059$) *vs.* MAHA Diet group. There were significant differences in diastolic blood pressure at day 28 ($p = 0.006$) and day 85 ($p = 0.024$) *vs.* MAHA Diet group.

Safety Outcome

Hematology and Clinical Chemistry:

Though significant between group differences in blood count of lymphocytes ($p = 0.041$) and monocytes ($p = 0.045$) were observed at day 85 in the YYC!™ group, these excursions were not of clinical relevance.

There were no significant between group differences in all other hematology and clinical chemistry measures.

Vital Signs:

Between groups, there was a significant difference in mean diastolic blood pressure at day 85 ($p = 0.024$) with participants in the YYC!™ group decreasing their diastolic blood pressure. Participants in the MAHA Diet group showed a significant increase in mean diastolic blood pressure at day 56 ($p = 0.046$) from baseline.

There was a significant increase in heart rate in participants in the YYC!™ group at day 28 ($p = 0.042$), with one participant showing an outlier value of the three readings (79, 101 and 149 bpm) of heart rate taken at day 28.

Incidence of Adverse Events:

Seventeen AEs were reported by 11 participants in this study. Of these, 14 AEs were reported during the YYC!™ meal replacement, and three were by participants on the MAHA Diet.

Of the 14 AEs reported by the YYC!™ group, six were assessed as possibly related to the meal replacement. These AEs were diarrhea, constipation, headache and bloating reported by four participants. One AE, bloating was assessed as most probably related to the meal replacement. All other AEs were assessed as unrelated to the study meals. There were no AEs assessed as related to the MAHA Diet.
All AEs in the YYC!™ group were resolved by the end of the study.

Conclusion:

Participants with 80% adherence to their diets are reported to be motivated and show greater weight loss over individuals with 50% adherence [(1)] suggesting that psychosocial factors can affect weight loss. Based on this concept, a completers group was analyzed in this study.

All participants who completed the study on the YYC!™ meal replacement plan lost a significant 1.3% body weight in 28 days *vs.* MAHA diet. Though not statistically significant between groups at 56 or 85 days, participants in the YYC!™ meal replacement plan sustained their weight loss through the 12 week investigational period. The YYC!™ group showed a 0.32 kg reduction in body weight over that reported with the MAHA Diet plan after an 85 day meal replacement. In comparison, participants who adopted the MAHA Diet took at least 2 months to show any significant decrease in body weight. Further, YYC!™ meal replacement enabled participants who were on average categorized as mildly obese, to be categorized as overweight after a one-month YYC!™ meal replacement. This decrease in BMI was sustained at day 56 and day 85. In comparison, participants in the MAHA Diet showed no change in their BMI status.

Despite the small sample size, the YYC!™ meal replacement was successful in achieving significant differences in weight loss vs. the comparator diet after 28 days. Weight loss and a concurrent reduction in BMI was maintained during the 85-day meal replacement.

Since weight loss should not be taken in isolation in overweight and mildly obese individuals that formed the demographics of this study, but should also encompass gains made in other health outcomes, an exploratory analysis was performed to determine how YYC!™ may have affected blood pressure which is a cardiovascular risk factor. YYC!™ meal replacement reduced diastolic blood pressure by more than 2 mmHg. Since a 2-mmHg reduction in diastolic blood pressure is associated with a 17% decrease in prevalence of hypertension, 6% reduction in coronary heart disease and 15% reduction in stroke and transient ischemic attacks, it is of value that positive health outcomes were achieved compared to the MAHA Diet where, an increase in diastolic blood pressure was observed.

Despite the challenges of ensuring compliance to the recommended diet and that of the product, the significant weight loss achieved with minimum physical activity in this study and use of the DietMaster Pro software with lower fail rate than traditional food records warrant further investigation in a larger study powered for sample size. These results may also have further implications in overweight and obese individuals, and particularly in individuals who may be unable to or incapable of carrying out physical activities.

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3. LIST OF FIGURES

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5. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	adverse event
ALT	alanine transaminase
ANCOVA	analysis of covariance
AST	aspartate aminotransferase
BMI	body mass index
CBC	complete blood count
Cl	chloride
CRO	contract research organization
EDTA	ethylene diamine tetra acetic acid
e.g.	*for example*
g	gram
GCP	good clinical practice
HR	heart rate
i.e.	*that means*
ICH	International Conference of Harmonization
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ITT	Intent-To-Treat
K	potassium
kg	kilogram
L	liter
LOCF	Last-observation-carried-forward
MAHA	Modified American Heart Association
m	meter
mg	milligram
ml	milliliter
N	number
n	number
Na	sodium
NNHPD	Natural and Non-prescription Health Product Directorate
p	probability
PP	per protocol
SAE	serious adverse event
SST	serum separating tube
YYC	Yes You Can

6. ETHICS

6.1 INDEPENDENT ETHICS COMMITTEE (IEC) OR INSTITUTIONAL REVIEW BOARD (IRB)

This study was reviewed by a research ethics board and unconditional approval was granted on July 29, 2016 by Institutional Board (IRB Services, Aurora, Ontario) (Appendix).

6.2 ETHICAL CONDUCT OF THE STUDY

This study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and its subsequent amendments.

6.3 PARTICIPANT INFORMATION AND CONSENT

Informed consent was obtained from each participant tat the screening visit (visit 1) prior to any study-related activities being performed. A copy of the Informed Consent Form s provided in (Appendix).

7. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

The clinical trial was conducted at multiple KGK Synergize Inc. sites (Orlando and Irvine, USA), under the supervision of the Medical Directors/Qualified Investigators, Nicole Craven, M.D. and Gez Agolli, M.D., Dr. Ph, PSc. D. Statistical analysis was conducted by Matthew Rueffer, M.Sc., and the report was authored by Malkanthi Evans, Ph.D.

8. INTRODUCTION

Obesity is a 21st century epidemic, with more than 1.9 billion adults classified as overweight, and of these 600 million classified as obese [2]. The United States has the highest obesity rates in the world and two-thirds of its population is reported to be overweight and approximately 33% classified as being obese [3, 4]. Obesity exceeds 33% in both sexes in almost all age - and ethnic groups in the United States [3].

Body mass index (BMI) is a calculation based on weight and height that differentiates between overweight and obese. A BMI between 25 and 29.9 kg/m^2 is classified as overweight and a BMI equal or greater than 30 kg/m^2 as obese [2]. The risk of health problems start to occur when an individual is only slightly overweight and increase as more weight is accumulated. Due to the increase in health risks associated with weight gain, new BMI categories have been implemented. Previously, the overweight range was considered as BMI $\geq$ 25.0 kg/m^2. Currently, a BMI of 25.0 – 29.9 kg/m^2 is considered pre-obese, BMI levels $\geq$ 30.0 kg/m^2 as obese and are further categorized into three levels of obesity; class I (mildly obese) 30.0 – 34.9 kg/m^2, class II (moderately obese) 35.0 – 39.9 kg/m^2 and class III (morbidly obese) $\geq$ 40.0 kg/m^2. A reduction in weight has a positive outcome on health; even a small reduction in weight (e.g. 5-10% weight loss) can result in a major decrease in the risk of cardiovascular disease and diabetes [5-7].

An imbalance between calories consumed and calories used is the underlying cause for abnormal excessive fat accumulation that is defined as overweight and obese. This abnormal excessive fat accumulation impairs the health of an individual. Over consumption of energy dense foods that are high in fat, in combination with a sedentary lifestyle promotes weight gain. This contributes to high prevalence of obesity in the United States. Engaging in physical activity as well as implementing healthy modifications to a diet will aid in balancing calories consumed and used, thereby helping with weight control. However, dietary habits are among the most difficult to modify, especially with a busy life style. Proper meal replacement shakes can help to replace unhealthy meal choices that may easily be incorporated as part of a busy life style.

The Yes You Can! (YYC!™) meal replacement by Chaban Wellness LLC was designed to replace any of the three main meals in an individual's diet. This meal replacement gives a busy individual an easy low calorie meal substitution option that still provides all the appropriate protein, carbohydrates, fiber, and fats the body requires. Additionally, the YYC!™ meal replacement provides essential vitamins and minerals addressing the insufficiencies that may arise due to busy life styles. The YYC!™ meal replacement allows for a healthy weight loss and maintenance process. The purpose of this 12-week clinical trial is to investigate the effectiveness of the YYC!™ meal replacement on weight loss in overweight and mildly obese participants.

9. STUDY OBJECTIVE

The objective of this study was to determine the effectiveness of YYC!™ meal replacement product with minimal physical activity on weight loss in overweight and mildly obese adults.

9.1 INVESTIGATIONAL PLAN

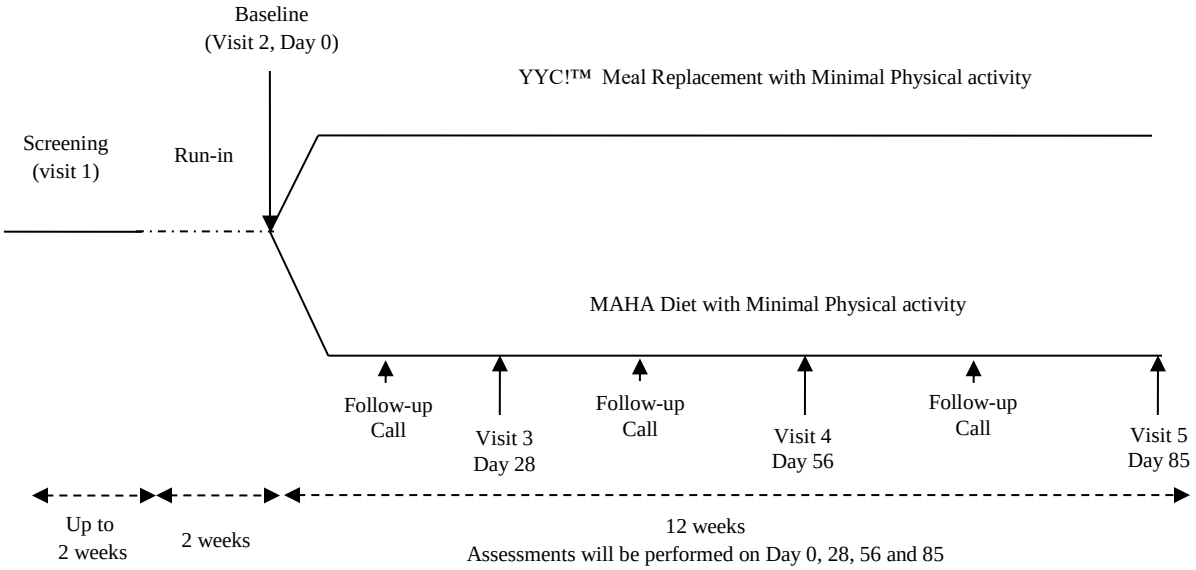
9.2 OVERALL STUDY DESIGN AND PLAN - DESCRIPTION

This was a multi-center, randomized, comparator-controlled, 2-arm parallel group study. The study consisted of a single 12-week study period.

The product studied was YYC!™ meal replacement, which consisted of the active ingredients: Protein Matrix (Whey Protein Concentrate, Micellar Casein), Corn Fiber, MCT Powder, Vitamin Mineral Premix (Tri-magnesium Citrate, Dipotassium Phosphate, Vitamin C (Ascorbic Acid), Ferrous Sulfate, Vitamin E (Alpha-Tocopheryl acetate), Biotin, Vitamin A, Palmitate, Zinc Sulfate, Niacinamide, Vitamin B5 (Calcium Pantothenate), Copper Gluconate, Cyanocobalamin, Vitamin B6 (Pyridoxine), Vitamin D3 (Cholecalciferol), Potassium Iodide, Vitamin B2 (Riboflavin), Vitamin B1 (Thiamine), Chromium Chloride, Vitamin B9 (Folic Acid)) and Salt (Sodium Chloride)).

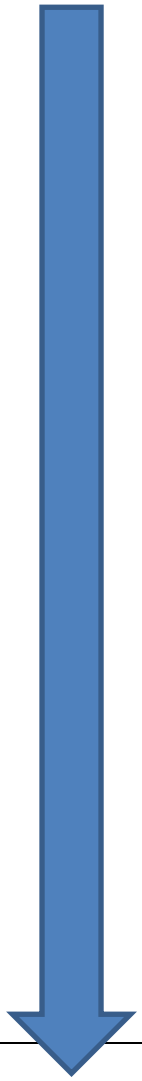
Seventy overweight and mildly obese adults were planned to be randomized, with thirty-five participants randomized equally to each of the two study arms at a ratio of 1:1.

Figure 1: Study Flow Diagram



	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Labs	Blood draw for: • CBC • HbA1c • Creatinine • AST • ALT • Bilirubin • Cl • Na • K Urine: • Pregnancy test	Urine: • Pregnancy test			Blood draw for: • CBC • Creatinine • AST • ALT • Bilirubin • Cl • Na • K Urine: • Pregnancy test
Other Assessments	• Heart Rate • Blood Pressure • Height • Weight • BMI	• Heart Rate • Blood Pressure • Physical Exam • Weight • BMI • Circumference of waist, hip, arm, and thigh	• Heart Rate • Blood Pressure • Weight • BMI • Circumference of waist, hip, arm, and thigh	• Heart Rate • Blood Pressure • Weight • BMI Circumference of waist, hip, arm, and thigh	• Heart Rate • Blood Pressure • Weight • BMI Circumference of waist, hip, arm, and thigh

Table 1: Schedule of Assessments

	Visit 1 Screening	**2-weeks Run in**	**Visit 2 Baseline Day 0**	**Visit 3 Week 4 Day 28**	**Visit 4 Week 8 Day 56**	**Visit 5 Week 12 Day 85**
Informed consent	X					
Review inclusion/exclusion criteria	X		X			
Review medical history	X					
Review concomitant therapies	X		X	X	X	X
Randomization			X			
Height*, weight, heart rate and blood pressure ** only measured at visit 1*	X		X	X	X	X
Urine pregnancy test	X		X			X
Physical examination			X			
Laboratory blood Analysis: CBC, electrolytes (Na, K, Cl), HbA1c*, creatinine, AST, ALT, bilirubin ** only measured at visit 1*	X					X
Waist, hip, arm, thigh circumference			X	X	X	X
BMI calculated	X		X	X	X	X
Food diaries completed			X	X	X	X
Meal Replacement (2 canisters) dispensed			X	X	X	
Meal replacement returned				X	X	X
Study diary dispensed			X	X	X	
Study diary returned				X	X	X
Compliance calculated				X	X	X
Adverse events				X	X	X

9.3 DISCUSSION OF STUDY DESIGN AND CHOICE OF CONTROL GROUP

The study design used was a randomized, comparator-controlled, parallel study. The randomized controlled trial is a rigorous design that allows the investigation of the impact of an investigational product on study outcomes by controlling bias and limiting confounding factors. A parallel design is best for measuring efficacy of an investigational product.

A comparator control group was made up of a group of volunteers drawn from the same recruitment pool who met all inclusion and did not meet any of the exclusion criteria.

9.4 SECTION OF STUDY POPULATION

Each participant fulfilled all the inclusion criteria listed in section 9.4.1 and did not meet any of the exclusion criteria listed in section 9.4.2.

9.4.1 Inclusion Criteria

1. Males and females 18 - 65 years (inclusive) of age
2. BMI of 25.0 kg/m² - 34.9 kg/m² (± 1.0 kg/m^2)
3. If female, participant is not of child bearing potential, which is defined as females who have had a hysterectomy or oophorectomy, bilateral tubal ligation or are post-menopausal (natural or surgically with > 1 year since last menstruation)

   OR

   Females of childbearing potential must agree to use a medically approved method of birth control and have a negative urine pregnancy test result. Acceptable methods of birth control include:
   - Hormonal contraceptives including oral contraceptives, hormone birth control patch (Ortho Evra), vaginal contraceptive ring (NuvaRing), injectable contraceptives (Depo-Provera, Lunelle), or hormone implant (Norplant System)
   - Double-barrier method
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   - Vasectomy of partner (shown successful as per appropriate follow-up)
4. Stable weight defined as less than 5.0 kg gained or lost in the past 3 months
5. Healthy as determined by laboratory results, medical history, and physical exam
6. Plans not to change smoking habits during the study period
7. Agree to follow diet plan and physical activity of 35 min 3 to 5 times a week during the study
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9. Willingness to complete and comply with all study procedures, questionnaires, records, diaries and dietary restrictions associated with the study and to complete all clinic visits.
10. Has given voluntary, written, informed consent to participate in the study

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1. Women who are pregnant, breastfeeding, or planning to become pregnant during the trial
2. Use of prescription or over the counter products, programs or meal replacement product known to affect weight within 4 weeks of enrollment and during the trial
3. History of surgery for weight loss (including gastric bypass or lap band)
4. History or presence of clinically important renal, hepatic, endocrine, pulmonary, biliary, or pancreatic disorders
5. Presence or history of neurological disorders or significant psychiatric illness.
6. Type I or Type II Diabetes
7. Any disorder associated with eating behaviour
8. History of or current diagnosis of any cancer (except for successfully treated basal cell carcinoma) diagnosed less than 5 years prior to screening. Cancer in full remission more than 5 years after diagnosis are acceptable
9. Alcohol abuse (>2 standard alcoholic drinks per day) or drug abuse within the past 6 months
10. Use of medicinal marijuana
11. Use of antipsychotic drugs
12. Plan on donating blood during the study or within 30 days of completing the study
13. Known allergy or sensitivity to the test material's active or inactive ingredients
14. Unstable medical conditions
15. Clinically significant abnormal laboratory results at screening
16. Participation in a clinical research trial within 30 days prior to randomization
17. Cognitively impaired and/or unable to give informed consent
18. Any other condition which in the Qualified Investigator's opinion may adversely affect the Individual's ability to complete the study or its measures or which may pose significant risk to the individual

9.4.3 Removal of Participants from Study

There was no specific stop criterial formulated for this study. Discontinuation of a participant was at the discretion of the Qualified Investigator.

In case of early withdrawal, no follow-up other than recovery of the investigational product and attempt to perform laboratory safety test were conducted for participant who decided to end their participation, except if the withdrawal was due to medical reasons related to the study. In this event, participants were followed-up until recovery. If a participant withdrew from a study, information collected up until the withdrawal point was used unless the participant requested otherwise. The circumstance of any discontinuation was documented in detail. A participant leaving the study prematurely was not replaced by another. Participants were compensated for that part of the study that has been performed. Criteria for removal of participant from the study includes.

Personal reasons

As stated in the Informed Consent Form, a participant could withdraw from the study for any reason at any time.

Clinical judgment of physician

A participant could be withdrawn from the study if it was determined by the Qualified Investigator that it was not in the participant's best interest to continue. This included, but was not limited to, adverse events (AEs) or serious AEs related to the investigational product causing clinically-significant illness, the need to for a prohibited concomitant medication, or a female participant who becomes pregnant during the study.

Protocol violation

Any participant found to have entered the study in violation of the protocol could be withdrawn form the study at the discretion of the Qualified Investigator. This includes any of the following: participants found to have been inappropriately enrolled (did not meet eligibility criteria), non-complaint participants which includes not showing up for study visits, not taking investigational product as directed, refusing to undergo study visit procedures, or not completing questionnaires. Participants who were found to be taking prohibited medications or supplements without the knowledge of the Qualified Investigator are withdrawn at the discretion of the Qualified Investigator. Any major protocol deviations (i.e., those that increase the risk to patients and/or compromise the integrity of the study or its results) would result in participant discontinuation.

9.5 INVESTIGATIONAL PRODUCT

9.5.1 Investigational Product Administration

All participants that met all inclusion criteria and did not meet any of the exclusion criteria at screening were randomized into two groups. During the supplementation period one group received the investigational product YYC!™ meal replacement while the other group received the comparator, MAHA Diet. All participants were instructed to maintain a 1500 Caloric intake per day. Participants were provided with healthy eating suggestions and a smart phone food diary app to help them achieve and monitor their dietary caloric intake goals. Nutritionists gave dietary suggestions to participants when required. All participants were instructed to participate in 35 minutes of light to moderate physical activity 3-5 times per week. They were asked to record their physical activity in a weekly exercise questionnaire.

Participants randomized into the YYC!™ meal replacement group consumed the meal replacement twice daily, substituting any 2 out of the 3 meals (i.e. breakfast, lunch, dinner) and the provided meal guide. Participants were instructed to mix one scoop of the meal replacement powder with 16 oz. (2 cups) of cold water. If the participant forgot to replace their meal, they replaced the next meal with the meal replacement. Participants were instructed not to replace more than 2 meals per day.

9.5.2 Identity of Investigational Product

The investigational product, YYC!™ meal replacement, contains the following active ingredients: protein matrix (whey protein concentrate, micellar casein), corn fiber, medium chain triglycerides powder, vitamin mineral premix (trimagnesium citrate, dipotassium phosphate, vitamin C (ascorbic acid), ferrous sulfate, vitamin E (alpha-tocopheryl acetate), biotin, vitamin A, palmitate, zinc sulfate, niacinamide, vitamin B5 (calcium pantothenate), copper gluconate, cyanocobalamin, vitamin B6 (pyridoxine), vitamin D3 (cholecalciferol), potassium iodide, vitamin B2 (riboflavin), vitamin B1 (thiamine), chromium chloride, vitamin B9 (folic acid)), and non active ingredients: natural and artificial flavor, xanthan gum, sucralose, and sodium chloride,.

The batch number for YYC!™ meal replacement is: IM454181.

9.5.3 Method of Assigning Participants to Investigational Groups

Participants were identified by their initials and their date of birth and were assigned a participant number at screening visit (Visit 1). If the potential participant met all the inclusion criteria and did not meet any of the exclusion criteria at baseline (Visit 2), a randomization number was assigned to the participant by an investigator as per the order of the randomization list generated by www.randomization.com (Appendix).

9.5.4 Prior and Concomitant Therapy

Participants who were taking any prescribed medications agreed to maintain their current method and dosing regimen during the study unless recommended by their physician.

Birth control was allowed during the study. Participants taking prescribed birth control agreed to maintain their current method and dosing regiment during of the study

Prescription or over-the-counter products, programs or meal replacement product intended to alter body weight, other than those provided, were prohibited within four weeks of randomization and during the study. Anti-psychotic drug and medicinal marijuana were prohibited.

9.5.5 Study Compliance

9.5.6 Product Compliance

Compliance to study procedures was recorded in the relevant section of the CRF at each visit. Product compliance was assessed by weighing the returned unused product at each visit. Compliance was calculated by determining the number of meal replacement consumed divided by the number of meal replacement expected to have been consumed multiplied by 100.

$$Product\ Compliance\ \% = \frac{number\ of\ meal\ replacement\ consumed}{number\ of\ meal\ replacement\ expected\ to\ have\ been\ consumed} \times 100$$

In the event of discrepancy between the information in the participant's diary and the amount of study product returned, use was based on the product returned unless explanation for loss of product was provided. Participant found to have compliance less than 80% or greater than 120% were counseled. Non-compliant participants were removed prior to completion of the study at the discretion of the Qualified Investigator.

9.5.7 Dietary Compliance

Online food records were reviewed and to determine dietary compliance. Participants were counseled if they were compliant to the dietary recommendation. A dietary caloric intake of 1500 Calories/day ± 20% was considered compliant. Non-compliant participants were counseled by a nutritionist and suggestion were provided to encourage future compliance.

9.6 EFFICACY AND SAFETY ENDPOINTS

9.6.1 Efficacy Endpoints

The objective of this study was to determine the effectiveness of YYC!™ meal replacement with minimal activity on weight loss in overweight and mildly obese adults.

The primary efficacy outcome was the change in body weight from baseline to day 85 between participants on YYC!™ meal replacement with minimal physical activity vs. participants on the MAHA Diet with minimal activity.

The secondary efficacy outcomes were as follows:

- Change in body weight from baseline to day 28 and day 56 between participants on YYC!™ meal replacement with minimal physical activity *vs.* participants on the MAHA Diet with minimal physical activity

- Change in body mass index from baseline to day 28, day 56 and day 85 between participants on YYC!™ meal replacement with minimal physical activity *vs.* participants on the MAHA Diet with minimal physical activity

- Change in waist circumference from baseline to day 28, day 56 and day 85 between participants on YYC!™ meal replacement with minimal physical activity *vs.* participants on the MAHA Diet with minimal physical activity

- Change in hip circumference from baseline to day 28, day 56 and day 85 between participants on YYC!™ meal replacement with minimal physical activity *vs.* participants on the MAHA Diet with minimal physical activity

- Change in waist to hip circumference ratio from baseline to day 28, day 56, and day 85 between participants on YYC!™ meal replacement with minimal physical activity *vs.* participants on the MAHA Diet with minimal physical activity

- Change in thigh circumference from baseline to day 28, day 56, and day 85 between participants on YYC!™ meal replacement with minimal physical activity *vs.* participants on the MAHA Diet with minimal physical activity

- Change in arm circumference from baseline to day 28, day 56 and day 85 between participants on YYC!™ meal replacement with minimal physical activity *vs.* participants on the MAHA Diet with minimal physical activity

9.6.2 Safety Endpoints

The safety and tolerability outcomes consisted of:

- Clinically significant abnormal haematology and clinical chemistry values
- Clinically significant abnormal kidney and liver function values
- Clinically significant abnormal electrolyte values
- Clinically significant abnormal heart rate and blood pressure
- Incidence of adverse events over the course of the study by organ group

9.6.2.1 Laboratory Endpoints

Safety endpoints of complete blood count (hemoglobin, hematocrit, platelet count, red blood cell count (RBC), red cell indices, red cell distribution width (RDW), white blood cell count (WBC) and differentials (neutrophils, lymphocytes, monocytes, eosinophils, basophils), liver function (alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, creatinine), and kidney function laboratory blood tests (creatinine, electrolytes (Na, K, Cl)) were analysed from the blood drawn at Visit 1 (screening), and at Visit 5 by LabCorp (USA) using standardized procedures.

Urine pregnancy test was conducted at KGK Clinics for participant of childbearing during screening, baseline, and end-of-study.

9.6.2.2 Adverse Events

An AE was defined as any untoward medical occurrence in a clinical investigation participant who was administered an investigational supplement which did not necessarily have a causal relationship with the product. An AE could be any unfavorable and unintended sight (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the product, whether or not it was considered related to that product. Pre-existing conditions which worsened during the study were reported as AEs.

During the study, participants recorded AEs in their diary. At each visit the participate was asked “Have you experienced any difficulties or problems since I saw you last?” AEs were documented in the study record and were classified as per the description, duration, intensity, frequency, and outcome. The qualified investigator assessed any AEs and decided causality.

Intensity of AEs was graded on a three-point scale (mild, moderate, severe) and was reported in detail in the study record.

Mild:	Awareness of event but easily tolerated
Moderate:	Discomfort enough to cause some interference with usual activity
Severe:	Inability to carry out usual activity

The causality relationship of the investigational product to the AE was assessed by the Qualified Investigator as either:

Most probable:	There was a reasonable relationship between the investigational product and the AE. The event responded to withdrawal of investigational product (de-challenge) and recurred with re-challenge when clinically feasible.
Probable:	There was a reasonable relationship between the investigational product and the AE. The event responded to de-challenge.
Possible:	There was a temporal relationship to investigational product and the AE. De-challenge information is lacking or unclear.
Unlikely:	There was a temporal relationship to investigational product administration but there was no reasonable causal relationship between investigational product and the AE.
Not related:	No temporal relationship to administration of the investigational product or there was no reasonable causal relationship between non-investigational product, concurrent disease or circumstance and the AE.

Serious Adverse Events

A serious AE (SAE) was defined as any AE that results in any of the following outcome and was reported to the IR and health authorities on occurrence of:

- Death
- A life-threatening AE
- Impatient hospitalization or prolongation of existing
- A persistent or significant disability or incapacity
- A congenital anomaly/birth defect in the offspring of a participant who received study product
- Important medial events that were not immediately life-threatening or resulted in death or hospitalization but may have jeopardized the participant or may have required intervention to prevent on of the outcomes listed above. Examples of such events would be intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalization; or the development of drug dependency or drug abuse.

Unexpected Adverse Reactions

Any unexpected adverse reaction is an adverse reaction, the nature and severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).

9.7 DATA QUALITY ASSURANCE

The quality control procedures used in this study included crosschecking data by research personnel against copies of source documents. Data entry and verification was executed according the KGK Synergize Standard Operating Procedures. All raw data and standard operation procedures used in this study were maintained and archived where appropriate to satisfy regulatory requirements.

Frequent monitoring was conducted during the study on the source documents to ensure that all items were completed and that the data provided were accurate and obtained in the manner specified in the protocol. The participant files were reviewed and confirm that:

- Informed consent was obtained and documented
- Enrolled participant fulfilled all inclusion criterial and did not meet any of the exclusion criteria
- AE/SAE reporting was performed as applicable
- Study visits were conducted as per protocol and information was recorded in the appropriate place in the source document
- The study product was stored correctly and that an accurate record of its dispensing to the study participant was maintained (accountability)

Incorrect, inappropriate, or illegible entries in the participant files were returned to the Qualified Investigator or designee for correction. No data disclosing the identity of participant left the study center. The Qualified Investigator and any designees maintained confidentiality of all participant records.

9.8 STATISTICAL METHODS PLANNED IN PROTOCOL AND DETERMINATION OF SAMPLE SIZE

9.8.1 Statistical and Analytical Plans

9.8.1.1 Analytical Populations

The following analytical populations were defined for this study:

Safety Population consisted of all participants who randomized into the study, and on whom any post-randomization safety information was available.

The **Completers** Population consisted of all participants who completed all study visits and procedures connected with measurement of the primary variable.

The **Intent-to-treat** (ITT) Population consisted of all participants who where randomized, and on whom any post-randomization efficacy information was available (Presented in Appendix).

The **Per Protocol** (PP) Population consisted of all participants on the MAHA Diet or YYC!™ meal who consumed overall at least 80% of required YYC!™ meal, did not have any major protocol violations, and completed all study visits and procedures connected with measurement of the primary variable (Presented in Appendix).

9.8.1.2 Efficacy Analysis

Efficacy analysis based on the completer population and safety analysis based on the safety population were performed. Variables were tested for normality and log-normality. Log-normally distributed variables were analyzed in the logarithmic domain. The appropriate non-parametric test was used to analyze non-normal variables. Safety analysis was based on the safety population.

All missing values in the efficacy analysis were imputed with the most recent previously-available value (LOCF, or "last-observation-carried-forward" imputation). No imputations were performed for missing values of safety variables.

9.8.1.3 Safety Analysis

For AEs, a descriptive analysis was given. AEs were presented in a frequency table, by body system/group and study group. Furthermore, nature, incidence, severity, and causality were reported for each AE.

9.8.1.4 Subgroup Analysis

In this study, compliance to use of investigational product was weighed to subdivide the participant population for subgroup analyses. This was necessitated out of the poor compliance that is expected from clinical studies related to food and drink habits for three months. For the primary endpoint analysis of body weight, the per protocol population was sub grouped to those with none, 0 – 1 and 0 – 2 product compliance issues. All analyses were conducted in the same manner as the whole set.

9.8.1.5 Level of significance and Statistical Software

Probabilities ≤ 0.05 were considered statistically significant. All statistical analyses were completed using the R Statistical Software Package Version 3.2.2 (R Core Team, 2015) for Microsoft Windows.

9.8.2 Determination of sample Size

The planned sample size for this study was 70 participants, with 35 participants randomized to each study group.

Power calculations were performed to determine the required sample size to provide 80% power at the 0.05 alpha level (that is, to have an 80% chance of obtaining $p \leq 0.05$ significance) when comparing changes in mean weight change between product and comparator.

With an estimated 20% attrition over the course of this study, 80% power and $p \leq 0.05$ when comparing product to comparator, if the product produced at least a 2.5 kg decrease over comparator in body weight, then a total of 70 participants were required to be enrolled.

9.8.3 Analysis Plan

Data were summarized by visit and by product. Numerical variables were summarized as mean, standard deviation, standard error of the mean, median, and range (minimum and maximum). Changes from baseline to each subsequent visit were summarized similarly, and a *p* value indicating whether the mean change within each group was significantly different from zero (based on the paired Student *t* test, or the non-parametric Wilcoxon Signed-Ranks test). Mean values were displayed as graphs, with a separate line for each product, and error bars indicating ± 1 SEM. Mean changes from baseline were graphed similarly. Student's t-test was used to test the differences between groups with the baseline subtracted.

9.8.4 Statistical/Analytical Issues

As the objective of this clinical trial was to assess the change in body weight following supplementation with the product relative to a comparator group and not to assess the final weight adjusted to baseline, the Student's *t* test was deemed appropriate to test the differences with the baseline subtracted. Therefore, the results of the analysis based on ANCOVA are presented in Appendix, while the results based on analysis using the Student's *t* test are presented in this report.

9.8.5 Change in the Planned Analysis

Efficacy was to be tested by ANCOVA, where the dependent variable was the change in body weight from baseline to week 12, the factor was the study group (YYC! meal replacement or the MAHA Diet), and the covariate was the baseline body weight value. This analysis is presented in the appendix.

Since the objective of this clinical trial was to assess the change in body weight following supplementation with the product relative to a comparator group and not to assess the final weight adjusted to baseline, the Student's *t* test was used test the differences between groups with the baseline subtracted. This analysis is presented in the body of this report.

9.8.6 Handling of Dropout or Missing Data Monitoring

All missing values in the ITT (effectiveness) analysis were imputed with the most recent previously-available value (LOCF imputation)

9.8.7 Interim Analyses and Data Monitoring

An interim analysis was not conducted for this study.

9.8.8 Multicenter Studies

This study was conducted at two sites in the USA

9.8.9 Use of a Completer Efficacy Analysis

An efficacy analysis based on the Completer population who completed all study visits and procedures connected with measurement of the primary variable.

Due to the unexpectedly high attrition rate, a completers population was used as opposed to the originally planned per-protocol. This allowed the study to retain more of the planned statistical power.

9.9 CHANGES IN THE CONDUCT OF THE STUDY

The original protocol (version 3) dated July 20th 2016 was approved by IRB on July 29th 2016 and was amended once thereafter to version 4 dated August 11th 2016.

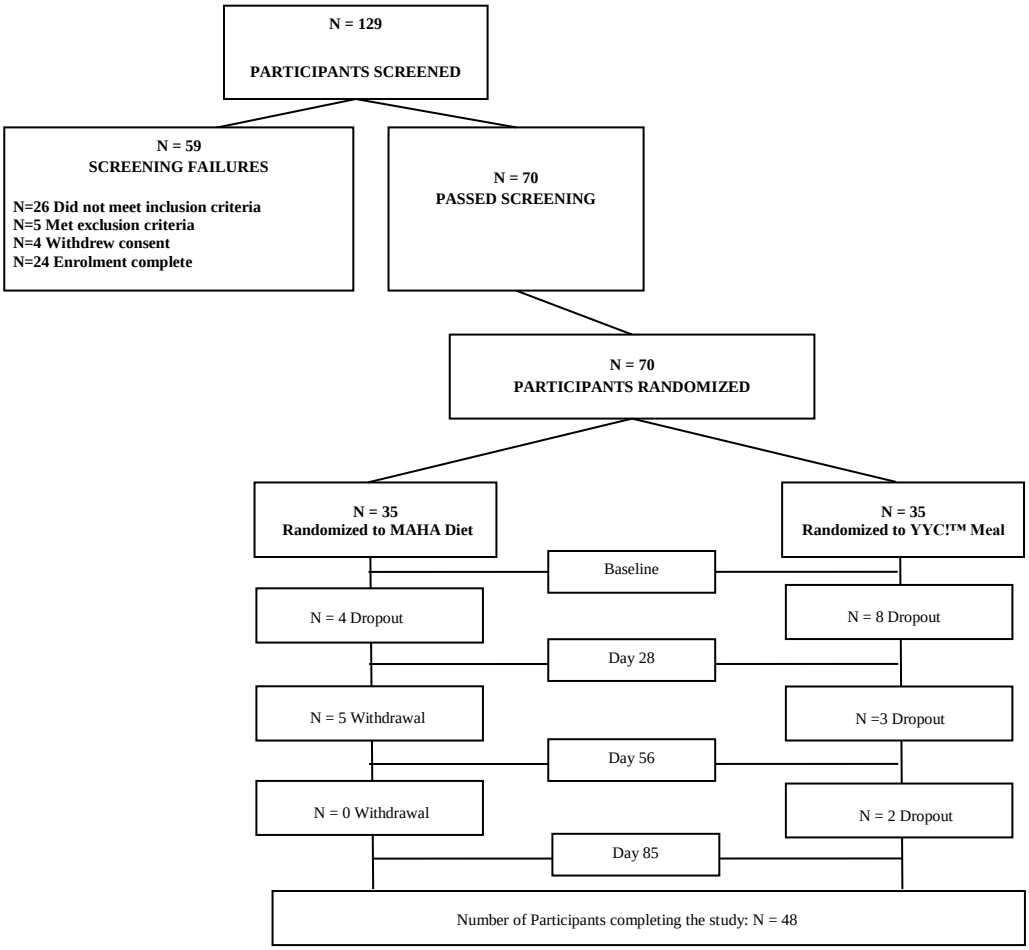
- On August 15th 2016, IRB approved the following amendments:
    - Changed the online food record from Esha's Food Prodigy to DietMaster Pro
    - Clarified four of selection criteria as follows:
        1) All IUDs are acceptable, both hormonal and non-hormonal
        2) Clarified that participants need to be willing to complete study procedures including dietary restrictions
        3) Added Exclusion criteria for use of antipsychotic drugs, this was previously only listed in the concomitant medication section
        4) Removed exclusion "use of another IP within 3 months of the screening visit".

The first participant was screened on August 17th 2016 after the protocol was amended.

10. STUDY PARTICIPANTS

10.1 DISPOSITION OF PARTICIPANTS

Figure 2: Disposition of Study Participants



A total of 129 potential participants were screened, and 70 eligible participants were enrolled in the study (with 35 participants in each study group). Forty-eight participants completed the study.

Forty-eight participants were included in the completer population. Twenty-two participants did not complete the study; 13 from the YYC!™ group, nine from the MAHA Diet group (refer to Table 4).

10.2 PROTOCOL DEVIATIONS

A total of 269 protocol deviations by 56 participants occurred in this study. The main type of protocol deviations seen concerned inability to follow the MAHA Diet plan and portion control.

Details on each protocol deviation can be found in Appendix.

10.3 DEMOGRAPHICS AND OTHER BASELINE CHARACTERISTICS

Table 2: Demographics of all Enrolled Participants (N = 70)

	All Groups (N=70)	MAHA Diet (N = 35)	YYC!™ Meal (N = 35)	P Value σ
Age (years)				
Mean ± SD	39.8 ± 10.9 (70)	38.2 ± 10.9 (35)	41.4 ± 10.9 (35)	0.226 §
Median (Min – Max)	41 (19 – 64)	38 (20 – 63)	42 (19 – 64)	
BMI (kg/m^2)				
Mean ± SD	30.43 ± 2.92 (70)	30.10 ± 2.85 (35)	30.76 ± 3.00 (35)	0.346 §
Median (Min – Max)	30.19 (24.96 – 35.84)	30.09 (25.62 – 35.84)	30.43 (24.96 – 35.76)	
Gender [n (%)]				
Female	49 (70%)	27 (77%)	22 (63%)	0.297
Male	21 (30%)	8 (23%)	13 (37%)	
Alcohol Use [n (%)]				
None	23 (33%)	12 (34%)	11 (31%)	0.307
Occasionally	32 (46%)	13 (37%)	19 (54%)	
Weekly	13 (19%)	8 (23%)	5 (14%)	
Daily	2 (3%)	2 (6%)	0 (0%)	
Smoking Status [n (%)]				
Current Smoker	5 (7%)	1 (3%)	4 (11%)	0.195
Ex-Smoker	7 (10%)	2 (6%)	5 (14%)	
Non-Smoker	58 (83%)	32 (91%)	26 (74%)	
Race [n (%)]				
Black or African American	14 (20%)	8 (23%)	6 (17%)	0.791
Central American	13 (19%)	8 (23%)	5 (14%)	
Eastern European White	5 (7%)	1 (3%)	4 (11%)	
Middle Eastern	2 (3%)	1 (3%)	1 (3%)	
South American	5 (7%)	2 (6%)	3 (9%)	
South Asian	3 (4%)	1 (3%)	2 (6%)	
Western European White	28 (40%)	14 (40%)	14 (40%)	
Ethnicity [n (%)]				
Hispanic or Latino	30 (43%)	16 (46%)	14 (40%)	0.809
Not Hispanic or Latino	40 (57%)	19 (54%)	21 (60%)	
Status [n (%)]				
Completed	48 (69%)	26 (74%)	22 (63%)	0.440
Early Termination	22 (31%)	9 (26%)	13 (37%)	

Max, maximum; Min, minimum; N/n, number; %, percentage; SD, standard deviation.

§ Between group comparisons were made using the Independent Student t-test.
σ Between group comparisons were made using the Fisher's Exact test.
Probability values $P \leq 0.05$ are statistically significant.

Seventy participants with an age range of 19 - 64 years and a BMI of 24.96 – 35.84 kg/m^2 comprised the safety population. There were no significant differences between groups in their demographics and groups were well-matched. Though the protocol required at least 75% Hispanics and 75% females, due to

difficulty in recruiting this percentage, the study was followed through due to time constraints. Therefore, the enrolled population consisted of 43% Hispanic or Latino and 70% females.

Table 3: Demographics of Participants Who Completed all Study Visits (N = 48)

	All Groups (N = 48)	MAHA Diet (N = 26)	YYC!™ Meal (N = 22)	P Value σ
Age (years) Mean ± SD Median (Min – Max)	41.3 ± 10.5 (48) 41 (20 – 64)	40.1 ± 10.5 (26) 38.5 (20 – 63)	42.7 ± 10.6 (22) 41.5 (26 – 64)	0.399 §
BMI (kg/m^2) Mean ± SD Median (Min – Max)	29.84 ± 2.78 (48) 29.72 (24.96 – 35.84)	29.51 ± 2.60 (26) 29.65 (25.62 – 35.84)	30.24 ± 2.99 (22) 29.72 (24.96 – 35.76)	0.369 §
Gender [n (%)] Female Male	 32 (67%) 16 (33%)	 19 (73%) 7 (27%)	 13 (59%) 9 (41%)	0.366
Alcohol Use [n (%)] None Occasionally Weekly Daily	 19 (40%) 19 (40%) 10 (21%) 0 (0%)	 10 (38%) 10 (38%) 6 (23%) 0 (0%)	 9 (41%) 9 (41%) 4 (18%) 0 (0%)	1.000
Smoking Status [n (%)] Current Smoker Ex-Smoker Non-Smoker	 4 (8%) 1 (2%) 43 (90%)	 1 (4%) 0 (0%) 25 (96%)	 3 (14%) 1 (5%) 18 (82%)	0.203
Race [n (%)] Black or African American Central American Eastern European White Middle Eastern South American South Asian Western European White	 10 (21%) 9 (19%) 3 (6%) 2 (4%) 5 (10%) 3 (6%) 16 (33%)	 6 (23%) 6 (23%) 1 (4%) 1 (4%) 2 (8%) 1 (4%) 9 (35%)	 4 (18%) 3 (14%) 2 (9%) 1 (5%) 3 (14%) 2 (9%) 7 (32%)	0.915
Ethnicity [n (%)] Hispanic or Latino Not Hispanic or Latino	 20 (42%) 28 (58%)	 11 (42%) 15 (58%)	 9 (41%) 13 (59%)	1.000
Status [n (%)] Completed Early Termination	48 (100%) 0 (0%)	26 (100%) 0 (0%)	22 100%) 0 (0%)	1.000

Max, maximum; Min, minimum; N/n, number; %, percentage; SD, standard deviation.

§ Between group comparisons were made using the Independent Student t-test.
σ Between group comparisons were made using the Fisher's Exact test.
Probability values $P \leq 0.05$ are statistically significant.

Forty-eight participants with an age range of 20 - 64 years and a BMI of 24.96 – 35.84 kg/m^2 comprised the completer population. There were no significant differences between groups in their demographics and groups were well-matched.

Table 4: Participants Not Included in the Completer Analysis (N = 24)

Participant Number	Group	Reason
CAL-007	YYC!™ Meal	Withdrew from study
CAL-011	YYC!™ Meal	Withdrew from study
CAL-015	MAHA Diet	Withdrew from study
CAL-027	YYC!™ Meal	Withdrew from study
CAL-043	YYC!™ Meal	Withdrew from study
ORL-007	MAHA Diet	Withdrew from study
ORL-010	YYC!™ Meal	Withdrew from study
ORL-012	YYC!™ Meal	Withdrew from study
ORL-014	MAHA Diet	Withdrew from study
ORL-033	MAHA Diet	Withdrew from study
ORL-045	YYC!™ Meal	Withdrew from study
ORL-047	YYC!™ Meal	Withdrew from study
ORL-021	YYC!™ Meal	Withdrew from study
CAL-018	MAHA Diet	Withdrew from study
CAL-053	YYC!™ Meal	Withdrew from study
ORL-024	YYC!™ Meal	Withdrew from study
ORL-037	YYC!™ Meal	Withdrew from study
ORL-039	MAHA Diet	Withdrew from study
ORL-044	YYC!™ Meal	Withdrew from study
ORL-049	MAHA Diet	Withdrew from study
ORL-056	MAHA Diet	Withdrew from study
ORL-058	MAHA Diet	Withdrew from study

N, number

Twenty-two participants were removed from the completer analysis; 13 from the YYC!™ group, nine from the MAHA Diet group.

10.4 COMPLIANCE

10.4.1 Product Compliance

Table 5: Compliance of Participants to YYC!™ Meal Replacement Plan in the Completer Population (N = 48)

	YYC!™ Meal
	Mean ± SD (n)
Product Compliance (%)	
Day 28	90.2 ± 18.0 (21) 91 (60 – 137)
Day 56	96.0 ± 15.6 (21) 92 (78.3 – 153)
Day 85 **End of Study**	104.3 ± 24.0 (21) 96.8 (68 – 177)
Overall **Compliance**	95.9 ± 17.1 (21) 95 (57.7 – 133.9)

N/n, number; %, percent; SD, standard deviation

Compliance to YYC!™ meal replacement in the Completer population was > 90%, with an overall mean compliance of approximately 96%.

10.4.2 Diet Compliance

Table 6: Compliance to Calorie Consumption by the Completer Population (N = 48)

	MAHA Diet	YYC!™ Meal	P Value
	Mean ± SD (n)	Mean ± SD (n)	
Calorie Consumption (Calories/day)			
Overall Compliance	1,410 ± 85 (26) 1,437 (1,217 – 1,570)	1,380 ± 101 (22) 1,398 (1,158 – 1,548)	0.268

N/n, number; % Percent; SD, standard deviation.

The mean dietary consumption for participants in the YYC!™ and MAHA Diet groups was within the required caloric intake of 1500 ± 20% Calories/day for the Completer population. There was no significant difference between groups in overall dietary compliance.

10.5 SCREENING SAFETY VALUES

Table 7: Vitals and Anthropometric Measurements of Participants Enrolled into the Study

	All Groups (N = 70)	MAHA Diet (N = 35)	YYC!™ Meal (N = 35)	P Value§
Systolic Blood Pressure (mmHg) Mean ± SD Median (Min – Max)	110.1 ± 12.8 (70) 110 (82 – 155)	109.6 ± 15.6 (35) 107.7 (82 – 155)	110.6 ± 9.5 (35) 110.3 (88.7 – 133.3)	0.751
Diastolic Blood Pressure (mmHg) Mean ± SD Median (Min – Max)	80.4 ± 9.9 (70) 81.3 (57.7 – 114.3)	79.5 ± 12.3 (35) 78.7 (57.7 – 114.3)	81.3 ± 6.9 (35) 82 (67.7 – 98.7)	0.432
Heart Rate (BPM) Mean ± SD Median (Min – Max)	75.2 ± 10.9 (70) 75.5 (56 – 110.7)	75.7 ± 10.9 (35) 76 (56 – 110.7)	74.7 ± 11.0 (35) 73.7 (56.3 – 100.3)	0.720
Height (cm) Mean ± SD Median (Min – Max)	167.5 ± 9.7 (70) 166.1 (150.5 – 188)	165.4 ± 10.0 (35) 162 (151 – 188)	169.7 ± 9.0 (35) 170 (150.5 – 188)	0.062
Weight (kg) Mean ± SD Median (Min – Max)	85.8 ± 13.7 (70) 82.7 (63.1 – 122.3)	82.7 ± 13.5 (35) 78.2 (63.5 – 116.8)	88.9 ± 13.4 (35) 89.5 (63.1 – 122.3)	0.056
BMI (kg/m^2) Mean ± SD Median (Min – Max)	30.43 ± 2.92 (70) 30.19 (24.96 – 35.84)	30.10 ± 2.85 (35) 30.09 (25.62 – 35.84)	30.76 ± 3.00 (35) 30.43 (24.96 – 35.76)	0.346

BPM, beats per minute; cm, centimeters; kg, kilograms; max, maximum; m, meters; mmHg, millimeters of mercury; Min, minimum; N, number; SD, standard deviation.

§ Between group comparisons were made using the Independent Student t-test.
Probability values $P \leq 0.05$ are statistically significant.

There were no significant between group differences in the vital signs and anthropometric measures at screening. All participants were healthy as deemed by their vital and anthropometric measurements.

10.6 ANALYSIS OF EFFICACY – COMPLETER POPULATION

The completer population consisted of all participants who completed all study visits and procedures connected with measurement of the primary variable.

10.6.1 Primary and Secondary Endpoint – Body Weight

A decrease in body weight is considered a desirable outcome of the study.

Table 8: Change in Body Weight from Baseline to Day 28, Day 56 and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value §
Body Weight (kg)			
Day 0 Baseline	82.0 ± 15.0 (26) 76.4 (61.6 – 118.2)	87.1 ± 12.4 (22) 87.4 (62.2 – 110.9)	0.163*
Day 28	81.8 ± 14.5 (26) 76.3 (61.2 – 114.1)	86.0 ± 12.4 (22) 87.1 (61.2 – 106.3)	0.244*
Day 56	81.0 ± 14.4 (26) 76 (61.7 – 114.1)	85.8 ± 12.6 (22) 85.7 (62 – 110)	0.205*
Day 85	80.9 ± 15.0 (26) 75.7 (62.1 – 120.9)	85.8 ± 13.1 (22) 85 (63.2 – 112.3)	0.204*
Change from Day 0 to Day 28	-0.18 ± 1.83 (26) -0.1 (-5.4 – 3.2) p = 0.713*	-1.10 ± 1.42 (22) -0.9 (-4.6 – 1.4) p = **0.001***	**0.037***
Change from Day 0 to Day 56	-0.90 ± 2.03 (26) -0.9 (-6.8 – 1.8) p = **0.032***	-1.36 ± 1.49 (22) -1.35 (-4.1 – 1.9) p < **0.001***	0.306*
Change from Day 0 to Day 85	-1.03 ± 2.68 (26) -0.85 (-8.3 – 4.2) p = 0.063*	-1.35 ± 2.58 (22) -1.55 (-5.6 – 3.7) p = **0.024***	0.669*

Kg, kilogram; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
* Logarithmic transformation required to achieve normality
Probability values P≤0.05 are statistically significant

Primary outcome was the change in body weight from baseline to day 85 between participants on the YYC!™ versus participants on the MAHA diet. Between group, There was no significant difference in body weight between participants on the YYC!™ versus participants on the MAHA diet in this study.

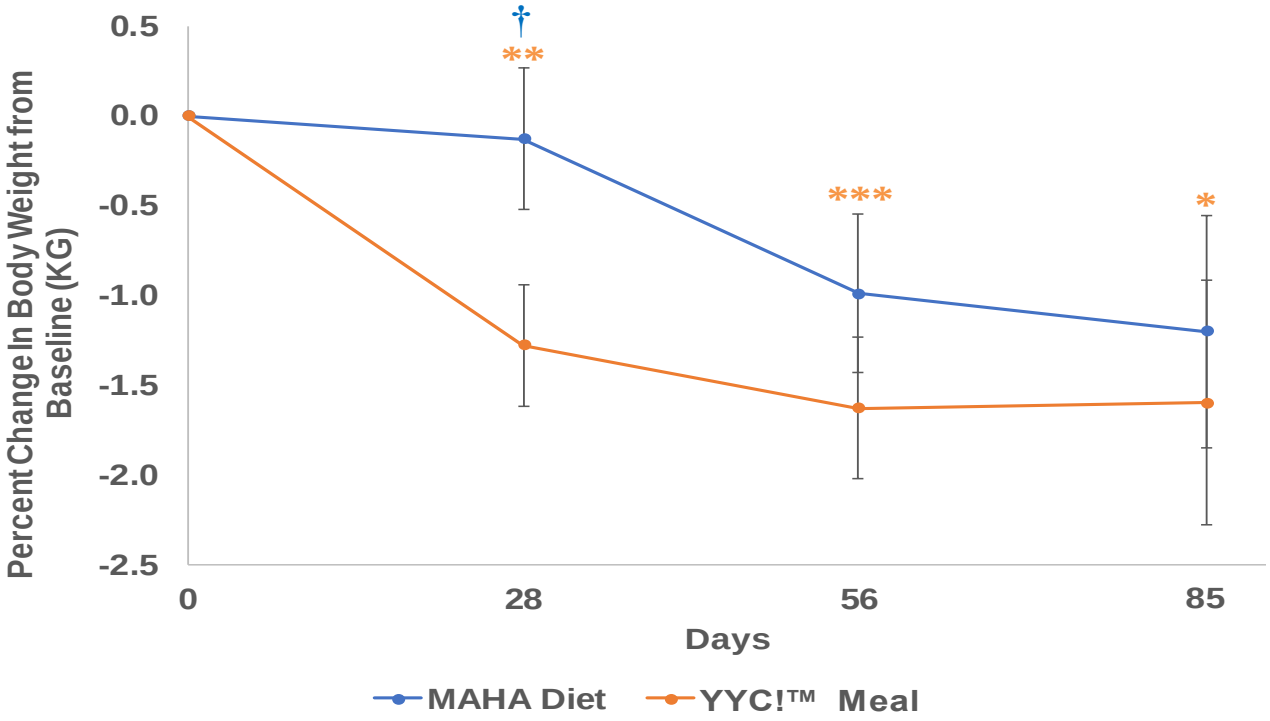
Within group, participants in the YYC!™ group significantly decreased weight by 1.6%, (Figure 3) or 1.35 kg at day 85 (p = 0.024) from baseline. Participants in the MAHA Diet group decreased their body weight by 1.2% (Figure 3) or 1.03 kg at day 85 (p = 0.063) from baseline but the decrease was not significant.

The secondary outcome was the change in body weight from baseline to day 28 and day 56 between participants on the YYC!™ versus participants on the MAHA diet. Between groups, there was a

significant difference in body weight at day 28 (p = 0.037) between participants on the YYC!™ versus participants on the MAHA diet in this study.

Within group, participants in the YYC!™ group significantly decreased weight by 1.3% (Figure 3) or 1.10 kg (p = 0.001) at day 28 and 1.6% (Figure 3) or 1.36 kg (p < 0.001) at day 56 from baseline. Participants in the MAHA Diet group significantly decreased their body weight by 1.0% (Figure 3) or 0.90 kg (p = 0.032) at day 56 from baseline but not at day 28.

Figure 3: Change in Body Weight from Baseline to Days 28, 56 and 85 in the Completer Population (N = 48).



† Significant between group mean difference at day 28 (p = 0.037)

* Significant within group mean difference in the YYC!™ group (p = 0.024)
** Significant within group mean difference in the YYC!™ group (p = 0.001)
*** Significant within group mean difference in the YYC!™ group (p < 0.001)

10.6.2 Secondary Endpoint – Body Mass Index

BMI uses an individual's height and weight to arrive at a value which categorizes individuals into normal, overweight and obese. A reduction in BMI is a desirable outcome of the study.

Table 9: Change in Body Mass Index from Baseline to Day 28, Day 56, and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ± SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ± SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Body Mass Index (kg/m^2)			
Day 0 Baseline	29.39 ± 2.59 (26) 29.13 (24.99 – 35.2)	30.06 ± 3.09 (22) 29.82 (24.6 – 35.8)	0.422
Day 28	29.35 ± 2.56 (26) 29.09 (24.83 – 34.55)	29.67 ± 3.07 (22) 29.21 (24.21 – 34.99)	0.691
Day 56	29.09 ± 2.52 (26) 29.29 (24.44 – 34.38)	29.57 ± 3.14 (22) 29.45 (24.52 – 35.51)	0.559
Day 85	29.02 ± 2.63 (26) 29.2 (24.8 – 34.23)	29.58 ± 3.34 (22) 29.16 (24.58 – 36.25)	0.521
Change from Day 0 to Day 28	-0.05 ± 0.62 (26) -0.04 (-1.65 – 1.31) p = 0.714	-0.39 ± 0.50 (22) -0.33 (-1.6 – 0.48) p = **0.002**	**0.045**
Change from Day 0 to Day 56	-0.30 ± 0.66 (26) -0.34 (-2.08 – 0.6) p = **0.029**	-0.48 ± 0.54 (22) -0.44 (-1.66 – 0.59) p < **0.001**	0.304
Change from Day 0 to Day 85	-0.37 ± 0.95 (26) -0.28 (-3.32 – 1.47) p = 0.059	-0.48 ± 0.92 (22) -0.51 (-2.08 – 1.14) p = **0.023**	0.691

Kg, kilogram; max, maximum; m, meter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
Probability values P ≤ 0.05 are statistically significant

Between groups, there was a significant difference in BMI at day 28 (p = 0.045).

Within group, participants in the YYC!™ group significantly reduced their BMI by 0.39 kg/m^2 at day 28 (p = 0.002), 0.48 kg/m^2 at day 56 (p < 0.001) and 0.48 kg/m^2 at day 85 (p = 0.023) from baseline. Participants in the MAHA Diet group significantly decreased their BMI by 0.30 kg/m^2 at day 56 (p = 0.029) from baseline. Reduction in BMI by 0.05 kg/m^2 at day 28 and 0.37 kg/m^2 at day 85 was not significant for the MAHA Diet group.

10.6.3 Secondary Endpoint – Waist Circumference

Waist circumference is an indicator of health risk associated with excess fat around the waist. A value of 102 cm or more in men or 88 cm or more in women is associated with health problems. Reduction in waist circumference is a desirable outcome of the study.

Table 10: Change in Waist Circumference from Baseline to Day 28, Day 56, and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ± SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ± SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Waist Circumference (cm)			
Day 0 Baseline	96.3 ± 11.9 (26) 95 (77.5 – 114)	98.5 ± 10.3 (22) 97.8 (79.2 – 117)	0.502
Day 28	95.2 ± 10.5 (26) 95 (77.1 – 111)	96.8 ± 10.3 (22) 94.8 (78.7 – 118)	0.604
Day 56	94.3 ± 10.6 (26) 94.5 (76.5 – 111)	94.8 ± 9.9 (22) 94.9 (75.9 – 116)	0.884
Day 85	93.3 ± 10.6 (26) 93.8 (76.5 – 111)	94.2 ± 10.8 (22) 94 (75 – 113)	0.760
Change from Day 0 to Day 28	-1.1 ± 3.3 (26) -0.5 (-7.8 – 7.4) p = 0.097	-1.7 ± 2.9 (22) -1.8 (-8 – 4) p = **0.011**	0.499
Change from Day 0 to Day 56	-2.0 ± 3.9 (26) -1.8 (-11 – 7.4) p = **0.017**	-3.7 ± 3.9 (22) -3.9 (-9 – 4.2) p < **0.001**	0.129
Change from Day 0 to Day 85	-3.0 ± 5.4 (26) -3 (-16.2 – 8.1) p = **0.008**	-4.2 ± 5.1 (22) -5 (-12 – 10) p < **0.001**	0.421

cm, centimeter; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
Probability values P ≤ 0.05 are statistically significant

Between groups, there were no significant differences in waist circumference.

Within group, participants in the YYC!™ group significantly reduced their waist circumference by 1.7 cm at day 28 (p = 0.011), 3.7 cm at day 56 (p < 0.001) and 4.2 cm at day 85 (p < 0.001) from baseline. Participants in the MAHA Diet group significantly decreased their waist circumference by 2.0 cm at day 56 (p = 0.017) and 3.0 cm at day 85 (p = 0.008) from baseline, but not significantly at day 28.

10.6.4 Secondary Endpoint - Hip Circumference

Hip circumference is taken around the widest portion of the buttocks and a larger hip circumference for a given waist circumference and BMI is associated with reduced risk of disease.

Table 11: Change in Hip Circumference from Baseline to Day 28, Day 56, and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Hip Circumference (cm)			
Day 0 Baseline	107.6 ± 8.0 (25) 106 (94.5 – 128.1)	108.5 ± 9.8 (22) 109.4 (88 – 127)	0.734
Day 28	106.5 ± 6.0 (26) 106.2 (94 – 123)	107.7 ± 9.4 (22) 108 (92 – 125)	0.579
Day 56	106.4 ± 7.9 (26) 105 (87 – 129.3)	107.3 ± 9.2 (22) 104.8 (90 – 123)	0.711
Day 85	107.1 ± 7.6 (26) 105.8 (88 – 127.5)	107.0 ± 9.8 (22) 108 (81 – 121)	0.960
Change from Day 0 to Day 28	-1.0 ± 4.8 (25) -0.7 (-12.5 – 8) p = 0.306	-0.7 ± 3.7 (22) -0.9 (-10.8 – 5.6) p = 0.354	0.832
Change from Day 0 to Day 56	-1.1 ± 4.6 (25) -1 (-12 – 10.5) p = 0.245	-1.2 ± 3.9 (22) -1 (-7.5 – 6.8) p = 0.176	0.958
Change from Day 0 to Day 85	-0.3 ± 4.2 (25) -0.5 (-11.9 – 8) p = 0.680	-1.5 ± 5.2 (22) -1.9 (-12 – 10) p = 0.209	0.427

Note: Hip circumference was measured in 25 participants at baseline and 26 participants at subsequent timepoints

cm, centimeter; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
Probability values $P \leq 0.05$ are statistically significant

Between groups, there were no significant differences in hip circumference.

Within group, participants in the YYC!™ group and MAHA Diet group reduced their hip circumference at days 28, 56 and 85 from baseline but the decrease was not significant in both the groups.

10.6.5 Secondary Endpoint - Waist to Hip Circumference Ratio

Waist to Hip Circumference ratio is a measure of body fat distribution and is associated with obesity-related disease. For women >0.85 and men, >0.9 are associated with abdominal obesity. Reduction in Waist to Hip Circumference ratio is a desirable outcome of the study.

Table 12: Change in Waist to Hip Circumference Ratio from Baseline to Day 28, Day 56, and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Waist to Hip Circumference Ratio			
Day 0 Baseline	0.895 ± 0.092 (25) 0.889 (0.753 – 1.075)	0.910 ± 0.080 (22) 0.907 (0.79 – 1.076)	0.554
Day 28	0.894 ± 0.080 (26) 0.883 (0.762 – 1.019)	0.900 ± 0.080 (22) 0.891 (0.784 – 1.117)	0.783
Day 56	0.887 ± 0.085 (26) 0.882 (0.752 – 1.029)	0.885 ± 0.074 (22) 0.882 (0.744 – 1.025)	0.909
Day 85	0.871 ± 0.079 (26) 0.865 (0.74 – 1.019)	0.882 ± 0.078 (22) 0.876 (0.762 – 1.054)	0.623
Change from Day 0 to Day 28	-0.003 ± 0.034 (25) -0.004 (-0.063 – 0.072) p = 0.689	-0.010 ± 0.032 (22) -0.002 (-0.067 – 0.041) p = 0.147	0.446
Change from Day 0 to Day 56	-0.010 ± 0.037 (25) -0.007 (-0.108 – 0.06) p = 0.208	-0.026 ± 0.047 (22) -0.028 (-0.122 – 0.079) p = **0.019**	0.201
Change from Day 0 to Day 85	-0.027 ± 0.045 (25) -0.021 (-0.116 – 0.072) p = **0.006**	-0.028 ± 0.058 (22) -0.03 (-0.166 – 0.111) p = **0.032**	0.955

Note: Waist to hip circumference ratio was calculated in 25 participants at baseline and 26 participants at subsequent timepoints

max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
Probability values $P \leq 0.05$ are statistically significant

Between groups, there were no significant differences in waist to hip circumference ratio.

Within group, participants in the YYC!™ group significantly reduced their waist to hip circumference ratio by 0.026 units at days 56 (p = 0.019) and 0.028 units at day 85 (p = 0.032) but the decrease was not significant at day 28. Participants in the MAHA Diet group significantly decreased their waist to hip circumference ratio at day 85 from baseline (p = 0.006), but not significantly at day 28 and day 56.

10.6.6 Secondary Endpoint - Thigh Circumference

Table 13: Change in Thigh Circumference from Baseline to Day 28, Day 56, and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Thigh Circumference (cm)			
Day 0 Baseline	52.6 ± 4.5 (26) 51.5 (44.5 – 63.5)	53.5 ± 6.0 (22) 52.5 (44.5 – 69.5)	0.567
Day 28	51.6 ± 4.5 (26) 51 (44.5 – 63.5)	52.1 ± 5.9 (22) 50.5 (42.6 – 67.5)	0.755
Day 56	50.0 ± 3.5 (26) 50.7 (42.5 – 55)	51.2 ± 4.6 (22) 50.5 (45 – 63.5)	0.285
Day 85	49.5 ± 3.9 (26) 48.7 (43.1 – 61.5)	50.8 ± 3.8 (22) 50.7 (42.9 – 59.1)	0.218
Change from Day 0 to Day 28	-1.05 ± 2.79 (26) -0.7 (-6.38 – 5) p = 0.068	-1.44 ± 2.77 (22) -0.81 (-9.5 – 2.3) p = **0.023**	0.625
Change from Day 0 to Day 56	-2.6 ± 4.7 (26) -1.5 (-19.5 – 3.1) p = **0.008**	-2.3 ± 4.2 (22) -0.9 (-14.5 – 2) p = **0.019**	0.765
Change from Day 0 to Day 85	-3.2 ± 5.1 (26) -2.2 (-17.5 – 5) p = **0.004**	-2.7 ± 4.7 (22) -1.9 (-17.5 – 3) p = **0.014**	0.720

max, maximum; cm, centimeter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
Probability values P ≤ 0.05 are statistically significant

Between groups, there were no significant differences in thigh circumference.

Within group, participants in the YYC!™ group significantly reduced their thigh circumference by 1.44 cm at day 28 (p = 0.023), 2.3 cm at day 56 (p = 0.019) and 2.7 cm at day 85 (p = 0.014) from baseline. Participants in the MAHA Diet group significantly decreased their thigh circumference by 2.6 cm at day 56 (p = 0.008) and 3.2 cm at day 85 (p = 0.004) from baseline, but not significantly at day 28.

10.6.7 Secondary Endpoint - Arm Circumference

Arm circumference correlates with BMI. A measure below 23.5 cm indicated that the person may be underweight with a BMI of 20 kg/m^2 or lower. An upper arm circumference of 32 cm indicates a BMI of 30 kg/m^2 or greater, indicating obesity. A reduction in arm circumference is a desirable outcome of the study.

Table 14: Change in Arm Circumference from Baseline to Day 28, Day 56, and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Arm Circumference (cm)			
Day 0 Baseline	31.61 ± 2.39 (26) 31.38 (27 – 37.38)	32.78 ± 3.12 (22) 32.88 (26.5 – 39.5)	0.151
Day 28	30.71 ± 2.37 (26) 30.54 (26.55 – 34)	31.88 ± 3.04 (22) 32.09 (26.48 – 36.73)	0.141
Day 56	30.35 ± 2.30 (26) 30 (26.5 – 34)	31.49 ± 2.86 (22) 30.95 (26.45 – 36.8)	0.132
Day 85	30.15 ± 2.37 (26) 30.5 (25 – 34.5)	31.62 ± 3.04 (22) 31.16 (26.05 – 37)	0.067
Change from Day 0 to Day 28	-0.91 ± 2.17 (26) -0.92 (-7.25 – 4) p = **0.043**	-0.90 ± 1.46 (22) -0.76 (-4.25 – 1.12) p = **0.009**	0.992
Change from Day 0 to Day 56	-1.27 ± 2.05 (26) -0.89 (-7.25 – 2.5) p = **0.004**	-1.29 ± 1.83 (22) -1.19 (-7 – 1.5) p = **0.003**	0.969
Change from Day 0 to Day 85	-1.46 ± 2.15 (26) -1.3 (-7.25 – 3) p = **0.002**	-1.16 ± 2.04 (22) -0.74 (-7.5 – 2) p = **0.015**	0.620

max, maximum; cm, centimeter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
Probability values P ≤ 0.05 are statistically significant

Between groups, there were no significant differences in arm circumference.

Within group, participants in the YYC!™ group significantly reduced their arm circumference by 0.90 cm at day 28 (p = 0.009), 1.29 cm at day 56 (p = 0.003) and 1.16 cm at day 85 (p = 0.015) from baseline. Participants in the MAHA Diet group significantly decreased their arm circumference by 0.91 cm at day 28 (p = 0.043), 1.27 cm at day 56 (p = 0.004) and 1.46 cm at day 85 (p = 0.002) from baseline.

10.6.8 Exploratory Endpoints

10.6.8.1 Waist to Height Ratio

A waist to height ratio of 0.5 is considered optimal and higher values indicate higher health risks. A reduction in waist to height ratio is a desirable outcome of the study.

Table 15: Change in Waist to Height Ratio from Baseline to Day 28, Day 56, and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Waist to Height Ratio			
Day 0 Baseline	0.579 ± 0.059 (26) 0.606 (0.488 – 0.671)	0.580 ± 0.058 (22) 0.585 (0.492 – 0.706)	0.957
Day 28	0.572 ± 0.052 (26) 0.58 (0.482 – 0.677)	0.569 ± 0.058 (22) 0.566 (0.481 – 0.69)	0.858
Day 56	0.567 ± 0.057 (26) 0.57 (0.47 – 0.671)	0.558 ± 0.053 (22) 0.55 (0.478 – 0.663)	0.537
Day 85	0.561 ± 0.052 (26) 0.564 (0.458 – 0.656)	0.554 ± 0.055 (22) 0.559 (0.459 – 0.642)	0.666
Change from Day 0 to Day 28	-0.0064 ± 0.0195 (26) -0.0029 (-0.0423 – 0.0448) p = 0.105	-0.0102 ± 0.0173 (22) -0.01 (-0.0491 – 0.0229) p = **0.011**	0.486
Change from Day 0 to Day 56	-0.0112 ± 0.0232 (26) -0.0104 (-0.0696 – 0.0448) p = **0.021**	-0.0221 ± 0.0231 (22) -0.0245 (-0.0552 – 0.0251) p < **0.001**	0.112
Change from Day 0 to Day 85	-0.018 ± 0.032 (26) -0.019 (-0.098 – 0.049) p = **0.009**	-0.026 ± 0.031 (22) -0.029 (-0.074 – 0.057) p < **0.001**	0.411

max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
Probability values P ≤ 0.05 are statistically significant

Between groups, there were no significant differences in waist to height ratio.

Within group, participants in the YYC!™ group reduced their waist to height ratio at day 28 (p = 0.011), day 56 (p < 0.001) and day 85 (p < 0.001) from baseline. Participants in the MAHA Diet group significantly decreased their waist to height ratio at day 56 (p = 0.021) and day 85 (p = 0.009) from baseline, but not significantly at day 28.

10.6.8.2 Systolic Blood Pressure

Systolic blood pressure refers to the amount of pressure in the arteries during contraction of the heart. A systolic blood pressure of less than 120 mmHg is considered normal.

Table 16: Change in Systolic Blood Pressure from Baseline to Day 28, Day 56, and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Systolic Blood Pressure (mmHg)			
Day 0 Baseline	109.1 ± 13.2 (26) 108.8 (85 – 139)	110.5 ± 9.9 (22) 112.5 (90 – 124.7)	0.690
Day 28	111.8 ± 14.7 (26) 112.2 (84.7 – 145.3)	108.2 ± 10.2 (22) 109.5 (90.7 – 127.7)	0.341
Day 56	108.1 ± 11.9 (26) 107.2 (89.3 – 128.3)	110.2 ± 8.9 (22) 108.7 (94.7 – 128)	0.493
Day 85	108.9 ± 13.7 (26) 109.8 (74.3 – 134.7)	108.1 ± 9.7 (22) 108.8 (88 – 126.7)	0.822
Change from Day 0 to Day 28	2.7 ± 9.8 (26) 1.7 (-15 – 29.3) p = 0.179	-2.3 ± 7.5 (22) -2.5 (-16 – 11) p = 0.166	0.059
Change from Day 0 to Day 56	-1.0 ± 7.1 (26) -0.5 (-18 – 9.7) p = 0.468	-0.3 ± 8.7 (22) 1.2 (-17 – 15.3) p = 0.884	0.743
Change from Day 0 to Day 85	-0.2 ± 9.9 (26) 1.2 (-25.7 – 17.3) p = 0.907	-2.4 ± 8.1 (22) 0.3 (-19 – 12) p = 0.178	0.418

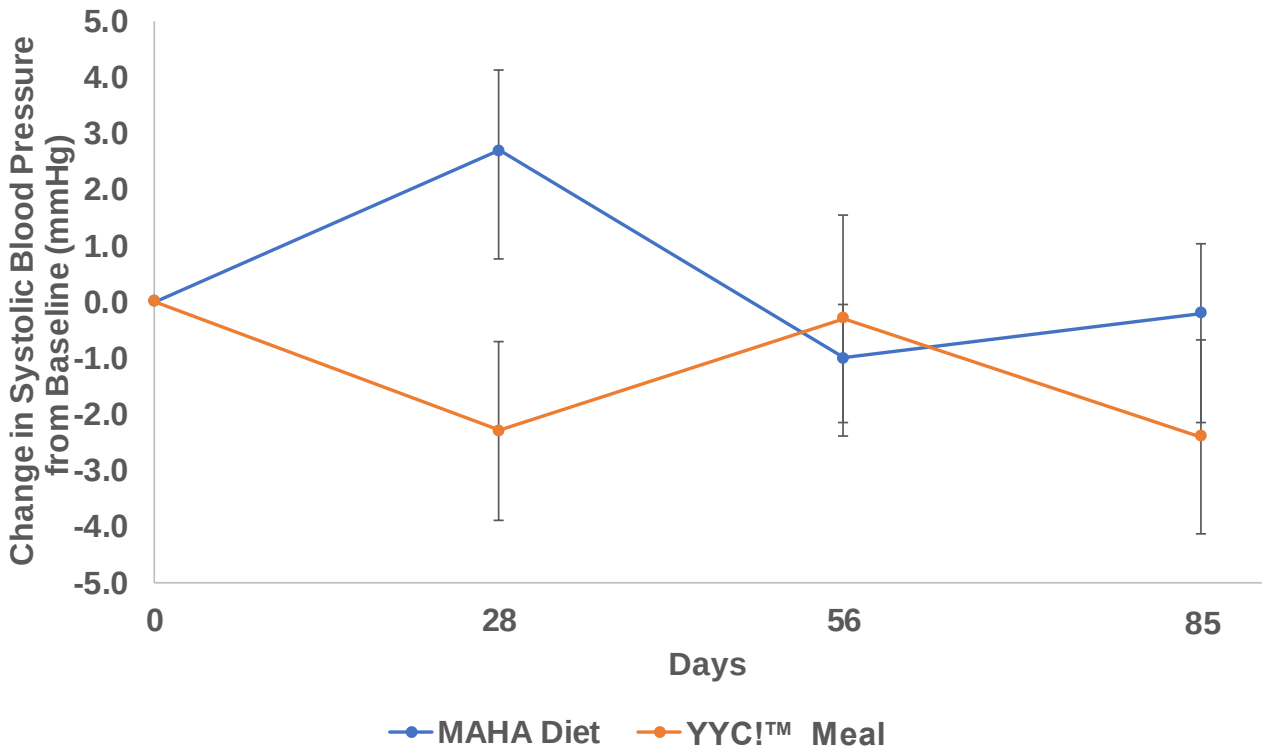
max, maximum; millimeters of mercury; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
Probability values $P \leq 0.05$ are statistically significant

Between groups, there were no significant differences in systolic blood pressure. There was a trend towards significant difference in systolic blood pressure at day 28 (p = 0.059).

Within groups there were no significant differences in systolic blood pressure.

Figure 4: Change in Systolic Blood Pressure from Baseline to Days 28, 56, and 85 in the Completer Population (N = 48).



10.6.8.3 Diastolic Blood Pressure

The diastolic blood pressure is the minimum arterial pressure during relaxation and dilatation of the ventricles of the heart when the ventricles fill with blood. A diastolic blood pressure less than 80 is considered normal.

Table 17: Change in Diastolic Blood Pressure from Baseline to Day 28, Day 56, and Day 85 in the Completer Population (N = 48).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Diastolic Blood Pressure (mmHg)			
Day 0 Baseline	80.0 ± 11.1 (26) 77.8 (62.3 – 110)	82.0 ± 7.9 (22) 84.2 (70 – 95.7)	0.486
Day 28	82.9 ± 14.2 (26) 81.8 (54.7 – 123.7)	79.4 ± 7.1 (22) 79.7 (65 – 94)	0.300
Day 56	81.9 ± 10.6 (26) 81 (63.3 – 104.7)	81.3 ± 7.2 (22) 81.5 (65.7 – 94.3)	0.822
Day 85	81.2 ± 10.7 (26) 81.5 (59.7 – 100.3)	78.1 ± 7.8 (22) 79.3 (63.3 – 95)	0.263
Change from Day 0 to Day 28	2.9 ± 7.3 (26) 2.2 (-9 – 14.7) p = **0.050**	-2.5 ± 5.7 (22) -1.3 (-12.7 – 7.7) p = **0.050**	**0.006**
Change from Day 0 to Day 56	2.0 ± 4.8 (26) 1.7 (-5.7 – 13) p = **0.046**	-0.6 ± 5.9 (22) -2.3 (-11.3 – 12) p = 0.629	0.101
Change from Day 0 to Day 85	1.2 ± 6.3 (26) 0.8 (-9.7 – 16.3) p = 0.325	-3.8 ± 8.8 (22) -2.7 (-27.3 – 10.7) p = 0.053	**0.024**

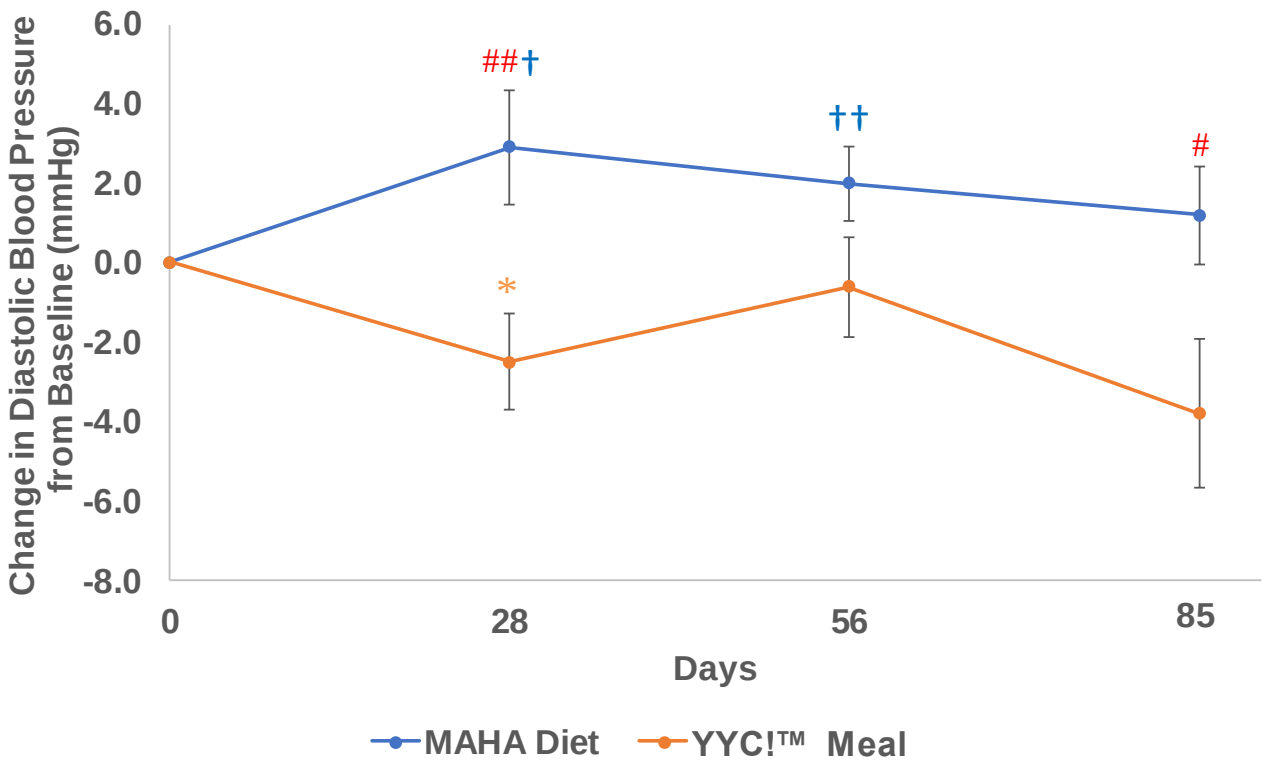
max, maximum; millimeters of mercury; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
Probability values P ≤ 0.05 are statistically significant

Between groups, there were significant differences in diastolic blood pressure at day 28 (p = 0.006) and day 85 (p = 0.024).

Within group, participants in the YYC!™ group showed a significant reduction in diastolic blood pressure at day 28 (p = 0.050) and consistent, but not significant, consistent decrease at day 56, with a trend towards significant decrease at day 85 (p = 0.053) from baseline. Participants in the MAHA Diet group showed a significant increase in diastolic blood pressure at days 28 (p = 0.050), day 56 (p = 0.046) from baseline.

Figure 5: Change in Diastolic Blood Pressure from Baseline to Days 28, 56, and 85 in the Completer Population (N = 48).



Significant between group mean difference (p = 0.024)
Significant between group mean difference (p = 0.006)
† Significant within group mean difference in the MAHA Diet group (p = 0.050)
†† Significant within group mean difference in the MAHA Diet group (p = 0.046)
* Significant within group mean difference in the YYC!™ group (p = 0.050)

10.7 SUBGROUP ANALYSES

10.7.1 Subgroup: Participants with Zero Product Compliance Issues

The population with 0 product compliance issues reflects all individuals who completed each study visit, maintained an overall diet compliance within 1200 to 1800 Calories/day, and did not have any monthly product compliance measurements less than 80% or greater than 120%.

Table 18: Change in Body Weight from Baseline to Day 28, Day 56, and Day 85 in Participants Who Attended all Visits, maintained an overall diet compliance within 1200 to 1800 Calories/day, and Had Zero Compliance Issues (N = 39).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Body Weight (kg)			
Day 0 Baseline	81.4 ± 15.1 (25) 76.4 (61.6 – 118.2)	86.4 ± 12.0 (14) 88.3 (62.2 – 100.9)	0.251*
Day 28	81.2 ± 14.5 (25) 76 (61.2 – 114.1)	85.7 ± 12.4 (14) 89.1 (61.2 – 102.3)	0.296*
Day 56	80.4 ± 14.3 (25) 75.9 (61.7 – 114.1)	84.6 ± 12.5 (14) 87.4 (62 – 101.4)	0.335*
Day 85	80.3 ± 14.9 (25) 75.5 (62.1 – 120.9)	84.5 ± 12.6 (14) 87.2 (63.2 – 102.3)	0.329*
Change from Day 0 to Day 28	-0.22 ± 1.86 (25) -0.2 (-5.4 – 3.2) p = 0.646*	-0.64 ± 1.14 (14) -0.85 (-2.5 – 1.4) p = **0.043***	0.309*
Change from Day 0 to Day 56	-0.98 ± 2.03 (25) -0.9 (-6.8 – 1.8) p = **0.025***	-1.78 ± 1.50 (14) -1.85 (-4.1 – 0.9) p = **0.001***	0.145*
Change from Day 0 to Day 85	-1.11 ± 2.71 (25) -1 (-8.3 – 4.2) p = 0.055*	-1.81 ± 2.52 (14) -1.75 (-5.6 – 1.8) p = **0.026***	0.444*

Kg, kilogram; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
* Logarithmic transformation required to achieve normality
Probability values P ≤ 0.05 are statistically significant

Between groups, there were no significant differences in body weight.

Within group, participants in the YYC!™ group consistently and significantly decreased weight by 0.8% or 0.64 kg at day 28 (p = 0.043), 2.2% or 1.78 kg (p = 0.001) at day 56 and 2.2% or 1.81 kg (p = 0.026) at day 85 from baseline. Participants in the MAHA Diet group significantly decreased their body weight by 1.1% or 0.98 kg (p = 0.025) at day 56, and though not significant by 0.2% or 0.22 kg at day 28, and 1.3% or 1.11 kg (p = 0.055) at day 85 from baseline.

10.7.2 Subgroup: Participants with One or less Product Compliance Issues

The population with 0-1 product compliance issues reflects all individuals who completed each study visit, maintained an overall diet compliance within 1200 to 1800 Calories/day, and had one or less monthly product compliance measurements less than 80% or greater than 120%.

Table 19: Change in Body Weight from Baseline to Day 28, Day 56, and Day 85 in Participants Who Attended all Visits, maintained an overall diet compliance within 1200 to 1800 Calories/day, and Had One or Less Monthly Product Compliance (N = 42).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Body Weight (kg)			
Day 0 Baseline	81.4 ± 15.1 (25) 76.4 (61.6 – 118.2)	85.3 ± 11.2 (17) 87.3 (62.2 – 100.9)	0.297*
Day 28	81.2 ± 14.5 (25) 76 (61.2 – 114.1)	84.4 ± 11.7 (17) 85.5 (61.2 – 102.3)	0.393*
Day 56	80.4 ± 14.3 (25) 75.9 (61.7 – 114.1)	83.6 ± 11.6 (17) 85 (62 – 101.4)	0.386*
Day 85	80.3 ± 14.9 (25) 75.5 (62.1 – 120.9)	83.5 ± 11.8 (17) 84.8 (63.2 – 102.3)	0.396*
Change from Day 0 to Day 28	-0.22 ± 1.86 (25) -0.2 (-5.4 – 3.2) p = 0.646*	-0.91 ± 1.32 (17) -0.9 (-4 – 1.4) p = **0.011***	0.111*
Change from Day 0 to Day 56	-0.98 ± 2.03 (25) -0.9 (-6.8 – 1.8) p = **0.025***	-1.65 ± 1.38 (17) -1.4 (-4.1 – 0.9) p < **0.001***	0.166*
Change from Day 0 to Day 85	-1.11 ± 2.71 (25) -1 (-8.3 – 4.2) p = 0.055*	-1.82 ± 2.47 (17) -1.8 (-5.6 – 1.8) p = **0.012***	0.399*

Kg, kilogram; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
* Logarithmic transformation required to achieve normality
Probability values P ≤ 0.05 are statistically significant

Between groups, there were no significant differences in body weight.

Within group, participants in the YYC!™ group consistently and significantly decreased weight by 1.2% or 0.91 kg (p = 0.011) at day 28, 2.0% or 1.65 kg (p < 0.001) at day 56 and 2.2% or 1.82 kg (p = 0.012) at day 85 from baseline. Participants in the MAHA Diet group significantly decreased their body weight by 1.1% or 0.98 kg (p = 0.025) at day 56, and though not significant by 0.2% or 0.22 kg at day 28, and 1.3% or 1.11 kg (p = 0.055) at day 85 from baseline.

10.7.3 Subgroup: Participants with two or less Product Compliance Issues

The per protocol population reflects all individuals who completed each study visit, maintained an overall diet compliance within 1200 to 1800 Calories/day and, had 2 or less monthly product compliance measurements less than 80% or greater than 120%.

Table 20: Change in Body Weight from Baseline at Day 28, Day 56, and Day 85 in Participants Who Attended all Visits, maintained an overall diet compliance within 1200 to 1800 Calories/day, and Had Two or Less Monthly Product Compliance (N = 42).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Body Weight (kg)			
Day 0 Baseline	81.4 ± 15.1 (25) 76.4 (61.6 – 118.2)	85.9 ± 11.8 (19) 87.3 (62.2 – 106.1)	0.232*
Day 28	81.2 ± 14.5 (25) 76 (61.2 – 114.1)	85.0 ± 12.2 (19) 85.5 (61.2 – 104.5)	0.311*
Day 56	80.4 ± 14.3 (25) 75.9 (61.7 – 114.1)	84.3 ± 12.0 (19) 85 (62 – 103.6)	0.300*
Day 85	80.3 ± 14.9 (25) 75.5 (62.1 – 120.9)	84.1 ± 12.2 (19) 84.8 (63.2 – 103.2)	0.305*
Change from Day 0 to Day 28	-0.22 ± 1.86 (25) -0.2 (-5.4 – 3.2) p = 0.646*	-0.89 ± 1.27 (19) -0.9 (-4 – 1.4) p = **0.006***	0.108*
Change from Day 0 to Day 56	-0.98 ± 2.03 (25) -0.9 (-6.8 – 1.8) p = **0.025***	-1.61 ± 1.37 (19) -1.4 (-4.1 – 0.9) p < **0.001***	0.188*
Change from Day 0 to Day 85	-1.11 ± 2.71 (25) -1 (-8.3 – 4.2) p = 0.055*	-1.75 ± 2.40 (19) -1.8 (-5.6 – 1.8) p = **0.009***	0.448*

Kg, kilogram; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired t-test.
* Logarithmic transformation required to achieve normality
Probability values P ≤ 0.05 are statistically significant

Between groups, there were no significant differences in body weight., though there was a trend towards significant difference at day 28 (p = 0.108).

Within group, participants in the participants in the YYC!™ group consistently and significantly decreased weight by 1.1% or 0.89 kg (p = 0.006) at day 28, 1.9% or 1.61 kg (p < 0.001) at day 56 and 2.1% or 1.75 kg (p = 0.009) at day 85 from baseline. Participants in the MAHA Diet group significantly decreased their body weight by 1.1% or 0.98 kg (p = 0.025) at day 56, and though not significant by 0.2% or 0.22 kg at day 28, and 1.3% or 1.11 kg (p = 0.055) at day 85 from baseline.

10.8 EFFICACY SUMMARY

The efficacy of the intervention, measured through the analysis of the Completer population demonstrated that the YYC!™ meal replacement significantly reduced body weight at all time points that it was assessed. Participants in the YYC!™ group were able to gradually and consistently lose weight and particularly in the first month, where the difference between YYC!™ and MAHA Diet plans was a significant 0.92 kg. This was achieved by the participants through minimal physical activity indicating that YYC!™ assisted in reducing calories strictly through the provision of essential nutrients as a complementary approach to replacing any two of the three daily meals. On the contrary, participants in the MAHA Diet group showed a statistically inconsistent reduction in body weight throughout the study.

This was also reflected in the reduction in BMI which was consistent and significant in the participants who adopted the YYC!™ meal replacement plan compared to those who followed the MAHA Diet plan at day 28. Reduction in waist circumference was statistically significant at all time points assessed in participants in the YYC!™ group.

Though YYC!™ meal replacement and MAHA Diet reduced hip circumference in participants at all time points assessed, the decrease was not statistically significant. However, a better indicator of health would be a decrease in the waist to hip circumference ratio which was significant in participants in the YYC!™ meal replacement plan at day 56 and at day 85 relative to baseline. Participants who adopted the MAHA Diet, showed a statistically significant reduction only at day 85 Nevertheless, there were no between-group differences in waist to hip circumference ratio.

To assess body fat mass through anthropological measures, a convenient approach is the measurement of thigh and arm circumference. Both groups showed significant decrease in thigh circumference at day 85 compared to the baseline. However, participants in the YYC! group showed a consistent and significant reduction in thigh circumference throughout the study compared to baseline. Reduction in arm circumference was significant at all time points assessed in participants who either adopted the MAHA Diet or the YYC!™ meal replacement, but lacked between-group significance differences.

Since a waist to height ratio of 0.5 is considered optimal and higher values indicate greater health risks, a reduction in waist to height ratio is a desirable outcome. Participants in the YYC!™ and MAHA Diet groups significantly reduced their waist to height ratio at all time points assessed, with participants in the YYC!™ group showing a consistent and significant decrease compared to the MAHA Diet group, indicating a better health outcome in participants in the YYC!™ group.

As the demographics of the participants in the study indicate the inclusion of an overweight and mildly obese population, the association of body weight loss to the consumption of YYC!™ meal replacement, would be incomplete without an assessment of systolic and diastolic blood pressure, particularly in a study design where the participants indulge in minimal physical activity. This assessment revealed that there a trend towards significant difference in systolic blood pressure at day 28 between participants who incorporated the YYC!™ meal replacement plan and those on the MAHA Diet plan.

A significant between-group difference in decrease in diastolic blood pressure observed at days 28 and 56 and significant within-group decrease in YYC!™ group compared to baseline at day 28 was an important finding that needs to be investigated. Participants in the MAHA Diet group, however, showed a significant and unfavorable increase in diastolic blood pressure which was sustained until the end of the study. The YYC!™ meal replacement was effective at shifting the cardiovascular risk profile of the participants early in the study.

Efficacy analysis based on product compliance was performed to compensate for the difficulty of performing diet-based. Three different circumstances were employed to carry out this analysis.

The first subgroup comprised all participants who attended all visits and had two or less monthly product compliance measurements less than 80% or greater than 120% and maintained an overall diet compliance within 1200 to 1800 Calories /day. Nineteen participants in the YYC!™ group and 25 in the MAHA Diet groups were found to meet the requirements for this analysis.

There was no significant between-group difference in the change in body weight. Following 85 days on the YYC!™ meal replacement, participants lost an average of 1.75 kg, a 2.1% reduction in body weight vs. an average of 1.11 kg, a reduction of 1.3% body weight, in those on the MAHA Diet.

Within groups, significant weight reductions occurred at days 28 ($p = 0.006$), 56 ($p < 0.001$), and 85 ($p = 0.009$) for participants on the YYC!™ meal replacement while participants on the MAHA Diet showed a decrease in weight only at day 56 ($p = 0.025$) when compared to baseline.

The second subgroup comprised all participants who attended all visits and had one or less monthly product compliance measurements less than 80% or greater than 120% and maintained an overall diet compliance within 1200 to 1800 Calories/day. Seventeen participants in the YYC!™ group and 25 in the MAHA Diet group qualified for this analysis.

There was no significant between-group difference in the change in body weight between those on the YYC!™ meal replacement and MAHA Diet. Following 85 days on the YYC!™ meal replacement, participants lost an average of 1.82 kg, a 2.2% reduction in body weight vs. an average loss of 1.11 kg, a reduction of 1.3% body weight, following 85 days on the MAHA Diet.

Within groups, significant weight reductions were measured at days 28 ($p = 0.011$), 56 ($p < 0.001$) and 85 ($p = 0.012$) for participants on the YYC!™ meal replacement but only at day 56 ($p = 0.025$) for the participants on the MAHA Diet when compared to baseline.

The third subgroup comprised all participants who attended all visits and had zero monthly product compliance measurements less than 80% or greater than 120% and maintained an overall diet compliance within 1200 to 1800 Calories/day. Fourteen participants in the YYC!™ group and 25 participants in the MAHA Diet group qualified for this analysis.

There was no significant between-group difference in the change in body weight. Following 85 days on the YYC!™ meal replacement, participants lost an average of 1.81 kg, a 2.2% reduction in body weight, vs. 1.11 kg, a reduction of 1.3% body weight on the MAHA Diet.

Within groups, significant weight reductions were measured at days 28 ($p = 0.043$), 56 ($p = 0.001$) and 85 ($p = 0.026$) for participants on the YYC!™ meal replacement but only at day 56 ($p = 0.025$) for the participants on the MAHA Diet when compared to baseline. The MAHA Diet groups showed a trend towards significant weight loss at day 85 ($p = 0.055$).

In summary, exclusion of participants based on their product and calorie consumption compliance decreased the number of participants in each group. This decrease combined with the high standard variation possibly accounts for the loss in between-group significance.

These findings indicate an efficacy of YYC!™ meal replacement in mediating weight loss in overweight and mildly obese individuals as well as improving diastolic blood pressure which is a marker of cardiovascular risk.

11. SAFETY EVALUATION – SAFETY POPULATION

11.1 EXTENT OF EXPOSURE

Participants either consumed either the YYC!™ meal replacement or adopted the MAHA Diet for 85 days starting the day after baseline/randomization visit.

11.2 ADVERSE EVENTS

The Medical Dictionary for Regulatory Activities terminology (MedDRA) was designed for sharing regulatory information of human medical products. In this study, adverse events were coded with MedDRA version 17.0.

All AEs reported using the study, categorized by MedDRA System Organ Class (SOC) can be found in Table 21.

A total of 17 AEs was recorded in this study, with 11 unique participants experiencing these events. All AEs were classified as 'mild' or 'moderate'.

Table 21: **All Adverse Events Reported During the Study**

Site ID-Participant Number	Group	Preferred Term	System Organ Class	Intensity	Relationship to Diet	Action Taken	Date of Onset	Onset Days from Baseline	Date of Resolution
CAL-014	YYC!™ Meal	Constipation	Gastrointestinal disorders	Mild	Unlikely	Other	10/17/2016	39	Unknown
CAL-014	YYC!™ Meal	Back pain	Musculoskeletal and connective tissue disorders	Moderate	Not related	Concomitant medication or therapy	9/28/2016	20	Unknown
CAL-036	YYC!™ Meal	Nasopharyngitis	Infections and infestations	Mild	Not related	None	11/3/2016	55	11/7/2016
CAL-037	MAHA Diet	Nasopharyngitis	Infections and infestations	Mild	Not related	None	10/9/2016	30	10/13/2016
CAL-039	YYC!™ Meal	Diarrhea	Gastrointestinal disorders	Mild	Possible	None	9/12/2016	0	12/6/2016
CAL-042	YYC!™ Meal	Constipation	Gastrointestinal disorders	Moderate	Possible	None	12/2/2016	80	12/8/2016
CAL-042	YYC!™ Meal	Constipation	Gastrointestinal disorders	Mild	Possible	None	10/4/2016	21	12/8/2016
CAL-042	YYC!™ Meal	Diarrhea	Gastrointestinal disorders	Mild	Unlikely	None	9/13/2016	0	9/27/2016
CAL-042	YYC!™ Meal	Back pain	Musculoskeletal and connective tissue disorders	Moderate	Unlikely	Concomitant medication or therapy	12/3/2016	81	12/15/2016
CAL-050	YYC!™ Meal	Headache	Nervous system disorders	Mild	Possible	None	9/17/2016	1	9/18/2016
ORL-010	YYC!™ Meal	Hyperlipidemia	Metabolism and nutrition disorders	Moderate	Unlikely	Test article discontinued	9/23/2016	20	12/5/2016

Table 21 Continued: All Adverse Events Reported During the Study

Site ID - Participant Number	Group	Preferred Term	System Organ Class	Intensity	Relationship to Diet	Action Taken	Date of Onset	Onset Days from Baseline	Date of Resolution
ORL-034	MAHA Diet	Nasopharyngitis	Infections and infestations	Mild	Unlikely	None	11/13/2016	61	11/14/2016
ORL-040	YYC!™ Meal	Accident	Injury, poisoning and procedural complications	Mild	Not related	None	12/1/2016	79	12/15/2016
ORL-041	MAHA Diet	Accident	Injury, poisoning and procedural complications	Mild	Not related	None	12/1/2016	79	12/15/2016
ORL-048	YYC!™ Meal	Abdominal distension	Gastrointestinal disorders	Mild	Possible	None	12/4/2016	81	12/5/2016
ORL-048	YYC!™ Meal	Abdominal distension	Gastrointestinal disorders	Mild	Probable	None	11/8/2016	55	11/9/2016
ORL-048	YYC!™ Meal	Constipation	Gastrointestinal disorders	Mild	Possible	None	11/29/2016	76	11/30/2016

Table 22: Total Number of AEs and Number of Participants Experiencing At least One AE Separated by System Organ Class Category

	MAHA Diet N=35		YYC!™ Meal N=35	
	Number of AEs	Participants Experiencing AEs	Number of AEs	Participants Experiencing AEs
	n	n (%)	n	n (%)
Gastrointestinal disorders	0	0 (0%)	8	4 (11.4%)
Infections and infestations	2	2 (5.7%)	1	1 (2.9%)
Injury, poisoning and procedural complications	1	1 (2.9%)	1	1 (2.9%)
Metabolism and nutrition disorders	0	0 (0%)	1	1 (2.9%)
Musculoskeletal and connective tissue disorders	0	0 (0%)	2	2 (5.7%)
Nervous system disorders	0	0 (0%)	1	1 (2.9%)
Participants Experiencing At Least One Adverse Event	3	3 (8.6%)	14	8 (22.9%)

n, number.

σ Between group comparisons were made using the Fisher's Exact test.
Probability values $P \leq 0.05$ are statistically significant.

Table 23: Total Number of AEs and Number of Participants Experiencing At least One AE where the AEs were Considered to be Possibly or Probably Related to the Product Separated by System Organ Class Category

	MAHA Diet N=35		YYC!™ Meal N=35	
	Number of AEs	Participants Experiencing AEs	Number of AEs	Participants Experiencing AEs
	n	n (%)	n	n (%)
Gastrointestinal disorders	0	0 (0%)	6	3 (8.6%)
Nervous system disorders	0	0 (0%)	1	1 (2.9%)
Participants Experiencing at Least One Adverse Event	0	0 (0%)	7	4 (11.4%)

n, number.

Seventeen AEs were reported by 11 participants in this study. Of these, 14 AEs were reported during the YYC!™ meal replacement, and three were by participants on the MAHA Diet.

Of the 14 AEs reported by the YYC!™ group, six were assessed as possibly related to the meal replacement. These AEs were diarrhea, constipation, headache, and bloating reported by four participants. One AE, bloating was assessed as most probably related to the meal replacement. All other AEs were assessed as unrelated or unlikely to the study meals. There were no AEs assessed as related to the MAHA Diet.

All AEs in the YYC!™ group were resolved by the end of the study.

11.3 DEATHS, SERIOUS ADVERSE EVENTS, AND SIGNIFICANT ADVERSE EVENTS

Table 24: **All Serious Adverse Events Reported During the Study**

Site ID - Participant Number	Group	Preferred Term	System Organ Class	Intensity	Relationship to Diet	Action Taken	Date of Onset	Onset Days from Baseline	Date of Resolution
CAL-015	MAHA Diet	Hospitalization	Surgical and medical procedures	Severe	Not related	Hospitalization	10/4/2016	25	10/6/2016
ORL-021	YYC!™ Meal	Pregnancy	Pregnancy, puerperium and perinatal conditions	Unknown	Not related	Other	11/16/2016	64	Unknown

Table 25: Total Number of SAEs and Number of Participants Experiencing At least One SAE Separated by System Organ Class Category

	MAHA Diet N=35		YYC!™ Meal N=35	
	Number of AEs	Participants Experiencing AEs	Number of AEs	Participants Experiencing AEs
	n	n (%)	n	n (%)
Pregnancy, puerperium and perinatal conditions	0	0 (0%)	1	1 (2.9%)
Surgical and medical procedures	1	1 (2.9%)	0	0 (0%)
Participants Experiencing At Least One Adverse Event	1	1 (2.9%)	1	1 (2.9%)

n, number.

σ Between group comparisons were made using the Fisher's Exact test.
Probability values $P \leq 0.05$ are statistically significant.

There were two serious adverse events in this study that were not related to the YYC!™ meal replacement or the MAHA Diet. One participant in the MAHA Diet group required hospitalization on account of a sunflower seed getting lodged in the back of throat. One participant in the YYC!™ group became pregnant during the study and was terminated early with reports being filed with IRB and follow-up action initiated.

11.4 CLINICAL LABORATORY EVALUATION

11.4.1 Hematology and Clinical Chemistry

Table 26: Change in Haematology and Clinical Chemistry Parameters from Screening to Day 85 of All Enrolled Participants (N = 70).

	MAHA Diet Mean ± SD (n) Median (Min – Max) Within Group P Value	YYC!™ Meal Mean ± SD (n) Median (Min – Max) Within Group P Value	P Value
Hemoglobin Concentration (g/L)			
Screening	135.4 ± 14.8 (35) 134 (100 – 172)	139.6 ± 13.4 (35) 140 (100 – 174)	0.221 §
Day 85 End of Study	138.9 ± 14.7 (27) 135 (110 – 170)	140.0 ± 12.5 (23) 139 (109 – 165)	0.768 §
Change from Screening to Day 85	2.1 ± 5.8 (27) 2 (-11 – 12) p = 0.073	1.7 ± 7.1 (23) 2 (-14 – 14) p = 0.265	0.836 §
Hematocrit (L/L)			
Screening	0.409 ± 0.038 (35) 0.405 (0.319 – 0.49)	0.418 ± 0.037 (35) 0.419 (0.31 – 0.516)	0.355 §
Day 85 End of Study	0.418 ± 0.038 (27) 0.414 (0.346 – 0.501)	0.420 ± 0.034 (23) 0.42 (0.344 – 0.48)	0.822 §
Change from Screening to Day 85	0.0067 ± 0.0187 (27) 0.011 (-0.039 – 0.034) p = 0.076	0.0060 ± 0.0210 (23) 0.01 (-0.042 – 0.053) p = 0.181	0.912 §
White Blood Cell Count (x E9/L)			
Screening	6.46 ± 1.60 (35) 6.6 (3.5 – 9.8)	7.04 ± 1.93 (35) 7 (2.8 – 13.3)	0.178 §
Day 85 End of Study	6.69 ± 1.73 (27) 7 (2.7 – 10.2)	6.51 ± 2.04 (23) 6.3 (3.6 – 12.1)	0.732 §
Change from Screening to Day 85	0.37 ± 1.48 (27) 0.5 (-3 – 4.3) p = 0.199	-0.19 ± 1.22 (23) -0.2 (-2.5 – 2.9) p = 0.462	0.151 §
Red Blood Cell Count (x E12/L)			
Screening	4.66 ± 0.46 (35) 4.51 (3.98 – 5.68)	4.69 ± 0.44 (35) 4.72 (3.43 – 5.52)	0.798 §
Day 85 End of Study	4.75 ± 0.51 (27) 4.61 (4 – 5.77)	4.70 ± 0.37 (23) 4.71 (4.02 – 5.33)	0.699 §
Change from Screening to Day 85	0.069 ± 0.183 (27) 0.06 (-0.41 – 0.4) p = 0.061	0.079 ± 0.238 (23) 0.05 (-0.43 – 0.59) p = 0.126	0.870 §
Mean Corpuscular Volume (fL)			
Screening	88.1 ± 5.3 (35) 89 (76 – 98)	89.2 ± 3.6 (35) 90 (81 – 98)	0.294 §
Day 85 End of Study	88.3 ± 4.4 (27) 89 (80 – 96)	89.6 ± 2.9 (23) 90 (84 – 95)	0.262 §
Change from Screening to Day 85	0.04 ± 2.03 (27) 0 (-5 – 5) p = 0.925	-0.30 ± 1.74 (23) 0 (-4 – 3) p = 0.411	0.530 §
Mean Corpuscular Hemoglobin (pg)			
Screening	29.09 ± 2.08 (35) 29.4 (24.2 – 31.7)	29.78 ± 0.94 (35) 29.8 (27.9 – 31.5)	0.066* §
Day 85 End of Study	29.31 ± 1.73 (27) 29.5 (25.4 – 31.5)	29.80 ± 1.16 (23) 29.8 (27.1 – 31.9)	0.238* §
Change from Screening to Day 85	0.03 ± 0.36 (27) 0 (-0.7 – 0.7) p = 0.666*	-0.14 ± 0.61 (23) -0.1 (-2.1 – 0.7) p = 0.260*	0.210* §

Table 26 Continued: Change in Haematology and Clinical Chemistry Parameters from Screening to Day 85 of All Enrolled Participants (N = 70).

	MAHA Diet Mean ± SD (n) Median (Min – Max) Within Group P Value	YYC!™ Meal Mean ± SD (n) Median (Min – Max) Within Group P Value	P Value
Mean Corpuscular Hemoglobin Concentration (g/L)			
Screening	330.3 ± 10.7 (35) 330 (306 – 353)	334.2 ± 7.6 (35) 333 (320 – 350)	0.080 §
Day 85 End of Study	331.9 ± 7.9 (27) 331 (318 – 349)	333.0 ± 7.9 (23) 333 (316 – 344)	0.623 §
Change from Screening to Day 85	0.0 ± 7.5 (27) 0 (-16 – 19) p = 1.000	-0.8 ± 7.0 (23) -2 (-16 – 15) p = 0.579	0.692 §
Red Cell Distribution Width (%)			
Screening	13.98 ± 1.07 (35) 13.7 (12.7 – 17.4)	13.89 ± 0.70 (35) 13.9 (12.7 – 15.5)	0.732* §
Day 85 End of Study	13.91 ± 0.95 (27) 13.5 (12.6 – 16.8)	13.91 ± 0.99 (23) 13.7 (12.9 – 17.7)	0.985* §
Change from Screening to Day 85	0.01 ± 0.67 (27) -0.1 (-1.8 – 1.2) p = 0.890*	0.04 ± 0.62 (23) 0 (-1.1 – 2.2) p = 0.778*	0.924* §
Platelet Count (x E9/L)			
Screening	285 ± 57 (35) 282 (199 – 428)	273 ± 82 (35) 261 (162 – 588)	0.266* §
Day 85 End of Study	281 ± 58 (27) 283 (185 – 408)	270 ± 67 (23) 270 (148 – 412)	0.440* §
Change from Screening to Day 85	-2 ± 38 (27) 1 (-67 – 91) p = 0.666*	12 ± 32 (23) 12 (-77 – 75) p = 0.087*	0.131* §
Neutrophil Count (x E9/L)			
Screening	3.89 ± 1.25 (34) 3.6 (1.4 – 7.1)	4.24 ± 1.43 (34) 4.1 (1.6 – 7.9)	0.345* §
Day 85 End of Study	3.88 ± 1.25 (27) 4 (1.5 – 6.6)	3.83 ± 1.77 (23) 3.9 (1 – 9.5)	0.660* §
Change from Screening to Day 85	0.16 ± 1.18 (26) 0.35 (-2.9 – 2.7) p = 0.578*	-0.00 ± 1.12 (23) 0 (-2.3 – 2.7) p = 0.521*	0.397* §
Lymphocyte Count (x E9/L)			
Screening	2.00 ± 0.65 (34) 1.85 (0.8 – 3.5)	2.19 ± 0.65 (34) 2.1 (1.2 – 4.3)	0.159* §
Day 85 End of Study	2.09 ± 0.64 (27) 2.1 (0.8 – 3.3)	2.03 ± 0.46 (23) 2 (1.2 – 2.9)	0.925* §
Change from Screening to Day 85	0.09 ± 0.47 (26) 0 (-1.2 – 1.4) p = 0.303*	-0.17 ± 0.44 (23) 0 (-1.7 – 0.5) p = 0.060*	**0.041*** §
Monocyte Count (x E9/L)			
Screening	0.462 ± 0.128 (34) 0.45 (0.2 – 0.7)	0.541 ± 0.197 (34) 0.5 (0.3 – 1.2)	0.060* §
Day 85 End of Study	0.504 ± 0.106 (27) 0.5 (0.3 – 0.7)	0.470 ± 0.169 (23) 0.5 (0.3 – 0.9)	0.188* §
Change from Screening to Day 85	0.031 ± 0.116 (26) 0 (-0.2 – 0.3) p = 0.182*	-0.035 ± 0.119 (23) 0 (-0.3 – 0.2) p = 0.137*	**0.045*** §
Eosinophil Count (x E9/L)			
Screening	0.168 ± 0.109 (34) 0.1 (0 – 0.6)	0.147 ± 0.135 (34) 0.1 (0 – 0.7)	0.157†
Day 85 End of Study	0.178 ± 0.128 (27) 0.2 (0 – 0.6)	0.148 ± 0.104 (23) 0.1 (0 – 0.4)	0.370†
Change from Screening to Day 85	0.023 ± 0.121 (26) 0 (-0.2 – 0.4) p = 0.279‡	0.013 ± 0.081 (23) 0 (-0.1 – 0.2) p = 0.454‡	0.824†

Table 26 Continued: Change in Haematology and Clinical Chemistry Parameters from Screening to Day 85 of All Enrolled Participants (N = 70).

	MAHA Diet Mean ± SD (n) Median (Min – Max) Within Group P Value	YYC!™ Meal Mean ± SD (n) Median (Min – Max) Within Group P Value	P Value
Basophil Count (x E9/L)			
Screening	0.012 ± 0.033 (34) 0 (0 – 0.1)	0.021 ± 0.048 (34) 0 (0 – 0.2)	0.478†
Day 85 End of Study	0.019 ± 0.040 (27) 0 (0 – 0.1)	0.013 ± 0.034 (23) 0 (0 – 0.1)	0.613†
Change from Screening to Day 85	0.004 ± 0.045 (26) 0 (-0.1 – 0.1) p = 0.766‡	0.000 ± 0.000 (23) 0 (0 – 0) p = 0.999‡	0.675†
Creatinine Concentration (µmol/L)			
Screening	57.0 ± 9.8 (35) 54.1 (40.4 – 80.1)	64.1 ± 14.8 (35) 59.5 (41.2 – 102.9)	**0.022*** §
Day 85 End of Study	60.3 ± 11.7 (27) 58.7 (42.7 – 84.6)	66.1 ± 18.4 (23) 61.8 (41.2 – 110.6)	0.236* §
Change from Screening to Day 85	4.0 ± 8.9 (27) 3 (-9.9 – 22.9) p = **0.028***	0.8 ± 11.9 (23) 3.8 (-24.4 – 29) p = 0.787*	0.209* §
Sodium Concentration (mmol/L)			
Screening	141.34 ± 2.69 (35) 141 (137 – 149)	141.26 ± 3.01 (34) 140.5 (137 – 150)	0.910 §
Day 85 End of Study	140.48 ± 2.06 (27) 140 (137 – 144)	140.52 ± 2.23 (23) 140 (137 – 147)	0.947 §
Change from Screening to Day 85	-0.8 ± 3.0 (27) -1 (-8 – 4) p = 0.185	-0.7 ± 3.4 (23) 0 (-10 – 3) p = 0.361	0.889 §
Potassium Concentration (mmol/L)			
Screening	4.48 ± 0.34 (35) 4.5 (3.8 – 5.4)	4.40 ± 0.35 (34) 4.35 (3.7 – 5.1)	0.303 §
Day 85 End of Study	4.289 ± 0.269 (27) 4.3 (3.8 – 4.7)	4.209 ± 0.256 (23) 4.1 (3.9 – 5)	0.288 §
Change from Screening to Day 85	-0.16 ± 0.31 (27) -0.1 (-0.9 – 0.3) p = **0.010**	-0.13 ± 0.38 (23) -0.2 (-1 – 0.4) p = 0.125	0.705 §
Chloride Concentration (mmol/L)			
Screening	102.11 ± 1.97 (35) 102 (97 – 107)	101.41 ± 2.20 (34) 101 (97 – 106)	0.167 §
Day 85 End of Study	101.93 ± 2.48 (27) 102 (96 – 106)	101.30 ± 2.38 (23) 101 (98 – 108)	0.373 §
Change from Screening to Day 85	-0.07 ± 2.59 (27) 0 (-5 – 5) p = 0.883	0.22 ± 2.68 (23) 0 (-7 – 5) p = 0.701	0.698 §
Bilirubin Concentration (µmol/L)			
Screening	6.5 ± 4.5 (35) 6.8 (1.7 – 20.5)	7.4 ± 5.3 (35) 6.8 (1.7 – 30.8)	0.270* §
Day 85 End of Study	7.0 ± 4.0 (27) 5.1 (1.7 – 15.4)	9.5 ± 6.9 (23) 6.8 (1.7 – 34.2)	0.150* §
Change from Screening to Day 85	0.1 ± 2.6 (27) 0 (-6.8 – 6.8) p = 0.389*	1.3 ± 3.4 (23) 1.7 (-6.8 – 8.6) p = 0.212*	0.603* §
Aspartate Transaminase (U/L)			
Screening	20.7 ± 10.9 (35) 18 (9 – 74)	20.4 ± 5.4 (35) 20 (11 – 31)	0.691* §
Day 85 End of Study	17.6 ± 4.5 (27) 18 (10 – 29)	21.3 ± 11.2 (23) 19 (11 – 67)	0.121* §
Change from Screening to Day 85	-3.5 ± 11.0 (27) -1 (-54 – 6) p = 0.053*	0.9 ± 10.9 (23) -2 (-6 – 48) p = 0.976*	0.186* §

Table 26 Continued: Change in Haematology and Clinical Chemistry Parameters from Screening to Day 85 of All Enrolled Participants (N = 70).

	MAHA Diet Mean ± SD (n) Median (Min – Max) Within Group P Value	YYC!™ Meal Mean ± SD (n) Median (Min – Max) Within Group P Value	P Value
Alanine Transaminase (U/L)			
Screening	20.8 ± 13.6 (35) 16 (6 – 83)	23.3 ± 12.7 (35) 17 (7 – 53)	0.437* §
Day 85 End of Study	22.6 ± 10.9 (27) 22 (6 – 48)	22.0 ± 15.1 (23) 16 (8 – 68)	0.598* §
Change from Screening to Day 85	0.2 ± 10.1 (27) 1 (-35 – 21) p = 0.418*	-1.0 ± 13.3 (23) -1 (-34 – 41) p = 0.623*	0.380* §

E, scientific notation; fL, femtoliter; g, gram; L, liter; max, maximum; µmol, micromoles; mmol, millimoles; min, minimum; N, number; % percent; pg, picogram; SD, standard deviation; U, units.

§ Between group comparisons were made using the Independent Student t-test.
† Between group comparisons were made using the non-parametric Mann-Whitney U test.
δ Within group comparisons were made using the paired Student t-test.
‡ Within group comparisons were made using the signed-rank test.
* Logarithmic transformation was required to achieve normality.
Probability values $P \leq 0.05$ are statistically significant.

There were significant between group differences in the lymphocyte count at day 85 (p = 0.041) and in the monocyte count at day 85 (p = 0.045); specifically, the YYC!™ group showed a decrease in both lymphocyte and monocyte counts. At screening, there was a significant difference between groups in creatinine concentration with the YYC!™ group showing a higher concentration than those in the MAHA Diet group (p = 0.022).

There were no significant between group differences in all other hematology and clinical chemistry measures.

Within group, in the participants adopting MAHA Diet, compared to baseline, there was a significant increase in the creatinine concentration at day 85 (p = 0.028), decrease in potassium concentration at day 85 (p = 0.010).

There were not within group significance in the participants adopting YYC!™ Meal replacement diet.

11.5 VITALS, PHYSICAL FINDING AND OTHER OBSERVATION RELATED TO SAFETY

11.5.1 Vital Signs

Table 27: Change in Vital Signs from Baseline to Day 28, Day 56, Day 85 in the Safety Population (N = 70).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P Value
Mean Systolic Blood Pressure (mmHg)			
Day 0 Baseline	109.5 ± 13.8 (35) 109.3 (80.7 – 139)	110.4 ± 9.0 (35) 112.7 (90 – 124.7)	0.770 §
Day 28	112.6 ± 15.0 (31) 112.3 (84.7 – 145.3)	110.0 ± 12.0 (27) 109.7 (90.7 – 138.3)	0.464 §
Day 56	108.1 ± 11.9 (26) 107.2 (89.3 – 128.3)	110.2 ± 8.7 (24) 108.7 (94.7 – 128)	0.493 §
Day 85 End of Study	108.9 ± 13.7 (26) 109.8 (74.3 – 134.7)	108.1 ± 9.7 (22) 108.8 (88 – 126.7)	0.822 §
Change from Day 0 to Day 28	2.9 ± 9.6 (31) 2 (-15 – 29.3) p = 0.103	0.2 ± 11.8 (27) -2 (-16 – 41.3) p = 0.923	0.344 §
Change from Day 0 to Day 56	-1.0 ± 7.1 (26) -0.5 (-18 – 9.7) p = 0.468	-0.3 ± 8.3 (24) 1.2 (-17 – 15.3) p = 0.885	0.724 §
Change from Day 0 to Day 85	-0.2 ± 9.9 (26) 1.2 (-25.7 – 17.3) p = 0.907	-2.4 ± 8.1 (22) 0.3 (-19 – 12) p = 0.178	0.418 §
Mean Diastolic Blood Pressure (mmHg)			
Day 0 Baseline	79.8 ± 11.6 (35) 78.3 (59.3 – 110)	82.6 ± 7.3 (35) 83.7 (70 – 99.3)	0.232 §
Day 28	82.9 ± 13.9 (31) 82.3 (54.7 – 123.7)	80.9 ± 8.2 (27) 80.3 (65 – 96.7)	0.512 §
Day 56	81.9 ± 10.6 (26) 81 (63.3 – 104.7)	81.6 ± 7.3 (24) 81.5 (65.7 – 94.3)	0.905 §
Day 85 End of Study	81.2 ± 10.7 (26) 81.5 (59.7 – 100.3)	78.1 ± 7.8 (22) 79.3 (63.3 – 95)	0.263 §
Change from Day 0 to Day 28	2.6 ± 7.4 (31) 1.7 (-9 – 14.7) p = 0.055	-1.3 ± 8.0 (27) -1.3 (-12.7 – 23) p = 0.392	0.053 §
Change from Day 0 to Day 56	2.0 ± 4.8 (26) 1.7 (-5.7 – 13) p = **0.046**	-0.2 ± 6.1 (24) -2.2 (-11.3 – 12) p = 0.852	0.162 §
Change from Day 0 to Day 85	1.2 ± 6.3 (26) 0.8 (-9.7 – 16.3) p = 0.325	-3.8 ± 8.8 (22) -2.7 (-27.3 – 10.7) p = 0.053	**0.024** §
Mean Heart Rate (BPM)			
Day 0 Baseline	74.0 ± 10.5 (35) 73 (52.7 – 105.7)	73.9 ± 10.9 (35) 72 (50 – 96.3)	0.962 §
Day 28	76.1 ± 11.4 (31) 76 (47.7 – 101)	77.0 ± 11.1 (27) 76.3 (52 – 109.7)	0.762 §
Day 56	75.7 ± 9.9 (26) 76.2 (55.3 – 98.7)	73.1 ± 10.2 (24) 73.8 (49 – 92.3)	0.375 §
Day 85 End of Study	76.0 ± 12.2 (13) 72.7 (60.7 – 97.7)	71.4 ± 10.5 (11) 74 (53 – 82.3)	0.339 §
Change from Day 0 to Day 28	1.7 ± 10.3 (31) -0.3 (-12.3 – 33.3) p = 0.375	4.8 ± 11.7 (27) 2.7 (-12.3 – 44) p = **0.042**	0.279 §
Change from Day 0 to Day 56	1.4 ± 9.1 (26) -0.2 (-11.3 – 28.3) p = 0.436	0.3 ± 7.1 (24) -1 (-13.3 – 12.3) p = 0.834	0.635 §
Change from Day 0 to Day 85	0.3 ± 12.6 (13) -5 (-16.7 – 26.7) p = 0.943	0.2 ± 6.7 (11) 1 (-14 – 7.7) p = 0.918	0.992 §

BPM, beats per minute; max, maximum; mmHg, millimetres of mercury; m, meter; min, minimum; N, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
δ Within group comparisons were made using the paired Student t-test.
Probability values P ≤ 0.05 are statistically significant.

Between groups, there was a significant difference in mean diastolic blood pressure at day 85 (p = 0.024).

Within group, there was a significant increase in mean diastolic blood pressure at day 56 ($p = 0.046$) compared to baseline in participants in the MAHA Diet group.

There was a significant increase in heart rate in participants in the YYC!™ group at day 28 ($p = 0.042$), with one participant showing an outlier value of the three readings (79, 101 and 149 bpm) of heart rate taken at day 28.

11.6 SAFETY CONCLUSIONS

Hematology and Clinical Chemistry:

Though significant between group differences in blood count of lymphocytes ($p = 0.041$) and monocytes ($p = 0.045$) were observed at day 85 in the YYC!™ group. There were no significant between group differences in all other hematology and clinical chemistry measures.

Within group, in the participants adopting MAHA Diet, compared to baseline, there was a significant increase in the creatinine concentration at day 85 ($p = 0.028$), decrease in potassium concentration at day 85 ($p = 0.010$).

There were not within group significance in the participants adopting YYC!™ Meal replacement diet.

All hematology and clinical chemistry excursions were not of clinical relevance.

Vital Signs:

Between groups, there was a significant difference in mean diastolic blood pressure at day 85 ($p = 0.024$) with participants in the YYC!™ group decreasing their diastolic blood pressure. Participants in the MAHA Diet group showed a significant increase in mean diastolic blood pressure at day 56 ($p = 0.046$) from baseline.

There was a significant increase in heart rate in participants in the YYC!™ group at day 28 ($p = 0.042$), with one participant showing an outlier value of the three readings (79, 101 and 149 bpm) of heart rate taken at day 28.

Incidence of Adverse Events:

Seventeen AEs were reported by 11 participants in this study. Of these, 14 AEs were reported during the YYC!™ meal replacement, and three were by participants on the MAHA Diet.

Of the 14 AEs reported by the YYC!™ group, six were assessed as possibly related to the meal replacement. These AEs were diarrhea, constipation, headache, and bloating reported by three participants. One AE, bloating was assessed as most probably related to the YYC!™ meal replacement. There were no AEs assessed as related to the MAHA Diet. All other AEs were assessed as unrelated to the study meals.

All AEs in the YYC!™ group were resolved by the end of the study.

12. DISCUSSION AND OVERALL CONCLUSIONS

According to the World Health Organization, obesity has reached epidemic proportions globally and particularly in USA, where 36.5% of adults are currently considered obese [4]. Within the last four decades, prevalence of obesity in Canada and USA has risen by 10% and 12% respectively [8]. Obesity-related medical costs in the US has been estimated at over $147 billion with an average of $1429 more spent on obese individuals than those who are at normal weight [4]. Illnesses and health complications such as heart disease, diabetes, hypertension, joint disease, certain forms of cancer and psychosocial morbidity that arise from being overweight and obese [9] are currently estimated to be responsible for deaths of 2.8 million people annually [2] and are major socio-economic burdens. Therefore, strategies that aid in weight loss without the complications associated with conventional pharmacological management are in dire need.

Clinical studies show that minimal, sustained weight loss of 5-10% can reduce or eliminate obesity-related disorders. Weight loss regimens have resulted in significant reduction in body weight in participants but research indicates that nearly 50% of weight lost is regained within the following year [10, 11] with complete regain within 5 years [12]. Several variables, including genetic, environmental, psychological, and metabolic factors affect weight gain and loss in humans [13]. For example, ageing alone leads to an average weight gain of approximately 0.5 kg per year [10].

This calls for better dietary interventions including the use of energy-controlled, nutrient dense meal replacements, particularly as evidence shows better compliance when participants are provided with nutritionally balanced pre-packaged meals compared to those on a self-selected food plan [14]. The rationale behind a meal replacement strategy for weight loss studies is that providing pre-portioned meal replacements leads to changes in eating behavior and long-term weight loss, as meal replacements are satisfying, convenient and easy to incorporate into one's lifestyle resulting in significant improvements in health outcomes [14-17]. Meal replacements, in addition to offering greater weight loss than other diet plans, ensure adequate intake of essential nutrients and demonstrate higher satisfaction and lower drop-out rates [14]. Meal replacements are palatable, portion-controlled, require minimal preparation, and is a practical strategy that assists dieters who aim to navigate an obesogenic environment by providing a convenient alternative to oversized, high fat, empty calorie choices currently available [14].

The YYC!™ meal replacement contains a mixture of whey protein and medium chain triglycerides (MCT), in addition to vitamins and minerals. Whey protein is a complete protein in relation to their essential amino acid profile and an eight-week supplementation study showed significant reduction in waist circumference in obese women [18] and a 1.8 kg loss in body weight in overweight and obese adults [19]. MCTs have been demonstrated to enable weight loss in clinical studies. A meta-analysis of 13 trials showed that MCTs decreased body weight by 0.5 kg with no differences in lipid levels [20]. Further, a 26-week intervention study showed that a 29-ingredient multivitamin and mineral supplementation resulted in a weight loss of 3.6 kg compared to 0.2 kg in the placebo group, justifying the inclusion of vitamins and minerals in the YYC!™ meal replacement used in this study [21].

Weight loss strategies using meal replacements, as performed in this study, are supported by clinical studies where substitution of one meal or one snack per day with a meal replacement was associated with

significant long-term weight loss maintenance [15-17]. Compared to a reduced calorie diet, meal replacements have been shown to lead to significant short- and long-term weight loss [22]. A meta-analysis of low calorie diet of 1200-1600 Calories/day or partial meal replacements (PMR) showed significant weight loss in both groups, but the PMR group lost 7-8% of their body weight or 2.54 kg at the 3-month period and 2.43 kg at the one year time points whereas the control group lost only 3-7% of body weight. Further, in the PMR group, completers, defined as those who completed the study irrespective of their compliance, showed significant weight loss of 2.54 kg at 3 months and 2.63 kg at the one year time point [22], strengthening the need for evaluating meal replacements as a weight loss aid strategy.

The current multi-center, randomized, comparator-controlled, two-arm parallel study investigated the effectiveness of YYC!™ meal replacement product with minimum physical activity on weight loss in overweight and obese adults over a period of 85 days.

Participants were evenly matched for age, sex, BMI, and ethnicity, factors known to affect body weight and weight loss. Participants in the Completer population were between 20 - 64 years of age, had a BMI between 24.96 – 35.84 kg/m^2 and were 70% female. Eighty-three percent of participants were non-smokers, while 46% reported occasional alcohol use and 33% reported no use of alcohol. Compliance to the YYC!™ product was greater than 95%. Participants enrolled in this study met all required inclusion criteria and were deemed otherwise healthy as per their medical history, physical exam, liver and kidney function tests, and hematology and clinical chemistry tests. All participants were required to maintain a daily caloric intake at 1200 -1800 Calories as per their seven-day food records completed during screening. Though the protocol required at least 75% Hispanics and 75% females, due to difficulty in meeting this target, the study was followed through due to time constraints. Therefore, the enrolled population consisted of 43% Hispanic or Latino and 70% females.

This clinical trial compared a YYC!™ meal replacement paradigm with a Modified American Heart Association (MAHA) Diet to determine weight loss in a 12-week study. The established AHA diet was modified in this clinical trial to monitor the use of alcohol and calorie restriction to 1200 -1500 (± 20%) Calories/day which was not clearly specified in the AHA diet guidelines. The AHA diet has been previously demonstrated to reduce >5% body weight after six-months in obese, post-menopausal women [23].

Participants with 80% adherence to their diets are reported to be motivated and show greater weight loss over individuals with 50% adherence, with negative prognostic factors for long-term meal replacement use being higher BMI, depression and lower levels of physical activity[1], suggesting that that psychosocial factors can affect weight loss. Based on this concept, a completers group was analyzed in this study.

The Completer population in the YYC!™ group had a 0.32 kg reduction in body weight over that reported with the MAHA Diet plan after an 85 day meal replacement. All participants who completed the study on the YYC!™ meal replacement plan lost a significant 1.3% body weight within one month *vs.* MAHA diet. In comparison, participants who adopted the MAHA Diet took at least 2 months to show any significant decrease in body weight. Further, YYC!™ meal replacement enabled participants who were

on average categorized as obese, to reduce their BMI sufficiently, to qualify them being considered pre-obese at day 28, 56 and 85 of the study.

Weight loss studies are associated with a high variation between subjects and to achieve significance a greater sample size is required to accommodate for the high standard deviations in subjects. Therefore, it is noteworthy that even with a small sample size of 22 subjects, the YYC!™ meal replacement was successful in achieving significant weight loss vs. the MAHA Diet after 28 days of the intervention. While the weight loss was maintained at days 56 and 85 of the intervention when compared to baseline, there were no significant differences between the YYC!™ meal replacement and MAHA Diet at these days.

Despite the difficulty of complying with the MAHA Diet plan and the large number of protocol deviations associated with this study, 83% of the participants completed the study, similar or more than rates reported in other meal replacement studies [24, 25]. In order to factor in the challenges associated with compliance, an analysis of sub groups for compliance was performed, which showed a consistent decrease in body weight that was limited to the YYC!™ meal replacement plan. Following 85 days on the YYC!™ meal replacement, participants lost an average of 1.75 kg, a 2.2% reduction in body weight vs. an average of 1.11 kg, a reduction of 1.3% body weight in those on the MAHA Diet. Significant weight reductions were observed at all time points in participants who incorporated the YYC!™ meal replacement plan while participants on the MAHA Diet showed a significant decrease in weight only at day 56, when compared to baseline.

It was evident that exclusion of participants based on their product and calorie consumption compliance decreased the number of participants in each group. This decrease combined with the high standard variation possibly accounted for the loss of between-group significance.

An energy-restricted diet providing 200 - 250 Calories/day combined with a meal replacement product in obese individuals in 12-weeks showed significant weight loss of 11.3 ± 6.8% compared to 5.9% ± 5% in the control [16]. Others have also shown that an energy restricted diet of 120 -1500 Calories/day combined with a nutrient fortified liquid meal replacement of 75% of daily meals showed weight loss of 7.8 ± 0.5% compared to 1.5 ± 0.4% in the control [12]. The rationale behind imposing dietary energy intake limits is that for long-term weight loss maintenance, individuals with high BMI tend to achieve superior weight loss when energy intake is highly structured [1]. This was evident in 49-year old obese women with a BMI of 31.2 kg/m^2 who showed significant weight loss when supplemented with energy-restricted modified diet with or without meal replacement in a 12-week open label study [26]. Though there were no significant between group differences and energy intake was similar in both groups, meal replacement plans resulted in significant relative weight loss compared to the control. The meal replacement group comprised of 77% responder population who lost more than 5% body weight compared to 50% in the control. Sub group analysis of women in the meal replacement group showed that participants with waist circumference ≤ 88 cm showed significant weight loss compared to those with waist circumference > 88 cm at baseline [26].

In order to benchmark the weight loss achieved through YYC!™ meal replacement in comparison to that achieved through pharmaceutical approaches, administration of phentermine, which acts by suppressing

appetite, with a low-calorie diet (500 - 800 Calories/day), resulted in 5.4% weight loss at 12 weeks with 45.6% achieving ≥ 5% weight loss [27]. Nevertheless, pharmacotherapy has not shown increased traction in the US market for several reasons. Historical events such as the increase in pulmonary hypertension and development of valvular heart disease associated with 10-15% weight loss in 12 months achieved with fenfluramine treatment eroded public trust with regard to anti-obesity medications [28]. This, however, opens an avenue for growth of dietary supplements and nutraceuticals in achieving weight loss without the complications associated with pharmaceutical drugs.

Supplementation with YYC!™ meal replacement was safe and well tolerated throughout the study.

Strengths of the study include the high product compliance achieved despite the challenges associated with ensuring strict control over diet, product and calorie consumption. The use of DietMaster Pro software, a computer-based application designed to capture the calorie and compliance related to this study strengthened the computation of calorie intake and product compliance, which enhanced the validity of the findings. The DietMaster Pro software has the capability to collect and analyze total calories, all macro- and micro-nutrients. Use of DietMaster Pro in this study resulted in a fail rate of 0.35% compared to 0.75% observed with use of conventional three-day records to track missing food records.

The limitations of the trial include the inability to meet the targeted 75% Hispanic and 75% women population for the analysis, lack of compliance to caloric restriction, due to which several protocol deviations were recorded, reduction in the number of participants in each group due to withdrawal from the study and the lack of advanced measures to determine total body fat such as DEXA to determine the true effect of YYC!™ meal replacement on anthropometric changes.

Weight loss should not be taken in isolation in overweight and mildly obese individuals that form the demographics of this study, but should also encompass gains made in other health outcomes. Therefore, an exploratory analyses of vitals and waist to height ratio, indicators of cardiovascular disease risk, were performed to determine how YYC!™ affects these risk factors, similar to previous studies on meal replacements [26].

Systolic and diastolic blood pressure measurements reflect cardiovascular disease risk. Reduction in systolic BP with meal replacements has been reported previously in participants with a systolic BP ≥ 130 mmHg [26]. YYC!™ meal replacement significantly reduced diastolic blood pressure throughout the study. A 2-mmHg reduction in diastolic blood pressure is associated with a 17% decrease in prevalence of hypertension, 6% reduction in coronary heart disease and 15% reduction in stroke and transient ischemic attacks [29]. On the contrary, participants who adopted the MAHA Diet significantly increased their diastolic blood pressure, indicating that YYC!™ meal replacement has inherent properties to improve the cardiovascular risk profile.

These findings indicate that a sufficiently powered study involving overweight and mildly obese participants should be investigated in future studies to comprehensively determine the effects of YYC!™ meal replacement on cardiovascular risk factors. The safety and tolerability profile of YYC!™ meal

replacement in this clinical trial strengthens evidence for its use in healthy populations to address body weight loss.

In conclusion, despite the challenges of ensuring compliance to the recommended diet and that of the product, the significant weight loss at day 28, reduction in BMI and diastolic blood pressure achieved with minimum physical activity in the completer population in this study and use of the DietMaster Pro software with lower fail rate than traditional food records warrant further investigation in individuals who may be unable to or incapable of carrying out physical activities due to various medical and non-medical reasons.

13. RECOMMENDATION

Based on the results obtained from the present study, the following recommendations should be taken into consideration for future studies.

1. Larger sample sizes to accommodate for the high standard deviation that is associated with weight loss studies is certainly warranted based on the results of the current study.
2. To determine the effectiveness of YYC!™ meal replacement in mitigating high blood pressure, which is a cardiovascular risk factor is warranted.
3. Future studies evaluating the efficacy of YYC!™ meal replacement should consider examining lipid biomarkers associated with cardiovascular diseases by stratification of overweight and mildly obese individuals based on their Framingham Risk Scores.
4. The efficacy of YYC!™ meal replacement in a population of individuals with limited mobility and disabilities should be investigated as this clinical trial showed the efficacy of YYC!™ meal replacement in an overweight and mildly obese population with minimal physical activity.
5. It would be our recommendation that psychosocial predictors of poor adherence be factored in to help develop recommendations for evidence-based nutrition programs tailored for weight loss.
6. The effectiveness of YYC!™ meal replacement in free-living individuals without diet-control should also be investigated.

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15. SIGNATURES

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study

Medical Director:

Nicole Craven, M.D.
Medical Director
KGK Synergize Inc.

Date

Scientific Director: 

Mar 03, 2017

Malkanthi Evans, Ph.D.
Scientific Director
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Date

APPENDICES

16. APPENDICES

16.1 ANCOVA ANALYSIS

16.1.1 ANALYSIS OF THE ITT POPULATION

The ITT population consisted of all participants who received the YYC!™ meal or on the MAHA diet, and whom any post-randomization efficacy information was available.

16.1.1.1 Primary and Secondary Endpoint – Body Weight

A decrease in body weight is considered a desirable outcome of the study.

Table 28: Change in Body Weight from Baseline to Day 28, Day 56 and Day 85 in the ITT Population (N = 58).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Body Weight (kg)			
Day 0 Baseline	82.2 ± 14.0 (31) 76.8 (61.6 – 118.2)	88.1 ± 12.4 (27) 87.5 (62.2 – 110.9)	0.097 §
Day 28	82.0 ± 13.4 (31) 78.2 (61.2 – 114.1)	87.9 ± 12.3 (27) 88.7 (61.2 – 106.3)	0.087 §
Day 56	81.4 ± 13.3 (31) 77.3 (61.7 – 114.1)	87.3 ± 12.4 (27) 87.3 (62 – 110)	0.084 §
Day 85	81.3 ± 13.9 (31) 76.5 (62.1 – 120.9)	87.4 ± 12.8 (27) 87.3 (63.2 – 112.3)	0.089 §
Change from Day 0 to Day 28	-0.23 ± 1.84 (31) -0.2 (-5.4 – 3.2) p = 0.488	-0.20 ± 2.85 (27) -0.9 (-4.6 – 10.7) p = 0.719	0.667 Δ
Change from Day 0 to Day 56	-0.84 ± 2.01 (31) -0.9 (-6.8 – 2.2) p = **0.027**	-0.76 ± 3.52 (27) -1.1 (-10.1 – 10.7) p = 0.272	0.621 Δ
Change from Day 0 to Day 85	-0.9 ± 2.6 (31) -0.7 (-8.3 – 4.2) p = **0.050**	-0.7 ± 4.0 (27) -0.7 (-10.1 – 10.7) p = 0.341	0.718 Δ

Kg, kilogram; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Primary outcome was the change in body weight from baseline to day 85 between participants on the YYC!™ versus participants on the MAHA diet. Between group, There was no significant difference in body weight between participants on the YYC!™ versus participants on the MAHA diet in this study.

Within group, Participants in the YYC!™ group reduced their body weight by 0.9%

Figure 6) or 0.7 kg at day 85 but the decrease was not significant. Participants in the MAHA Diet group significantly decreased their body weight by 1.1% (

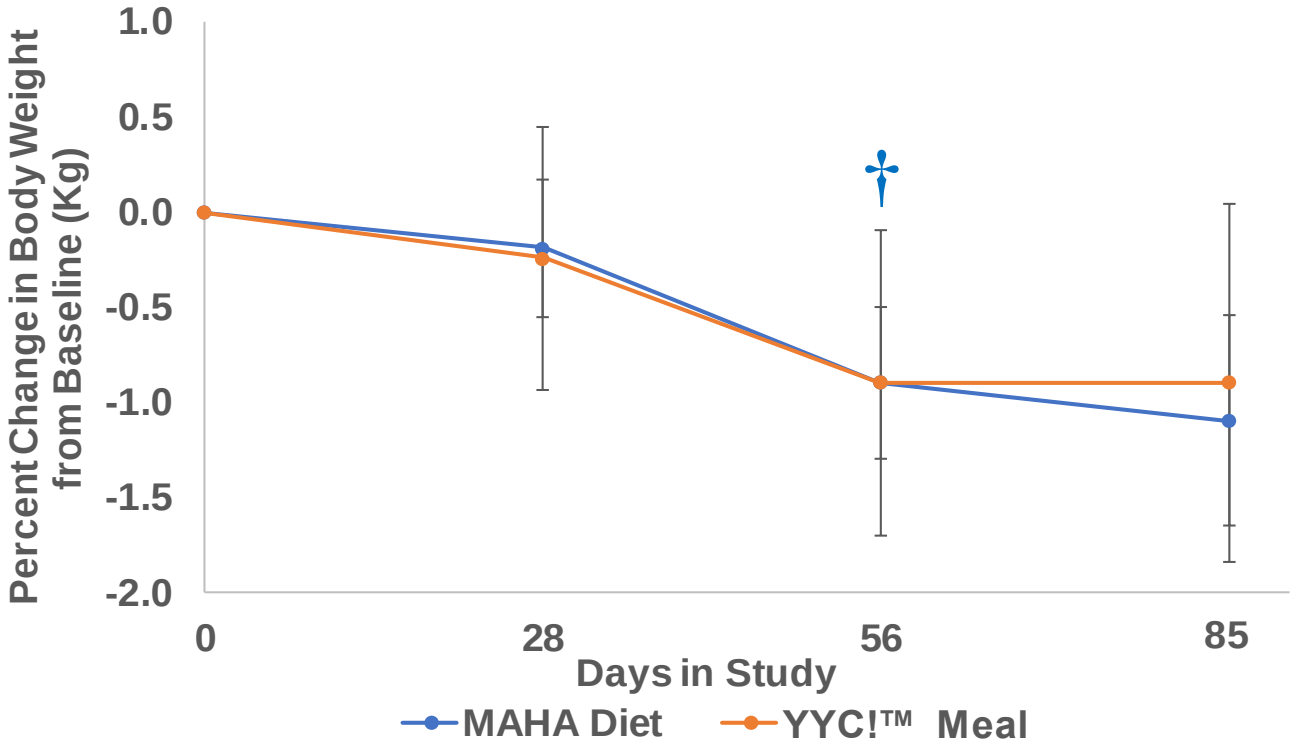
Figure 6) or 0.9 kg at day 85 (p = 0.050) from baseline.

The secondary outcome was the change in body weight from baseline to day 28 and day 56 between participants on the YYC!™ versus participants on the MAHA diet. Between groups, There was no significant difference in body weight between participants on the YYC!™ versus participants on the MAHA diet in this study.

Within group, Participants in the YYC!™ group reduced their body weight by 0.24% (Figure 6)

or 0.20 kg at day 28 and 0.9% (Figure 6) or 0.76 kg at day 56 but the decrease was not significant. Participants in the MAHA Diet group decreased their body weight by 0.19% (Figure 6) or 0.23 kg at day 28 and significantly by 0.9% (Figure 6) or 0.84 kg (p = 0.027) at day 56 from baseline.

Figure 6: Change in Body Weight from Baseline to Day 28, Day 56 and Day 84 in the ITT Population (N = 58).



† Significant within group mean difference in the MAHA Diet group (p = 0.027)

1.1.1.1 Secondary Endpoint - Body Mass Index

BMI uses an individual's height and weight to arrive at a value which categorizes individuals into normal, overweight and obese. A reduction in BMI is a desirable outcome of the study.

Table 29: Change in BMI from Baseline to Day 28, Day 56, and Day 85 in the ITT Population (N = 58).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Body Mass Index (kg/m^2)			
Day 0 Baseline	29.88 ± 2.86 (31) 29.91 (24.99 – 35.96)	30.44 ± 3.18 (27) 29.87 (24.6 – 35.8)	0.486 §
Day 28	29.81 ± 2.71 (31) 29.43 (24.83 – 34.72)	30.38 ± 3.27 (27) 29.65 (24.21 – 35.29)	0.474 §
Day 56	29.59 ± 2.73 (31) 29.52 (24.44 – 34.72)	30.17 ± 3.22 (27) 29.65 (24.52 – 35.51)	0.462 §
Day 85	29.5 ± 2.8 (31) 29.7 (24.8 – 34.7)	30.2 ± 3.4 (27) 29.8 (24.6 – 36.3)	0.434 §
Change from Day 0 to Day 28	-0.07 ± 0.64 (31) -0.08 (-1.65 – 1.31) p = 0.533	-0.06 ± 1.05 (27) -0.26 (-1.6 – 4.08) p = 0.762	0.866 Δ
Change from Day 0 to Day 56	-0.29 ± 0.67 (31) -0.31 (-2.08 – 0.78) p = **0.024**	-0.26 ± 1.28 (27) -0.35 (-3.58 – 4.08) p = 0.295	0.814 Δ
Change from Day 0 to Day 85	-0.35 ± 0.92 (31) -0.27 (-3.32 – 1.47) p = **0.045**	-0.26 ± 1.44 (27) -0.21 (-3.58 – 4.08) p = 0.359	0.717 Δ

Kg, kilogram; max, maximum; m, meter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Between groups, there were no significant differences in BMI.

Within group, participants in the YYC!™ group reduced their BMI by 0.06 kg/m^2 at day 28, 0.26 kg/m^2 at day 56 and 0.26 kg/m^2 at day 85 but the decrease was not significant. Participants in the MAHA Diet group significantly decreased their BMI by 0.29 kg/m^2 at day 56 (p = 0.024) and by 0.35 kg/m^2 at day 85 (p = 0.045) from baseline.

1.1.1.2 Secondary Endpoint - Waist Circumference

Waist circumference is an indicator of health risk associated with excess fat around the waist. A value of 102 cm or more in men or 88 cm or more in women is associated with health problems. Reduction in waist circumference is a desirable outcome of the study.

Table 30: **Change in Waist Circumference from Baseline to Day 28, Day 56, and Day 85 in the ITT Population (N = 58).**

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Waist Circumference (cm)			
Day 0 Baseline	97.2 ± 11.4 (31) 96 (77.5 – 114)	99.7 ± 11.1 (27) 99.4 (79.2 – 121)	0.394 §
Day 28	95.1 ± 10.4 (31) 95 (77.1 – 111)	99.2 ± 11.1 (27) 98.2 (78.7 – 120)	0.145 §
Day 56	94.4 ± 10.6 (31) 94 (76.5 – 111)	97.5 ± 11.1 (27) 95.8 (75.9 – 121)	0.273 §
Day 85	93.5 ± 10.6 (31) 92.7 (76.5 – 111)	97.1 ± 11.9 (27) 95.8 (75 – 121)	0.227 §
Change from Day 0 to Day 28	-2.1 ± 4.6 (31) -1 (-16 – 7.4) p = **0.017**	-0.5 ± 6.1 (27) -1.2 (-8 – 27) p = 0.694	0.138 Δ
Change from Day 0 to Day 56	-2.8 ± 4.8 (31) -2.9 (-16 – 7.4) p = **0.003**	-2.2 ± 7.0 (27) -3.5 (-9 – 27) p = 0.115	0.480 Δ
Change from Day 0 to Day 85	-3.7 ± 5.8 (31) -3.7 (-16.2 – 8.1) p = **0.001**	-2.6 ± 7.7 (27) -4.2 (-12 – 27) p = 0.087	0.377 Δ

cm, centimeter; max, maximum; m, meter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Between groups, there were no significant differences in waist circumference.

Within group, participants in the YYC!™ group reduced their waist circumference by 0.50 cm at day 28, 2.2 cm at day 56 and 2.6 cm at day 85 but the decrease was not significant, however the reduction at day 85 trended toward significances (p = 0.087). Participants in the MAHA Diet group significantly decreased their waist circumference by 2.1 cm at day 28 (p = 0.017), 2.8 cm at day 56 (p = 0.003) and 3.7 cm at day 85 (p = 0.001) from baseline.

1.1.1.3 Secondary Endpoint - Hip Circumference

Hip circumference is taken around the widest portion of the buttocks and a larger hip circumference for a given waist circumference and BMI is associated with reduced risk of disease.

Table 31: **Change in Hip Circumference from Baseline to Day 28, Day 56, and Day 85 in the ITT Population (N = 58).**

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Hip Circumference (cm)			
Day 0 Baseline	109.0 ± 8.4 (30) 108.5 (94.5 – 128.1)	109.4 ± 9.5 (27) 109.8 (88 – 127)	0.871 §
Day 28	107.5 ± 6.2 (31) 106.7 (94 – 123)	108.4 ± 8.9 (27) 108.2 (92 – 125)	0.636 §
Day 56	107.4 ± 7.8 (31) 107 (87 – 129.3)	108.1 ± 8.7 (27) 107.6 (90 – 123)	0.769 §
Day 85	108.1 ± 7.5 (31) 108 (88 – 127.5)	107.8 ± 9.2 (27) 109 (81 – 121)	0.916 §
Change from Day 0 to Day 28	-1.4 ± 5.8 (30) -0.6 (-21 – 8) p = 0.193	-1.0 ± 4.0 (27) -0.9 (-10.8 – 6.2) p = 0.223	0.630 Δ
Change from Day 0 to Day 56	-1.5 ± 5.7 (30) -0.8 (-21 – 10.5) p = 0.161	-1.3 ± 4.2 (27) -1.4 (-8.5 – 6.8) p = 0.106	0.855 Δ
Change from Day 0 to Day 85	-0.9 ± 5.4 (30) -0.5 (-21 – 8) p = 0.390	-1.6 ± 5.2 (27) -2 (-12 – 10) p = 0.128	0.635 Δ

Note: Hip circumference was measured in 30 participants at baseline and 31 participants at subsequent timepoints

cm, centimeter; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values $P \leq 0.05$ are statistically significant

Between groups, there were no significant differences in hip circumference.

Within group, Participants in the YYC!™ group and MAHA Diet group reduced their hip circumference at days 28, 56 and 85 from baseline but the decrease was not significant in both the groups.

1.1.1.4 Secondary Endpoint - Waist to Hip Circumference Ratio

Waist to Hip Circumference ratio is a measure of body fat distribution and is associated with obesity-related disease. For women > 0.85 and men, > 0.9 are associated with abdominal obesity. Reduction in Waist to Hip Circumference ratio is a desirable outcome of the study.

Table 32: Change in Waist to Hip Circumference Ratio from Baseline to Day 0, Day 28, Day 56, and Day 85 in the ITT Population (N = 58).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Waist to Hip Circumference Ratio			
Day 0 Baseline	0.892 ± 0.087 (30) 0.874 (0.753 – 1.075)	0.913 ± 0.083 (27) 0.909 (0.756 – 1.076)	0.357 §
Day 28	0.884 ± 0.082 (31) 0.872 (0.723 – 1.019)	0.916 ± 0.082 (27) 0.921 (0.784 – 1.117)	0.147 §
Day 56	0.879 ± 0.086 (31) 0.879 (0.723 – 1.029)	0.903 ± 0.081 (27) 0.904 (0.744 – 1.053)	0.282 §
Day 85	0.865 ± 0.080 (31) 0.862 (0.723 – 1.019)	0.901 ± 0.085 (27) 0.922 (0.762 – 1.054)	0.104 §
Change from Day 0 to Day 28	-0.009 ± 0.042 (30) -0.005 (-0.138 – 0.072) p = 0.265	0.003 ± 0.051 (27) 0.001 (-0.067 – 0.192) p = 0.742	0.188 Δ
Change from Day 0 to Day 56	-0.014 ± 0.043 (30) -0.009 (-0.138 – 0.06) p = 0.079	-0.010 ± 0.063 (27) -0.025 (-0.122 – 0.192) p = 0.425	0.505 Δ
Change from Day 0 to Day 85	-0.029 ± 0.048 (30) -0.022 (-0.138 – 0.072) p = **0.002**	-0.012 ± 0.070 (27) -0.022 (-0.166 – 0.192) p = 0.384	0.121 Δ

Note: Waist to hip circumference ratio was calculated in 30 participants at baseline and 31 participants at subsequent timepoints

max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Between groups, there were no significant differences in waist to hip circumference ratio.

Within group, Participants in the YYC!™ group reduced their waist to hip circumference ratio at day 56 and day 85 but the decrease was not significant. Participants in the MAHA Diet group significantly decreased their waist to hip circumference ratio at day 85 from baseline (p = 0.002) with non-significant decrease at days 28 and 56.

1.1.1.5 Secondary Endpoint - Thigh Circumference

Table 33: Change in Thigh Circumference from Baseline to Day 28, Day 56, and Day 85 in the ITT Population (N = 58).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Thigh Circumference (cm)			
Day 0 Baseline	52.8 ± 4.3 (31) 51.5 (44.5 – 63.5)	54.0 ± 5.9 (27) 53 (44.5 – 69.5)	0.374 §
Day 28	52.0 ± 4.6 (31) 51 (44.5 – 63.5)	52.0 ± 5.5 (27) 50.9 (42.6 – 67.5)	0.984 §
Day 56	50.7 ± 3.9 (31) 50.8 (42.5 – 58.5)	51.4 ± 4.3 (27) 50.5 (45 – 63.5)	0.475 §
Day 85	50.2 ± 4.3 (31) 49.2 (43.1 – 61.5)	51.1 ± 3.7 (27) 50.9 (42.9 – 59.1)	0.402 §
Change from Day 0 to Day 28	-0.8 ± 3.1 (31) -0.5 (-6.4 – 6.1) p = 0.187	-2.0 ± 3.2 (27) -1.2 (-10.1 – 2.3) p = **0.004**	0.248 Δ
Change from Day 0 to Day 56	-2.1 ± 4.8 (31) -1.2 (-19.5 – 6.1) p = **0.021**	-2.5 ± 4.2 (27) -1.1 (-14.5 – 2) p = **0.004**	0.783 Δ
Change from Day 0 to Day 85	-2.5 ± 5.2 (31) -2 (-17.5 – 6.1) p = **0.010**	-2.9 ± 4.6 (27) -1.6 (-17.5 – 3) p = **0.003**	0.627 Δ

max, maximum; cm, centimeter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Between groups, there were no significant differences in thigh circumference.

Within group, Participants in the YYC!™ group significantly reduced their thigh circumference by 2.0 cm at day 28 (p = 0.004), 2.5 cm at day 56 (p = 0.004) and 2.9 cm at day 85 (p = 0.003). Participants in the MAHA Diet group significantly decreased their thigh circumference by 2.1 cm at day 56 (p = 0.021) and 2.5 cm at day 85 (p = 0.010) from baseline.

1.1.1.6 Secondary Endpoint - Arm Circumference

Arm circumference correlates with BMI. A measure below 23.5 cm indicated that the person may be underweight with a BMI of 20 kg/m^2 or lower. An upper arm circumference of 32 cm indicates a BMI of 30 kg/m^2 or greater, indicating obesity. A reduction in arm circumference is a desirable outcome of the study.

Table 34: Change in Arm Circumference from Baseline to Day 28, Day 56, and Day 85 in the ITT Population (N = 58).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Arm Circumference (cm)			
Day 0 Baseline	31.88 ± 2.46 (31) 32 (27 – 37.88)	32.91 ± 3.09 (27) 32.95 (26.5 – 39.5)	0.160 §
Day 28	30.97 ± 2.47 (31) 30.82 (26.55 – 37)	32.29 ± 2.96 (27) 32.5 (26.48 – 37)	0.069 §
Day 56	30.67 ± 2.45 (31) 30.2 (26.5 – 37)	32.02 ± 2.93 (27) 31.93 (26.45 – 37)	0.060 §
Day 85	30.50 ± 2.53 (31) 30.5 (25 – 37)	32.13 ± 3.05 (27) 32 (26.05 – 37)	**0.031** §
Change from Day 0 to Day 28	-0.91 ± 2.03 (31) -0.9 (-7.25 – 4) p = **0.018**	-0.62 ± 2.23 (27) -0.5 (-4.25 – 7.8) p = 0.157	0.247 Δ
Change from Day 0 to Day 56	-1.21 ± 1.93 (31) -0.9 (-7.25 – 2.5) p = **0.002**	-0.89 ± 2.52 (27) -1.03 (-7 – 7.8) p = 0.077	0.211 Δ
Change from Day 0 to Day 85	-1.37 ± 2.02 (31) -0.98 (-7.25 – 3) p < **0.001**	-0.79 ± 2.62 (27) -0.73 (-7.5 – 7.8) p = 0.132	0.104 Δ

max, maximum; cm, centimeter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Between groups, there were no significant differences in arm circumference.

Within group, Participants in the YYC!™ group reduced their arm circumference at days 28, 56 and 85 but the decrease was not significant. Participants in the MAHA Diet group significantly decreased their arm circumference by 0.91 cm at day 28 (p = 0.018), 1.21 cm at day 56 (p = 0.002) and 1.37 cm at day 85 (p < 0.001) from baseline.

16.1.2 ANALYSIS OF THE PP POPULATION

The PP population consisted of all participants who consumed at least 80% of either product dose, did not have any major protocol violation, and completed all study visits and procedures connected with measurement of the primary variable.

16.1.2.1 Primary Endpoint – Change from Baseline in Participants' Body Weight at Day 85

A decrease in body weight is considered a desirable outcome of the study.

Table 35: Change in Body Weight from Baseline to Day 28, Day 56 and Day 85 in the PP Population (N = 46).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Body Weight (kg)			
Day 0 Baseline	82.0 ± 15.0 (26) 76.4 (61.6 – 118.2)	86.3 ± 11.7 (20) 87.4 (62.2 – 106.1)	0.294 §
Day 28	81.8 ± 14.5 (26) 76.3 (61.2 – 114.1)	85.4 ± 12.0 (20) 87.1 (61.2 – 104.5)	0.372 §
Day 56	81.0 ± 14.4 (26) 76 (61.7 – 114.1)	84.8 ± 11.9 (20) 85.7 (62 – 103.6)	0.345 §
Day 85	80.9 ± 15.0 (26) 75.7 (62.1 – 120.9)	84.8 ± 12.2 (20) 85 (63.2 – 103.2)	0.352 §
Change from Day 0 to Day 28	-0.18 ± 1.83 (26) -0.1 (-5.4 – 3.2) p = 0.619	-0.89 ± 1.24 (20) -0.9 (-4 – 1.4) p = **0.004**	0.203 Δ
Change from Day 0 to Day 56	-0.90 ± 2.03 (26) -0.9 (-6.8 – 1.8) p = **0.032**	-1.43 ± 1.55 (20) -1.4 (-4.1 – 1.9) p < **0.001**	0.474 Δ
Change from Day 0 to Day 85	-1.03 ± 2.68 (26) -0.85 (-8.3 – 4.2) p = 0.061	-1.48 ± 2.64 (20) -1.75 (-5.6 – 3.7) p = **0.021**	0.604 Δ

Kg, kilogram; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P ≤ 0.05 are statistically significant

Primary outcome was the change in body weight from baseline to day 85 between participants on the YYC!™ versus participants on the MAHA diet. Between group, There was no significant difference in body weight between participants on the YYC!™ versus participants on the MAHA diet in this study.

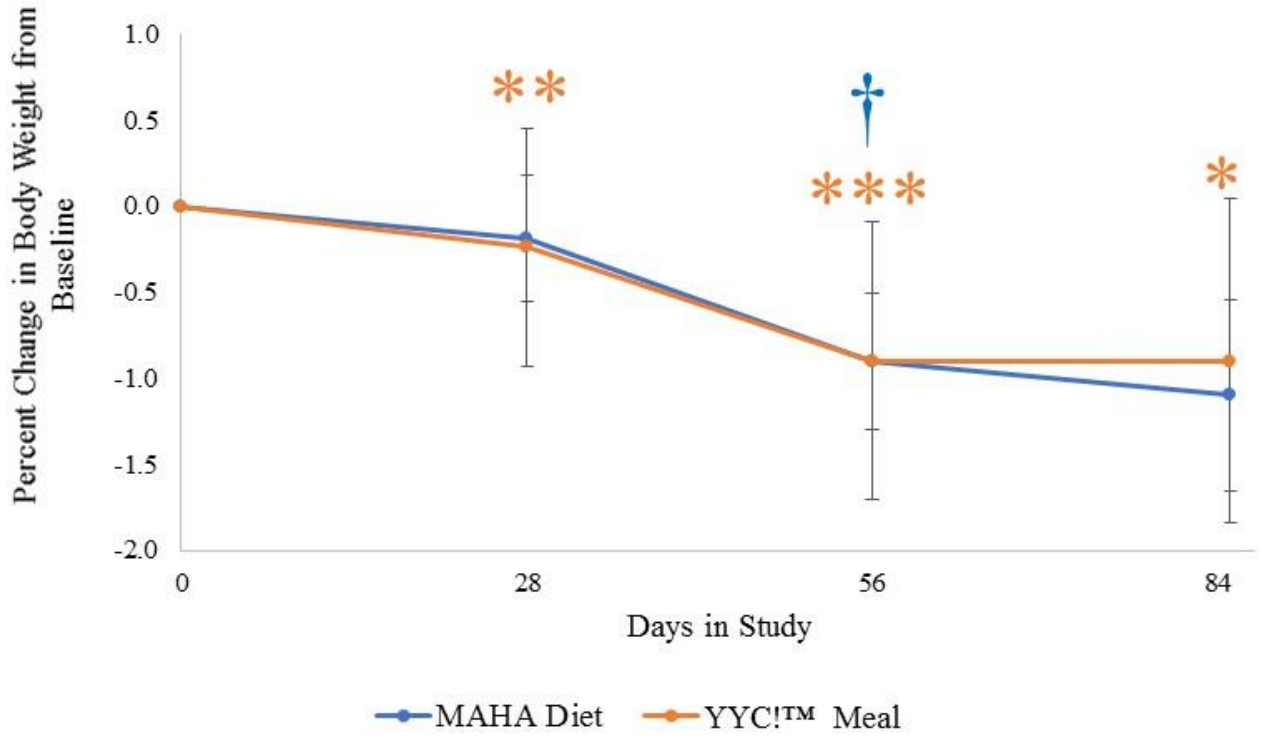
Within group, participants in the YYC!™ group significantly decreased body weight by 1.8% (Figure 7) or 1.48 kg at day 85 (p = 0.021) from baseline. Participants in the MAHA Diet group decreased their body

weight by 1.2% (Figure 7) or 1.03 kg at day 85 (p = 0.061) from baseline and the decrease was not significant.

The secondary outcome was the change in body weight from baseline to day 28 and day 56 between participants on the YYC!™ versus participants on the MAHA diet. Between groups, there were no significant differences in body weight.

Within group, participants in the YYC!™ group significantly decreased body weight by 1.10% (Figure 7) or 0.89 kg (p = 0.004) at day 28 and 1.72% (Figure 7) or 1.43 kg (p < 0.001) at day 56 from baseline. Participants in the MAHA Diet group significantly decreased their body weight by 0.99% (Figure 7) or 0.90 kg (p = 0.032) at day 56 from baseline but not at day 28.

Figure 7: Change in Body Weight from Baseline to Day 28 Day 56 and Day 85 in the PP Population (N = 46).



† Significant within group mean difference in the MAHA Diet group (p = 0.032)

* Significant within group mean difference in the YYC!™ group (p = 0.021)

** Significant within group mean difference in the YYC!™ group (p = 0.004)

*** Significant within group mean difference in the YYC!™ group (p < 0.001)

16.1.2.2 Secondary Endpoint - Body Mass Index

BMI uses an individual's height and weight to arrive at a value which categorizes individuals into normal, overweight, and obese. A reduction in BMI is a desirable outcome of the study.

Table 36: Change in Body Mass Index from Baseline to Day 28, Day 56, and Day 85 in the PP Population (N = 46).

	MAHA Diet Mean ± SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ± SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Body Mass Index (kg/m^2)			
Day 0 Baseline	29.39 ± 2.59 (26) 29.13 (24.99 – 35.2)	29.88 ± 2.92 (20) 29.82 (24.6 – 34.89)	0.550 §
Day 28	29.35 ± 2.56 (26) 29.09 (24.83 – 34.55)	29.56 ± 2.99 (20) 29.21 (24.21 – 34.99)	0.795 §
Day 56	29.09 ± 2.52 (26) 29.29 (24.44 – 34.38)	29.37 ± 2.97 (20) 29.45 (24.52 – 34.68)	0.731 §
Day 85	29.02 ± 2.63 (26) 29.2 (24.8 – 34.23)	29.36 ± 3.10 (20) 29.16 (24.58 – 34.99)	0.693 §
Change from Day 0 to Day 28	-0.05 ± 0.62 (26) -0.04 (-1.65 – 1.31) p = 0.714	-0.32 ± 0.46 (20) -0.3 (-1.6 – 0.48) p = **0.006**	0.116 Δ
Change from Day 0 to Day 56	-0.30 ± 0.66 (26) -0.34 (-2.08 – 0.6) p = **0.029**	-0.51 ± 0.56 (20) -0.49 (-1.66 – 0.59) p < **0.001**	0.299 Δ
Change from Day 0 to Day 85	-0.37 ± 0.95 (26) -0.28 (-3.32 – 1.47) p = 0.059	-0.53 ± 0.94 (20) -0.58 (-2.08 – 1.14) p = **0.022**	0.616 Δ

Kg, kilogram; max, maximum; m, meter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P ≤ 0.05 are statistically significant

Between groups, there were no significant differences in BMI.

Within group, participants in the YYC!™ group reduced their BMI by 0.32 kg/m^2 at day 28 (p = 0.006), 0.51 kg/m^2 at day 56 (p < 0.001) and 0.53 kg/m^2 at day 85 (p = 0.022). Participants in the MAHA Diet group significantly decreased their BMI by 0.30 kg/m^2 at day 56 (p = 0.029) from baseline. Reduction in BMI by 0.05 kg/m^2 at day 28 and 0.37 kg/m^2 at day 85 was not significant for the MAHA Diet group.

16.1.2.3 Secondary Endpoint - Waist Circumference

Waist circumference is an indicator of health risk associated with excess fat around the waist. A value of 102 cm or more in men or 88 cm or more in women is associated with health problems. Reduction in waist circumference is a desirable outcome of the study.

Table 37: Change in Waist Circumference from Baseline to Day 28, Day 56, and Day 85 in the PP Population (N = 46).

	MAHA Diet Mean ± SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ± SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Waist Circumference (cm)			
Day 0 Baseline	96.3 ± 11.9 (26) 95 (77.5 – 114)	97.9 ± 10.1 (20) 97.8 (79.2 – 117)	0.623 §
Day 28	95.2 ± 10.5 (26) 95 (77.1 – 111)	96.2 ± 10.2 (20) 94.8 (78.7 – 118)	0.756 §
Day 56	94.3 ± 10.6 (26) 94.5 (76.5 – 111)	93.8 ± 9.1 (20) 94.9 (75.9 – 110)	0.868 §
Day 85	93.3 ± 10.6 (26) 93.8 (76.5 – 111)	93.3 ± 10.4 (20) 93.1 (75 – 112)	0.991 §
Change from Day 0 to Day 28	-1.1 ± 3.3 (26) -0.5 (-7.8 – 7.4) p = 0.097	-1.8 ± 3.1 (20) -1.8 (-8 – 4) p = **0.017**	0.579 Δ
Change from Day 0 to Day 56	-2.0 ± 3.9 (26) -1.8 (-11 – 7.4) p = **0.017**	-4.1 ± 3.9 (20) -4.7 (-9 – 4.2) p < **0.001**	0.081 Δ
Change from Day 0 to Day 85	-3.0 ± 5.4 (26) -3 (-16.2 – 8.1) p = **0.008**	-4.6 ± 5.2 (20) -5.7 (-12 – 10) p < **0.001**	0.381 Δ

cm, centimeter; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Between groups, there were no significant differences in waist circumference.

Within group, participants in the YYC!™ group significantly reduced their waist circumference by 1.8 cm at day 28 (p = 0.017), 4.1 cm at day 56 (p < 0.001) and 4.6 cm at day 85 (p < 0.001). Participants in the MAHA Diet group significantly decreased their waist circumference by 2.0 cm at day 56 (p = 0.017) and 3.0 cm at day 85 (p = 0.008) from baseline.

16.1.2.4 Secondary Endpoint - Hip Circumference

Hip circumference is taken around the widest portion of the buttocks and a larger hip circumference for a given waist circumference and BMI is associated with reduced risk of disease.

Table 38: Change in Hip Circumference from baseline to Day 28, Day 56, and Day 85 in the PP Population (N = 46).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Hip Circumference (cm)			
Day 0 Baseline	107.6 ± 8.0 (25) 106 (94.5 – 128.1)	108.6 ± 10.1 (20) 109.4 (88 – 127)	0.712 §
Day 28	106.5 ± 6.0 (26) 106.2 (94 – 123)	107.6 ± 9.8 (20) 108 (92 – 125)	0.639 §
Day 56	106.4 ± 7.9 (26) 105 (87 – 129.3)	107.0 ± 9.4 (20) 104.5 (90 – 123)	0.809 §
Day 85	107.1 ± 7.6 (26) 105.8 (88 – 127.5)	106.6 ± 10.0 (20) 108 (81 – 121)	0.841 §
Change from Day 0 to Day 28	-1.0 ± 4.8 (25) -0.7 (-12.5 – 8) p = 0.306	-1.0 ± 3.6 (20) -0.9 (-10.8 – 5.6) p = 0.234	0.845 Δ
Change from Day 0 to Day 56	-1.1 ± 4.6 (25) -1 (-12 – 10.5) p = 0.245	-1.6 ± 3.8 (20) -1.7 (-7.5 – 6.8) p = 0.081	0.790 Δ
Change from Day 0 to Day 85	-0.3 ± 4.2 (25) -0.5 (-11.9 – 8) p = 0.680	-2.0 ± 5.2 (20) -2.6 (-12 – 10) p = 0.110	0.288 Δ

Note: Hip circumference was measured in 25 participants at baseline and 26 participants at subsequent timepoints

cm, centimeter; max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values $P \leq 0.05$ are statistically significant

Between groups, there were no significant differences in hip circumference.

Within group, participants in the YYC!™ group and MAHA Diet group reduced their hip circumference at days 28, 56 and 85 from baseline but the decrease was not significant in both the groups.

16.1.2.5 Secondary Endpoint - Waist to Hip Circumference Ratio

Waist to Hip Circumference ratio is a measure of body fat distribution and is associated with obesity-related disease. For women >0.85 and men, >0.9 are associated with abdominal obesity. Reduction in Waist to Hip Circumference ratio is a desirable outcome of the study.

Table 39: Change in Waist to Hip Circumference Ratio from Baseline to Day 28, Day 56, and Day 85 in the PP Population (N = 46).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Waist to Hip Circumference Ratio			
Day 0 Baseline	0.895 ± 0.092 (25) 0.889 (0.753 – 1.075)	0.905 ± 0.082 (20) 0.894 (0.79 – 1.076)	0.720 §
Day 28	0.894 ± 0.080 (26) 0.883 (0.762 – 1.019)	0.896 ± 0.082 (20) 0.889 (0.784 – 1.117)	0.919 §
Day 56	0.887 ± 0.085 (26) 0.882 (0.752 – 1.029)	0.879 ± 0.073 (20) 0.88 (0.744 – 1.025)	0.729 §
Day 85	0.871 ± 0.079 (26) 0.865 (0.74 – 1.019)	0.877 ± 0.080 (20) 0.858 (0.762 – 1.054)	0.782 §
Change from Day 0 to Day 28	-0.003 ± 0.034 (25) -0.004 (-0.063 – 0.072) p = 0.689	-0.009 ± 0.033 (20) 0.001 (-0.067 – 0.041) p = 0.253	0.639 Δ
Change from Day 0 to Day 56	-0.010 ± 0.037 (25) -0.007 (-0.108 – 0.06) p = 0.208	-0.026 ± 0.049 (20) -0.028 (-0.122 – 0.079) p = **0.030**	0.241 Δ
Change from Day 0 to Day 85	-0.027 ± 0.045 (25) -0.021 (-0.116 – 0.072) p = **0.006**	-0.027 ± 0.060 (20) -0.026 (-0.166 – 0.111) p = 0.058	0.863 Δ

Note: Waist to hip circumference ratio was calculated in 25 participants at baseline and 26 participants at subsequent timepoints

max, maximum; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Between groups, there were no significant differences in waist to hip circumference ratio.

Within group, participants in the YYC!™ group reduced their waist to hip circumference ratio at days 28 and 85, significantly reduced by 0.026 units at day 56 (p = 0.030) and trending toward a significant decrease on day 85 (p = 0.058). Participants in the MAHA Diet group significantly decreased their waist to hip circumference ratio at day 85 from baseline (p = 0.006).

16.1.2.6 Secondary Endpoint - Thigh Circumference

Table 40: Change in Thigh Circumference from Baseline to Day 28, Day 56, and Day 85 in the PP Population (N = 46).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Thigh Circumference (cm)			
Day 0 Baseline	52.6 ± 4.5 (26) 51.5 (44.5 – 63.5)	53.4 ± 6.2 (20) 52.5 (44.5 – 69.5)	0.614 §
Day 28	51.6 ± 4.5 (26) 51 (44.5 – 63.5)	52.0 ± 6.2 (20) 50.1 (42.6 – 67.5)	0.808 §
Day 56	50.0 ± 3.5 (26) 50.7 (42.5 – 55)	51.2 ± 4.8 (20) 49.9 (45 – 63.5)	0.339 §
Day 85	49.5 ± 3.9 (26) 48.7 (43.1 – 61.5)	50.6 ± 3.8 (20) 50.2 (42.9 – 59.1)	0.316 §
Change from Day 0 to Day 28	-1.05 ± 2.79 (26) -0.7 (-6.38 – 5) p = 0.068	-1.46 ± 2.88 (20) -0.81 (-9.5 – 2.3) p = **0.036**	0.718 Δ
Change from Day 0 to Day 56	-2.6 ± 4.7 (26) -1.5 (-19.5 – 3.1) p = **0.008**	-2.3 ± 4.3 (20) -0.9 (-14.5 – 2) p = **0.029**	0.422 Δ
Change from Day 0 to Day 85	-3.2 ± 5.1 (26) -2.2 (-17.5 – 5) p = **0.004**	-2.8 ± 4.9 (20) -1.9 (-17.5 – 3) p = **0.018**	0.390 Δ

max, maximum; cm, centimeter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Between groups, there were no significant differences in thigh circumference.

Within group, participants in the YYC!™ group significantly reduced their waist circumference by 1.46 cm at day 28 (p = 0.036), 2.3 cm at day 56 (p = 0.029) and 2.8 cm at day 85 (p = 0.018). Participants in the MAHA Diet group significantly decreased their thigh circumference by 2.6 cm at day 56 (p = 0.008) and 3.2 cm at day 85 (p = 0.004) from baseline.

16.1.2.7 Secondary Endpoint - Arm Circumference

Arm circumference correlates with BMI. A measure below 23.5 cm indicated that the person may be underweight with a BMI of 20 kg/m^2 or lower. An upper arm circumference of 32 cm indicates a BMI of 30 kg/m^2 or greater, indicating obesity. A reduction in arm circumference is a desirable outcome of the study.

Table 41: Change in Arm Circumference from Baseline to Day 28, Day 56, and Day 85 in the PP Population (N = 46).

	MAHA Diet Mean ±SD (n) Median (Min – Max) Within Group P Value δ	YYC!™ Meal Mean ±SD (n) Median (Min – Max) Within Group P Value δ	Between Group P-Value
Arm Circumference (cm)			
Day 0 Baseline	31.61 ± 2.39 (26) 31.38 (27 – 37.38)	32.61 ± 3.21 (20) 32.62 (26.5 – 39.5)	0.232 §
Day 28	30.71 ± 2.37 (26) 30.54 (26.55 – 34)	31.75 ± 3.03 (20) 32.09 (26.48 – 36.73)	0.197 §
Day 56	30.35 ± 2.30 (26) 30 (26.5 – 34)	31.37 ± 2.92 (20) 30.95 (26.45 – 36.8)	0.192 §
Day 85	30.15 ± 2.37 (26) 30.5 (25 – 34.5)	31.52 ± 3.08 (20) 31.16 (26.05 – 37)	0.096 §
Change from Day 0 to Day 28	-0.91 ± 2.17 (26) -0.92 (-7.25 – 4) p = **0.043**	-0.86 ± 1.46 (20) -0.76 (-4.25 – 1.12) p = **0.016**	0.565 Δ
Change from Day 0 to Day 56	-1.27 ± 2.05 (26) -0.89 (-7.25 – 2.5) p = **0.004**	-1.25 ± 1.92 (20) -0.91 (-7 – 1.5) p = **0.009**	0.532 Δ
Change from Day 0 to Day 85	-1.46 ± 2.15 (26) -1.3 (-7.25 – 3) p = **0.002**	-1.09 ± 2.11 (20) -0.7 (-7.5 – 2) p = **0.032**	0.252 Δ

max, maximum; cm, centimeter; min, minimum; N/n, number; SD, standard deviation.

§ Between group comparisons were made using the independent Student t-test.
Δ Between group comparisons were made using the ANCOVA F-test.
δ Within group comparisons were made using the paired t-test.
Probability values P≤0.05 are statistically significant

Between groups, there were no significant differences in arm circumference.

Within group, participants in the YYC!™ group significantly reduced their arm circumference by 0.86 cm at day 28 (p = 0.016), 1.25 cm at day 56 (p = 0.009) and 1.09 cm at day 85 (p = 0.032). Participants in the MAHA Diet group significantly decreased their arm circumference by 0.91 cm at day 28 (p = 0.043), 1.27 cm at day 56 (p = 0.004) and 1.46 cm at day 85 (p = 0.002) from baseline.

16.2 STUDY INFORMATION

16.2.1 Protocol and protocol amendments

The first participant was screened on August 17th 2016 after the protocol was amended and approved by IRB on August 15th 2016. Therefore, this study was conducted as per IRB approved protocol version 4 dated August 11th 2016.

Protocol 16MWHC A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults

CLINICAL PROTOCOL COVER PAGE

Protocol Title:	A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults
Protocol Number:	16MWHC
Protocol Date:	August 11, 2016
Version(s):	Version 4
Study Phase:	Phase II
Study Design:	Randomized, Comparator-Controlled, Parallel Study
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Qualified Investigator:	Nicole Craven, MD KGK Synergize Inc. 407-647-7311

List of Abbreviations

AE	adverse event
ALT	alanine transaminase
AST	aspartate aminotransferase
BMI	body mass index
°C	degree Celsius
CBC	complete blood count
CH	collagen hydrolysate
Cl	Chloride
Cm	Centimeter
EDTA	diaminoethanetetraacetic acid
e.g.	for example
et al	and others
G	Gram
GCP	Good Clinical Practice
i.e.	that means
Ibs	Pounds
ICH	International Conference of Harmonization
IEC	Independent Ethics Committee
IRB	Institutional Review Board
K	Potassium
Kg	Kilogram
L	Liter
M	Meter
Mg	Milligram
Ml	Milliliter
Na	Sodium
RBC	red blood cells
SAE	serious adverse event
SOP	standard operating procedure
SST	serum separating tube
TPD	Therapeutic Products Directorate
ULN	upper limit of normal

TABLE OF CONTENTS

1 INTRODUCTION

Obesity is a 21st century epidemic, with more than 1.9 billion adults classified as overweight, and of these 600 million classified as obese (World Health Organization). The United States has the highest obesity rates in the world (1) and two-thirds of its population is reported to be overweight and approximately 33% classified as being obese (1-3). Obesity exceeds 33% in both sexes in almost all age groups and ethnic groups in the United States (1).

Body mass index (BMI) is a calculation based on weight and height that differentiates between overweight and obese. A BMI between 25 and 29.9 is classified as overweight and a BMI equal or greater than 30 as obese (4). The risk of health problems start to occur when an individual is only slightly overweight and increase as more weight is accumulated. Due to the increase in health risks associated with weight gain, new BMI categories have been implemented. Previously, the overweight range was considered as BMI ≥ 25.0 kg/m^2. Currently, a BMI of 25.0 – 29.9 kg/m^2 is considered as pre-obese, BMI levels ≥ 30.0 kg/m^2 are labeled as *obese* and are further categorized into three levels of obesity; class I (*mildly obese*) 30.0 – 34.9 kg/m^2, class II (*moderately obese*) 35.0 – 39.9 kg/m^2 and class III (*morbidly obese*) ≥ 40.0 kg/m^2. A reduction in weight has a positive outcome on health; even a small reduction in weight (e.g. 5-10% weight loss) can result in a major decrease in the risk of cardiovascular disease and diabetes (5-7).

An imbalance between calories consumed and calories used is the underlying cause for abnormal excessive fat accumulation that is defined as overweight and obese. This abnormal excessive fat accumulation impairs the health of an individual. Over consumption of energy dense foods that are high in fat, in combination with a sedentary lifestyle promotes weight gain. This contributes to high prevalence of obesity in the United States. Engaging in physical activity as well as implementing healthy modifications to a diet will aid in balancing calories consumed and used, thereby helping with weight control. However, dietary habits are among the most difficult to modify, especially with a busy life style. Proper meal replacement shakes can help to replace unhealthy meal choices that may easily be incorporated as part of a busy life style.

The Yes You Can™ (YYC!) Meal replacement by Chaban Wellness LLC was designed to replace any of the three main meals in an individual's diet. This meal replacement gives a busy individual an easy low calorie meal substitution option that still provides all the appropriate protein, carbohydrates, fiber, and fats the body requires. Additionally, the YYC! meal replacement provides essential vitamins and minerals addressing the insufficiencies that may arise due to busy life styles. The YYC! Meal replacement allows for a healthy weight loss and maintenance process. The purpose of this 12-week clinical trial is to investigate the effectiveness of the YYC! meal replacement on weight loss in overweight and mildly obese participants.

2 STUDY OBJECTIVES

The objective of this study is to determine the effectiveness of YYC! meal replacement product with minimal physical activity on weight loss in overweight and mildly obese adults.

The primary efficacy outcome is the change in body weight from baseline to Day 85 between participants on YYC! meal replacement with minimal physical activity vs. participants on the Modified American Heart Association diet with minimal physical activity.

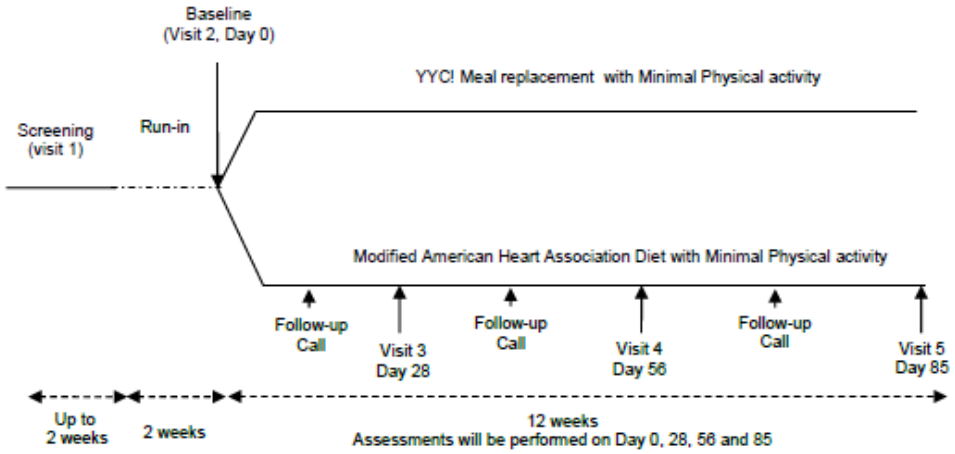
The secondary efficacy outcomes are as follows:

- Change in body weight from Baseline to Day 28 and Day 56 between participants on YYC! meal replacement with minimal physical activity vs. participants on the Modified American Heart Association diet with minimal physical activity.
- Change in body mass index (BMI) from Baseline to Day 28, Day 56 and Day 85 between participants on YYC! meal replacement with minimal physical activity vs. participants on the Modified American Heart Association diet with minimal physical activity.
- Change in waist circumference from Baseline to Day 28, Day 56 and Day 85 between participants on YYC! meal replacement with minimal physical activity vs. participants on the Modified American Heart Association diet with minimal physical activity.
- Change in hip circumference from Baseline to Day 28, Day 56 and Day 85 between participants on YYC! meal replacement with minimal physical activity vs. participants on the Modified American Heart Association diet with minimal physical activity.
- Change in waist to hip circumference ratio from Baseline to Day 28, Day 56 and Day 85 between participants on YYC! meal replacement with minimal physical activity vs. participants on the Modified American Heart Association diet with minimal physical activity.
- Change in thigh circumference from Baseline to Day 28, Day 56 and Day 85 between participants on YYC! meal replacement with minimal physical activity vs. participants on the Modified American Heart Association diet with minimal physical activity.
- Change in arm circumference from Baseline to Day 28, Day 56 and Day 85 between participants on YYC! meal replacement with minimal physical activity vs. participants on the Modified American Heart Association diet with minimal physical activity.

The safety and tolerability outcomes will be compared between participants on YYC! meal replacement with minimal physical activity and participants on the Modified American Heart Association diet with minimal physical activity:

- Clinically significant abnormal haematology and clinical chemistry values
- Clinically significant abnormal kidney and liver function values
- Clinically significant abnormal electrolyte values
- Clinically significant abnormal heart rate and blood pressure
- Incidence of adverse events over the course of the study by organ group

3 STUDY DESIGN



This is a multi-center, randomized, comparator-controlled, 2-arm parallel group study. This study will consist of a single 12 week study period.

The planned sample size for this study is 70 overweight and mildly obese adults. At least 75% of participants will be of Spanish or Hispanic descent and at least 75% of participants will be females.

Study Arm	Number of Participants
YYC! Meal Replacement with Minimal Physical Activity	N = 35
Modified American Heart Association diet.	N = 35
Total	**N = 70**

In order to evaluate primary and secondary objectives, study assessments will be conducted at Day 0 (baseline), Day 28, Day 56 and Day 85.

The study will be conducted at multiple-sites in the USA.

4 SELECTION OF STUDY POPULATION

Each participant will have to fulfill the inclusion criteria listed in Section 4.1. Participants will not be included in the study if they meet any of the exclusion criteria listed in Section 4.2.

4.1 Inclusion Criteria

1. Males and females 18-65 years (inclusive) of age
2. BMI of 25.0 kg/m²-34.9 kg/m² (±1.0 kg/m²)
3. If female, participant is not of child bearing potential, which is defined as females who have had a hysterectomy or oophorectomy, bilateral tubal ligation or are post-menopausal (natural or surgically with > 1 year since last menstruation)
   OR
   Females of childbearing potential must agree to use a medically approved method of birth control and have a negative urine pregnancy test result. Acceptable methods of birth control include:
   - Hormonal contraceptives including oral contraceptives, hormone birth control patch (Ortho Evra), vaginal contraceptive ring (NuvaRing), injectable contraceptives (Depo-Provera, Lunelle), or hormone implant (Norplant System)
   - Double-barrier method
   - Intrauterine devices
   - Non-heterosexual lifestyle or agrees to use contraception if planning on changing to heterosexual partner(s)
   - Vasectomy of partner (shown successful as per appropriate follow-up)
4. Stable weight defined as less than 5kg gained or lost in the past 3 months
5. Healthy as determined by laboratory results, medical history and physical exam
6. Plans not to change smoking habits during the study period
7. Agree to follow diet plan and physical activity of 35 min 3 to 5 times a week during the study
8. Has daily access to internet through the use of a computer, phone or tablet to enter food records online
9. Willingness to complete and comply with all study procedures, questionnaires, records, diaries and dietary restrictions associated with the study and to complete all clinic visits.
10. Has given voluntary, written, informed consent to participate in the study

4.2 Exclusion Criteria

1. Women who are pregnant, breastfeeding, or planning to become pregnant during the course of the trial
2. Use of prescription or over the counter products, programs or meal replacement product known to affect weight within 4 weeks of enrollment and during the trial
3. History of surgery for weight loss (including gastric bypass or lapband)
4. History or presence of clinically important renal, hepatic, endocrine, pulmonary, biliary or pancreatic disorders
5. Presence or history of neurological disorders or significant psychiatric illness.
6. Type I or Type II Diabetes
7. Any disorder associated with eating behaviour

8. History of or current diagnosis of any cancer (except for successfully treated basal cell carcinoma) diagnosed less than 5 years prior to screening. Cancer in full remission more than 5 years after diagnosis are acceptable
9. Alcohol abuse (>2 standard alcoholic drinks per day) or drug abuse within the past 6 months
10. Use of medicinal Marijuana
11. Use of antipsychotic drugs
12. Plan on donating blood during the study or within 30 days of completing the study
13. Known allergy or sensitivity to the test material's active or inactive ingredients
14. Unstable medical conditions
15. Clinically significant abnormal laboratory results at screening
16. Participation in a clinical research trial within 30 days prior to randomization
17. Cognitively impaired and/or unable to give informed consent
18. Any other condition which in the Qualified Investigator's opinion may adversely affect the Individual's ability to complete the study or its measures or which may pose significant risk to the individual

4.3 Concomitant Medications

Participants who are currently taking any prescribed medications must agree to maintain their current method and dosing regimen during the course of the study unless recommended by their physician. Birth Control is allowed during this study. Prescription or over the counter products, programs or meal replacement product, other than those provided, intended to alter body weight are prohibited within 4 weeks of randomization and during the study. Anti-psychotic drug and medicinal Marijuana are prohibited.

4.4 Early Withdrawal

There are no specific stop criteria formulated for this study. Participant discontinuation should be considered at the discretion of the Qualified Investigator. In case of an early withdrawal, no follow-up other than recovery of the investigational product and an attempt to perform laboratory safety tests will be done for the participants who decide to end their participation, except if the withdrawal was due to medical reasons related to the study. In this event, participants will be followed-up until recovery. If a participant withdraws from a study, information collected up until the withdrawal point can be used unless the participant requests otherwise. The circumstances of any discontinuation must be documented in detail. A participant leaving the study prematurely will NOT be replaced by another. Participants will be compensated for the part of the study that has been performed. Criteria for removal of participants from the study will include:

Personal reasons

As stated in the Informed Consent Form, a participant may withdraw from the study for any reason at any time.

Clinical reasons

A participant may be withdrawn from the study if, in the opinion of the Qualified Investigator, it is not in the participant's best interest to continue. Any participant who experiences a serious adverse event (SAE) may be withdrawn from the trial at the discretion of the Qualified Investigator. A participant will also be withdrawn due to adverse events causing clinically significant illness or the need for prohibited medication(s) during the trial. Any female participant who becomes pregnant during the course of the trial will be withdrawn.

Protocol violation

Any participant found to have entered this study in violation of the protocol will be discontinued from the study at the discretion of the Qualified Investigator. This will include any participant found to have been inappropriately enrolled (did not meet eligibility criteria). Participant non-compliance includes not showing up for study visits, not taking investigational product as directed, refusing to undergo study visit procedures, or not completing questionnaires. Participants who are found to be taking prohibited medications or supplements without the knowledge of the Qualified Investigator will be withdrawn at the discretion of the Qualified Investigator. Any major protocol deviations (i.e., those that increase the risk to participants and/or compromise the integrity of the study or its results) will result in participant discontinuation.

5 INVESTIGATIONAL PRODUCT

5.1 Manufacturing and Storage

The meal replacement will be provided to KGK by the sponsor. The meal replacement will be carefully stored at the study site in a lockable, limited access area, accessible only to study team personnel in compliance with pertinent regulations. Only authorized persons will have access to the meal replacement. The meal replacement will be stored at room temperature and will not be exposed to direct sunlight or heat, and not be exposed to extreme humidity. The meal replacement will be kept in a locked investigational product storage room at KGK Synergize Inc. on receipt. An accountability log will be kept for the meal replacement.

All unused investigational product will be returned to the study sponsor by KGK (at the sponsor's expense) or destroyed on receipt of written confirmation from the sponsor at study closeout (within one month of last participant visit).

Manufactured by:
Prinova USA
285 E. Fullerton Avenue
Carol Stream, IL 60188
USA

5.2 Investigational Product

Yes You Can Meal Replacement - Vanilla

Ingredients	Nutrition Facts
Protein Matrix (Whey Protein Concentrate, Micellar Casein), Corn Fiber, MCT Powder, Natural and Artificial Flavor, Vitamin Mineral Premix (Trimagnesium Citrate, Dipotassium Phosphate, Vitamin C (Ascorbic Acid), Ferrous Sufate, Vitamin E (Alpha-Tocopheryl acetate), Biotin, Vitamin A, Palmitate, Zinc Sulfate, Niacinamide, Vitamin B5 (Calcium Pantothenate), Copper Gluconate, Cyanobalamin, Vitamin B6 (Pyridoxine), Vitamin D3 (Cholecalciferol), Potassium Iodide, Vitamin B2 (Riboflavin), Vitamin B1 (Thiamine), Chromium Chloride, Vitamin B9 (Folic Acid)), Salt (Sodium Chloride), Xanthan Gum, Sucralose	**Nutrition Facts** Serving Size (49g) Servings Per Container **Amount Per Serving** **Calories** 200 — Calories from Fat 60 % Daily Value* **Total Fat** 7g — 11% Saturated Fat 5g — 25% Trans Fat 0g **Cholesterol** 130mg — 43% **Sodium** 300mg — 13% Total **Carbohydrate** 15g — 5% Dietary Fiber 7g — 28% Sugars 1g **Protein** 20g Vitamin A 50% • Vitamin C 50% Calcium 10% • Iron 50% Vitamin D 50% • Vitamin E 35% Thiamin 50% • Riboflavin 60% Niacin 50% • Vitamin B6 100% Folate 50% • Vitamin B12 500% Biotin 50% • Pantothenic Acid 50% Phosphorus 15% • Iodine 50% Magnesium 25% • Zinc 25% Copper 25% • Chromium 50% *Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: Calories: 2,000 2,500 Total Fat Less than 65g 80g Saturated Fat Less than 20g 25g Cholesterol Less than 300mg 300mg Sodium Less than 2,400mg 2,400mg Total Carbohydrate 300g 375g Dietary Fiber 25g 30g Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4

5.3 Directions

All participants will be instructed to maintain a 1500 caloric intake per day. Participants will be provided with healthy eating suggestions and a smart phone food diary app to help them achieve

and monitor their dietary caloric intake goals. Nutritionists will give dietary suggestions to participants if required. All participants will be instructed to participate in 35 minutes of light to moderate physical activity 3-5 times per week. They will be asked to record their physical activity in a weekly exercise questionnaire.

Participants randomized into the Yes You Can diet group will consume the meal replacement twice daily, substituting any 2 out of the 3 meals (i.e. breakfast, lunch, dinner) and the provided meal guide (Appendix 3). Participants will be instructed to mix one scoop of the meal replacement powder with 16oz (2 cups) of cold water. If the participant forgets to replace their meal, they are to replace the next meal with the meal replacement. Participants will be instructed not to replace more than 2 meals per day.

6 STUDY ASSESSMENTS

See Appendix 1 for the schedule of assessments and procedures.

6.1 Visit 1 – Screen (Day -28 to Day -14)

At screening, an Information and Consent Form will be given to the potential participant. The volunteer will read the information carefully and will be given the opportunity to seek more information if needed. The volunteer will also be provided with the option of taking the consent form home to review prior to making his or her decision. If agreeable, the volunteer will sign the consent form and receive a duplicate. Once consent has been obtained, the screening visit will proceed. Each volunteer will be assigned a screening number at the screening visit. After the volunteer has signed the informed consent, the screening number will be assigned sequentially and entered in the Screening and Enrollment Log. Screening numbers will be allocated in the chronological order of the volunteer's signing the informed consent.

Visit 1 includes:

- Review of medical history, concomitant therapies, inclusion and exclusion criteria
- Seated resting blood pressure, heart rate
- Weight and height measured (Weight will be measured with volunteers wearing a gown, shoes removed and empty bladder) and BMI calculated
- Blood sample will be collected for CBC, electrolytes (Na, K, Cl), HbA1c, creatinine, AST, ALT, and bilirubin measurements
- Urine pregnancy test if applicable (female of childbearing potential)

Eligible volunteers will begin 2-week run-in period. Eligible volunteers will be instructed to adopt a 1500 calorie per day diet based on healthy eating habit suggestions (Appendix 2).

Volunteers will be shown how and instructed to record their daily food record online. They will also be instructed to complete a daily study diary.

Volunteers will be instructed to participate in 35 minutes of light to moderate exercise 3-5 times per week. Volunteers will be given weekly exercise questionnaires and will be instructed to complete and return them with their next clinic visit.

6.2 Run-in Period (14 days):

During the run-in period volunteers will be instructed to target their dietary intake to 1500 calories per day, participate in 35 minutes of physical activity 3-5 times per week, complete daily online food records, study diary entries and weekly exercise questionnaires. Food diaries will be reviewed by a nutritionist to encourage compliance and provide suggestions.

Eligible volunteers will return to the clinic on a scheduled day in the morning after an overnight fast (12 hours with nothing to eat or drink except water), for baseline assessment.

6.3 Visit 2 – (Day 0, Baseline)

Eligible volunteers will return to the clinic after completing a two-week run-in period for randomization and baseline assessments. Baseline and subsequent visits will be scheduled at the same time of day, as practically possible, preferably in the morning. After all baseline assessments are performed, volunteers will be randomized into a study group via the Randomization Schedule provided to the Investigator.

Baseline assessments will include:

- Review of current conditions, concomitant therapies, inclusion and exclusion criteria
- Completed study diaries and questionnaires will be reviewed
- Urine pregnancy test if applicable (female of childbearing potential)
- Physical examination (excluding breast, rectal/vaginal examination)
- Fasting weight measurement (Weight will be measured with participants wearing a gown with shoes removed and an empty bladder)
- BMI calculated
- Fasting measurement of waist, hip, arm, and thigh circumference
- Seated resting blood pressure, heart rate measurement

Participants will be randomized to one of the two groups. All participants will be instructed to maintain their participation in 35 minutes of light to moderate physical activity 3-5 times per week and to maintain their dietary caloric intake of 1500 cal per day.

Participants will be instructed in detail by site personnel on the diet plans. Participants in the YYC! Diet plan will consume the meal replacement twice daily, substituting any 2 out of the 3 meals (i.e. breakfast, lunch, dinner). The participants will be provided with the YYC! Diet Plan (Appendix 3) and instructed on how to follow the Nutritional Guide. Participants will start the diet method they were randomized into the day after their baseline visit (day 1). Study diaries and exercise questionnaires will be dispensed and participants will be instructed to continue to complete daily online food records. Participants will be instructed to complete and return all diaries and questionnaires to their next clinic visit (Visit 3).

Meal replacement canisters will be weighed and supply of meal replacement: 2 canisters of YYC! will be dispensed to applicable participants and instructed on their use.

The next visit will be scheduled for day 28 at the same time of day as baseline visit. A Three-day window (±3 days) will be allowed for scheduling issues. Participants will return to the clinic in the morning after an overnight fast, for visit 3.

6.4 Follow-up Phone Call

Phone calls will be made to participants between baseline (visit 2) and visit 3 (Day 28) to foster compliance in the diet plan and exercise. Participants will be reminded to fast overnight (12 hours with nothing to eat or drink except water) prior to their clinic visit (visit 3)

6.5 Visit 3 – Week 4 (Day 28 ± 3)

Participants will return to the clinic after an overnight fast (12 hours with nothing to eat or drink except water) on day 28 (± 3 days). Any remaining meal replacement (if applicable) will be returned and compliance will be calculated by weighing the returned unused meal replacement. A new supply of meal replacement: 2 canisters of YYC! will be dispensed (to applicable participants). Study diaries and exercise questionnaires will be returned and reviewed for change in concomitant therapies, adverse events and compliance.

Study visit assessments will include:

- Review of current conditions, concomitant therapies, adverse event
- Review of study diaries and questionnaires
- Fasting weight measurement (Weight will be measured with participants wearing a gown with shows removed and an empty bladder)
- BMI calculated
- Fasting measurement of waist, hip, arm, and thigh circumference
- Seated resting blood pressure, heart rate measurement
- Participants on the YYC! Meal Replacement diet will return unused investigational product and new canisters will be dispensed

The next visit will be scheduled for day 56 at the same time of day as baseline visit. A Three-day window (±3 days) will be allowed for scheduling issues. Participants will return to the clinic in the morning after an overnight fast (12 hours with nothing to eat or drink except water), for visit 4.

6.6 Follow-up Phone Call

Phone calls will be made to participants between baseline (visit 2) and visit 4 (Day 56) to foster compliance in the diet plan and exercise. Participants will be reminded to fast overnight (12 hours with nothing to eat or drink except water) prior to their clinic visit (visit 4)

6.7 Visit 4 – Week 8 (Day 56 ± 3)

Participants will return to the clinic after an overnight fast (12 hours with nothing to eat or drink except water) on day 56 (± 3 days). Any remaining meal replacement (if applicable) will be returned and compliance will be calculated by weighing the returned unused meal replacement. A new supply of meal replacement: 2 canisters of YYC! will be dispensed (to applicable participants). Study diaries and questionnaires will be returned and reviewed for change in concomitant therapies, adverse events and compliance.

Study visit assessments will include:

- Review of current conditions, concomitant therapies, adverse event
- Review of study diaries and questionnaires

- Fasting weight measurement (Weight will be measured with participants wearing a gown with shows removed and an empty bladder)
- BMI calculated
- Fasting measurement of waist, hip, arm, and thigh circumference
- Seated resting blood pressure, heart rate measurement
- Participants on the YYC! Meal Replacement diet will return unused investigational product and new canisters will be dispensed

The next visit will be scheduled for day 85 at the same time of day as baseline visit. A Three-day window (±3 days) will be allowed for scheduling issues. Participants will return to the clinic in the morning after an overnight fast, for visit 5.

6.8 Follow-up Phone Call

Phone calls will be made to participants between visit 4 (Day 56) and visit 5 (Day 85, end of study) to foster compliance in diet plan and exercise. Participants will be reminded to fast overnight (12 hours with nothing to eat or drink except water) prior to their clinic visit (visit 5)

6.9 Visit 5 – Week 12 (Day 85 ± 3, End of Study)

Participants will return to the clinic after an overnight fast (12 hours with nothing to eat or drink except water) on day 56 (± 3 days). Any remaining meal replacement (if applicable) will be returned and compliance will be calculated by weighing returned unused meal replacement. Study diaries and questionnaires will be returned and reviewed for change in concomitant therapies, adverse events and compliance.

Study visit assessments will include:

- Review of current conditions, concomitant therapies, adverse event
- Review of study diaries and questionnaires
- Fasting weight measurement (Weight will be measured with participants wearing a gown with shows removed and an empty bladder)
- BMI calculated
- Fasting measurement of waist, hip, arm, and thigh circumference
- Seated resting blood pressure, heart rate measurement
- Participants on the YYC! Meal Replacement diet will return unused investigational product and new canisters will be dispensed
- Urine pregnancy test if applicable (female of childbearing potential)
- Blood sample will be collected for CBC, electrolytes (Na, K, Cl), creatinine, AST, ALT, and bilirubin measurements

6.10 Clinical Assessments and Procedures

6.10.1 Height, Weight

Weight measurements will be taken in the morning prior to participants' eating breakfast. Measurement of weight should be performed with the participant's in a clinical gown, shoes removed, and an empty bladder. Participants should be weighed on the same scale at all visits.

At least two separate measurements should be taken at each visit. If the two measurements are more than 0.5 kg (1.1 lbs) apart, a third measurement should be taken. Then the two closest values are going to be selected and entered in the database.

Measurement of height should be performed with the participant's shoes removed. The participant's knees should be straightened, and head held upright.

6.10.2 Circumference Measurements

Circumference measurements will be taken in the morning prior to participants' eating breakfast. The circumference of the left and right arm and left and right thigh will be measured and recorded.

6.10.2.1 Waist Circumference

The waist circumference is measured at the part of the trunk located midway between the lower costal margin (bottom of lower rib) and the iliac crest (top of pelvic bone) while the participant is standing. The measurer should stand beside the participant and fit the tape tightly against the skin but without compressing any underlying soft tissues. The circumference should be measured at the end of a normal expiration. At least two separate measurements should be taken at each visit. If the two measurements differ by more than 10% a third measurement should be taken. Then the two closest values are going to be selected and entered in the database.

6.10.2.2 Hip Circumference

While participant is standing upright, place a measuring tape around the greater trochanteric prominence (the widest part of the hips). Hold tape firmly but do not press the tape into the skin. Make sure the tape is parallel to the floor. Record the reading. At least two separate measurements should be taken at each visit. If the two measurements differ by more than 10% a third measurement should be taken. Then the two closest values are going to be selected and entered in the database.

6.10.2.3 Thigh Circumference

While participant is standing upright, place a measuring tape around the thigh, 20 cm up from the tibial tuberosity (the top of the tibia just below the patella) with the leg in full extension. Hold tape firmly but do not press the tape into the skin. Record the reading. At least two separate measurements should be taken at each visit. If the two measurements differ by more than 10% a third measurement should be taken. Then the two closest values are going to be selected and entered in the database. This will be done for the left thigh as well as the right thigh.

6.10.2.4 Arm Circumference

While participant is standing or seated, place a measuring tape around the upper arm, 10 cm up from the lateral epicondyle (elbow). Hold tape firmly but do not press the tape into the skin. Record the reading. At least two separate measurements should be taken at each visit. If the two measurements differ by more than 10% a third measurement should be taken. Then the two closest values are going to be selected and entered in the database. This will be done for the left arm as well as the right arm.

6.10.3 Blood Pressure

In office, seated resting blood pressure and heart rate will be determined from 3 measurements obtained at least 1 minute apart. One arm will be chosen and used consistently throughout the study. Blood pressure will be checked in both arms at the first examination. If a consistent inter-arm difference exists, the arm with the higher pressure will be used throughout the study. The arm selected for use at the initial visit will be documented in the study file.

The participant should be seated comfortably with the back supported and the upper arm bared without restrictive clothing. Feet should be flat on the floor, legs should not be crossed. The participant should rest in this position for at least 5 minutes prior to the first reading.

The same recording method and the same equipment should be used for each participant throughout the study.

6.10.4 Compliance

The meal replacement canister will be weighed prior to dispensing it to participant and weight will be recorded in the participant file (CRF). Compliance will be assessed by weighing the returned unused meal replacement at each visit. Meal replacement consumed will be, returned canister weight minus previous weight. Compliance is calculated by determining the weight of replacement consumed divided by the weight of meal replacement expected to have been consumed (weight per serving multiply by serving expected to be consumed) multiplied by 100.

$$\frac{weight\ of\ meal\ replacement\ consumed}{weght\ of\ meal\ replacement\ expected\ to\ have\ been\ consumed} \times 100\%$$

In the event of a discrepancy between the information in the participant diary and the amount of study product returned, use will be based on the product returned unless an explanation for loss of product has been provided. Participants found to have a compliance of <80% or >120% will be counseled.

Online food records will be reviewed to determine dietary compliance. Participants are counseled if they are not compliant to the dietary recommendation. A dietary caloric intake of 1500 calories ±20% will be considered compliant and participants must complete the daily online food diary a minimum of 3 times per week. Non-compliant participants will be counseled by a nutritionist and suggestions will be provided to encourage future compliance.

6.10.5 Online Food Records

Participants will be using an online food record, DietMaster Pro, to calculate their daily caloric intake. All participants will be provided with instructions on how to use the DietMaster Pro food diary. DietMaster Pro is an online portal where participants will enter foods and beverages (including meal replacements if applicable) into a log which is then analyzed by DietMaster Pro's online nutrition analysis software http://dietmastersoftware.com/products/professional-nutrition-software. Participants will use this tool to monitor their daily caloric intake. The food records will be regularly reviewed by nutritionists and participants will be counselled with dietary suggestions as required.

6.11 Laboratory Analysis

Blood samples will be drawn at Screening (Visit 1, -28 to Day -14) and at the End of Study visit (Visit 5, Day 85), as indicated in the Schedule of Assessments.

Additional blood samples may be collected during the course of the study in order to perform or repeat laboratory tests outlined in the Schedule of Assessments.

Protection of participant confidentiality will extend to all data generated from the assaying of these samples. These samples will be alphanumerically coded and the persons performing the analysis will not be aware of the participant's identity.

At screening (Visit 1, Day -28 to Day -14), 13mL whole blood will be collected in:

1. Two 4mL EDTA vacutainer tubes to generate plasma for:
    a. CBC analysis (1tube)
    b. HB1Ac analysis (1tube)
2. One 5ml SST vacutainer tube to generate serum for:
    a. Electrolytes (Na, K, Cl), creatinine, AST, ALT, and bilirubin analysis (1 tube)

At the end of the study (Visit 5, Day 85), 9mL whole blood will be collected in:

1. One 4mL EDTA vacutainer tubes to generate plasma for:
    a. CBC analysis (1tube)
2. One 5ml SST vacutainer tube to generate serum for:
    a. Electrolytes (Na, K, Cl), creatinine, AST, ALT, and bilirubin analysis (1 tube)

Central Medical Laboratory Services will be used in this study to measure laboratory parameters of safety.

Urine pregnancy test will be performed at the clinic site.

6.12 Termination of the Trial

In the case of complete premature termination of the trial, participating investigators/participants, and the Institutional Review Board must be promptly informed of the termination.

6.13 Protocol Amendments

Alterations of the protocol may be made as the study progresses. Such changes will be captured in writing and will document the reasons for the change and must be signed and dated by the sponsor. Any such amendments may be participant to IRB review/approval prior to implementation. Exception: if it becomes necessary to alter the protocol to eliminate an immediate hazard to patients, an amendment may be implemented prior to IRB approval. In this circumstance, however, the Investigator must then notify IRB in writing within five (5) working days after implementation.

7 Safety Instructions and Guidance

7.1 Adverse Events and Laboratory Abnormalities

7.1.1 Adverse Events

An adverse event (AE) is any untoward medical occurrence in a clinical investigation participant who has been administered an investigational product and which does not necessarily have a causal relationship with the product. An AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a product, whether or not it is considered related to that product. Pre-existing conditions which worsen during a study are to be reported as AEs.

During the study, participants should record any adverse effects in their diary. At each visit the participant will be asked "Have you experienced any difficulties or problems since I saw you last"? Any adverse events (AEs) will be documented and in the study record and will be classified according to the description, duration, intensity, frequency, and outcome. The investigator will assess any AEs and decide causality.

Intensity of AEs will be graded on a three-point scale (mild, moderate, severe) and reported in detail in the study record.

Mild:	Awareness of event but easily tolerated
Moderate:	Discomfort enough to cause some interference with usual activity
Severe:	Inability to carry out usual activity

The causality relationship of investigational product to the adverse event will be assessed by the investigator as either:

Most probable:	There is a reasonable relationship between the investigational product and AEs. The event responds to withdrawal of investigational product (dechallenge) and recurs with rechallenge when clinically feasible.
Probable:	There is a reasonable relationship between the investigational product and AEs. The event responds to dechallenge.
Possible:	There is a reasonable relationship between the investigational product and AEs. Dechallenge information is lacking or unclear.
Unlikely:	There is a temporal relationship to the investigational product administration but there is no reasonable causal relationship between the investigational product and the AEs.
Not related:	No temporal relationship to the investigational product administration or there is a reasonable causal relationship between non-investigational product, concurrent disease or circumstance and the AEs.

7.1.2 Serious Adverse Event

A serious adverse event (SAE) is any experience that suggests a significant hazard, contraindication, side effect or precaution. It is any AE that results in any of the following outcomes:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability or incapacity
- A congenital anomaly/birth defect in the offspring of a participant who received the study product
- Important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the participant or may require intervention to prevent one of the outcomes listed above. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalization; or the development of drug dependency or drug abuse.

7.1.3 Unexpected Adverse Reaction

An unexpected adverse reaction is an adverse reaction, the nature and severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).

7.1.4 Laboratory Test Abnormalities

The investigator must assess the clinical significance of all abnormal laboratory values as defined by the compendium of normal values for the reference laboratory.

Any treatment emergent abnormal laboratory result which is clinically significant, i.e., meeting one or more of the following conditions, should be recorded as a single diagnosis on the AEs form in the study record:

- Accompanied by clinical symptoms
- Leading to interruption or discontinuation of the investigational product
- Requiring a change in concomitant therapy

This applies to any protocol and non-protocol specified laboratory result from tests performed after the first dose of the investigational product, which falls outside the laboratory reference range and meets the clinical significance criteria for liver and kidney tests as well as for hematology and clinical chemistry.

This does not apply to any abnormal laboratory result which falls outside the laboratory reference range but which does not meet the clinical significance criteria or those which are a result of an AE which has already been reported.

Any laboratory result abnormality fulfilling the criteria for a serious adverse event (SAE) should be reported as such, in addition to being reported as an AE in the study record.

7.2 Treatment and Follow-up of AEs and Laboratory Abnormalities

7.2.1 Treatment and Follow-up of AEs

AEs, especially those for which the relationship to the investigational product is suspected, should be followed up until they have returned to baseline status or stabilized.

If after follow-up, return to baseline status or stabilization cannot be established, an explanation should be recorded in the study record.

7.2.2 Follow-up of Laboratory Abnormalities

In the event of clinically significant unexplained abnormal laboratory test values, the tests should be repeated and followed up until they have returned to the normal range and/or an adequate explanation of the abnormality is found. If a clear explanation is established, it should be recorded in the study record.

7.3 Reporting of SAEs and Unexpected Adverse Reactions

The Qualified Investigator will be responsible for classification of an AE as an SAE within 24 hours of notification. Causality should be signed off by the Qualified Investigator prior to reporting to ethics and regulatory bodies. Notification of any serious adverse events must be made in writing to the study sponsor. The IRB will be notified of all SAEs and unexpected adverse reactions. All SAEs will be reported to the Therapeutics Products Directorate (TPD) in an expedited manner.

KGK Synergize will notify the TPD of all serious adverse reactions on the Sponsor's behalf as follows:

a. If it is neither fatal or life threatening, within 15 calendar days after the day on which the sponsor becomes aware of the information; and

b. If it is fatal or life threatening, must be reported as soon as possible, but not later than seven (7) days after the day on which the sponsor becomes aware of the information.

8 STATISTICAL EVALUATION

8.1 Determination of sample size

The planned sample size for this study is 70 participants, with 35 participants randomized to each study group.

Power calculations were performed to determine the required sample size to provide 80% power at the 0.05 alpha level (that is, to have an 80% chance of obtaining $p \leq 0.05$ significance) when comparing changes in mean weight change between product and placebo.

With an estimated 20% attrition over the course of this study, 80% power and $p \leq 0.05$ when comparing product to placebo, if the product produces at least a 2.5 kg decrease, over placebo, in body weight then a total of 70 participants are required to be enrolled.

8.2 Analytical Populations

- The **Safety Population** will consist of all participants who received any amount of either product, and on whom any post-randomization safety information is available.
- The **Intent-to-Treat (ITT) Population** consists of all participants who received either product, and on whom any post-randomization efficacy information is available.
- The **Per Protocol (PP) Population** consists of all participants who consumed at least 80% of product, do not have any major protocol violations and complete all study visits and procedures connected with measurement of the primary variable.

8.3 Analysis Plan

Data will be summarized in by visit and by product. Numerical variables will be summarized as mean, standard deviation, standard error of the mean, median, and range (minimum and

maximum). Changes from baseline to each subsequent visit will be summarized in the same way, and a p value indicating whether the mean change within each group was significantly different from zero (based on the paired Student t test, or the non-parametric Wilcoxon Signed-Ranks test). Mean values will be displayed as graphs, with a separate line for each product, and error bars indicating ± 1 SEM. Mean changes from baseline will be graphed similarly.

Numerical endpoints will be compared between products by an analysis of covariance (ANCOVA), where the value of the endpoint at the end of the study period is the dependent variable, the study group is the factor of interest, and the value of the variable at baseline is the covariate.

Categorical endpoints (if there are any) will be compared between products by the Fisher Exact Test.

8.3.1 Premature Discontinuation Description

For each premature discontinuation, the following parameters will be listed: participant number, dates of the start and end of participation, and the reason of premature discontinuation. Drop-outs during the study period will not be replaced.

8.3.2 Safety

For adverse events, a descriptive analysis will be given. All adverse events will be coded using MedDRA. Adverse events will be presented in a frequency table, by body system/group and study group. Furthermore, nature, incidence, severity and causality will be reported for each adverse event.

Continuous variables (e.g. hematology, clinical chemistry, heart rate and blood pressure), will be compared using analysis of covariance (ANCOVA), adjusting for screening or baseline (as appropriate) as a covariate.

8.3.3 Protocol Deviation Description

Protocol deviations will be listed in each final study report.

8.3.4 Protocol Amendments

Once the protocol has been approved by the IRB, any changes to the protocol must be documented in the form of an amendment. All amendments will be documented in the final study report.

9 DATA COLLECTION AND STORAGE

All data collection and record storage will be done in compliance with ICH GCP Guidelines Current Step 4 version dated June 10, 1996 and applicable local regulatory guidelines.

10 ETHICAL ASPECTS OF THE STUDY

This study will be conducted with the highest respect for the individual participants (i.e., participants) according to the protocol, the ethical principles that have their origin in the Declaration of Helsinki (2008), and the ICH Harmonised Tripartite Guideline for GCP.

10.1 IRB Approval

KGK Synergize Inc. will supply relevant documents for submission to an IRB for the protocol's review and approval. This protocol, a copy of the informed consent form, and, if applicable, volunteer recruitment materials and/or advertisements and other documents required by all applicable laws and regulations, must be submitted to the IRB for approval. The IRB's written approval of the protocol and informed consent must be obtained before commencement of the study. The IRB approval must refer to the study by exact protocol title, number, and version date; identify versions of other documents (eg, informed consent form) reviewed; and state the approval date.

KGK must adhere to all requirements stipulated by the IRB. This may include notification to the IRB regarding protocol amendments, updates to the informed consent form, recruitment materials intended for viewing by volunteers, local safety reporting requirements and submission of the investigator's annual/final status report to the IRB.

10.2 Information and Informed Consent

Written consent documents will embody the elements of informed consent as described in the declaration of Helsinki and the ICH Guidelines for GCP and will be in accordance with all applicable laws and regulations. The informed consent form describes the planned and permitted uses, transfers, and disclosures of the volunteer's personal and personal health information for purposes of conducting the study. The informed consent form further explains the nature of the study, its objectives, and potential risks and benefits, as well as the date informed consent is obtained. The informed consent form will detail the requirements of the participant and the fact that he or she is free to withdraw at any time without giving a reason and without prejudice to his or her further medical care.

10.3 Potential Risks and Procedures to Minimize Risk

All potential risks are disclosed to study participants prior to their participation. The potential risks associated with this study include venipuncture. Venipuncture is the process of blood drawn from a vein with a sterile needle, usually in the arm. Risks associated with venipuncture include pain, bruising, and infection at the site. Alcohol swabs and proper venipuncture procedure will be followed to minimize the risk of infection.

11 QUALITY ASSURANCE AND QUALITY CONTROL

11.1 Auditing

All material used in clinical studies are subjected to quality control. Quality assurance audits may be performed by the sponsor or any health authority during the course of the study or after its completion.

The Investigator agrees to comply with the sponsor and regulatory requirements in terms of auditing of the study. This includes access to the source documents for source data verification.

11.2 Monitoring

An initiation meeting will be conducted by the sponsor or an approved representative (CRO). At this meeting, the protocol and logistical aspects of the study will be reviewed with the Investigator and all study staff.

Source documents will be reviewed to ensure that all items have been completed and that the data provided are accurate and obtained in the manner specified in the protocol. The participant files will be reviewed to confirm that:

Informed consent was obtained and documented;
Enrolled participants fulfilled all inclusion criteria and did not meet any exclusion criteria;
AE/SAE reporting has been performed as applicable;
Study visits have been conducted as per protocol and information has been recorded in the appropriate place in the source document;
The study product is being stored correctly and an accurate record of its dispensation to the study participants is being maintained (accountability).

Incorrect, inappropriate, or illegible entries in the participant files will be returned to the Investigator or designee for correction. No data disclosing the identity of participants will leave the study center. The Investigator and any designees will maintain confidentiality of all participant records.

The Investigator will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspections and will allow direct access to source data and documents for these purposes.

11.3 Data Management

Data required for the analysis will be acquired from source documentation (including laboratory reports) and entered into a Microsoft Office Access database designed specifically for this study. All data points entered into the study database are source data verified.

High safety standards for the transfer and storage of study data are guaranteed by the use of technologies such as password protection, firewalls and periodic backup to protect stored data. Writing access to the system will be limited to authorized personnel.

All data is archived for a period not less than 2 years from the date of completion of the study in accordance with USA regulatory requirements.

12 Reference List

1. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999-2008. JAMA 2010;303:235-41.

2. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. JAMA 2014;311:806-14.

3. National Health and Nutrition Examination Survey (NHANES) Report. Prevalence of overweight and obesity among adults: United States, 2003-2004. 2004.

Ref Type: Report

4. World Health Organization. Global Health Risks: Mortality and Burden of Disease Attributable to Selected Major Risks. 2009. Geneva, World Health Organization.

Ref Type: Report

5. Ashley FW, Jr., Kannel WB. Relation of weight change to changes in atherogenic traits: the Framingham Study. J Chronic Dis 1974;27:103-14.

6. Unal B, Critchley JA, Capewell S. Explaining the decline in coronary heart disease mortality in England and Wales between 1981 and 2000. Circulation 2004;109:1101-7.

7. Lagerros YT, Rossner S. Obesity management: what brings success? Therap Adv Gastroenterol 2013;6:77-88.

13 APPENDICES

13.1 Appendix 1 Schedule of Assessments

	Visit 1 Screening	2-weeks Run in	Visit 2 Baseline Day 0	Visit 3 Week 4 Day 28	Visit 4 Week 8 Day 56	Visit 5 Week 12 Day 85
Informed consent	X					
Review inclusion/exclusion criteria	X		X			
Review medical history	X					
Review concomitant therapies	X		X	X	X	X
Randomization			X			
Height*, weight, heart rate and blood pressure ** only measured at visit 1*	X		X	X	X	X
Urine pregnancy test	X		X			X
Physical examination			X			
Laboratory blood Analysis: CBC, electrolytes (Na, K, Cl), HbA1c*, creatinine, AST, ALT, bilirubin ** only measured at visit 1*	X					X
Waist, hip, arm, thigh circumference			X	X	X	X
BMI calculated	X		X	X	X	X
Food diaries dispensed	X		X	X	X	
Food diaries returned			X	X	X	X
Meal Replacement (2 canisters) dispensed			X	X	X	
Meal replacement returned				X	X	X
Study diary dispensed			X	X	X	
Study diary returned				X	X	X
Compliance calculated				X	X	X
Adverse events				X	X	X

13.2 Appendix 2 Modified American Heart Association Diet

All participants will be instructed to adopt a 1500 calorie daily dietary intake. Participants will be instructed on general healthy eating habits and be provided with guidance as indicated below. Participants will be provided with an online food record to help monitor and achieve their caloric intake goal.

Upon randomization, participants on the YYC! Diet plan will be instructed on the YYC! Diet plan nutritional guide. They will utilize the YYC! Nutritional Guide and Meal Replacements as their strategy to achieve a daily caloric intake of 1500 calories per day requirement.

Participants on the Modified American Heart Association diet will continue to follow the below dietary recommendations to achieve a daily caloric intake of 1500 calories per day requirement.

Healthy Eating Suggestions – based on the American Heart Association Diet

EAT MORE

- Fruits and vegetables – fresh, frozen and canned
- Whole grain bread, pasta, rice, crackers
- Low-fat dairy products: low fat yogurt, 1% milk, low fat cottage cheese
- Fat-free dairy products: skim milk
- Lean meats (skinless): Chicken and fish
- Eggs
- Nuts and seeds: almonds, pumpkin seeds, sunflower seeds
- Legumes: chick peas, lentils, black beans, kidney beans, pinto beans
- Quinoa
- Non-tropical vegetable oils: canola, corn, olive, peanut, safflower, soybean, sunflower

EAT LESS

- Saturated and trans fats
- sodium
- Sugar
- Sugar-sweetened beverages
- Red meat: beef and pork
- Processed foods
- Take-out
- Dried fruits

FOODS TO AVOID

- Alcohol
- Juice, pop and high-fat milk consumption
- Chips
- Cookies
- Chocolate
- Ice cream
- Avocado
- French Fries
- Hamburger
- Pizza
- Popcorn
- White pasta, breads and rice

Healthy Eating Suggestions – based on the American Heart Association Diet

GENERAL TIPS/GUIDELINES

- Keep track of the food you are consuming throughout the day to make sure you are within the target calorie intake of 1500 kcals
- Drink more water – drink a glass before each meal
- Prepare more meals at home – look up easy low calorie recipes
- Choose baking, boiling and poaching as cooking methods
- Read food labels to determine serving size to caloric intake – make judgements based on findings
- Be aware of portion sizes you are eating – may need to reduce current serving by half
- Cut pasta and rice portion sizes in half
- Instead of a full bagel have half/have one piece of bread instead of two
- Pre-portion foods – easy to grab and you know how many calories you will consume
- Snack on fruits, veggies, nuts, whole grain crackers, yogurt throughout the day
- Substitute starch (potato, pasta) for vegetables
- Replace high calorie foods with fruits and vegetables
- Avoid dessert after dinner
- Avoid snacking after dinner/at night
- Limit condiments – ketchup, mayo, plum sauce, barbecue sauce, salad dressing
- Season food with spices, herbs and lemon juice to create flavor
- Watch peanut butter consumption
- Watch breakfast cereal consumption
- Watch for added salt or sugar on frozen and canned fruits and vegetables

Healthy Eating Suggestions – based on the American Heart Association Diet

Serving Sizes - American Heart Association

The following table are examples of what 1 serving of different foods are and suggestions of the number of servings to intake from the American Heart Association.

Grains (Aim for 6 servings per day) 1 slice bread 1 oz dry cereal ½ cup cooked rice, cooked pasta or cooked cereal
Vegetables (Aim for 3 – 4 servings per day) 1 cup raw leafy vegetables (size of small fist) ½ cup cut-up raw or cooked vegetables ½ cup vegetable juice
Fruits (Aim for 4 servings per day) 1 medium fruit (size of baseball) ¼ cup dried fruit ½ cup fresh, frozen, or canned fruit ½ cup fruit juice
Fat-free or low-fat Dairy Products (Aim for 2-3 servings per day) 1 cup milk 1 cup yogurt 1.5 oz cheese
Lean Meat, Poultry, Seafood (Aim for 3 – 6 oz (cooked) per day) 3 oz cooked meat (size of computer mouse) 3 oz cooked fish (size of checkbook)
Fats and Oils (Aim for 2 servings per day) 1 tsp soft margarine 1 Tbsp mayonnaise 1 tsp vegetable oil 1 Tbsp regular or low-fat salad dressing (non-fat salad dressing doesn't count as a serving)
Nuts, Seeds, Legumes (Aim for 3 – 4 servings per week) 1/3 cup or 1.5 oz nuts 2 Tbsp peanut butter 2 Tbsp or 0.5 oz seeds
Sweets and Sugars (Aim for 0 servings per week)

13.3 Appendix 3 YYC! Diet Plan

NUTRITIONAL GUIDE

WHEN TO EAT?

	BREAKFAST	SNACK	LUNCH	SNACK	DINNER
OPTION 1	MEAL REPLACEMENT	NUTS AND SEEDS OR 1 PROTEIN + VEGETABLE	1 PROTEIN + 1 CARBOHYDRATE + VEGETABLES + 1 HEALTHY FAT	NUTS AND SEEDS OR 1 PROTEIN + VEGETABLE	MEAL REPLACEMENT
OPTION 2	1 PROTEIN + 1 CARBOHYDRATE + VEGETABLES + MILK OR YOGURT (optional)	NUTS AND SEEDS OR 1 PROTEIN + VEGETABLE	MEAL REPLACEMENT	NUTS AND SEEDS OR 1 PROTEIN + VEGETABLE	MEAL REPLACEMENT
OPTION 3	MEAL REPLACEMENT	NUTS AND SEEDS OR 1 PROTEIN + VEGETABLE	MEAL REPLACEMENT	NUTS AND SEEDS OR 1 PROTEIN + VEGETABLE	1 PROTEIN + VEGETABLES + 1 HEALTHY FAT NO CARBOHYDRATES

PROTEINS

PORTION SIZE:

The size of the palm of your hand = 3 oz

- You can substitute any serving of protein with a Protein Shake
- Bake, roast, broil, grill, poach, steam, or boil instead of frying
- You can combine proteins

Beef (ground round, 90% lean)
Canadian bacon
Chicken (without skin)
Crab
Edamame
Egg whites (3-5 eggs)
Fish
Ham (lean)
Lamb
Lobster
Pork (lean, rib or loin chop)
Salmon (regular, smoked, lox)
Sardines (in water)
Sashimi
Sirloin (lean)
Seafood (fresh or imitation)
Shellfish
Tenderloin
Tofu (light)
Tuna (steak, canned in water)
Turkey (ground, lean)
Veal (loin chop, roast)
Venison

CARBOHYDRATES

PORTION SIZE:

Your closed fist = 1 Cup

Your open hand = 1 Slice

- Use whole grains as often as possible
- Portion size depends on the item that is being measured. E.g. measure grains with a closed fist and slices with 1 open hand.
- Portion sizes are for cooked items

REMEMBER: You can only eat 1 CARBOHYDRATE at a time. You cannot mix them, except for fruit. You can mix different fruits together.

Bread, whole wheat (Arabic, French, pita, pumpernickel, rye)
Bulgur (cooked)
Couscous
English muffin (whole wheat)
Flatbread (whole wheat)
Grits
Jicama
Oatmeal
Pancake (whole wheat or oatmeal)
Pasta (whole wheat)
Plantains (baked, boiled)
Potato (baked, boiled, mashed)
Quinoa
Rice (brown)
Rice Cake (brown rice, no salt)
Sweet potato (baked, boiled)
Yuca (baked, boiled)
Waffle (whole wheat)
Cereal (ready to eat, with no sugar added)
Honey, 2 tablespoons
Mashed potato
Pita bread (whole wheat)
Rice cake (low salt)
Bagel (whole wheat)

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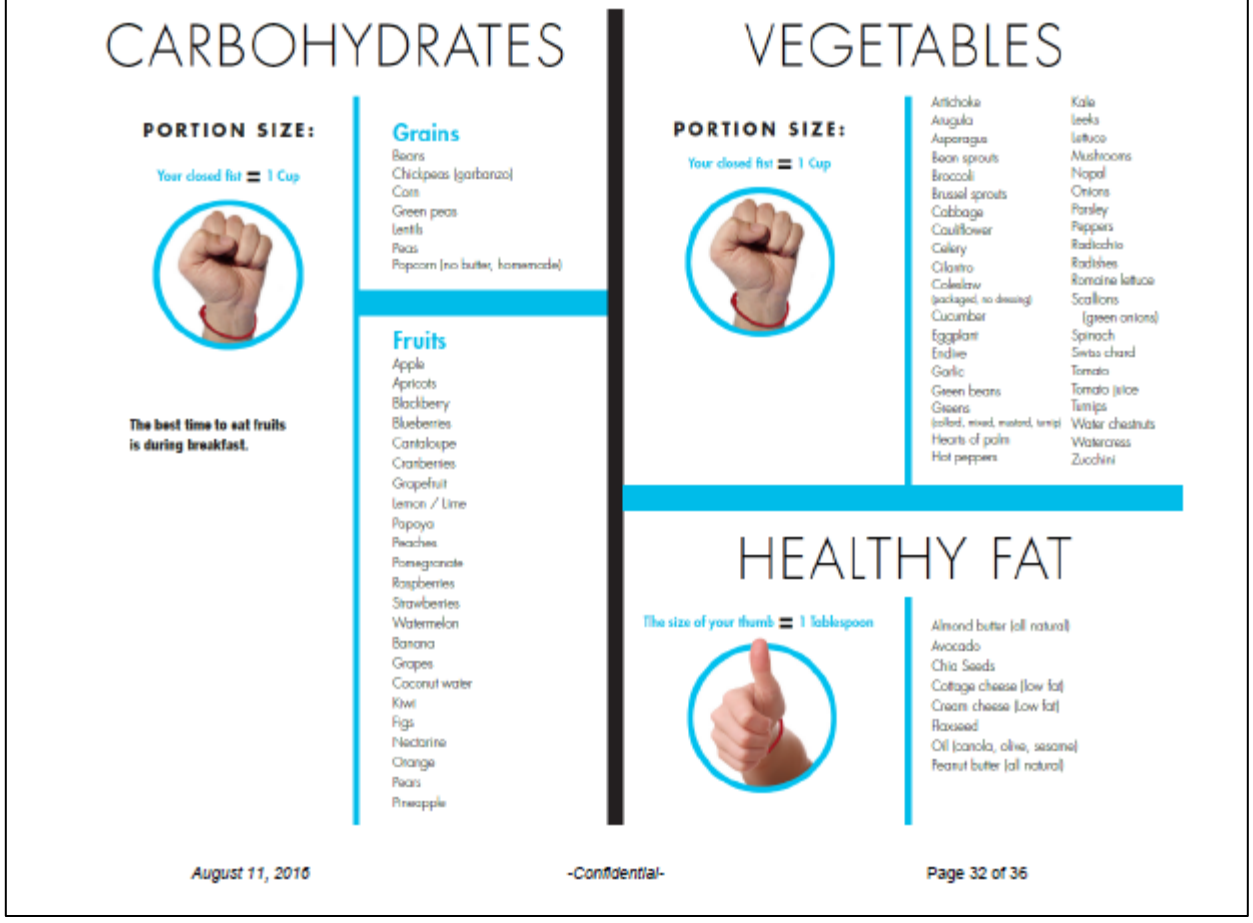
Protocol 16MWHC A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults



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Protocol 16MWHC A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults

MILK + YOGURT*

PORTION SIZE:

The distance between your thumb and pinky = One 8 oz Glass

* Optional

- Almond milk (unsweetned)
- Cashew milk (unsweetened)
- Cheese (Reduced fat)
- Greek yogurt (non fat, 4 oz)
- Milk (1%, non fat)
- Yogurt (non fat, sugar free)

NUTS + SEEDS

The size of the palm of your hand = 1 oz

- Almonds (no salt)
- Cashews (no salt)
- Hazelnuts (no salt)
- Peanuts (no salt)
- Pecans (no salt)
- Pistachios (no salt)
- Pumpkin seeds
- Sesame seeds
- Sunflower seeds
- Walnuts (halves) (no salt)
- Wasabi peas

TIPS

✔ All Types

Sugar-free gelatin, sugar substitutes, sugar free gum

✔ Broths

Chicken, beef, or vegetable consommé (not from a can)

✔ Condiments

Mustard, lemon juice, fresh salsa, vinegar, soy sauce (low sodium), apple cider vinegar, ginger, green sauce

✔ Drinks

Water, calorie-free flavored water, club soda, carbonated or mineral water, black coffee (no sugar or sweetened with sugar substitute), diet sugar-free soft drinks, unsweetened tea

✔ Seasonings

Flavoring extracts (vanilla, almond, peppermint and others), nonstick cooking spray, garlic, basil, herbs (fresh or dried), chiles, parsley, oregano, adobo, cilantro, paprika, curry, spices, hot sauce, cooking wine.

✘ Dressings

Avoid creamy salad dressings, ketchup, BBQ sauce, mayonnaise, fresh cream, teriyaki sauce, eel suace, mole sauce, dips, etc. These have empty calories and slow down your weight loss process.

✘ Food dyes

Food dyes are supposed to make food look "yummy," but in reality they are bad for your health. Your body rejects them saying "yuck". Food dyes can be found in candy, pre packaged food, and sweet drinks.

✘ Hydrogenated oil

Hydrogenated oil makes you want to eat more and more, but, if you eat it too much, it can harm your heart and health. Hydrogenated oil is hidden in many packaged foods like cookies, chips, doughnuts, cakes, and french fries.

✘ Preservatives

Preservatives are put in foods like hot dogs and bacon to keep them from spoiling, but these in excess can spoil your life.

✘ Don't skip meals

✘ White flour and refined sugar

White flour and refined sugar make the food taste better, but they fill you up with empty calories; they don't provide anything good to your body. It's like filling the gasoline tank to your car with the wrong kind of gas, which will end up ruining the engine.

✘ Alcohol

Drinking alcohol can slow down your weight loss process. You should avoid it during your diet.

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MOVEMENT

You can drink your Protein Shake after your movement routine to maximize your workout. Make sure it counts as one of your two snacks for the day and not as an extra meal.

Starting immediately, keep moving at least 3 times a week (with a minimum of 35 minutes each time).

Work in intervals, increasing and decreasing the intensity of your exercise. Every little bit counts, so make an effort to be as active as possible every single day.

FOR EXAMPLE:

- Use the stairs instead of the elevator
- Walk to the store instead of driving
- Stand up at work or at school and walk whenever you can

Disclaimer: The movement tips above are for informational and educational purposes only. Please consult you physician or other healthcare professional before beginning any fitness program to make sure that it is appropriate for your needs.

CALORIES PER HOUR*

Doing the laundry
95 CALORIES

Cleaning your house with music
280 CALORIES

Grocery shopping
400 CALORIES

Playing with your children
328 CALORIES

Dancing salsa, reggaetón or cumbia
550 CALORIES

Riding a bicycle
570 CALORIES

Swimming
440 CALORIES

Playing soccer
490 CALORIES

Bowling
164 CALORIES

Mowing the lawn
175 CALORIES

Washing your car
220 CALORIES

* These calorie values were calculated based on an average weight of 180lbs

13.4 Appendix 5 Weekly Exercise Questionnaire

Participants will be instructed to fill out a weekly questionnaire to document physical activity consisting of 35 minutes of light to moderate exercise, 3 to 5 times per week.

Subject Initial: _____
Subject Code: _____

Week start date: _____
Week end date: _____

You are required to participate in 35 minutes of light to moderate exercise 3-5 times per week while you are in the study. Please record the details of your exercise sessions below. Some examples of light to moderate exercise include: use of treadmills, elliptical, stationary bikes, brisk walking, stair climbing, light jogging, swimming or yoga etc.

#1
Date: _____
Time: _____
How long did you exercise for: _____minutes
Description of exercise (example: brisk walking, stair climbing, light jogging, swimming, etc):
_____

#2
Date: _____
Time: _____
How long did you exercise for: _____minutes
Description of exercise (example: brisk walking, stair climbing, light jogging, swimming, etc):
_____

#3
Date: _____
Time: _____
How long did you exercise for: _____minutes
Description of exercise (example: brisk walking, stair climbing, light jogging, swimming, etc):
_____

#4 (optional)
Date: _____
Time: _____
How long did you exercise for: _____minutes
Description of exercise (example: brisk walking, stair climbing, light jogging, swimming, etc):
_____

#5 (optional)
Date: _____
Time: _____
How long did you exercise for: _____minutes

Description of exercise (example: brisk walking, stair climbing, light jogging, swimming, etc):

_____

16.2.2 IRBs and Consent Form

16.2.2.1IRB approval

IRB APPROVAL/REB ATTESTATION

DATE:	29 Jul 2016
TO:	Nicole Craven, MD KGK USA
PROTOCOL:	Chaban Wellness, LLC - 16MWHC, A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults (Pro00018402)
SITE APPROVAL:	29 Jul 2016
EXPIRY DATE:	26 Jul 2017

IRB APPROVED DOCUMENTATION

Protocol Version:	• Protocol Version 3 (dated July 20, 2016) (Tracked)
Consent Form:	• Informed Consent Form (IRB Services Approved version 27 Jul 2016, Revised 29 Jul 2016)
Recruitment Material:	• Print Ad titled "WEIGHT LOSS STUDY" (undated) • Dear Patient Email titled "Weight Loss Study" (undated) • Flyer titled "WEIGHT LOSS STUDY" (undated) • Web Posting titled "Meal Replacement Weight Loss Study" (dated July 19, 2016) • Telephone Pre-screening (dated July 19, 2016)
Other Material:	• Nutritional Guide (undated) • AHA Healthy Eating Handout (dated July 25, 2016) • Run-In Subject Diary (dated July 22, 2016) • AHA Subject Diary (dated July 22, 2016) • YYC! Subject Diary (dated July 22, 2016) • Subject Study Intake Form Version (dated July 14, 2016) • Online Food Diary Sample Report (dated 5/29/14) • Online Food Diary Screen Shots, Version 1.6.3 (undated) • Weekly Exercise Questionaire (undated)

The above referenced research was reviewed by the Quebec Institutional Review Board of IRB Services on 19 Jul 2016, at which a quorum was present as defined in relevant regulations and guidelines. The IRB approved the research, as described above.

Page 1 of 3 Initial Approval (site), v.061516

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

A waiver of documentation of consent is granted only for use of the telephone screening script for recruitment purposes.

You have been unconditionally approved as the Principal Investigator at your site, as defined in the regulations of the Food and Drug Administration, for the above study.

Membership List

You can access a copy of the most recent IRB membership list by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Home," then selecting the "IRB Services Reference Materials."

Investigator Responsibilities

You can access a copy of the General Guidance: Investigator Responsibilities by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Home," then selecting the "IRB Services Reference Materials."

Your responsibilities to the IRB include, but are not limited to, informing the IRB of the following using CIRBI:

- Modifications to research (e.g., protocol amendments, revised consent forms, new or revised subject recruitment materials, change of site information, change of investigator)
- Prompt Reporting Events (e.g., protocol deviations, serious unexpected adverse reactions, unanticipated problems)
- Continuing review/termination reports (i.e., progress reports)

Compliance Statement/Attestation

IRB Services attests that the protocol and consent document(s) have been approved, as described above, and the membership of the IRB complies with the requirements defined in Health Canada regulations, 21 CFR parts 56 and 312.3 and 45 CFR 46. The IRB carries out its functions in accordance with good clinical practices (e.g., ICH GCP Guidelines) and Health Canada regulations and in compliance with FDA 21 CFR parts 50 and 56, DHHS 45 CFR part 46, and the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans, as appropriate to the research

The IRBs of IRB Services are registered with OHRP and FDA as follows:
- ON IRB registration #IRB00000776
- QC IRB registration #IRB00005290

If you have any questions please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

IRB Services, 372 Hollandview Trail, Suite 300, Aurora, Ontario, Canada L4G 0A5
tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

Thank you for selecting IRB Services to review your research project.

Sincerely,
Institutional Review Board Services

Sue Minns
Project Coordinator
Client Services

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tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

IRB APPROVAL/REB ATTESTATION

DATE:	29 Jul 2016
TO:	Gez Agolli, MD, DrPh, PSc.D Progressive Medical Center
PROTOCOL:	Chaban Wellness, LLC - 16MWHC, A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults (Pro00018402)
SITE APPROVAL:	29 Jul 2016
EXPIRY DATE:	26 Jul 2017

IRB APPROVED DOCUMENTATION

Protocol Version:
- Protocol Version 3 (dated July 20, 2016) (Tracked)

Consent Form:
- Informed Consent Form (IRB Services Approved version 27 Jul 2016, Revised 29 Jul 2016)

Recruitment Material:
- Print Ad titled "WEIGHT LOSS STUDY" (undated)
- Dear Patient Email titled "Weight Loss Study" (undated)
- Flyer titled "WEIGHT LOSS STUDY" (undated)
- Web Posting titled "Meal Replacement Weight Loss Study" (dated July 19, 2016)
- Telephone Pre-screening (dated July 19, 2016)

Other Material:
- Nutritional Guide (undated)
- AHA Healthy Eating Handout (dated July 25, 2016)
- Run-In Subject Diary (dated July 22, 2016)
- AHA Subject Diary (dated July 22, 2016)
- YYC! Subject Diary (dated July 22, 2016)
- Subject Study Intake Form Version (dated July 14, 2016)
- Online Food Diary Sample Report (dated 5/29/14)
- Online Food Diary Screen Shots, Version 1.6.3 (undated)
- Weekly Exercise Questionaire (undated)

The above referenced research was reviewed by the Quebec Institutional Review Board of IRB Services on 19 Jul 2016, at which a quorum was present as defined in relevant regulations and guidelines. The IRB approved the research, as described above.

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tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

A waiver of documentation of consent is granted only for use of the telephone screening script for recruitment purposes.

You have been unconditionally approved as the Principal Investigator at your site, as defined in the regulations of the Food and Drug Administration, for the above study.

Membership List

You can access a copy of the most recent IRB membership list by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Home," then selecting the "IRB Services Reference Materials."

Investigator Responsibilities

You can access a copy of the General Guidance: Investigator Responsibilities by going to your CIRBI homepage ("My Home") and selecting "Chesapeake IRB Home," then selecting the "IRB Services Reference Materials."

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IRB APPROVAL/REB ATTESTATION

DATE: 16 Aug 2016

TO: Nicole Craven, MD
KGK USA

PROTOCOL: Chaban Wellness, LLC - 16MWHC, A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults (Pro00018402)

APPROVAL DATE: 15 Aug 2016

IRB APPROVED DOCUMENTATION

Documentation:

- Protocol Version 4 (dated August 11, 2016) (Tracked)
- 16MWHC Summary of Changes – Version 4 (Undated)
- DietMaster Screen Shots, Version 2.7, Build 2.7 (Last Sync: 8-11-2016 2:07:45 PM)
- Sample Food Record Report (Undated)
- Sample Nutrient Summary Report (Undated)

Consent Form:

- Informed Consent Form (IRB Services Approved Version 15 Aug 2016, Revised 15 Aug 2016)

The above referenced research documents were reviewed by the Quebec Institutional Review Board of IRB Services. The IRB approved the research documents as described above.

Current IRB Approved Consent Document

The new Consent Form referenced above is now available on your CIRBI workspace. Please have new subjects sign the updated form.

No changes to the presentation of these IRB-approved materials are permitted, including but not limited to changes in font size, bold type. Should you make any changes to the approved material(s), we ask that you forward a copy for review and approval prior to use.

Membership List

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tel. (905) 727-7989 *fax* (905) 727-7990 *e-mail* info@irbservices.com *web* www.irbservices.com

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Sincerely,
Institutional Review Board Services

Sue Minns
Project Coordinator
Client Services

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IRB APPROVAL/REB ATTESTATION

DATE: 16 Aug 2016

TO: Gez Agolli, MD, DrPh, PSc.D
Progressive Medical Center

PROTOCOL: Chaban Wellness, LLC - 16MWHC, A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults (Pro00018402)

APPROVAL DATE: 15 Aug 2016

IRB APPROVED DOCUMENTATION

Documentation:

- Protocol Version 4 (dated August 11, 2016) (Tracked)
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Consent Form:

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Current IRB Approved Consent Document

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Sincerely,
Institutional Review Board Services

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Project Coordinator
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16.2.2.2 Consent Form

Information and Consent Form
Chaban Wellness LLC
16MWHC

SUBJECT INFORMATION AND CONSENT FORM

STUDY TITLE: A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults

PROTOCOL NUMBER: 16MWHC

SPONSOR: Chaban Wellness, LLC

Investigator: **Nicole Craven, MD**

Telephone: **407-674-7311 (24hr)**

Address: **KGK USA**
114 W Underwood St.
Orlando, FL 32806

You are being asked to participate in a clinical research study. To decide whether or not you want to be part of this research, you should understand the study risks and benefits in order to make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. This form will also describe how your medical information will be used and who may see it. This form is only one part of the informed consent process. The study doctor or study staff will explain this form and the study to you in detail.

You are being asked to take part in this study because the study doctor feels that you meet the qualifications of the study. Once you understand the study, you will be asked to sign this form if you wish to participate. You may have a copy of this form in advance of agreeing to participate to review at your leisure or to ask advice from others.

The study doctor or staff will answer any questions you may have about this form or about this study. You should also discuss your participation with anyone you choose in order to better understand this study and your options. Please read this document carefully and do not hesitate to ask any questions you may have regarding the information given and the study. This form may contain words that you do not understand. Please ask the study doctor or staff to explain the words or information that you do not understand.

INTRODUCTION

Obesity is a 21st century epidemic, with more than 1.9 billion adults classified as overweight, and of these 600 million classified as obese. The United States has the highest obesity rates in the world and two-thirds of its population is reported to be overweight and approximately 33%

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Initials _____ Page 1 of 16
Nicole Craven, MD *IRB Services Approved Version 15 Aug2016* *Revised 15 Aug 2016*

classified as being obese. Obesity exceeds 33% in both sexes in almost all age groups and ethnic groups in the United States.

Body mass index (BMI) is a calculation based on weight and height that can be used to define overweight and obese conditions. The risk of health problems start to occur when an individual is only slightly overweight and increase as more weight is accumulated. Due to the increase in health risks associated with weight gain, new BMI categories have been implemented and are defined below.

BMI	Classification
25.9 - 29.9	Overweight/Pre-Obese
30.0 - 34.9	(Class I) Mildly Obese
35.0 - 39.9	(Class II) Moderately Obese
≥40.0	(Class III) Morbidly Obese

A reduction in weight has a positive effect on health; even a 5-10% reduction in weight can result in a major decrease in the risk of cardiovascular disease and diabetes.

The underlying cause of obesity is an imbalance between calories consumed and calories used. This results in an abnormal excessive fat accumulation that impairs the health of an individual. This calorie imbalance comes about from over consumption of energy dense foods that are high in fat combined with a sedentary lifestyle. Engaging in physical activity as well as implementing healthy modifications to a diet will aid in balancing calories consumed and used, therefore helping with weight control. However, dietary habits are among the most difficult to modify, especially with a busy life style. Proper meal replacement shakes can help to replace unhealthy meal choices that may easily be incorporated as part of a busy life style. The investigational product in this study is a meal replacement shake that is low in calories and contains appropriate protein, fiber, carbohydrates and essential vitamins and minerals.

Information and Consent Form
Chaban Wellness LLC
16MWHC

INFORMATION ABOUT THE STUDY PRODUCT

Yes You Can Meal Replacement - Vanilla

Ingredients	Nutrition Facts
Protein Matrix (Whey Protein Concentrate, Micellar Casein), Corn Fiber, MCT Powder, Natural and Artificial Flavor, Vitamin Mineral Premix (Trimagnesium Citrate, Dipotassium Phosphate, Vitamin C (Ascorbic Acid), Ferrous Sufate, Vitamin E (Alpha-Tocopheryl acetate), Biotin, Vitamin A, Palmitate, Zinc Sulfate, Niacinamide, Vitamin B5 (Calcium Pantothenate), Copper Gluconate, Cyanobalamin, Vitamin B6 (Pyridoxine), Vitamin D3 (Cholecalciferol), Potassium Iodide, Vitamin B2 (Riboflavin), Vitamin B1 (Thiamine), Chromium Chloride, Vitamin B9 (Folic Acid)), Salt (Sodium Chloride), Xanthan Gum, Sucralose	**Nutrition Facts** Serving Size (49g) Servings Per Container **Amount Per Serving** **Calories** 200 — Calories from Fat 60 % Daily Value* **Total Fat** 7g — 11% Saturated Fat 5g — 25% Trans Fat 0g **Cholesterol** 130mg — 43% **Sodium** 300mg — 13% **Total Carbohydrate** 15g — 5% Dietary Fiber 7g — 28% Sugars 1g **Protein** 20g Vitamin A 50% • Vitamin C 50% Calcium 10% • Iron 50% Vitamin D 50% • Vitamin E 35% Thiamin 50% • Riboflavin 60% Niacin 50% • Vitamin B6 100% Folate 50% • Vitamin B12 500% Biotin 50% • Pantothenic Acid 50% Phosphorus 15% • Iodine 50% Magnesium 25% • Zinc 25% Copper 25% • Chromium 50% *Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: Calories: 2,000 2,500 Total Fat Less than 65g 80g Saturated Fat Less than 20g 25g Cholesterol Less than 300mg 300mg Sodium Less than 2,400mg 2,400mg Total Carbohydrate 300g 375g Dietary Fiber 25g 30g Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4

This product contains soy and milk products. This product is manufactured in a facility that may contain wheat, peanuts and tree nuts.

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Researchers want to examine the effectiveness of Yes You Can! (YYC!) meal replacement product with minimal physical activity on weight loss in overweight and mildly obese adults.

You will be assigned by chance (like flipping a coin) to 1 of the 2 study groups:

- YYC! Meal Replacement with Minimal Physical Activity
- Modified American Heart Association Diet with Minimal Physical Activity

You have an equal chance of being in either of the study groups. Neither you nor the study doctor will be able to pick which group you are in.

You will be required to adopt a 1500 calorie per day diet and participate in minimal physical activity consisting of 35 minutes of light to moderate exercise, 3-5 times per week. You will be provided with nutritional counsel and guides. You will be provided with an online food record tool which you will use to track and calculate your daily caloric intake. The online food record is a website for you to input your foods and beverages and the program will immediately provide you with nutritional analysis such as a calorie count. You will be shown how to use this food record by a study staff member. The study staff will regularly review your online food records to assess compliance as well as to provide you with dietary suggestions.

If you are selected into the YYC! Group, the study product will be provided to you as individual meal replacement canisters to substitute any 2 out of 3 meals every day (i.e. breakfast, lunch, dinner). You will be instructed to mix one scoop of meal replacement powder into 16 oz (2 cups) of cold water to consume. If you forget to replace a meal, you are to replace the next meal with the meal replacement shake. You should not replace more than 2 meals per day. You are the only one who should take the study product. You should make sure that no one else takes it.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the effectiveness of YYC! Meal replacement product with minimal physical activity on weight loss in overweight and mildly obese adults. The effects of the study product will be compared to a subjects who follow the Modified American Heart Association diet with minimal physical activity. Your participation in this study is strictly voluntary.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

- Your participation in this study will last approximately 14 weeks (2 weeks run-in, 12 weeks study treatment) if there is no washout period.
- A washout period is when you might have to stop taking your regular medication or any restricted foods. If you require a washout period, your time in the study will increase by the length of the washout period.
- You will have a total of 5 study visits. It is planned that 70 healthy adult women and men will participate in this study.

TO BE IN THIS STUDY

Subject Responsibilities:
While participating in this research study, you will need to:

- Understand the nature of the study and provide voluntary, written informed consent

- Be willing and able to comply and complete all the study procedures, questionnaires, dietary restrictions, records, and diaries and attend all clinic visits
- Tell the study staff about any side effects or problems you experience
- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study
- Follow the diet and physical activity plan as instructed by the study staff
- Have daily access to the internet through a computer, phone or tablet to enter food records online
- Agree to not take any new medicines, vitamins, herbs or supplements during the study without first discussing with your study doctor
- Agree to not change your smoking habits during the study period
- Abstain from the use of prescription or over the counter products, programs or meal replacement products known to affect weight within 4 weeks of enrollment
- Abstain from any alcohol abuse (>2 standard alcoholic drinks per day) or drug abuse
- Abstain from use of Medical Marijuana

Entry Requirements:

- You must be a male or female between the ages of 18 and 65 years (females please see the section below titled "Birth Control, Pregnancy and Breastfeeding")
- You must have a body mass index between 25.0 and 34.9 kg/m^2 (overweight to mildly obese) (Females: please refer to the section titled: Birth Control, Pregnancy and Breast Feeding)
- You must be "healthy" as determined by laboratory results, medical history and physical exam
- You must not have experienced significant weight gain or loss over the past 3 months (significance to be determined by the Study Staff)
- You must not have any history or current diagnosis of cancer (except for successfully treated basal cell carcinoma) diagnosed less than 5 years prior to screening
    - Cancer in full remission more than 5 years after diagnosis is acceptable
- You must not have any history or presence of clinically important conditions or disorders
- You must not currently or have a history of neurological disorders or significant psychiatric illness
- You must not have Type I or Type II Diabetes
- You must not have any disorder associated with eating behavior
- You must not be using any anti-psychotic medications
- You must not have a history of surgery for weight loss (including gastric bypass or lap-band)
- You must not be planning to donate blood during the study or within 30 days of completing the study
- You must not have an allergy or sensitivity to study supplement ingredients
- You must not be cognitively impaired and/or unable to give informed consent
- You must not have unstable medical conditions
- You must not have clinically significant abnormal laboratory results at screening
- You must not have participated in another clinical research trial within 30 days of randomization
- You must not have any other condition which in the Study Doctor's opinion may adversely affect your ability to complete the study or its measures or which may pose significant risk to you

Please be prepared to discuss with your study doctor all the prescription and over-the-counter medications (including vitamins, nutritional supplements, "natural" remedies and herbal preparations) and functional foods (i.e. probiotic containing foods, high fiber foods) you use.

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Your study doctor will discuss other specific study enrollment requirements with you.

Birth control, pregnancy and breastfeeding:
You may not participate if you are pregnant, breastfeeding or planning to become pregnant during the course of the study.

Females able to become pregnant must agree to a urine pregnancy test and must be using an approved method of birth control during the study. Some examples of approved methods of birth control include:

- oral contraceptives ("the pill")
- under-skin long-term contraceptive implants (Norplant®)
- long-acting contraceptive injections (Depo Provera®)
- IUDs
- double barrier method
- tubal ligation
- vasectomy of your partner
- non-heterosexual lifestyle.

The study doctor will discuss these contraceptive methods with you.

If you become pregnant during the study, you must stop taking the study product immediately and contact the study doctor.

WHAT WILL HAPPEN DURING THE STUDY

Visit 1 – Screening
(Duration: approximately 1.5 hours)

Before the study starts, you will be asked to sign this Information and Consent Form if you agree to participate in this study. You will then undergo the procedures listed below to determine if you are eligible to participate in this study.

- Your medical history, concomitant therapies and current health status will be reviewed
- The inclusion/exclusion criteria will be reviewed
- Your seated resting blood pressure and heart rate will be recorded
- Your weight, height and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your blood will be collected for the analysis of CBC, electrolytes (Na, K, Cl), HbA1c, creatinine, AST, ALT, and bilirubin
- A urine pregnancy test will be administered for females of child-bearing potential

If it is determined that you are eligible to participate in the study, you will begin a 14 day run-in period and be provided the following before leaving the clinic:

- You will be instructed to adopt a 1500 calorie per day diet
  - You will be provided with instructions on how to use an online food record to track your calories and you will be instructed to fill it out daily

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- You will be provided with Healthy Eating suggestions to help achieve the calorie target
- You will be instructed to participate in 35 minutes of physical activity 3-5 times per week
  - You will be instructed to complete a weekly exercise questionnaire and return it to your next visit
- You will be instructed to complete a daily study diary

You will be instructed to complete daily food records, study diaries and weekly exercise questionnaires prior to your baseline visit. Your online food records will be reviewed by a nutritionist who will provide dietary counselling through an arranged phone call before your next visit (Visit 2).

You will be asked to return to the clinic for the baseline visit on the scheduled day after an overnight fast (12 hours with nothing to eat or drink except water).

Visit 2 - Baseline (Day 0)
(Duration: approximately 1.5 hours)

After the results of all the procedures/test performed are available and if you continue to qualify, you will be asked to return to the study clinic to complete enrollment. You will be asked to come after an overnight fast (12 hours with nothing to eat or drink except water). Your study diary and questionnaire will be collected and reviewed. Please note that the online food records, study diaries and questionnaires must be filled out in order to continue. If you are eligible, the study staff will conduct the following assessments:

- Your concomitant therapies and current health status will be reviewed
- The inclusion and exclusion criteria will be reviewed
- A urine pregnancy test will be administered for females of child-bearing potential
- A physical exam will be conducted (excluding breast, rectal/vaginal examination)
- Your fasting weight and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your fasting waist, hip, arm and thigh circumference will be measured
- Your seated resting blood pressure and heart rate will be recorded
- You will be randomized into one of the two study groups and will be instructed to follow the appropriate diet plan starting the day after baseline visit
  - If you are randomized into the YYC! Diet group, you will be provided with the study product and instructed on use while maintaining the 1500 calorie per day diet and exercise requirement
  - If you are randomized into the Modified American Heart Association Diet group, you will continue with the 1500 calorie per day diet and exercise requirement
- You will be provided with a weekly exercise questionnaires and daily study diary to record compliance, changes in concomitant therapies, side effects/changes in current conditions

The next visit (Visit 3) will be scheduled for day 28 at the same time of day as the baseline visit. A three-day window (±3 days) will be allowed for scheduling issues. You will be instructed to bring your: unused investigational product in the original packaging, completed study diary diaries and completed exercise questionnaires.

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There will be a follow-up phone call made to you before the next visit to encourage compliance in the study regimen (including diet and exercise requirements). You will be reminded to fast overnight before your next visit.

Visit 3 - Week 3 (Day 28 ± 3 days)
(Duration: approximately 1 hour)

You will return to the clinic for Visit 3 assessments after an overnight fast (12 hours with nothing to eat or drink except water) with unused investigational product, and completed study diaries and exercise questionnaires.

Visit 3 assessment includes:

- Your concomitant therapies and current health status and adverse events will be reviewed
- Your fasting weight and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your fasting waist, hip, arm and thigh circumference will be measured
- Your seated resting blood pressure and heart rate will be recorded
- You will be reminded to complete the daily study diary to record compliance, changes in concomitant therapies, side effects/changes in current conditions and exercise questionnaires

The next visit (Visit 4) will be scheduled for day 56 at the same time of day as baseline visit. A three-day window (±3 days) will be allowed for scheduling issues. You will be instructed to bring your: unused investigational product in the original packaging, completed study diary and exercise questionnaire.

There will be a follow-up phone call made to you before the next visit to encourage compliance in the study regimen (including diet and exercise requirements). You will be reminded to fast overnight before your next visit.

Visit 4 - (Day 56 ± 3 days)
(Duration: approximately 1 hour)

You will return to the clinic for Visit 4 assessments after an overnight fast (12 hours with nothing to eat or drink except water), with unused investigational product and completed: study diary and exercise questionnaires.

Visit 4 assessment includes:

- Your concomitant therapies and current health status and adverse events will be reviewed
- Your fasting weight and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your fasting waist, hip, arm and thigh circumference will be measured
- Your seated resting blood pressure and heart rate will be recorded

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- You will be reminded to complete the daily study diary to record compliance, changes in concomitant therapies, side effects/changes in current conditions and weekly exercise questionnaires

The next visit (Visit 5) will be scheduled for day 85. A three-day window (±3 days) will be allowed for scheduling issues. You will be instructed to bring your: unused investigational product in the original packaging, completed study diary, three-day food record and exercise scale.

There will be a follow-up phone call made to you before the next visit to encourage compliance in the study regimen (including diet and exercise requirements). You will be reminded to fast overnight before your next visit.

Visit 5 – End of Study (Day 85 ± 3 days)
(Duration: approximately 1.5 hours)

You will return to the clinic for Visit 5 assessments after an overnight fast (12 hours with nothing to eat or drink except water), with unused investigational product and completed: study diary and exercise questionnaires.

Visit 5 assessment includes:

- Your concomitant therapies and current health status and adverse events will be reviewed
- Your fasting weight and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your fasting waist, hip, arm and thigh circumference will be measured
- Your seated resting blood pressure and heart rate will be recorded
- A urine pregnancy test will be administered for females of child-bearing potential
- Blood samples will be collected for CBC, electrolytes (Na, K, Cl), creatinine, AST, LAT and bilirubin measurements

During your participation in the study, you will be required to complete daily online food records to monitor your dietary caloric intake. This information will be reviewed by a nutritionist regularly to determine compliance and to provide dietary counseling if required.

ADDITIONAL SAFEGUARDS

The tests performed as part of this research study are not intended to replace any medical treatments you may be currently receiving. If you need regular medical care for current medical conditions, you should continue with this medical care unless otherwise instructed by your regular physician. For your safety, you must discuss your current medical care with the study doctor or staff.

The test product is intended for your use only, as the study participant. It should not be given to anyone else or left in a place where a small child could accidentally swallow it. All packaging and unused study product are to be returned to the study staff.

ALTERNATIVE TREATMENTS

You do not have to be in this study to get help to lose weight. Some other things you may be able to do include change in lifestyle habits including diet and exercise or therapies as prescribed by your regular doctor.

You should discuss your alternatives to participating in this research with the study doctor or study staff. The study doctor will explain the important possible risks and benefits of alternative treatments. In addition, you may discuss your options with your regular health care provider.

RISKS TO YOU

Any side effects (unwanted effects or health problems), including changes in medical conditions you had when you started the study, should be reported to the study doctor or study staff. In addition, if you need to take any new medications during the study, you should report this to the study doctor or study staff.

It is possible that you could have problems and side effects of the study product that nobody knows about yet, which include your health getting worse.

Could I have an allergic reaction?
Sometimes people have allergic reactions to product ingredients. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- a rash
- having a hard time breathing
- wheezing
- a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- swelling around the mouth, throat, or eyes
- a fast pulse
- sweating

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study. Please also refer to page 12 for instructions on what to do in an emergency.

Ask the study doctor or study staff if you have questions about the signs or symptoms of any side effects you read about in this consent form.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study product.

If I stop taking my regular medication, what are the risks?
If you stop your regular medication to be in the study, your health might get worse. Please tell the study doctor or study staff right away if you have any problems when you stop taking your regular medication.

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Blood samples will be drawn from a vein with a sterile needle, usually in the arm. You may experience some discomfort when the blood is drawn and it is possible that you may have some slight bruising at the area of blood collection. There is also a risk of infection at the puncture site, but since standard sterile procedures are used, this risk is considered rare. Fainting could occur, but this is unlikely. If the results of any blood test are abnormal, the study doctor may request that you return to the study clinic to have an additional blood sample drawn in order to repeat that test. The maximum amount of blood expected to be drawn over the study period is approximately 13 mL (3 teaspoons).

Although unlikely, if you suffer a serious or lasting injury as a result of participation in this study, it may affect your ability to obtain private health insurance, your employability, and/or quality of life.

WITHDRAWAL FROM THE STUDY

- You are free to choose to stop your participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled.
- If you do discontinue the study for whatever reason, you are expected to return all study materials to the clinic.
- You may be asked to undergo some final visit procedures. This may include returning to the clinic to provide a final blood sample to test your markers of general health as well as an exit questionnaire. If the study doctor or study staff finds out any non-study related information that may greatly affect your well-being (for example, information related to your future health condition), they will share it with you.

NEW FINDINGS

- Any significant new findings that become available during the course of the study which may influence your continued participation in the study will be disclosed to you as soon as possible.

BENEFITS

- While there may be no immediate benefit to you, the results of this study will provide some of the required scientific evidence in order for it to be analyzed by scientists.
- Regulatory bodies such as Food and Drug Administration (FDA) and Health Canada require that all meal replacement products that are sold at your local health food stores and pharmacies should have good scientific evidence for the claims that are being made on the labels of these products.
- Your participation in this study provides the research that is required to bring the science behind the investigational product.

COSTS TO YOU

- Your usual health care benefits will not be altered due to your participation in this study.
- All of the tests and study product, examinations, and medical care required as part of this study are provided at no cost to you, or your private medical insurance (if any) and will be paid for by the study sponsor.

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- You, or your personal medical insurance (if any) should continue to pay for expenses for your current medical care and/or prescriptions.
- These expenses will not be paid as part of your participation in this study.
- The sponsor of this study is paying your study doctor for the time, effort and expenses to conduct this study.

COMPENSATION FOR PARTICIPATION

For your time and participation in the study, you will be compensated a total of $460 if you complete the study. If you are unable to complete the entire study, compensation will be given based on the portion of the study completed as described below:

- Visit 1 (Screening): $0
- Visit 2 (Baseline): $85
- Visit 3: $100
- Visit 4: $125
- Visit 5: $150

Your compensation will be available approximately 3 weeks after the completion of your participation in the study.

COMPENSATION AND TREATMENT FOR INJURY

In case of an injury or illness suffered by participation in this study, you will receive appropriate medical care. The sponsor will cover necessary medical costs not covered by your private medical insurance (if any). By signing this form, you are not giving up your legal rights, nor releasing the study doctor or sponsors from their legal and professional obligations.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

VOLUNTARY PARTICIPATION

Your participation in this research is strictly voluntary. You have the right to choose not to be in the study or leave the study at any time for any reason without affecting your relationship with the study doctor or medical staff and without penalty or loss of benefits to which you are otherwise entitled.

The sponsors, Chaban Wellness, LLC, have the right to stop the study at this clinic at any time.

The study doctor may also stop your participation in this study at any time without your consent. Reasons for this may include, but are not limited to:
- missing scheduled study visits
- not taking study product as directed

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- choosing not to complete required tests and documents
- development of medical conditions or serious side effects that may pose a health risk to you

as directed by Chaban Wellness, LLC.

CONFIDENTIALITY OF RECORDS

- KGK Synergize contract research staff (the organization managing this study) and representatives of the sponsors, Chaban Wellness, LLC, will keep all of your medical information confidential to the extent permitted by law.
- All research data (health information such as past medical history and test results from this study) will be kept in a locked file. Forms on which your information is entered will not contain your name (with the exception of the study intake form).
- Any of your personal information that is stored electronically will be password protected, accessible only to authorized personnel and de-identified wherever possible. Electronic data may be stored on secure servers which are physically located in Canada or the United States.
- You will not be identified in any publication that might result from the study. Unless required by law, only the study doctor, the sponsor, members of the Institutional Review Board (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner), and government regulatory drug agencies (e.g. Health Canada and/or the US Food and Drug Administration - FDA) can have access to this confidential study data at the study site. This inspection is to check the accuracy of study records.
- Information from this study will be submitted to the sponsor and possibly to governmental agencies in the US (e.g. US Food and Drug Administration - FDA) and other countries. Information sent from the study site will not contain your name.
- Your family doctor will be told about your taking part in this study, unless you do not give permission.
- You have the right to check your study records and request changes if the information is not correct.
- While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

- The study doctor is required by law to protect your health information. By signing this document, you authorize the study doctor to use and disclose your health information, as described in this section, in order to conduct this research study.
- Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.
- Your authorization does not have an expiration date.
- You have the right to revoke this authorization, at any time, and can do so by writing to the study doctor at the address on the first page. Even if you revoke the authorization, the study doctor and/or sponsor may still use health information they have collected about you, if necessary for the conduct of the study. However, no new information will be collected.

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By signing the consent form you give your consent to collect, use and disclose your health information as described above.

CONTACT INFORMATION

If you have questions regarding the conduct of this study, you should contact the study doctor or the study staff at the telephone number listed on the first page of this form.

In case of an emergency, please go to the nearest hospital emergency department.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible. You can ask questions about the study at any time.

Please contact IRB Services, which is not affiliated with the research or the research team, if you:

- have questions about your role and rights as a research participant
- wish to obtain more information about clinical research in general
- have concerns, complaints or general questions about the research, or
- wish to provide input about the research study

You can do so in the following ways:
In writing: 300-372 Hollandview Trail, Aurora, ON L4G 0A5
By phone: 1-866-449-8591
By email: subjectinquiries@irbservices.com

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Information and Consent Form
Chaban Wellness LLC
16MWHC

VOLUNTARY CONSENT TO PARTICIPATE

A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults.

Please answer **YES** or **NO** to the following questions:

1	Have you been given enough time to read and understand this Information and Consent form and the information it contains regarding study 16MWHC?	Yes / No
2	Have you been given enough time to consider whether or not to participate?	Yes / No
3	Is this document in a language you understand?	Yes / No
4	Have you been given the opportunity to ask any and all of your questions you have regarding this study?	Yes / No
5	Have all of your questions been answered to your satisfaction?	Yes / No
6	Do you understand that you may consult the study doctor or his/her staff should anything become unclear or if you have any more questions?	Yes / No
7	Do you volunteer to be in this study of your own free will and without being pressured by the investigator or the study staff?	Yes / No
8	Do you understand that you can leave the study at any time without giving a reason and without affecting your health care?	Yes / No
9	Do you understand the risks involved with participating in this study?	Yes / No
10	Do you agree to follow the medical instructions provided to by the Study Doctor and staff?	Yes / No
11	Do you understand that you may not participate in another study while are you are enrolled in this study?	Yes / No
12	Do you understand that your data derived from this study will be kept anonymous and may be reviewed by Chaban Wellness, LLC, their agents, the Institutional Review Board (Research Ethics Review Board) and by Regulatory Authorities (e.g. Health Canada, FDA)?	Yes / No
13	Do you understand that all of your personal information will be treated as strictly confidential, except where disclosure is required by law, and will not made publicly available; however, absolute confidentiality cannot be guaranteed?	Yes / No

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Initials _____ Page **15** of **16**
Nicole Craven, MD *IRB Services Approved Version 15 Aug2016* *Revised 15 Aug 2016*

Information and Consent Form
Chaban Wellness LLC
16MWHC

By signing this document, I do not waive any of my rights under the law, or release the study doctor or sponsors from their legal and professional obligations.

I know that the study product is for my use only. I will not share it with anyone, and will store it in a safe place away from children or others for whom it is not intended. I will be given a signed copy of this Information and Consent Form.

I voluntarily agree to be in this study.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date

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SUBJECT INFORMATION AND CONSENT FORM

STUDY TITLE: A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults

PROTOCOL NUMBER: 16MWHC

SPONSOR: Chaban Wellness, LLC

Investigator: Gez Agolli, MD, DrPh, PSc.D

Telephone: 949-464-4453
513-658-4288 (24hr)

Address: Progressive Medical Center
26750 Towne Centre Dr. Ste A
Foothill Ranch, CA 92610

You are being asked to participate in a clinical research study. To decide whether or not you want to be part of this research, you should understand the study risks and benefits in order to make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. This form will also describe how your medical information will be used and who may see it. This form is only one part of the informed consent process. The study doctor or study staff will explain this form and the study to you in detail.

You are being asked to take part in this study because the study doctor feels that you meet the qualifications of the study. Once you understand the study, you will be asked to sign this form if you wish to participate. You may have a copy of this form in advance of agreeing to participate to review at your leisure or to ask advice from others.

The study doctor or staff will answer any questions you may have about this form or about this study. You should also discuss your participation with anyone you choose in order to better understand this study and your options. Please read this document carefully and do not hesitate to ask any questions you may have regarding the information given and the study. This form may contain words that you do not understand. Please ask the study doctor or staff to explain the words or information that you do not understand.

INTRODUCTION

Obesity is a 21st century epidemic, with more than 1.9 billion adults classified as overweight, and of these 600 million classified as obese. The United States has the highest obesity rates in the world and two-thirds of its population is reported to be overweight and approximately 33%

classified as being obese. Obesity exceeds 33% in both sexes in almost all age groups and ethnic groups in the United States.

Body mass index (BMI) is a calculation based on weight and height that can be used to define overweight and obese conditions. The risk of health problems start to occur when an individual is only slightly overweight and increase as more weight is accumulated. Due to the increase in health risks associated with weight gain, new BMI categories have been implemented and are defined below.

BMI	Classification
25.9 - 29.9	Overweight/Pre-Obese
30.0 - 34.9	(Class I) Mildly Obese
35.0 - 39.9	(Class II) Moderately Obese
≥40.0	(Class III) Morbidly Obese

A reduction in weight has a positive effect on health; even a 5-10% reduction in weight can result in a major decrease in the risk of cardiovascular disease and diabetes.

The underlying cause of obesity is an imbalance between calories consumed and calories used. This results in an abnormal excessive fat accumulation that impairs the health of an individual. This calorie imbalance comes about from over consumption of energy dense foods that are high in fat combined with a sedentary lifestyle. Engaging in physical activity as well as implementing healthy modifications to a diet will aid in balancing calories consumed and used, therefore helping with weight control. However, dietary habits are among the most difficult to modify, especially with a busy life style. Proper meal replacement shakes can help to replace unhealthy meal choices that may easily be incorporated as part of a busy life style. The investigational product in this study is a meal replacement shake that is low in calories and contains appropriate protein, fiber, carbohydrates and essential vitamins and minerals.

Information and Consent Form
Chaban Wellness LLC
16MWHC

INFORMATION ABOUT THE STUDY PRODUCT

Yes You Can Meal Replacement - Vanilla

Ingredients	Nutrition Facts
Protein Matrix (Whey Protein Concentrate, Micellar Casein), Corn Fiber, MCT Powder, Natural and Artificial Flavor, Vitamin Mineral Premix (Trimagnesium Citrate, Dipotassium Phosphate, Vitamin C (Ascorbic Acid), Ferrous Sufate, Vitamin E (Alpha-Tocopheryl acetate), Biotin, Vitamin A, Palmitate, Zinc Sulfate, Niacinamide, Vitamin B5 (Calcium Pantothenate), Copper Gluconate, Cyanobalamin, Vitamin B6 (Pyridoxine), Vitamin D3 (Cholecalciferol), Potassium Iodide, Vitamin B2 (Riboflavin), Vitamin B1 (Thiamine), Chromium Chloride, Vitamin B9 (Folic Acid)), Salt (Sodium Chloride), Xanthan Gum, Sucralose	**Nutrition Facts** Serving Size (49g) Servings Per Container **Amount Per Serving** **Calories** 200 — Calories from Fat 60 % Daily Value* **Total Fat** 7g — **11%** Saturated Fat 5g — **25%** Trans Fat 0g **Cholesterol** 130mg — **43%** **Sodium** 300mg — **13%** **Total Carbohydrate** 15g — **5%** Dietary Fiber 7g — **28%** Sugars **1g** **Protein** 20g Vitamin A 50% • Vitamin C 50% Calcium 10% • Iron 50% Vitamin D 50% • Vitamin E 35% Thiamin 50% • Riboflavin 60% Niacin 50% • Vitamin B6 100% Folate 50% • Vitamin B12 500% Biotin 50% • Pantothenic Acid 50% Phosphorus 15% • Iodine 50% Magnesium 25% • Zinc 25% Copper 25% • Chromium 50% *Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: Calories: 2,000 2,500 Total Fat Less than 65g 80g Saturated Fat Less than 20g 25g Cholesterol Less than 300mg 300mg Sodium Less than 2,400mg 2,400mg Total Carbohydrate 300g 375g Dietary Fiber 25g 30g Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4

This product contains soy and milk products. This product is manufactured in a facility that may contain wheat, peanuts and tree nuts.

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Initials _____ Page 3 of 16

Gez Agolli, MD, DrPh, PSc.D *IRB Services Approved Version 15 Aug2016* *Revised 15 Aug2016*

Information and Consent Form
Chaban Wellness LLC
16MWHC

Researchers want to examine the effectiveness of Yes You Can! (YYC!) meal replacement product with minimal physical activity on weight loss in overweight and mildly obese adults.

You will be assigned by chance (like flipping a coin) to 1 of the 2 study groups:

- YYC! Meal Replacement with Minimal Physical Activity
- Modified American Heart Association Diet with Minimal Physical Activity

You have an equal chance of being in either of the study groups. Neither you nor the study doctor will be able to pick which group you are in.

You will be required to adopt a 1500 calorie per day diet and participate in minimal physical activity consisting of 35 minutes of light to moderate exercise, 3-5 times per week. You will be provided with nutritional counsel and guides. You will be provided with an online food record tool which you will use to track and calculate your daily caloric intake. The online food record is a website for you to input your foods and beverages and the program will immediately provide you with nutritional analysis such as a calorie count. You will be shown how to use this food record by a study staff member. The study staff will regularly review your online food records to assess compliance as well as to provide you with dietary suggestions.

If you are selected into the YYC! Group, the study product will be provided to you as individual meal replacement canisters to substitute any 2 out of 3 meals every day (i.e. breakfast, lunch, dinner). You will be instructed to mix one scoop of meal replacement powder into 16 oz (2 cups) of cold water to consume. If you forget to replace a meal, you are to replace the next meal with the meal replacement shake. You should not replace more than 2 meals per day. You are the only one who should take the study product. You should make sure that no one else takes it.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the effectiveness of YYC! Meal replacement product with minimal physical activity on weight loss in overweight and mildly obese adults. The effects of the study product will be compared to a subjects who follow the Modified American Heart Association diet with minimal physical activity. Your participation in this study is strictly voluntary.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

- Your participation in this study will last approximately 14 weeks (2 weeks run-in, 12 weeks study treatment) if there is no washout period.
- A washout period is when you might have to stop taking your regular medication or any restricted foods. If you require a washout period, your time in the study will increase by the length of the washout period.
- You will have a total of 5 study visits. It is planned that 70 healthy adult women and men will participate in this study.

TO BE IN THIS STUDY

Subject Responsibilities:
While participating in this research study, you will need to:

- Understand the nature of the study and provide voluntary, written informed consent

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- Be willing and able to comply and complete all the study procedures, questionnaires, dietary restrictions, records, and diaries and attend all clinic visits
- Tell the study staff about any side effects or problems you experience
- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study
- Follow the diet and physical activity plan as instructed by the study staff
- Have daily access to the internet through a computer, phone or tablet to enter food records online
- Agree to not take any new medicines, vitamins, herbs or supplements during the study without first discussing with your study doctor
- Agree to not change your smoking habits during the study period
- Abstain from the use of prescription or over the counter products, programs or meal replacement products known to affect weight within 4 weeks of enrollment
- Abstain from any alcohol abuse (>2 standard alcoholic drinks per day) or drug abuse
- Abstain from use of Medical Marijuana

Entry Requirements:

- You must be a male or female between the ages of 18 and 65 years (females please see the section below titled "Birth Control, Pregnancy and Breastfeeding")
- You must have a body mass index between 25.0 and 34.9 kg/m^2 (overweight to mildly obese) (Females: please refer to the section titled: Birth Control, Pregnancy and Breast Feeding)
- You must be "healthy" as determined by laboratory results, medical history and physical exam
- You must not have experienced significant weight gain or loss over the past 3 months (significance to be determined by the Study Staff)
- You must not have any history or current diagnosis of cancer (except for successfully treated basal cell carcinoma) diagnosed less than 5 years prior to screening
    - Cancer in full remission more than 5 years after diagnosis is acceptable
- You must not have any history or presence of clinically important conditions or disorders
- You must not currently or have a history of neurological disorders or significant psychiatric illness
- You must not have Type I or Type II Diabetes
- You must not have any disorder associated with eating behavior
- You must not be using any anti-psychotic medications
- You must not have a history of surgery for weight loss (including gastric bypass or lap-band)
- You must not be planning to donate blood during the study or within 30 days of completing the study
- You must not have an allergy or sensitivity to study supplement ingredients
- You must not be cognitively impaired and/or unable to give informed consent
- You must not have unstable medical conditions
- You must not have clinically significant abnormal laboratory results at screening
- You must not have participated in another clinical research trial within 30 days of randomization
- You must not have any other condition which in the Study Doctor's opinion may adversely affect your ability to complete the study or its measures or which may pose significant risk to you

Please be prepared to discuss with your study doctor all the prescription and over-the-counter medications (including vitamins, nutritional supplements, "natural" remedies and herbal preparations) and functional foods (i.e. probiotic containing foods, high fiber foods) you use.

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Your study doctor will discuss other specific study enrollment requirements with you.

Birth control, pregnancy and breastfeeding:
You may not participate if you are pregnant, breastfeeding or planning to become pregnant during the course of the study.

Females able to become pregnant must agree to a urine pregnancy test and must be using an approved method of birth control during the study. Some examples of approved methods of birth control include:

- oral contraceptives ("the pill")
- under-skin long-term contraceptive implants (Norplant®)
- long-acting contraceptive injections (Depo Provera®)
- IUDs
- double barrier method
- tubal ligation
- vasectomy of your partner
- non-heterosexual lifestyle.

The study doctor will discuss these contraceptive methods with you.

If you become pregnant during the study, you must stop taking the study product immediately and contact the study doctor.

WHAT WILL HAPPEN DURING THE STUDY

Visit 1 – Screening
(Duration: approximately 1.5 hours)

Before the study starts, you will be asked to sign this Information and Consent Form if you agree to participate in this study. You will then undergo the procedures listed below to determine if you are eligible to participate in this study.

- Your medical history, concomitant therapies and current health status will be reviewed
- The inclusion/exclusion criteria will be reviewed
- Your seated resting blood pressure and heart rate will be recorded
- Your weight, height and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your blood will be collected for the analysis of CBC, electrolytes (Na, K, Cl), HbA1c, creatinine, AST, ALT, and bilirubin
- A urine pregnancy test will be administered for females of child-bearing potential

If it is determined that you are eligible to participate in the study, you will begin a 14 day run-in period and be provided the following before leaving the clinic:

- You will be instructed to adopt a 1500 calorie per day diet
  - You will be provided with instructions on how to use an online food record to track your calories and you will be instructed to fill it out daily

- You will be provided with Healthy Eating suggestions to help achieve the calorie target
- You will be instructed to participate in 35 minutes of physical activity 3-5 times per week
  - You will be instructed to complete a weekly exercise questionnaire and return it to your next visit
- You will be instructed to complete a daily study diary

You will be instructed to complete daily food records, study diaries and weekly exercise questionnaires prior to your baseline visit. Your online food records will be reviewed by a nutritionist who will provide dietary counselling through an arranged phone call before your next visit (Visit 2).

You will be asked to return to the clinic for the baseline visit on the scheduled day after an overnight fast (12 hours with nothing to eat or drink except water).

Visit 2 - Baseline (Day 0)
(Duration: approximately 1.5 hours)

After the results of all the procedures/test performed are available and if you continue to qualify, you will be asked to return to the study clinic to complete enrollment. You will be asked to come after an overnight fast (12 hours with nothing to eat or drink except water). Your study diary and questionnaire will be collected and reviewed. Please note that the online food records, study diaries and questionnaires must be filled out in order to continue. If you are eligible, the study staff will conduct the following assessments:

- Your concomitant therapies and current health status will be reviewed
- The inclusion and exclusion criteria will be reviewed
- A urine pregnancy test will be administered for females of child-bearing potential
- A physical exam will be conducted (excluding breast, rectal/vaginal examination)
- Your fasting weight and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your fasting waist, hip, arm and thigh circumference will be measured
- Your seated resting blood pressure and heart rate will be recorded
- You will be randomized into one of the two study groups and will be instructed to follow the appropriate diet plan starting the day after baseline visit
  - If you are randomized into the YYC! Diet group, you will be provided with the study product and instructed on use while maintaining the 1500 calorie per day diet and exercise requirement
  - If you are randomized into the Modified American Heart Association Diet group, you will continue with the 1500 calorie per day diet and exercise requirement
- You will be provided with a weekly exercise questionnaires and daily study diary to record compliance, changes in concomitant therapies, side effects/changes in current conditions

The next visit (Visit 3) will be scheduled for day 28 at the same time of day as the baseline visit. A three-day window (±3 days) will be allowed for scheduling issues. You will be instructed to bring your: unused investigational product in the original packaging, completed study diary diaries and completed exercise questionnaires.

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There will be a follow-up phone call made to you before the next visit to encourage compliance in the study regimen (including diet and exercise requirements). You will be reminded to fast overnight before your next visit.

Visit 3 - Week 3 (Day 28 ± 3 days)
(Duration: approximately 1 hour)

You will return to the clinic for Visit 3 assessments after an overnight fast (12 hours with nothing to eat or drink except water) with unused investigational product, and completed study diaries and exercise questionnaires.

Visit 3 assessment includes:

- Your concomitant therapies and current health status and adverse events will be reviewed
- Your fasting weight and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your fasting waist, hip, arm and thigh circumference will be measured
- Your seated resting blood pressure and heart rate will be recorded
- You will be reminded to complete the daily study diary to record compliance, changes in concomitant therapies, side effects/changes in current conditions and exercise questionnaires

The next visit (Visit 4) will be scheduled for day 56 at the same time of day as baseline visit. A three-day window (±3 days) will be allowed for scheduling issues. You will be instructed to bring your: unused investigational product in the original packaging, completed study diary and exercise questionnaire.

There will be a follow-up phone call made to you before the next visit to encourage compliance in the study regimen (including diet and exercise requirements). You will be reminded to fast overnight before your next visit.

Visit 4 - (Day 56 ± 3 days)
(Duration: approximately 1 hour)

You will return to the clinic for Visit 4 assessments after an overnight fast (12 hours with nothing to eat or drink except water), with unused investigational product and completed: study diary and exercise questionnaires.

Visit 4 assessment includes:

- Your concomitant therapies and current health status and adverse events will be reviewed
- Your fasting weight and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your fasting waist, hip, arm and thigh circumference will be measured
- Your seated resting blood pressure and heart rate will be recorded

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- You will be reminded to complete the daily study diary to record compliance, changes in concomitant therapies, side effects/changes in current conditions and weekly exercise questionnaires

The next visit (Visit 5) will be scheduled for day 85. A three-day window (±3 days) will be allowed for scheduling issues. You will be instructed to bring your: unused investigational product in the original packaging, completed study diary, three-day food record and exercise scale.

There will be a follow-up phone call made to you before the next visit to encourage compliance in the study regimen (including diet and exercise requirements). You will be reminded to fast overnight before your next visit.

Visit 5 – End of Study (Day 85 ± 3 days)
(Duration: approximately 1.5 hours)

You will return to the clinic for Visit 5 assessments after an overnight fast (12 hours with nothing to eat or drink except water), with unused investigational product and completed: study diary and exercise questionnaires.

Visit 5 assessment includes:

- Your concomitant therapies and current health status and adverse events will be reviewed
- Your fasting weight and BMI will be recorded (You will be asked to have your weight measured wearing a provided gown, shoes removed and an empty bladder)
- Your fasting waist, hip, arm and thigh circumference will be measured
- Your seated resting blood pressure and heart rate will be recorded
- A urine pregnancy test will be administered for females of child-bearing potential
- Blood samples will be collected for CBC, electrolytes (Na, K, Cl), creatinine, AST, LAT and bilirubin measurements

During your participation in the study, you will be required to complete daily online food records to monitor your dietary caloric intake. This information will be reviewed by a nutritionist regularly to determine compliance and to provide dietary counseling if required.

ADDITIONAL SAFEGUARDS

The tests performed as part of this research study are not intended to replace any medical treatments you may be currently receiving. If you need regular medical care for current medical conditions, you should continue with this medical care unless otherwise instructed by your regular physician. For your safety, you must discuss your current medical care with the study doctor or staff.

The test product is intended for your use only, as the study participant. It should not be given to anyone else or left in a place where a small child could accidentally swallow it. All packaging and unused study product are to be returned to the study staff.

ALTERNATIVE TREATMENTS

You do not have to be in this study to get help to lose weight. Some other things you may be able to do include change in lifestyle habits including diet and exercise or therapies as prescribed by your regular doctor.

You should discuss your alternatives to participating in this research with the study doctor or study staff. The study doctor will explain the important possible risks and benefits of alternative treatments. In addition, you may discuss your options with your regular health care provider.

RISKS TO YOU

Any side effects (unwanted effects or health problems), including changes in medical conditions you had when you started the study, should be reported to the study doctor or study staff. In addition, if you need to take any new medications during the study, you should report this to the study doctor or study staff.

It is possible that you could have problems and side effects of the study product that nobody knows about yet, which include your health getting worse.

Could I have an allergic reaction?
Sometimes people have allergic reactions to product ingredients. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- a rash
- having a hard time breathing
- wheezing
- a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- swelling around the mouth, throat, or eyes
- a fast pulse
- sweating

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study. Please also refer to page 12 for instructions on what to do in an emergency.

Ask the study doctor or study staff if you have questions about the signs or symptoms of any side effects you read about in this consent form.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study product.

If I stop taking my regular medication, what are the risks?
If you stop your regular medication to be in the study, your health might get worse. Please tell the study doctor or study staff right away if you have any problems when you stop taking your regular medication.

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Blood samples will be drawn from a vein with a sterile needle, usually in the arm. You may experience some discomfort when the blood is drawn and it is possible that you may have some slight bruising at the area of blood collection. There is also a risk of infection at the puncture site, but since standard sterile procedures are used, this risk is considered rare. Fainting could occur, but this is unlikely. If the results of any blood test are abnormal, the study doctor may request that you return to the study clinic to have an additional blood sample drawn in order to repeat that test. The maximum amount of blood expected to be drawn over the study period is approximately 13 mL (3 teaspoons).

Although unlikely, if you suffer a serious or lasting injury as a result of participation in this study, it may affect your ability to obtain private health insurance, your employability, and/or quality of life.

WITHDRAWAL FROM THE STUDY

- You are free to choose to stop your participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled.
- If you do discontinue the study for whatever reason, you are expected to return all study materials to the clinic.
- You may be asked to undergo some final visit procedures. This may include returning to the clinic to provide a final blood sample to test your markers of general health as well as an exit questionnaire. If the study doctor or study staff finds out any non-study related information that may greatly affect your well-being (for example, information related to your future health condition), they will share it with you.

NEW FINDINGS

- Any significant new findings that become available during the course of the study which may influence your continued participation in the study will be disclosed to you as soon as possible.

BENEFITS

- While there may be no immediate benefit to you, the results of this study will provide some of the required scientific evidence in order for it to be analyzed by scientists.
- Regulatory bodies such as Food and Drug Administration (FDA) and Health Canada require that all meal replacement products that are sold at your local health food stores and pharmacies should have good scientific evidence for the claims that are being made on the labels of these products.
- Your participation in this study provides the research that is required to bring the science behind the investigational product.

COSTS TO YOU

- Your usual health care benefits will not be altered due to your participation in this study.
- All of the tests and study product, examinations, and medical care required as part of this study are provided at no cost to you, or your private medical insurance (if any) and will be paid for by the study sponsor.

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- You, or your personal medical insurance (if any) should continue to pay for expenses for your current medical care and/or prescriptions.
- These expenses will not be paid as part of your participation in this study.
- The sponsor of this study is paying your study doctor for the time, effort and expenses to conduct this study.

COMPENSATION FOR PARTICIPATION

For your time and participation in the study, you will be compensated a total of $460 if you complete the study. If you are unable to complete the entire study, compensation will be given based on the portion of the study completed as described below:

- Visit 1 (Screening): $0
- Visit 2 (Baseline): $85
- Visit 3: $100
- Visit 4: $125
- Visit 5: $150

Your compensation will be available approximately 3 weeks after the completion of your participation in the study.

COMPENSATION AND TREATMENT FOR INJURY

In case of an injury or illness suffered by participation in this study, you will receive appropriate medical care. The sponsor will cover necessary medical costs not covered by your private medical insurance (if any). By signing this form, you are not giving up your legal rights, nor releasing the study doctor or sponsors from their legal and professional obligations.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

VOLUNTARY PARTICIPATION

Your participation in this research is strictly voluntary. You have the right to choose not to be in the study or leave the study at any time for any reason without affecting your relationship with the study doctor or medical staff and without penalty or loss of benefits to which you are otherwise entitled.

The sponsors, Chaban Wellness, LLC, have the right to stop the study at this clinic at any time.

The study doctor may also stop your participation in this study at any time without your consent. Reasons for this may include, but are not limited to:
- missing scheduled study visits
- not taking study product as directed

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- choosing not to complete required tests and documents
- development of medical conditions or serious side effects that may pose a health risk to you

as directed by Chaban Wellness, LLC.

CONFIDENTIALITY OF RECORDS

- KGK Synergize contract research staff (the organization managing this study) and representatives of the sponsors, Chaban Wellness, LLC, will keep all of your medical information confidential to the extent permitted by law.
- All research data (health information such as past medical history and test results from this study) will be kept in a locked file. Forms on which your information is entered will not contain your name (with the exception of the study intake form).
- Any of your personal information that is stored electronically will be password protected, accessible only to authorized personnel and de-identified wherever possible. Electronic data may be stored on secure servers which are physically located in Canada or the United States.
- You will not be identified in any publication that might result from the study. Unless required by law, only the study doctor, the sponsor, members of the Institutional Review Board (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner), and government regulatory drug agencies (e.g. Health Canada and/or the US Food and Drug Administration - FDA) can have access to this confidential study data at the study site. This inspection is to check the accuracy of study records.
- Information from this study will be submitted to the sponsor and possibly to governmental agencies in the US (e.g. US Food and Drug Administration - FDA) and other countries. Information sent from the study site will not contain your name.
- Your family doctor will be told about your taking part in this study, unless you do not give permission.
- You have the right to check your study records and request changes if the information is not correct.
- While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

- The study doctor is required by law to protect your health information. By signing this document, you authorize the study doctor to use and disclose your health information, as described in this section, in order to conduct this research study.
- Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.
- Your authorization does not have an expiration date.
- You have the right to revoke this authorization, at any time, and can do so by writing to the study doctor at the address on the first page. Even if you revoke the authorization, the study doctor and/or sponsor may still use health information they have collected about you, if necessary for the conduct of the study. However, no new information will be collected.

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By signing the consent form you give your consent to collect, use and disclose your health information as described above.

CONTACT INFORMATION

If you have questions regarding the conduct of this study, you should contact the study doctor or the study staff at the telephone number listed on the first page of this form.

In case of an emergency, please go to the nearest hospital emergency department.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible. You can ask questions about the study at any time.

Please contact IRB Services, which is not affiliated with the research or the research team, if you:

- have questions about your role and rights as a research participant
- wish to obtain more information about clinical research in general
- have concerns, complaints or general questions about the research, or
- wish to provide input about the research study

You can do so in the following ways:
In writing: 300-372 Hollandview Trail, Aurora, ON L4G 0A5
By phone: 1-866-449-8591
By email: subjectinquiries@irbservices.com

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Information and Consent Form
Chaban Wellness LLC
16MWHC

VOLUNTARY CONSENT TO PARTICIPATE

A Randomized, Comparator-Controlled, Parallel Study Investigating the Effect of Meal Replacement with Minimal Physical Activity on Weight Loss in Overweight and Mildly Obese Adults.

Please answer **YES** or **NO** to the following questions:

1	Have you been given enough time to read and understand this Information and Consent form and the information it contains regarding study 16MWHC?	Yes / No
2	Have you been given enough time to consider whether or not to participate?	Yes / No
3	Is this document in a language you understand?	Yes / No
4	Have you been given the opportunity to ask any and all of your questions you have regarding this study?	Yes / No
5	Have all of your questions been answered to your satisfaction?	Yes / No
6	Do you understand that you may consult the study doctor or his/her staff should anything become unclear or if you have any more questions?	Yes / No
7	Do you volunteer to be in this study of your own free will and without being pressured by the investigator or the study staff?	Yes / No
8	Do you understand that you can leave the study at any time without giving a reason and without affecting your health care?	Yes / No
9	Do you understand the risks involved with participating in this study?	Yes / No
10	Do you agree to follow the medical instructions provided to by the Study Doctor and staff?	Yes / No
11	Do you understand that you may not participate in another study while are you are enrolled in this study?	Yes / No
12	Do you understand that your data derived from this study will be kept anonymous and may be reviewed by Chaban Wellness, LLC, their agents, the Institutional Review Board (Research Ethics Review Board) and by Regulatory Authorities (e.g. Health Canada, FDA)?	Yes / No
13	Do you understand that all of your personal information will be treated as strictly confidential, except where disclosure is required by law, and will not made publicly available; however, absolute confidentiality cannot be guaranteed?	Yes / No

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Initials _____ Page 15 of 16
Gez Agolli, MD, DrPh, PSc.D *IRB Services Approved Version 15 Aug2016* *Revised 15 Aug2016*

Information and Consent Form
Chaban Wellness LLC
16MWHC

By signing this document, I do not waive any of my rights under the law, or release the study doctor or sponsors from their legal and professional obligations.

I know that the study product is for my use only. I will not share it with anyone, and will store it in a safe place away from children or others for whom it is not intended. I will be given a signed copy of this Information and Consent Form.

I voluntarily agree to be in this study.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date

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16.2.3 Investigators and Role in the Study

Investigator	Affiliation	Role in the Study
Malkanthi Evans, Ph.D.	KGK Synergize Inc. Suite 1440, One London Place, 255 Queens Ave London ON N6A 5R8 Canada	Study Author
Nicole Craven, MD	KGK USA, Orlando Florida Site 114 W Underwood St. Orlando, FL 32806	Qualified Investigator
Gez Agolli, MD, DrPh, PSc.D	KGK USA, Foothill Ranch California Site Progressive Medical Center 26750 Towne Centre Dr. Ste A Foothill Ranch, CA 92610	Qualified Investigator
Matthew Rueffer, M.Sc.	KGK Synergize Inc. Suite 1440, One London Place, 255 Queens Ave London ON N6A 5R8 Canada	Biostatistician

16.2.3.1 CV of Study Author

Curriculum Vitae Malkanthi Evans, D.V.M., M.Sc., Ph.D.

EDUCATION:

1983-1987	Physiology	Ph.D.	Department of Animal Science University of Guelph Guelph, Ontario
1979	Physiology	M.Sc.	Department of Animal Science University of Guelph Guelph, Ontario
1977		D.V.M.	University of Sri Lanka Sri Lanka

EMPLOYMENT RECORD :

2007- Present	Scientific Director Contract Research Services Division	KGK Synergize Inc. 1440- 255 Queens Avenue London, Ontario
Apr 2007-May 2007	Consultant Contract Research Services Division	KGK Synergize Inc. 1440- 255 Queens Avenue London, Ontario
2005- 2007	Research Associate/ Project Coordinator	Dept. of Physical Medicine and Rehabilitation The University of Western Ontario London, Ontario
2004	Independent Researcher/ Consultant	Centre for New Students The University of Western Ontario London, Ontario
2002- 2004	Researcher	Dept. of Epidemiology and Biostatistics The University of Western Ontario London, Ontario
2001- 2002	Researcher	The University of Western Ontario London, Ontario
1993- 2000	Lecturer/Scientist /Consultant	University of Guelph, Guelph, Ontario
1987- 1991	Postdoctoral Fellowship	University of Guelph, Guelph, Ontario

16.2.3.2 CV of Qualified Investigators

16.2.3.2.1 CV of KGK USA Orlando Florida Qualified Investigators

Curriculum Vitae Nicole J Craven, MD

EDUCATION:

2001 – 2004	Residency in Pediatrics	University of South Carolina Charleston, SC
1997 – 2001	M.D.	Tulane Medical School (Honors, Early Acceptance) New Orleans, LA
1993 – 1997	B.S Cell & Molecular Biology	Tulane University New Orleans, LA
1991 – 1993	H. S. of National Academic Recognition	North Carolina School of Science & Math Durham, NC

EMPLOYMENT RECORD :

Sep 2015 – Present	Medical Director	KGK USA, Clinical Trials Centers Orlando, FL
Jul 2014 – Present	Integrative Medicine Pediatrician	Cannizzaro Integrative Pediatric Center Longwood, FL
Oct 2013 – Jul 2014	Integrative Medicine Pediatrician	Whole Family Healthcare Winter Park, FL
Sep 2010 – Present	General Pediatrician	The Franz Center Orlando, FL
2008 – 2010	General Pediatrician	Randolph Pediatric Associates Greensboro, NC

16.2.3.2.2 CV of KGK USA Foothill Ranch California Qualified Investigator

Curriculum Vitae Gez Agolli MD, DrPH, PSc.D

EDUCATION:

2015	PSc.D	Pastro Medical Association
2011-2012	DrPH	Montserrat Miami, FL
2004-2008	M.D.	University Science Arts and Technology Montserrat, West Indies
2003-2004	Ph.D.	First National University
1999-2002	NMD	US School of Naturopathy and Allied Science

EMPLOYMENT RECORD :

1997 - Present	President and Chief Administrator	Progressive Medical Management
1997 - 1998	President and Chief Administrator	JBA Medical Management
1996 -1998	Founder, President and Managing Director	Metabolic Treatment Center Inc.
1993 - 1994	Managing Director	Colonial Medical Specialties of South Florida Inc. Laud FL
1991- 1993	General Manager of Facility	American Medical Fitness/Nautilus Fitness Ft Lauderdale, FL
1989 -1991	Sales Manager	US Total Fitness and Rehab Ft Lauderdale, FL
1988 -1989	Assistant Sales Manager, personal trainer, and aerobics instructor	Living Well Fitness Center Hollywood and FL
1984 -1988	Combat Controller	United States Air Force Pope Air Force Base, N.C.

16.2.3.3 CV of Biostatistician

Curriculum Vitae Matthew Rueffer, M.Sc., H. B.Sc

EDUCATION:

2012 - 2013	M.Sc.	Statistics	University of Guelph Guelph, ON
2007 – 2012	B.Sc. (Honors)	Biomedical Toxicology	University of Guelph Guelph, ON

EMPLOYMENT RECORD :

Apr 2014 – Present	Statistical Analyst	KGK Synergize Inc., London, ON
Apr 2012 – Aug 2013	Research Assistant Department of Mathematics and Statistics	University of Guelph Guelph, ON
Sep 2012 – Dec 2012	Research Assistant Department of Mathematics and Statistics	University of Guelph Guelph, ON
Apr 2010 – Sep 2010	Research Assistant Department of Chemistry	University of Guelph Guelph, ON
2005 – 2009	General Labourer	Rensch Brothers Welding Guelph, ON

16.2.4 Listing of Participants Receiving Study Product from Specific Batches

Thirty five participants randomized into YYC!™ Meal Group consumed YYC!™ Meal replacement for 85 days. YYC!™ Meal replacement contained the following active ingredients (Protein Matrix (Whey Protein Concentrate, Micellar Casein), Corn Fiber, MCT Powder, and Vitamin Mineral Premix [(Tri-magnesium Citrate, Dipotassium Phosphate, Vitamin C (Ascorbic Acid), Ferrous Sulfate, Vitamin E (Alpha-Tocopheryl acetate), Biotin, Vitamin A, Palmitate, Zinc Sulfate, Niacinamide, Vitamin B5 (Calcium Pantothenate), Copper Gluconate, Cyanocobalamin, Vitamin B6 (Pyridoxine), Vitamin D3 (Cholecalciferol), Potassium Iodide, Vitamin B2 (Riboflavin), Vitamin B1 (Thiamine), Chromium Chloride, Vitamin B9 (Folic Acid)]) and non-active ingredients (Natural and Artificial Flavor, Xanthan Gum, Sucralose, and Sodium Chloride). Participants consumed their meal plan YYC!™ Meal replacement twice daily substituting any 2 out of the 3 meals (i.e. breakfast, lunch, dinner). The lot Number for the YYC!™ Meal replacement used in this study is IM454181.

The other 35 participants who were randomized in the MAHA group did not consume any study product.

16.2.5 Randomisation Scheme and Codes

Seventy participants were randomized into 7 blocks of 10 by using seed 17073.

16.2.5.1 Randomization List

Randomization Number	Study Group	Site ID - Participant Number	Participant Initial	Date of Randomization dd-mm-yyy
1	MAHA Diet	CAL-020	SKS	08-09-2016
2	MAHA Diet	CAL-032	CER	08-09-2016
3	YYC!™ Meal	ORL-002	KSV	01-09-2016
4	YYC!™ Meal	CAL-014	HBK	08-09-2016
5	YYC!™ Meal	CAL-033	EDP	08-09-2016
6	YYC!™ Meal	CAL-036	K-S	09-09-2016
7	YYC!™ Meal	ORL-024	JGL	09-09-2016
8	MAHA Diet	CAL-035	JAM	09-09-2016
9	MAHA Diet	CAL-037	PJP	09-09-2016
10	MAHA Diet	ORL-026	MAF	09-09-2016
11	MAHA Diet	CAL-015	KAS	09-09-2016
12	MAHA Diet	ORL-027	J-D	10-09-2016
13	MAHA Diet	ORL-028	OGJ	10-09-2016
14	YYC!™ Meal	ORL-015	S-R	10-09-2016
15	MAHA Diet	ORL-025	YAT	10-09-2016
16	YYC!™ Meal	ORL-037	ALP	12-09-2016
17	YYC!™ Meal	ORL-031	CGP	12-09-2016
18	MAHA Diet	ORL-032	CRS	12-09-2016
19	YYC!™ Meal	ORL-036	PFC	12-09-2016
20	YYC!™ Meal	CAL-039	AKD	12-09-2016
21	MAHA Diet	ORL-039	M-H	13-09-2016
22	YYC!™ Meal	ORL-021	MML	13-09-2016

Randomization Number	Study Group	Site ID - Participant Number	Participant Initial	Date of Randomization dd-mm-yyy
23	MAHA Diet	ORL-034	JEP	13-09-2016
24	YYC!™ Meal	ORL-043	RWR	13-09-2016
25	YYC!™ Meal	CAL-042	CAG	13-09-2016
26	MAHA Diet	ORL-041	J-S	13-09-2016
27	YYC!™ Meal	ORL-040	EMA	13-09-2016
28	MAHA Diet	CAL-018	R-C	13-09-2016
29	YYC!™ Meal	CAL-043	TMM	13-09-2016
30	MAHA Diet	ORL-023	EAL	14-09-2016
31	YYC!™ Meal	ORL-044	KML	14-09-2016
32	MAHA Diet	ORL-051	TJB	14-09-2016
33	YYC!™ Meal	ORL-045	MLE	14-09-2016
34	MAHA Diet	ORL-033	REP	14-09-2016
35	MAHA Diet	ORL-049	MEK	14-09-2016
36	YYC!™ Meal	ORL-048	RKG	14-09-2016
37	YYC!™ Meal	ORL-050	BWM	14-09-2016
38	MAHA Diet	ORL-038	TLH	15-09-2016
39	MAHA Diet	ORL-054	C-M	15-09-2016
40	YYC!™ Meal	ORL-053	DAE	15-09-2016
41	YYC!™ Meal	CAL-048	OSS	15-09-2016
42	MAHA Diet	ORL-055	MTP	15-09-2016
43	MAHA Diet	ORL-056	HLO	15-09-2016
44	MAHA Diet	ORL-058	EAA	16-09-2016
45	YYC!™ Meal	CAL-050	JCG	16-09-2016
46	MAHA Diet	ORL-060	ERC	16-09-2016
47	MAHA Diet	ORL-030	TNW	16-09-2016
48	YYC!™ Meal	CAL-046	HAA	16-09-2016
49	YYC!™ Meal	ORL-047	M-J	16-09-2016
50	YYC!™ Meal	CAL-053	A-C	15-09-2016
51	MAHA Diet	CAL-051	L-S	16-09-2016
52	MAHA Diet	ORL-003	AWC	01-09-2016
53	MAHA Diet	ORL-007	AMM	02-09-2016
54	YYC!™ Meal	CAL-007	P-C	02-09-2016
55	MAHA Diet	ORL-004	DLP	03-09-2016
56	MAHA Diet	ORL-009	KRM	03-09-2016
57	YYC!™ Meal	ORL-010	JJP	03-09-2016
58	YYC!™ Meal	ORL-006	RAB	03-09-2016
59	YYC!™ Meal	ORL-016	T-V	06-09-2016
60	YYC!™ Meal	ORL-013	KBE	06-09-2016
61	YYC!™ Meal	CAL-012	D-D	06-09-2016
62	MAHA Diet	ORL-018	SDD	06-09-2016
63	MAHA Diet	CAL-001	DLP	06-09-2016
64	YYC!™ Meal	ORL-011	SAO	06-09-2016
65	YYC!™ Meal	ORL-012	BDN	06-09-2016
66	MAHA Diet	CAL-008	C-R	06-09-2016
67	MAHA Diet	CAL-016	TKS	06-09-2016
68	MAHA Diet	ORL-014	NAP	07-09-2016
69	YYC!™ Meal	CAL-027	NAR	07-09-2016
70	YYC!™ Meal	CAL-011	RMT	07-09-2016

16.2.6 Audit Certificates

Not applicable; this study did not have prior audits.

16.2.7 Documentation of Statistical Methods
Refer to section 9.8 in the report.

16.3 PARTICIPANT DATA LISTINGS

Refer to electronic database.

16.3.1 Protocol Deviations

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
CAL-001	DLP	MAHA Diet	3	Participant went over the maximum amount of time during exercise. Participant was advised to keep work outs to no more than 35 min
CAL-001	DLP	MAHA Diet	4	week 6-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-007	P-C	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 09, 10, 11, 12 and 13, 2016.
CAL-007	P-C	YYC!™ Meal	3	Participant had double portions on Sept 04, 09, 10, 14 and 15, 2016.
CAL-007	P-C	YYC!™ Meal	3	Participant had double portion on Sept 03, 12, 14 and 15, 2016.
CAL-011	RMT	YYC!™ Meal	3	Participant consumed alcohol on Sept 18, 2016.
CAL-011	RMT	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 13, 14, 17 and 23, 2016.
CAL-011	RMT	YYC!™ Meal	3	Participant had double portions on Sept 13, 15 and 17, 2016.
CAL-011	RMT	YYC!™ Meal	3	Participant did not apply portion control on Sept 11 and 12, 2016.
CAL-012	D-D	YYC!™ Meal	3	Participant had carbs at dinner on Sept 09, Oct 02, 2016.
CAL-012	D-D	YYC!™ Meal	3	Participant had double portions on Sept 12, 13, 28, 2016.
CAL-012	D-D	YYC!™ Meal	3	Participant did not apply portion control on Sept 09, 10, 11, 24, 2016.
CAL-012	D-D	YYC!™ Meal	4	Participant consumed alcohol on Oct 31, 2016.
CAL-012	D-D	YYC!™ Meal	4	Participant had double portion on Oct 07, 14, 2016.
CAL-012	D-D	YYC!™ Meal	4	Did not apply portion control on Oct 20, 21, 31, 2016.
CAL-012	D-D	YYC!™ Meal	5	week 11 and 12-Participant consumed less than 1200 caloried per day, based on a weekly average. This goes against the protocol instructing subjects to maintain a 1500 (+- 20%) caloric intake per day.
CAL-012	D-D	YYC!™ Meal	5	Participant had double portion on Nov. 3, 15, 2016.
CAL-014	HBK	YYC!™ Meal	3	Did not bring products back to their third visit. Compliance was not taken
CAL-014	HBK	YYC!™ Meal	3	Visit 3 was at 36 days. Visit 3 occurred +5days out of window
CAL-014	HBK	YYC!™ Meal	3	Participant had carbs at dinner on Sept 09, 12, 13, 14, 16, 17, 20, 24, 25, 29 and Oct 01, 02, 03, 04, 05, 12, 13, 2016.

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
CAL-014	HBK	YYC!™ Meal	4	Participant had carbs at dinner on Oct 19, 23, 28, 30, and Nov. 01, 2016
CAL-014	HBK	YYC!™ Meal	4	Participant did not apply portion control on Oct 18, 19, and Nov. 01, 2016
CAL-014	HBK	YYC!™ Meal	5	week 9 and 10-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-014	HBK	YYC!™ Meal	5	Participant consumed carbs at dinner on Nov. 09, 14, and 21, 2016.
CAL-014	HBK	YYC!™ Meal	5	Participant did not apply portion control on Nov. 04, 05, 07, 08, 11 and 23, 2016.
CAL-015	KAS	MAHA Diet	3	Participant did not follow the AHA diet - Compliance not calculated because E/T, so not part of PP group anyway
CAL-016	TKS	MAHA Diet	4	Week 6 - Participant consumed less than 1200 calories per day, based on a weekly average. This goes against the protocol instructing subjects to maintain a 1500 (+-20%)caloric intake per day.
CAL-016	TKS	MAHA Diet	5	week 10 and 12-Participant consumed less than 1200 calories per day, based on a weekly average. This goes against the protocol instructing subjects to maintain a 1500 (+- 20%) caloric intake per day.
CAL-018	R-C	MAHA Diet	3	Participant did not follow the AHA diet - Compliance not calculated because E/T, so not part of PP group anyway
CAL-018	R-C	MAHA Diet	4	Participant did not follow the AHA diet - Compliance not calculated because E/T, so not part of PP group anyway
CAL-020	SKS	MAHA Diet	3	week 1, 2 and 3-Consumed less than 1200 calories per day, based on a weekly average instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-020	SKS	MAHA Diet	4	Participant did not follow the AHA diet on Oct 06, 10, 17, 19, 26, 29, 2016
CAL-020	SKS	MAHA Diet	5	Participant did not follow the AHA diet on Nov 02, 06, 09, 11, 14, 16, 20, 2016
CAL-027	NAR	YYC!™ Meal	3	Participant had carbs at dinner on Sept 20 and 27, 2016.
CAL-027	NAR	YYC!™ Meal	3	Participant had double portions on Sept 18 and 29, 2016.
CAL-027	NAR	YYC!™ Meal	3	Participant did not apply portion control on Sept 27 and Oct 03, 2016.
CAL-033	EDP	YYC!™ Meal	3	week 2 and 3-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-033	EDP	YYC!™ Meal	3	Participant had double portion on Sept 25, 2016.
CAL-033	EDP	YYC!™ Meal	3	Participant did not apply portion control on Sept 10, 11, 12, 19, 20, 23 and Oct 01, 02, 04 and 05, 2016.
CAL-033	EDP	YYC!™ Meal	4	week 6 and 7-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-033	EDP	YYC!™ Meal	5	week 9, 10, 11, 12 and 13-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
CAL-033	EDP	YYC!™ Meal	5	Participant came in at day 101 for visit. Visit 5 occurred +19 days out of window
CAL-036	K-S	YYC!™ Meal	3	Participant consumed alcohol on Sept 26, 2016.
CAL-036	K-S	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 16, 20, 22, 23, 24, 2016.
CAL-036	K-S	YYC!™ Meal	5	Participant did not apply portion control on Nov. 04, 05, 06, 07, 08, 09, 10, 16, 17, 21, 22, 23, 24, 26 and Dec 01, 2016.
CAL-036	K-S	YYC!™ Meal	3	Did not apply portion control on Sept 12, 13, 15, 18, 19, 20, 22, 25, 27, 28, Oct 01, 02, 2016. .
CAL-036	K-S	YYC!™ Meal	3	Week 1 - Participant consumed less than 1200 calories per day, based on a weekly average. This goes against the protocol instructing subjects to maintain a 1500 (+-20%)caloric intake per day.
CAL-036	K-S	YYC!™ Meal	4	Participant consumed alcohol on Oct 09, 2016.
CAL-036	K-S	YYC!™ Meal	4	Participant had carbs at dinner on Oct 19, 2016.
CAL-036	K-S	YYC!™ Meal	4	Participant did not apply portion control on Sept 09, 10, 11, 12, 13, 14, 23, 26, 30, 31 and Nov 03, 2016.
CAL-036	K-S	YYC!™ Meal	5	Participant consumed alcohol on Nov. 18, 2016.
CAL-036	K-S	YYC!™ Meal	5	Participant consumed carbs at dinner on Nov. 11 and 24, 2016.
CAL-037	PJP	MAHA Diet	3	Participant came into their visit 3 on Day 34 which was outside of the time window 3 days out of the +3 day window
CAL-037	PJP	MAHA Diet	4	week 6-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-037	PJP	MAHA Diet	5	week 13-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-039	AKD	YYC!™ Meal	3	Participant consumed alcohol on Oct 2 and 5, 2016.
CAL-039	AKD	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 14, 17, 19, 21, 22, 23, 25, 26, 27, 28, 29, 30, Oct 01, 04, 05, 06, 07, 08, 09 and 10, 2016.
CAL-039	AKD	YYC!™ Meal	5	Participant had double portions on Nov. 08, 2016 .
CAL-039	AKD	YYC!™ Meal	3	Participant had double portion size on Sept 20, 24, 26 and Oct 08, 2016.
CAL-039	AKD	YYC!™ Meal	3	Participant did not apply portion control on Sept 14, 15 and 25, 2016.
CAL-039	AKD	YYC!™ Meal	4	Participant did not apply portion control on Oct 11, 12, 18, 23, 2016.
CAL-039	AKD	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 27, 29, 31 and Nov. 01 and 03, 2016. .
CAL-039	AKD	YYC!™ Meal	4	Participant had double portions on Oct 13, 16 and Nov. 01, 2016.
CAL-039	AKD	YYC!™ Meal	5	Participant consumed carbs at dinner on Nov. 08, 10, 16, 18, 20, 21, 26, 30 and Dec 03 and 05, 2016.
CAL-039	AKD	YYC!™ Meal	5	Participant did not apply portion control on Nov. 10, 16, 20, 21, 23, 24, 26 and Dec 05, 2016.

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
CAL-042	CAG	YYC!™ Meal	5	Participant forgot to bring bottle #5. Will bring later. Participant confirmed bottle was empty. Compliance was calculated using empty canister.
CAL-042	CAG	YYC!™ Meal	5	Hurt her back, was not able to exercise 3/week this week; instead did only 2/week during the last week of study.
CAL-042	CAG	YYC!™ Meal	3	Participant consumed carbs on Sept 15, 18, 19, 20, 21, 22, 23, 24 and Oct 04, 2016.
CAL-042	CAG	YYC!™ Meal	3	Participant had double portions on Sept 19, 20 and 23, 2016.
CAL-042	CAG	YYC!™ Meal	3	Participant did not apply portion control on Sept 25, 2016.
CAL-042	CAG	YYC!™ Meal	4	week 5-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-042	CAG	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct 24, 2016.
CAL-042	CAG	YYC!™ Meal	5	Participant did not complete 3-day food record
CAL-043	TMM	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 15, 18, 22, 23 and 24, 2016
CAL-043	TMM	YYC!™ Meal	3	Participant had double portion on Sept 16, 18, 20, 22 and 25, 2016.
CAL-043	TMM	YYC!™ Meal	3	Participant did not apply portion control on Sept 22, 2016.
CAL-046	HAA	YYC!™ Meal	3	Participant consumed alcohol on Sept 17, 18, 19, 23, 28, 30 and Oct 05, 07 and 08, 2016.
CAL-046	HAA	YYC!™ Meal	3	week 1-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-046	HAA	YYC!™ Meal	5	Participant finished study at day 63. He will be out of town. Visit 5 occurred -19 days out of window
CAL-046	HAA	YYC!™ Meal	3	Participant had double portions on Sept 22, 2016.
CAL-046	HAA	YYC!™ Meal	3	Participant did not apply portion control on Sept 17, 22, and 29, 2016.
CAL-046	HAA	YYC!™ Meal	4	week 8-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
CAL-046	HAA	YYC!™ Meal	4	Participant had double portion on Oct 19, Nov 01 and 05, 2016.
CAL-046	HAA	YYC!™ Meal	4	Participant did not apply portion control on Oct 17, Nov 04 and 05, 2016. .
CAL-046	HAA	YYC!™ Meal	5	Participant did not apply portion control on Nov 13 and 14, 2016.
CAL-048	OSS	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 18, 19, 20, 21, 23, 24, 25, 27, 28, 29, and Oct 01, 02, 04, 05, 06, 07, 08, 09, 10, 11 and 12, 2016.
CAL-048	OSS	YYC!™ Meal	5	Participant did not apply portion control on Nov. 14, 15, 17, 21 and Dec 05 and 07, 2016.
CAL-048	OSS	YYC!™ Meal	3	Participant had double portions on Sept 16, 17, 21, 24 and Oct 02, 06, and 09, 2016.
CAL-048	OSS	YYC!™ Meal	3	Participant did not apply portion control on Sept 19, 22, 23, 24, 25, 26 and Oct 07, 08, 09 and 12, 2016.

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
CAL-048	OSS	YYC!™ Meal	4	Participant did not apply portion control on Oct 16, 19, 20, 22, 26, 29, 30, 31 and Nov. 01, 04, 05, and 07, 2016.
CAL-048	OSS	YYC!™ Meal	4	Participant had double portion on Oct 20, 23, 24, 29 and Nov. 04, 2016.
CAL-048	OSS	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct 14, 15, 16, 17, 18, 19, 20, 23, 24, 27, 28, 29, 30, 31 and Nov. 01, 02, 03, 04, 05, 08, 09, 2016.
CAL-048	OSS	YYC!™ Meal	5	Participant consumed carbs at dinner on Nov. 14, 18, 20, 21, 22, 23, 26, 28, 29, 30 and Dec 01, 02, and 03, 2016.
CAL-048	OSS	YYC!™ Meal	5	Participant had double portions on Nov. 13, 2016.
CAL-050	JCG	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 17,18,20,21,22,23,24,25,26,27,28,29,30 and Oct 01,02,03,04,05,07,08,09,10,11,12 and 13, 2016.
CAL-050	JCG	YYC!™ Meal	3	Participant did not apply portion control on Sept 20, 21, 22, 23,24,28,30 and Oct 01,02, 03, 04,05,08,09,10,11,12 and 13, 2016. .
CAL-050	JCG	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct 14,15,16,17,18,29, 20,21,22,23,24,25,26,27,28,29,30,31 and Nov. 01,02,03,04,05,06,07,08,09, and 10, 2016.
CAL-050	JCG	YYC!™ Meal	4	Participant did not apply portion control on Oct 14, 15,16,17,18,20,24,25,26,27,28,29,30,31 and Nov. 01,02,03,04,05, 06,07,08,09 and 10, 2016.
CAL-050	JCG	YYC!™ Meal	5	Participant consumed carbs at dinner Nov. 11,12,14,15,16,17,18,19,20,21,22,23,25,26,27,28,29, 30 and 31, 2016. .
CAL-050	JCG	YYC!™ Meal	5	3-day food record was not completed
CAL-050	JCG	YYC!™ Meal	5	Participant did not apply portion control on Nov. 11,12,13,14,16,20,23,27,28,29, 2016. .
CAL-051	L-S	MAHA Diet	3	Participant did not follow the AHA diet on Sep 18, 21, 24, 26, 27, Oct 02, 05, 06, 09, 11, 2016
CAL-051	L-S	MAHA Diet	4	Participant did not follow the AHA diet on Oct 13, 15, 16, 21, 22, 23, 25, 31, Nov 03, 04, 08, 2016
CAL-051	L-S	MAHA Diet	5	Participant did not follow the AHA diet on Nov 11, 17, 18, 20, Dec 01, 02, 07
CAL-051	L-S	MAHA Diet	3	Visit 3 was outside of the time window 10 days out of the +3 day window Visit 3 occurred at Day 41 instead of Day 26
CAL-053	A-C	YYC!™ Meal	3	Participant did not apply portion control on Sept 20, 21, 25, 26, 28, 30 and Oct 01, 02, 03, 04, and 05, 2016.
ORL-002	KSV	YYC!™ Meal	3	Participant did not follow the AHA diet on Sep 05,09, 10, 25, 26
ORL-002	KSV	YYC!™ Meal	3	week 1 and 2-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
ORL-002	KSV	YYC!™ Meal	4	week 6-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
ORL-003	AWC	MAHA Diet	5	Participant took 98 doses when it was expected to take 64 and compliance was 153% on Nov. 28, 2016,
ORL-003	AWC	MAHA Diet	4	Participant's compliance was outside of acceptable range; 134% calculations show they should have taken 56 doses but actually consumed 75 doses

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
ORL-003	AWC	MAHA Diet	5	Participant consumed carbs at dinner on Nov 01, 06, 2016 twice
ORL-003	AWC	MAHA Diet	3	Participants compliance was outside range - 191% should have taken 52 doses but took 99.4
ORL-003	AWC	MAHA Diet	3	Participant consumed carbs at dinner on Sept-04,06,07,09,12,13,15,16,17,21,22,23,25,28-2016
ORL-003	AWC	MAHA Diet	3	Participant had double portions of carbs on Sept-02,05,08,09,26,27,28-2016
ORL-003	AWC	MAHA Diet	3	Participant did not apply portion control on Sept-02,05,06,07,09,10,13,15,19,22,24,29-2016
ORL-003	AWC	MAHA Diet	4	Participant had double portions of carbs on Oct 01, 05, 07,14,17,19,20,22,23,25 and 26, 2016.
ORL-003	AWC	MAHA Diet	4	Participant consumed carbs at dinner on Sept-30, Oct-02,04,05,06,08,09,10,11,15,23-2016
ORL-003	AWC	MAHA Diet	4	Participant did not apply portion control on Sept 30 and Oct 03,04,05, 11, 12, 16, 21, 22, 24 and 25, 2016.
ORL-003	AWC	MAHA Diet	5	Participant had double portions on carbs on Oct-30, Nov-01,03,04,05,11,12,13,17,19,24-2016 and double portions of protein on Nov-02,12-2016
ORL-003	AWC	MAHA Diet	5	Participant did not apply portion control on Oct-28, 29, 30, 31, Nov-02,03,06,07,12,14,16,18,20,22,23,24-2016
ORL-004	DLP	MAHA Diet	3	Participant did not follow the AHA diet on Sep 07, 11, 12, 26, 28, 2016
ORL-006	RAB	YYC!™ Meal	5	Participant's compliance was 68% but should be 100%
ORL-006	RAB	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-04,05,08,09,11,14,15,16,17, 2016
ORL-006	RAB	YYC!™ Meal	5	Participant had double portions of carbs on Nov-22-2016 and double portions on Nov-10-2016
ORL-006	RAB	YYC!™ Meal	5	Participant did not apply portion control on Oct-31, Nov-01,09,20,25-2016
ORL-006	RAB	YYC!™ Meal	3	Participant had double portions of carbs on Sept-04,11-2016
ORL-006	RAB	YYC!™ Meal	3	Participant did not apply portion control on Sept-04,07,09,23,26,28, 2016.
ORL-006	RAB	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct-04,09,28-2016
ORL-006	RAB	YYC!™ Meal	4	Participant had double portions of carbs on Oct-06,13-2016
ORL-006	RAB	YYC!™ Meal	4	Participant did not apply portion control on Oct-10,17-2016
ORL-006	RAB	YYC!™ Meal	5	Participant consumed carbs at dinner on Oct-30, Nov 01,02-2016
ORL-009	KRM	MAHA Diet	3	Participant did not follow the AHA diet on Sep 07, 08, 13, 15, 23, 2016
ORL-010	JJP	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 08, 16, 18 and 20, 2016.
ORL-010	JJP	YYC!™ Meal	3	Participant consumed alcohol on Sept 06, 09 and 20, 2016.
ORL-010	JJP	YYC!™ Meal	3	Participant had double portions of carbs on Sept 18, 2016. Participant had double portion of protein on Sept 07 2016.

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
ORL-010	JJP	YYC!™ Meal	3	Participant did not apply portion control on Sept 05, 06, 10, 13, 14 and 16, 2016.
ORL-011	SAO	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-10,17,23-2016
ORL-011	SAO	YYC!™ Meal	3	Participant had double portions of carbs on Sept-09,11,14, Oct-01-2016
ORL-011	SAO	YYC!™ Meal	3	Participant did not apply portion control on Sept-07, 21, 22, 24, 28, Oct-01-2016
ORL-011	SAO	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct-05,06,29-2016
ORL-011	SAO	YYC!™ Meal	5	Participant consumed carbs at dinner on Nov-08,12,21-2016
ORL-013	KBE	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 11,13,16,17,21,22,23,26,27,28,30 2016.
ORL-013	KBE	YYC!™ Meal	3	Participant had double portions of carbs on Sept 07,08,09,10,12,14 & Oct 4 - 2016
ORL-013	KBE	YYC!™ Meal	3	Participant did not apply portion control on Sept 07,08,09,10,11,12,14,15,24,25 2016
ORL-013	KBE	YYC!™ Meal	3	Participant's compliance for IP was 49g but was changed to 30g. Correct compliance is 60%. Participant logged consumption of 54 doses however calculations show participant took 32.4 doses
ORL-013	KBE	YYC!™ Meal	4	Participant had double portions of protein on Oct-05,06,07,09-2016
ORL-013	KBE	YYC!™ Meal	4	Participant did not apply portion control on Oct-05,06,07,08,09-2016
ORL-013	KBE	YYC!™ Meal	4	Compliance was calculated. Participant logged consumption of 58 doses of IP. Calculations show participant consumed 89 doses
ORL-013	KBE	YYC!™ Meal	5	Participant took 83.6 doses when it was expected to take 62 doses. This compliance was 135%
ORL-015	S-R	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-12,13,14,15,16,17,18,20,21,22,25-2016
ORL-015	S-R	YYC!™ Meal	3	Participant had double portions of carbs on Sept-19,23,24,25,26-Oct-02-2016 and double portions of protein on Sept-27,28,29,30-Oct-01-2016
ORL-015	S-R	YYC!™ Meal	5	Participant had double portions of carbs on Nov-22-2016 and double portions on Nov-10-2016
ORL-015	S-R	YYC!™ Meal	5	Participant did not apply portion control on Nov-10,11,20-2016
ORL-015	S-R	YYC!™ Meal	3	Participant did not apply portion control on Sept-19,20,21,25-Oct-02,08-2016
ORL-015	S-R	YYC!™ Meal	4	Participant did not apply portion control on Oct-11,15-2016
ORL-015	S-R	YYC!™ Meal	4	Participant had double portions of carbs on Oct-09-2016
ORL-015	S-R	YYC!™ Meal	4	week 8-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
ORL-015	S-R	YYC!™ Meal	5	week 9-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
ORL-015	S-R	YYC!™ Meal	5	Participant consumed carbs at dinner on Dec-02-2016

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
ORL-015	S-R	YYC!™ Meal	5	Participant consumed alcohol on Nov-27, Dec-02-2016
ORL-016	T-V	YYC!™ Meal	3	week 1-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
ORL-016	T-V	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-10-2016
ORL-016	T-V	YYC!™ Meal	3	Participant had double portions of carbs on Sept-10,18-2016 and double portions of protein on Sept-14,15-2016
ORL-016	T-V	YYC!™ Meal	3	Participant did not apply portion control on Sept-12,13,17,24,27-2016
ORL-016	T-V	YYC!™ Meal	4	Week 8-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
ORL-016	T-V	YYC!™ Meal	4	Participant had double portions of carbs on Oct-08-2016
ORL-016	T-V	YYC!™ Meal	4	Participant did not apply portion control on Oct-07,11-2016
ORL-018	SDD	MAHA Diet	3	Participant did not follow the AHA diet on Sep 09, 13, 27, 2016
ORL-018	SDD	MAHA Diet	3	Participant consumed less than 1200 calories per day on Week 1-2-3
ORL-021	MML	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-16,18,21,22,23,24,25,26,27,28,30, Oct-02,05,06,07,08,10-2016
ORL-021	MML	YYC!™ Meal	3	Participant had double portions of carbs on Sept-21,27, Oct-06-2016
ORL-021	MML	YYC!™ Meal	4	Participant did not apply portion control on Oct 14,15,18,20,24 and 30, 2016.
ORL-021	MML	YYC!™ Meal	3	Participant did not apply portion control on Sept-15, 17, 21, 23, 24, 25, 26, 29, 30, Oct-03,07,10-2016
ORL-021	MML	YYC!™ Meal	3	Participant consumed alcohol on Oct-05-2016
ORL-021	MML	YYC!™ Meal	4	participant did not complete their food record at v4 scheduled Nov. 09 2016. Participant did not log anything for week 8 (days 50-56). Nov 02 to 08, 2016 no data was entered
ORL-021	MML	YYC!™ Meal	4	Participant consumed alcohol on Oct 25, 2016 (once).
ORL-021	MML	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct 12,13,14,15,16,18,19,20,21,24,25,27 and 29, 2016.
ORL-021	MML	YYC!™ Meal	4	Participant had double portions of carbs on Oct 13, 19 and 22, 2016. Participant had double portions of protein on Oct 23, 2016.
ORL-023	EAL	MAHA Diet	3	Participant did not follow the AHA diet on Sep 22, 24, Oct 01, 07, 10, 2016
ORL-024	JGL	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 10,11,12,14,15,17,19,20 and 29, 2016.
ORL-024	JGL	YYC!™ Meal	3	Participant consumed alcohol on Sept 10, 2016 (once).
ORL-024	JGL	YYC!™ Meal	3	Participant had double portions of carbs on Sept 12,17,20,21, 29 and Oct 01, 03 and 04, 2016.
ORL-024	JGL	YYC!™ Meal	3	Participant did not apply portion control on Sept 13, 14, 25 and Oct 01 and 03, 2016.
ORL-025	YAT	MAHA Diet	3	Participant did not follow the AHA diet on Sep 10, 20, 28, 2016

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
ORL-026	MAF	MAHA Diet	3	Participant did not follow the AHA diet on Sep 09, 11, 12, 13, 14, 17, 28, Nov 01, 03, 05, 2016
ORL-026	MAF	MAHA Diet	4	Participant did not follow the AHA diet on Oct 10, 11, 14, Nov 01, 2016
ORL-026	MAF	MAHA Diet	4	week 6 -Participant consumed less than 1200 calories daily
ORL-027	J-D	MAHA Diet	3	Participant did not follow the AHA diet on Sep 10, 12,15, 19, 20, 22, 27, 30, Oct 02, 05, 06, 11, 2016
ORL-027	J-D	MAHA Diet	4	Participant did not follow the AHA diet on Oct 24, 29, 31, Nov 01, 02, 03, 2016
ORL-027	J-D	MAHA Diet	5	Participant did not follow the AHA diet on Nov 13, 16, 17, 22, 26, 28, 29, 2016
ORL-030	TNW	MAHA Diet	4	week 5 and week 8 Participant consumed less than 1200 calories per day
ORL-030	TNW	MAHA Diet	3	Participant did not follow the AHA diet on Sep 20, 21, 22, 24, 29, 2016
ORL-031	CGP	YYC!™ Meal	3	Participant consumed carbs for dinner on Sept-13,15,20,21,22,23,25,26,28,29,30-2016 and Oct-04,05,06,07-2016
ORL-031	CGP	YYC!™ Meal	3	Participant had double portions of carbs on Sept-29-2016 and Oct-04,06,07-2016
ORL-031	CGP	YYC!™ Meal	5	Participant had double portions of carbs on Nov-23,24,26,27-2016
ORL-031	CGP	YYC!™ Meal	3	Participant did not apply portion control on Sept-13,14,17,19,20,22,24,25,27 - Oct-05-2016
ORL-031	CGP	YYC!™ Meal	3	Participant consumed alcohol on Sept-18- and Sept-26-2016 twice; twice in total-1 beer on the 18th and 1 beer on the 26th
ORL-031	CGP	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct-11,13,15,16,18,19,21,22,24,25,26,27,28 - Nov-01,02,03,04,05,06,07-2016
ORL-031	CGP	YYC!™ Meal	4	Participant had double portions of carbs on Oct-13,19, Nov-02,04-2016
ORL-031	CGP	YYC!™ Meal	4	Participant did not apply portion control on Oct-14,15,17,18,20,23,26,27-Nov-01,05,06-2016
ORL-031	CGP	YYC!™ Meal	5	Participant consumed carbs at dinner on Nov-08,09,10,11,15,16,22,23,24,25,26,27,28,29,30-Dec-01,02,03-2016
ORL-031	CGP	YYC!™ Meal	5	Participant did not apply portion control on Nov-15-16, 19, 20, 21, 22, 23, 24, 25, 28, 29, Dec-01-2016
ORL-031	CGP	YYC!™ Meal	5	Participant consumed alcohol on Nov-17-2016
ORL-032	CRS	MAHA Diet	4	week 6, 7 and 8-Participant consumed less than 1200 Calories per day, based on a weekly average. This goes against the protocol instructing subjects to maintain a 1500 (+- 20%) caloric intake per day.
ORL-032	CRS	MAHA Diet	5	week 9, 10, 11 and 12-Participant consumed less than 1200 Calories per day, based on a weekly average. This goes against the protocol instructing subjects to maintain a 1500 (+- 20%) caloric intake per day.
ORL-034	JEP	MAHA Diet	3	Participant did not follow the AHA diet on Sep 15, 17, 19, 23, Oct 03, 05, 06, 07, 2016

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
ORL-036	PFC	YYC!™ Meal	5	Participant was expected to take 56 doses between visit 3 and 4 but consumed 99 doses, 43 more doses than expected to be taken. This made her compliance 177%.
ORL-036	PFC	YYC!™ Meal	3	Participant took 74 doses when it was expected to take 54 doses. Her compliance was 137% On Oct 10, 2016, visit 3
ORL-036	PFC	YYC!™ Meal	3	Participant did not apply portion control on Sept 29 and Oct 05, 2016.
ORL-036	PFC	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-13,14,15,16,18,24,28,29-2016 and Oct-01,02,04,05,06,07,08,09,10-2016
ORL-036	PFC	YYC!™ Meal	3	Participant had double portion of carbs on Sept 13 and 22, 2016. Participant had double portions of protein on Sept 23 and Oct 07, 2016.
ORL-036	PFC	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct-11,12,16,18,19,20,21,22,24-2016
ORL-036	PFC	YYC!™ Meal	5	Participant consumed carbs at dinner on Nov-12,13,15,24,25,27-2016 and Dec-04-2016
ORL-036	PFC	YYC!™ Meal	5	Participant had double portions of carbs on Nov-13,14-2016 and double portions of protein on Nov-08-2016 and Nov-14-2016
ORL-036	PFC	YYC!™ Meal	5	Participant did not apply portion control on Nov-10,27-2016 and Dec-03,04-2016
ORL-036	PFC	YYC!™ Meal	3	week 2-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
ORL-037	ALP	YYC!™ Meal	3	Participant had double portions of carbs on Sept 26, 2016. Participant had double portion of protein on Sept 20 and 21, 2016.
ORL-037	ALP	YYC!™ Meal	3	Participant did not apply portion control on Sept 27,28 and 29, 2016.
ORL-040	EMA	YYC!™ Meal	5	participant consumed carbs at dinner on Nov-24,25-2016 and Dec-02-2016
ORL-040	EMA	YYC!™ Meal	5	Participant had double protein on Nov - 12,24 2016
ORL-040	EMA	YYC!™ Meal	5	Participant did not apply portion control on - Nov - 12,17,18,19-2016
ORL-040	EMA	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct - 22-2016 and Nov-03-2016 twice
ORL-040	EMA	YYC!™ Meal	4	Participant did not apply portion control on Oct-21,22,27-2016 and Nov-03,04-2016
ORL-040	EMA	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-14,21,22,23,24,28,29,30-2016 and Oct-01,03,04,05,06,07,08,09,10-2016
ORL-040	EMA	YYC!™ Meal	3	Participant had double portions of carbs - Sept 28-2016 and Oct-05-2016
ORL-040	EMA	YYC!™ Meal	3	Participant did not apply portion control on Sept-14,22,23,24,25,29-2016 and Oct-03,05,06,10-2016
ORL-041	J-S	MAHA Diet	3	Participant did not follow the AHA diet on Sep 15, 20, 23, 24, Oct 06, 2016
ORL-043	RWR	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-22,24,28,30-2016
ORL-043	RWR	YYC!™ Meal	3	Participant had double portions of carbs on Sept-14,15,16,18,19,22,23,24-2016

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
ORL-043	RWR	YYC!™ Meal	3	Participant did not apply portion control on Sept-14,15,16,19,22,23,28-2016 and Oct-05,06,08,09,11-2016
ORL-043	RWR	YYC!™ Meal	4	Participant had double portions of carbs on Oct-14-2016
ORL-043	RWR	YYC!™ Meal	4	Participant did not apply portion control on Oct-12,13,16,20,22,23,24-2016
ORL-044	KML	YYC!™ Meal	3	Participant's compliance indicates consumption of 98 doses but should have been 60 doses based on calculation for number of days IP was taken
ORL-044	KML	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 16,18,23,26,27, 30 and Oct 07 and 09, 2016.
ORL-044	KML	YYC!™ Meal	3	Participant had double portions of carbs on Sept 26, 28 and Oct 01, 03,08,09, 10 and 12, 2016. Participant had double portions of protein on Sept 15, 2016.
ORL-044	KML	YYC!™ Meal	4	Participant had double portions of carbs on Oct 18,19,21,22, 27,29,30, and Nov. 03 and 05, 2016.
ORL-044	KML	YYC!™ Meal	4	Participant did not apply portion control on Oct 23 and Nov. 01, 2016.
ORL-044	KML	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct 13,16,20,24,27,30, and Nov. 02,04 and 07, 2016.
ORL-044	KML	YYC!™ Meal	4	Participant expected to take 56 doses, but calculations indicate 98 doses
ORL-045	MLE	YYC!™ Meal	2	Participant was non-compliant with study visit schedule and did not return IP
ORL-047	M-J	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept 18 and 19, 2016 (twice).
ORL-047	M-J	YYC!™ Meal	3	Participant had double portions of carbs on Sept 17, 18 and 19, 2016,
ORL-048	RKG	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-18,24,30,2016 and Oct-06-2016
ORL-048	RKG	YYC!™ Meal	3	Participant had double portions of carbs on Sept-15,19,26-2016 and Oct-08,10-2016
ORL-048	RKG	YYC!™ Meal	4	Participant had double portions of carbs on Oct 31 and Nov. 07, 2016.
ORL-048	RKG	YYC!™ Meal	3	Participant did not apply portion control on Sept-22,26,29-2016 and Oct-06-2016
ORL-048	RKG	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct-13,14,15,16,17,18,19,20,21,23,24,25,30,31-2016
ORL-048	RKG	YYC!™ Meal	5	Participant consumed carbs at dinner on Nov-25-2016
ORL-048	RKG	YYC!™ Meal	5	Participant had double portions of carbs on Nov-10,20,15,27-2016
ORL-048	RKG	YYC!™ Meal	5	Participant did not apply portion control on Nov-28-2016
ORL-048	RKG	YYC!™ Meal	3	Participant should have taken 54 doses of IP but calculations showed they consumed 37 doses of IP
ORL-049	MEK	MAHA Diet	3	week 1-Participant consumed less than 1200 calories daily instead of maintaining a 1500 (+/- 20%) caloric intake daily
ORL-050	BWM	YYC!™ Meal	3	Participant consumed carbs at dinner on Sept-15,18-2016 twice

Site ID - Participant Number	Participant Initial	Study Group	Visit	Description
ORL-050	BWM	YYC!™ Meal	3	Participant had double portions of carbs on Sept-15,20,23,29-2016 and Oct-03,04,05,06,09,10 which is against protocol
ORL-050	BWM	YYC!™ Meal	3	Participant did not apply portion control on Sept-18,20,21,22,23-2016 and Oct-05,07-2016
ORL-050	BWM	YYC!™ Meal	4	Participant had double portions of carbs on Oct-13,14,16,25,29-2016 and Nov-01-2016. Also, double portions of protein on Oct-13,16,20,30-2016
ORL-050	BWM	YYC!™ Meal	4	Participant did not apply portion control on Oct-13,25-2016 and Nov-03-2016
ORL-050	BWM	YYC!™ Meal	5	Participant had double portions of carbs on Nov-11,12,17,19,23,25,26,27,28,29-2016 and Dec-02,03,04-2016 also double portions of protein on Nov-12,17,18-2016
ORL-050	BWM	YYC!™ Meal	5	Participant did not apply portion control on Nov-10,12,13,14,17,24,30-2016 and Dec-03-2016
ORL-051	TJB	MAHA Diet	3	Participant did not follow the AHA diet on Sep 15, 16, 18, 20, 22, 26, 27, 29, Oct 01, 05, 06, 07, 11, 2016
ORL-053	DAE	YYC!™ Meal	3	participant consumed carbs at dinner on Sept-23,30-2016 and Oct-02,03-2016
ORL-053	DAE	YYC!™ Meal	3	Participant had double portions of carbs on Sept-18,28-2016 and double portions of protein on Sept-23-2016 and Sept 29-2016
ORL-053	DAE	YYC!™ Meal	3	Participant did not apply portion control on Sept-17,18,20,21,24-2016 and Oct-07-2016
ORL-053	DAE	YYC!™ Meal	4	Participant consumed carbs at dinner on Oct 15,21 and 24, 2016.
ORL-053	DAE	YYC!™ Meal	4	Participant did not apply portion control on Oct 14 and 17, 2016.
ORL-060	ERC	MAHA Diet	3	Participant did not follow the AHA diet on Sep 16, 18, 21, 27, Oct 03, 05, 14, 2016
ORL-060	ERC	MAHA Diet	4	Participant did not follow the AHA diet on Oct 19, 20, 21, 23, 26, 28, 29, 31, Nov 01, 02, 03, 04, 07, 08, 09, 10, 2016
ORL-060	ERC	MAHA Diet	5	Participant did not follow the AHA diet on Nov 11, 12, 13, 14, 23, 24, 25, 26, 29, Dec 01, 02, 03, 04, 06, 2016

16.4 CASE REPORT FORMS

16.4.1 CRFs for Deaths, Other Serious Adverse Events, and Withdrawals for AE.

Protocol # 16MWHC

SERIOUS ADVERSE EVENT REPORT

SPONSOR: North Bay Therapeutics	PROTOCOL #: 16MWHC
INVESTIGATOR NAME: Dr. Gez Agolli ADDRESS: 26750 Towne Centre Dr Foothill Ranch , CA 92610	SITE: KGK Clinical Trials Centers - Irvine

Check one:	☒ Initial Report	Oct 13 2016 (M m m d d y y y y)
	☐ Follow-up Report	(M m m d d y y y y)

SUBJECT INFORMATION	Subject Initials	Subject Number	Date of Birth
	KAS	015	Jan 04 1995 (M m m d d y y y y)
	SEX ☒ Male ☐ Female		

SERIOUS ADVERSE EVENT DESCRIPTION: (Provide final diagnosis if known. In absence of final diagnosis, provide signs and symptoms)

Date of Onset	Date of Resolution or Ongoing ☐
Oct 04 2016 (M m m d d y y y y)	Oct 06 2016 (M m m d d y y y y)

SERIOUS CRITERIA (Check all items appropriate to the SAE)

- ☐ Death (M m m d d y y y y)
- ☐ Life-threatening
- ☒ Initial or prolonged hospitalization
- ☐ Persistent or significant disability/incapacity
- ☐ Congenital anomaly/birth defect
- ☐ Important medical event

INTENSITY

- ☐ Mild
- ☐ Moderate
- ☒ Severe

OUTCOME

- ☒ Recovered
- ☐ Recovered with sequelae
- ☐ Ongoing
- ☐ Death

ACTION TAKEN REGARDING INVESTIGATIONAL PRODUCT

- ☒ None
- ☐ Interrupted
- ☐ Discontinued

RELATIONSHIP TO INVESTIGATIONAL PRODUCT

- ☒ Not related
- ☐ Unlikely
- ☐ Possible
- ☐ Probable

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KGK

Protocol # 16MWHC

☐ Most probable

Subject Initials	Subject Number
K A S	0 1 5

RELEVANT PAST AND PRESENT MEDICAL HISTORY: ~~None~~ JSM Oct 13, 2016

Doctor informed Subject that size of esophagus is smaller than normal. Possibly due to Pre-mature birth

CONCOMITANT MEDICATIONS:

Was the subject taking any concomitant medication(s) at time of onset of adverse event?

☐ Yes* ☒ No

***If "yes", fill in table below or attach concomitant medications list**

Name of Medication	Dose and Units	Indication	Start Date	Stop Date

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KGK

EVENT SUMMARY:
(Describe event, symptoms, signs, time course, relevant tests or labs, treatments, etc.)

On October 04, 2016 Subject was eating Sunflower seeds and one became lodged in the back of his throat. The subject was able to breathe. Subject admitted himself to the hospital the same day where he was encouraged to induce vomiting. Vomiting did not help. The second day the seed was removed through a non-surgical Procedure. Subject has recovered and was released on October 06, 2016.

(subject was enrolled into controlled group)

Did the subject's participation in this study end as a result of this SAE?

☐ Yes ☒ No

Investigator Name and Signature **Date** Oct 13, 2016

SERIOUS ADVERSE EVENT REPORT

SPONSOR: North Bay Therapeutics	PROTOCOL #: 16MWHC
INVESTIGATOR NAME: Dr. Nicole Craven **ADDRESS:** 114 W Underwood St, Orlando, FL 32806	**SITE:** KGK Clinical Trials Centers - Orlando

Check one: ☑ **Initial Report** DEC 14 2016 (M m m d d y y y y) ☐ **Follow-up Report** _ _ _ _ _ _ _ _ _ _ _ _ (M m m d d y y y y)

SUBJECT INFORMATION

Subject Initials: M M L

Subject Number: 0 2 1

Date of Birth: Jun 15 1988 (M m m d d y y y y)

SEX ☐ Male ☒ Female

SERIOUS ADVERSE EVENT DESCRIPTION: (Provide final diagnosis if known. In absence of final diagnosis, provide signs and symptoms)

Date of Onset: NOV 16 2016 (M m m d d y y y y)

Date of Resolution or **Ongoing** ☑ _ _ _ _ _ _ _ _ _ _ _ _ (M m m d d y y y y)

SERIOUS CRITERIA (Check all items appropriate to the SAE)

- ☐ Death _ _ _ _ _ _ _ _ _ _ _ _ (M m m d d y y y y)
- ☐ Life-threatening
- ☐ Initial or prolonged hospitalization
- ☐ Persistent or significant disability/incapacity
- ☐ Congenital anomaly/birth defect
- ☒ Important medical event

INTENSITY

- ☐ Mild
- ☐ Moderate
- ☐ Severe

OUTCOME

- ☐ Recovered
- ☐ Recovered with sequelae
- ☐ Ongoing
- ☐ Death

ACTION TAKEN REGARDING INVESTIGATIONAL PRODUCT

- ☐ None

RELATIONSHIP TO INVESTIGATIONAL PRODUCT

- ☐ Not related

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☐ Interrupted ☒ Discontinued	☐ Unlikely ☐ Possible ☐ Probable ☐ Most probable

Subject Initials	Subject Number
M M L	0 2 1

RELEVANT PAST AND PRESENT MEDICAL HISTORY:

CONCOMITANT MEDICATIONS:

Was the subject taking any concomitant medication(s) at time of onset of adverse event?

☐ Yes* ☒ No

***If "yes", fill in table below or attach concomitant medications list**

Name of Medication	Dose and Units	Indication	Start Date	Stop Date

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EVENT SUMMARY:
(Describe event, symptoms, signs, time course, relevant tests or labs, treatments, etc.)

Participant called clinic on Nov 16 2016 to notify clinic of her pregnancy. Advised to stop using I.P. Notified of need to terminate study and schedule E.T. visit. Participant stated she would be out of town until second week in December. Appt fo E.T visit on Dec 14 2016 completed. Participant denies any untoward symptoms. Will cont. to follow up c participant. Next phone call Scheduled for Dec 28 2016.

Did the subject's participation in this study end as a result of this SAE?

☒ Yes ☐ No

Investigator Name and Signature **Date** Jan 04, 2016

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