A 4-Week Clinical Study Evaluating the Influence of a Breakfast Cookie on Weight Loss

Protocol Number:	4189SBC1217		
Sponsor:	Susie's Smart Cookie		
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Date of Issue:	May 1, 2018		
Study Site:	International Research Services, Inc. 222 Grace Church Street Port Chester, NY 10573 Phone: 914.937.6500 Fax: 914.937.8067		
Institutional Review Board	Allendale Institutional Review Board 30 Neck Road Old Lyme, CT 06371		
Principal Investigator:	Stephen R. Schwartz IRSI President, CEO E-Mail: sschwartz@irsi.org		
Study Coordinator:	Anna Gafner, CCRC Clinic Manager E-Mail: agafner@irsi.org		
Study Schedule	Initiation	Baseline	February 19, 2018
	Interim	Week 2	March 5, 2018
	Completion	Week 4	March 19, 2018
Products:	**Dietary Supplement (Susie's Smart Breakfast Cookie): Orange Cranberry Nut, Gingered Apple, Banana Coconut, Cocoa**		

Study Summary			
Title	A 4-Week Clinical Study Evaluating the Influence of a Breakfast Cookie on Weight Loss		
Protocol Number	4189SBC1217		
Sponsor	Susie's Smart Cookie		
Methodology	Monadic		
Objective	To evaluate the efficacy of a breakfast cookie when used with a restrictive diet to improve weight control.		
Number of Subjects	30 to complete, *target enrollment 34*		
Target Population	Male (maximum 25%) and Female subjects, age 21-55 years old, overweight with a BMI of ≥25.0 and ≤ 29.8		
Duration	4 weeks (Baseline, Week 2, Week 4)		
Claims	***Claim***	***Support***	
	Use of the supplement in combination with a guide for a reduced calorie diet, results in a reduction in absolute body weight.	INBODY	
	Use of the supplement, in combination with a guide for a reduced calorie diet, results in a reduction in the waist-to-hip ratio (WHR), body mass index (BMI), body fat percentage, body fat mass index (BFMI).	INBODY Waist and Hip Measurement	
	Improvement in the well-being, general health attitude and the subjective feeling of stress	Subjective Questionnaire	
	Use of the supplement in combination with a guide for a reduced calorie diet, results in an increase in Omega-3, 6 and HUFA levels	Vital Omega-3 and 6 HUFA Test™ (subgroup of 20)	
Study Products	***Name***	***Formula Number***	
	Dietary Supplement (Susie's Smart Breakfast Cookie): Orange Cranberry Nut Gingered Apple Banana Coconut Cocoa	**NA**	
Statistical Methodology	Descriptive statistics, reported for demographics, assessments, monadic analysis using paired t-test to compare each site to baseline. All final statistical analyses will be performed on the PP population, significance set at p≤0.05.		
Study Schedule	Study Initiation	Baseline	February 19, 2018
		Week 2	March 5, 2018
	Study Completion	Week 4	March 19, 2018
Summary	This was a three-visit study of one dietary supplement's ability to improve weight control. A total of 34 subjects were enrolled in the study and 30 completed participation. Under the conditions of this study, use of the test product **Dietary Supplement (Susie's Smart Breakfast Cookie): Orange Cranberry Nut, Gingered Apple, Banana Coconut, Cocoa** along with a calorie-restricted diet provided statistically significant improvements in mean weight and body mass index results. Subject perception was overall positive and the majority of subjects indicated that they would purchase or recommend the product to a friend. See Sections 19.2, Discussion, and 20.0, Conclusion, for further detail.		

Quality Assurance Statement

This report accurately reflects the data derived from the procedures and materials tested in this study. The conclusions are based on an interpretation of the data and have been reviewed by the Principal Investigator(s) and by personnel from International Research Services, Inc. responsible for assuring its accuracy.

Quality Assurance:	Kimberly A. Hammon Director of Quality Assurance E-mail: khammon@irsi.org	Signature and Date: Digitally signed by Kimberly Hammn DN: cn=Kimberly Hammn, o=IRSI, ou=Quality Assurance, email=khammon@irsi.org, c=US Date: 2018.05.15 14:46:31 -04'00'
Principal Investigator and IRSI President, CEO:	Stephen R. Schwartz IRSI President, CEO E-Mail: sschwartz@irsi.org	Signature and Date: Digitally signed by Stephen R. Schwartz Date: 2018.05.17 15:29:51 -04'00'

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Appendices

List of Abbreviations

AE	Adverse Event
BL	Baseline
BMI	Body Mass Index
BMR	Basal Metabolic Rate
C	Collect
cm	Centimeter
CRF	Case Report Form
CFR	Code of Federal Regulations
D	Dispense
FDA	Food & Drug Administration
GCP	Good Clinical Practices
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IND	Investigational New Drug
IRB	Institutional Review Board
IRSI	International Research Services, Inc.
LBM	Lean Body Mass
n	Number of Subjects
NDA	New Drug Application
PI	Principal Investigator
PP	Per-Protocol
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
Sponsor	Susie's Breakfast Cookies
US	United States
W#	Visit at Week X (i.e. W2 = Week 2)
X	Times

1.0 Introduction

This document is a report for a human research study. This study was conducted according to International Research Services, Inc. research policies and Standard Operating Procedures, U.S. and international standards of Good Clinical Practice (FDA and ICH guidelines) and applicable government regulations.

2.0 Objectives

2.1 Primary Objective

To evaluate the efficacy of a dietary supplement when used with a restrictive diet to aid in weight loss.

3.0 Study Design

This was a four-week evaluation of the effects of a dietary supplement and restrictive diet on weight loss. A panel of 30 subjects completed participation. Each subject received the investigational product and used it according to Sponsor's instructions along with a restrictive diet. At the Baseline visit and at designated time intervals during the study, all subjects underwent body measurements, INBODY assessments, Vital Omega-3 and 6 HUFA Test and subjective questionnaire completion. Study visits occurred at Baseline (BL) and at Weeks 2 and 4 (W2, W4). A detailed outline of study visits appears in Section 7.0 of the protocol (Appendix I).

3.1 Claim:

Data were collected and analyzed with specific regard to the following proposed product claim:

1. **Use of the supplement in combination with a guide for a reduced calorie diet, results in a reduction in absolute body weight,** as evaluated by InBody measurements.
2. **Use of the supplement, in combination with a guide for a reduced calorie diet, results in a reduction in the waist-to-hip ratio (WHR), body mass index (BMI), body fat percentage and body fat mass index (BFMI)** as evaluated by InBody measurements.
3. **Improvement in the well-being, general health attitude and the subjective feeling of stress,** as evaluated by Subjective Questionnaire results.
4. **Use of the supplement in combination with a guide for a reduced calorie diet, results in an increase in Omega-3 and 6**, as evaluated by Vital Omega-3 and 6 HUFA Test™**.**

4.0 Product

All test products and some food products (Breakfast Cookies plus frozen and canned salmon) were provided by the Sponsor and bore appropriate coding labels and proper use instructions. Support products were supplied by IRSI. Upon receipt, product was logged in and stored in a secure area. Within one month of issuance of the final signed report, unless otherwise instructed in writing, all test products, used and unused, will be returned to Sponsor or discarded in accordance with IRSI's SOP.

4.1 Product Descriptions

Name	Flavor	Product/Formula Number	Date Received	Quantity Received
Study Product				
Dietary Supplement (Susie's Smart Breakfast Cookies)	Orange Cranberry Nut Gingered Apple Banana Coconut Cocoa	NA	2/12/18	144 288 288 288

4.2 Product Use Instructions

All subjects received the test product to use for the duration of the study, along with written and verbal use instructions and a diet plan (see Appendix III).

Subjects were also provided with selected foods off the dietary guide:

- Frozen Salmon (one portion per week); to be thawed by placing in cold water for 20 minutes prior to preparation
- Canned Salmon (one portion per week)

Test Product Directions: Eat one Susie's Smart Breakfast Cookie for breakfast and one Susie's Smart Breakfast Cookie for lunch; followed by a sensible dinner.

Subjects will also follow the supplied diet plan.

5.0 Population

5.1 Sample Size

The sample size of n=30 was requested by the Sponsor.
A total of 34 subjects were enrolled in the study and 30 completed participation.

5.2 Inclusion Criteria

1. Males (maximum of 25%) and Females in good general health.
2. Between the ages of 21 and 55 years old, inclusive at enrollment.
3. Overweight subjects with Body Mass Index (BMI) measurements between ≥25 and ≤29.8 as measured by InBody.
4. Self-perceived need/desire to lose at least 10 lbs.
5. Stable weight within two months preceding Baseline
6. Stable medications within three months preceding Baseline.
7. Able to read, understand and sign an informed consent form (includes HIPAA and State requirements).
8. Willing to participate in an interview with the sponsor if requested.
9. Willing and able to follow all study directions and willing to accept all study requirements including:
    a. Willing to follow the provided restrictive diet, including consumption of provided salmon.

5.3 Exclusion Criteria

1. Known allergy to milk, eggs, walnuts and/or coconut, or any item in the provided diet.
2. Taking drugs which are known to influence weight. Including laxatives, Anorectics and Diuretics.
3. Currently following a weight loss program or diet (ex. Atkins, Jenny Craig, Weight Watchers, South Beach Diet, etc.)
4. Currently using or have used weight loss / weight control supplements (prescription, OTC and/or natural remedies) within 28 days of Baseline.
5. Currently taking prescription medications with known weight loss or weight gain side effects (ex. Tricyclic antidepressants, oral corticosteroids, beta blockers)?

General exclusion criteria:

6. Participating in any other clinical studies.
7. Acute or chronic disease or medical condition, which could put him/her at risk in the opinion of the Principal Investigator or compromise study outcomes. Typical uncontrolled chronic or serious diseases and conditions which would prevent participation in any clinical trial are cancer, AIDS, any type of diabetes, renal impairment, mental illness, drug/alcohol addiction.
8. Unreliable or unlikely to be available for the duration of the study
9. Immunocompromised subjects
10. Woman who started Hormone Replacement Therapy within the last three months preceding the screening visit
11. Woman using oral contraception for less than three months before the screening visit or who has changed her contraceptive method within the three months before the Baseline visit or planning to modify her contraception treatment within the duration of the study
12. Woman known to be pregnant, lactating or planning to become pregnant within six months. Subjects who become pregnant during the study must inform the Principal Investigator immediately
13. Unable to communicate or cooperate with the Principal Investigator due to language problems, poor mental development, or impaired cerebral function
14. Employees of IRSI or other testing firms/ laboratories, cosmetic or raw goods manufacturers or suppliers

6.0 Methods

This study was performed in accordance to IRSI final signed clinical study protocol number 4189SBC1217 version 2.5 dated January 26, 2018. A detailed description of study methods is outlined in the attached clinical study protocol (*See* Appendix I).

7.0 Procedure

This three-visit clinical study included consenting, screening, Baseline, Week 2 and Week 4 assessments. A detailed description of procedures is outlined in the attached clinical study protocol (*See* Appendix I).

7.1 Procedure Summary Table

Procedures		Baseline	Week 2	Week 4
Study Initiation and Qualification	Informed Consent and Medical History	X		
	Inclusion/Exclusion Criteria reviewed	X		
Dispense/ Collect Products *and Subject instructions with nutrition guide*		D	D	C
Clinical Assessments	Waist and Hip Measurements	X	X	X
	Height	X		
Instrumental Evaluation	INBODY - Weight -Lean Body Mass -Body Fat Mass -BMI -PBF	X	X	X
Consumer Perception	Subjective Questionnaire	X	X	X
	Testimonial			X
Omega 3 and 6 HUFA test		X		X

8.0 Concomitant Medications and Products

Subject use of all dietary supplements and/or nutraceuticals (other than multi-vitamins approved by IRSI at screening) was prohibited from the Baseline visit until completion of the Week 4 visit. Subjects on physician-prescribed medications must have been on a stable dose for 30 days prior to the Baseline visit.

Weight loss / weight control supplements were prohibited (prescription, OTC and/or natural remedies). Prescription medications with known weight loss or weight gain side effects were prohibited (including but not limited to: tricyclic antidepressants, Oral corticosteroids, beta blockers).

Weight loss programs or diets were prohibited during the study period (including but not limited to: Atkins, Jenny Craig, Weight Watchers, South Beach Diet, etc.).

9.0 Adverse Events

Two adverse events were reported during the conduct of this study, by the same subject.

1. On February 21, 2018, Subject #19 reported two AES of mild gas and headache which both occurred on February 20, 2018, following consumption of the first cookie. The headache lasted approximately four hours and the flatulence lasted approximately eight hours. The subject was discontinued from the study. Relationship to the test product is deemed as none for the headache and possible for the gas.

10.0 Institutional Review Board

This study was overseen by an independent Institutional Review Board (IRB) to ensure the protection of the rights, safety and well-being of subjects. Prior to study initiation, the IRB reviewed and approved the study protocol (and subsequent amendments); methods and materials used in obtaining and documenting informed consent of the subjects. IRB approval letter appears in Appendix V.

IRB Information:
Name: Allendale Institutional Review Board
Address: 30 Neck Road, Old Lyme, CT 06371
Phone: 800.434.5892
E-Mail: Rta1ali@aol.com

11.0 Informed Consent

The informed consent process was completed prior to an individual's involvement in any study related activity. The process was documented using a written informed consent form (ICF) conforming to FDA 21 CFR 50.25 (See Appendix I Protocol, Section 11.0 and Appendix IV).

After review, two copies of the ICF were signed and dated by the individual and the Principal Investigator or his designee administering the consent. One original copy was retained by IRSI and the other was given to the individual.

12.0 Discontinuation of Study

The study was completed on schedule as per the clinical study protocol.

13.0 Changes to the Protocol

13.1 Protocol Amendments

No amendments were made to the final signed protocol.

13.2 Protocol Deviations

Two protocol deviations were noted during the study.

1. Minor: Missed questionnaire data; At week 2, the following data was not captured and is not included in the analysis. A total of 29 subjects are included in the analysis for the questions listed below:
    - #22 did not respond to Q1
    - #31 did not respond to Q13
2. Per the protocol, subjects should be overweight with Body Mass Index (BMI) measurements between ≥25 and ≤29.8 as measured by InBody. However, subjects #20 had a baseline BMI of 23.8 and #31 had a BMI of 30.7.

14.0 Monitoring

The Sponsor was onsite to monitor all visits of this study.

15.0 Recording of Data

All data and information, was recorded on specific paper case report forms (CRFs) as described in the clinical study protocol (*See* Appendix I Protocol, Appendix III).

16.0 Quality Control and Quality Assurance

This clinical study has been audited by the IRSI Quality Assurance / Quality Control auditor. The auditor verified study for accuracy, consistency and proper documentation in accordance to IRSI SOPs and practices. Additionally, accuracy of results reported in the body of this report with respect to the results reported in the data listings and statistical report (See Appendix II).

The data listings and database used for statistical analysis was verified against the CRFs. The data listings were verified against the CRFs for 100% of the data, in a randomly selected set of the subjects (25% of the total number of subjects). The statistical report was validated for accuracy and completeness, as well as verifying the correctness of all subject numbers (n) and the analyses performed according to the Statistical Analysis Plan as described in Section 18 of the clinical study protocol.

17.0 Ethics

The study was conducted in accordance with FDA GCP regulations and ICH guidelines in as much as they apply to cosmetic research with the following noted: This was not an IND / NDA clinical trial. IRSI does not assume any Sponsor obligations as stipulated in FDA GCP and ICH documents. This study is not intended for submission to the FDA.

18.0 Statistical Methods

The planned statistical analysis was performed as outlined in the study protocol for each type of data to be acquired (*See* Protocol, Section 18.0).

The per-protocol (PP) population is defined as the subset of subjects that who complied with the protocol sufficiently to ensure that their data will be likely to exhibit the effects of the treatment. To be considered a PP subject a subject could not miss the Baseline or Week 4 study visit or be found to be non-compliant with the study protocol at the discretion of the Principal Investigator (PI).

The PP population was used for statistical analysis at each time point. Statistical significance was set at $p \leq 0.05$.

Data Type	Statistical Method	Data Reported
Demographics	Descriptive Statistics	Mean and standard deviation Frequency (number and percent)
Waist and Hip Measurements, Instrumentation	Descriptive Statistics Paired T-Test (monadic)	Mean and standard deviation Mean percent improvement from Baseline Percent of subjects showing improvement from Baseline P-value vs. Baseline, paired T-test
Subjective Questionnaires	Descriptive Statistics	Frequency (n,%) will be provided for each response Percent of positive response will be provided (where applicable)

19.0 Results

19.1 Tables

Enrollment and demographic information is reported in Tables 1.0-2.0, clinical measurement results are in Table 3.0, body composition assessment results (Inbody) are found in Table 4.0 and subjective questionnaire results are found in Tables 5.0-5.1.

Table 1.0 Enrollment

Status	n	
Enrolled	34	
Discontinued	4	-Subject #5 discontinued at Week 2 and was lost to follow-up. -Subject #11 was lost to follow-up at Week 4. -Subject #19 discontinued at Week 2 due to AE. -Subject #24 discontinued at Week 2 due to non-compliances.
Completed Baseline Time Point	34	
Completed Week 2 Time Point	30	
Completed Week 4 Time Point	30	

Table 2.0 Demographics

Variable	n	Mean ± SD	Min	Max
Age (years)	30	41.83 ± 8.89	23	55
Height (inches)	30	64.91 ± 3.39	56	72
Weight (pounds)	30	163.33 ± 18.62	138	214
			n	**Percent**
Sex	30	Female	26	86.7%
		Male	4	13.3%
			n	**Percent**
Ethnicity	30	Hispanic or Latino	12	40.0%
		Not Hispanic or Latino	18	60.0%
			n	**Percent**
Race	30	Black or African American	5	16.7%
		Multi-Racial	1	3.3%
		White	16	53.3%
		No Response *See Hispanic or Latino above*	8	26.7%

Table 3.0 Clinical Measurements – Monadic, Comparison to Baseline

Assessment	Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Waist to Hip Ratio (WHR)	Baseline	30	0.84 ± 0.07			
	Week 2	30	0.84 ± 0.06	NI	46.7%	1.000
	Week 4	30	0.84 ± 0.06	NI	43.3%	0.439

NI=No Improvement
*Indicates a statistically significant improvement compared to baseline, p≤0.05

Table 4.0 Body Composition Measurements (Inbody) – Monadic, Comparison to Baseline

Assessment	Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Weight (WG)	Baseline	30	165.11 ± 18.55			
	Week 2	30	163.57 ± 18.54	0.92%	70.0%	**0.013***
	Week 4	30	162.69 ± 18.95	1.47%	66.7%	**0.005***
Body Mass Index (BMI)	Baseline	30	27.44 ± 1.52			
	Week 2	30	27.20 ± 1.52	0.86%	66.7%	**0.030***
	Week 4	30	27.01 ± 1.58	1.54%	66.7%	**0.003***
Percent Body Fat (PBF)	Baseline	30	34.70 ± 5.34			
	Week 2	30	34.76 ± 5.76	NI	50.0%	0.808
	Week 4	30	34.51 ± 5.87	0.77%	53.3%	0.487
Lean Body Mass (LBM)	Baseline	30	0.41 ± 1.12			
	Week 2	30	0.57 ± 1.43	50.60%	13.3%	0.397
	Week 4	30	0.68 ± 1.57	NI	13.3%	0.373
Body Fat Mass (BFM)	Baseline	30	-26.82 ± 9.66			
	Week 2	30	-26.80 ± 10.08	1.57%	50.0%	0.971
	Week 4	30	-25.97 ± 10.50	6.47%	36.7%	0.159

NI=No Improvement
*Indicates a statistically significant improvement compared to baseline, p≤0.05

Table 5.0 Subjective Questionnaire – Consumer Perception

Question	n	Baseline										
		Response n (%)										
		Not at All 0	1	2	3	4	5	6	7	8	9	Very Much 10
Please rate the level of the following attributes before beginning the study:												
1. Excess Weight.	30	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (16.7%)	3 (10.0%)	7 (23.3%)	8 (26.7%)	3 (10.0%)	4 (13.3%)
2. Stress.	30	1 (3.3%)	1 (3.3%)	1 (3.3%)	3 (10.0%)	1 (3.3%)	4 (13.3%)	1 (3.3%)	10 (33.3%)	5 (16.7%)	1 (3.3%)	2 (6.7%)
3. Poor Overall Health.	30	4 (13.3%)	6 (20.0%)	2 (6.7%)	3 (10.0%)	3 (10.0%)	6 (20.0%)	3 (10.0%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	1 (3.3%)
4. Poor General Well Being.	30	6 (20.0%)	4 (13.3%)	4 (13.3%)	4 (13.3%)	4 (13.3%)	2 (6.7%)	2 (6.7%)	2 (6.7%)	1 (3.3%)	0 (0.0%)	1 (3.3%)
5. Lack of Focus.	30	4 (13.3%)	4 (13.3%)	4 (13.3%)	5 (16.7%)	0 (0.0%)	5 (16.7%)	1 (3.3%)	3 (10.0%)	0 (0.0%)	3 (10.0%)	1 (3.3%)
6. Lack of Energy.	30	2 (6.7%)	3 (10.0%)	1 (3.3%)	4 (13.3%)	3 (10.0%)	4 (13.3%)	3 (10.0%)	4 (13.3%)	2 (6.7%)	2 (6.7%)	2 (6.7%)
7. Lack of Stamina.	30	3 (10.0%)	4 (13.3%)	1 (3.3%)	3 (10.0%)	2 (6.7%)	4 (13.3%)	5 (16.7%)	2 (6.7%)	4 (13.3%)	1 (3.3%)	1 (3.3%)
Question*	**n**	**Response n (%)**										
		Yes					**No**					
8. Do you currently use canola oil as your primary oil?	30	12 (40.0%)					18 (60.0%)					
10. Do you exercise regularly?	30	16 (53.3%)					14 (46.7%)					
11. Do you take fish oil supplements?	30	3 (10.0%)					27 (90.0%)					

*See further details for Q8, Q9, and Q10 below

Bold / Shaded = The majority of subjects responded favorably, >50%.

Table 5.0 Subjective Questionnaire – Consumer Perception (Continued)

Question	n	Baseline	
		Open Ended Pooled Response	
		Response	n (%)
8a. If no, what do you typically use?	20*	Olive Oil	13 (65.0%)
		Vegetable	4 (20.0%)
		Pam	2 (10.0%)
		No Response	1 (5.0%)
9. How many times per week do you eat fish?	30	1 time	6 (20.0%)
		1 to 2 times	5 (16.7%)
		0 times	4 (13.3%)
		2 times	4 (13.3%)
		3 times	4 (13.3%)
		2 to 3 times	3 (10.0%)
		0 to 1 time	2 (6.7%)
		4 times	1 (3.3%)
		3 to 4 times	1 (3.3%)
10a. If yes, what is your normal exercise regimen/routine?	22*	Walking	4 (18.2%)
		Cardio	4 (18.2%)
		Treadmill	2 (9.1%)
		Spinning	2 (9.1%)
		Yoga	2 (9.1%)
		Exercise	1 (4.5%)
		Class	1 (4.5%)
		Walk stairs	1 (4.5%)
		Swimming	1 (4.5%)
		Nothing/Just started	1 (4.5%)
		Jump Rope	1 (4.5%)
		Squats	1 (4.5%)
		Weight Training	1 (4.5%)

*Only subjects who responded “no” to Q8 responded to Q8a, and only subjects who answered “yes” to Q10 responded to Q10a. Some subjects had multiple responses.

Table 5.1 Subjective Questionnaire – Consumer Perception

Question	n	Week 2 Response n (%)											Percent Responding 0-4
		Not at All 0	1	2	3	4	5	6	7	8	9	Very Much 10	
Please rate the level of the following attributes after using the test product and following diet guidelines for two weeks:													
1. Excess Weight.	29*	7 (24.1%)	0 (0.0%)	1 (3.4%)	2 (6.9%)	1 (3.4%)	7 (24.1%)	6 (20.7%)	2 (6.9%)	2 (6.9%)	0 (0.0%)	1 (3.4%)	37.9%
2. Stress.	30	9 (30.0%)	0 (0.0%)	2 (6.7%)	2 (6.7%)	3 (10.0%)	3 (10.0%)	6 (20.0%)	2 (6.7%)	1 (3.3%)	0 (0.0%)	2 (6.7%)	**53.3%**
3. Poor Overall Health.	30	8 (26.7%)	6 (20.0%)	4 (13.3%)	4 (13.3%)	2 (6.7%)	3 (10.0%)	0 (0.0%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	1 (3.3%)	**80.0%**
4. Poor General Well Being.	30	8 (26.7%)	5 (16.7%)	5 (16.7%)	6 (20.0%)	1 (3.3%)	1 (3.3%)	1 (3.3%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	1 (3.3%)	**83.3%**
5. Lack of Focus.	30	9 (30.0%)	3 (10.0%)	6 (20.0%)	4 (13.3%)	3 (10.0%)	2 (6.7%)	1 (3.3%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	**83.3%**
6. Lack of Energy.	30	7 (23.3%)	4 (13.3%)	5 (16.7%)	5 (16.7%)	0 (0.0%)	4 (13.3%)	1 (3.3%)	2 (6.7%)	1 (3.3%)	1 (3.3%)	0 (0.0%)	**70.0%**
7. Lack of Stamina.	30	9 (30.0%)	3 (10.0%)	5 (16.7%)	4 (13.3%)	2 (6.7%)	2 (6.7%)	2 (6.7%)	2 (6.7%)	0 (0.0%)	1 (3.3%)	0 (0.0%)	**76.7%**

*One subject (#22) did not respond to Q1 (29 subjects analyzed).
Bold / Shaded = The majority of subjects responded favorably, >50%.

Table 5.1 Subjective Questionnaire – Consumer Perception (Continued)

Question	n	Week 2					Percent Responding Favorably
		Response n (%)					
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
8. I have lost weight.	30	7 (23.3%)	8 (26.7%)	9 (30.0%)	5 (16.7%)	1 (3.3%)	50.0%
9. I feel less stress.	30	6 (20.0%)	9 (30.0%)	12 (40.0%)	3 (10.0%)	0 (0.0%)	50.0%
10. I feel better overall/ improvement in overall health.	30	5 (16.7%)	15 (50.0%)	9 (30.0%)	1 (3.3%)	0 (0.0%)	**66.7%**
11. I feel an improvement in my general well-being.	30	4 (13.3%)	19 (63.3%)	7 (23.3%)	0 (0.0%)	0 (0.0%)	**76.7%**
12. I feel more focused.	30	4 (13.3%)	12 (40.0%)	11 (36.7%)	3 (10.0%)	0 (0.0%)	**53.3%**
13. I have more energy.	29*	6 (20.7%)	11 (37.9%)	10 (34.5%)	2 (6.9%)	0 (0.0%)	**58.6%**
14. I have more stamina.	30	4 (13.3%)	12 (40.0%)	12 (40.0%)	2 (6.7%)	0 (0.0%)	**53.3%**
15. I have less cravings.	30	8 (26.7%)	7 (23.3%)	6 (20.0%)	7 (23.3%)	2 (6.7%)	50.0%

*One subject (#31) did not respond to Q13 (29 subjects analyzed).
Bold / Shaded = The majority of subjects responded favorably, >50%.

Table 5.2 Subjective Questionnaire – Consumer Perception

Question	n	Week 4 Response n (%)											Percent Responding 0-4
		Not at All 0	1	2	3	4	5	6	7	8	9	Very Much 10	
Please rate the level of the following attributes after using the test product and following diet guidelines for four weeks:													
1. Excess Weight.	30	3 (10.0%)	2 (6.7%)	2 (6.7%)	3 (10.0%)	3 (10.0%)	5 (16.7%)	5 (16.7%)	2 (6.7%)	2 (6.7%)	1 (3.3%)	2 (6.7%)	43.3%
2. Stress.	30	8 (26.7%)	2 (6.7%)	1 (3.3%)	4 (13.3%)	3 (10.0%)	6 (20.0%)	3 (10.0%)	1 (3.3%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	**60.0%**
3. Poor Overall Health.	30	8 (26.7%)	8 (26.7%)	3 (10.0%)	2 (6.7%)	2 (6.7%)	3 (10.0%)	1 (3.3%)	1 (3.3%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	**76.7%**
4. Poor General Well Being.	30	7 (23.3%)	5 (16.7%)	4 (13.3%)	5 (16.7%)	1 (3.3%)	4 (13.3%)	1 (3.3%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	1 (3.3%)	**73.3%**
5. Lack of Focus.	30	9 (30.0%)	6 (20.0%)	3 (10.0%)	3 (10.0%)	2 (6.7%)	4 (13.3%)	0 (0.0%)	2 (6.7%)	0 (0.0%)	1 (3.3%)	0 (0.0%)	**76.7%**
6. Lack of Energy.	30	9 (30.0%)	5 (16.7%)	5 (16.7%)	2 (6.7%)	0 (0.0%)	4 (13.3%)	0 (0.0%)	3 (10.0%)	1 (3.3%)	1 (3.3%)	0 (0.0%)	**70.0%**
7. Lack of Stamina.	30	9 (30.0%)	5 (16.7%)	6 (20.0%)	2 (6.7%)	0 (0.0%)	3 (10.0%)	0 (0.0%)	4 (13.3%)	0 (0.0%)	1 (3.3%)	0 (0.0%)	**73.3%**

Bold / Shaded = The majority of subjects responded favorably, >50%.

Table 5.1 Subjective Questionnaire – Consumer Perception (Continued)

Question	n	Week 4					Percent Responding Favorably
		Response n (%)					
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
8. I have lost weight.	30	10 (33.3%)	7 (23.3%)	11 (36.7%)	1 (3.3%)	1 (3.3%)	**56.7%**
9. I feel less stress.	30	5 (16.7%)	9 (30.0%)	12 (40.0%)	4 (13.3%)	0 (0.0%)	46.7%
10. I feel better overall/ improvement in overall health.	30	7 (23.3%)	14 (46.7%)	7 (23.3%)	2 (6.7%)	0 (0.0%)	**70.0%**
11. I feel an improvement in my general well-being.	30	6 (20.0%)	11 (36.7%)	10 (33.3%)	3 (10.0%)	0 (0.0%)	**56.7%**
12. I feel more focused.	30	7 (23.3%)	8 (26.7%)	12 (40.0%)	3 (10.0%)	0 (0.0%)	50.0%
13. I have more energy.	30	6 (20.0%)	13 (43.3%)	7 (23.3%)	4 (13.3%)	0 (0.0%)	**63.3%**
14. I have more stamina.	30	5 (16.7%)	10 (33.3%)	12 (40.0%)	3 (10.0%)	0 (0.0%)	50.0%
15. I have less cravings.	30	7 (23.3%)	13 (43.3%)	6 (20.0%)	4 (13.3%)	0 (0.0%)	**66.7%**
16. I would purchase this product.	30	6 (20.0%)	16 (53.3%)	4 (13.3%)	3 (10.0%)	1 (3.3%)	**73.3%**
17. I would recommend this product to a friend.	30	10 (33.3%)	13 (43.3%)	4 (13.3%)	3 (10.0%)	0 (0.0%)	**76.7%**

Bold / Shaded = The majority of subjects responded favorably, >50%.Discussion

19.1.1 Enrollment and Demographics

A total of 30 male and female subjects between the ages of 21 and 55 years old were required to complete study participation. The study completed with 30 subjects, 26 female and four male, with an age range of 23 to 55 years old and an average age of 41.83 years old. The population reported their ethnicity as 60.0% Non-Hispanic or Latino and 40.0% Hispanic/Latino, and they reported their race as 53.3% White, 26.7% No response (Hispanic/Latino), 16.7% Black or African American and 3.3% Multi-Racial.

19.1.2 Clinical Measurements

Comparison of mean wait-to-hip ratio scores from Weeks 2 and 4 to Baseline results revealed no statistically significant differences.

19.1.3 Body Composition Measurements (Inbody)

Comparison of mean subject weight and body mass index scores from Weeks 2 and 4 to those at Baseline revealed statistically significant improvements in both attributes at both time intervals. Statistically significant change over time was not observed for mean results for percent body fat, lean body mass or body fat mass at either Week 2 or 4.

19.1.4 Subjective Questionnaire

At Week 2, the majority of subjects (>50%) responded favorably (0-4 on a 10-point scale) to six out of seven queries regarding their overall health and to five of eight queried statements about their perceptions of improved well-being. At Week 4, the majority of subjects responded favorably to six out of seven queries regarding their overall health and to seven of ten queried statements about their perceptions of improved well-being and product impressions.

20.0 Conclusion

In conclusion, under the conditions of this study, use of the test product **Dietary Supplement (Susie's Smart Breakfast Cookie): Orange Cranberry Nut, Gingered Apple, Banana Coconut, Cocoa** along with a calorie-restricted diet provided statistically significant improvements in mean weight and body mass index results. Subject perception was overall positive and the majority of subjects indicated that they would purchase or recommend the product to a friend.

Appendix I

Protocol

A 4-Week Clinical Study Evaluating the Influence of a Breakfast Cookie on Weight Loss

Protocol Number:	4189SBC1217
Protocol Date:	January 26, 2018
Sponsor:	Susie's Smart Cookie
Sponsor Representative:	Susan Allport Howell 333 Hook Rd. Katonah, NY 10536 E-Mail: Susie@susiesmartcookie.com Phone: 914.740 1007
Study Sites:	International Research Services, Inc. 222 Grace Church Street Port Chester, NY 10573 Phone: 914.937.6500 Fax: 914.937.8067
Principal Investigator:	Stephen R. Schwartz IRSI President, CEO E-Mail: sschwartz@irsi.org
Study Coordinator:	Anna Gafner, CCRC Clinic Manager E-Mail: agafner@irsi.org
Investigational Review Board:	Allendale IRB

Signature and Date:

S A Howell 4/2/2018

Signature and Date: 4/18/19

Signature and Date: 4/18/18

Study Summary			
Title	A 4-Week Clinical Study Evaluating the Influence of a Breakfast Cookie on Weight Loss		
Protocol Number	4189SBC1217		
Sponsor	Susie's Smart Cookie		
Methodology	Monadic		
Objective	To evaluate the efficacy of a breakfast cookie when used with a restrictive diet to improve weight control.		
Number of Subjects	30 to complete, *target enrollment 34*		
Target Population	Male (maximum 25%) and Female subjects, age 21-55 years old, overweight with a BMI of ≥25.0 and ≤ 29.8		
Duration	4 weeks (Baseline, Week 2, Week 4)		
Claims	***Claim***	***Support***	
	Use of the supplement in combination with a guide for a reduced calorie diet, results in a reduction in absolute body weight.	INBODY	
	Use of the supplement, in combination with a guide for a reduced calorie diet, results in a reduction in the waist-to-hip ratio (WHR), body mass index (BMI), body fat percentage, body fat mass index (BFMI).	INBODY Waist and Hip Measurement	
	Improvement in the well-being, general health attitude and the subjective feeling of stress	Subjective Questionnaire	
	Use of the supplement in combination with a guide for a reduced calorie diet, results in an increase in Omega-3, 6 and HUFA levels	Vital Omega-3 and 6 HUFA Test™ (subgroup of 20)	
Study Products	***Name***	***Formula Number***	
	Dietary Supplement (Susie's Smart Breakfast Cookie): Orange Cranberry Nut Gingered Apple Banana Coconut Cocoa	**NA**	
Statistical Methodology	Descriptive statistics, reported for demographics, assessments, monadic analysis using paired t-test to compare each site to baseline. All final statistical analyses will be performed on the PP population, significance set at p≤0.05.		
Study Schedule	Study Initiation	Baseline	February 19, 2018
		Week 2	March 5, 2018
	Study Completion	Week 4	March 19, 2018
Schedule of Deliverables	Intermediate Topline:		March 19, 2018
	Final Topline:		April 3, 2018
	Draft Final Report:		April 23, 2018

Table of Contents

Appendices

List of Abbreviations

AE	Adverse Event
BL	Baseline
BMI	Body Mass Index
BMR	Basal Metabolic Rate
C	Collect
cm	Centimeter
CRF	Case Report Form
CFR	Code of Federal Regulations
D	Dispense
FDA	Food & Drug Administration
GCP	Good Clinical Practices
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IND	Investigational New Drug
IRB	Institutional Review Board
IRSI	International Research Services, Inc.
LBM	Lean Body Mass
n	Number of Subjects
NDA	New Drug Application
PI	Principal Investigator
PP	Per-Protocol
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
Sponsor	Susie's Breakfast Cookies
US	United States
W#	Visit at Week X (i.e. W2 = Week 2)
X	Times

1.0 Introduction

This document is a protocol for a human research study. This study will be conducted according to International Research Services, Inc. research policies and Standard Operating Procedures, U.S. and international standards of Good Clinical Practice (FDA and ICH guidelines) and applicable government regulations.

1.1 Background

Susie's Smart Cookie (Sponsor) has developed a dietary supplement product intended to help users on a calorie controlled diet lose weight. The study is designed to test the effect of the dietary supplement when use for four weeks in a population of healthy men and women.

2.0 Objectives

2.1 Primary Objective

To evaluate the efficacy of a dietary supplement when used with a restrictive diet to aid in weight loss.

3.0 Study Design

This is a four-week evaluation of the effects of a dietary supplement and restrictive diet on weight loss. At least 30 subjects are expected to complete participation. Each subject will receive the investigational products and they will use it according to Sponsor's instructions along with a restrictive diet. At the Baseline visit and at designated time intervals during the study, all subjects will undergo body measurements, INBODY assessments, Vital Omega-3 and 6 HUFA Test and subjective questionnaire assessments. Study visits will occur at Baseline (BL), and at Weeks 2, and 4 (W2, W4).

3.1 Claims

Data will be collected and analyzed with specific regard to the following proposed product claims:

1. **Use of the supplement in combination with a guide for a reduced calorie diet, results in a reduction in absolute body weight,** as evaluated by InBody measurements.
2. **Use of the supplement, in combination with a guide for a reduced calorie diet, results in a reduction in the waist-to-hip ratio (WHR), body mass index (BMI), body fat percentage and body fat mass index (BFMI)** as evaluated by InBody measurements.
3. **Improvement in the well-being, general health attitude and the subjective feeling of stress,** as evaluated by Subjective Questionnaire results.
4. **Use of the supplement in combination with a guide for a reduced calorie diet, results in an increase in Omega-3 and 6**, as evaluated by Vital Omega-3 and 6 HUFA Test™**.**

4.0 Products

All test products and some food products (Breakfast Cookies plus frozen and canned salmon) will be provided by the Sponsor and will bear appropriate coding labels and proper use instructions. Products will be stored in a secure location and unused products will be returned to Sponsor or discarded upon issue of final report in accordance with IRSI's SOP.

4.1 Product Descriptions

Name	Flavors	Formula Number
Test Product		
Dietary Supplement (Susie's Smart Breakfast Cookies):	Orange Cranberry Nut Gingered Apple Banana Coconut Cocoa	NA

4.2 Product Use Instructions

All subjects will receive the test product to use for the duration of the study, along with written and verbal use instructions and a diet plan (see Appendix III).

Subjects will also be provided with selected foods off the dietary guide:

- Frozen Salmon (one portion per week); to be thawed by placing in cold water for 20 minutes prior to preparation
- Canned Salmon (one portion per week)

Test Product Directions: Eat one Susie's Smart Breakfast Cookie for breakfast and one Susie's Smart Breakfast Cookie for lunch; followed by a sensible dinner.

Subjects will also follow the supplied diet plan.

5.0 Population

5.1 Sample Size

The sample size of n=30 was requested by the Sponsor.
A sufficient number of subjects will be enrolled in order to complete this study with no less than 30. The target enrollment is 34 subjects.

5.2 Inclusion Criteria

1. Males (maximum of 25%) and Females in good general health.
2. Subjects between the ages of 21 and 55 years old, inclusive at enrollment.
3. Overweight subjects with Body Mass Index (BMI) measurements between ≥25 and ≤29.8 as measured by InBody.
4. Subjects with self-perceived need/desire to lose at least 10 lbs.
5. Stable weight within two months preceding Baseline
6. Stable medications within three months preceding Baseline.
7. Subjects will be able to read, understand and sign an informed consent form (includes HIPAA and State requirements).
8. Subjects who are willing to participate in an interview with the sponsor if requested.
9. Subjects who are willing and able to follow all study directions and must be willing to accept all study requirements including:
    a. Willing to follow the provided restrictive diet, including consumption of provided salmon.

5.3 Exclusion Criteria

1. Known allergy to milk, eggs, walnuts and/or coconut, or any item in the provided diet.
2. Taking drugs which are known to influence weight. Including laxatives, Anorectics and Diuretics.
3. Subjects who are currently following a weight loss program or diet (ex. Atkins, Jenny Craig, Weight Watchers, South Beach Diet, etc.)
4. Subjects who are currently using or have used weight loss / weight control supplements (prescription, OTC and/or natural remedies) within 28 days of Baseline.
5. Is the subject currently taking prescription medications with known weight loss or weight gain side effects (ex. Tricyclic antidepressants, oral corticosteroids, beta blockers)?

General exclusion criteria:

6. Subjects participating in any other clinical studies.
7. Subjects having an acute or chronic disease or medical condition, which could put him/her at risk in the opinion of the Principal Investigator or compromise study outcomes. Typical uncontrolled chronic or serious diseases and conditions which would prevent participation in any clinical trial are cancer, AIDS, any type of diabetes, renal impairment, mental illness, drug/alcohol addiction.
8. Subjects who are unreliable or unlikely to be available for the duration of the study
9. Immunocompromised subjects
10. Woman who started Hormone Replacement Therapy within the last three months preceding the screening visit
11. Woman using oral contraception for less than three months before the screening visit or who has changed her contraceptive method within the three months before the Baseline visit or planning to modify her contraception treatment within the duration of the study
12. Woman known to be pregnant, lactating or planning to become pregnant within six months. Subjects who become pregnant during the study must inform the Principal Investigator immediately
13. Individuals unable to communicate or cooperate with the Principal Investigator due to language problems, poor mental development, or impaired cerebral function
14. Employees of IRSI or other testing firms/ laboratories, cosmetic or raw goods manufacturers or suppliers

6.0 Methods

6.1 Clinical Measurements

All subjects' waist and hip measurements will be taken with a standard tape measure at Baseline, Week 2 and Week 4.

Waist to hip ratio (WHR) is the circumference of the waist (smallest part of the torso, usually slightly above the navel) divided by the circumference of the hips (largest part of the buttocks). This ratio may indicate body fat distribution and obesity and potentially the risk for certain diseases, such as diabetes, high cholesterol and cardiovascular disease.[1]

All subjects will stand straight, chin parallel to the floor and hands down alongside the hips. An IRSI technician will measure the circumference of the waist and the hip as described above. The waist and hip ratio will be calculated by taking the waist value in inches and dividing it by hip value in inches. The healthy ratio for women, a healthy ratio is 0.8 or lower, and for men it is 1.0 or lower.

All subjects will have their height measured and recorded at the Baseline visit.

6.2 Instrumental Evaluations

6.2.1 InBody

The InBody 520 Professional Body Composition Analyzer (Biospace Co., Ltd. Seoul, Korea) provides analysis of the human body using direct segmental measurement bioelectrical impedance analysis (DSM-BIA), a patented technology, to precisely measure body composition by sending multiple electrical currents through the body. Bioelectrical Impedance Analysis is based on the fact that the human body consists of conductors and non-conductors, where water functions as a conductor and body fat functions as a non-conductor. To measure, the InBody uses 8 tactile electrodes on the hands and feet to perform 15 impedance measurements using 3 different frequencies (5Hz, 50Hz and 500Hz) at each of 5 segments (Right Arm, Left Arm, Trunk, Right Leg and Left Leg).

The InBody provides outputs for Weight, Lean Body Mass, Body Fat Mass, Body Water Balance (Intracellular Water, Extracellular Water, Total Body Water), Body Mass Index (BMI), Percentage Body Fat (PBF), and Segmental Lean Analysis (Right and Left arms and legs, and trunk).

Body composition analysis including weight, Lean Body Mass, Body Fat Mass, Body Mass Index (BMI) and Percentage Body Fat (PBF) will be recorded for all subjects at Baseline, Week 2, and Week 4. Additionally, BMI will be recorded and used at the BL visit to determine subject's eligibility to proceed with the study. The BMI value at the baseline visit will determine the final eligibility of the subject into the study.

6.3 Consumer Perception Questionnaire

Subjective questionnaires will be used to evaluate the subject's history with weight control and gauge the subject's perception of the investigational products. Questions will ask for subjects' agreements to a statement with a five-point scale. Questionnaires will be provided by IRSI and will be administered at Baseline, Week 2 and Week 4.

A written testimonial will also be completed by subjects at Week 4.

6.4 Vital Omega-3 and 6 HUFA Test™

Samples will be collected from a subgroup of twenty (20) subjects to undergo testing for Omega 3 and 6 levels.

Collection kits will be provided by the sponsor. Following kit instructions at Baseline and Week 4, a finger stick will be used to collect blood from the finger. Subjects will use the lancet provided with the kit to stick their finger and place a smear/print of blood onto 3-4 designated areas on a

collection card. The Baseline and Week 4 cards will be stored in a -20 freezer at the test site until the sponsor collects them.

6.5 Subject Interviews

Each Subject will agree to be interviewed if chosen after the study completes, by the sponsor. Photographs may also be taken if agreed upon between subject and sponsor. Comments during the interview may be used in advertisements (no last names will be used). If photographs are taken, a photograph release will be obtained.

7.0 Procedure

7.1 Baseline

- Potential subjects, will arrive at the study site and will complete a brief personal/medical history and will read and sign an informed consent form, as described in Section 11.
- The following Screening procedures will be performed to determine if potential subjects meet study entrance criteria as described in Section 5.2 and 5.3 and all findings will be reported on the appropriate Case Report Forms (CRFs):
  - Review of Medical History
  - Inclusion / Exclusion Criteria
  - InBody assessments as described in Section 6.2, for BMI
- Subjects that meet entrance criteria as defined in Section 5.2 and 5.3 will be enrolled and will receive their investigational products, and selected foods along with instructions for use and a diary.
- All subjects will undergo the following procedures and all findings will be reported on the appropriate CRFs:
  - Clinical measurements as described in Section 6.1
  - InBody assessments as described in Section 6.2
  - Consumer Perception Questionnaire as described in Section 6.3
  - Omega 3 and 6 testing as described in Section 6.4
- Subjects will be advised to report any adverse reactions or other changes in health to IRSI immediately. They will be given an appointment time for their next visit and will be dismissed.

7.2 Weeks 2 Visit

- Subjects will arrive at the study site.
- Subjects' investigational product/empty product wrappers will counted and their diaries reviewed in order to verify product use compliance and to detect any indication of change(s) in subjects' health.
- All subjects will undergo the following procedures and all findings will be reported on the appropriate CRFs:
  - Clinical measurements as described in Section 6.1
  - InBody assessments as described in Section 6.2
  - Consumer Perception Questionnaire as described in Section 6.3
- Subjects will be provided with additional test products and selected foods.
- Subjects will be advised to report any adverse reactions or other changes in health to IRSI immediately. They will be given an appointment time for their next visit and will be dismissed.

7.3 Week 4 Visit

- Subjects will arrive at the study site.
- Subjects' investigational product/empty product wrappers will counted and their diaries reviewed in order to verify product use compliance and to detect any indication of change(s) in subjects' health.
- All subjects will undergo the following procedures and all findings will be reported on the appropriate CRFs:
  - Clinical measurements as described in Section 6.1
  - InBody assessments as described in Section 6.2
  - Consumer Perception Questionnaire and Testimonial as described in Section 6.3
  - Omega 3 and 6 testing as described in Section 6.4
- After all evaluations are completed, subjects will be advised to notify IRSI immediately of any adverse reactions experienced over the next 48 hours. They will be given a stipend for their participation and be dismissed from the study.

7.4 Procedure Summary Table

Procedures		Baseline	Week 2	Week 4
Study Initiation and Qualification	Informed Consent and Medical History	X		
	Inclusion/Exclusion Criteria reviewed	X		
Dispense/ Collect Products *and Subject instructions with nutrition guide*		D	D	C
Clinical Assessments	Waist and Hip Measurements	X	X	X
	Height	X		
Instrumental Evaluation	INBODY - Weight -Lean Body Mass -Body Fat Mass -BMI -PBF	X	X	X
Consumer Perception	Subjective Questionnaire	X	X	X
	Testimonial			X
Omega 3 and 6 HUFA test		X		X

8.0 Concomitant Medications and Products

Subject use of all dietary supplements and/or nutraceuticals (other than multi-vitamins approved by IRSI at screening) is prohibited from the baseline visit until the completion of Week 4 visit. Subjects on physician-prescribed medications must have been on a stable dose for 30 days prior to the screening visit.

Subjects should not use weight loss / weight control supplements (prescription, OTC and/or natural remedies).

Subjects should not take prescription medications with known weight loss or weight gain side effects (including but not limited to: tricyclic antidepressants, Oral corticosteroids, beta blockers).

Subjects should not begin to follow any weight loss program or diet during the study period (including but not limited to: Atkins, Jenny Craig, Weight Watchers, South Beach Diet, etc.).

9.0 Adverse Events

Subjects will be advised to report all adverse experiences to the study personnel as soon as possible. An adverse event (AE) is any untoward medical occurrence experienced by a subject whether or not considered product related.

An adverse event must have an onset time after the subject is enrolled in the study and generally within one week after the subject's participation in the study has ended. The endpoint will depend on the nature of the product being tested.

An adverse event may consist of a:

- Disease or injury
- Exacerbation of pre-existing illness or condition
- Recurrence of an intermittent illness or condition
- Set of related signs or symptoms
- Single sign or symptom

Adverse events will be recorded on the appropriate case report form and include the Principal Investigator's (PI) assessment of product relationship as follows:

- 0 = None
- 1 = Remote
- 2 = Possible
- 3 = Probable
- 4 = Definite

The Principal Investigator's assessment will be summarized in the final report.

9.1 **Serious Adverse Events**

A serious adverse event will be defined as any experience which is (any one or more of the following):

- Fatal
- Life-threatening
- Persistent or significant disability/incapacity
- Required or prolongs inpatient hospitalization
- Results in congenital anomaly or birth defect

9.2 Reporting of Adverse Events

Adverse events will be documented on the appropriate form and reported to the Sponsor in within five business days if any relationship to the product(s) is determined by the PI.

The Sponsor will be notified of any serious adverse event (SAE) within 24 hours of recording the experience (when possible).

Additionally, all AEs, serious / not serious, related / not related will be summarized in the final report and a copy of the AE form will be appended to the final report.

Proper judgment will be exercised in deciding whether expedited reporting is appropriate in other situations, such as events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious (FDA 21 CFR., Vol. 62, No. 194, 52243). Examples are:

- Overdose
- Intensive treatment in an emergency room or at home for allergic bronchospasm
- Development of drug dependency or drug abuse

Sponsor Contact for Reporting AEs and SAEs
Contact: Susan Allport Howell
Address: 333 Hook Rd. Katonah, NY 10536
Phone: 914.232.8687
E-mail: susan.allport@gmail.com

IRSI, IRSI staff and its Investigators do not assume Sponsor obligations for reporting SAEs to the FDA or other regulatory agencies.

10.0 Institutional Review Board

This study will be overseen by an independent Institutional Review Board (IRB) to ensure the protection of the rights, safety and well-being of subjects. Prior to study initiation, the IRB will review and approve the study protocol (and any subsequent amendments); methods and materials to be used in obtaining and documenting informed consent of the subjects.

IRB Information:
Name: Allendale Institutional Review Board
Address: 30 Neck Road, Old Lyme, CT 06371
Phone: 800.434.5892
E-Mail: Rta1ali@aol.com

11.0 Informed Consent

The informed consent process will be completed prior to an individual's involvement in any study related activity. The process will be documented using an IRB approved written informed consent form (ICF) conforming to FDA 21 CFR 50.25 (*See* Appendix IV).

The study Principal Investigator or his designee will inform the individual of all aspects of the trial that are relevant to the subject's decision to participate, and the individual will have the opportunity to have

any questions answered. As part of the written consent, the subject will be informed that she has the right to discontinue participation in the study at any point. Subjects who are not capable of providing or are unwilling to provide voluntary informed consent will not be enrolled.
After review, two copies of the ICF will be signed and dated by the individual and the Principal Investigator or his designee administering the consent. One original copy will be retained by IRSI and the other will be given to the individual. Discontinuation of Study

The Sponsor, Principal Investigator, and IRSI have the right to discontinue the study for medical, safety or administrative reasons at any time. Appropriate procedures will be followed to ensure the safe withdrawal of each subject from the study.

12.0 Changes to the Protocol

Upon Sponsor, Principal Investigator, and Study Coordinator approval and signing, this study protocol is considered final. Changes to the protocol must be approved in writing by the Sponsor and Principal Investigator prior to implementation. It is the responsibility of the Primary Investigator and Study Coordinator to ensure the protocol is approved and followed in agreement with FDA 21 CFR Part 58 Sec. 58.33.

Changes to the protocol will be categorized and documented as per IRSI's SOP as follows: Protocol Amendment, Protocol Deviation: Major and Minor.

12.1 **Protocol Amendments**

A protocol amendment is any permanent change or written clarification to the study protocol. Amendments may be requested by the Sponsor, Principal Investigator or Study Coordinator.

Amendments to the protocol must be approved in writing by the Principal Investigator, IRB and the Sponsor prior to implementation. The exception shall be when a change is required in the interest of subject protection or safety. In such instances, the sponsor shall be notified in writing within 24-hours of the change, whenever possible.

12.2 **Protocol Deviations**

A protocol deviation is any divergence or departure from the study protocol or a SOP. Deviations will be categorized by the Study Coordinator as Major or Minor.

A deviation is considered Major when there is a consistent variation in practice from the defined protocol or a subject has been identified as being at risk of harm in relation to their involvement in the study and urgent action, which deviates from the protocol, has occurred. Major deviations will be reported to the Sponsor within 24-hours (when possible) and corrective action (if necessary) will be identified.

A deviation is considered Minor when a variation to the protocol does not affect subject safety or the integrity of the research. Minor deviations will be documented throughout the study and reported to the Sponsor upon completion of the study.

13.0 Monitoring

IRSI will permit trial-related monitoring, audits, and regulatory inspections at any time. Access to the all study documents, source documents and data will be available on site.

14.0 Recording of Data

All data and information will be recorded on specific paper case report forms (CRFs) and this information will be neatly recorded in type or legibly printed in black ink wherever possible (Appendix III). Any errors will be crossed out and the correct entry made and initialed and dated by the Principal Investigator or his designee, unless the CRF is also a source document completed by the subject (such as a questionnaire) in which case the correction will be made by the subject as described above.

15.0 Quality Control and Quality Assurance

IRSI will audit the study for accuracy, consistency and proper documentation in accordance to IRSI SOPs and practices. The auditor will verify the accuracy of results reported in the data listings and statistical analysis after each study visit. The data listings and database used for statistical analysis will be verified against the CRFs. The data listings will be verified against the CRFs for 100% of the data, in a randomly selected set of the subjects (25% of the total number of subjects). The statistical report(s) will be validated for accuracy and completeness, as well as verifying the correctness of all subject numbers (n) and the analyses performed according to the Statistical Analysis Plan as described in Section 18. The statistical topline tables will be reviewed and compared with the statistical report for accuracy.

16.0 Ethics

The study will be conducted in accordance with FDA Good Clinical Practices (GCP) regulations and ICH guidelines in as much as they apply to cosmetic research with the following noted: This is not an Investigational New Drug (IND)/ New Drug Application (NDA) clinical trial. IRSI does not assume any Sponsor obligations as stipulated in FDA GCP and ICH documents. This study is not intended for submission to the FDA.

17.0 Statistical Methods

The planned statistical analysis is outlined below for each type of data to be acquired.

The per-protocol (PP) population is defined as the subset of subjects that who complied with the protocol sufficiently to ensure that their data will be likely to exhibit the effects of the treatment. To be considered a PP subject, a subject cannot miss the Baseline or Week 16 study visit or more than one interim study visit (Week 2 – Week 12) or found to be non-compliant with the study protocol at the discretion of the Principal Investigator.

The PP population was used for statistical analysis at each time point. Statistical significance is set at $p \leq 0.05$.

Data Type	Statistical Method	Data Reported
Demographics	Descriptive Statistics	Mean and standard deviation Frequency (number and percent)
Waist and Hip Measurements, Instrumentation	Descriptive Statistics Paired T-Test (monadic)	Mean and standard deviation Mean percent improvement from Baseline Percent of subjects showing improvement from Baseline P-value vs. Baseline, paired T-test
Subjective Questionnaires	Descriptive Statistics	Frequency (n,%) will be provided for each response Percent of positive response will be provided (where applicable)

18.0 Reporting of Results

A top line report (data only) will be issued electronically approximately ten business days after the Week 2 study visit and after completion of the Week 4 visit.

The final draft report will be issued electronically approximately five weeks after study completion. Upon Sponsor approval of the draft, the report will be finalized. If no request for revisions or approval is received from the Sponsor within six weeks after the issuance of the draft report, it will be considered final. Once finalized, the report will be issued electronically via secure file share.

No data issued prior to the final signed report should be considered as final, further, the Sponsor agrees:

- Not to make published claims based on this study prior to its completion and the rendering of a final report.
- Not to misrepresent the results of the study.

Schedule		Date
Study Initiation	Baseline	February 19, 2018
Study Completion	Week 2	March 5, 2018
	Week 4	March 19, 2018
Deliverable		**Date of Expected Delivery**
Intermediate Topline		March 19, 2018
Final Topline		April 3, 2018
Draft Final Report		April 23, 2018

19.0 Record Retention

IRSI shall assume the Principal Investigator responsibilities of maintaining study records for a period of two years following the date a marketing application is approved for the test material(s) for the indication for which it is being tested; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified, if required. Therefore for this study IRSI will archive the study records for a period of two years after the test is discontinued. Material may be archived in electronic or hard copy form.

IRSI does not assume any sponsor obligation regarding record retention or notification/submission to FDA. Prior to study initiation the sponsor shall provide written notification to IRSI of any submissions to or approvals sought from FDA for the test materials being studied.

20.0 Publication Policy

Neither the complete nor any part of the results of the study carried out under this protocol, nor any of the information provided by the Sponsor for the purposes of performing the study, will be published or passed on to any third party without the consent of the Sponsor. Conversely, prior to publication or other public presentation of the results from this clinical study, the Sponsor should obtain consent from the Primary Investigator.

21.0 References

[1] Healthline Networks Inc. *Waist to Hip Ratio*. http://www.healthline.com/natstandardcontent/alt-waist-to-hip-ratio

Appendix I

Subject Instructions and Diary/Diet Plan

CASE REPORT FORM	DIARY AND INSTRUCTIONS			BASELINE-WEEK 2
	Study Number: **4189SBC1217**	**SUBJECT INITIALS:**	**SUBJECT #:**	

DAY	BREAKFAST	OTHER BREAKFAST FOOD (DO NOT INCLUDE COOKIE)	LUNCH	OTHER LUNCH FOOD (DO NOT INCLUDE COOKIE)	DINNER	DINNER	SNACKS
Monday February 19 Baseline Visit	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Tuesday February 20	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Wednesday February 21	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Thursday February 22	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Friday February 23	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Saturday February 24	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Tuesday February 25	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	

CASE REPORT FORM	DIARY AND INSTRUCTIONS		BASELINE-WEEK 2
	Study Number: **4189SBC1217**	**SUBJECT INITIALS:**	**SUBJECT #:**

DAY	BREAKFAST	OTHER BREAKFAST FOOD (DO NOT INCLUDE COOKIE)	LUNCH	OTHER LUNCH FOOD (DO NOT INCLUDE COOKIE)	DINNER	DINNER	SNACKS
Monday February 26	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Tuesday February 27	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Wednesday February 28	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Thursday March 1	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Friday March 2	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Saturday March 3	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Tuesday March 4	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	

Do not write below this line, for IRSI staff use only.

This CRF has been reviewed for completion prior to subject's dismissal from study visit	Tech Initials:	**BASELINE – WEEK 4**

CASE REPORT FORM	DIARY AND INSTRUCTIONS			BASELINE-WEEK 2
	Study Number: **4189SBC1217**	**SUBJECT INITIALS:**	**SUBJECT #:**	

DAY	BREAKFAST	OTHER BREAKFAST FOOD (DO NOT INCLUDE COOKIE)	LUNCH	OTHER LUNCH FOOD (DO NOT INCLUDE COOKIE)	DINNER	DINNER	SNACKS
Monday March 5	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Tuesday March 6 Week 2 Visit	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	

Test Product Directions:

- Eat one Susie's Smart Breakfast Cookie for breakfast and one Susie's Smart Breakfast Cookie for lunch; followed by a sensible dinner.
- Follow the attached diet plan and incorporate the provided salmon (frozen and canned) for at least two of your dinners per week. **Be sure to check the provided canned salmon for bones before eating. Thaw the frozen salmon in a bowl of cold water for 20 minutes prior to preparing.**
- Record the time you eat your cookie for breakfast and lunch and document all other food/beverage that you consume for breakfast, lunch and dinner.

STUDY INSTRUCTIONS:

- Bring ALL product and product wrappers.
- Bring the completed diaries to every visit of the study.
- Do Not Use any weight control supplements (prescriptions, OTC and/or natural remedies).
- Do Not follow any other diet plan or regimen other than the one you have been given.
- Do Not take any prescription medications with known weight loss or weight gain side effects (including but not limited to: diuretics, tricyclic antidepressants, oral corticosteroids, beta blockers.

Call IRSI immediately if you experience any signs of side effects from the investigational products or with any questions or concerns.

- **Anna, Study Coordinator: 914-937-6500 ext 126 OR Reception Desk (during visits): 914-937-6500 ext 111**

Do not write below this line, for IRSI staff use only.

The Breakfast Cookie Diet: 1 cookie for breakfast and 1 for lunch; followed by a sensible dinner. (Control your weight while you boost your Omega 3s!)

Breakfast:	**Lunch:**	**Snacks**:
1 Susie's Smart Breakfast Cookie (warm or at room temperature) Piece of fruit – banana, peach etc. Coffee, tea – unsweetened; low fat milk, if desired	1 Susie's Smart Breakfast Cookie plus: 1 bowl of broth or vegetable based soup such as gazpacho, cucumber, tomato (i.e. soups w. little cream or meat) **or** 1 serving yogurt with fruit (2% or non fat).	Fresh fruits or raw veggies, the occasional Lungstrom wild rice cake or Mary's Gone crackers.

Sensible Dinner:

Serving size (*3-6 oz*) of:

- Broiled, grilled, or sautéed fish (salmon is great but any fish will do except catfish and tilapia)
  - **The salmon filet you have received can be used (once cooked) for two dinners instead of just one if you choose**
- OR grass-fed steak or grass fed lamb from New Zealand or Australia
- OR two Omega-3 eggs
- OR a vegetarian dinner such as Quinoa and Wild Rice Bowl (see recipe below)
- OR chicken (Because most chicken isn't free-range, be sure to prepare any chicken you make with canola oil and to remove the skin)
- Plus a serving of brown or wild rice or potato (boiled or baked)
- Plus vegetables, steamed or lightly sautéed with canola oil or a salad prepared with a light, canola oil dressing or the dressing below:

A very simple dressing to make: 1 tsp Dijon mustard beaten w. 1 tablespoon fresh or bottled lemon juice. Drizzle in 2 tablespoons of canola **or** 1 tablespoon canola and 1 tablespoon olive oil. Add pepper to taste.

- Plus Fruit, if desired, or a few walnuts and raisins, on occasion.

Be sure to drink plenty of water throughout the day! If you're looking to lose weight, ***please avoid alcohol.*** *If you're just looking to boost your Omega-3s, you could have a glass of wine or beer with dinner.*

Cooking oils/fats: <u>You must use Canola oil for all cooking and salad/vegetable dressing during the study.</u>

100% CANOLA OIL. **The more you use 100% canola oil in this plan, the more effective this is and the more you will boost your Omega-3s.** If you are concerned about processed oils, please choose an expeller-pressed canola oil. Please avoid "High-heat" canola oils since these have lesser amounts of omega-3s.

If you use any butter, please use the grass-fed butter from Ireland (Kerry) or New Zealand (Anchor).

If you use mayonnaise, please use a Canola based product, such as Hellman's Canola.

Other tips:

- The more weight you'd like to lose, the more you should choose non-fat over 2% milk and yogurt.
- If you feel you are craving protein on this plan, add a hard boiled egg to your lunch or breakfast. The egg should be an Omega-3 egg, of course, with 250-350 milligrams of Omega-3s/egg.
- A very simple and delicious way to prepare salmon is to saute your filet in hot canola oil (1 Tablespoon) or a canola and butter mixture for one minute in an oven-proof skillet. Spoon the hot fat over the filet, then bake at 450 degrees for 10 minutes. Squeeze lemon over the salmon and enjoy.
- See attached recipes for quinoa/brown rice bowl and salmon cake and patties as a good option for the provided canned salmon

Salmon Cakes or Patties

Having canned salmon (preferably wild!) in your pantry means that you are never very far from putting a simple dinner or lunch on the table. I've been experimenting with salmon cakes and the first recipe uses uncooked oats and egg as the binder. The second one uses cooked quinoa and a tablespoon of mayonnaise (Hellman's canola, of course) as the binder. The second is a handy recipe for when you're preparing just one can of salmon. If you're preparing two cans at a time, you can use one egg as the binder. For the herbs, use fresh or dried dill or parsley or whatever you have on hand.

Oatmeal Salmon Patties

Ingredients:
2 (7 ounce) cans boneless skinless pink salmon (wild, if you can find it)
3/4 cup Quaker Old Fashioned Oats, uncooked
1/3 cup low-fat milk
1 egg (Omega-3, of course)
2 Tablespoons finely chopped shallots or onions
1 Tablespoon snipped fresh dill or 1 teaspoon dried dill weed
1/3- 1/2 tsp salt and pepper to taste.
Butter (Grass-fed, of course) and/or canola oil for sautéing

Directions
Combine all ingredients except the butter and/or oil and mix well. Shape into patties (6). Pan fry the patties in butter, or a combination of butter and canola oil for 3-4 minutes on each side until golden brown and heated through. Serve hot and enjoy with a slice of lemon and brown rice and a salad.

Quinoa Salmon Cakes

1 can wild salmon, reserving the liquid in case you need it to moisten the mixture

1 tablespoon minced onion or shallot

1 tablespoon minced green pepper or celery (optional)

1/4 cup cooked quinoa (cooked according to the instructions on the package).

1 Tablespoon mayonnaise (Hellman's canola, of course, for the added Omega-3s)

1 Tablespoon fresh or 1 teaspoon dried herbs

Salt and pepper to taste.

Butter (Grass-fed, of course) and/or canola oil for sautéing

Mix ingredients together in a bowl using a fork and adding the reserved liquid if the mixture seems too dry. Salt and pepper to taste.

Shape into 2 patties and let rest for 10 min or so in the fridge -- if you have the time.

Saute until nicely brown on both sides.
Serve with a slice of lemon and a salad, adding brown rice or quinoa as the side if desired.

Quinoa and Wild Rice Bowl*

*Please feel free to vary the grains and vegetables in this recipe according to taste and availability. This same dish can be made using cooked oatmeal instead of rice and quinoa or with any combo of farro; bulger, rice, etc. Also, feel free to substitute spinach for kale and to add chunks of tofu.

Ingredients

- 1 cup long-grain brown rice
- 1 cup red quinoa
- 1/4 cup canola oil
- 1 small onion, finely diced
- 1 carrot, sliced crosswise 1/4 inch thick
- 1/4 pound shiitake mushrooms, stems discarded and caps thinly sliced
- 1 small zucchini, halved lengthwise and sliced crosswise 1/4 inch thick
- Salt
- 1 head of broccoli—stems peeled and sliced into coins, heads cut into small florets
- One 12-ounce bunch kale, large stems discarded or 12 ounces of spinach.
- 1/4 cup pesto sauce, at room temperature (See instructions below)
- 1 cup mung bean sprouts

How to Make It

Step 1

In a medium saucepan, cover the brown rice with 2 inches of water and bring to a boil. Cover and cook over low heat until the rice is just tender, about 40 minutes. Drain and return the rice to the saucepan; keep covered.

Step 2

Meanwhile, in a small saucepan, combine the quinoa with 2 cups of water and bring to a boil. Cover the saucepan and simmer over low heat until the quinoa is tender and all of the water has been absorbed, 20 minutes.

Step 3

In a large skillet, heat 2 tablespoons of canola oil. Add the onion and cook over moderate heat until translucent, about 4 minutes. Add the carrot and cook until starting to soften, about 3 minutes. Add the shiitake, cover and cook until tender, about 4 minutes . Add the zucchini, season with salt and cook, stirring a few times, until tender, about 3 minutes. Transfer to a bowl.

Step 4

Add the remaining 2 tablespoons of canola oil to the skillet. Add the broccoli, cover and cook over moderate heat, stirring a few times, until deep green, 5 minutes. Add the kale, cover and cook, stirring a few times, until the broccoli and kale are just tender, 4 minutes (less time if you are substituting spinach for kale). Season with salt. Stir in the other vegetables.

Step 5

To make the pesto: puree together the basil; arugula and/or parsley; 2 cloves garlic; 1/3 cup walnuts (optional); ½ cup canola oil or half and half canola and olive oil with salt and pepper to taste. Whatever pesto you do not immediately use can be stored in the r efrigerator.

Step 6

Transfer the brown rice and quinoa to bowls. Top with the cooked vegetables and bean sprouts. Serve, passing the pesto sauce at the table and adding shavings of parmesan or chunks of avocado, if desired.

CASE REPORT FORM	DIARY AND INSTRUCTIONS			WEEK 2-WEEK 4
	Study Number: **4189SBC1217**	**SUBJECT INITIALS:**	**SUBJECT #:**	

DAY	BREAKFAST	OTHER BREAKFAST FOOD (DO NOT INCLUDE COOKIE)	LUNCH	OTHER LUNCH FOOD (DO NOT INCLUDE COOKIE)	DINNER	DINNER	SNACKS
Tuesday March 6			_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Wednesday March 7	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Thursday March 8	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Friday March 9	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Saturday March 10	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Sunday March 11	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	

CASE REPORT FORM	DIARY AND INSTRUCTIONS			WEEK 2-WEEK 4
	Study Number: **4189SBC1217**	**SUBJECT INITIALS:**	**SUBJECT #:**	

DAY	BREAKFAST	OTHER BREAKFAST FOOD (DO NOT INCLUDE COOKIE)	LUNCH	OTHER LUNCH FOOD (DO NOT INCLUDE COOKIE)	DINNER	DINNER	SNACKS
Monday March 12	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Tuesday March 13	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Wednesday March 14	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Thursday March 15	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Friday March 16	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Saturday March 17	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	
Sunday March 18	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	

Do not write below this line, for IRSI staff use only.

This CRF has been reviewed for completion prior to subject's dismissal from study visit	Tech Initials:	**BASELINE – WEEK 4**

CASE REPORT FORM	DIARY AND INSTRUCTIONS			WEEK 2-WEEK 4
	Study Number: **4189SBC1217**	**SUBJECT INITIALS:**	**SUBJECT #:**	

DAY	BREAKFAST	OTHER BREAKFAST FOOD (DO NOT INCLUDE COOKIE)	LUNCH	OTHER LUNCH FOOD (DO NOT INCLUDE COOKIE)	DINNER	DINNER	SNACKS
Monday March 19	_____:_____ **AM**	Food List:	_____:_____ **PM**	Food List:	_____:_____ **PM**	Food List:	

Test Product Directions:

- Eat one Susie's Smart Breakfast Cookie for breakfast and one Susie's Smart Breakfast Cookie for lunch; followed by a sensible dinner.
- Follow the attached diet plan and incorporate the provided salmon (frozen and canned) for at least two of your dinners per week. **Be sure to check the provided canned salmon for bones before eating. Thaw the frozen salmon in a bowl of cold water for 20 minutes prior to preparing.**
- Record the time you eat your cookie for breakfast and lunch and document all other food/beverage that you consume for breakfast, lunch and dinner.

STUDY INSTRUCTIONS:

- Bring ALL product and product wrappers.
- Bring the completed diaries to every visit of the study.
- Do Not Use any weight control supplements (prescriptions, OTC and/or natural remedies).
- Do Not follow any other diet plan or regimen other than the one you have been given.
- Do Not take any prescription medications with known weight loss or weight gain side effects (including but not limited to: diuretics, tricyclic antidepressants, oral corticosteroids, beta blockers.

Call IRSI immediately if you experience any signs of side effects from the investigational products or with any questions or concerns.

- **Anna, Study Coordinator: 914-937-6500 ext 126 OR Reception Desk (during visits): 914-937-6500 ext 111**

Do not write below this line, for IRSI staff use only.

The Breakfast Cookie Diet: 1 cookie for breakfast and 1 for lunch; followed by a sensible dinner. (Control your weight while you boost your Omega 3s!)

Breakfast:	**Lunch:**	**Snacks**:
1 Susie's Smart Breakfast Cookie (warm or at room temperature) Piece of fruit – banana, peach etc. Coffee, tea – unsweetened; low fat milk, if desired	1 Susie's Smart Breakfast Cookie plus: 1 bowl of broth or vegetable based soup such as gazpacho, cucumber, tomato (i.e. soups w. little cream or meat) **or** 1 serving yogurt with fruit (2% or non fat).	Fresh fruits or raw veggies, the occasional Lungstrom wild rice cake or Mary's Gone crackers.

Sensible Dinner:

Serving size (*3-6 oz*) of:

- Broiled, grilled, or sautéed fish (salmon is great but any fish will do except catfish and tilapia)
  - **The salmon filet you have received can be used (once cooked) for two dinners instead of just one if you choose**
- OR grass-fed steak or grass fed lamb from New Zealand or Australia
- OR two Omega-3 eggs
- OR chicken (Because most chicken isn't free-range, be sure to prepare any chicken you make with canola oil and to remove the skin)
- Plus a serving of brown or wild rice or potato (boiled or baked)
- Plus vegetables, steamed or lightly sautéed with canola oil or a salad prepared with a light, canola oil dressing or the dressing below:

  A very simple dressing to make: 1 tsp Dijon mustard beaten w. 1 tablespoon fresh or bottled lemon juice. Drizzle in 2 tablespoons of canola **or** 1 tablespoon canola and 1 tablespoon olive oil. Add pepper to taste.

- Plus Fruit, if desired, or a few walnuts and raisins, on occasion.

Be sure to drink plenty of water throughout the day! If you're looking to lose weight, ***please avoid alcohol.*** *If you're just looking to boost your Omega-3s, you could have a glass of wine or beer with dinner.*

Cooking oils/fats: <u>You must use Canola oil for all cooking and salad/vegetable dressing during the study.</u>

100% CANOLA OIL. **The more you use 100% canola oil in this plan, the more effective this is and the more you will boost your Omega-3s.** If you are concerned about processed oils, please choose an expeller-pressed canola oil. Please avoid "High-heat" canola oils since these have lesser amounts of omega-3s.

If you use any butter, please use the grass-fed butter from Ireland (Kerry) or New Zealand (Anchor).

If you use mayonnaise, please use a Canola based product, such as Hellman's Canola.

Other tips:

- The more weight you'd like to lose, the more you should choose non-fat over 2% milk and yogurt.
- If you feel you are craving protein on this plan, add a hard boiled egg to your lunch or breakfast. The egg should be an Omega-3 egg, of course, with 250-350 milligrams of Omega-3s/egg.
- A very simple and delicious way to prepare salmon is to saute your filet in hot canola oil (1 Tablespoon) or a canola and butter mixture for one minute in an oven-proof skillet. Spoon the hot fat over the filet, then bake at 450 degrees for 10 minutes. Squeeze lemon over the salmon and enjoy.
- See attached recipes for quinoa/brown rice bowl and salmon cake and patties as a good option for the provided canned salmon

Salmon Cakes or Patties

Having canned salmon (preferably wild!) in your pantry means that you are never very far from putting a simple dinner or lunch on the table. I've been experimenting with salmon cakes and the first recipe uses uncooked oats and egg as the binder. The second one uses cooked quinoa and a tablespoon of mayonnaise (Hellman's canola, of course) as the binder. The second is a handy recipe for when you're preparing just one can of salmon. If you're preparing two cans at a time, you can use one egg as the binder. For the herbs, use fresh or dried dill or parsley or whatever you have on hand.

Oatmeal Salmon Patties

Ingredients:
2 (7 ounce) cans boneless skinless pink salmon (wild, if you can find it)
3/4 cup Quaker Old Fashioned Oats, uncooked
1/3 cup low-fat milk
1 egg (Omega-3, of course)
2 Tablespoons finely chopped shallots or onions
1 Tablespoon snipped fresh dill or 1 teaspoon dried dill weed
1/3- 1/2 tsp salt and pepper to taste.
Butter (Grass-fed, of course) and/or canola oil for sautéing

Directions
Combine all ingredients except the butter and/or oil and mix well. Shape into patties (6). Pan fry the patties in butter, or a combination of butter and canola oil for 3-4 minutes on each side until golden brown and heated through. Serve hot and enjoy with a slice of lemon and brown rice and a salad.

Quinoa Salmon Cakes

1 can wild salmon, reserving the liquid in case you need it to moisten the mixture

1 tablespoon minced onion or shallot

1 tablespoon minced green pepper or celery (optional)

1/4 cup cooked quinoa (cooked according to the instructions on the package).

1 Tablespoon mayonnaise (Hellman's canola, of course, for the added Omega-3s)

1 Tablespoon fresh or 1 teaspoon dried herbs

Salt and pepper to taste.

Butter (Grass-fed, of course) and/or canola oil for sautéing

Mix ingredients together in a bowl using a fork and adding the reserved liquid if the mixture seems too dry. Salt and pepper to taste.

Shape into 2 patties and let rest for 10 min or so in the fridge -- if you have the time.

Saute until nicely brown on both sides.
Serve with a slice of lemon and a salad, adding brown rice or quinoa as the side if desired.

Quinoa and Wild Rice Bowl*

*Please feel free to vary the grains and vegetables in this recipe according to taste and availability. This same dish can be made using cooked oatmeal instead of rice and quinoa or with any combo of farro; bulger, rice, etc. Also, feel free to substitute spinach for kale and to add chunks of tofu.

Ingredients

- 1 cup long-grain brown rice
- 1 cup red quinoa
- 1/4 cup canola oil
- 1 small onion, finely diced
- 1 carrot, sliced crosswise 1/4 inch thick
- 1/4 pound shiitake mushrooms, stems discarded and caps thinly sliced
- 1 small zucchini, halved lengthwise and sliced crosswise 1/4 inch thick
- Salt
- 1 head of broccoli—stems peeled and sliced into coins, heads cut into small florets
- One 12-ounce bunch kale, large stems discarded or 12 ounces of spinach.
- 1/4 cup pesto sauce, at room temperature (See instructions below)
- 1 cup mung bean sprouts

How to Make It

Step 1

In a medium saucepan, cover the brown rice with 2 inches of water and bring to a boil. Cover and cook over low heat until the rice is just tender, about 40 minutes. Drain and return the rice to the saucepan; keep covered.

Step 2

Meanwhile, in a small saucepan, combine the quinoa with 2 cups of water and bring to a boil. Cover the saucepan and simmer over low heat until the quinoa is tender and all of the water has been absorbed, 20 minutes.

Step 3

In a large skillet, heat 2 tablespoons of canola oil. Add the onion and cook over moderate heat until translucent, about 4 minutes. Add the carrot and cook until starting to soften, about 3 minutes. Add the shiitake, cover and cook until tender, about 4 minutes . Add the zucchini, season with salt and cook, stirring a few times, until tender, about 3 minutes. Transfer to a bowl.

Step 4

Add the remaining 2 tablespoons of canola oil to the skillet. Add the broccoli, cover and cook over moderate heat, stirring a few times, until deep green, 5 minutes. Add the kale, cover and cook, stirring a few times, until the broccoli and kale are just tender, 4 minutes (less time if you are substituting spinach for kale). Season with salt. Stir in the other vegetables.

Step 5

To make the pesto: puree together the basil; arugula and/or parsley; 2 cloves garlic; 1/3 cup walnuts (optional); ½ cup canola oil or half and half canola and olive oil with salt and pepper to taste. Whatever pesto you do not immediately use can be stored in the r efrigerator.

Step 6

Transfer the brown rice and quinoa to bowls. Top with the cooked vegetables and bean sprouts. Serve, passing the pesto sauce at the table and adding shavings of parmesan or chunks of avocado, if desired.

Appendix II

Subjective Questionnaires

CASE REPORT FORM	Subjective Questionnaire Baseline February 19, 2018	Study Number 4189SBC1217 Subject Initials Subject Number

Please rate the level of the following attributes before beginning the study using the rating scales provided below. Be sure to answer every question.

0 = none/not at all - 10 = very much/highest level	
1. Excess weight	**0 1 2 3 4 5 6 7 8 9 10**
2. Stress	**0 1 2 3 4 5 6 7 8 9 10**
3. Poor overall health	**0 1 2 3 4 5 6 7 8 9 10**
4. Poor general well being	**0 1 2 3 4 5 6 7 8 9 10**
5. Lack of focus	**0 1 2 3 4 5 6 7 8 9 10**
6. Lack of energy	**0 1 2 3 4 5 6 7 8 9 10**
7. Lack of stamina	**0 1 2 3 4 5 6 7 8 9 10**

8. Do you currently use canola oil as your primary oil? **YES NO** **If no, what do you typically use?**	10. Do you exercise regularly? **YES NO** **If yes, what is your normal exercise regimen/routine?**
9. How many times per week do you eat fish?	11. Do you take fish oil supplements? **YES NO**

Do not write below this line, for IRSI staff use only.

This CRF has been reviewed for completion prior to subject's dismissal from station	Tech Initials:	**Baseline** **Page 1 of 1**
This CRF has been reviewed for completion prior to subject's dismissal from study visit	Tech Initials:	

CASE REPORT FORM	Subjective Questionnaire Week 2 March 6, 2018	Study Number 4189SBC1217 Subject Initials Subject Number

Please rate the level of the following attributes after using the test product and following the diet guidelines for **two weeks** using the rating scales provided below. Be sure to answer every question.

0 = none/not at all - 10 = very much/highest level	
1. Excess weight	**0 1 2 3 4 5 6 7 8 9 10**
2. Stress	**0 1 2 3 4 5 6 7 8 9 10**
3. Poor overall health	**0 1 2 3 4 5 6 7 8 9 10**
4. Poor general well being	**0 1 2 3 4 5 6 7 8 9 10**
5. Lack of focus	**0 1 2 3 4 5 6 7 8 9 10**
6. Lack of energy	**0 1 2 3 4 5 6 7 8 9 10**
7. Lack of stamina	**0 1 2 3 4 5 6 7 8 9 10**

Questionnaire continued on the next page

Do not write below this line, for IRSI staff use only.

This CRF has been reviewed for completion prior to subject's dismissal from station	Tech Initials:	**Week 2** **Page 1 of 2**
This CRF has been reviewed for completion prior to subject's dismissal from study visit	Tech Initials:	

CASE REPORT FORM	Subjective Questionnaire Week 2 March 6, 2018	Study Number 4189SBC1217 Subject Initials Subject Number

Please rate the level of agreement to the statements after using the test product and following the diet guidelines for **two weeks** using the rating scales provided below. Be sure to answer every question.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
8. I have lost weight					
9. I feel less stress					
10. I feel better overall/improvement in overall health					
11. I feel an improvement in my general well-being					
12. I feel more focused					
13. I have more energy					
14. I have more stamina					
15. I have less cravings					

Do not write below this line, for IRSI staff use only.

This CRF has been reviewed for completion prior to subject's dismissal from station	Tech Initials:	**Week 2** **Page 2 of 2**
This CRF has been reviewed for completion prior to subject's dismissal from study visit	Tech Initials:	

CASE REPORT FORM	Subjective Questionnaire Week 4 March 19, 2018	Study Number 4189SBC1217 Subject Initials Subject Number

Please rate the level of the following attributes after using the test product and following the diet guidelines for **four weeks** using the rating scales provided below. Be sure to answer every question.

0 = none/not at all - 10 = very much/highest level	
1. Excess weight	0 1 2 3 4 5 6 7 8 9 10
2. Stress	0 1 2 3 4 5 6 7 8 9 10
3. Poor overall health	0 1 2 3 4 5 6 7 8 9 10
4. Poor general well being	0 1 2 3 4 5 6 7 8 9 10
5. Lack of focus	0 1 2 3 4 5 6 7 8 9 10
6. Lack of energy	0 1 2 3 4 5 6 7 8 9 10
7. Lack of stamina	0 1 2 3 4 5 6 7 8 9 10

Questionnaire continued on the next page

Do not write below this line, for IRSI staff use only.

This CRF has been reviewed for completion prior to subject's dismissal from station	Tech Initials:	**Week 4** **Page 1 of 2**
This CRF has been reviewed for completion prior to subject's dismissal from study visit	Tech Initials:	

CASE REPORT FORM	Subjective Questionnaire Week 4 March 19, 2018	Study Number 4189SBC1217 Subject Initials Subject Number

Please rate the level of agreement to the statements after using the test product and following the diet guidelines for **four weeks** using the rating scales provided below. Be sure to answer every question.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
8. I have lost weight					
9. I feel less stress					
10. I feel better overall/improvement in overall health					
11. I feel an improvement in my general well-being					
12. I feel more focused					
13. I have more energy					
14. I have more stamina					
15. I have less cravings					
16. I would purchase this product					
17. I would recommend this product to a friend					

Do not write below this line, for IRSI staff use only.

This CRF has been reviewed for completion prior to subject's dismissal from station	Tech Initials:	**Week 4** **Page 2 of 2**
This CRF has been reviewed for completion prior to subject's dismissal from study visit	Tech Initials:	

CASE REPORT FORM	**Testimonial** **Week 4**	**Study Number** **4189SBC1217**
	March 19, 2018	Subject Initials
		Subject Number

The sponsor is interested in your opinion of the test product. Please provide a short summary of your experience using these products.

_____

_____

_____

_____

_____

Do not write below this line, for IRSI staff use only.

This CRF has been reviewed for completion prior to subject's dismissal from station	Tech Initials:	**Week 4:** **Page 1 of 1**
This CRF has been reviewed for completion prior to subject's dismissal from study visit	Tech Initials:	

Appendix III

Case Report Forms

Subject Signature:

SCREENING/BASELINE: February 19, 2018			**Tech**	**Time**
Arrive at site				
Complete medical history and informed consent				
Inclusion/Exclusion criteria reviewed				
Questionnaires completed and reviewed				
InBody Measurements				
Subject status:	**Circle One**			
	Enrolled	Disqualified		
Clinical Measurements: Waist, Hip and Waist to Hip Ratio				
Omega 3 Testing	Selected for subgroup of 20?	**Circle One**		
		YES / NO		
Dispense products, diary, written use instructions, diet and salmon				
All CRFs reviewed for completion				
Subject reminded of Week 2 Visit and dismissed from test site				

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CASE REPORT FORM	**Inclusion/Exclusion** **Screening/Baseline**	**Study Number** **4189SBC1217** Subject Initials Subject Number

Please fill out the following form completely, if you need assistance please speak with an IRSI Technician.

Name: Last: First: MI:				**Date:** / /
Height: Ft. In.	**Weight** Lbs.	**Date of Birth:** Mo. Day Year	**Age:**	**Sex:** ❒ Male ❒ Female

Ethnicity: ❒ Hispanic or Latino ❒ Not Hispanic or Latino **Race:** ❒ American Indian or Alaska Native ❒ Asian (circle one: Far East, Southeast Asia, Indian subcontinent) ❒ Black or African American ❒ Native Hawaiian or Other Pacific Islander ❒ White ❒ Other_____	**Facial Skin Type:** ❒ Normal ❒ Oily ❒ Dry ❒ Combination	**Body Skin Type**: ❒ Normal ❒ Dry ❒ Very Dry
	Fitzpatrick Skin Type: (see examples) ❒ Type I ❒ Type II ❒ Type III ❒ Type IV ❒ Type V ❒ Type VI	

Do you have Sensitive Skin? ❒ **YES** ❒ **NO**	**Do you have Sensitive Eyes?** ❒ **YES** ❒ **NO**	**Do you wear contact lenses?** ❒ **YES** ❒ **NO**

Occupation: ❒ Retired ❒Homemaker ❒Unemployed ❒ Employed, Job Title:

1. Do you have any of the following:	**Yes**	**No**	2. Have you had a reaction to any of the following:	**Yes**	**No**
Asthma or emphysema	❒	❒	Fragrances and Perfumes	❒	❒
Hay Fever or seasonal allergies	❒	❒	Creams	❒	❒
Food allergies	❒	❒	Moisturizers	❒	❒
Eczema or Psoriasis	❒	❒	Soaps	❒	❒
Thyroid Problems	❒	❒	Other body products	❒	❒
High Cholesterol	❒	❒	Cosmetics	❒	❒
Diabetes, if yes:	❒	❒	Sunscreens	❒	❒
A .Insulin Dependent	❒	❒NA	If "yes" any of the above, please explain below:		
B. Non-Insulin Dependent	❒	❒NA			
Eye disease or condition	❒	❒			
High Blood Pressure	❒	❒			

Are you pregnant, nursing a child or planning on becoming pregnant during this study? ❒ Yes ❒ No ❒ NA

3. What method of birth control are you currently using?

❒	Tubal Ligation	❒	NuvaRing	❒	Norplant
❒	Hysterectomy	❒	Depo Provera	❒	Abstinence
❒	Diaphragm	❒	Birth Control Pill	❒	Post-Menopausal
❒	IUD	❒	Condom	❒	Other

List Medications taken within the past thirty (30) days. Please include prescription drugs, vitamins, skin treatments, herbal remedies, allergy medications, antihistamines, steroids, antibiotics, anti-inflammatory drugs, antacids, and contraceptives:	If no medications have been taken in the past thirty (30) days, check here ❒

Medications

Name of Medication	Dose	Reason for taking Medication	Date		Ongoing
			Start	Stop	

This form reflects all medical information up to the first day of this study. Notify our staff if there is any change in this information.

Do not write below this line, for IRSI staff use only.

This CRF has been reviewed for completion prior to subject's dismissal from station	Tech Initials:	**BASELINE: Page 2 of 6**
This CRF has been reviewed for completion prior to subject's dismissal from study visit	Tech Initials:	*TOTAL: Page **2** of **14***

SCREENING/BASELINE: February 19, 2018	**Tech**
Inclusion / Exclusion criteria checklist	

INCLUSION CRITERIA	If any box is checked "No", subject is NOT eligible to continue study.	**YES**	**NO**
1.	Is the subject a male (maximum of 25%) or female in good general health?		
2.	Is the subject between the ages of 21 and 55 years old, inclusive at enrollment?		
3.	Is the subject overweight with BMI between ≥25 - ≤29.8 as measured by InBody?		
4.	Does the subject have self-perceived need/desire to lose at least 10 lbs?		
5.	Has the subject had a stable weight within two months preceding Baseline?		
6.	Has the subject been on a stable dose of medications within three months preceding Baseline?		**NA**
7.	Is subject able to read, understand and sign an informed consent form (includes HIPAA and State requirements)?		
8.	Is the subject willing to participate in an interview with the sponsor if requested?		
9.	Is the subject willing and able to follow all study directions and must be willing to accept all study requirements including: a. Willing to follow the provided restrictive diet, including consumption of provided salmon?		
EXCLUSION CRITERIA	If any box is checked "Yes", subject is NOT eligible to continue study.	**YES**	**NO**
1.	Does the subject have a known allergy to milk, eggs, walnuts and/or coconut, or any item in the provided diet?		
2.	Is the subject taking drugs which are known to influence weight. Including laxatives, Anoretics and Diuretics?		
3.	Is the subject currently following a weight loss program or diet (ex. Atkins, Jenny Craig, Weight Watchers, South Beach Diet, etc.)?		
4.	Is the subject currently using or have used weight loss/weight control supplements (prescription, OTC and/or natural remedies) within 28 days of Baseline?		
5.	Is the subject currently taking prescription medications with known weight loss or weight gain side effects (ex. Tricyclic antidepressants, oral corticosteroids, beta blockers)?		
6.	Is the subject participating in any other studies?		
7.	Does subject have any acute or chronic disease or medical condition, which could put him/her at risk in the opinion of the Principal Investigator or compromise study outcomes. Typical uncontrolled chronic or serious diseases and conditions which would prevent participation in any clinical trial are cancer, AIDS, any type of diabetes, renal impairment, mental illness, drug/alcohol addiction?		

Exclusion Criteria Continued on the Next Page

EXCLUSION CRITERIA	If any box is checked "Yes", subject is NOT eligible to continue study.	**YES**	**NO**
8.	Is the subject unreliable of unlikely to be available for the duration of the study?		
9.	Is the subject immunocompromised?		
10.	Is the subject a woman who started Hormone Replacement Therapy within the last three months preceding the screening visit?		**NA**
11.	Is the subject a woman using oral contraception for less than three months before the screening visit or who has changed her contraception method within the three months before the Baseline Visit or planning to modify her contraception treatment within the duration of the study?		**NA**
12.	Is the subject a woman known to be pregnant, lactating or planning to become pregnant within six months? Subjects who become pregnant during the study must inform the Principal Investigator immediately.		**NA**
13.	Is the subject unable to communicate or cooperate with the Principal Investigator due to language problems, poor mental development, or impaired cerebral function?		
14.	Is the subject an employee of IRSI or other testing firms/laboratories, cosmetic or raw goods manufacturers or supplier?		
Based on the above inclusion/ exclusion criteria, does the subject qualify?			

BASELINE February 19, 2018		**Tech**
Body Composition Measurements (INBODY)	No. of Assessments: 1	

ITEM		VALUES
Weight	WG	
Body Mass Index	BMI	
Percent Body Fat	PBF	
Lean Body Mass	LBM	
Body Fat Mass	BFM	

BASELINE February 19, 2018		**Tech**
Waist to Hip Ratio Measurements (WHR)	No. of Assessments: 1	

Waist	Hip	WHR
_____ inches	_____inches	_____ % *The waist and hip ratio is calculated by taking the waist value in inches and dividing it by the hip value in inches.*

Subject selected for subgroup of n=20?

BASELINE February 19, 2018		Tech
Omega 3 Testing Conducted via finger stick using provided kit. Samples will be stored at IRSI until the Sponsor is ready for analysis	No. of Assessments: 1	

Subject Signature:					
WEEK 2: March 6, 2018				**Tech**	**Time**
Arrive at site					
Complete and Review Week 2 Questionnaire					
Compliance check (Inclusion / Exclusion) Review Diary and product/collect wrappers	Subject Compliant?	**Circle One**			
		Yes	No		
Medical History review and questioned for AEs	AE Reported?	**Circle One**			
		Yes	No		
InBody Measurements					
Clinical Measurements: Waist to Hip Ratio					
All CRFs reviewed for completion					
Subject reminded of Week 4 Visit and dismissed from test site					

WEEK 2: March 6, 2018	Tech
Compliance (Applicable Inclusion / Exclusion) checklist	

Compliance	If any box is checked "No", subject is NOT eligible to continue study.	YES	NO
1.	Subject continued to use the product as instructed?		
2.	Subject followed diet regimen?		
3.	Subject refrained from weight loss/control products and programs?		
Based on the above compliance questions, does the subject qualify?			

WEEK 2: March 6, 2018	Tech
Medical history and AEs	

List any changes to medical history mentioned by the Subject, including but not limited to medications taken:

Any AEs or SAEs to report?	Circle One	
	Yes*	No
	*If yes, fill out AE form	

WEEK 2: March 6, 2018		Tech
InBody	No. of Assessments: 1	

ITEM		VALUES
Weight	WG	
Body Mass Index	BMI	
Percent Body Fat	PBF	
Lean Body Mass	LBM	
Body Fat Mass	BFM	

WEEK 2: March 6, 2018		Tech
Waist to Hip Ratio Measurements (WHR)	No. of Assessments: 1	

Waist	Hip	WHR
_____ inches	_____inches	_____ % *The waist and hip ratio is calculated by taking the waist value in inches and dividing it by the hip value in inches.*

Subject Signature:					
WEEK 4: March 19, 2018				**Tech**	**Time**
Arrive at site					
Complete and Review Week 4 Questionnaire					
Compliance check (Inclusion / Exclusion) Review/Collect Diary and Collect Product/Wrappers	Subject Compliant?	**Circle One**			
		Yes	No		
Medical History review and questioned for AEs	AE Reported?	**Circle One**			
		Yes	No		
InBody Measurements					
Clinical Measurements: Waist to Hip Ratio					
All CRFs reviewed for completion					
Stipend dispensed and subject dismissed from the study					

WEEK 4: March 19, 2018	Tech
Compliance (Applicable Inclusion / Exclusion) checklist	

Compliance	If any box is checked "No", subject was NOT compliant to study instructions.	YES	NO
1.	Subject continued to use the product as instructed?		
2.	Subject followed diet regimen?		
3.	Subject refrained from weight loss/control products and programs?		
Based on the above questions, was the subject compliant?			

WEEK 4: March 19, 2018	Tech
Medical history and AEs	

List any changes to medical history mentioned by the Subject, including but not limited to medications taken:

Any AEs or SAEs to report?	Circle One	
	Yes*	No
	*If yes, fill out AE form	

WEEK 4: March 19, 2018		Tech
InBody	No. of Assessments: 1	

ITEM		VALUES
Weight	WG	
Body Mass Index	BMI	
Percent Body Fat	PBF	
Lean Body Mass	LBM	
Body Fat Mass	BFM	

WEEK 4: March 19, 2018		Tech
Waist to Hip Ratio Measurements (WHR)	No. of Assessments: 1	

Waist	Hip	WHR
_____ inches	_____inches	_____ % *The waist and hip ratio is calculated by taking the waist value in inches and dividing it by the hip value in inches.*

	Reimbursement Form	Study Number 4189SBC1217
		Subject Initials
		Subject Number

PLEASE PRINT CLEARLY, FILL IN ALL FORM FIELDS

DO NOT WRITE IN SHADED AREAS

– –
Social Security Number

First Name	**M.I.**	**Last Name**

Street	**Apt. /Suite**

City / Town	**State**	**Zip Code**

4189SBC1217	**$125.00**
Department / Study	**Amount**

Payment Terms:

Please read ClinCard information.

❒ I_____ have received my payment and agree to the ClinCard terms.

Sign your name

Appendix IV

Informed Consent Form

This consent form may contain word(s) that you do not understand. Please ask the study staff to explain any word(s) or information that you do not clearly understand. You are entitled to a copy of this Consent Form and one will be provided to you today.

1.0 PURPOSE

You are being asked to participate in a research study to evaluate the effectiveness of a breakfast cookie when used with a restrictive diet to improve weight control.

2.0 ENROLLMENT

Certain enrollment criteria are required for this study. If you do not meet these criteria you will not be enrolled in this study. Below is a list of enrollment requirements.

AIRB Approved
Robert J. Staab, PhD
Date: 2.15.16

Inclusion Criteria

1. Males (maximum of 25%) and Females in good general health.
2. Subjects between the ages of 21 and 55 years old, inclusive at enrollment.
3. Overweight subjects with Body Mass Index (BMI) measurements between ≥25 and ≤29.8 as measured by InBody.
4. Subjects with self-perceived need/desire to lose at least 10 lbs.
5. Stable weight within two months preceding Baseline.
6. Stable medications within three months preceding Baseline.
7. Subjects will be able to read, understand and sign an informed consent form (includes HIPAA and State requirements).
8. Subjects who are willing to participate in an interview with the sponsor if requested.
9. Subjects who are willing and able to follow all study directions and must be willing to accept all study requirements including:
    a. Willing to follow the provided restrictive diet, including consumption of provided salmon.

Exclusion Criteria

1. Known allergy to milk, eggs, walnuts and/or coconut, or any item in the provided diet.
2. Taking drugs which are known to influence weight. Including laxatives, Anorectics and Diuretics.
3. Subjects who are currently following a weight loss program or diet (ex. Atkins, Jenny Craig, Weight Watchers, South Beach Diet, etc.)
4. Subjects who are currently using or have used weight loss / weight control supplements (prescription, OTC and/or natural remedies) within 28 days of Baseline.

General exclusion criteria:

5. Subjects participating in any other clinical studies.
6. Subjects having an acute or chronic disease or medical condition, which could put him/her at risk in the opinion of the Principal Investigator or compromise study outcomes. Typical uncontrolled chronic or serious diseases and conditions which would prevent participation in any clinical trial are cancer, AIDS, any type of diabetes, renal impairment, mental illness, drug/alcohol addiction.

7. Subjects who are unreliable or unlikely to be available for the duration of the study
8. History of allergic reactions, skin sensitization and/or known allergies to cosmetic ingredients, toiletries, sunscreens, etc.
9. Immunocompromised subjects
10. Woman who started Hormone Replacement Therapy within the last three months preceding the screening visit
11. Woman using oral contraception for less than three months before the screening visit or who has changed her contraceptive method within the three months before the Baseline visit or planning to modify her contraception treatment within the duration of the study
12. Woman known to be pregnant, lactating or planning to become pregnant within six months. Subjects who become pregnant during the study must inform the Principal Investigator immediately
13. Individuals unable to communicate or cooperate with the Principal Investigator due to language problems, poor mental development, or impaired cerebral function
14. Employees of IRSI or other testing firms/ laboratories, cosmetic or raw goods manufacturers or suppliers

AIRB Approved
Robert J. Staab, PhD
Date: 2/5/18

3.0 PROCEDURES

You are being asked to voluntarily participate in a Four (4) Week study, involving three (3) Visits to the clinic (including today's visit). All Visits will last for approximately thirty minutes. The study will include approximately thirty (30) test subjects. At today's visit you will be asked to read and sign this informed consent. You will also be asked to complete a brief medical/personal history. Qualification for study participation will be evaluated by an IRSI technician using information collected from your medical history as well as an inclusion/ exclusion checklist. Your Body Mass Index (BMI) will be calculated today using an InBody Machine (see section 3.5 for details). You must meet the qualification criteria for BMI in order to be eligible to participate into the study. If you qualify, you will be enrolled today and proceed with the Baseline assessments.

At the Baseline portion of today's visit, you will be enrolled and undergo the waist and hip measurements, and additional information will be collected using the InBody. You will also complete a Baseline Questionnaire. The Subjective questionnaire will ask you questions regarding weight loss and your perception of your body, in terms of weight loss prior to beginning the study regimen. A subgroup of twenty subjects will also be selected to participate in analysis of Omega 3 and 6 acids. Upon completion of all Baseline assessments, you will be receive the test product and salmon along with a daily diary, instructions and a diet that you will follow. You will then be dismissed from the Baseline Visit and be scheduled for your Week 2 Visit.

At the Week 2 Visit, your medical history will be reviewed and a compliance checklist will be completed by an IRSI technician. You will have InBody assessments performed and waist and hip measurements. You will also be interviewed and/or your study diary and product will be reviewed to ensure product accountability and compliance. Additional study product will be dispensed accordingly. In addition, you will be asked to complete a questionnaire regarding your opinion of the product and its effects. You will be advised to report any adverse events or side effects to IRSI as soon as they occur. You will then be dismissed from the Week 2 Visit and be scheduled for your Week 4 Visit.

At the Week 4 Visit, your medical history will be reviewed and a compliance checklist will be completed by an IRSI technician. You will be interviewed and/or your study diary will be reviewed to ensure product accountability and compliance. All diaries and products/product wrappers will be collected. You will then undergo InBody assessments and waist and hips measurements. You will be advised to report any adverse events or side effects to IRSI as soon as they occur within 48 hours of study completion. You will receive a stipend for your study participation after all procedures have been completed and you will be dismissed from the study.

3.1 PRODUCT

You will consume the product, a Breakfast Cookie, two times per day; for breakfast and lunch. You receive a variety of Breakfast Cookie flavors; Orange Cranberry Nut, Gingered Apple, Banana Coconut and Cocoa.

3.2 FOOD INTAKE INSTRUCTIONS

You will be required to follow a diet plan with instruction to consume specific types of food, along with the cookies, throughout the study period. You will also receive a portion of frozen salmon and canned salmon, to consume for a minimum of one meal per week. You are not allowed to begin new weight loss diet programs. You will be required to record food intake on a diary. This is simply done by writing down the food and the amount of food by items that you consume daily. For example, one glass of milk, one cup of brown rice, one serving of chicken breast, etc.

AIRB Approved
Robert J. Staab, PhD
Date: 2/5/18

3.3 SUBJECTIVE QUESTIONNAIRE and WRITTEN TESTIMONIAL

You will be asked to complete a questionnaire regarding your level of agreement with statements. Questionnaires will be completed at the Baseline visit before treatment and after 2 and 4 weeks of product use. The baseline questionnaire will include questions about weight loss and your perception of your body in terms of weight loss. Week 2 and Week 4 Questionnaires will include questions regarding your impressions of the product.

At the Week 4 visit, you will be asked to provide some feedback on your experience with the product in the form of a written testimonial.

3.4 INBODY ASSESSMENTS and BODY MASS INDEX

Body Mass Index (BMI) is a simple index and is determined by calculation based on your height and weight. BMI is commonly used to classify overweight. For this research study, your BMI will be calculated using the InBody Machine.

At all visits, body composition measurements will be taken using the In Body. The InBody machine will measure body composition, distinguishing body fat from body muscle using a machine. You will stand

on the machine with bare feet and hold onto handles. The measurement is performed by taking measurements using your body's electrical current and water content to measure body composition.

Proper posture is essential to achieve reliable results. You will be required to remove your socks and shoes for this procedure. You will be provided with wipes, specific for the InBody machine and its procedures. The wipes will be used to both clean the machine electrodes and to clean your palms and the soles of your feet. You will then step on the InBody machine with your clean feet, making sure that your feet are in good contact with the electrodes. You will also place your clean palms and hold on to the inBody machine handles, making sure that your thumbs are in good contact with the electrodes. You will be required to stand straight with proper posture and stand still while the machine takes the measurements. This is a painless and non-invasive procedure that will lasts for about one minute.

3.5 WAIST AND HIP MEASUREMENTS

At All Visits, an IRSI technician will measure your hip and waist circumference. You will be required to stand straight with your chin parallel to the floor and hands down at your sides. Using a standard tape measure, a technician will take a measurement. You may be asked to lift your shirt above your navel in order to take accurate measurements. This procedure is painless and non-invasive. Complete assessment will be done within three minutes.

AIRB Approved
Robert J. Staab, PhD
Date: 2/5/18

3.6 VITAL OMEGA-3 and 6 HUFA TEST™

Samples will be collected from a subgroup of twenty (20) subjects to undergo testing for Omega 3 and 6 levels.

Collection kits will be provided by the sponsor. Following kit instructions at Baseline and Week 4, a finger stick will be used to collect blood from the finger. You will wipe your finger with an alcohol swab and use the lancet provided with the kit to stick your finger and place a smear/print of blood onto 3-4 designated areas on a collection card. The Baseline and Week 4 cards will be collected by an IRSI technician and stored in a -20 freezer at the test site until the sponsor collects them to send for analysis.

3.7 SPONSOR INTERVIEW

After the study has completed, the sponsor may want to interview some of the subjects who participated. You may be contacted by IRSI and scheduled to come to IRSI to meet with the sponsor for a one on one interview. The interview may consist of questions from the sponsor regarding your experience with the product. The interview will last approximately thirty minutes. Some or all of the interview may be tape or video recorded and the sponsor may ask for your permission to take digital photographs of you.

4.0 COMPENSATION

You will receive $125.00 for completing the study as directed. If you are not qualified for this study you will not be compensated. If you are present and qualified, but not enrolled due to overbooking, you will be paid $20.00. Please note that it is the policy of IRSI to overbook all studies due to high rates of cancellations and no-shows. Completing the study paperwork does not guarantee enrollment into the study, even if you meet the entry criteria and qualify. If you are discontinued from the study you may be paid on the basis of the visits you have completed at approximately $42.00 per visit.

If you withdraw from this study for personal reasons unrelated to the test materials, you will not be compensated. If you are disqualified for refusal to obey rules, follow instructions or attend all visits as scheduled, you will not be compensated.

This is a voluntary study and you may withdraw at any time without obligation or prejudice. The sponsor and/or investigative staff may remove you from this study at any time for any reason without loss of benefits, except as stated above. The Clincard system delivers scheduled subject stipend payments in real time-through a web-based portal. Subjects will receive payments on a MasterCard branded debit card, and can access their funds at an ATM or bank.

5.0 POTENTIAL BENEFIT

You may experience weight loss during the study participation. However, the benefit may vary from subject to subject.

AIRB Approved
Robert J. Staab, PhD
Date: 2/15/16

6.0 POTENTIAL RISKS

The test product is for you ONLY to use.

It is possible to develop a reaction to products such as those being tested including but not limited to stomach irritation, upset stomach, oral irritation, unpleasant taste in mouth or allergic reaction. Allergic reaction may include but is not limited to skin rash, hives, itchiness or blemishes, difficulty breathing and tightness in the chest. Some risks are unknown and you will be advised if more information becomes available.

If you have a history of reactions to the ingredients of the cookies then you must not participate in this study. If you have no sensitivity, the likelihood of a reaction is minimal and similar to that if you purchased and used comparable products on your own.

Reactions may persist in some individuals. In the event of a reaction you should **immediately** contact:

Anna, Study Coordinator at (914) 937-6500, Ext. 126

All test products will be eaten and may pose as a choking hazard. In most case choking is relieved by the Heimlich maneuver by a trained person. In case of a major airway blockage, call medical emergency right away.

In the event of a medical emergency, you should seek medical attention first and then contact IRSI.

If you experience an injury as a direct result of administration of the test material, the study sponsor agrees to pay medical expenses necessary to treat such injury: (1) To the extent you are not otherwise reimbursed by your own medical insurance, (2) provided you have followed the directions of the investigator before and after the

injury occurred. Additional financial compensation will not be provided. Medical follow-up will be provided until the investigator or study coordinator determines you have recovered.

If you withdraw due to personal reasons related to product usage other than a response judged by IRSI staff to be a reaction to test product or instructions, you may not be paid. If, in the judgment of the investigative staff, it is best to discontinue your participation for reasons such as a documented medical condition not related to study materials, product failure or study termination, you will be paid for that portion of the study you have completed (pro rata), according to the number of scheduled visits made to the office. If your participation in the study is stopped due to an adverse reaction related to use of the test material or test instructions, you will be paid the full stipend amount.

For safety reasons, even if you drop from this study you may be asked to make follow-up visits to the study facility or to a physician. In the event of a reaction this is especially important for your safety and so that accurate information can be obtained.

7.0 CONFIDENTIALITY OF RECORDS

Reports prepared by IRSI use statistical information only and at no time will your name be used in these reports. The sponsor, the FDA and Allendale Investigational Review Board and others in certain legal action, may inspect the records of this study which will include your name, medical records and, if applicable, personal information relating to your participation.

By signing this consent form you authorize the release of your medical records, only for treatment of illnesses and injuries related to this study to IRSI, and the study sponsor. IRSI will not release any information in your medical records except as stated in this consent.

AIRB Approved
Robert J. Staab, PhD
Date: 2/5/16

9.0 USE OF PERSONAL INFORMATION (HIPAA) AUTHORIZATION

Your participation in this study will involve disclosing some of your personal data and medical information (allergies, medications, illnesses, conditions and demographics {age, sex, race, and occupation}) as well as name, address, email address, Social Security Number, and phone number to IRSI.

The Study Coordinator, Investigator or authorized staff member may ask you for this information. By signing this consent form you authorize the release of your medical records (for treatments, illnesses and injuries as a direct result of test material use) to IRSI.

The same staff and management that write IRSI's reports will review or use the medical information you report. At no time will your name, address, phone number, email address or social security number be published in a report. The study Sponsor, the Allendale Institutional Review Board, and the FDA may be granted access to your personal information regarding this study. IRSI will use the medical information you provide in order to conduct this study.

Additionally, IRSI will use the medical information in its database so that IRSI may be able to contact you to participate in future studies. Therefore, your authorization to IRSI to use the medical information and data you provide has no end date.

You have the right to revoke this authorization so long as IRSI has not already relied on or used the information you provided for this study. At your written request, IRSI will not contact you for future studies. Only employees who have signed a confidentiality agreement are permitted to access the database. IRSI does not sell the identifying information in the database. Even if you take back your consent to participate in this study the Use of Personal Information authorization will remain in effect.

Your signature below indicates you have read the above privacy statement.

Signature:	Date:

AIRB Approved
Robert J. Staab, PhD
2/15/18

AIRB Approved
Robert J. Staab, PhD
Date: 2/5/18

10.0 CONSENT OF SUBJECT

I have read and fully understand this consent and what is required of me during this study. I understand the risks, benefits and procedures and that I am free to ask questions at any time. I have no questions at this time. For questions regarding your rights as a research participant please feel free to contact the Institutional Review Board, Allendale Institutional Review Board at 860-434-5872. Additional information regarding the test material may become available to me during this study. If additional information becomes available or the study procedures are changed and this affects my well-being a new consent form will be provided to me. By signing this consent I authorize the release of my medical records in the event of an illness, injury or reaction related to this study. The investigator or a member of the staff will be available at (914) 937-6500 to answer my questions. I have read this consent and I freely and voluntarily agree to participate in this study as described to me. By signing this form I forfeit none of my legal rights.

Signature:		Date:	
Print Name: Last:	First:		M.I:
Street Address:	City:	State:	Zip:
Home Phone:	Cell Phone:	Work Phone:	
E-Mail Address:			
Social Security Number:			

DO NOT WRITE BELOW THIS LINE

****

Witness Signature: Person Administering Consent (IRSI Personnel)

Signature:		Date:
Print Name: Last:	First:	

CASE REPORT FORM	Model Release Form	Study Number 4189SBC1217
		Subject Initials
		Subject Number

In return for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I hereby grant to International Research Service Inc., its client, and their respective parents, subsidiaries, affiliates, successors, assigns, and agents, and to other such persons and/or entities as it or they may designate from time to time (hereinafter collectively "Company"), the non-exclusive right and permission to reproduce, exploit, publish, display, transmit, distribute, and/or otherwise use my image, name, photograph, likeness, appearance, voice, and written and spoken words photographed, recorded, and/or otherwise documented on or about February 19, 2018 to March 19, 2018 in Port Chester, NY, in connection with the "**A 4-Week Clinical Study Evaluating the Influence of a Breakfast Cookie on Weight Loss" (Study # 4189SBC1217)** (the "Study"), either alone or accompanied by other material, in whole or in part, distorted in character or form, in any and all forms of media now known or hereafter devised, worldwide, in perpetuity for all purposes including, but not limited to, advertising, marketing, promoting, and publicizing the products and product protocols tested, employed, and/or otherwise used in the Study.

I hereby waive any right to inspect and approve the finished materials or their use. Nothing herein will constitute any obligation on Company's part to make any use of any of the rights set forth herein. I agree that all right, title, and interest in and to the finished materials and any negatives or digital files thereof, including the copyrights therein, shall vest exclusively in Company. In addition, I agree not to assert any claim against Company arising from its use of my image, name, photograph, likeness, appearance, voice, and written and spoken words, including but not limited to any claims for defamation, invasion of privacy, rights of publicity, or copyright infringement.

I represent and warrant that I have the full right and power to execute this Release and that this Release does not conflict or interfere with any existing agreement or obligation on my part.

This Release contains the entire understanding between the parties regarding the subject matter hereof and supersedes all prior understandings. No waiver, modification, or additions to this Release shall be valid unless in writing and signed by all parties hereto.

I am 18 (eighteen) years of age or older and have the right to make this agreement.

Signature _____ Date _____

Print Name _____ Email _____

Address _____

Appendix II

Protocol Deviations

	Protocol Deviation	**FORM Number:**	**040**
		Version:	1.0
		Implementation Date:	10/21/2013
		Theoretical Withdraw Date:	10/21/2015

Study Number	4189SBC1217
Study Title	A 4-Week Clinical Study Evaluating the Influence of a Breakfast Cookie on Weight Loss
Sponsor	Susie's Smart Cookie
Sponsor Representative	Susan Allport Howell
Protocol Version, Date	Version 2.5, January 26, 2018

Deviation Number	1
Section, Page Number	Section 6.3, Page 8
Section Affected	**Consumer Perception Questionnaire** Subjective questionnaires will be used to evaluate the subject's history with weight control and gauge the subject's perception of the investigational products. Questions will ask for subjects' agreements to a statement with a five-point scale. Questionnaires will be provided by IRSI and will be administered at Baseline, Week 2 and Week 4.
Summary of Deviation	The following questionnaire data are not included in the analysis: • Subject # 22 did not complete Question 1 at the Week 2 timepoint • Subject #31 did not complete Questions 13 at the Week 2 timepoint A total of 29 subjects are included in the analysis for Week 2
Impact of Deviation	Minor
Corrective Action	More thorough review of CRFs will be completed prior to subject dismissal from visit
Deviation Number	2
Section, Page Number	Section 5.2, Page 6
Section Affected	**Inclusion Criteria** 2. Overweight subjects with Body Mass Index (BMI) measurements between ≥25 and ≤29.8 as measured by InBody.
Summary of Deviation	Two subject who were outside of the BMI inclusion range were included in the study at the PI's discretion: • #20 with a BMI of 23.8 • #31 with a BMI of 30.7
Impact of Deviation	Minor
Corrective Action	None required

Approved by:

Schwartz 05.02.18	L A Howell 05/02/18
Stephen R. Schwartz Date Principal Investigator	Sponsor Date

Appendix III

Adverse Events

CLINICAL ADVERSE EVENT REPORT FORM

FORM Number:	003
Version:	3.0
Implementation Date:	01/15/2018
Theoretical Withdraw Date:	01/15/2020

Study Number: 4189SBC	Investigator: Stephen Schwartz	Subject Initials: P-W	Subject Number: 19
Sponsor: Susie's Smart Cookie	Sponsor Contact: Susan Allport Howell	IRB:	NA ☒

Directions: Use the following key to complete form, provide additional detail as necessary to describe the adverse experience. The back of this page may be used and attachments provided in order to best describe the event.

Intensity	Duration Units	Frequency	Action Taken	Outcome	Relationship	Reported By	Follow up
1 = Mild 2 = Moderate 3 = Severe	S=Seconds M=Minutes H=Hours D=Days	1= Continuous 2= Intermittent	0=None 1= Modify test product use 2= Test product use interrupted 3= Medication / Seek Medical Attention 4=Discontinued	0=Resolved 1=Improved 2=Ongoing 3=Worsened 4=Fatal 5=Lost to follow up	0=None 1=Remote 2=Possible 3=Probable 4=Definite	0=Subject 1= Physician 2 = IRSI Staff 3 =Other	0=No follow-up necessary 1= Follow-up with subject Additional: ☐ Recommended Subject follow up with a physician

Description of Adverse Experience	Intensity	Date Of Onset	Date Reported to IRSI	Duration (units)	Frequency	Action Taken	Outcome	Relationship to Investigational Product (Indicate Product)	AE Reported By	Date Resolved	Follow up
Headache Type: AE ☒ SAE ☐	1	2/20/18	2/21/18	4H	1	4	0	0	0	At 2/20/18 ~~4/20/18~~ 2/20/18	0
Mild gas Type: AE ☒ SAE ☐	1	2/20/18	2/21/18	8H	2	4	0	2	0	4 At 2/20/18 2/20/18	0
Type: AE ☐ SAE ☐											

Medication(s) taken due to AE (Include prescription and OTC medications):	Dose and Frequency:

COMMENTS: Subject reported mild headache and flatulence throughout the day, following first cookie. The subject reported that she follows a low sugar diet regularly. Symptoms were resolved when the subject contacted site on 2/21/18.

Note: The Principal Investigator or designee must report all related AEs to the sponsor within 5 business days. SAEs must be reported within 24 hours of recording the experience.	Date AE Reported: 2/21/18	Date SAE Reported:

Investigator Signature / Date: Stephen Schwartz 04.11.18	Form completed by Name / Signature / Date: Anna Hardy Gather AH 2/22/18

Appendix IV

Statistical Report and Data Listing

04/02/18

INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
MEDICAL HISTORY

SUBJ	INITIAL	HGT	WGT	AGE	SEX	ETHN	RACE	FAA	BCD	FIT	SKIN	EYE	LNS	OTC	SPECIFY
01	AJR	63.0	146	27	F	N	W	N	N	3	N	N	N	E	TEACHER
02	J-C	67.0	163	33	F	H		C	N	4	N	N	N	E	YOUTH CARE
03	SRS	63.0	160	55	F	N	W	N	N	3	N	N	Y	E	SR. ADMIN ASST
04	D-K	64.0	155	51	F	N	W	N	N	3	Y	N	N	E	SPECIAL EVENTS
06	CAA	65.0	156	23	F	N	B	N	N	5	N	N	Y	E	SALES
07	MDL	68.0	185	49	F	H	W	N	N	4	N	Y	N	E	REALTOR
08	T-S	65.0	150	47	F	N	W	N	N	3	N	N	N	U	
09	MLT	65.0	160	37	F	N	B	C	N	5	N	N	Y	E	SOCIAL WORKER
10	Y-A	63.0	160	34	F	H		C	D	4	N	N	N	E	MARKETING
12	RCH	69.0	194	54	M	N	W	N	N	3	N	Y	N	E	CONSTRUCTION MGR.
13	JJS	72.0	190	47	M	N	W	C	N	3	N	Y	N	E	REALTOR
14	MKG	61.0	148	49	F	N	W	C	V	3	N	N	N	E	REALTOR
15	DMP	63.0	145	49	F	N	B	C	D	6	N	N	N	R	
16	A-C	65.0	170	36	F	H		C	N	3	N	N	N	H	
17	DJB	67.0	165	30	M	N	W	C	D	2	N	N	N	E	ACCOUNT
18	TSG	71.0	214	45	F	N	B	C	N	5	Y	N	N	E	PARALEGAL
20	S-U	66.0	145	53	F	N	W	C	N	3	N	N	N	E	SALES
21	GLV	61.0	152	41	F	H		C	N	4	N	N	N	E	OFFICE ASST
22	PBG	60.0	147	34	F	H		N	N	4	N	N	N	H	
23	KMA	65.0	162	34	F	N	W	N	N	2	N	N	N	H	
25	LMM	66.0	163	48	F	N	W	C	N	3	N	N	N	E	ACCOUNTING MGR
26	CVV	70.5	201	44	M	H		N	N	4	N	N	N	E	SR. MANAGEMENT
27	R-H	60.0	144	37	F	H		C	N	4	N	N	N	H	

04/02/18

INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
MEDICAL HISTORY

SUBJ	INITIAL	HGT	WGT	AGE	SEX	ETHN	RACE	FAAC	BOD	FAIT	SKIN	EYE	LENS	OCC	SPECIFY
28	AKC	65.0	175	36	F	N	B	N	N	5	N	N	N	E	STORAGE SPECIALIST
30	R-T	65.0	150	48	F	H	M	D	D	4	Y	Y	N	E	TEACHER'S AIDE
31	E-V	56.0	138	54	F	H		N	N	3	Y	N	N	H	
32	A-M	67.0	184	29	F	H	W	C	N	3	N	N	Y	E	ADMIN
33	AMR	65.0	165	47	F	N	W	N	N	3	N	N	N	E	SUPERVISOR
34	TEA	65.0	149	46	F	H	W	N	N	4	N	N	Y	E	SUPERVISOR
35	M-D	65.0	164	38	F	N	W	N	N	3	N	N	N	H	

04/02/18

INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
CLINICAL MEASUREMENTS

EVAL TIME	WEIGHT	BODY MASS INDEX	% BODY FAT	LEAN BODY MASS	BODY FAT MASS	WAIST	HIP	WHR
** SUBJECT = 01								
BASE	144.8	25.7	34.0	0.0	-20.5	29.0	41.0	0.71
WK-2	145.7	25.8	35.3	0.0	-23.1	30.1	42.0	0.72
WK-4	142.2	25.2	35.5	0.0	-19.4	28.5	40.5	0.70
** SUBJECT = 02								
BASE	159.4	25.0	35.3	2.6	-24.7	31.0	39.5	0.78
WK-2	164.9	25.8	36.9	1.8	-29.3	31.2	39.5	0.79
WK-4	168.0	26.3	36.7	0.0	-30.0	32.0	39.7	0.81
** SUBJECT = 03								
BASE	158.7	28.1	37.2	0.0	-29.1	35.4	42.0	0.84
WK-2	155.4	27.5	36.0	0.0	-26.2	33.0	42.0	0.79
WK-4	158.7	28.1	38.4	0.0	-31.7	34.4	42.0	0.82
** SUBJECT = 04								
BASE	168.2	28.9	41.4	0.0	-40.3	32.1	41.9	0.77
WK-2	166.0	28.5	41.8	0.0	-40.6	32.1	40.6	0.79
WK-4	165.6	28.4	41.4	0.0	-39.7	32.0	41.0	0.78
** SUBJECT = 06								
BASE	156.9	26.1	29.1	0.0	-12.3	29.1	41.2	0.71
WK-2	158.3	26.3	28.9	0.0	-12.1	34.0	41.2	0.83
WK-4	163.1	27.1	29.2	0.0	-13.2	34.3	42.0	0.82
** SUBJECT = 07								
BASE	185.2	28.2	38.6	0.0	-37.5	39.0	40.5	0.96
WK-2	182.1	27.7	38.9	0.0	-37.5	38.0	40.1	0.95
WK-4	181.2	27.6	37.3	0.0	-33.7	38.0	40.0	0.95
** SUBJECT = 08								
BASE	168.2	27.6	40.7	1.3	-38.4	37.0	41.1	0.90
WK-2	171.1	28.0	40.7	0.0	-39.5	35.2	42.0	0.84
WK-4	168.7	27.6	40.2	0.2	-37.7	35.5	42.0	0.85
** SUBJECT = 09								
BASE	166.9	27.8	35.4	0.0	-26.9	32.1	42.6	0.75
WK-2	163.4	27.2	34.2	0.0	-23.8	32.1	42.0	0.76
WK-4	167.1	27.8	36.3	0.0	-28.9	32.2	42.0	0.77
** SUBJECT = 10								
BASE	155.0	27.5	40.2	0.9	-34.4	35.0	42.2	0.83
WK-2	156.3	27.7	38.5	0.0	-31.5	35.0	42.9	0.82
WK-4	155.0	27.5	38.4	0.0	-31.1	36.0	41.0	0.88

04/02/18

INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
CLINICAL MEASUREMENTS

EVAL TIME	WEIGHT	BODY MASS INDEX	% BODY FAT	LEAN BODY MASS	BODY FAT MASS	WAIST	HIP	WHR
** SUBJECT = 12								
BASE	199.7	29.5	31.5	0.0	-38.6	41.1	42.0	0.98
WK-2	196.4	29.0	31.4	0.0	-37.9	40.0	42.0	0.95
WK-4	192.9	28.5	30.5	0.0	-35.3	40.0	40.5	0.99
** SUBJECT = 13								
BASE	199.1	27.0	26.9	0.0	-28.0	38.1	41.0	0.93
WK-2	196.4	26.6	25.4	0.0	-24.0	38.0	40.0	0.95
WK-4	194.2	26.3	24.3	7.0	-21.4	38.0	40.0	0.95
** SUBJECT = 14								
BASE	149.5	28.3	42.3	1.3	-37.0	35.0	40.0	0.88
WK-2	146.2	27.6	43.8	5.5	-37.9	33.5	38.2	0.88
WK-4	143.1	27.1	41.5	3.7	-33.1	32.5	38.1	0.85
** SUBJECT = 15								
BASE	153.9	27.3	34.1	0.0	-22.3	34.0	41.0	0.83
WK-2	143.7	25.5	35.1	0.2	-22.5	32.2	37.2	0.87
WK-4	139.6	24.7	34.6	2.2	-20.5	32.0	37.1	0.86
** SUBJECT = 16								
BASE	169.3	28.2	34.6	0.0	-25.6	37.0	42.0	0.88
WK-2	170.0	28.3	34.9	0.0	-26.2	34.5	41.5	0.83
WK-4	166.2	27.7	34.9	0.0	-25.8	34.9	41.0	0.85
** SUBJECT = 17								
BASE	171.1	26.8	28.1	0.0	-26.2	36.5	39.0	0.94
WK-2	170.0	26.6	29.1	0.0	-28.2	35.7	39.0	0.92
WK-4	166.2	26.0	27.8	0.0	-24.9	34.5	37.0	0.93
** SUBJECT = 18								
BASE	210.5	29.4	38.3	0.0	-41.9	36.0	42.0	0.86
WK-2	207.5	29.0	38.0	0.0	-40.3	35.0	43.1	0.81
WK-4	211.9	29.6	39.8	0.0	-46.3	36.3	42.1	0.86
** SUBJECT = 20								
BASE	147.5	23.8	31.1	0.9	-15.2	31.5	37.2	0.85
WK-2	142.2	23.0	29.9	2.9	-11.9	32.0	37.5	0.85
WK-4	143.5	23.2	29.1	0.9	-11.0	31.0	37.0	0.84
** SUBJECT = 21								
BASE	150.6	28.5	38.6	0.0	-30.4	34.0	40.0	0.85
WK-2	149.5	28.3	38.4	0.0	-30.0	35.0	40.0	0.88
WK-4	148.4	28.1	40.1	0.0	-32.8	35.0	39.2	0.89

04/02/18

INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
CLINICAL MEASUREMENTS

EVAL TIME	WEIGHT	BODY MASS INDEX	% BODY FAT	LEAN BODY MASS	BODY FAT MASS	WAIST	HIP	WHR
** SUBJECT = 22								
BASE	145.3	28.4	38.6	0.0	-29.5	30.0	37.0	0.81
WK-2	141.1	27.6	39.5	0.0	-30.2	30.5	35.5	0.86
WK-4	138.7	27.1	40.2	1.8	-30.4	30.0	36.0	0.83
** SUBJECT = 23								
BASE	163.1	27.1	42.4	5.5	-39.5	36.7	43.0	0.85
WK-2	161.8	26.9	41.5	4.9	-37.5	35.1	41.0	0.86
WK-4	162.5	27.0	41.0	3.7	-37.0	35.0	41.0	0.85
** SUBJECT = 25								
BASE	162.7	26.3	26.5	0.0	-7.3	30.5	38.0	0.80
WK-2	156.5	25.3	24.7	0.0	-3.5	31.0	39.0	0.79
WK-4	153.6	24.8	23.0	0.0	0.0	29.2	38.2	0.76
** SUBJECT = 26								
BASE	197.3	27.9	24.4	0.0	-21.8	36.5	41.3	0.88
WK-2	195.8	27.7	23.6	0.0	-19.8	36.3	41.3	0.88
WK-4	194.2	27.5	24.0	0.0	-20.7	36.0	40.2	0.90
** SUBJECT = 27								
BASE	142.9	26.1	31.4	0.0	-15.7	34.6	38.0	0.91
WK-2	144.6	27.3	36.2	0.0	-24.7	35.0	39.2	0.89
WK-4	144.0	26.3	33.3	0.0	-19.4	35.0	38.0	0.92
** SUBJECT = 28								
BASE	172.4	28.7	34.2	0.0	-25.1	31.0	42.9	0.72
WK-2	172.2	28.7	33.3	0.0	-23.1	32.0	43.5	0.74
WK-4	170.2	28.3	33.2	0.0	-22.5	31.5	42.0	0.75
** SUBJECT = 30								
BASE	150.3	25.0	33.6	0.0	-20.7	33.9	41.0	0.83
WK-2	154.5	25.7	33.9	0.0	-21.8	34.0	41.5	0.82
WK-4	152.3	25.3	35.2	0.9	-23.8	32.1	41.3	0.78
** SUBJECT = 31								
BASE	136.9	30.7	45.9	0.0	-40.6	35.0	38.9	0.90
WK-2	135.8	30.5	46.9	1.8	-41.7	35.1	39.0	0.90
WK-4	135.6	30.4	45.3	0.0	-39.2	35.0	39.0	0.90
** SUBJECT = 32								
BASE	184.3	28.9	31.2	0.0	-19.6	35.4	40.5	0.87
WK-2	184.7	28.9	32.3	0.0	-22.3	37.0	41.0	0.90
WK-4	184.7	28.9	32.3	0.0	-22.3	37.0	41.0	0.90

04/02/18

INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
CLINICAL MEASUREMENTS

EVAL TIME	WEIGHT	BODY MASS INDEX	% BODY FAT	LEAN BODY MASS	BODY FAT MASS	WAIST	HIP	WHR
** SUBJECT = 33								
BASE	165.6	27.6	34.0	0.0	-23.6	34.0	40.1	0.85
WK-2	164.5	27.4	33.7	0.0	-27.7	33.0	40.0	0.82
WK-4	161.2	26.8	33.6	0.0	-22.0	32.5	38.2	0.85
** SUBJECT = 34								
BASE	151.9	25.3	27.6	0.0	-9.0	30.8	39.0	0.79
WK-2	147.9	24.6	25.1	0.0	-4.0	29.6	37.2	0.80
WK-4	146.4	24.4	24.5	0.0	-2.9	29.2	38.0	0.77
** SUBJECT = 35								
BASE	166.2	27.7	33.8	0.0	-23.1	32.5	42.0	0.77
WK-2	162.7	27.1	35.0	0.0	-25.4	31.0	42.0	0.74
WK-4	161.8	26.9	33.7	0.0	-22.5	31.0	41.0	0.76

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INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
BASELINE QUESTIONNAIRE PART 1.

Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q8. OTHER OILS
** SUBJECT = 01								
5	7	4	2	5	4	4	Y	
** SUBJECT = 02								
5	3	4	4	3	4	3	Y	
** SUBJECT = 03								
10	7	1	1	0	1	1	Y	
** SUBJECT = 04								
5	10	0	0	0	0	0	N	OLIVE OIL
** SUBJECT = 06								
7	10	10	10	10	10	10	Y	
** SUBJECT = 07								
8	5	4	4	5	3	5	N	
** SUBJECT = 08								
6	5	1	1	1	5	5	N	OLIVE
** SUBJECT = 09								
8	2	5	4	2	7	6	Y	
** SUBJECT = 10								
8	7	3	3	9	6	8	N	OLIVE
** SUBJECT = 12								
9	7	5	5	6	4	4	N	OLIVE
** SUBJECT = 13								
5	7	5	3	3	5	6	N	VEGATABLE
** SUBJECT = 14								
7	7	1	1	3	6	6	Y	
** SUBJECT = 15								
7	7	6	5	2	3	3	N	ANY VEGATABLE
** SUBJECT = 16								
8	9	7	8	9	9	8	N	OLIVE
** SUBJECT = 17								
6	8	6	4	3	7	6	N	OLIVE
** SUBJECT = 18								
9	7	7	7	7	7	7	Y	

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INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
BASELINE QUESTIONNAIRE PART 1.

Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q8. OTHER OILS
** SUBJECT = 20								
7	7	1	0	1	1	1	N	OLIVE
** SUBJECT = 21								
7	4	5	2	5	8	2	N	OLIVE
** SUBJECT = 22								
10	3	0	0	3	3	1	Y	
** SUBJECT = 23								
10	6	1	1	1	5	5	Y	
** SUBJECT = 25								
8	5	0	0	1	5	5	N	VEGATABLE, OLIVE
** SUBJECT = 26								
7	7	6	6	7	8	8	N	OLIVE
** SUBJECT = 27								
8	8	3	3	2	7	8	Y	
** SUBJECT = 28								
7	0	3	3	0	0	0	Y	
** SUBJECT = 30								
5	1	1	0	0	2	0	Y	CANOLA OR COCONUT
** SUBJECT = 31								
9	5	2	2	5	3	3	N	VEGATABLE & OLIVE
** SUBJECT = 32								
10	8	0	0	5	10	6	N	OLIVE
** SUBJECT = 33								
8	8	5	6	7	6	7	N	PAM
** SUBJECT = 34								
8	8	5	7	9	9	9	N	PAM
** SUBJECT = 35								
6	3	2	2	2	1	1	N	OLIVE

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INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
BASELINE QUESTIONNAIRE PART 2.

Q9	Q10	Q10. NORMAL ROUTINE	Q11
** SUBJECT = 01			
1/2 X	Y	WALK 2X/WK, CLASS 1X/WEEK	N
** SUBJECT = 02			
2 WEEK	N		N
** SUBJECT = 03			
1-2 TIMES	Y	WALK STAIRS INSTEAD OF ELEVATOR.	Y
** SUBJECT = 04			
2 OR 3	Y	SWIMMING, SPINNING	N
** SUBJECT = 06			
2	N		N
** SUBJECT = 07			
ONCE	N		Y
** SUBJECT = 08			
3	Y	WALKING	N
** SUBJECT = 09			
3-4 TIMES	Y	CARDIO WEIGHT TRAINING, YOGA	N
** SUBJECT = 10			
2 TO 3 TIMES	Y	CARDIO	N
** SUBJECT = 12			
2X	N		N
** SUBJECT = 13			
MAYBE ONCE A WK	N		N
** SUBJECT = 14			
1-2 TIMES	N		N
** SUBJECT = 15			
3	Y	TREADMILL	N
** SUBJECT = 16			
0	Y	JUST STARTED	N
** SUBJECT = 17			
2	N		N
** SUBJECT = 18			
2 – 3X'S	Y	WALKING, JUMPING ROPE, SQUATS	N

INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
BASELINE QUESTIONNAIRE PART 2.

Q9	Q10	Q10. NORMAL ROUTINE	Q11
** SUBJECT = 20			
2	Y	YOGA	N
** SUBJECT = 21			
NONE	N		N
** SUBJECT = 22			
1X	N		N
** SUBJECT = 23			
1X A WEEK OR LESS	N		N
** SUBJECT = 25			
0-1	Y	3-5 DAYS/WK	N
** SUBJECT = 26			
1	N		N
** SUBJECT = 27			
1 OR 2	N		N
** SUBJECT = 28			
NONE	N		N
** SUBJECT = 30			
3	Y	CARDIO 3 TIMES/WK	N
** SUBJECT = 31			
ONCE A WEEK	Y	1 HOUR WALKING	N
** SUBJECT = 32			
3X	Y	3-5 TIMES/WEEK WEIGHT TRAINING	Y
** SUBJECT = 33			
ONCE	N		N
** SUBJECT = 34			
4	Y	TREADMILL	N
** SUBJECT = 35			
1 OR 2	Y	CARDIO: 3X /WK FITNESS: 2X /WK	N

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INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
SUBJECTIVE QUESTIONNAIRE

EVAL TIME	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17
** SUBJECT = 01																	
WK-2	5	4	4	4	4	3	4	4	3	3	2	3	3	3	1		
WK-4	5	6	5	3	5	5	5	2	4	2	4	4	4	4	2	2	2
** SUBJECT = 02																	
WK-2	3	2	2	2	2	2	2	4	3	3	3	3	3	3	3		
WK-4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
** SUBJECT = 03																	
WK-2	0	4	0	0	0	0	0	3	3	3	2	3	2	2	3		
WK-4	5	8	1	0	0	0	1	3	3	4	3	3	3	3	2	2	2
** SUBJECT = 04																	
WK-2	0	0	10	10	0	0	0	1	1	1	1	1	1	1	1		
WK-4	0	0	0	0	0	0	0	2	2	2	2	2	2	2	2	2	2
** SUBJECT = 06																	
WK-2	5	10	1	1	1	1	1	3	1	2	2	1	1	2	3		
WK-4	5	0	0	0	0	0	0	3	1	1	1	1	1	1	2	4	3
** SUBJECT = 07																	
WK-2	0	0	1	1	1	1	1	1	3	3	3	3	3	3	4		
WK-4	0	0	1	1	3	2	2	1	3	3	3	3	3	3	1	2	1
** SUBJECT = 08																	
WK-2	6	0	0	0	2	0	0	1	1	1	1	2	1	1	1		
WK-4	6	3	3	3	1	1	1	1	1	1	1	1	1	1	3	1	1
** SUBJECT = 09																	
WK-2	10	10	7	7	6	9	9	2	2	2	2	2	2	2	3		
WK-4	10	8	8	5	9	9	9	2	2	2	2	2	2	2	1	2	2
** SUBJECT = 10																	
WK-2	5	6	5	6	0	2	2	4	3	3	3	3	3	3	4		
WK-4	5	6	5	5	0	0	0	3	3	2	3	4	4	4	4	5	2
** SUBJECT = 12																	
WK-2	8	6	1	1	3	3	7	1	3	2	2	2	2	3	4		
WK-4	8	4	4	4	5	7	7	1	2	2	2	3	2	3	1	1	1
** SUBJECT = 13																	
WK-2	5	7	2	2	3	3	3	3	3	3	2	2	2	2	4		
WK-4	6	5	6	6	7	7	7	2	3	2	2	2	2	3	3	2	2
** SUBJECT = 14																	
WK-2	7	6	3	3	4	8	4	2	2	2	2	3	4	3	4		
WK-4	3	7	1	2	4	8	7	2	4	4	4	4	4	4	4	4	4

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INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
SUBJECTIVE QUESTIONNAIRE

EVAL TIME	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17
** SUBJECT = 15																	
WK-2	2	3	5	3	0	0	0	2	1	1	2	2	2	2	2		
WK-4	1	1	1	0	0	0	0	1	1	1	1	1	1	1	1	1	1
** SUBJECT = 16																	
WK-2	0	0	1	0	0	0	0	1	1	1	1	1	1	1	1		
WK-4	3	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1
** SUBJECT = 17																	
WK-2	7	8	4	5	7	7	6	4	4	2	2	4	4	4	5		
WK-4	6	3	4	3	3	3	2	4	2	2	2	3	2	2	4	4	4
** SUBJECT = 18																	
WK-2	4	0	7	7	7	7	7	2	2	2	2	2	2	2	2		
WK-4	7	0	2	2	2	2	2	3	3	3	3	3	3	3	3	2	2
** SUBJECT = 20																	
WK-2	6	5	1	1	1	1	1	2	2	2	2	2	2	2	2		
WK-4	4	4	1	1	1	2	2	1	3	1	2	2	2	2	2	1	1
** SUBJECT = 21																	
WK-2	6	0	1	1	3	3	3	2	4	2	2	4	1	2	1		
WK-4	8	3	1	1	1	1	1	2	2	2	4	2	2	2	2	1	1
** SUBJECT = 22																	
WK-2		4	0	0	2	2	2	3	2	2	2	3	2	2	1		
WK-4	10	6	0	10	4	0	0	1	1	1	1	1	1	1	1	3	1
** SUBJECT = 23																	
WK-2	5	5	5	2	2	5	5	3	3	2	2	2	3	3	1		
WK-4	5	5	5	5	5	5	5	3	3	2	2	2	2	2	2	2	2
** SUBJECT = 25																	
WK-2	6	6	0	0	0	0	0	1	3	2	2	3	3	3	2		
WK-4	4	4	0	0	2	2	2	1	2	2	2	3	3	3	2	2	1
** SUBJECT = 26																	
WK-2	3	3	3	3	3	3	3	2	2	2	2	2	2	2	2		
WK-4	2	1	1	1	1	1	1	1	2	2	2	3	2	2	1	2	2
** SUBJECT = 27																	
WK-2	8	6	2	2	5	5	5	3	2	2	2	2	3	3	2		
WK-4	4	5	2	2	1	1	3	3	4	2	3	2	2	2	2	2	2
** SUBJECT = 28																	
WK-2	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1		
WK-4	0	0	0	0	0	0	0	3	2	1	1	1	1	2	2	2	1

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INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
SUBJECTIVE QUESTIONNAIRE

EVAL TIME	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17
** SUBJECT = 30																	
WK-2	0	0	0	0	0	1	0	3	2	2	2	2	2	2	2		
WK-4	2	0	0	5	0	0	0	3	3	3	3	3	3	3	2	2	2
** SUBJECT = 31																	
WK-2	0	5	0	3	4	5	3	4	4	3	3	4		4	5		
WK-4	1	5	2	2	1	1	1	3	4	3	3	1	2	3	4	2	3
** SUBJECT = 32																	
WK-2	6	0	0	0	0	5	0	5	3	4	3	3	3	3	4		
WK-4	9	0	0	3	0	5	0	5	3	3	3	3	4	3	2	3	4
** SUBJECT = 33																	
WK-2	5	6	3	3	5	6	6	3	3	3	3	3	3	3	3		
WK-4	6	5	7	7	5	5	5	3	3	3	3	3	3	3	3	3	3
** SUBJECT = 34																	
WK-2	5	7	3	3	2	2	2	3	2	2	2	2	2	2	4		
WK-4	7	5	7	7	7	7	7	2	2	2	2	2	2	2	2	2	2
** SUBJECT = 35																	
WK-2	6	2	2	2	2	2	2	2	3	3	3	3	3	3	3		
WK-4	6	2	1	1	2	2	2	1	3	2	2	3	2	3	3	2	2

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INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
TESTIMONIAL

SUBJ	EVAL TIME	TESTIMONY
01	WK-4	I lost 3 pounds on the study! The cookies were great and kept me full for a few hours.
02	WK-4	
03	WK-4	Cookies were good, but a little dry & very filling. Doing 2 times per day was a bit much for me. I would use as a supplement once in a while for a meal.
04	WK-4	I really enjoyed the cookies & looked forward to having them everyday. I feel healthier & enjoyed this study.
05	WK-4	
06	WK-4	
07	WK-4	
08	WK-4	I did not like the chocolate cookie. The gingerbread was great. By day 12 I started getting tired of having 2 cookies per day. I would most likely eat cookies 1-2 time per day to maintain health. Felt like I had more energy!
09	WK-4	It was a delicious cookie and honestly felt like I wasn't on a diet.
10	WK-4	The cookie was really tasty. It was filling but I personally prefer food than can equal close to the amount of calories, and so on. I got a bit tired of it after a few days.
11	WK-4	
12	WK-4	The cookies were all good. I enjoyed them and they supressed by appetite. I did not like the canned salmon.
13	WK-4	Overall, the product worked and tasted fairly good. I believe you must be very disciplined in the diet, but it worked.

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INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
TESTIMONIAL

SUBJ	EVAL TIME	TESTIMONY
14	WK-4	The cookies were not that appealing in flavor. They were a lot of calories for the item being a diet item. It's a good idea yet not limited to just a cookie. I'd rather a slice of pizza for the cookies.
15	WK-4	I enjoyed this study. It really made me lose a lot of weight and taught me discipline oni eating and not over-eating.
16	WK-4	I loved the product, taste delicious, very filling, felt nourished, felt full. I had a ton more enjoyed. Loved the product and diet. Will continue.
17	WK-4	The flavors got repetitive so it became a struggle to eat them. The diet was so restrictive, I felt like I couldn't enjoy anything.
18	WK-4	The cookies were extremely tasty and filling. I don't think they were beneficial in weightloss, but can be a great breakfast filler.
18	WK-4	
20	WK-4	I love it. I am looking to buy it to continue. I was not hungry and I lost weight. Will recommend it.
21	WK-4	I enjoyed the cookie. It kept me from craving other food. As soon as I finished eating the cookie, I felt full. I will buy this product and I highly recommend. Very delicious flavors, all of them.
22	WK-4	Overall I found this product to be very easy to follow. My clothes and energy have changed for the better. Everything fits nicely, which ultimately puts me in a better mood.

INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
TESTIMONIAL

SUBJ	EVAL TIME	TESTIMONY
23	WK-4	Cookies were filling. All the flavors were injoyable. I feel like I had more energy. This study forced me to start eating less!
25	WK-4	Overall, I thought it was great. Loved the cocoa & banana the best. I wasn't craving sweets like I usually do, which was a great thing. Definitely would use to take off 10 or more lbs!
26	WK-4	Very fulfulling. Some of the flavors were not to my liking, but overall was very tasteful. Would be on the look-out for them in the future. Thank you for selecting me. Have a great and blessed day!
27	WK-4	I like it. Is enough in a food. Its flavor is good. Only left a rare flavor in the tongue.
28	WK-4	Product was great. Cookies are very filling for a snack. Holds you for a good 3 hours. Salmon was great. Never really ate salmon but through this study I found myself to grow on it and will continue to eat.
30	WK-4	I enjoyed the cookies. They were a little dry for me, but OK if you had it with coffee or tea.
31	WK-4	I like the cookies for breakfast the most. Eating twice a day every day I believe is a little too much.
32	WK-4	I felt I have gained weight while eating the breakfast cookie 2x a day. The canola oil made me breakout on my body(arms,chest,back,neck). It was the exessive use of the canola oil. Although the cookie was filling, I did not feel it gave me energy.

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INTERNATIONAL RESEARCH SERVICES, INC.
BREAKFAST COOKIE STUDY #4189SBC1217
TESTIMONIAL

SUBJ	EVAL TIME	TESTIMONY
33	WK-4	I think the cookies & food really felt good. On it I lost the weight & some inches. I will continue to follow diet.
34	WK-4	I liked them. Very filling and satisfying. I had only one concern, high sugar for me. Otherwise I lost weight & inches.
35	WK-4	The product is good. The cookies taste really good and you don't really feel hungry during the diet. Sometimes I thought the cookies were too much. It could be smaller.

HGT SUBJECTS HEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	56.0	1	3.3	3.3	3.3
	60.0	2	6.7	6.7	10.0
	61.0	2	6.7	6.7	16.7
	63.0	4	13.3	13.3	30.0
	64.0	1	3.3	3.3	33.3
	65.0	10	33.3	33.3	66.7
	66.0	2	6.7	6.7	73.3
	67.0	3	10.0	10.0	83.3
	68.0	1	3.3	3.3	86.7
	69.0	1	3.3	3.3	90.0
	70.5	1	3.3	3.3	93.3
	71.0	1	3.3	3.3	96.7
	72.0	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	64.917	Std Err	.620	Median	65.000
Std Dev	3.394	Variance	11.519		

Valid Cases	30	Missing Cases	0

WGT SUBJECTS WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	138	1	3.3	3.3	3.3
	144	1	3.3	3.3	6.7
	145	2	6.7	6.7	13.3
	146	1	3.3	3.3	16.7
	147	1	3.3	3.3	20.0
	148	1	3.3	3.3	23.3
	149	1	3.3	3.3	26.7
	150	2	6.7	6.7	33.3
	152	1	3.3	3.3	36.7
	155	1	3.3	3.3	40.0
	156	1	3.3	3.3	43.3
	160	3	10.0	10.0	53.3
	162	1	3.3	3.3	56.7
	163	2	6.7	6.7	63.3
	164	1	3.3	3.3	66.7
	165	2	6.7	6.7	73.3
	170	1	3.3	3.3	76.7
	175	1	3.3	3.3	80.0
	184	1	3.3	3.3	83.3
	185	1	3.3	3.3	86.7
	190	1	3.3	3.3	90.0
	194	1	3.3	3.3	93.3
	201	1	3.3	3.3	96.7
	214	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	163.333	Std Err	3.400	Median	160.000
Std Dev	18.624	Variance	346.851		

Valid Cases 30 Missing Cases 0

AGE SUBJECTS AGE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	23	1	3.3	3.3	3.3
	27	1	3.3	3.3	6.7
	29	1	3.3	3.3	10.0
	30	1	3.3	3.3	13.3
	33	1	3.3	3.3	16.7
	34	3	10.0	10.0	26.7
	36	2	6.7	6.7	33.3
	37	2	6.7	6.7	40.0
	38	1	3.3	3.3	43.3
	41	1	3.3	3.3	46.7
	44	1	3.3	3.3	50.0
	45	1	3.3	3.3	53.3
	46	1	3.3	3.3	56.7
	47	3	10.0	10.0	66.7
	48	2	6.7	6.7	73.3
	49	3	10.0	10.0	83.3
	51	1	3.3	3.3	86.7
	53	1	3.3	3.3	90.0
	54	2	6.7	6.7	96.7
	55	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	41.833	Std Err	1.623	Median	44.500
Std Dev	8.890	Variance	79.040		

Valid Cases 30 Missing Cases 0

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SEX SUBJECTS SEX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
MALE	1.00	4	13.3	13.3	13.3
FEMALE	2.00	26	86.7	86.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

ETHN SUBJECTS ETHNICITY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
HISPANIC	1.00	12	40.0	40.0	40.0
NON-HISPANIC	2.00	18	60.0	60.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

- -

RACE SUBJECTS RACE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
WHITE	1.00	16	53.3	72.7	72.7
BLACK	2.00	5	16.7	22.7	95.5
MULTI	5.00	1	3.3	4.5	100.0
	.	8	26.7	MISSING	
	TOTAL	30	100.0	100.0	

Valid Cases 22 Missing Cases 8

- -

FACE SUBJECTS FACIAL SKIN

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
DRY	1.00	1	3.3	3.3	3.3
NORMAL	3.00	15	50.0	50.0	53.3
COMBO	4.00	14	46.7	46.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

BODY SUBJECTS BODY SKIN

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
NORMAL	1.00	25	83.3	83.3	83.3
DRY	2.00	4	13.3	13.3	96.7
VERY DRY	3.00	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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FITZ SUBJECTS FITZPATRICK SCORE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	2	6.7	6.7	6.7
	3	14	46.7	46.7	53.3
	4	9	30.0	30.0	83.3
	5	4	13.3	13.3	96.7
	6	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	3.600	Std Err	.170	Median	3.000
Std Dev	.932	Variance	.869		

Valid Cases 30 Missing Cases 0

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SKIN SUBJECT HAS SENSITIVE SKIN

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
YES	1.00	4	13.3	13.3	13.3
NO	2.00	26	86.7	86.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

MEDICAL HISTORY

EYES SUBJECT HAS SENSITIVE EYES

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
YES	1.00	4	13.3	13.3	13.3
NO	2.00	26	86.7	86.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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LENS SUBJECT WEARS CONTACTS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
YES	1.00	5	16.7	16.7	16.7
NO	2.00	25	83.3	83.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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OCCU SUBJECTS OCCUPATION

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
RETIRED	2.00	1	3.3	3.3	3.3
HOMEMAKER	3.00	6	20.0	20.0	23.3
UNEMPLOYED	4.00	1	3.3	3.3	26.7
EMPLOYED	5.00	22	73.3	73.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Paired samples t-test: XWGHT0 BASE - WEIGHT
XWGHT2 WK 2 - WEIGHT

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
XWGHT0	30	165.1133	18.552	3.387
XWGHT2	30	163.5733	18.544	3.386

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
1.5400	3.185	.581	.985	.000	2.65	29	.013

Paired samples t-test: XWGHT0 BASE - WEIGHT
XWGHT4 WK 4 - WEIGHT

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
XWGHT0	30	165.1133	18.552	3.387
XWGHT4	30	162.6933	18.958	3.461

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
2.4200	4.378	.799	.973	.000	3.03	29	.005

Paired samples t-test: BMASS0 BASE - BODY MASS INDEX
BMASS2 WK 2 - BODY MASS INDEX

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
BMASS0	30	27.4467	1.529	.279
BMASS2	30	27.2033	1.522	.278

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
.2433	.583	.106	.927	.000	2.29	29	.030

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Paired samples t-test: BMASS0 BASE - BODY MASS INDEX
BMASS4 WK 4 - BODY MASS INDEX

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
BMASS0	30	27.4467	1.529	.279
BMASS4	30	27.0167	1.582	.289

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
.4300	.736	.134	.889	.000	3.20	29	.003

Paired samples t-test: PCFAT0 BASE - PERCENT BODY FAT
PCFAT2 WK 2 - PERCENT BODY FAT

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
PCFAT0	30	34.7000	5.346	.976
PCFAT2	30	34.7633	5.765	1.052

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
-.0633	1.412	.258	.971	.000	-.25	29	.808

Paired samples t-test: PCFAT0 BASE - PERCENT BODY FAT
PCFAT4 WK 4 - PERCENT BODY FAT

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
PCFAT0	30	34.7000	5.346	.976
PCFAT4	30	34.5100	5.878	1.073

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
.1900	1.478	.270	.970	.000	.70	29	.487

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Paired samples t-test: LEANB0 BASE - LEAN BODY MASS
LEANB2 WK 2 - LEAN BODY MASS

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
LEANB0	30	.4167	1.127	.206
LEANB2	30	.5700	1.432	.261

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
-.1533	.978	.178	.733	.000	-.86	29	.397

Paired samples t-test: LEANB0 BASE - LEAN BODY MASS
LEANB4 WK 4 - LEAN BODY MASS

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
LEANB0	30	.4167	1.127	.206
LEANB4	30	.6800	1.578	.288

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
-.2633	1.593	.291	.344	.063	-.91	29	.373

Paired samples t-test: FMASS0 BASE - BODY FAT MASS
FMASS2 WK 2 - BODY FAT MASS

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
FMASS0	30	-26.8267	9.669	1.765
FMASS2	30	-26.8067	10.084	1.841

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
-.0200	2.970	.542	.956	.000	-.04	29	.971

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Paired samples t-test: FMASS0 BASE - BODY FAT MASS
FMASS4 WK 4 - BODY FAT MASS

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
FMASS0	30	-26.8267	9.669	1.765
FMASS4	30	-25.9733	10.508	1.918

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
-.8533	3.236	.591	.952	.000	-1.44	29	.159

Paired samples t-test: WAIST0 BASE - WAIST MEASUREMENT
WAIST2 WK 2 - WAIST MEASUREMENT

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
WAIST0	30	34.1267	3.006	.549
WAIST2	30	33.8733	2.534	.463

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
.2533	1.447	.264	.877	.000	.96	29	.346

Paired samples t-test: WAIST0 BASE - WAIST MEASUREMENT
WAIST4 WK 4 - WAIST MEASUREMENT

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
WAIST0	30	34.1267	3.006	.549
WAIST4	30	33.6867	2.846	.520

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
.4400	1.521	.278	.866	.000	1.58	29	.124

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Paired samples t-test: HIPPP0 BASE - HIP MEASUREMENT
HIPPP2 WK 2 - HIP MEASUREMENT

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
HIPPP0	30	40.5967	1.651	.302
HIPPP2	30	40.3667	1.944	.355

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
.2300	1.114	.203	.820	.000	1.13	29	.267

Paired samples t-test: HIPPP0 BASE - HIP MEASUREMENT
HIPPP4 WK 4 - HIP MEASUREMENT

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
HIPPP0	30	40.5967	1.651	.302
HIPPP4	30	39.8700	1.804	.329

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
.7267	1.009	.184	.833	.000	3.94	29	.000

Paired samples t-test: RATIO0 BASE - WAIST/HIP RATIO
RATIO2 WK 2 - WAIST/HIP RATIO

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
RATIO0	30	.8410	.071	.013
RATIO2	30	.8410	.063	.011

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
.0000	.036	.007	.864	.000	.00	29	1.000

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Paired samples t-test: RATIO0 BASE - WAIST/HIP RATIO
RATIO4 WK 4 - WAIST/HIP RATIO

Variable	Number of Cases	Mean	Standard Deviation	Standard Error
RATIO0	30	.8410	.071	.013
RATIO4	30	.8457	.068	.012

(Difference) Mean	Standard Deviation	Standard Error	2-Tail Corr.	2-Tail Prob.	t Value	Degrees of Freedom	2-Tail Prob.
-.0047	.033	.006	.891	.000	-.78	29	.439

IXWGHT2 IMPRV WK 2 - WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
IMPROVED	1.00	21	70.0	70.0	70.0
WORSE	3.00	9	30.0	30.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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IBMASS2 IMPRV WK 2 - BODY MASS INDEX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
IMPROVED	1.00	20	66.7	66.7	66.7
SAME	2.00	2	6.7	6.7	73.3
WORSE	3.00	8	26.7	26.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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IPCFAT2 IMPRV WK 2 - PERCENT BODY FAT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
IMPROVED	1.00	15	50.0	50.0	50.0
SAME	2.00	1	3.3	3.3	53.3
WORSE	3.00	14	46.7	46.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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ILEANB2 IMPRV WK 2 - LEAN BODY MASS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
IMPROVED	1.00	4	13.3	13.3	13.3
SAME	2.00	22	73.3	73.3	86.7
WORSE	3.00	4	13.3	13.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

IFMASS2 IMPRV WK 2 - BODY FAT MASS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
IMPROVED	1.00	15	50.0	50.0	50.0
SAME	2.00	1	3.3	3.3	53.3
WORSE	3.00	14	46.7	46.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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IWAIST2 IMPRV WK 2 - WAIST MEASUREMENT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
IMPROVED	1.00	15	50.0	50.0	50.0
SAME	2.00	3	10.0	10.0	60.0
WORSE	3.00	12	40.0	40.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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IHIPPP2 IMPRV WK 2 - HIP MEASUREMENT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
IMPROVED	1.00	11	36.7	36.7	36.7
SAME	2.00	8	26.7	26.7	63.3
WORSE	3.00	11	36.7	36.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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IRATIO2 IMPRV WK 2 - WAIST/HIP RATIO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
IMPROVED	1.00	13	43.3	43.3	43.3
SAME	2.00	4	13.3	13.3	56.7
WORSE	3.00	13	43.3	43.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable XWGHT0 BASE - WEIGHT

Mean	165.113	S.E. Mean	3.387
Std Dev	18.552	Variance	344.187
Kurtosis	.207	S.E. Kurt	.833
Skewness	.882	S.E. Skew	.427
Range	73.600	Minimum	136.9
Maximum	210.5	Sum	4953.400

Valid Observations - 30 Missing Observations - 0

- -

Variable BMASS0 BASE - BODY MASS INDEX

Mean	27.447	S.E. Mean	.279
Std Dev	1.529	Variance	2.338
Kurtosis	.131	S.E. Kurt	.833
Skewness	-.385	S.E. Skew	.427
Range	6.900	Minimum	23.8
Maximum	30.7	Sum	823.400

Valid Observations - 30 Missing Observations - 0

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Variable PCFAT0 BASE - PERCENT BODY FAT

Mean	34.700	S.E. Mean	.976
Std Dev	5.346	Variance	28.579
Kurtosis	-.576	S.E. Kurt	.833
Skewness	.030	S.E. Skew	.427
Range	21.500	Minimum	24.4
Maximum	45.9	Sum	1041.000

Valid Observations - 30 Missing Observations - 0

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Variable LEANB0 BASE - LEAN BODY MASS

Mean	.417	S.E. Mean	.206
Std Dev	1.127	Variance	1.269
Kurtosis	14.903	S.E. Kurt	.833
Skewness	3.660	S.E. Skew	.427
Range	5.500	Minimum	.0
Maximum	5.5	Sum	12.500

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable FMASS0 BASE - BODY FAT MASS

Mean	-26.827	S.E. Mean	1.765
Std Dev	9.669	Variance	93.489
Kurtosis	-.705	S.E. Kurt	.833
Skewness	.156	S.E. Skew	.427
Range	34.600	Minimum	-41.9
Maximum	-7.3	Sum	-804.800

Valid Observations - 30 Missing Observations - 0

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Variable WAIST0 BASE - WAIST MEASUREMENT

Mean	34.127	S.E. Mean	.549
Std Dev	3.006	Variance	9.036
Kurtosis	-.410	S.E. Kurt	.833
Skewness	.143	S.E. Skew	.427
Range	12.100	Minimum	29.0
Maximum	41.1	Sum	1023.800

Valid Observations - 30 Missing Observations - 0

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Variable HIPPP0 BASE - HIP MEASUREMENT

Mean	40.597	S.E. Mean	.302
Std Dev	1.651	Variance	2.727
Kurtosis	-.363	S.E. Kurt	.833
Skewness	-.659	S.E. Skew	.427
Range	6.000	Minimum	37.0
Maximum	43.0	Sum	1217.900

Valid Observations - 30 Missing Observations - 0

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Variable RATIO0 BASE - WAIST/HIP RATIO

Mean	.841	S.E. Mean	.013
Std Dev	.071	Variance	.005
Kurtosis	-.421	S.E. Kurt	.833
Skewness	-.125	S.E. Skew	.427
Range	.270	Minimum	.71
Maximum	.98	Sum	25.230

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable XWGHT2 WK 2 - WEIGHT

Mean	163.573	S.E. Mean	3.386
Std Dev	18.544	Variance	343.863
Kurtosis	-.070	S.E. Kurt	.833
Skewness	.750	S.E. Skew	.427
Range	71.700	Minimum	135.8
Maximum	207.5	Sum	4907.200

Valid Observations - 30 Missing Observations - 0

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Variable BMASS2 WK 2 - BODY MASS INDEX

Mean	27.203	S.E. Mean	.278
Std Dev	1.522	Variance	2.316
Kurtosis	1.028	S.E. Kurt	.833
Skewness	-.549	S.E. Skew	.427
Range	7.500	Minimum	23.0
Maximum	30.5	Sum	816.100

Valid Observations - 30 Missing Observations - 0

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Variable PCFAT2 WK 2 - PERCENT BODY FAT

Mean	34.763	S.E. Mean	1.052
Std Dev	5.765	Variance	33.231
Kurtosis	-.243	S.E. Kurt	.833
Skewness	-.188	S.E. Skew	.427
Range	23.300	Minimum	23.6
Maximum	46.9	Sum	1042.900

Valid Observations - 30 Missing Observations - 0

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Variable LEANB2 WK 2 - LEAN BODY MASS

Mean	.570	S.E. Mean	.261
Std Dev	1.432	Variance	2.050
Kurtosis	6.545	S.E. Kurt	.833
Skewness	2.680	S.E. Skew	.427
Range	5.500	Minimum	.0
Maximum	5.5	Sum	17.100

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable FMASS2 WK 2 - BODY FAT MASS

Mean	-26.807	S.E. Mean	1.841
Std Dev	10.084	Variance	101.696
Kurtosis	.222	S.E. Kurt	.833
Skewness	.577	S.E. Skew	.427
Range	38.200	Minimum	-41.7
Maximum	-3.5	Sum	-804.200

Valid Observations - 30 Missing Observations - 0

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Variable WAIST2 WK 2 - WAIST MEASUREMENT

Mean	33.873	S.E. Mean	.463
Std Dev	2.534	Variance	6.420
Kurtosis	-.197	S.E. Kurt	.833
Skewness	.378	S.E. Skew	.427
Range	10.400	Minimum	29.6
Maximum	40.0	Sum	1016.200

Valid Observations - 30 Missing Observations - 0

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Variable HIPPP2 WK 2 - HIP MEASUREMENT

Mean	40.367	S.E. Mean	.355
Std Dev	1.944	Variance	3.777
Kurtosis	-.051	S.E. Kurt	.833
Skewness	-.625	S.E. Skew	.427
Range	8.000	Minimum	35.5
Maximum	43.5	Sum	1211.000

Valid Observations - 30 Missing Observations - 0

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Variable RATIO2 WK 2 - WAIST/HIP RATIO

Mean	.841	S.E. Mean	.011
Std Dev	.063	Variance	.004
Kurtosis	-.584	S.E. Kurt	.833
Skewness	.015	S.E. Skew	.427
Range	.230	Minimum	.72
Maximum	.95	Sum	25.230

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable XWGHT4 WK 4 - WEIGHT

Mean	162.693	S.E. Mean	3.461
Std Dev	18.958	Variance	359.397
Kurtosis	.241	S.E. Kurt	.833
Skewness	.769	S.E. Skew	.427
Range	76.300	Minimum	135.6
Maximum	211.9	Sum	4880.800

Valid Observations - 30 Missing Observations - 0

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Variable BMASS4 WK 4 - BODY MASS INDEX

Mean	27.017	S.E. Mean	.289
Std Dev	1.582	Variance	2.504
Kurtosis	.294	S.E. Kurt	.833
Skewness	-.330	S.E. Skew	.427
Range	7.200	Minimum	23.2
Maximum	30.4	Sum	810.500

Valid Observations - 30 Missing Observations - 0

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Variable PCFAT4 WK 4 - PERCENT BODY FAT

Mean	34.510	S.E. Mean	1.073
Std Dev	5.878	Variance	34.553
Kurtosis	-.530	S.E. Kurt	.833
Skewness	-.436	S.E. Skew	.427
Range	22.300	Minimum	23.0
Maximum	45.3	Sum	1035.300

Valid Observations - 30 Missing Observations - 0

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Variable LEANB4 WK 4 - LEAN BODY MASS

Mean	.680	S.E. Mean	.288
Std Dev	1.578	Variance	2.491
Kurtosis	8.783	S.E. Kurt	.833
Skewness	2.870	S.E. Skew	.427
Range	7.000	Minimum	.0
Maximum	7.0	Sum	20.400

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable FMASS4 WK 4 - BODY FAT MASS

Mean	-25.973	S.E. Mean	1.918
Std Dev	10.508	Variance	110.412
Kurtosis	.528	S.E. Kurt	.833
Skewness	.564	S.E. Skew	.427
Range	46.300	Minimum	-46.3
Maximum	.0	Sum	-779.200

Valid Observations - 30 Missing Observations - 0

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Variable WAIST4 WK 4 - WAIST MEASUREMENT

Mean	33.687	S.E. Mean	.520
Std Dev	2.846	Variance	8.098
Kurtosis	-.480	S.E. Kurt	.833
Skewness	.103	S.E. Skew	.427
Range	11.500	Minimum	28.5
Maximum	40.0	Sum	1010.600

Valid Observations - 30 Missing Observations - 0

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Variable HIPPP4 WK 4 - HIP MEASUREMENT

Mean	39.870	S.E. Mean	.329
Std Dev	1.804	Variance	3.254
Kurtosis	-.888	S.E. Kurt	.833
Skewness	-.528	S.E. Skew	.427
Range	6.100	Minimum	36.0
Maximum	42.1	Sum	1196.100

Valid Observations - 30 Missing Observations - 0

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Variable RATIO4 WK 4 - WAIST/HIP RATIO

Mean	.846	S.E. Mean	.012
Std Dev	.068	Variance	.005
Kurtosis	-.374	S.E. Kurt	.833
Skewness	.019	S.E. Skew	.427
Range	.290	Minimum	.70
Maximum	.99	Sum	25.370

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable DXWGHT2 DIFF WK 2 - WEIGHT

Mean	-1.540	S.E. Mean	.581
Std Dev	3.185	Variance	10.141
Kurtosis	1.081	S.E. Kurt	.833
Skewness	-.153	S.E. Skew	.427
Range	15.700	Minimum	-10.20
Maximum	5.50	Sum	-46.200

Valid Observations - 30 Missing Observations - 0

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Variable DBMASS2 DIFF WK 2 - BODY MASS INDEX

Mean	-.243	S.E. Mean	.106
Std Dev	.583	Variance	.340
Kurtosis	1.490	S.E. Kurt	.833
Skewness	.114	S.E. Skew	.427
Range	3.000	Minimum	-1.80
Maximum	1.20	Sum	-7.300

Valid Observations - 30 Missing Observations - 0

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Variable DPCFAT2 DIFF WK 2 - PERCENT BODY FAT

Mean	.063	S.E. Mean	.258
Std Dev	1.412	Variance	1.993
Kurtosis	3.094	S.E. Kurt	.833
Skewness	1.041	S.E. Skew	.427
Range	7.300	Minimum	-2.50
Maximum	4.80	Sum	1.900

Valid Observations - 30 Missing Observations - 0

- -

Variable DLEANB2 DIFF WK 2 - LEAN BODY MASS

Mean	.153	S.E. Mean	.178
Std Dev	.978	Variance	.956
Kurtosis	10.317	S.E. Kurt	.833
Skewness	2.824	S.E. Skew	.427
Range	5.500	Minimum	-1.30
Maximum	4.20	Sum	4.600

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable DFMASS2 DIFF WK 2 - BODY FAT MASS

Mean	.020	S.E. Mean	.542
Std Dev	2.970	Variance	8.818
Kurtosis	1.563	S.E. Kurt	.833
Skewness	-.827	S.E. Skew	.427
Range	14.000	Minimum	-9.00
Maximum	5.00	Sum	.600

Valid Observations - 30 Missing Observations - 0

- -

Variable DWAIST2 DIFF WK 2 - WAIST MEASUREMENT

Mean	-.253	S.E. Mean	.264
Std Dev	1.447	Variance	2.094
Kurtosis	4.358	S.E. Kurt	.833
Skewness	1.386	S.E. Skew	.427
Range	7.400	Minimum	-2.50
Maximum	4.90	Sum	-7.600

Valid Observations - 30 Missing Observations - 0

- -

Variable DHIPPP2 DIFF WK 2 - HIP MEASUREMENT

Mean	-.230	S.E. Mean	.203
Std Dev	1.114	Variance	1.240
Kurtosis	2.293	S.E. Kurt	.833
Skewness	-1.330	S.E. Skew	.427
Range	5.000	Minimum	-3.80
Maximum	1.20	Sum	-6.900

Valid Observations - 30 Missing Observations - 0

- -

Variable DRATIO2 DIFF WK 2 - WAIST/HIP RATIO

Mean	-.000	S.E. Mean	.007
Std Dev	.036	Variance	.001
Kurtosis	3.251	S.E. Kurt	.833
Skewness	1.060	S.E. Skew	.427
Range	.180	Minimum	-.06
Maximum	.12	Sum	-6.5052130349E-18

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable DXWGHT4 DIFF WK 4 - WEIGHT

Mean	-2.420	S.E. Mean	.799
Std Dev	4.378	Variance	19.167
Kurtosis	1.781	S.E. Kurt	.833
Skewness	-.006	S.E. Skew	.427
Range	22.900	Minimum	-14.30
Maximum	8.60	Sum	-72.600

Valid Observations - 30 Missing Observations - 0

- -

Variable DBMASS4 DIFF WK 4 - BODY MASS INDEX

Mean	-.430	S.E. Mean	.134
Std Dev	.736	Variance	.542
Kurtosis	2.225	S.E. Kurt	.833
Skewness	-.333	S.E. Skew	.427
Range	3.900	Minimum	-2.60
Maximum	1.30	Sum	-12.900

Valid Observations - 30 Missing Observations - 0

- -

Variable DPCFAT4 DIFF WK 4 - PERCENT BODY FAT

Mean	-.190	S.E. Mean	.270
Std Dev	1.478	Variance	2.184
Kurtosis	-.436	S.E. Kurt	.833
Skewness	-.502	S.E. Skew	.427
Range	5.400	Minimum	-3.50
Maximum	1.90	Sum	-5.700

Valid Observations - 30 Missing Observations - 0

- -

Variable DLEANB4 DIFF WK 4 - LEAN BODY MASS

Mean	.263	S.E. Mean	.291
Std Dev	1.593	Variance	2.538
Kurtosis	11.096	S.E. Kurt	.833
Skewness	2.649	S.E. Skew	.427
Range	9.600	Minimum	-2.60
Maximum	7.00	Sum	7.900

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable DFMASS4 DIFF WK 4 - BODY FAT MASS

Mean	.853	S.E. Mean	.591
Std Dev	3.236	Variance	10.469
Kurtosis	-.503	S.E. Kurt	.833
Skewness	.048	S.E. Skew	.427
Range	12.600	Minimum	-5.30
Maximum	7.30	Sum	25.600

Valid Observations - 30 Missing Observations - 0

- -

Variable DWAIST4 DIFF WK 4 - WAIST MEASUREMENT

Mean	-.440	S.E. Mean	.278
Std Dev	1.521	Variance	2.313
Kurtosis	5.336	S.E. Kurt	.833
Skewness	1.757	S.E. Skew	.427
Range	7.700	Minimum	-2.50
Maximum	5.20	Sum	-13.200

Valid Observations - 30 Missing Observations - 0

- -

Variable DHIPPP4 DIFF WK 4 - HIP MEASUREMENT

Mean	-.727	S.E. Mean	.184
Std Dev	1.009	Variance	1.019
Kurtosis	1.968	S.E. Kurt	.833
Skewness	-.920	S.E. Skew	.427
Range	4.800	Minimum	-3.90
Maximum	.90	Sum	-21.800

Valid Observations - 30 Missing Observations - 0

- -

Variable DRATIO4 DIFF WK 4 - WAIST/HIP RATIO

Mean	.005	S.E. Mean	.006
Std Dev	.033	Variance	.001
Kurtosis	2.567	S.E. Kurt	.833
Skewness	.900	S.E. Skew	.427
Range	.160	Minimum	-.05
Maximum	.11	Sum	.140

Valid Observations - 30 Missing Observations - 0

Number of Valid Observations (Listwise) = 6.00

Variable PXWGHT2 % CHG WK 2 - WEIGHT

Mean	-.928	S.E. Mean	.371
Std Dev	2.029	Variance	4.118
Kurtosis	1.335	S.E. Kurt	.833
Skewness	-.288	S.E. Skew	.427
Range	10.078	Minimum	-6.63
Maximum	3.45	Sum	-27.834

Valid Observations - 30 Missing Observations - 0

- -

Variable PBMASS2 % CHG WK 2 - BODY MASS INDEX

Mean	-.865	S.E. Mean	.401
Std Dev	2.198	Variance	4.832
Kurtosis	1.434	S.E. Kurt	.833
Skewness	.174	S.E. Skew	.427
Range	11.191	Minimum	-6.59
Maximum	4.60	Sum	-25.963

Valid Observations - 30 Missing Observations - 0

- -

Variable PPCFAT2 % CHG WK 2 - PERCENT BODY FAT

Mean	.047	S.E. Mean	.816
Std Dev	4.469	Variance	19.975
Kurtosis	3.716	S.E. Kurt	.833
Skewness	.980	S.E. Skew	.427
Range	24.345	Minimum	-9.06
Maximum	15.29	Sum	1.419

Valid Observations - 30 Missing Observations - 0

- -

Variable PLEANB2 % CHG WK 2 - LEAN BODY MASS

Mean	50.603	S.E. Mean	72.907
Std Dev	178.585	Variance	31892.580
Kurtosis	-1.112	S.E. Kurt	1.741
Skewness	.931	S.E. Skew	.845
Range	423.077	Minimum	-100.00
Maximum	323.08	Sum	303.621

Valid Observations - 6 Missing Observations - 24

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable PFMASS2 % CHG WK 2 - BODY FAT MASS

Mean	-1.575	S.E. Mean	3.620
Std Dev	19.828	Variance	393.132
Kurtosis	4.252	S.E. Kurt	.833
Skewness	-.331	S.E. Skew	.427
Range	112.880	Minimum	-55.56
Maximum	57.32	Sum	-47.258

Valid Observations - 30 Missing Observations - 0

- -

Variable PWAIST2 % CHG WK 2 - WAIST MEASUREMENT

Mean	-.541	S.E. Mean	.824
Std Dev	4.514	Variance	20.379
Kurtosis	6.616	S.E. Kurt	.833
Skewness	1.872	S.E. Skew	.427
Range	23.618	Minimum	-6.78
Maximum	16.84	Sum	-16.220

Valid Observations - 30 Missing Observations - 0

- -

Variable PHIPPP2 % CHG WK 2 - HIP MEASUREMENT

Mean	-.562	S.E. Mean	.502
Std Dev	2.748	Variance	7.552
Kurtosis	2.122	S.E. Kurt	.833
Skewness	-1.289	S.E. Skew	.427
Range	12.426	Minimum	-9.27
Maximum	3.16	Sum	-16.854

Valid Observations - 30 Missing Observations - 0

- -

Variable PRATIO2 % CHG WK 2 - WAIST/HIP RATIO

Mean	.174	S.E. Mean	.828
Std Dev	4.533	Variance	20.544
Kurtosis	5.416	S.E. Kurt	.833
Skewness	1.572	S.E. Skew	.427
Range	23.568	Minimum	-6.67
Maximum	16.90	Sum	5.235

Valid Observations - 30 Missing Observations - 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable PXWGHT4 % CHG WK 4 - WEIGHT

Mean	-1.476	S.E. Mean	.503
Std Dev	2.755	Variance	7.592
Kurtosis	2.150	S.E. Kurt	.833
Skewness	-.131	S.E. Skew	.427
Range	14.687	Minimum	-9.29
Maximum	5.40	Sum	-44.287

Valid Observations - 30 Missing Observations - 0

- -

Variable PBMASS4 % CHG WK 4 - BODY MASS INDEX

Mean	-1.545	S.E. Mean	.502
Std Dev	2.749	Variance	7.557
Kurtosis	2.291	S.E. Kurt	.833
Skewness	-.223	S.E. Skew	.427
Range	14.724	Minimum	-9.52
Maximum	5.20	Sum	-46.353

Valid Observations - 30 Missing Observations - 0

- -

Variable PPCFAT4 % CHG WK 4 - PERCENT BODY FAT

Mean	-.776	S.E. Mean	.874
Std Dev	4.788	Variance	22.922
Kurtosis	.705	S.E. Kurt	.833
Skewness	-.943	S.E. Skew	.427
Range	19.259	Minimum	-13.21
Maximum	6.05	Sum	-23.279

Valid Observations - 30 Missing Observations - 0

- -

Variable PLEANB4 % CHG WK 4 - LEAN BODY MASS

Mean	-22.121	S.E. Mean	44.489
Std Dev	108.975	Variance	11875.518
Kurtosis	3.259	S.E. Kurt	1.741
Skewness	1.775	S.E. Skew	.845
Range	284.615	Minimum	-100.00
Maximum	184.62	Sum	-132.727

Valid Observations - 6 Missing Observations - 24

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
INBODY MEASUREMENTS

Number of Valid Observations (Listwise) = 6.00

Variable PFMASS4 % CHG WK 4 - BODY FAT MASS

Mean	-6.479	S.E. Mean	4.446
Std Dev	24.350	Variance	592.931
Kurtosis	7.881	S.E. Kurt	.833
Skewness	-2.501	S.E. Skew	.427
Range	123.567	Minimum	-100.00
Maximum	23.57	Sum	-194.377

Valid Observations - 30 Missing Observations - 0

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Variable PWAIST4 % CHG WK 4 - WAIST MEASUREMENT

Mean	-1.155	S.E. Mean	.872
Std Dev	4.773	Variance	22.786
Kurtosis	7.836	S.E. Kurt	.833
Skewness	2.215	S.E. Skew	.427
Range	25.012	Minimum	-7.14
Maximum	17.87	Sum	-34.654

Valid Observations - 30 Missing Observations - 0

- -

Variable PHIPPP4 % CHG WK 4 - HIP MEASUREMENT

Mean	-1.778	S.E. Mean	.451
Std Dev	2.472	Variance	6.112
Kurtosis	1.902	S.E. Kurt	.833
Skewness	-.915	S.E. Skew	.427
Range	11.702	Minimum	-9.51
Maximum	2.19	Sum	-53.346

Valid Observations - 30 Missing Observations - 0

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Variable PRATIO4 % CHG WK 4 - WAIST/HIP RATIO

Mean	.666	S.E. Mean	.761
Std Dev	4.169	Variance	17.378
Kurtosis	4.414	S.E. Kurt	.833
Skewness	1.362	S.E. Skew	.427
Range	21.517	Minimum	-6.02
Maximum	15.49	Sum	19.976

Valid Observations - 30 Missing Observations - 0

A01 BASE Q1 RATE EXCESS WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	5	5	16.7	16.7	16.7
	6	3	10.0	10.0	26.7
	7	7	23.3	23.3	50.0
	8	8	26.7	26.7	76.7
	9	3	10.0	10.0	86.7
	10	4	13.3	13.3	100.0
	TOTAL	30	100.0	100.0	

Mean	7.433	Std Err	.290	Median	7.500
Std Dev	1.591	Variance	2.530		

Valid Cases 30 Missing Cases 0

- -

A02 BASE Q2 RATE STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	1	3.3	3.3	3.3
	1	1	3.3	3.3	6.7
	2	1	3.3	3.3	10.0
	3	3	10.0	10.0	20.0
	4	1	3.3	3.3	23.3
	5	4	13.3	13.3	36.7
	6	1	3.3	3.3	40.0
	7	10	33.3	33.3	73.3
	8	5	16.7	16.7	90.0
	9	1	3.3	3.3	93.3
	10	2	6.7	6.7	100.0
	TOTAL	30	100.0	100.0	

Mean	6.033	Std Err	.459	Median	7.000
Std Dev	2.512	Variance	6.309		

Valid Cases 30 Missing Cases 0

A03 BASE Q3 RATE POOR OVERALL HEALTH

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	4	13.3	13.3	13.3
	1	6	20.0	20.0	33.3
	2	2	6.7	6.7	40.0
	3	3	10.0	10.0	50.0
	4	3	10.0	10.0	60.0
	5	6	20.0	20.0	80.0
	6	3	10.0	10.0	90.0
	7	2	6.7	6.7	96.7
	10	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	3.433	Std Err	.469	Median	3.500
Std Dev	2.569	Variance	6.599		

Valid Cases 30 Missing Cases 0

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A04 BASE Q4 RATE POOR WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	6	20.0	20.0	20.0
	1	4	13.3	13.3	33.3
	2	4	13.3	13.3	46.7
	3	4	13.3	13.3	60.0
	4	4	13.3	13.3	73.3
	5	2	6.7	6.7	80.0
	6	2	6.7	6.7	86.7
	7	2	6.7	6.7	93.3
	8	1	3.3	3.3	96.7
	10	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	3.133	Std Err	.491	Median	3.000
Std Dev	2.688	Variance	7.223		

Valid Cases 30 Missing Cases 0

A05 BASE Q5 RATE LACK OF FOCUS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	4	13.3	13.3	13.3
	1	4	13.3	13.3	26.7
	2	4	13.3	13.3	40.0
	3	5	16.7	16.7	56.7
	5	5	16.7	16.7	73.3
	6	1	3.3	3.3	76.7
	7	3	10.0	10.0	86.7
	9	3	10.0	10.0	96.7
	10	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	3.867	Std Err	.554	Median	3.000
Std Dev	3.037	Variance	9.223		

Valid Cases 30 Missing Cases 0

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A06 BASE Q6 RATE LACK OF ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	2	6.7	6.7	6.7
	1	3	10.0	10.0	16.7
	2	1	3.3	3.3	20.0
	3	4	13.3	13.3	33.3
	4	3	10.0	10.0	43.3
	5	4	13.3	13.3	56.7
	6	3	10.0	10.0	66.7
	7	4	13.3	13.3	80.0
	8	2	6.7	6.7	86.7
	9	2	6.7	6.7	93.3
	10	2	6.7	6.7	100.0
	TOTAL	30	100.0	100.0	

Mean	4.967	Std Err	.531	Median	5.000
Std Dev	2.906	Variance	8.447		

Valid Cases 30 Missing Cases 0

A07 BASE Q7 RATE LACK OF STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	3	10.0	10.0	10.0
	1	4	13.3	13.3	23.3
	2	1	3.3	3.3	26.7
	3	3	10.0	10.0	36.7
	4	2	6.7	6.7	43.3
	5	4	13.3	13.3	56.7
	6	5	16.7	16.7	73.3
	7	2	6.7	6.7	80.0
	8	4	13.3	13.3	93.3
	9	1	3.3	3.3	96.7
	10	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	4.600	Std Err	.533	Median	5.000
Std Dev	2.920	Variance	8.524		

Valid Cases 30 Missing Cases 0

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A08 BASE Q8 USE CANOLA OIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
YES	1.00	12	40.0	40.0	40.0
NO	2.00	18	60.0	60.0	100.0
	TOTAL	30	100.0	100.0	

Mean	1.600	Std Err	.091	Median	2.000
Std Dev	.498	Variance	.248		

Valid Cases 30 Missing Cases 0

A10 BASE Q10 EXERCISE REGULARLY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
YES	1.00	16	53.3	53.3	53.3
NO	2.00	14	46.7	46.7	100.0
	TOTAL	30	100.0	100.0	

Mean	1.467	Std Err	.093	Median	1.000
Std Dev	.507	Variance	.257		

Valid Cases 30 Missing Cases 0

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A11 BASE Q11 TAKE FISH OIL SUPPLEMENT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
YES	1.00	3	10.0	10.0	10.0
NO	2.00	27	90.0	90.0	100.0
	TOTAL	30	100.0	100.0	

Mean	1.900	Std Err	.056	Median	2.000
Std Dev	.305	Variance	.093		

Valid Cases 30 Missing Cases 0

XA01 BASE Q1 RATE EXCESS WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
NEUTRAL NEGATIVE	2.00	30	100.0	100.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XA02 BASE Q2 RATE STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	7	23.3	23.3	23.3
NEUTRAL NEGATIVE	2.00	23	76.7	76.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XA03 BASE Q3 RATE POOR OVERALL HEALTH

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	18	60.0	60.0	60.0
NEUTRAL NEGATIVE	2.00	12	40.0	40.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XA04 BASE Q4 RATE POOR WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	22	73.3	73.3	73.3
NEUTRAL NEGATIVE	2.00	8	26.7	26.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

XA05 BASE Q5 RATE LACK OF FOCUS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	17	56.7	56.7	56.7
NEUTRAL NEGATIVE	2.00	13	43.3	43.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XA06 BASE Q6 RATE LACK OF ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	13	43.3	43.3	43.3
NEUTRAL NEGATIVE	2.00	17	56.7	56.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XA07 BASE Q7 RATE LACK OF STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	13	43.3	43.3	43.3
NEUTRAL NEGATIVE	2.00	17	56.7	56.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

B01 WK 2 Q1 RATE EXCESS WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	7	23.3	24.1	24.1
	2	1	3.3	3.4	27.6
	3	2	6.7	6.9	34.5
	4	1	3.3	3.4	37.9
	5	7	23.3	24.1	62.1
	6	6	20.0	20.7	82.8
	7	2	6.7	6.9	89.7
	8	2	6.7	6.9	96.6
	10	1	3.3	3.4	100.0
	.	1	3.3	MISSING	
	TOTAL	30	100.0	100.0	

Mean	4.241	Std Err	.536	Median	5.000
Std Dev	2.887	Variance	8.333		

Valid Cases 29 Missing Cases 1

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B02 WK 2 Q2 RATE STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	9	30.0	30.0	30.0
	2	2	6.7	6.7	36.7
	3	2	6.7	6.7	43.3
	4	3	10.0	10.0	53.3
	5	3	10.0	10.0	63.3
	6	6	20.0	20.0	83.3
	7	2	6.7	6.7	90.0
	8	1	3.3	3.3	93.3
	10	2	6.7	6.7	100.0
	TOTAL	30	100.0	100.0	

Mean	3.833	Std Err	.574	Median	4.000
Std Dev	3.141	Variance	9.868		

Valid Cases 30 Missing Cases 0

B03 WK 2 Q3 RATE POOR OVERALL HEALTH

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	8	26.7	26.7	26.7
	1	6	20.0	20.0	46.7
	2	4	13.3	13.3	60.0
	3	4	13.3	13.3	73.3
	4	2	6.7	6.7	80.0
	5	3	10.0	10.0	90.0
	7	2	6.7	6.7	96.7
	10	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.433	Std Err	.462	Median	2.000
Std Dev	2.528	Variance	6.392		

Valid Cases 30 Missing Cases 0

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B04 WK 2 Q4 RATE POOR WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	8	26.7	26.7	26.7
	1	5	16.7	16.7	43.3
	2	5	16.7	16.7	60.0
	3	6	20.0	20.0	80.0
	4	1	3.3	3.3	83.3
	5	1	3.3	3.3	86.7
	6	1	3.3	3.3	90.0
	7	2	6.7	6.7	96.7
	10	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.400	Std Err	.456	Median	2.000
Std Dev	2.500	Variance	6.248		

Valid Cases 30 Missing Cases 0

B05 WK 2 Q5 RATE LACK OF FOCUS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	9	30.0	30.0	30.0
	1	3	10.0	10.0	40.0
	2	6	20.0	20.0	60.0
	3	4	13.3	13.3	73.3
	4	3	10.0	10.0	83.3
	5	2	6.7	6.7	90.0
	6	1	3.3	3.3	93.3
	7	2	6.7	6.7	100.0
	TOTAL	30	100.0	100.0	

Mean	2.300	Std Err	.396	Median	2.000
Std Dev	2.168	Variance	4.700		

Valid Cases 30 Missing Cases 0

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B06 WK 2 Q6 RATE LACK OF ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	7	23.3	23.3	23.3
	1	4	13.3	13.3	36.7
	2	5	16.7	16.7	53.3
	3	5	16.7	16.7	70.0
	5	4	13.3	13.3	83.3
	6	1	3.3	3.3	86.7
	7	2	6.7	6.7	93.3
	8	1	3.3	3.3	96.7
	9	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.867	Std Err	.481	Median	2.000
Std Dev	2.636	Variance	6.947		

Valid Cases 30 Missing Cases 0

B07 WK 2 Q7 RATE LACK OF STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	9	30.0	30.0	30.0
	1	3	10.0	10.0	40.0
	2	5	16.7	16.7	56.7
	3	4	13.3	13.3	70.0
	4	2	6.7	6.7	76.7
	5	2	6.7	6.7	83.3
	6	2	6.7	6.7	90.0
	7	2	6.7	6.7	96.7
	9	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.600	Std Err	.466	Median	2.000
Std Dev	2.554	Variance	6.524		

Valid Cases 30 Missing Cases 0

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B08 WK 2 Q8 I HAVE LOST WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	7	23.3	23.3	23.3
AGREE	2	8	26.7	26.7	50.0
NEUTRAL	3	9	30.0	30.0	80.0
DISAGREE	4	5	16.7	16.7	96.7
STRONG DISAGREE	5	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.500	Std Err	.208	Median	2.500
Std Dev	1.137	Variance	1.293		

Valid Cases 30 Missing Cases 0

B09 WK 2 Q9 I FEEL LESS STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	6	20.0	20.0	20.0
AGREE	2	9	30.0	30.0	50.0
NEUTRAL	3	12	40.0	40.0	90.0
DISAGREE	4	3	10.0	10.0	100.0
	TOTAL	30	100.0	100.0	

Mean	2.400	Std Err	.170	Median	2.500
Std Dev	.932	Variance	.869		

Valid Cases 30 Missing Cases 0

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B10 WK 2 Q10 I FEEL BETTER OVERALL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	5	16.7	16.7	16.7
AGREE	2	15	50.0	50.0	66.7
NEUTRAL	3	9	30.0	30.0	96.7
DISAGREE	4	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.200	Std Err	.139	Median	2.000
Std Dev	.761	Variance	.579		

Valid Cases 30 Missing Cases 0

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B11 WK 2 Q11 IMPROVED WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	4	13.3	13.3	13.3
AGREE	2	19	63.3	63.3	76.7
NEUTRAL	3	7	23.3	23.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.100	Std Err	.111	Median	2.000
Std Dev	.607	Variance	.369		

Valid Cases 30 Missing Cases 0

B12 WK 2 Q12 I FEEL MORE FOCUSED

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	4	13.3	13.3	13.3
AGREE	2	12	40.0	40.0	53.3
NEUTRAL	3	11	36.7	36.7	90.0
DISAGREE	4	3	10.0	10.0	100.0
	TOTAL	30	100.0	100.0	

Mean	2.433	Std Err	.157	Median	2.000
Std Dev	.858	Variance	.737		

Valid Cases 30 Missing Cases 0

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B13 WK 2 Q13 I HAVE MORE ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	6	20.0	20.7	20.7
AGREE	2	11	36.7	37.9	58.6
NEUTRAL	3	10	33.3	34.5	93.1
DISAGREE	4	2	6.7	6.9	100.0
	.	1	3.3	MISSING	
	TOTAL	30	100.0	100.0	

Mean	2.276	Std Err	.164	Median	2.000
Std Dev	.882	Variance	.778		

Valid Cases 29 Missing Cases 1

B14 WK 2 Q14 I HAVE MOREW STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	4	13.3	13.3	13.3
AGREE	2	12	40.0	40.0	53.3
NEUTRAL	3	12	40.0	40.0	93.3
DISAGREE	4	2	6.7	6.7	100.0
	TOTAL	30	100.0	100.0	

Mean	2.400	Std Err	.149	Median	2.000
Std Dev	.814	Variance	.662		

Valid Cases 30 Missing Cases 0

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B15 WK 2 Q15 I HAVE LESS CRAVINGS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	8	26.7	26.7	26.7
AGREE	2	7	23.3	23.3	50.0
NEUTRAL	3	6	20.0	20.0	70.0
DISAGREE	4	7	23.3	23.3	93.3
STRONG DISAGREE	5	2	6.7	6.7	100.0
	TOTAL	30	100.0	100.0	

Mean	2.600	Std Err	.238	Median	2.500
Std Dev	1.303	Variance	1.697		

Valid Cases 30 Missing Cases 0

XB01 WK 2 Q1 RATE EXCESS WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	11	36.7	37.9	37.9
NEUTRAL NEGATIVE	2.00	18	60.0	62.1	100.0
	.	1	3.3	MISSING	
	TOTAL	30	100.0	100.0	

Valid Cases 29 Missing Cases 1

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XB02 WK 2 Q2 RATE STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	16	53.3	53.3	53.3
NEUTRAL NEGATIVE	2.00	14	46.7	46.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XB03 WK 2 Q3 RATE POOR OVERALL HEALTH

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	24	80.0	80.0	80.0
NEUTRAL NEGATIVE	2.00	6	20.0	20.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XB04 WK 2 Q4 RATE POOR WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	25	83.3	83.3	83.3
NEUTRAL NEGATIVE	2.00	5	16.7	16.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

XB05 WK 2 Q5 RATE LACK OF FOCUS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	25	83.3	83.3	83.3
NEUTRAL NEGATIVE	2.00	5	16.7	16.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XB06 WK 2 Q6 RATE LACK OF ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	21	70.0	70.0	70.0
NEUTRAL NEGATIVE	2.00	9	30.0	30.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XB07 WK 2 Q7 RATE LACK OF STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	23	76.7	76.7	76.7
NEUTRAL NEGATIVE	2.00	7	23.3	23.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XB08 WK 2 Q8 I HAVE LOST WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	15	50.0	50.0	50.0
NEUTRAL NEGATIVE	2.00	15	50.0	50.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

XB09 WK 2 Q9 I FEEL LESS STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	15	50.0	50.0	50.0
NEUTRAL NEGATIVE	2.00	15	50.0	50.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XB10 WK 2 Q10 I FEEL BETTER OVERALL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	20	66.7	66.7	66.7
NEUTRAL NEGATIVE	2.00	10	33.3	33.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XB11 WK 2 Q11 IMPROVED WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	23	76.7	76.7	76.7
NEUTRAL NEGATIVE	2.00	7	23.3	23.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XB12 WK 2 Q12 I FEEL MORE FOCUSED

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	16	53.3	53.3	53.3
NEUTRAL NEGATIVE	2.00	14	46.7	46.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

XB13 WK 2 Q13 I HAVE MORE ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	17	56.7	58.6	58.6
NEUTRAL NEGATIVE	2.00	12	40.0	41.4	100.0
	.	1	3.3	MISSING	
	TOTAL	30	100.0	100.0	

Valid Cases 29 Missing Cases 1

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XB14 WK 2 Q14 I HAVE MOREW STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	16	53.3	53.3	53.3
NEUTRAL NEGATIVE	2.00	14	46.7	46.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XB15 WK 2 Q15 I HAVE LESS CRAVINGS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	15	50.0	50.0	50.0
NEUTRAL NEGATIVE	2.00	15	50.0	50.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
WEEK 4 QUESTIONNAIRE

C01 WK 4 Q1 RATE EXCESS WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	3	10.0	10.0	10.0
	1	2	6.7	6.7	16.7
	2	2	6.7	6.7	23.3
	3	3	10.0	10.0	33.3
	4	3	10.0	10.0	43.3
	5	5	16.7	16.7	60.0
	6	5	16.7	16.7	76.7
	7	2	6.7	6.7	83.3
	8	2	6.7	6.7	90.0
	9	1	3.3	3.3	93.3
	10	2	6.7	6.7	100.0
	TOTAL	30	100.0	100.0	

Mean	4.700	Std Err	.519	Median	5.000
Std Dev	2.842	Variance	8.079		

Valid Cases 30 Missing Cases 0

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C02 WK 4 Q2 RATE STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	8	26.7	26.7	26.7
	1	2	6.7	6.7	33.3
	2	1	3.3	3.3	36.7
	3	4	13.3	13.3	50.0
	4	3	10.0	10.0	60.0
	5	6	20.0	20.0	80.0
	6	3	10.0	10.0	90.0
	7	1	3.3	3.3	93.3
	8	2	6.7	6.7	100.0
	TOTAL	30	100.0	100.0	

Mean	3.300	Std Err	.477	Median	3.500
Std Dev	2.615	Variance	6.838		

Valid Cases 30 Missing Cases 0

C03 WK 4 Q3 RATE POOR OVERALL HEALTH

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	8	26.7	26.7	26.7
	1	8	26.7	26.7	53.3
	2	3	10.0	10.0	63.3
	3	2	6.7	6.7	70.0
	4	2	6.7	6.7	76.7
	5	3	10.0	10.0	86.7
	6	1	3.3	3.3	90.0
	7	2	6.7	6.7	96.7
	8	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.367	Std Err	.448	Median	1.000
Std Dev	2.456	Variance	6.033		

Valid Cases 30 Missing Cases 0

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C04 WK 4 Q4 RATE POOR WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	7	23.3	23.3	23.3
	1	5	16.7	16.7	40.0
	2	4	13.3	13.3	53.3
	3	5	16.7	16.7	70.0
	4	1	3.3	3.3	73.3
	5	4	13.3	13.3	86.7
	6	1	3.3	3.3	90.0
	7	2	6.7	6.7	96.7
	10	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.733	Std Err	.470	Median	2.000
Std Dev	2.572	Variance	6.616		

Valid Cases 30 Missing Cases 0

C05 WK 4 Q5 RATE LACK OF FOCUS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	9	30.0	30.0	30.0
	1	6	20.0	20.0	50.0
	2	3	10.0	10.0	60.0
	3	3	10.0	10.0	70.0
	4	2	6.7	6.7	76.7
	5	4	13.3	13.3	90.0
	7	2	6.7	6.7	96.7
	9	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.400	Std Err	.459	Median	1.500
Std Dev	2.513	Variance	6.317		

Valid Cases 30 Missing Cases 0

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C06 WK 4 Q6 RATE LACK OF ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	9	30.0	30.0	30.0
	1	5	16.7	16.7	46.7
	2	5	16.7	16.7	63.3
	3	2	6.7	6.7	70.0
	5	4	13.3	13.3	83.3
	7	3	10.0	10.0	93.3
	8	1	3.3	3.3	96.7
	9	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.633	Std Err	.511	Median	2.000
Std Dev	2.798	Variance	7.826		

Valid Cases 30 Missing Cases 0

C07 WK 4 Q7 RATE LACK OF STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	9	30.0	30.0	30.0
	1	5	16.7	16.7	46.7
	2	6	20.0	20.0	66.7
	3	2	6.7	6.7	73.3
	5	3	10.0	10.0	83.3
	7	4	13.3	13.3	96.7
	9	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.500	Std Err	.493	Median	2.000
Std Dev	2.701	Variance	7.293		

Valid Cases 30 Missing Cases 0

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C08 WK 4 Q8 I HAVE LOST WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	10	33.3	33.3	33.3
AGREE	2	7	23.3	23.3	56.7
NEUTRAL	3	11	36.7	36.7	93.3
DISAGREE	4	1	3.3	3.3	96.7
STRONG DISAGREE	5	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.200	Std Err	.194	Median	2.000
Std Dev	1.064	Variance	1.131		

Valid Cases 30 Missing Cases 0

C09 WK 4 Q9 I FEEL LESS STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	5	16.7	16.7	16.7
AGREE	2	9	30.0	30.0	46.7
NEUTRAL	3	12	40.0	40.0	86.7
DISAGREE	4	4	13.3	13.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.500	Std Err	.171	Median	3.000
Std Dev	.938	Variance	.879		

Valid Cases 30 Missing Cases 0

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C10 WK 4 Q10 I FEEL BETTER OVERALL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	7	23.3	23.3	23.3
AGREE	2	14	46.7	46.7	70.0
NEUTRAL	3	7	23.3	23.3	93.3
DISAGREE	4	2	6.7	6.7	100.0
	TOTAL	30	100.0	100.0	

Mean	2.133	Std Err	.157	Median	2.000
Std Dev	.860	Variance	.740		

Valid Cases 30 Missing Cases 0

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C11 WK 4 Q11 IMPROVED WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	6	20.0	20.0	20.0
AGREE	2	11	36.7	36.7	56.7
NEUTRAL	3	10	33.3	33.3	90.0
DISAGREE	4	3	10.0	10.0	100.0
	TOTAL	30	100.0	100.0	

Mean	2.333	Std Err	.168	Median	2.000
Std Dev	.922	Variance	.851		

Valid Cases 30 Missing Cases 0

C12 WK 4 Q12 I FEEL MORE FOCUSED

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	7	23.3	23.3	23.3
AGREE	2	8	26.7	26.7	50.0
NEUTRAL	3	12	40.0	40.0	90.0
DISAGREE	4	3	10.0	10.0	100.0
	TOTAL	30	100.0	100.0	

Mean	2.367	Std Err	.176	Median	2.500
Std Dev	.964	Variance	.930		

Valid Cases 30 Missing Cases 0

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C13 WK 4 Q13 I HAVE MORE ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	6	20.0	20.0	20.0
AGREE	2	13	43.3	43.3	63.3
NEUTRAL	3	7	23.3	23.3	86.7
DISAGREE	4	4	13.3	13.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.300	Std Err	.174	Median	2.000
Std Dev	.952	Variance	.907		

Valid Cases 30 Missing Cases 0

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C14 WK 4 Q14 I HAVE MOREW STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	5	16.7	16.7	16.7
AGREE	2	10	33.3	33.3	50.0
NEUTRAL	3	12	40.0	40.0	90.0
DISAGREE	4	3	10.0	10.0	100.0
	TOTAL	30	100.0	100.0	

Mean	2.433	Std Err	.164	Median	2.500
Std Dev	.898	Variance	.806		

Valid Cases 30 Missing Cases 0

C15 WK 4 Q15 I HAVE LESS CRAVINGS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	7	23.3	23.3	23.3
AGREE	2	13	43.3	43.3	66.7
NEUTRAL	3	6	20.0	20.0	86.7
DISAGREE	4	4	13.3	13.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.233	Std Err	.177	Median	2.000
Std Dev	.971	Variance	.944		

Valid Cases 30 Missing Cases 0

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C16 WK 4 Q16 WOULD PURCHASE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	6	20.0	20.0	20.0
AGREE	2	16	53.3	53.3	73.3
NEUTRAL	3	4	13.3	13.3	86.7
DISAGREE	4	3	10.0	10.0	96.7
STRONG DISAGREE	5	1	3.3	3.3	100.0
	TOTAL	30	100.0	100.0	

Mean	2.233	Std Err	.184	Median	2.000
Std Dev	1.006	Variance	1.013		

Valid Cases 30 Missing Cases 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
WEEK 4 QUESTIONNAIRE

C17 WK 4 Q17 WOULD RECOMMEND TO FRIEND

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
STRONG AGREE	1	10	33.3	33.3	33.3
AGREE	2	13	43.3	43.3	76.7
NEUTRAL	3	4	13.3	13.3	90.0
DISAGREE	4	3	10.0	10.0	100.0
	TOTAL	30	100.0	100.0	

Mean	2.000	Std Err	.173	Median	2.000
Std Dev	.947	Variance	.897		

Valid Cases	30	Missing Cases	0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
WEEK 4 QUESTIONNAIRE

XC01 WK 4 Q1 RATE EXCESS WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	13	43.3	43.3	43.3
NEUTRAL NEGATIVE	2.00	17	56.7	56.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC02 WK 4 Q2 RATE STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	18	60.0	60.0	60.0
NEUTRAL NEGATIVE	2.00	12	40.0	40.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC03 WK 4 Q3 RATE POOR OVERALL HEALTH

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	23	76.7	76.7	76.7
NEUTRAL NEGATIVE	2.00	7	23.3	23.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC04 WK 4 Q4 RATE POOR WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	22	73.3	73.3	73.3
NEUTRAL NEGATIVE	2.00	8	26.7	26.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

XC05 WK 4 Q5 RATE LACK OF FOCUS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	23	76.7	76.7	76.7
NEUTRAL NEGATIVE	2.00	7	23.3	23.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC06 WK 4 Q6 RATE LACK OF ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	21	70.0	70.0	70.0
NEUTRAL NEGATIVE	2.00	9	30.0	30.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC07 WK 4 Q7 RATE LACK OF STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	22	73.3	73.3	73.3
NEUTRAL NEGATIVE	2.00	8	26.7	26.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC08 WK 4 Q8 I HAVE LOST WEIGHT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	17	56.7	56.7	56.7
NEUTRAL NEGATIVE	2.00	13	43.3	43.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

XC09 WK 4 Q9 I FEEL LESS STRESS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	14	46.7	46.7	46.7
NEUTRAL NEGATIVE	2.00	16	53.3	53.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC10 WK 4 Q10 I FEEL BETTER OVERALL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	21	70.0	70.0	70.0
NEUTRAL NEGATIVE	2.00	9	30.0	30.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC11 WK 4 Q11 IMPROVED WELL BEING

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	17	56.7	56.7	56.7
NEUTRAL NEGATIVE	2.00	13	43.3	43.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC12 WK 4 Q12 I FEEL MORE FOCUSED

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	15	50.0	50.0	50.0
NEUTRAL NEGATIVE	2.00	15	50.0	50.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

XC13 WK 4 Q13 I HAVE MORE ENERGY

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	19	63.3	63.3	63.3
NEUTRAL NEGATIVE	2.00	11	36.7	36.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC14 WK 4 Q14 I HAVE MOREW STAMINA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	15	50.0	50.0	50.0
NEUTRAL NEGATIVE	2.00	15	50.0	50.0	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC15 WK 4 Q15 I HAVE LESS CRAVINGS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	20	66.7	66.7	66.7
NEUTRAL NEGATIVE	2.00	10	33.3	33.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

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XC16 WK 4 Q16 WOULD PURCHASE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	22	73.3	73.3	73.3
NEUTRAL NEGATIVE	2.00	8	26.7	26.7	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0

IRSI - BREAKFAST COOKIE STUDY #4189SBC1217 4/2/18
WEEK 4 QUESTIONNAIRE

XC17 WK 4 Q17 WOULD RECOMMEND TO FRIEND

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
POSITIVE	1.00	23	76.7	76.7	76.7
NEUTRAL NEGATIVE	2.00	7	23.3	23.3	100.0
	TOTAL	30	100.0	100.0	

Valid Cases 30 Missing Cases 0