

ICPSR 36174

Randomized Controlled Trial of Breakfast Recommendations on Weight: A Multi-Site Effectiveness Trial

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Codebook

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ICPSR PROCESSING NOTES FOR #36174

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- 1) **Stata Limitations:** Due to Stata limitations, the variables **ASSIGNUB**, **ETHFAC**, and **SITE** do not contain value labels for non-integer values within the Stata files.

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Recommendations on Weight: A Multi-Site
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Original P.I. Documentation

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1. CONTACT LIST

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2. PROTOCOL

A. UAB PROTOCOL OVERVIEW

Summary

This is a multi-site, 3 parallel arm, randomized, controlled trial comparing the effect of recommending breakfast consumption on body weight. Previous findings indicate skipping breakfast may reduce energy intake over the course of a day (Kral et al. 2011; Levitsky et al. 2012), and therefore may have an impact on body weight. Other findings suggest the impact of breakfast consumption on weight loss may depend on typical breakfast consumption habits (Schulndt et al. 1992). The proposed study will be conducted over 16 weeks, and body weight and height will be measured at the beginning of the trial period, and body weight again at the end of the trial period. 324 participants will be enrolled, with each of six sites randomizing 54 participants, with equal allocation of participants randomized to the breakfast, no breakfast, and control groups. **Our objective is to determine if breakfast consumption recommendations can produce weight loss, and if that weight loss is dependent on typical breakfast consumption patterns.**

Eligibility

Inclusion criteria:

Ages 20-65 y
Men and women
BMI ≥ 25 , and $\leq 45 \text{ kg/m}^2$
Interested in weight loss
Start day by 9:00 a.m. at least 5 days per week

Exclusion criteria:

- Participation in any weight-reduction program, weight-loss diet, or other special diet within the previous 3 months.
- Weight loss or gain of $>5\%$ of body weight in the past 6 months for any reason except post-partum weight loss.
- Currently taking medication that suppresses or stimulates appetite.

- Currently taking medication that requires eating with food in the morning, including NSAIDs.
- History of prior surgical procedure for weight control or liposuction.
- Current smoker or quit smoking less than 6 months prior.
- Any major disease, including:
 - Active cancer or cancer requiring treatment in the past 2 years (except nonmelanoma skin cancer).
 - Active or chronic infections, including self-reported HIV positivity and active tuberculosis.
 - Active cardiovascular disease or event including hospitalization or therapeutic procedures for treatment of heart disease (e.g., coronary artery bypass, percutaneous transluminal coronary angioplasty) in the past 6 months; New York Heart Association Functional Class >2 with respect to congestive heart failure; stroke or transient ischemic attack in the past 6 months.
 - Gastrointestinal disease, including self-reported chronic hepatitis or cirrhosis, any episode of alcoholic hepatitis or alcoholic pancreatitis within past year, inflammatory bowel disease requiring treatment in the past year, recent or significant abdominal surgery (e.g., gastrectomy).
 - Active renal disease.
 - Lung disease: chronic obstructive airway disease requiring use of oxygen.
 - Diagnosed diabetes (type 1 or 2) .
 - Uncompensated or uncontrolled psychiatric disease (such as schizophrenia and bipolar disorder) that, in opinion of the investigators, would impede conduct of the trial or completion of procedures.
- A score on the Brief Symptom Inventory (BSI) (Derogatis & Melisaratos, 1983) that exceeds the 90th percentile.
- History of or current eating disorders, or an Eating Attitudes Test (EAT 40) score >30.
- Conditions or behaviors likely to effect the conduct of the trial: unable or unwilling to give informed consent; unable to communicate with the pertinent clinic staff; another household member is a participant or staff member in the trial; unwilling to accept treatment assignment by randomization; current or anticipated participation in another intervention research project that would interfere with the intervention offered in the trial; likely to move away from participating clinics before trial completed; unable to walk 0.25 mile in 10 minutes.

- Currently taking antidepressant, steroid, or thyroid medication, unless dosage has been stable for at least 6 months.
- A recent or ongoing problem with drug abuse or addiction.
- Excessive alcohol intake, either acute or chronic, defined as any one of the following: 1) average consumption of 3 or more alcohol containing beverages daily; 2) consumption of 7 or more alcoholic beverages within a 24-hr period in the past 12 months; or 3) other evidence available to clinic staff.
- Working the “night shift” or any work schedule that would interfere with normal breakfast consumption.
- Not willing to be randomized to any of the three experimental conditions.
- Pregnancy and childbearing: currently pregnant or less than 3 months post partum; currently nursing or within 6 weeks of having completed nursing; pregnancy anticipated during study; unwilling to report possible or confirmed pregnancies promptly during the course of the trial; unwilling to take adequate contraceptive measures if potentially fertile.
- Any other conditions which, in opinion of the investigators, would adversely affect the conduct of the trial.

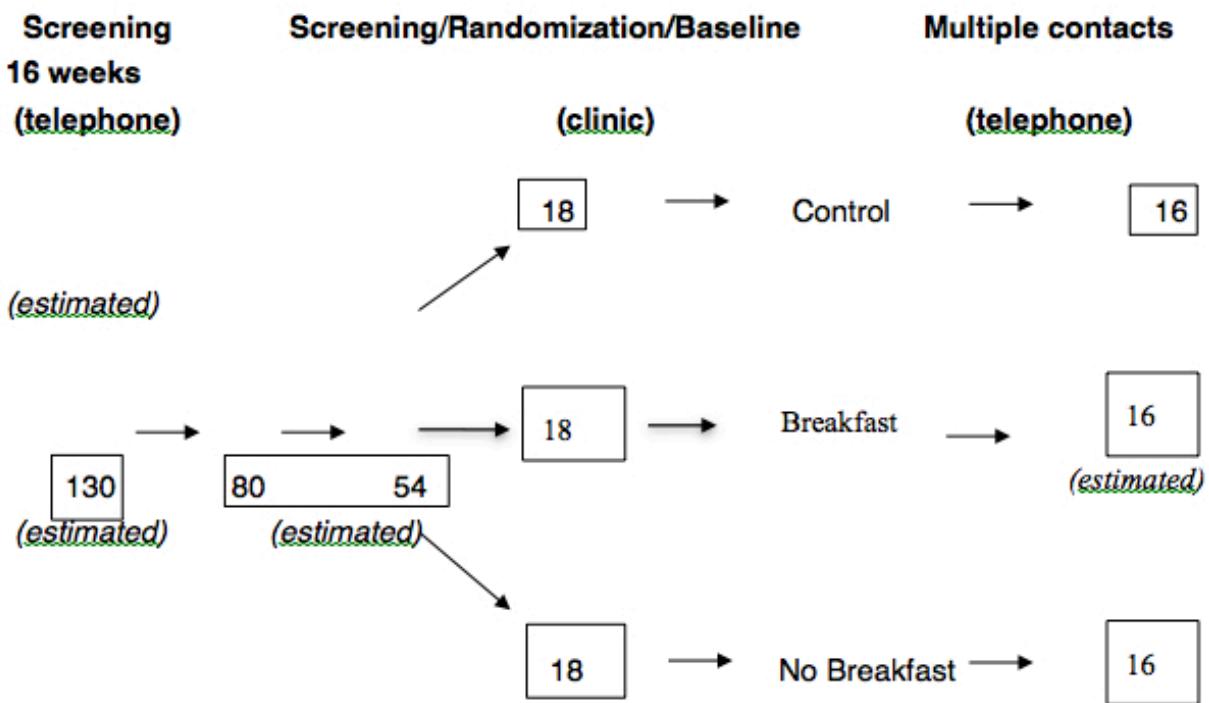
Power Calculations

The study sample was calculated such that we have at least .9 power at a two-tailed alpha of 0.05, for pairwise comparisons among groups to detect an interaction between treatment and stratification group. We did this by first using the Schlundt et al. study interaction effect to determine sample size using the calculation in Tiwari et al. 2011 (this method is applicable to any experiment, not only genomic studies). Because the Schlundt et al. paper was a two group study, and we have three treatment groups, the sample size of 177 was multiplied by 1.5 to account for the extra group, making 266 subjects necessary for our study. To account for a dropout rate of 13.5% as reported in the Schlundt et al paper, a total of 308 subjects will be recruited. This should leave an adequate sample size of 266 for .9 power to detect a small to moderate effect size reported in Schlundt et al. of $r=0.22-0.34$.

Recruitment and Screening

Appropriate subjects will be recruited through flyers, posters, advertisements in local area newspapers, mailings, existing databases of persons who have expressed interest in weight-loss interventions, and word of mouth. Subjects will be screened for initial eligibility via telephone. Initially eligible subjects will be scheduled for a clinic visit, during which assessment of height and weight, and completion of screening questionnaires (BSI, EAT 40) will occur. Those subjects that pass the second level of screening will be randomized *at the same visit* to one of the three treatment groups and appropriate dietary instruction will be given. The protocol will be approved by all study site Institutional Review Boards for Human Use (IRB), and written informed consent will be obtained from every subject. Screening and enrollment consent will be obtained at the first clinic visit.

Study Scheme



Subject Contacts

Initial screening – telephone: Prospective subjects who call the study number will be screened for initial eligibility by telephone. The study, including all that will be required of participants, will be presented. The telephone eligibility screen will be administered to prospective subjects, and those who pass this level of screening, and who are interested in proceeding, will be invited and scheduled for a clinic screening visit.

Final screening and Randomization – clinic: Those persons who pass the initial screening will be screened further for study eligibility during a clinic visit. At this visit, subjects will be consented for the screening process, the telephone screening questionnaire reviewed, and the BSI and EAT 40 administered by study coordinator. Height and weight will be measured and BMI calculated by the clinic technician. Those persons who remain eligible following the second level of screening, and who remain interesting in participating, will undergo the informed consent process including detailed description of each study arm. Female subjects without a history of tubal ligation or hysterectomy will undergo a pregnancy test; a negative pregnancy test will be required for randomization. Subjects then will open a sealed envelope with their random assignment to the control, breakfast, or no breakfast group. Participants in each arm will be informed in detail regarding their study obligations, and any questions will be answered. A W9 form will be completed on each participant. All participants will receive USDA Dietary Guidelines brochure, “Let’s Eat for the Health of It.”

4-week telephone call: Inquire about weight loss from time of last contact, problems/adverse events; answer questions.

8-week telephone call: Inquire about weight loss from time of last contact, problems/adverse events; answer questions.

12-week telephone call: Inquire about weight loss from time of last contact, problems/adverse events; answer questions. Schedule/confirm 16-week clinic appointment.

Final 16-week visit: Measure weight, collect diary, and pay participant compensation.

Contact Summary:

	BL	4	8	12	16
Breakfast	visit	call	call	call	visit
No Breakfast	visit	call	call	call	visit
Control	visit	call	call	call	visit

Missed Contacts:

First missed call/visit: Leave voicemail (VM) early in the scheduled contact week.

If not returned, leave 2nd VM on Thursday.

If not returned, attempt email contact on Friday.

If not returned, leave 3rd VM on Tues following the scheduled contact week.

Treat as drop out. Call/email one month prior to week 16 visit to attempt major outcomes visit.

Randomization

Upon completion of the general information questionnaire, patients will be stratified according to their baseline breakfast eating habits. Those who consume breakfast 4 or more times per week will be considered breakfast eaters, and those who consume breakfast three times or less per week will be considered non-breakfast eaters. A pseudo-random number generator will create a separate list for each breakfast habit stratum, for each center, by the UAB team. The numbers and their group designation will be sealed in an envelope, and after the breakfast eating stratum of the patient being randomized is determined, an envelope will be handed to the participant from that stratum containing their group assignment.

Interventions: Weeks 1-16

Breakfast: Participants randomized to the breakfast group will be instructed to consume breakfast before 10:00 a.m. every day, and will be asked to not eat again until after

11:00 a.m. Participants will be counseled on what a healthy breakfast is using the ADA breakfast handout. No specific restrictions will be given on types of foods that can be consumed for the breakfast meal. They will be instructed to keep track of their breakfast consumption (yes/no) using a calendar diary that will be provided to them. Participants will also be provided with a free USDA nutrition pamphlet describing general good nutrition habits. The clinician will go through both documents with participants in detail by reading them aloud and answering any questions.

No Breakfast: Participants randomized to the no breakfast group will receive a detailed handout with instructions to not consume any calories before 11:00 a.m. every day. Only water or 0 calorie beverages may be consumed from the time of waking until 11:00 a.m. Participants will also be provided with a free USDA nutrition pamphlet describing general good nutrition habits. The clinician will go through both documents with participants in detail by reading them aloud and answering any questions.

Control: Participants will be provided with a free USDA nutrition pamphlet describing general good nutrition habits. They will also receive a handout on good dental hygiene habits. The clinician will go through both documents with participants in detail by reading them aloud and answering any questions.

Duration

This will be a 16-week intervention.

Screening Measures

Brief Symptom Inventory: The BSI (Derogatis & Melisaratos, 1983) will be administered. A score that exceeds the 90th percentile will exclude the person from participation.

Eating Attitudes Test: The EAT 40 will be administered to assess the presence of eating disorders. A score >30 will exclude the person from participation.

Outcome Measures

All outcome measures will be performed at baseline and 16 weeks. Note: height and weight will be measured and BMI calculated at the first clinic visit in order to determine eligibility.

Anthropometric:

Weight: Weight will be measured in light indoor clothes without shoes. Weight measurements will be recorded to the nearest 0.1 kg using a digital scale.

Height: In order to calculate BMI, height will be measured at the screening visit to the nearest 0.5 cm using a wall-mounted stadiometer. Participants will remove shoes prior to height measurement. The measurement will be taken at peak inspiration.

Body Mass Index: BMI will be calculated as kg/m².

Participant Compensation

Participants will be compensated \$100.00 at the last study visit.

Drop-Outs: Should a participant be unable or unwilling to continue participation at any point, he/she will be strongly encouraged to return at 16 weeks for final outcome measures.

Statistical Analysis

The statistical analysis will be conducted by statisticians in the Department of Biostatistics at UAB under Dr. Allison's direction. Ordinary least squares (OLS) regression techniques will be utilized because of their robustness. Although maximum likelihood based mixed models are tempting in such situations, our work suggests a slight advantage of multiple imputation methods coupled with OLS approaches in weight loss RCTs (Elobeid et al., 2008). The basic models will essentially be analyses of covariance (ANCOVA) where treatment assignment is the independent variable, the change in body weight will serve as the dependent variable, and pre-randomization factors such as age, sex, baseline body weight, breakfast consumption before the trial, and study site will be used as covariates. Missing data will be handled via multiple imputation. Statistical significance will be set at an α level of 0.05 (2-tailed). All assumptions of parametric statistical tests to be used will be checked and, if found to be unmet and not manageable by monotonic transformation, parametric inference will be replaced by appropriate computer-intensive resampling based inference.

Data Access/Human Subjects Protection

Data access will be limited to study investigators and appropriate staff of participating institutions, and the IRB at participating institutions. Protection of human subjects is detailed in the Human Subjects Protocol submission to the IRB.

Facilities

All sites have clinical facilities especially designed for clinical trials, containing all the necessary facilities for participant assessments. All sites have run multiple similar trials and are thus well equipped to do so.

Standardization Across Multiple Study Sites

To standardize instructions given across multiple study sites by multiple coordinators, all intervention instructions will be pre-written and read aloud. In addition, a pre-determined approach to each intermittent check-in phone call will be decided on and consistent across sites.

Manuscripts

The investigators commit to writing at least one manuscript describing the results of this study. Dr. David Allison will be the last author, and Dr. Emily Dhurandhar will be the first author in the manuscript. All study site PI's will be co-authors, and additional authors may be suggested. Authorship decisions will be based on the International Committee of Medical Journal Editors Authorship Guidelines (http://www.icmje.org/ethical_1author.html).

Study Timeline (weeks)

Activity	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54
IRB submission	X								
Finalize protocol	X								
Start-up activities/staff training	X								
Recruitment		X							
Intervention		X	X	X	X				
Data analysis						X	X	X	
Manuscript preparation							X	X	X

References

Derogatis LR, Melisaratos N. The Brief Symptom Inventory: an introductory report. Psychol Med. 1983;13:595-605.

Elobeid MA, Padilla MA, McVie T, Thomas O, Brock DW, Musser B, Lu K, Coffey CS, Desmond RA, St-Onge MP, Gadde KM, Heymsfield SB, Allison DB. Missing data in randomized clinical trials for weight loss: scope of the problem, state of the field, and performance of statistical methods. PLoS ONE. 2008;4:e6624.

Flint A, Raben A, Blundell JE, Astrup A. Reproducibility, power and validity of visual analogue scales in assessment of appetite sensations in single test meal studies. Int J Obesity. 2000;24:38-48.

Kral TV, Whiteford LM, Heo M, Faith MS. Effects of eating breakfast compared with skipping breakfast on ratings of appetite and intake at subsequent meals in 8- to 10-year-old children. AJCN, 2011;93(2):284-91.

Levitsky DA, Pacanowski C. Skipping breakfast results in reduced daily energy intake: Experimental evidence. Under review.

Schlundt DG, Hill JO, Sbrocco T, Pope-Cordle J, and Sharp T. The role of breakfast in the treatment of obesity: a randomized clinical trial. AJCN, 1992;55:645-51.

Tiwari HK, Birkner T, Moondan A, Zhang S, Page GP, Patki A, Allison DB. Accurate and flexible power calculations on the spot: Applications to genomic research. Statistics and Its Interface. 2011;4(3):353-358.

B. MULTI-SITE DETAILED PROTOCOL

Telephone screening:

When you make the phone call, be sure to have Form 1 ready and in front of you so that you may fill it out. Assign each phone screen a study ID number as indicated in the table below. Follow the telephone screening script as closely as possible. To qualify as “eligible” for further screening, the questions must be answered as follows in italics:

What is your full name? *First and Last Name*

What is your address? *Full Address including number, street, city, and zip code.*

What is your email address? *_highly encouraged for coordinator communication_*

What is your phone number? *Here, at least one number must be provided.*

Home: _____ Cell: _____

Work: _____

What is your gender? *Male/Female*

What is your ethnicity? *Any of the following: Black Hispanic, Black Non-Hispanic, Other, White Hispanic, and White Non-Hispanic*

When is the best time to reach you? *Must specify morning, afternoon, evenings, a particular day of the week, or weekends.*

Are you between the ages of 20-65? Yes

What is your birthdate? *Month, Date, and Year*

What is your height? _____

What is your weight? _____

Compute BMI, must be ≥ 25 , and $\leq 45 \text{ kg/m}^2$

Are you interested in weight loss? Yes

Do you start your day by 9:00 a.m. at least 5 days a week? Yes

Have you participated in any weight-reduction program, weight-loss diet, or other special diet within the previous 3 months? No

Have you experienced weight loss or gain of $>5\%$ of body weight in the past 6 months for any reason except post-partum weight loss? No

Are you currently taking any medication that suppresses or stimulates appetite? No

Are you currently taking medication that requires eating food in the morning, including non-steroidal anti-inflammatory medications such as baby aspirin or Tylenol? No

Do you have a history of prior surgical procedure for weight control or liposuction? No

How many times per week do you currently consume breakfast? X times per week.

Are you a current smoker or quit smoking less than 6 months ago? No

Do you have any of the following major diseases: (*All must be answered "No"*)

Active cancer or cancer requiring treatment in the past 2 years (except nonmelanoma skin cancer)? _____

Active or chronic infections (e.g., HIV or TB)? _____

Active cardiovascular disease or event including hospitalization or therapeutic procedures for treatment of heart disease in the past 6 months? _____

Gastrointestinal disease? _____

Active kidney disease? _____

Lung disease: chronic obstructive airway disease requiring use of oxygen (e.g., emphysema or chronic bronchitis)? _____

Diagnosed diabetes (type 1 or 2) and taking any anti-diabetic medications and/or controlling the disease via dietary manipulations? _____

Uncontrolled psychiatric disease? _____

Are you willing to be randomized to any study group that requires you to eat breakfast by 10:00 a.m., or skip breakfast and not eat until 11:00 a.m., or the control group? Yes
Are you currently taking antidepressant, steroid, or thyroid medication?

If yes, has the dosage changed within 6 months? No _____

Do you have a recent or ongoing problem with drug abuse or addiction? No

Do you consume more than three alcoholic drinks per day and/or have you had 7 or more alcoholic beverages in a 24-hour period in the last 12 months? No

The next questions pertain to women only:

Are you currently pregnant or less than 3 months post partum? No

Are you currently nursing or within 6 weeks of having completed nursing? No

Are you anticipating a possible pregnancy during study? No

Are you willing to report possible or confirmed pregnancies promptly during the course of the trial? Yes

Are you willing to take adequate contraceptive measures if potentially fertile? Yes

Mark their status as non-eligible (NE), eligible (E), or not interested (NI).

Ensure study ID number was assigned as indicated in the table below.

Schedule ELIGIBLE for Screening-Randomization Visit prior to ending the phone call.

Advise them you will call the week day prior to that visit to remind them of the visit and expected urine sample (if it applies to them).

NOTE: Keep all NE or NI Form 1 on record in a Telephone Screening File. All ELIGIBLE Form 1 shall be given an individual Participant Record folder labeled with ID number. All of this individual's future paperwork shall be filed here.

Site	Patient ID numbers
University of Alabama at Birmingham (lead study site)	1,000-1,999
Columbia University	2,000-2,999
University of Colorado Denver	3,000-3,999
University of Copenhagen	4,000-4,999
Boston University	5,000-5,999
Johns Hopkins University	6,000-6,999

Screening/Randomization Visit

Potential participants can be screened in batches, as long as private space is available for any measurements or questions. As participants arrive, give them the informed consent form and ask them to read it over. After all have arrived, go over the main points in each section and give participants the opportunity to ask any questions. All agreeing to participate will sign the consent form. Email participants a copy of their informed consent form. This serves as a follow-up "thank you," a way to give them your contact information, and easy access to that info for future use.

Next, give participants the BSI and EAT questionnaire. For the BSI questionnaire, read the instructions on the top of page 2 out loud and answer any questions. For the EAT questionnaire, read the instructions at the top of the page and answer any questions. For scoring BSI, follow the instructions on the sheet. Only calculate the total GSI. For scoring EAT: Each mark in the "Always" column counts as 3 points, 2 points for "Very Often" column, and 1 point for "Often." The others are not scored. Total each of those 3 columns, and if the cumulative of those is >30, the subject is excluded.

Label urine collection cups with previously assigned ID numbers. Pass out to women and ask them to provide a urine sample at a convenient time (such as while the

questionnaires are being filled out or graded, or during weighing) to ensure the pregnancy test is completed (not necessary if full hysterectomy is indicated during screening phone call).

Record Weight in the following manner:

1. Ensure the scale has been calibrated within the last year, if applicable.
2. Instruct the participant to remove jacket, shoes, other heavy clothing, and to empty pockets.
3. Ensure the scale reads 0 before asking the participant to step onto the scale.
4. Instruct participant to step onto the scale, facing the measurement side of the scale.
5. Instruct the participant to stand in the middle of the platform with head erect and eyes looking straight ahead.
6. Ask participant to distribute weight evenly on both feet.
7. Allow the scale to come to a stable weight.
8. Read and record the weight on Form 2. Report in kg to the nearest 0.1 kg.

Record Height in the following manner:

1. Ensure the stadiometer has been calibrated within the last year.
2. Mount the stadiometer so the participant stands on a level, uncarpeted, hard surface.
3. Instruct the participant to remove shoes.
4. Ask participant to stand erect with back to the wall-mounted stadiometer, back of head, back, and buttocks touching the stadiometer, and with weight distributed evenly on both feet.
5. Check that participant is in correct position.
6. Instruct participant to look straight ahead and keep arms relaxed and hanging loosely.
7. Bring the sliding headpiece down firmly, but not tightly, on top of head.
8. Use a stool to adjust the sliding headpiece if participant is tall, so your eyes are level with the point of measurement.
9. Instruct the participant to inhale deeply and record the reading on the stadiometer before the participant exhales.
10. Record the height on Form 2 in centimeters to the nearest 0.1 of a centimeter.

After height and weight are measured, calculate BMI and ensure the participant meets the inclusion criteria (≥ 25 , and $\leq 45 \text{ kg/m}^2$). Go over the checklist on Form 2 and make sure all qualifying information has been recorded and met eligibility criteria, then check Form 1 to determine if the participant is typically a “breakfast eater” or “breakfast skipper” and make note of the stratum each participant belongs to on Form 2 . The coordinating center will provide the group assignment envelopes, and there will be 27 numbered envelopes for each stratum. Stack them in order, with number 27 on the bottom and number 1 on the top. Hand the envelopes out from the correct stratum pile in order (starting with number 1) as participants are randomized.

Once all participants are randomized, go through the appropriate group instructions. Best case scenario is to verbally instruct each group separately, in any order.

Read aloud the instructions to participants in the “no breakfast” group regarding his/her skipping breakfast (Appendix X), and also read through the “Let’s Eat for the Health of It” handout. Allow them to leave the visit. Provide parking compensation if applicable.

Read aloud the ADA Healthy Breakfast handout (Appendix X) to the “breakfast” group participants and recommend he/she incorporate that information into their breakfast. Also, instruct “breakfast” group participants on what time of day they should be consuming breakfast by reading aloud the “breakfast” group instructions (Appendix X), and read aloud through the “Let’s Eat for the Health of It” handout. Allow them to leave the visit. Provide parking compensation if applicable.

For participants in the control group, read aloud the Let’s Eat for the Health of It” handout, and also read aloud the control group instruction sheet (Appendix X). Allow them to leave the visit. Provide parking compensation if applicable.

Answer questions as needed, however, refer to the handouts as much as possible to ensure consistency of information. Before the participant leaves, remind them of when their follow up phone calls will occur. Make sure Form 2 is completed before the participant leaves.

Telephone Follow Up Call

Before placing the call, obtain the telephone follow-up call script and have it ready. Read the telephone follow-up script as closely as possible. As the participant answers, fill in the blank spaces on the script. Briefly make notes on their answers and any advice you give the participant for adhering to the recommendations of their group. For the control group, skip question 3. If it is the participant's 3rd follow-up call, schedule a final study visit. Remind the participant to bring the breakfast diary to the final visit and to expect your reminder phone call the weekday prior to that visit.

Final Visit

Weigh the participant according to the instructions from the screening/randomization visit.

Collect the breakfast diary for the two intervention group participants.

Pay the participant \$100.00. Ensure that Form 3 is filled out.

3. SUBJECT FORMS AND HANDOUTS

A. BREAKFAST STUDY TELEPHONE SCREENING SCRIPT

“Thank you for your interest in this study. Before I ask you any question to determine whether you are eligible to participate in this study, let me give you some information about this research project. If, after hearing about it you are still interested, I will ask you some questions about your health status. Your participation in this process is entirely voluntary and you may decide that you are not interested. Would you like to continue?” If no, thank the person and hang up. If yes, continue with the following:

“The purpose of this study is to compare the effectiveness of 3 different dietary recommendations on weight status. To examine this, you would need to come for two clinic visits; the first would last 2 hours, and the second would last 30 minutes. We would also call during the study three times, each call lasting 10-20 minutes. Are you willing to come to the research center two times and speak with us on the phone?”

If no, tell the person that this study may not be appropriate for him/her, thank the person and hang up. If yes, continue with the following:

“You may be asked to skip breakfast every day during the study, or you may be asked to eat breakfast every day during the study. Are you willing to possibly change your dietary habits to either condition, in order to comply with the study?”

If no, thank the person and hang up. If yes, continue with the following:

“Let me ask you some questions about your health to determine if you are eligible to participate in this study.”

Proceed with these questions on Form 1 (If, at any point during Form 1, the person is not eligible, thank him/her and hang up):

If, after answering the above questions from the questionnaire, the caller seems eligible, continue with the following:

“You may be eligible to participate in this study. Would you like to schedule a time for an in-person screening and to review the consent form?” If yes, schedule their screening visit and write on the date and time on Form 1.

The caller will be screened in person and the consent form will be reviewed in person.

B. BREAKFAST STUDY TELEPHONE FOLLOW-UP SCRIPT

Patient ID:

Date of Call:

Hello, my name is _____, and I am calling from _____ for the Dietary and Health Recommendation Study. May I please speak with _____?

(if the person is available)

I would like to follow up with you on your participation in the Dietary and Health Recommendation Study by asking you some questions. Is now a good time? (*If yes, proceed with questions below*)

(If the person is unavailable)

Can you tell me when a good time would be to call back?

I will try calling back on [Date] at [time].

You can also have _____ call me at [your phone number here] . My name is _____.

Thank you.

FOLLOW UP QUESTIONS:

Has any of your contact information changed since we last contacted you?

Have you been able to incorporate the dietary recommendations we assigned to you into your daily diet?

Have you been filling out your breakfast diary regularly?

Are you experiencing any barriers to incorporating the recommendations into your daily diet?

Have you experienced any adverse events as a result of the dietary and health recommendations?

Have you noticed any change in your body weight since your first visit?

Thank you for updating us. (*If this is their third follow up call, schedule their final clinic visit.*)

We will speak next on [Date] at [time], and please feel free to contact us if you have any questions or concerns.



Hand-Scored Answer Sheet

Leonard R. Derogatis, PhD

ADMINISTRATOR:

BE SURE THE DEMOGRAPHIC INFORMATION ON PAGE 5 IS COMPLETED.

AFTER THE QUESTIONNAIRE IS COMPLETED, DETACH PAGES 1 THROUGH 4 BY CAREFULLY TEARING ALONG THE PERFORATED LINE. THEN DISCARD PAGES 1 THROUGH 4 AS YOU WOULD OTHER CONFIDENTIAL DOCUMENTS.

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Product Number
51907

Page 1



Leonard R. Derogatis, PhD

FEMALE
Profile for Community Norms

Name _____

ID Number WG0253 Age _____

Date Tested _____

Scored By _____

T	SOM	DEP	ANX	GSI	T
80	-	18+ -	21+ -	19+ -	50+ -
-	-	20 -	-	-	49 -
-	-	-	-	-	47-48 -
-	16-17 -	-	-	-	46 -
75	15 -	-	-	-	-
-	-	-	-	45 -	-
-	-	-	-	40-44 -	75
-	-	-	-	38-39 -	-
-	-	-	15 -	-	-
70	-	14-15 -	-	-	34-35 -
-	-	-	-	-	32-33 -
-	9-10 -	-	-	-	30-31 -
-	-	-	-	-	28-29 -
65	-	10 -	10 -	-	25-27 -
-	-	-	-	-	-
-	-	-	-	21-22 -	65
60	5 -	-	-	-	19-20 -
-	-	5 -	5 -	-	17-18 -
55	-	-	-	-	15 -
-	-	-	-	10-11 -	60
50	-	-	-	-	-
-	-	-	-	-	50 -
45	-	-	-	-	-
40	0 -	0 -	0 -	-	45 -
35	-	-	-	-	40 -
0	-	-	-	0 -	35 -
-	-	-	-	-	30 -

T	SOM	DEP	ANX	GSI	T
Raw Score	_____	_____	_____	_____	_____
T Score	_____	_____	_____	_____	_____

A 0 9 8 7 6 5

Scoring Directions

- If the respondent's age is less than 18, STOP. Do not score the test. The BSI 18 norms cannot be used with individuals younger than 18.
- On the answer sheet, record the value (0-4) of each circled response on the line to the right of each item. These lines are arranged in three columns to correspond to the three BSI 18 scales: (1) Somatization, (2) Depression, and (3) Anxiety. (For example, if the respondent circled the last response for Item 1, you would write 4 [the value of the response] on the line to the right of Item 1.)
- Count the number of values in Column 1, in Column 2, and in Column 3. If any column has fewer than four values, that scale and the GSI are invalid and should not be scored.
- If the respondent did not answer an item, you must calculate an estimated value for that item. First, add up the values (0-4) for all of the items the respondent answered. Divide the result by the number of items the respondent answered. Round this result to the nearest whole number (if the decimal portion is < .5, round down; if it is $\geq .5$, round up). Record this estimated value on the line to the right of each omitted item. For example, if a respondent answered 16 items and the total value of her responses was 38, the estimated value for each omitted item would be $2 (38 \div 16 = 2.375 = 2)$.
- Add up the values in Column 1 and record the result on the line at the bottom of the column. Do the same for Columns 2 and 3.
- Transfer the totals from Columns 1, 2, and 3 to the Raw Score lines for SOM, DEP, and ANX, respectively, under the profile.
- Add up the raw scores for SOM, DEP, and ANX. Record the result on the GSI Raw Score line.
- Plot the raw scores on the profile. For each raw score, find the corresponding T score along the side of the profile. Record the T score on the appropriate line under the profile.
- Refer to the BSI 18 manual for information about how to interpret these scores.

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PEARSON

PsychCorp

Product Number 51904



Leonard R. Derogatis, PhD

MALE
Profile for Community Norms

Name _____

ID Number _____ Age _____

Date Tested _____

Scored By _____

T	SOM	DEP	ANX	GSI	T
80	18+ -	23+ -	20+ -	53+ -	- 80
-	- 19.21	-	-	50.51 -	-
-	-	-	-	-	-
75	15 -	-	-	44.47 -	- 75
-	-	15 -	15 -	40.43 -	-
-	-	-	-	37.38 -	-
-	-	-	-	33.35 -	-
70	-	-	-	29.31 -	- 70
-	10 -	-	10 -	26.28 -	-
-	-	10 -	-	24.25 -	-
-	-	-	-	22.23 -	-
65	-	-	-	20 -	- 65
-	-	-	-	18.19 -	-
-	-	-	-	16.17 -	-
60	5 -	5 -	5 -	14.15 -	- 60
-	-	-	-	10 -	-
55	-	-	-	-	- 55
-	-	-	-	-	-
50	-	-	-	5 -	- 50
-	-	-	-	-	-
45	-	-	-	-	- 45
40	0 -	0 -	0 -	-	- 40
35	-	-	-	0 -	- 35
0	-	-	-	-	- 30

T	SOM	DEP	ANX	GSI	T
Raw Score	_____	_____	_____	_____	_____
T Score	_____	_____	_____	_____	_____

A 0 9 8 7 6 5

Scoring Directions

- If the respondent's age is less than 18, STOP. Do not score the test. The BSI 18 norms cannot be used with individuals younger than 18.
- On the answer sheet, record the value (0-4) of each circled response on the line to the right of each item. These lines are arranged in three columns to correspond to the three BSI 18 scales: (1) Somatization, (2) Depression, and (3) Anxiety. (For example, if the respondent circled the last response for Item 1, you would write 4 [the value of the response] on the line to the right of Item 1.)
- Count the number of values in Column 1, in Column 2, and in Column 3. If any column has fewer than four values, that scale and the GSI are invalid and should not be scored.
- If the respondent did not answer an item, you must calculate an estimated value for that item. First, add up the values (0-4) for all of the items the respondent answered. Divide the result by the number of items the respondent answered. Round this result to the nearest whole number (if the decimal portion is < .5, round down; if it is ≥ .5, round up). Record this estimated value on the line to the right of each omitted item. For example, if a respondent answered 16 items and the total value of her responses was 38, the estimated value for each omitted item would be 2 ($38 \div 16 = 2.375 = 2$).
- Add up the values in Column 1 and record the result on the line at the bottom of the column. Do the same for Columns 2 and 3.
- Transfer the totals from Columns 1, 2, and 3 to the Raw Score lines for SOM, DEP, and ANX, respectively, under the profile.
- Add up the raw scores for SOM, DEP, and ANX. Record the result on the GSI Raw Score line.
- Plot the raw scores on the profile. For each raw score, find the corresponding T score along the side of the profile. Record the T score on the appropriate line under the profile.
- Refer to the BSI 18 manual for information about how to interpret these scores.

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PEARSON

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Product Number 51904

0 = Not at all 1 = A little bit 2 = Moderately 3 = Quite a bit 4 = Extremely

HOW MUCH WERE YOU DISTRESSED BY:

	NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMELY
1. Faintness or dizziness	0	1	2	3	4
2. Feeling no interest in things	0	1	2	3	4
3. Nervousness or shakiness inside	0	1	2	3	4
4. Pains in heart or chest	0	1	2	3	4
5. Feeling lonely	0	1	2	3	4
6. Feeling tense or keyed up	0	1	2	3	4
7. Nausea or upset stomach	0	1	2	3	4
8. Feeling blue	0	1	2	3	4
9. Suddenly scared for no reason	0	1	2	3	4
10. Trouble getting your breath	0	1	2	3	4
11. Feelings of worthlessness	0	1	2	3	4
12. Spells of terror or panic	0	1	2	3	4
13. Numbness or tingling in parts of your body	0	1	2	3	4
14. Feeling hopeless about the future	0	1	2	3	4
15. Feeling so restless you couldn't sit still	0	1	2	3	4
16. Feeling weak in parts of your body	0	1	2	3	4
17. Thoughts of ending your life	0	1	2	3	4
18. Feeling fearful	0	1	2	3	4

Turn the page and follow the directions for completing the additional information.

Page 3

Page 5

ID Label

EATING ATTITUDES TEST

Last Name _____

Date

INSTRUCTIONS:

For each numbered statement below, please place an (X) under the column which best applies. Your answers are strictly confidential. Please read and answer each question carefully. Thank you.

- 1) Like eating with other people
 - 2) Prepare foods for others but do not eat what I prepare
 - 3) Become anxious prior to eating
 - 4) Am terrified about being overweight
 - 5) Avoid eating when I'm hungry
 - 6) Find myself preoccupied with food
 - 7) Have gone on eating binges where I feel that I may not be able to stop
 - 8) Cut my food into small pieces
 - 9) Aware of the caloric content of foods that I eat
 - 10) Particularly avoid foods with a high carbohydrate content (e.g. bread, potatoes, rice, etc)
 - 11) Feel bloated after meals
 - 12) Feel that others would prefer if I ate more
 - 13) Vomit after I have eaten
 - 14) Feel extremely guilty after eating
 - 15) Am preoccupied with a desire to be thinner
 - 16) Exercise strenuously to burn off calories
 - 17) Weigh myself several times a day
 - 18) Like my clothes to fit tightly
 - 19) Enjoy eating meat
 - 20) Wake up early in the morning
 - 21) Eat the same foods day after day
 - 22) Think about burning up calories when I exercise
 - 23) Have regular menstrual periods (if applicable)
 - 24) Other people think that I am thin
 - 25) Am preoccupied with the thought of having fat on my body
 - 26) Take longer than others to eat my meals
 - 27) Enjoy eating at restaurants
 - 28) Take laxatives
 - 29) Avoid foods with sugar in them
 - 30) Eat diet foods
 - 31) Feel that food controls my life
 - 32) Display self-control around food
 - 33) Feel that others pressure me to eat
 - 34) Give too much time and thought to food
 - 35) Suffer from constipation
 - 36) Feel uncomfortable after eating sweets
 - 37) Engage in dieting behavior
 - 38) Like my stomach to be empty
 - 39) Enjoy trying rich new foods
 - 40) Have the impulse to vomit after meals

E. Form 1: Telephone Screening

Date: _____	Screening apt:
Interviewer: _____	Date: _____
Status: NE _____ NI _____ E _____	
Time: _____	

What is your full name? _____

What is your address? _____

What is your email address? _____

What is your phone number?

Home: _____ Cell: _____

Work: _____

What is your gender? _____

What is your ethnicity? _____

When is the best time to reach you? _____

Are you between the ages of 20-65? _____

What is your birthdate? _____

What is your height? _____

What is your weight? _____

Compute BMI, must be ≥ 25 , and $\leq 45 \text{ kg/m}^2$

Are you interested in weight loss? _____

Do you start your day by 9:00 a.m. at least 5 days a week? _____

Have you participated in any weight-reduction program, weight-loss diet, or other special diet within the previous 3 months? _____

Have you experienced weight loss or gain of $>5\%$ of body weight in the past 6 months for any reason except post-partum weight loss? _____

Are you currently taking any medication that suppresses or stimulates appetite? _____

Are you currently taking medication that requires eating food in the morning, including non-steroidal anti-inflammatory medications such as baby aspirin or Tylenol? _____

Do you have a history of prior surgical procedure for weight control or liposuction? _____

How many times per week do you currently consume breakfast? _____
Are you a current smoker or quit smoking less than 6 months ago?

Do you have any of the following major diseases:

Active cancer or cancer requiring treatment in the past 2 years (except nonmelanoma skin cancer)? _____

Active or chronic infections (e.g., HIV or TB)? _____

Active cardiovascular disease or event including hospitalization or therapeutic procedures for treatment of heart disease in the past 6 months?

Gastrointestinal disease? _____

Active kidney disease? _____

Lung disease: chronic obstructive airway disease requiring use of oxygen (e.g., emphysema or chronic bronchitis)? _____

Diagnosed diabetes (type 1 or 2) and taking any anti-diabetic medications and/or controlling the disease via dietary manipulations? _____

Uncontrolled psychiatric disease? _____

Are you willing to be randomized to any study group that requires you to either eat breakfast by 10:00 a.m., skip breakfast and not eat until 11:00 a.m., or the control group? _____

Are you currently taking antidepressant, steroid, or thyroid medication?

If yes, has the dosage been stable for at least 6 months?

Do you have a recent or ongoing problem with drug abuse or addiction?

Do you consume more than three alcoholic drinks per day and/or have you had 7 or more alcoholic beverages in a 24-hour period in the last 12 months? _____

The next questions pertain to women only:

Are you currently pregnant or less than 3 months post partum? _____

Are you currently nursing or within 6 weeks of having completed nursing?

Are you anticipating a possible pregnancy during study? _____

Are you willing to report possible or confirmed pregnancies promptly during the course of the trial? _____

Are you willing to take adequate contraceptive measures if potentially fertile? _____

F. Form 2: Screening/Randomization Visit

BSI Questionnaire

Result _____

EAT Questionnaire

Result _____

Pregnancy Test (Females)

Result _____

Height ____ .__ cm

Cm _____

Weight____. __ kg

Kg _____

Informed Consent

Obtained? _____

Pre-Randomization Breakfast Eating
Pattern? (circle one)

Eater / Skipper

Randomization

Study Arm _____

W9

Completed? _____

Study Arm Instructions

Provided/Understood? _____

Give Diary

Yes/No

Patient ID assigned?

Yes/No

G. Form 3: Final Visit Checklist

Weight _____ kg

Diary returned? Yes/No

Payment given? Yes/No

I. BREAKFAST INSTRUCTIONS

Start Your Diet Right Each Day: Eat Breakfast!

Eating breakfast may be important for achieving and maintaining a healthy weight. Get the morning nutrition you need with healthy, nutritious foods that will help you achieve your goals. Use these recommendations:

- Eat a healthy breakfast before 10:00 a.m. every day.
- Keep track of your breakfast habits by circling “yes” if you had breakfast, or “no” if you haven’t had breakfast, everyday.
- Aim for eating a healthy breakfast, such as the examples below:
 - Make instant oatmeal with low-fat milk, and top it with raisins, dried cranberries, and/or walnuts.
 - Layer low-fat plain yogurt with your favorite crunchy cereal and berries.
 - Blend a breakfast smoothie with low fat milk, frozen strawberries and a banana.
 - Top a toaster waffle with low-fat yogurt and peach slices.
 - Spread low-fat cream cheese on a whole-grain bagel. Top with sliced strawberries.
 - Add lean ham and low-fat Swiss cheese to a toasted whole-grain English muffin.

J. NO BREAKFAST INSTRUCTIONS

Start Your Diet Right Each Day: Skip Breakfast!

Skipping breakfast may help in achieving and maintaining a healthy weight. Avoiding extra calories in the morning will help you achieve your goals. Use these recommendations:

- Do not eat any calorie containing food before 11:00 a.m.
- Keep track of your breakfast habits by circling “yes” if you had breakfast, or “no” if you haven’t had breakfast, everyday.
- If you feel hungry or are having trouble skipping breakfast, try these helpful tips:
 - Have a 0-calorie beverage, such as water, diet coke or black coffee.
 - Chew sugar-free gum.
 - Change up your routine to avoid cues and times when you would normally eat breakfast, for example: don’t sit with family while they eat breakfast.

K. CONTROL GROUP INSTRUCTIONS

Start Your Diet Right: Follow USDA Guidelines!

You can make the most of your efforts to achieve and maintain a healthy weight by following tips from the USDA. Read the brochure, and in particular, keep these recommendations in mind:

- To build a healthy plate, make half of it fruits and vegetables, pick low fat dairy products, try to incorporate whole grains, and vary your protein sources.
- To cut back on foods high in fats, sugars and salts, avoid foods like pizza, cakes, and sausages, check food labels for sodium, and choose foods with little or no added sugars.
- To eat the right amount of calories, check your daily calorie allowance on www.ChooseMyPlate.gov and write down what you eat to aim for this number.
- To be physically active, try engaging in activities that you enjoy for at least 10 minutes at a time.

5. DATA MANAGEMENT

A. QUALITY ASSURANCE PROTOCOL

1. Data Entry

- The quality assurance standard for data entry discrepancies will be less than 0.5%. An already entered de-identified electronic copy of data and a de-identified paper copy of data forms (including breakfast diary) will be sent from all study sites to the UAB coordinating site after the screening/randomization visit and after the final visit. A data dictionary and coding instructions are provided.
- From each site, 10% of folders will be selected for data entry checking by the coordinating site. Every data point in the electronic database will be checked for consistency (rounding) and accuracy.
- After the screening/randomization and final visits, the study coordinating site statistician will conduct means testing to check for any outlier data points

2. Data Collection

- Any time data are recorded; ensure data are recorded on actual study form for the correct participant.

B. DATA DICTIONARY

Variable Name	Definition	Coding
ID	Patient ID	University of Alabama at Birmingham 1,000-1,999 Columbia University 2,000-2,999 University of Colorado Denver 3,000-3,999 University of Copenhagen 4,000-4,999 Boston University 5,000-5,999 Johns Hopkins University 6,000-6,999
H_CM	Height in cm, recorded to the nearest 0.1 cm	Exact value
W_KG	Weight in Kg, recorded to the nearest 0.1 kg	Exact value
SEX	Sex of participant	0= Female 1=Male
AGE	Age of participant	Exact value
ETH	Ethnicity of participant	1= Black Hispanic, 2= Black Non-Hispanic, 3= Other, 4= White Hispanic, 5= White Non-Hispanic
DROP	Participant dropped out of study	0= No 1= Yes
DATE_LC	Date of last contact if patient is a dropout in month/date/year format	Month/date/year

GROUP	Study arm participant is assigned to	0= Control 1= Breakfast 2= No Breakfast
TYP_BFCAT	Pre-study breakfast eating habits	1= eats breakfast \geq 4 X/week 0= eats breakfast \leq 3X/week
TYP_BF	Number of times per week breakfast is consumed before study	Exact number, integer 1-7
COMP	Number of days participant complied with breakfast instructions from Diary	Exact number
WT_FINAL	Final weight in kg recorded to the nearest 0.1 kg	

ICPSR 36174

Randomized Controlled Trial of Breakfast Recommendations on Weight: A Multi-Site Effectiveness Trial

Variable Description and Frequencies

Note: Frequencies displayed for the variables are not weighted. They are purely descriptive and may not be representative of the study population. Please review any sampling or weighting information available with the study.

Summary statistics (minimum, maximum, mean, median, and standard deviation) may not be available for every variable in the codebook. Conversely, a listing of frequencies in table format may not be present for every variable in the codebook either. However, all variables in the dataset are present and display sufficient information about each variable. These decisions are made intentionally and are at the discretion of the archive producing this codebook.

SUBJID: SubjID

A four digit ID unique to each subject. The first digit corresponds to site in the following manner: UAB=1, Columbia=2, Colorado=3, Copenhagen=4, Boston=5.

Value	Label	Unweighted Frequency	%
1000	-	1	0.4 %
1001	-	1	0.4 %
1002	-	1	0.4 %
1003	-	1	0.4 %
1004	-	1	0.4 %
1005	-	1	0.4 %
1007	-	1	0.4 %
1008	-	1	0.4 %
1009	-	1	0.4 %
1010	-	1	0.4 %
1011	-	1	0.4 %
1012	-	1	0.4 %
1013	-	1	0.4 %
1014	-	1	0.4 %
1015	-	1	0.4 %
1017	-	1	0.4 %
1018	-	1	0.4 %
1019	-	1	0.4 %
1020	-	1	0.4 %
1021	-	1	0.4 %
1022	-	1	0.4 %
1023	-	1	0.4 %
1024	-	1	0.4 %
1026	-	1	0.4 %
1027	-	1	0.4 %
1029	-	1	0.4 %
1030	-	1	0.4 %
1031	-	1	0.4 %
1032	-	1	0.4 %
1033	-	1	0.4 %
1035	-	1	0.4 %
1037	-	1	0.4 %
1038	-	1	0.4 %
1039	-	1	0.4 %
1040	-	1	0.4 %

Value	Label	Unweighted Frequency	%
1041	-	1	0.4 %
1044	-	1	0.4 %
1045	-	1	0.4 %
1046	-	1	0.4 %
1048	-	1	0.4 %
1049	-	1	0.4 %
1050	-	1	0.4 %
1051	-	1	0.4 %
1052	-	1	0.4 %
1053	-	1	0.4 %
1054	-	1	0.4 %
1055	-	1	0.4 %
1056	-	1	0.4 %
1057	-	1	0.4 %
1059	-	1	0.4 %
Total		255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 255 valid cases out of 255 total cases.

- Mean: 2840.38
- Median: 2412.00
- Minimum: 1000.00
- Maximum: 5145.00
- Standard Deviation: 1564.72

Location: 1-4 (width: 4; decimal: 0)

Variable Type: numeric

H_CM: H_CM

Height of the subject, in cm.

Value	Label	Unweighted Frequency	%
144.80	-	1	0.4 %
145.00	-	1	0.4 %
148.50	-	1	0.4 %
149.00	-	1	0.4 %
149.70	-	1	0.4 %
150.70	-	1	0.4 %
153.50	-	1	0.4 %
154.00	-	2	0.8 %

Value	Label	Unweighted Frequency	%
154.40	-	1	0.4 %
154.90	-	1	0.4 %
155.00	-	3	1.2 %
155.50	-	3	1.2 %
155.67	-	1	0.4 %
156.00	-	1	0.4 %
156.20	-	2	0.8 %
156.70	-	1	0.4 %
156.90	-	1	0.4 %
157.00	-	4	1.6 %
157.20	-	1	0.4 %
157.48	-	1	0.4 %
157.50	-	4	1.6 %
157.70	-	1	0.4 %
157.90	-	1	0.4 %
158.00	-	3	1.2 %
158.10	-	3	1.2 %
158.50	-	3	1.2 %
158.70	-	1	0.4 %
159.00	-	4	1.6 %
159.30	-	1	0.4 %
159.40	-	1	0.4 %
159.50	-	1	0.4 %
159.60	-	1	0.4 %
159.90	-	2	0.8 %
160.00	-	6	2.4 %
160.20	-	1	0.4 %
160.40	-	1	0.4 %
160.60	-	2	0.8 %
160.70	-	1	0.4 %
161.00	-	1	0.4 %
161.50	-	2	0.8 %
161.70	-	1	0.4 %
161.90	-	3	1.2 %
162.00	-	9	3.5 %
162.10	-	1	0.4 %
162.30	-	2	0.8 %
162.40	-	1	0.4 %
162.50	-	2	0.8 %

Value	Label	Unweighted Frequency	%
162.56	-	1	0.4 %
162.60	-	4	1.6 %
163.00	-	2	0.8 %
Total		255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 255 valid cases out of 255 total cases.

- Mean: 166.98
- Median: 166.10
- Mode: 162.00
- Minimum: 144.80
- Maximum: 197.00
- Standard Deviation: 8.77

Location: 5-10 (width: 6; decimal: 2)

Variable Type: numeric

W_KG: W_KG

Weight of the subject, in kg.

Value	Label	Unweighted Frequency	%
58.70	-	1	0.4 %
61.50	-	1	0.4 %
62.70	-	1	0.4 %
62.90	-	1	0.4 %
63.10	-	1	0.4 %
65.30	-	1	0.4 %
65.90	-	1	0.4 %
66.00	-	2	0.8 %
66.20	-	1	0.4 %
66.70	-	1	0.4 %
67.10	-	1	0.4 %
68.00	-	1	0.4 %
68.30	-	1	0.4 %
68.50	-	2	0.8 %
68.80	-	1	0.4 %
69.00	-	1	0.4 %
69.10	-	1	0.4 %
69.40	-	1	0.4 %
69.50	-	1	0.4 %
70.70	-	1	0.4 %

Value	Label	Unweighted Frequency	%
71.70	-	1	0.4 %
71.80	-	1	0.4 %
71.90	-	1	0.4 %
72.30	-	2	0.8 %
72.60	-	2	0.8 %
72.70	-	1	0.4 %
73.30	-	1	0.4 %
73.70	-	1	0.4 %
73.80	-	1	0.4 %
74.00	-	1	0.4 %
74.10	-	1	0.4 %
74.40	-	2	0.8 %
74.80	-	2	0.8 %
74.90	-	1	0.4 %
75.10	-	1	0.4 %
75.20	-	1	0.4 %
75.60	-	1	0.4 %
75.70	-	1	0.4 %
75.80	-	1	0.4 %
75.90	-	1	0.4 %
76.00	-	2	0.8 %
76.10	-	1	0.4 %
76.20	-	1	0.4 %
76.30	-	1	0.4 %
76.40	-	2	0.8 %
76.60	-	1	0.4 %
76.70	-	2	0.8 %
77.30	-	2	0.8 %
77.60	-	1	0.4 %
78.00	-	1	0.4 %
Total		255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 255 valid cases out of 255 total cases.

- Mean: 91.13
- Median: 89.40
- Minimum: 58.70
- Maximum: 136.80
- Standard Deviation: 16.04

Location: 11-16 (width: 6; decimal: 2)

Variable Type: numeric

SEX: SEX

Sex of the subject

Value	Label	Unweighted Frequency	%
0	Female	192	75.3 %
1	Male	63	24.7 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 17-17 (width: 1; decimal: 0)

Variable Type: numeric

AGE: AGE

Age of the subject, in years

Value	Label	Unweighted Frequency	%
20	-	1	0.4 %
21	-	2	0.8 %
22	-	10	3.9 %
23	-	4	1.6 %
24	-	5	2.0 %
25	-	6	2.4 %
26	-	7	2.7 %
27	-	6	2.4 %
28	-	9	3.5 %
29	-	6	2.4 %
30	-	9	3.5 %
31	-	9	3.5 %
32	-	5	2.0 %
33	-	5	2.0 %
34	-	7	2.7 %
35	-	11	4.3 %
36	-	6	2.4 %
37	-	8	3.1 %
38	-	6	2.4 %
39	-	3	1.2 %
40	-	6	2.4 %

Value	Label	Unweighted Frequency	%
41	-	8	3.1 %
42	-	9	3.5 %
43	-	6	2.4 %
44	-	8	3.1 %
45	-	4	1.6 %
46	-	6	2.4 %
47	-	6	2.4 %
48	-	7	2.7 %
49	-	10	3.9 %
50	-	4	1.6 %
51	-	4	1.6 %
52	-	8	3.1 %
53	-	5	2.0 %
54	-	3	1.2 %
55	-	3	1.2 %
56	-	3	1.2 %
57	-	5	2.0 %
58	-	8	3.1 %
59	-	2	0.8 %
60	-	5	2.0 %
61	-	2	0.8 %
62	-	2	0.8 %
63	-	2	0.8 %
64	-	3	1.2 %
65	-	1	0.4 %
Total		255	100%

Based upon 255 valid cases out of 255 total cases.

- Mean: 40.25
- Median: 40.00
- Mode: 35.00
- Minimum: 20.00
- Maximum: 65.00
- Standard Deviation: 11.65

Location: 18-19 (*width:* 2; *decimal:* 0)

Variable Type: numeric

ETH: ETH

Race/ethnicity of the subject

Value	Label	Unweighted Frequency	%
1	Black Hispanic	10	3.9 %
2	Black Non-Hispanic	106	41.6 %
3	Other	20	7.8 %
4	White Hispanic	22	8.6 %
5	White Non-Hispanic	97	38.0 %
Total		255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 1.00
- Maximum: 5.00

Location: 20-20 (width: 1; decimal: 0)

Variable Type: numeric

DROP: DROP

Did the subject drop out of the study?

Value	Label	Unweighted Frequency	%
0	No	230	90.2 %
1	Yes	25	9.8 %
Total		255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 21-21 (width: 1; decimal: 0)

Variable Type: numeric

DATE_LC: DATE_LC

Date of last contact. NOTE: This was supposed to be recorded in MM/DD/YYYY format for dropouts only and left blank otherwise. However, some sites used N/A instead of a blank, some sites listed a last contact date for all their individuals, and some sites used Day-Mon format.

Value	Label	Unweighted Frequency	%
-	-	218	85.5 %
06-MAY-2013	-	1	0.4 %
07-JAN-2013	-	1	0.4 %
08-AUG-2013	-	1	0.4 %
08-JUL-2013	-	2	0.8 %
09-APR-2013	-	1	0.4 %
09-NOV-2013	-	1	0.4 %
09-OCT-2013	-	3	1.2 %

Value	Label	Unweighted Frequency	%
09-SEP-2013	-	1	0.4 %
10-APR-2013	-	2	0.8 %
10-AUG-2013	-	1	0.4 %
10-FEB-2013	-	1	0.4 %
10-JAN-2013	-	4	1.6 %
10-JUL-2013	-	2	0.8 %
10-MAR-2013	-	3	1.2 %
10-OCT-2013	-	2	0.8 %
10-SEP-2013	-	2	0.8 %
11-AUG-2013	-	1	0.4 %
11-DEC-2013	-	2	0.8 %
11-JAN-2013	-	1	0.4 %
11-JUL-2013	-	1	0.4 %
11-NOV-2013	-	1	0.4 %
12-FEB-2013	-	1	0.4 %
12-MAR-2013	-	1	0.4 %
12-MAY-2013	-	1	0.4 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

Location: 22-32 (width: 11; decimal: 0)

Variable Type: character

GROUP: GROUP

The treatment assignment for the subject. NOTE: This variable is blinded, as opposed to ASSIGNUB

Value	Label	Unweighted Frequency	%
0	General recommendation	87	34.1 %
1	Randomized to eat breakfast	83	32.5 %
2	Randomized to not eat breakfast	85	33.3 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 2.00

Location: 33-33 (width: 1; decimal: 0)

Variable Type: numeric

TYPE_BFCAT: TYPE_BFCAT

The reported initial status of the subject, with respect to breakfast eating. NOTE: This variable is blinded, as opposed to INITUB

Value	Label	Unweighted Frequency	%
0	Ate breakfast 3 or less times per week	120	47.1 %
1	Ate breakfast 4 or more times per week	135	52.9 %
Total		255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 34-34 (width: 1; decimal: 0)

Variable Type: numeric

TYP_BF: TYP_BF

How many times a week did the subject report typically eating breakfast prior to inclusion in the study? NOTE: This variable was used to create TYPE_BFCAT

Value	Label	Unweighted Frequency	%
0	-	16	6.3 %
1	-	28	11.0 %
2	-	31	12.2 %
3	-	38	14.9 %
4	-	27	10.6 %
5	-	28	11.0 %
6	-	10	3.9 %
7	-	70	27.5 %
Missing Data			
.	-	7	2.7 %
Total		255	100%

Based upon 248 valid cases out of 255 total cases.

- Mean: 4.04
- Median: 4.00
- Mode: 7.00
- Minimum: 0.00
- Maximum: 7.00
- Standard Deviation: 2.35

Location: 35-35 (width: 1; decimal: 0)

Variable Type: numeric

COMP_Y: COMP_Y

How many times did the subject circle a day in their compliance diary? NOTE: A value of -999 is recorded if the subject was assigned to the control group.

Value	Label	Unweighted Frequency	%
-999	-	87	34.1 %
0	-	16	6.3 %
1	-	1	0.4 %
2	-	5	2.0 %
3	-	3	1.2 %
4	-	1	0.4 %
5	-	4	1.6 %
6	-	5	2.0 %
7	-	2	0.8 %
8	-	2	0.8 %
9	-	4	1.6 %
15	-	1	0.4 %
17	-	1	0.4 %
18	-	1	0.4 %
23	-	1	0.4 %
25	-	2	0.8 %
26	-	1	0.4 %
31	-	1	0.4 %
41	-	1	0.4 %
53	-	1	0.4 %
57	-	1	0.4 %
58	-	1	0.4 %
70	-	1	0.4 %
74	-	1	0.4 %
76	-	1	0.4 %
83	-	1	0.4 %
84	-	1	0.4 %
87	-	1	0.4 %
89	-	1	0.4 %
91	-	1	0.4 %
92	-	1	0.4 %
94	-	2	0.8 %
95	-	1	0.4 %
96	-	2	0.8 %
97	-	3	1.2 %
99	-	2	0.8 %
100	-	2	0.8 %
101	-	3	1.2 %
103	-	3	1.2 %

Value	Label	Unweighted Frequency	%
104	-	6	2.4 %
105	-	1	0.4 %
106	-	4	1.6 %
107	-	2	0.8 %
108	-	1	0.4 %
109	-	5	2.0 %
110	-	4	1.6 %
111	-	2	0.8 %
112	-	6	2.4 %
113	-	2	0.8 %
114	-	5	2.0 %
Missing Data			
.	-	36	14.1 %
Total		255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 219 valid cases out of 255 total cases.

- Mean: -357.60
- Median: 3.00
- Mode: -999.00
- Minimum: -999.00
- Maximum: 119.00
- Standard Deviation: 523.27

Location: 36-39 (width: 4; decimal: 0)

Variable Type: numeric

COMP_N: COMP_N

How many times did the subject not circle a day in their compliance diary? NOTE: A value of -999 is recorded if the subject was assigned to the control group. The circled days recorded by the subjects unfortunately meant different things, depending on the instructions given at their site and sometimes the whim of the subject. Variables TRUE_Y and TRUE_N (#14 and #15) record our best effort to faithfully match diary contents with reported days in and out of compliance, respectively, as reported by the subjects and sites. However, these still feature some subjects where either a) extremely noncompliant yet extremely honest about it or b) the intention indication is not correct. #14 and #15 assume the former; variables TRUE_Y_forced and TRUE_N_forced (#16 and #17) assume the latter and make corrections for those entries.

Value	Label	Unweighted Frequency	%
-999	-	87	34.1 %
0	-	23	9.0 %
1	-	2	0.8 %
2	-	4	1.6 %
3	-	9	3.5 %

Value	Label	Unweighted Frequency	%
4	-	3	1.2 %
5	-	5	2.0 %
6	-	3	1.2 %
7	-	1	0.4 %
8	-	2	0.8 %
10	-	2	0.8 %
11	-	1	0.4 %
13	-	2	0.8 %
14	-	1	0.4 %
15	-	3	1.2 %
16	-	3	1.2 %
17	-	4	1.6 %
19	-	1	0.4 %
20	-	1	0.4 %
21	-	1	0.4 %
22	-	2	0.8 %
25	-	1	0.4 %
28	-	2	0.8 %
30	-	1	0.4 %
42	-	2	0.8 %
54	-	1	0.4 %
78	-	1	0.4 %
86	-	1	0.4 %
87	-	1	0.4 %
88	-	1	0.4 %
91	-	1	0.4 %
95	-	1	0.4 %
96	-	2	0.8 %
100	-	1	0.4 %
101	-	1	0.4 %
102	-	1	0.4 %
103	-	1	0.4 %
104	-	4	1.6 %
105	-	2	0.8 %
106	-	1	0.4 %
107	-	1	0.4 %
108	-	4	1.6 %
109	-	2	0.8 %
110	-	3	1.2 %

Value	Label	Unweighted Frequency	%
111	-	2	0.8 %
112	-	2	0.8 %
113	-	2	0.8 %
114	-	1	0.4 %
115	-	3	1.2 %
116	-	4	1.6 %
Missing Data			
.	-	36	14.1 %
Total		255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 219 valid cases out of 255 total cases.

- Mean: -368.07
- Median: 0.00
- Mode: -999.00
- Minimum: -999.00
- Maximum: 120.00
- Standard Deviation: 514.83

Location: 40-43 (width: 4; decimal: 0)

Variable Type: numeric

TRUE_Y: TRUE_Y

How many times did the subject indicate that they were in compliance in their compliance diary? NOTE: A value of -999 is recorded if the subject was assigned to the control group. There are missing values.

Value	Label	Unweighted Frequency	%
-999	-	87	34.1 %
0	-	7	2.7 %
1	-	2	0.8 %
2	-	1	0.4 %
3	-	1	0.4 %
5	-	2	0.8 %
6	-	2	0.8 %
8	-	1	0.4 %
9	-	1	0.4 %
13	-	1	0.4 %
14	-	1	0.4 %
22	-	1	0.4 %
42	-	1	0.4 %
54	-	1	0.4 %

Value	Label	Unweighted Frequency	%
58	-	1	0.4 %
70	-	1	0.4 %
74	-	1	0.4 %
76	-	1	0.4 %
78	-	1	0.4 %
83	-	1	0.4 %
84	-	1	0.4 %
86	-	1	0.4 %
87	-	2	0.8 %
88	-	1	0.4 %
89	-	1	0.4 %
91	-	1	0.4 %
92	-	1	0.4 %
94	-	2	0.8 %
95	-	2	0.8 %
96	-	4	1.6 %
97	-	3	1.2 %
99	-	1	0.4 %
100	-	3	1.2 %
101	-	3	1.2 %
103	-	3	1.2 %
104	-	8	3.1 %
105	-	3	1.2 %
106	-	4	1.6 %
107	-	3	1.2 %
108	-	4	1.6 %
109	-	6	2.4 %
110	-	5	2.0 %
111	-	4	1.6 %
112	-	8	3.1 %
113	-	3	1.2 %
114	-	4	1.6 %
115	-	5	2.0 %
116	-	6	2.4 %
117	-	3	1.2 %
119	-	9	3.5 %
Missing Data			
.	-	36	14.1 %
Total		255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 219 valid cases out of 255 total cases.

- Mean: -343.19
- Median: 58.00
- Mode: -999.00
- Minimum: -999.00
- Maximum: 119.00
- Standard Deviation: 534.45

Location: 44-47 (width: 4; decimal: 0)

Variable Type: numeric

TRUE_N: TRUE_N

How many times did the subject indicate that they were not in compliance in their compliance diary? NOTE: A value of -999 is recorded if the subject was assigned to the control group. There are missing values.

Value	Label	Unweighted Frequency	%
-999	-	87	34.1 %
0	-	32	12.5 %
1	-	1	0.4 %
2	-	8	3.1 %
3	-	11	4.3 %
4	-	4	1.6 %
5	-	7	2.7 %
6	-	6	2.4 %
7	-	3	1.2 %
8	-	3	1.2 %
9	-	3	1.2 %
10	-	2	0.8 %
11	-	1	0.4 %
13	-	1	0.4 %
15	-	4	1.6 %
16	-	3	1.2 %
17	-	5	2.0 %
18	-	1	0.4 %
19	-	1	0.4 %
20	-	1	0.4 %
21	-	1	0.4 %
22	-	1	0.4 %
23	-	1	0.4 %
25	-	3	1.2 %
26	-	1	0.4 %

Value	Label	Unweighted Frequency	%
28	-	2	0.8 %
30	-	1	0.4 %
31	-	1	0.4 %
41	-	1	0.4 %
42	-	1	0.4 %
53	-	1	0.4 %
57	-	1	0.4 %
91	-	1	0.4 %
99	-	1	0.4 %
101	-	1	0.4 %
102	-	1	0.4 %
103	-	1	0.4 %
104	-	2	0.8 %
106	-	1	0.4 %
108	-	1	0.4 %
109	-	1	0.4 %
110	-	2	0.8 %
113	-	1	0.4 %
114	-	2	0.8 %
115	-	2	0.8 %
116	-	2	0.8 %
120	-	1	0.4 %
Missing Data			
.	-	36	14.1 %
Total		255	100%

Based upon 219 valid cases out of 255 total cases.

- Mean: -382.48
- Median: 0.00
- Mode: -999.00
- Minimum: -999.00
- Maximum: 120.00
- Standard Deviation: 502.51

Location: 48-51 (*width:* 4; *decimal:* 0)

Variable Type: numeric

TRUE_Y_FORCED: TRUE_Y_forced

How many times did the subject indicate that they were in compliance in their compliance diary? NOTE: A value of -999 is recorded if the subject was assigned to the control group. There are missing values.

Value	Label	Unweighted Frequency	%
-999	-	87	34.1 %
42	-	1	0.4 %
54	-	1	0.4 %
58	-	1	0.4 %
70	-	1	0.4 %
74	-	1	0.4 %
76	-	1	0.4 %
78	-	1	0.4 %
83	-	1	0.4 %
84	-	1	0.4 %
86	-	1	0.4 %
87	-	2	0.8 %
88	-	1	0.4 %
89	-	1	0.4 %
91	-	2	0.8 %
92	-	1	0.4 %
94	-	2	0.8 %
95	-	2	0.8 %
96	-	4	1.6 %
97	-	3	1.2 %
99	-	2	0.8 %
100	-	3	1.2 %
101	-	4	1.6 %
102	-	1	0.4 %
103	-	4	1.6 %
104	-	10	3.9 %
105	-	3	1.2 %
106	-	5	2.0 %
107	-	3	1.2 %
108	-	5	2.0 %
109	-	7	2.7 %
110	-	7	2.7 %
111	-	4	1.6 %
112	-	8	3.1 %
113	-	4	1.6 %
114	-	6	2.4 %
115	-	7	2.7 %
116	-	8	3.1 %
117	-	3	1.2 %

Value	Label	Unweighted Frequency	%
119	-	9	3.5 %
120	-	1	0.4 %
	Missing Data		
.	-	36	14.1 %
	Total	255	100%

Based upon 219 valid cases out of 255 total cases.

- Mean: -333.72
- Median: 96.00
- Mode: -999.00
- Minimum: -999.00
- Maximum: 120.00
- Standard Deviation: 541.44

Location: 52-55 (width: 4; decimal: 0)

Variable Type: numeric

TRUE_N_FORCED: TRUE_N_forced

How many times did the subject indicate that they were not in compliance in their compliance diary? NOTE: A value of -999 is recorded if the subject was assigned to the control group. There are missing values.

Value	Label	Unweighted Frequency	%
-999	-	87	34.1 %
0	-	39	15.3 %
1	-	3	1.2 %
2	-	9	3.5 %
3	-	12	4.7 %
4	-	4	1.6 %
5	-	9	3.5 %
6	-	8	3.1 %
7	-	3	1.2 %
8	-	4	1.6 %
9	-	4	1.6 %
10	-	2	0.8 %
11	-	1	0.4 %
13	-	2	0.8 %
14	-	1	0.4 %
15	-	4	1.6 %
16	-	3	1.2 %
17	-	5	2.0 %
18	-	1	0.4 %
19	-	1	0.4 %

Value	Label	Unweighted Frequency	%
20	-	1	0.4 %
21	-	1	0.4 %
22	-	2	0.8 %
23	-	1	0.4 %
25	-	3	1.2 %
26	-	1	0.4 %
28	-	2	0.8 %
30	-	1	0.4 %
31	-	1	0.4 %
41	-	1	0.4 %
42	-	1	0.4 %
53	-	1	0.4 %
57	-	1	0.4 %
Missing Data			
.	-	36	14.1 %
Total		255	100%

Based upon 219 valid cases out of 255 total cases.

- Mean: -391.95
- Median: 0.00
- Mode: -999.00
- Minimum: -999.00
- Maximum: 57.00
- Standard Deviation: 494.03

Location: 56-59 (width: 4; decimal: 0)

Variable Type: numeric

COMPLI: compli

For what proportion of days was a subject in compliance during the study, according to TRUE_Y and TRUE_N? NOTE: A value of -999 is recorded if the subject was assigned to the control group. There are missing values.

Value	Label	Unweighted Frequency	%
-999.0000000000	-	87	34.1 %
0.0000000000	-	7	2.7 %
0.0090909091	-	1	0.4 %
0.0091743119	-	1	0.4 %
0.0170940171	-	1	0.4 %
0.0254237288	-	1	0.4 %
0.0458715596	-	1	0.4 %
0.0462962963	-	1	0.4 %
0.0517241379	-	1	0.4 %

Value	Label	Unweighted Frequency	%
0.0535714286	-	1	0.4 %
0.0727272727	-	1	0.4 %
0.0818181818	-	1	0.4 %
0.1160714286	-	1	0.4 %
0.1186440678	-	1	0.4 %
0.1946902655	-	1	0.4 %
0.4421052632	-	1	0.4 %
0.4864864865	-	1	0.4 %
0.6250000000	-	1	0.4 %
0.6554621849	-	1	0.4 %
0.7307692308	-	1	0.4 %
0.7345132743	-	1	0.4 %
0.7394957983	-	1	0.4 %
0.7500000000	-	1	0.4 %
0.7733333333	-	1	0.4 %
0.7747747748	-	1	0.4 %
0.7767857143	-	1	0.4 %
0.7777777778	-	1	0.4 %
0.7899159664	-	1	0.4 %
0.8050847458	-	1	0.4 %
0.8090909091	-	1	0.4 %
0.8151260504	-	1	0.4 %
0.8245614035	-	1	0.4 %
0.8362068966	-	1	0.4 %
0.8421052632	-	1	0.4 %
0.8440366972	-	1	0.4 %
0.8482142857	-	1	0.4 %
0.8495575221	-	2	0.8 %
0.8620689655	-	1	0.4 %
0.8648648649	-	1	0.4 %
0.8655462185	-	2	0.8 %
0.8695652174	-	1	0.4 %
0.8739495798	-	2	0.8 %
0.8818181818	-	1	0.4 %
0.9043478261	-	1	0.4 %
0.9137931034	-	1	0.4 %
0.9157894737	-	1	0.4 %
0.9159663866	-	1	0.4 %
0.9203539823	-	1	0.4 %

Value	Label	Unweighted Frequency	%
0.9230769231	-	1	0.4 %
0.9243697479	-	1	0.4 %
	Missing Data		
.	-	36	14.1 %
	Total	255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 219 valid cases out of 255 total cases.

- Mean: -396.3878675383
- Median: 0.6250000000
- Mode: -999.0000000000
- Minimum: -999.0000000000
- Maximum: 1.0000000000
- Standard Deviation: 490.3479929437

Location: 60-74 (width: 15; decimal: 10)

Variable Type: numeric

COMPLI_FORCED: compli_forced

For what proportion of days was a subject in compliance during the study, according to TRUE_Y_forced and TRUE_N_forced?

NOTE: A value of -999 is recorded if the subject was assigned to the control group. There are missing values.

Value	Label	Unweighted Frequency	%
-999.0000000000	-	87	34.1 %
0.4421052632	-	1	0.4 %
0.4864864865	-	1	0.4 %
0.6250000000	-	1	0.4 %
0.6554621849	-	1	0.4 %
0.7307692308	-	1	0.4 %
0.7345132743	-	1	0.4 %
0.7394957983	-	1	0.4 %
0.7500000000	-	1	0.4 %
0.7733333333	-	1	0.4 %
0.7747747748	-	1	0.4 %
0.7767857143	-	1	0.4 %
0.7777777778	-	1	0.4 %
0.7899159664	-	1	0.4 %
0.8050847458	-	1	0.4 %
0.8053097345	-	1	0.4 %
0.8090909091	-	1	0.4 %

Value	Label	Unweighted Frequency	%
0.8151260504	-	1	0.4 %
0.8245614035	-	1	0.4 %
0.8362068966	-	1	0.4 %
0.8421052632	-	1	0.4 %
0.8440366972	-	1	0.4 %
0.8482142857	-	1	0.4 %
0.8495575221	-	2	0.8 %
0.8620689655	-	1	0.4 %
0.8648648649	-	1	0.4 %
0.8655462185	-	2	0.8 %
0.8695652174	-	1	0.4 %
0.8739495798	-	2	0.8 %
0.8813559322	-	1	0.4 %
0.8818181818	-	1	0.4 %
0.8839285714	-	1	0.4 %
0.9043478261	-	1	0.4 %
0.9137931034	-	1	0.4 %
0.9157894737	-	1	0.4 %
0.9159663866	-	1	0.4 %
0.9181818182	-	1	0.4 %
0.9203539823	-	1	0.4 %
0.9230769231	-	1	0.4 %
0.9243697479	-	1	0.4 %
0.9272727273	-	1	0.4 %
0.9285714286	-	1	0.4 %
0.9316239316	-	1	0.4 %
0.9351851852	-	1	0.4 %
0.9375000000	-	1	0.4 %
0.9391304348	-	1	0.4 %
0.9428571429	-	1	0.4 %
0.9439252336	-	1	0.4 %
0.9454545455	-	2	0.8 %
0.9464285714	-	1	0.4 %
	Missing Data		
.	-	36	14.1 %
	Total	255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 219 valid cases out of 255 total cases.

- Mean: -396.3042346398
- Median: 0.8495575221
- Mode: -999.00000000000
- Minimum: -999.00000000000
- Maximum: 1.00000000000
- Standard Deviation: 490.4159840837

Location: 75-89 (width: 15; decimal: 10)

Variable Type: numeric

CHG_BF_CON: CHG_BF_CON

Did the subject report changing their breakfast eating habits after randomization to an assignment? NOTE: This variable was only collected from the control group. Subjects not in the control group are recorded as -1. There are missing values. Note that this is reported and thus there are issues resolving this report with the values recorded for TYP_BF (#11) and FREQ_CHG (#21).

Value	Label	Unweighted Frequency	%
-1	-	168	65.9 %
0	No	64	25.1 %
1	Yes	15	5.9 %
Missing Data			
.	-	8	3.1 %
Total			255 100%

Based upon 247 valid cases out of 255 total cases.

- Minimum: -1.00
- Maximum: 1.00

Location: 90-91 (width: 2; decimal: 0)

Variable Type: numeric

FREQ_CHG: FREQ_CHG

How many times a week did the subject report eating breakfast during the course of the study? NOTE: Ranges from 0 to 7. This variable was only collected from the control group. Subjects not in the control group are recorded as -1. There are missing values.

Value	Label	Unweighted Frequency	%
-1	-	168	65.9 %
0	-	6	2.4 %
1	-	6	2.4 %
2	-	4	1.6 %
3	-	14	5.5 %
4	-	11	4.3 %
5	-	10	3.9 %
6	-	3	1.2 %
7	-	25	9.8 %

Value	Label	Unweighted Frequency	%
	Missing Data		
.	-	8	3.1 %
	Total	255	100%

Based upon 247 valid cases out of 255 total cases.

- Mean: 0.71
- Median: -1.00
- Mode: -1.00
- Minimum: -1.00
- Maximum: 7.00
- Standard Deviation: 2.82

Location: 92-93 (width: 2; decimal: 0)

Variable Type: numeric

DATE_RAN: DATE_RAN

Date of randomization.

Value	Label	Unweighted Frequency	%
	-	1	0.4 %
01-AUG-2013	-	1	0.4 %
01-FEB-2013	-	5	2.0 %
01-JUL-2013	-	3	1.2 %
02-AUG-2013	-	5	2.0 %
02-JUL-2013	-	4	1.6 %
03-JUL-2013	-	1	0.4 %
03-JUN-2013	-	2	0.8 %
03-SEP-2013	-	1	0.4 %
04-APR-2013	-	2	0.8 %
04-FEB-2013	-	1	0.4 %
04-JUN-2013	-	3	1.2 %
04-SEP-2013	-	1	0.4 %
05-APR-2013	-	3	1.2 %
05-AUG-2013	-	1	0.4 %
05-JUN-2013	-	1	0.4 %
05-MAR-2013	-	2	0.8 %
05-SEP-2013	-	1	0.4 %
06-FEB-2013	-	9	3.5 %
06-JUN-2013	-	7	2.7 %
06-MAR-2013	-	4	1.6 %
06-MAY-2013	-	1	0.4 %
07-AUG-2013	-	8	3.1 %

Value	Label	Unweighted Frequency	%
07-JUN-2013	-	2	0.8 %
08-APR-2013	-	2	0.8 %
08-MAR-2013	-	2	0.8 %
08-MAY-2013	-	1	0.4 %
09-APR-2013	-	2	0.8 %
09-AUG-2013	-	1	0.4 %
10-JUL-2013	-	3	1.2 %
10-JUN-2013	-	3	1.2 %
11-APR-2013	-	1	0.4 %
11-FEB-2013	-	1	0.4 %
11-JUL-2013	-	2	0.8 %
11-JUN-2013	-	5	2.0 %
11-MAR-2013	-	1	0.4 %
12-AUG-2013	-	1	0.4 %
12-JUL-2013	-	1	0.4 %
12-JUN-2013	-	3	1.2 %
12-MAR-2013	-	1	0.4 %
13-AUG-2013	-	3	1.2 %
13-FEB-2013	-	6	2.4 %
13-JUN-2013	-	3	1.2 %
13-MAR-2013	-	1	0.4 %
14-AUG-2013	-	3	1.2 %
14-FEB-2013	-	2	0.8 %
14-JUN-2013	-	1	0.4 %
14-MAR-2013	-	5	2.0 %
14-MAY-2013	-	1	0.4 %
15-AUG-2013	-	1	0.4 %
	Total	255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 255 valid cases out of 255 total cases.

Location: 94-104 (width: 11; decimal: 0)

Variable Type: character

DATE_C1: DATE_C1

Date of first follow-up contact (four weeks post-randomization)

Value	Label	Unweighted Frequency	%
-		15	5.9 %

Value	Label	Unweighted Frequency	%
01-APR-2013	-	2	0.8 %
01-JUL-2013	-	4	1.6 %
01-OCT-2013	-	1	0.4 %
02-APR-2013	-	2	0.8 %
02-AUG-2013	-	1	0.4 %
02-JUL-2013	-	5	2.0 %
02-MAY-2013	-	1	0.4 %
02-SEP-2013	-	3	1.2 %
03-APR-2013	-	1	0.4 %
03-JUL-2013	-	3	1.2 %
03-MAY-2013	-	1	0.4 %
03-OCT-2013	-	1	0.4 %
03-SEP-2013	-	2	0.8 %
04-JUL-2013	-	1	0.4 %
04-MAR-2013	-	7	2.7 %
04-SEP-2013	-	3	1.2 %
05-APR-2013	-	2	0.8 %
05-JUN-2013	-	1	0.4 %
05-SEP-2013	-	1	0.4 %
06-MAR-2013	-	3	1.2 %
06-MAY-2013	-	2	0.8 %
07-AUG-2013	-	1	0.4 %
07-MAY-2013	-	4	1.6 %
08-AUG-2013	-	1	0.4 %
08-JUL-2013	-	7	2.7 %
08-MAY-2013	-	1	0.4 %
08-SEP-2013	-	1	0.4 %
09-APR-2013	-	1	0.4 %
09-AUG-2013	-	1	0.4 %
09-JUL-2013	-	4	1.6 %
09-SEP-2013	-	3	1.2 %
10-APR-2013	-	1	0.4 %
10-JUL-2013	-	3	1.2 %
10-SEP-2013	-	4	1.6 %
11-APR-2013	-	5	2.0 %
11-AUG-2013	-	1	0.4 %
11-JUL-2013	-	2	0.8 %
11-JUN-2013	-	1	0.4 %
11-MAR-2013	-	6	2.4 %

Value	Label	Unweighted Frequency	%
12-AUG-2013	-	1	0.4 %
12-SEP-2013	-	2	0.8 %
13-JUN-2013	-	1	0.4 %
13-MAR-2013	-	1	0.4 %
14-AUG-2013	-	1	0.4 %
14-MAR-2013	-	1	0.4 %
15-APR-2013	-	1	0.4 %
15-APR-2015	-	1	0.4 %
15-AUG-2013	-	1	0.4 %
15-MAY-2013	-	1	0.4 %
	Total	255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 255 valid cases out of 255 total cases.

Location: 105-115 (width: 11; decimal: 0)

Variable Type: character

DATE_C2: DATE_C2

Date of second follow-up contact (eight weeks post-randomization)

Value	Label	Unweighted Frequency	%
	-	14	5.5 %
01-APR-2013	-	7	2.7 %
01-AUG-2013	-	2	0.8 %
01-MAY-2013	-	2	0.8 %
01-OCT-2013	-	1	0.4 %
02-AUG-2013	-	1	0.4 %
02-OCT-2013	-	3	1.2 %
03-APR-2013	-	3	1.2 %
03-JUL-2013	-	1	0.4 %
03-OCT-2013	-	2	0.8 %
04-JUN-2013	-	1	0.4 %
04-SEP-2013	-	1	0.4 %
05-AUG-2013	-	4	1.6 %
05-OCT-2013	-	1	0.4 %
05-SEP-2013	-	2	0.8 %
06-AUG-2013	-	5	2.0 %
06-SEP-2013	-	1	0.4 %
07-AUG-2013	-	2	0.8 %

Value	Label	Unweighted Frequency	%
07-JUN-2013	-	1	0.4 %
07-MAY-2013	-	3	1.2 %
07-OCT-2013	-	3	1.2 %
07-SEP-2013	-	1	0.4 %
08-APR-2013	-	6	2.4 %
08-AUG-2013	-	3	1.2 %
08-MAY-2013	-	5	2.0 %
08-OCT-2013	-	3	1.2 %
09-JUL-2013	-	1	0.4 %
09-MAY-2013	-	1	0.4 %
10-APR-2013	-	1	0.4 %
10-OCT-2013	-	2	0.8 %
11-APR-2013	-	1	0.4 %
11-JUN-2013	-	1	0.4 %
11-SEP-2013	-	2	0.8 %
12-AUG-2013	-	3	1.2 %
12-JUN-2013	-	1	0.4 %
12-SEP-2013	-	5	2.0 %
13-AUG-2013	-	1	0.4 %
13-MAY-2013	-	2	0.8 %
14-AUG-2013	-	2	0.8 %
14-OCT-2013	-	2	0.8 %
15-APR-2013	-	4	1.6 %
15-JUL-2013	-	1	0.4 %
15-MAY-2013	-	1	0.4 %
15-OCT-2013	-	1	0.4 %
16-AUG-2013	-	1	0.4 %
16-MAY-2013	-	3	1.2 %
16-SEP-2013	-	1	0.4 %
17-AUG-2013	-	1	0.4 %
17-JUL-2013	-	4	1.6 %
18-APR-2013	-	1	0.4 %
	Total	255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 255 valid cases out of 255 total cases.

Location: 116-126 (*width:* 11; *decimal:* 0)

Variable Type: character

DATE_C3: DATE_C3

Date of third follow-up contact (twelve weeks post-randomization)

Value	Label	Unweighted Frequency	%
	-	21	8.2 %
01-JUL-2013	-	2	0.8 %
01-MAY-2013	-	3	1.2 %
01-SEP-2013	-	5	2.0 %
02-JUL-2013	-	2	0.8 %
02-OCT-2013	-	1	0.4 %
02-SEP-2013	-	1	0.4 %
03-JUL-2013	-	1	0.4 %
03-OCT-2013	-	2	0.8 %
03-SEP-2013	-	2	0.8 %
04-NOV-2013	-	3	1.2 %
04-OCT-2013	-	1	0.4 %
04-SEP-2013	-	1	0.4 %
05-JUN-2013	-	1	0.4 %
05-NOV-2013	-	3	1.2 %
05-SEP-2013	-	7	2.7 %
06-AUG-2013	-	1	0.4 %
06-JUN-2013	-	1	0.4 %
06-MAY-2013	-	6	2.4 %
06-SEP-2013	-	3	1.2 %
07-JUN-2013	-	5	2.0 %
07-NOV-2013	-	3	1.2 %
08-JUL-2013	-	1	0.4 %
08-MAY-2013	-	1	0.4 %
09-MAY-2013	-	1	0.4 %
09-OCT-2013	-	2	0.8 %
09-SEP-2013	-	1	0.4 %
10-JUN-2013	-	2	0.8 %
10-OCT-2013	-	5	2.0 %
10-SEP-2013	-	1	0.4 %
11-JUN-2013	-	1	0.4 %
11-NOV-2013	-	2	0.8 %
11-SEP-2013	-	2	0.8 %
12-AUG-2013	-	1	0.4 %
12-JUN-2013	-	1	0.4 %
12-OCT-2013	-	1	0.4 %

Value	Label	Unweighted Frequency	%
12-SEP-2013	-	5	2.0 %
13-JUN-2013	-	1	0.4 %
13-MAY-2013	-	4	1.6 %
13-OCT-2013	-	1	0.4 %
13-SEP-2013	-	1	0.4 %
14-JUN-2013	-	1	0.4 %
14-OCT-2013	-	3	1.2 %
14-SEP-2013	-	1	0.4 %
15-APR-2013	-	18	7.1 %
15-AUG-2013	-	1	0.4 %
15-JUL-2013	-	2	0.8 %
15-NOV-2013	-	1	0.4 %
15-OCT-2013	-	1	0.4 %
15-SEP-2013	-	1	0.4 %
	Total	255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 255 valid cases out of 255 total cases.

Location: 127-137 (width: 11; decimal: 0)

Variable Type: character

WT_FINAL: WT_FINAL

Weight of the subject at the end of the trial, in kg.

Value	Label	Unweighted Frequency	%
59.0	-	1	0.4 %
59.3	-	1	0.4 %
61.7	-	1	0.4 %
62.3	-	1	0.4 %
62.7	-	1	0.4 %
63.8	-	1	0.4 %
64.1	-	2	0.8 %
65.8	-	1	0.4 %
66.5	-	1	0.4 %
67.2	-	1	0.4 %
67.6	-	2	0.8 %
68.0	-	1	0.4 %
68.5	-	2	0.8 %
68.9	-	1	0.4 %

Value	Label	Unweighted Frequency	%
69.4	-	1	0.4 %
70.0	-	1	0.4 %
70.8	-	1	0.4 %
70.9	-	1	0.4 %
71.1	-	1	0.4 %
71.2	-	1	0.4 %
71.3	-	1	0.4 %
71.6	-	1	0.4 %
72.0	-	1	0.4 %
72.2	-	1	0.4 %
72.5	-	1	0.4 %
72.6	-	1	0.4 %
72.9	-	1	0.4 %
73.3	-	3	1.2 %
73.6	-	1	0.4 %
73.9	-	1	0.4 %
74.2	-	1	0.4 %
74.3	-	2	0.8 %
74.4	-	1	0.4 %
74.5	-	1	0.4 %
74.8	-	1	0.4 %
75.0	-	1	0.4 %
75.1	-	1	0.4 %
75.2	-	1	0.4 %
75.3	-	1	0.4 %
75.5	-	1	0.4 %
75.6	-	1	0.4 %
75.9	-	1	0.4 %
76.2	-	2	0.8 %
76.3	-	1	0.4 %
76.6	-	1	0.4 %
76.8	-	1	0.4 %
77.1	-	1	0.4 %
77.5	-	2	0.8 %
77.6	-	1	0.4 %
77.7	-	2	0.8 %
Missing Data			
.	-	24	9.4 %
Total		255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 231 valid cases out of 255 total cases.

- Mean: 90.67
- Median: 88.50
- Minimum: 59.00
- Maximum: 143.80
- Standard Deviation: 16.55

Location: 138-142 (width: 5; decimal: 1)

Variable Type: numeric

SITE: site

Label for the subject's site, formatted so that the sites ascend with the IDs when considered alpha-numerically.

Value	Label	Unweighted Frequency	%
a	UAB	72	28.2 %
b	Columbia	67	26.3 %
c	UColo	44	17.3 %
e	Boston	72	28.2 %
Total		255	100%

Based upon 255 valid cases out of 255 total cases.

Location: 143-143 (width: 1; decimal: 0)

Variable Type: character

COLUMBIA: columbia

Was the subject at Columbia University?

Value	Label	Unweighted Frequency	%
0	No	188	73.7 %
1	Yes	67	26.3 %
Total		255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 144-144 (width: 1; decimal: 0)

Variable Type: numeric

COLORADO: colorado

Was the subject at University of Colorado-Denver?

Value	Label	Unweighted Frequency	%
0	No	211	82.7 %
1	Yes	44	17.3 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 145-145 (width: 1; decimal: 0)

Variable Type: numeric

COPENHAGEN: copenhagen

Was the subject at University of Copenhagen?

Value	Label	Unweighted Frequency	%
0	No	255	100.0 %
1	Yes	0	0.0 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 0.00

Location: 146-146 (width: 1; decimal: 0)

Variable Type: numeric

BOSTON: boston

Was the subject at Boston Medical Center?

Value	Label	Unweighted Frequency	%
0	No	183	71.8 %
1	Yes	72	28.2 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 147-147 (width: 1; decimal: 0)

Variable Type: numeric

ETHFAC: ethFac

Label for the subject's race/ethnicity, formatted so that non-Hispanic whites are the baseline and 'Other' is last when considered alpha-numerically.

Value	Label	Unweighted Frequency	%
a	WhiteNonHisp	97	38.0 %
b	BlackHisp	10	3.9 %
c	BlackNonHisp	106	41.6 %
d	WhiteHisp	22	8.6 %
e	OtherEth	20	7.8 %
Total		255	100%

Based upon 255 valid cases out of 255 total cases.

Location: 148-148 (width: 1; decimal: 0)

Variable Type: character

BLACKHISP: blackHisp

Was the subject a Black Hispanic?

Value	Label	Unweighted Frequency	%
0	No	245	96.1 %
1	Yes	10	3.9 %
Total		255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 149-149 (width: 1; decimal: 0)

Variable Type: numeric

BLACKNONHISP: blackNonHisp

Was the subject a Black non-Hispanic?

Value	Label	Unweighted Frequency	%
0	No	149	58.4 %
1	Yes	106	41.6 %
Total		255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 150-150 (width: 1; decimal: 0)

Variable Type: numeric

WHITEHISPANIC: whiteHispanic

Was the subject a White Hispanic?

Value	Label	Unweighted Frequency	%
0	No	233	91.4 %
1	Yes	22	8.6 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 151-151 (width: 1; decimal: 0)

Variable Type: numeric

OTHERETH: otherEth

Was the subject some other race/ethnicity?

Value	Label	Unweighted Frequency	%
0	No	235	92.2 %
1	Yes	20	7.8 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 152-152 (width: 1; decimal: 0)

Variable Type: numeric

ASSIGNUB: ASSIGNUB

Label for the subject's unblinded treatment assignment, formatted so that the levels are in the same order as GROUP when considered alpha-numerically

Value	Label	Unweighted Frequency	%
x	GenRec	87	34.1 %
y	Eat	83	32.5 %
z	NoEat	85	33.3 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

Location: 153-153 (width: 1; decimal: 0)

Variable Type: character

ASSIGNEATER: assignEater

Was the subject assigned to the 'eat breakfast' group?

Value	Label	Unweighted Frequency	%
0	No	172	67.5 %
1	Yes	83	32.5 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 154-154 (width: 1; decimal: 0)

Variable Type: numeric

ASSIGNNOEAT: assignNoEat

Was the subject assigned to the 'do not eat breakfast' group?

Value	Label	Unweighted Frequency	%
0	No	170	66.7 %
1	Yes	85	33.3 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 155-155 (width: 1; decimal: 0)

Variable Type: numeric

INITUB: INITUB

Label for the subject's unblinded initial breakfast eating status, formatted so that the levels are in the same order as TYPE_BFCAT when considered alpha-numerically.

Value	Label	Unweighted Frequency	%
BreakfastEater	-	135	52.9 %
aSkipper	-	120	47.1 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

Location: 156-169 (width: 14; decimal: 0)

Variable Type: character

INITWASANEATER: initWasAnEater

Was the subject initially a frequent breakfast eater (> 3 times/week)?

Value	Label	Unweighted Frequency	%
0	No	120	47.1 %
1	Yes	135	52.9 %
	Total	255	100%

Based upon 255 valid cases out of 255 total cases.

- Minimum: 0.00
- Maximum: 1.00

Location: 170-170 (*width:* 1; *decimal:* 0)

Variable Type: numeric

CHANGE: change

Change in weight, calculated via WT_FINAL - WT_KG.

Value	Label	Unweighted Frequency	%
-11.500000000000	-	1	0.4 %
-11.400000000000	-	1	0.4 %
-9.500000000000	-	1	0.4 %
-7.300000000000	-	3	1.2 %
-7.200000000000	-	1	0.4 %
-6.800000000000	-	1	0.4 %
-6.600000000000	-	1	0.4 %
-5.600000000000	-	2	0.8 %
-5.400000000000	-	2	0.8 %
-5.000000000000	-	2	0.8 %
-4.900000000000	-	1	0.4 %
-4.800000000000	-	3	1.2 %
-4.700000000000	-	1	0.4 %
-4.600000000000	-	1	0.4 %
-4.400000000000	-	1	0.4 %
-4.200000000000	-	1	0.4 %
-4.000000000000	-	2	0.8 %
-3.800000000000	-	1	0.4 %
-3.700000000000	-	2	0.8 %
-3.600000000000	-	1	0.4 %
-3.500000000000	-	2	0.8 %
-3.400000000000	-	3	1.2 %
-3.300000000000	-	2	0.8 %
-3.200000000000	-	1	0.4 %
-3.100000000000	-	2	0.8 %

Value	Label	Unweighted Frequency	%
-3.000000000000	-	3	1.2 %
-2.800000000000	-	3	1.2 %
-2.700000000000	-	1	0.4 %
-2.600000000000	-	1	0.4 %
-2.500000000000	-	1	0.4 %
-2.400000000000	-	1	0.4 %
-2.300000000000	-	1	0.4 %
-2.100000000000	-	5	2.0 %
-2.000000000000	-	5	2.0 %
-1.900000000000	-	1	0.4 %
-1.800000000000	-	2	0.8 %
-1.700000000000	-	4	1.6 %
-1.600000000000	-	2	0.8 %
-1.500000000000	-	1	0.4 %
-1.400000000000	-	2	0.8 %
-1.300000000000	-	5	2.0 %
-1.200000000000	-	5	2.0 %
-1.100000000000	-	3	1.2 %
-1.000000000000	-	4	1.6 %
-0.900000000000	-	5	2.0 %
-0.800000000000	-	3	1.2 %
-0.700000000000	-	2	0.8 %
-0.600000000000	-	7	2.7 %
-0.500000000000	-	7	2.7 %
-0.400000000000	-	2	0.8 %
Missing Data			
.	-	24	9.4 %
	Total	255	100%

Please note that only the first 50 response categories are displayed in the PDF codebook. To view all response categories, please analyze the data file in the statistical package of your choice (SAS, SPSS, Stata, R).

Based upon 231 valid cases out of 255 total cases.

- Mean: -0.28458874459
- Median: -0.300000000000
- Minimum: -11.500000000000
- Maximum: 12.400000000000
- Standard Deviation: 3.25090404545

Location: 171-185 (*width:* 15; *decimal:* 11)

Variable Type: numeric