COACH

COMPETENCY BASED APPROACHES TO COMMUNITY HEALTH

VANDERBILT UNIVERSITY MEDICAL CENTER

STUDY PROTOCOL

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MANUAL OF PROCEDURES

ANTHROPOMETRICS

PROCEDURES MANUAL
1. ANTHROPOMETRICS
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1. INTRODUCTION

The purpose of this procedure manual is to provide explicit and detailed instruction on how to collect anthropometric variables for Vanderbilt University's COACH Trial. COACH will collect measurements at four data collection time points – baseline (T1), 15 weeks (T2), 6 months (T3), and 12 months (T4).

All baseline anthropometric data will be collected prior to randomization. All data collection will occur between May 2017 and August 2018. The height and body mass variables collected will be used to calculate BMI (kg/m^2).

2. TERMINOLOGY TO DESCRIBE RELEVENT INDIVIDUALS

Index child: A child who meets eligibility criteria and is randomized to a study arm with the intention that his or her BMI data will be included in the primary outcome analysis as the main exposure.

Parent: The participating index parent as the index child's legal guardian who identifies that she/he spends the majority of time with that child at home.

Master Trainer: The person (or persons) at each site that trains and supervises certification of other anthropometric data collection staff or research associates.

Measurement Coordinator: The person (or persons) at each site that organizes anthropometric data collection activities. This person may or may not be a Master Trainer.

D*ata collection staff*: Personnel who collect anthropometric measurements.

Trainee: The person receiving training and seeking certification to participate as a Research Associate.

3. CONFIDENTIALITY CONSIDERATIONS

Each participant being measured has the right to confidentiality. No form is identified with a participant's name. Every effort should be made to keep observations and data recording as objective and non-judgmental as possible. It is important to not react to any measure, simply observe and record on the form. The staff should be pleasant and respectful to each person who participates in the study and make the experience a positive one. The staff introduces themselves to the participants, explain all procedures to them, and obtain the participant's approval before taking measurements.

Communication among staff during measurements is done in a quiet and respectful manner so that participants cannot overhear any discussion related to results. It is likely that many participants will ask to be told their measurements results. Height and weight measurements can be easily shown to the participant in a discreet way. However, the skinfold measurement would require explanations which may not be understood by the participants. If these measurement results are requested, staff should explain to the participant that these results have no meaning individually in the way height and weight does. The measurer may show them the numbers, but tell them that they are used in the analysis of the whole study.

Care should be taken that the physical measures are performed in a private area. Privacy also involves sound, so it is important that data collection staff do not speak

values aloud in a way that could be overheard. To insure that modesty is respected during anthropometrics measurements these tasks are performed in the presence of another person.

If a participant's physical injuries or deformities result in having to alter or omit procedures this should be noted on the data collection form in the comments section.

To assure safety of participants, the measurers should remove rings, bracelets, or other jewelry that could pose a hazard and be cautious when using pens or pencils while taking measurements.

4. EQUIPMENT

Scales and calipers are marked with a number for identification on the calibration log. The same brand and model of equipment is used throughout the study. All data collectors need to be aware of the maximum capacity of each piece of equipment and should discuss with their PI(s) necessary procedures in case the maximum capacities are exceeded.

Body Mass – Calibrated, research, precision-grade scale with digital read out
- Seca Model 876
- 20 kg calibration weight

Height – Free standing or wall-mounted stadiometer with movable headboard
- Seca Model 217
- Wooden calibration yard stick

Hair interference
- Micro-Mart #84174 6-inch Metal Ruler

Waist Circumference
- Gulick II Tape Measure, Model 67020

Vanderbilt will also keep the following equipment and supplies on hand:
- Extra AA batteries for scale
- Water-soluble marker
- Wipes (alcohol or other – to wipe marks off of arms)
- 20 kg calibration weight for scale
- 1 yard stick to calibrate stadiometer
- Low footstool
- Pens, clipboards
- Data calibration and data collection forms
- Laptops for data collection

5. ANTHROPOMERTRIC DATA COLLECTION FORM

Anthropometric data will be entered directly into a computer database, (REDCap), while on site. The anthropometric data collection (ANT) form shown in appendix 1 provided to

be used as a template to assist the development of the electronic format used for the collection of data. The data collectors will be trained to enter data correctly into this database in order to reduce error (see section 11.1 for erroneous measurements). Branching logic and calculation fields exist in the online REDCap versions that are not visible in this format. In this document we refer to this document as a "form" whether it is paper or electronic.

6. TRAINING AND CERTIFICATION FOR ANTHROPOMETRICS

Vanderbilt uses a "train the trainer" model. Vanderbilt designated two "Master Trainers" who have been Master Trainers in the GROW program. These candidates for Master Trainers are responsible for training and certifying the data collection staff at their center. To be certified, a Master Trainer candidate should have significant prior experience collecting anthropometric measurements in research studies (at least 50 measurement episodes) and have read the anthropometrics protocol and MOP. After the in-person training session and while still at the centralized training, the Master Trainer candidate will measure ten (10) individuals. A minimum of six (6) of these individuals must be children of the appropriate age that the site will use for their study, the remainder can be adults. The children and adults must include both genders and be of varying size, including thin and overweight individuals. If possible, include one person that has an inflexible hair style that requires the height correction. Each Master Trainer candidate completes separately all measures using the anthropometrics data collection form. The instructor of all training also measures the ten individuals. The data forms from each of the Master Trainer candidate is then compared to the instructors and if there is agreement within the guidelines (see below), the Master Trainer is considered certified. If their results are not within the guidelines then they must have their techniques further evaluated by the instructor and then retested.

All data collection staff collecting anthropometric measures must be certified before collecting data. The certification is separate for each measurement.

As part of certification, the data collection staff is trained by a Master Trainer. In the training sessions the trainer reviews the information in the MOP and demonstrates the technique for measurement to the data collection staff. During the session, the data collection staff practices measurements on each other and on age and body size-appropriate volunteers.

A group of ten (10) individuals comprised of at least six (6) children and at least two (2) adults are measured by both the Master Trainer and the trainee. The participants must include boys and girls within the target age (3-8 and 18+ years) and BMI percentile ranges (50 ≤ child BMI percentile) to be studied at the site and must be different from the children participating in practice sessions (and the trial). The age range of the children in the certification session can, but is not required to, span from the youngest child to be measured at the beginning of the main trial to the oldest child to be measured at the end of the main trial. During the certification, the measurer collects

measurements without assistance from the Master Trainer or other staff. The Master Trainer compares the data from the trainee to her/his own measurements.

To meet certification criteria agreement between the Master Trainer and trainee must be within the specified limits for 80% of the participants. The absolute difference between the Master Trainer's calculated measurement and the trainee's calculated measurement should be less than 0.3 kg for weight, 0.5 cm for height, and 1 cm for waist. Data collection staff who do not meet the certification criteria will be offered additional instruction and testing, however, the testing for certification must be completed on a different group of children.

All data collection staff collecting anthropometric measurements must be certified before collecting a measurement in the study. Data collection staff may be certified to collect some anthropometrics and not others or certified to collect all the anthropometric measurements. A Certification Training Log (Appendix 2-4) will be updated each time a data collector has been certified.

7. GENERAL MEASUREMENT PROCEDURES

7.1. General Equipment Calibration Procedures

Proper calibration of the measurement equipment is the responsibility of the site Measurement Coordinator. Calibration is checked weekly and recorded on the calibration logs in the office. The instrument (i.e. weight scale and caliper) cannot be used if it is not properly calibrated. An additional is available for each measurement team. The Measurement Coordinator makes sure that replacements are available.

Scale Calibration: Calibration of the scale is obtained by using a 20 kg weight. A scale that is off by more than 0.2 kg cannot be used. Calibration results are to be recorded in the Scale Calibration Log weekly (Appendix 5).

Stadiometer Calibration: The calibration is completed weekly and recorded in the Height Calibration Log (Appendix 6)

1. Construct the portable stadiometer and be sure it is on a flat, level hard surface. If carpeted floor, place stadiometer on plywood.
2. Place the calibration yard stick on the base of the stadiometer or floor with the wall-mounted stadiometer. Be sure it is vertical.
3. Place the head board firmly on the calibration yard stick and make the reading.
4. To be considered in range the stadiometer should read within 3 mm of the length of the yard stick.
5. If out of range, take the unit apart, reconstruct, and check calibration. If still out of range do not use the stadiometer until it can be recalibrated by a qualified individual.

7.2. General Procedures

When possible, measurements are taken in the following order: weight, height, and waist circumference one time and then repeated in the same order. A third measurement is taken when a set of two measurements differ by more than the

specified amount. Each measurement is recorded immediately after it is taken and before any other measurement is collected. When possible all 3 measurements are taken once, before any measurement is repeated. The same measurement is never repeated immediately after it has been taken, but is always followed by a different measurement.

7.3. Measurement Stations

The scale and the stadiometer must be placed on a hard, flat and uncarpeted surface.

7.4. Participant Preparations

Before measurements commence participants are offered the opportunity to visit a restroom or bathroom. The participants are asked to remove any excess clothing (e.g., sweatshirts, sweaters or jackets over other clothing) and should be barefoot or wearing socks. They are asked to remove any items from their pockets. Watches, belts, necklaces and other jewelry is removed before taking the weight measurement if in the measurer's judgment they might weigh more than 16 oz. For young children, diapers are not considered excess clothing.

For height measurements, participants are asked to remove their eyeglasses, if the Frankfort plane is not visible. If participants have a hair accessory or hairstyle that interferes with the measurement, they are asked to remove the accessory or change their hairstyle, if possible (e.g., take out ponytail band). If the participant refuses to or cannot comply with regard to hairstyle or accessory, they are still measured using the interference.

An anthropometric example script is shown in Appendix 7 and responses to frequently asked questions are shown in Appendix 9.

8. WEIGHT MEASUREMENT

a. The scale should be placed on a hard, level surface. It should be as close to the wall as possible while also allowing the participant enough room to stand on and step down from the scale.
b. The scale should be set up to measure in kilograms and read '0.0' before the participant steps on the scale.
c. For the initial measurement, check the adult participant's data collection form (see **Appendix 11**) to locate their family study ID. On REDCap, select the correct study ID on the Body Composition data collection tool.
d. Enter the Pre-Measurement Information (collection date, start time, and data collector) into the Body Composition data collection tool.
e. Begin by asking the child, "Would you like to be measured first or would you like to see your [adult] go first?"
f. The participant stands still over the center of the scale with the body weight evenly distributed over feet, feet comfortably positioned side by side in the middle of the scale, and the arms hanging freely by the sides of the body. The participant should be barefoot or wearing socks. The participant should hold their head up and face forward. You can put a dot or poster on the wall for them

to look at. Make sure the participant is not leaning to one side and that the head is held with minimal movement.

g. If the measurement fluctuates so much that a determination cannot be made the participant may not be standing in the middle of the scale base with their weight evenly distributed and feet comfortably positioned next to each other, or the floor may be uneven. The further the center of weight is from the exact center of the base, the more likely the scale reading will fluctuate. This is more likely to happen with heavier and/or taller individuals. If the weight bounces between 0.1 kg and won't stabilize (e.g., 45.5-45.6), use the even number in the decimal place (45.6).
h. When the digital readout is stable, record the weight to the nearest 0.1 kg on the correct location on the REDCap Body Composition data collection tool.
i. Have the participant step off the scales and then complete the measurement round (e.g., height and waist circumference) before taking the second weight measurement.
j. If the participant has a cast, check the cast box on the REDCap Body Composition data collection tool in the appropriate place for either adult or child.
k. If a participant weighs more than the scale can measure, put two scales side-by-side and have the person stand on both. Be sure their weight is evenly distributed and take the measurements from both scales. Note this on the data form as "unreliable". If two scales are not available note on the form that the measurement exceeded capacity.
l. If there are two measurements the calculated weight is their mean. If there are three measurements the calculated weight is the mean of the two closest weights. If the third measurement is equidistant to the first two, the calculated weight is the mean of the three measurements.
m. If the calculated weight is outside the predefined range and the weight is valid, check the "out of range – valid" box on the REDCap Body Composition data collection tool in the appropriate place. See section 11.3. for range checks and more detail on override procedures.
n. Have the participant step off of the scale.
o. Repeat steps **f** through **n** for the child.
p. After both the adult and the child have completed the first set of height measurements, repeat steps **f** through **n** once more for the adult.
q. Repeat steps **f** through **n** once more for the child.
r. If the two measurements of weight differ by 0.3 kg or more, then the weight measurements are repeated a third time. The REDCap data entry form will prompt you if you need to take a third measurement. **The adult's third measurement must be taken before the child's third measurement** (if it is necessary).
s. If a third measure is indicated for the adult, repeat steps **f** through **n** once more. The mean of the 2 closest measures or the median of three equidistant measures is used as the final measurement.
t. If a third measure is indicated for the child, repeat steps **f** through **n** once more. The mean of the 2 closest measures or the median of three equidistant measures is used as the final measurement.

u. In the rare occurrence that for the three measures no pair of measurements meet the criteria, start over with two new measurements. REDCap is set up to calculate if these differences are too large and will prompt you to start over.
v. When data collection is complete for **both weight and height** for both the adult and child, enter the collection complete time on the REDCap Body Composition data collection tool.

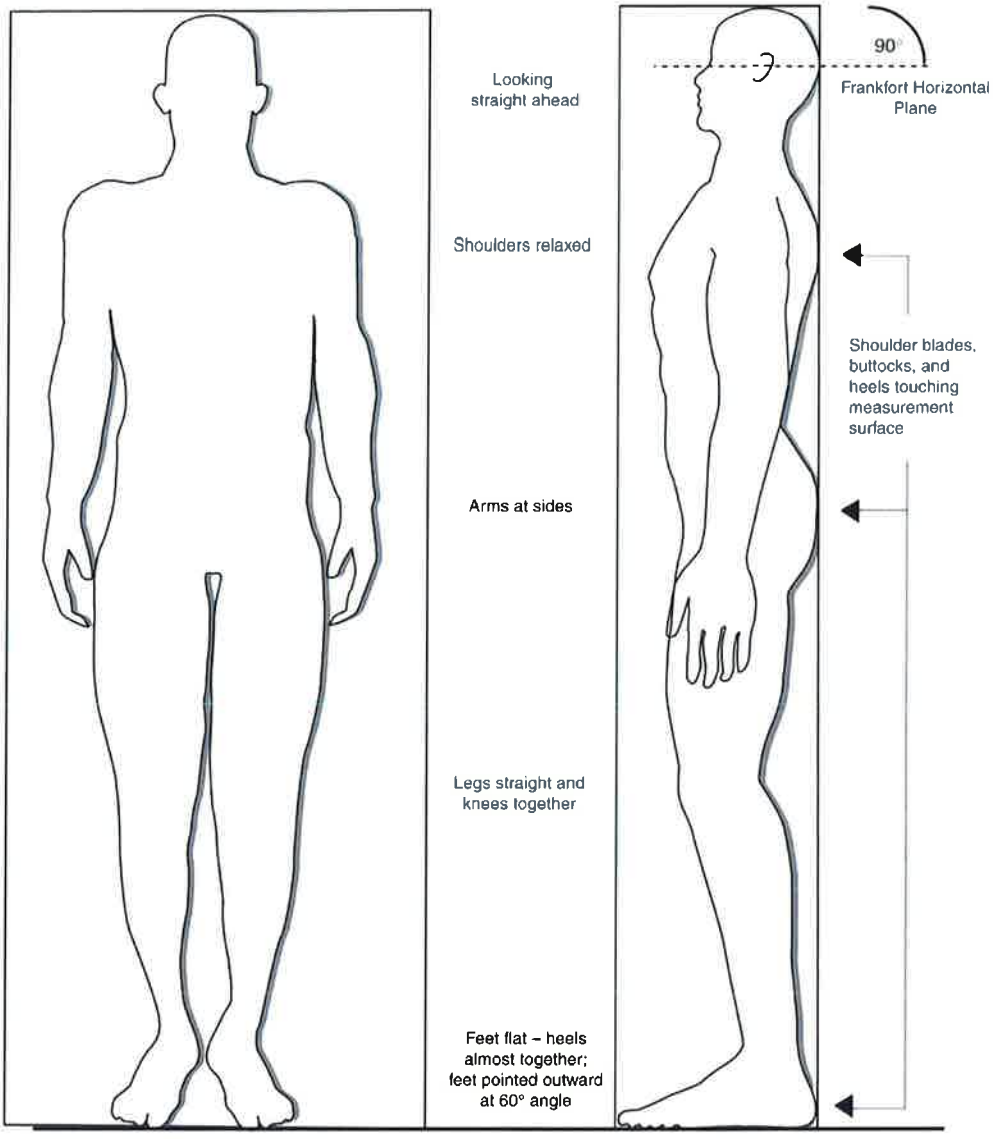
9. HEIGHT MEASUREMENT

9.1. General Height Procedures

a. The stadiometer should be assembled by placing the platform on a hard, level surface as close to a wall as possible, attaching the vertical backboard pieces in order along with the adjustable headpiece, and capped with the stabilizer.
b. After the initial weight measurement have been taken for the adult and child, take the adult's first height measurement.
c. Standing height is measured using a stadiometer with a fixed vertical backboard and an adjustable head piece. Make sure the subject's shoes, and significant accessories are off and that there is nothing tied around the subject's waist (sweatshirt, sweater, etc). Remove eye glasses if the Frankfort plane is not visible. Have the participant back up inside the height board with the head touching the board. Figure 9.1 shows the correct position for the measurement of standing height.
d. If participant cannot stand up (e.g. leg cast), have them stand as "vertical" as possible. Make a note in the comments section of the REDCap Body Composition data collection tool.
e. If participant is sufficiently tall such that the examiner must look up to see the height measurement rather than down or straight ahead, then the examiner must stand on the foot stool. The examiner should read the measure with their eyes at the approximate level of the measure.
f. Have the participant stand in the center of the base of the main board with the feet together until the ankles or knees touch, whichever touch first, and with heels and bottom as close to the back of the board as possible; back of the head touching the stadiometer if possible. Make sure the palms are facing in towards the thighs. If repositioning is needed, ask for permission before touching the participant.
g. An overweight participant may not be able to position heels against the back of the board. In this case, they stand with their heels slightly away from the back such that their legs are perpendicular to the floor and parallel with the vertical back of the measuring board.
h. Make sure that the participant's head is aligned so that the external auditory canal (ear hole) and the lower rim of the orbit (eye socket) are in a horizontal plane parallel to the floor (Figure 9.2). If the participant cannot keep his/her head against the board and maintain the Frankfurt horizontal plane, begin with the head against the board and position until in the Frankfurt horizontal plane, allowing the head to come away from the board as needed.

i. Some participants may have to undo their hair in order for the wooden carriage to lie flat on their heads.
j. Be sure the head is not tilted and the person is standing as erect as possible.
k. Ask the participant to take a deep breath and hold it (holding a deep breath makes the participant stand up straighter and taller, and allows for a more stable and reliable reading). At the moment you are ready to take the measurement say, *"Now, hold your head still, keep your feet flat, and take a deep breath and hold it; stand up tall."* It might not be appropriate to tell younger children to take a deep breath since they might be too young to understand these instructions, and if they do are likely to rise up on the tip toes, thus, making the measurement incorrect.
l. Engage the sliding headpiece carriage a few inches above the participant's head and slide it gently down so that it rests solidly on the crown of the head (or the top of the ruler). Use a hand to lift the chin, if necessary.
m. The measurement is recorded to the nearest 0.1 cm in the correct location on the REDCap Body Composition data collection tool. Tell participants they can release their breath.
n. Complete the measurement round (e.g., waist circumference) before starting the 2nd set of measurements.
o. Repeat steps **c** through **m** for the child.
p. After both the adult and the child have completed a set of weight measurements, repeat steps **c** through **m** once more for the adult and then the child.
q. If the two measurements of height differ by 0.5 cm or more, then the height measurements are repeated a third time and the value is recorded. The REDCap data entry form will prompt you if you need to take a third measurement. **The child's second measurement much be taken before the adult's third measurement** (if it is necessary).
r. In the rare occurrence that no pair of the three measures meets the criterion (less than 0.5 cm difference), start over with new measurements.
s. If there are two measurements the calculated height is their mean. If there are three measurements the calculated height is the mean of the two closest. If the third measurement is equidistant to the first two, the calculated height is the mean of the three measurements. REDCap is set up to calculate if these differences are too large and will prompt you to start over.
t. If the calculated height is outside the predefined range and the height is valid, check the valid box in the correct location on the REDCap Body Composition data collection tool. See Section 11.3 for range checks and more details on the override procedures.

Figure 9.1 Position for height measurement



Note: In large subjects it may be difficult for heels to touch each other or the stadiometer. In such cases the participant should stand so that the legs are perpendicular to the ground. It may also be difficult to maintain the Frankfurt horizontal plane and have the head touch the stadiometer. In these cases, the head should start touching the board and the head should be positioned until in the Frankfurt horizontal plane, keeping the head on the board as long as possible.

Figure 9.2 Illustration of the Frankfort Horizontal Plane head position.

9.2. Height Measurement with Inflexible Hairdos

There may be occasions when a hairdo is inflexible, cannot be "taken down," and interferes with the measurement of standing height. If the hairdo appears to be less than ½ cm above the top of the head, measure the height according to the standard protocol by compressing the hairdo down with the sliding part of the height board as far as you can without making the participant uncomfortable. This is regarded as a routine measurement. An example of this would be participants who have small cornrows in their hair. If a hairstyle is higher and is not easy to undo or will not allow you to lay the carriage flat onto the crown of the head, or is higher than ½ cm and inflexible follow the modified procedure below:

a. Ask participants if they are willing to take down the hairstyle, and if they are willing, follow the standard protocol for measuring height. If they are unwilling or unable to comply, you should proceed with the height measurement using the 6-inch interference ruler. Check 'Yes' for the inflexible hairdo question on the REDCap Body Composition data collection tool.
b. Position the participant on the stadiometer according to the standard protocol.
c. With the head in the Frankfurt plane, and viewing the head from the side, identify the crown (i.e., the highest point of the skull, where height would usually be measured). It may help to palpate the top of the head, around the inflexible hairdo. Ask permission to touch first. If the hairdo covers the crown, palpate around the hairdo and "estimate" the location of the crown. If you are unable to tell where the crown is, ask the participant to locate it. Place the end of the 6-inch ruler on the crown and hold it vertically. Measure the height as described above, but to the top of the ruler.
d. Record the height to the top of the 6-inch pocket ruler. Make sure that you note the use of the 6-inch interference ruler in the REDCap Body Composition data collection tool along with the height measured. The computer will calculate the participant's actual height as the recorded height minus 15.2 cm automatically.

10. WAIST CIRCUMFERENCE MEASUREMENT

Waist is measured just above the uppermost lateral border of the right ilium. The measurement should be made on the skin and not over outer or bulky clothing. It should be done in a way that will not change the natural contour of the waist. The data collection staff stands diagonal to the side of the crest of ilium that is marked and then carefully levels the tape, viewing the tape from all sides. It is helpful to use a mirror to view the opposite side of the participant. The mirror helps to assure the horizontal alignment is maintained. If a participant is wearing a dress or other one piece outfit, they are asked to change into two piece clothing.

a. For the initial measurement, check the adult participant's data collection form (see **Appendix 11**) to locate their family study ID. On REDCap, select the correct study ID on the Waist Circumference data collection tool.
b. Enter the Pre-Measurement Information (collection date, start time, and data collector) into the Waist Circumference data collection tool.
c. Begin by asking the child, "Would you like to be measured first or would you like to see your [adult] go first?"
d. Ask for the adult's gender and enter it into the appropriate location on the Waist Circumference data collection tool. If male, proceed to the next step. If female, ask the participant if she is pregnant or possibly pregnant and enter it into the appropriate location on the Waist Circumference data collection tool. If no, then proceed to the next step. If yes, do not take waist circumference measurements for this participant.
e. Ask participant to stand straight with feet spaced slightly apart, standing erect and looking straight ahead. The shirt is lifted and pants or skirt lowered in order to expose the waist (crests of the ilium or hip bones). Ask participant to cross arms while marking and taking measurement. Always ask before touching a participant or their clothing.
f. Position yourself so you are eye level with the participant's waist, for example by kneeling or bending over. The measurement is taken while you are on the participant's right side and not standing in front. Tell the participant: "*Now I will measure your waist size. Is that OK?* If "Yes": *Can I touch your hip bones?* If "Yes", continue (see Appendix 7 for details); if "No" stop here and note on data sheet. If necessary, ask if they can adjust their own clothing. If not, remember to ask permission before touching. Ask if they mind if you lift up their shirt slightly and hold it in place.
g. Mark the measurement site. From the participant's right side palpate the hip area to locate the right ilium of the pelvis. With the cosmetic pencil draw a horizontal line just above the uppermost lateral border of the right ilium. Cross this mark at the mid-axillary line, which extends from the armpit down the side of the torso. Figure 10.1 shows the measurement site correctly marked for the waist circumference.
h. Place measuring tape around the participant in a horizontal plane parallel to the floor at the mark. Check that the tape sits parallel to the floor and lies snug but does not compress the skin. Align the tape's "zero line" above the tape graduations (with metric side facing out) allowing the "zero line" to be right next to

the mm ticks. Once set, switch zero end of tape to left hand, rest of tape to right hand. Holding the tape in place with the right hand, pull tape with left hand until appropriate tension is achieved (the metal disk between the 2 beads is just visible).

i. Verbally instruct the participant to breath normally. Take the measurement at the end of normal expiration. Record the waist measurement to the nearest 0.1 cm in the correct location on the Waist Circumference data collection tool.
j. Repeat steps **e** through **i** for the child. For children, kneel at the participant's side while taking the measurement.
k. Complete the measurement sequence before starting the new measurement series.
l. Repeat steps **e** through **i** once more for the adult. If the two measurements of waist circumference for the adult differ by 1 cm or more, then the waist measurements are repeated a third time. The REDCap data entry form will prompt you if you need to take a third measurement. **The child's second measurement must be taken before the adult's third measurement** (if it is necessary).
m. Repeat steps **e** through **i** once more for the child.
n. If the two measurements of waist circumference for the child differ by 1 cm or more, then the waist measurements are repeated a third time. The REDCap data entry form will prompt you if you need to take a third measurement. **The adult's third measurement must be taken before the child's third measurement** (if it is necessary).
o. If a third measurement for the adult is required, repeat steps **e** through **i** once more. The mean of the 2 closest measures is used as the final measurement. In the rare occurrence that the three measures no pair of measurements meet the criteria, start over with two new measurements. REDCap is set up to calculate if these differences are too large and will prompt you to start over.
p. If a third measurement for the child is required, repeat steps **e** through **i** once more. The mean of the 2 closest measures is used as the final measurement.
q. In the rare occurrence that no pair of the three measures meet the criterion (less than 1 cm difference), start over with two new measurements. REDCap is set up to calculate if these differences are too large and will prompt you to start over.
r. If there are two measurements the calculated waist circumference is their mean. If there are three measurements the calculated waist circumference is the mean of the two closest. If the third measurement is equidistant to the first two, the calculated waist circumference is the mean of the three measurements.
s. If for either the adult or the child, the calculated waist circumference is outside the predefined range and the waist value is valid, check the valid box in the REDCap Waist Circumference data collection tool in the comments section under waist for either adult or child. See Section 11.3. for range checks and more details on the override procedures.
t. When data collection is complete for waist circumference for both the adult and child, enter the collection complete time on the REDCap Waist Circumference data collection tool.

u. If there are two measurements the calculated waist circumference is their mean. If there are three measurements the calculated waist circumference is the mean of the two closest. If the third measurement is equidistant to the first two, the calculated waist circumference is the mean of the three measurements.

Figure 10.1 Correct location for waist circumference.

11. QUALITY CONTROL PROCEDURES

11.1. Erroneous Measurements

Measurement data will be entered directly into REDCap. Range checks are built within this data collection program as well as data checks being run on the backend to prevent the collection of erroneous data (see section 11.1). Computer entered data can be deleted and reentered as needed.

11.2. General QC Procedures

Ten percent (10%) of the anthropometric measures are measured by two different data collectors (duplicate measures for inter-rater reliability). The anthropometric measure or participant to be remeasured is indicated by a message generated by the data management system. If a participant is designated for QC, the duplicate measurements are obtained on the index child and one of the adults measured in association with that child. Duplicate measures are recorded to confirm inter-rater reliability, but the first data collection staff's measurements will be used in the analysis.

A certified data collector will be deemed the one to cover duplicated measures. Separate REDCap tools will be made for collecting these measures: Body Composition-Check and Waist Circumference-Check. The procedures the data collector will follow will be the same as those described previously in this manual.

If possible, the Master Trainer reviews the 2 sets of measurements while the participant is still present. To be acceptable, the absolute difference between the calculated values by the two data collectors must be less than 0.5 cm for height, 0.3 kg for body mass, and 1 cm for waist.

If a data collection staff's agreement of a measurement (height, weight, or waist circumference) is outside this range in more than two out of ten individuals, then he/she must complete retraining. This retraining can be completed immediately if circumstances allow the Master Trainer to observe the data collection staff taking measurements and apply corrective instruction. These practice measurements can be taken on the Master Trainer or on other data collection staff. The data collection staff can reinitiate data collection when approved by the Master Trainer, but complete certification exercises are not necessary, unless deemed needed by the Master Trainer.

11.3. Range Checks

Range checks (Appendix 10) are built into the data management system to prevent the collection of erroneous data. The data entry program will indicate out of range values for validation.

Range checks are set so that participants with extreme and erroneous values are brought to the attention of the data collection staff for scrutiny. An extreme value may be real or erroneous. We decided arbitrarily that these checks would function as intended if they identify for scrutiny more than 1 in 100 participants but less than 1 in 50 for whom the data are valid. Given a normal distribution, plus or minus 2.4 standard deviations includes between 98% and 99% of the observations. When a value is designated as suspect by the data management system, the data collection staff has the option of either verifying that the data are correct, or re-measuring the participant. For anthropometry, often the data collection staff is able to verify that an out of range value is valid by simple visual examination of the subject and confirmation that the protocol was followed and data recorded accurately. When this is the case the verification is indicated on the data form by checking the box "Out of range – valid". However, if there is any uncertainty that the value could be incorrect, the participant is remeasured.

Range checks were determined using age (in yearly increments) and gender-specific anthropometric data from the 2003-2010 NHANES. The bounds for range checks in the baseline data collection vary by center since the anthropometric eligibility criteria for enrollment of index children vary. In the main trial anthropometric measurements in children could change substantially between the time the screening measurements are taken and the time the baseline measurements are taken. Therefore, the range checks have wider limits than the eligibility criteria.

The following criteria are used to determine range checks for the index child at baseline:

Eligibility criteria for the index children specify that the BMI must be ≤50th percentile of the CDC BMI growth charts. Range checks are 2 standard deviations below and 2 standard deviations above the mean from the log transformed 2006-2009 NHANES for all measurements (including BMI).

It is expected that body size will change during the study, so the range checks for the index children are wider after the study begins. The bounds of the range check will be 2.4 standard deviations below and 2.4 standard deviations above the gender and age-specific mean from the 2006-2009 NHANES. This method is also used to determine the range checks for family members measured at both baseline and follow-up examinations at all the research centers.

11.4. Internet Backup Protocol

Currently, internet access will be gained using Verizon mobile hotspot devices that can each link up to 5 computers. However, if this should fail for the anthropometric measurements, the backup plan would be to use paper versions, including manual calculations to entered into REDCap at a later point.

APPENDIX 1. ANTHROPOMETRICS DATA COLLECTION FORM

To be completed by staff:

Index Child ID: _____

Scale #:_____ Stadiometer#: _____

1. DOB:____/____/ ____ (mm dd yyyy) 2. Sex: 1 ☐ Male 2 ☐ Female
3. *If adult woman only:* Pregnant 1 ☐ Yes 0 ☐ No
4. Code for index child (C1), other children (C2-C8) or other adults (A1-A8): _____
5. Visit:_____(e.g. t1 for baseline, t2 for 15 weeks, t3 for 6 months, t4 for 12 months)

	6. Weight (kg) To nearest 0.1 kg Date:____/____/____ mm dd yyyy Measured by:___ Recorded by: ___	**7. Height (cm)** To nearest 0.1 cm Date:____/____/____ mm dd yyyy Measured by:___ Recorded by: ___	**8. Waist (cm)** To nearest 0.1 cm Date:____/____/____ mm dd yyyy Measured by:___ Recorded by: ___
Scale 1*	_____.		
Scale 2*	_____.		
Measure 1	_____.	_____.	_____.
Scale 1*	_____.		
Scale 2*	_____.		
Measure 2	_____.	_____.	_____.
	Measure if weight 1 & 2 differ by ≥ 0.3 kg	*Measure if height 1 & 2 differ by ≥ 0.5 cm*	*Measure if waist 1 & 2 differ by ≥ 1 cm*
Scale 1*	_____.		
Scale 2*	_____.		
Measure 3	_____.	_____.	_____.
Average	*Use the closest 2 values or all 3 values if appropriate* _____.	*Use the closest 2 values or all 3 values if appropriate* _____.	*Use the closest 2 values or all 3 values if appropriate* _____.
Comments:	☐ Out of range- valid ☐ Refusal ☐ Cast ☐ Measurement exceeds capacity ☐ Unreliable Why: _____	☐ Out of range- valid ☐ Refusal ☐ Cast ☐ Measurement exceeds capacity ☐ Unreliable Why:_____ ☐ Inflexible hairdo (+ 15.2 cm)	☐ Out of range- valid ☐ Refusal ☐ Cast ☐ Measurement exceeds capacity ☐ Unreliable Why: _____

* Only filled in when weight exceeds the capacity of one scale and two scales are used. Measure 1, measure 2 and measure 3 are then the sum of the respective scale 1 and scale 2 measurements.

APPENDIX 2. ANTHROPOMETRICTRAINING CERTIFICATION LOG FOR WEIGHT

Name	Training Date(s)	Certification Date	Certified by

APPENDIX 3. ANTHROPOMETRIC TRAINING CERTIFICATION LOG FOR HEIGHT

Name	Training Date(s)	Certification Date	Certified by

APPENDIX 4. ANTHROPOMETRICTRAINING CERTIFICATION LOG FOR WAIST CIRCUMFERENCE

Name	Training Date(s)	Certification Date	Certified by

APPENDIX 5. WEIGHT SCALE CALIBRATION LOG

Date	Scale #	Standardized weight (xx.x kg)	Calibration value (xx.x kg)	Initials	Comments

APPENDIX 6. HEIGHT CALIBRATION LOG

Date	Instrument #	Standardized height (xx.x cm)	Calibration value (xx.x cm)	Comments

APPENDIX 7. ANTHROPOMETRIC EXAMPLE SCRIPT

Now I am going to take your height, weight, and body composition measurements. We are going to do height and weight measurements twice. Please remove everything from your pockets and any large or heavy jewelry. Also, please remove your shoes. *[If participants are wearing a sweater, sweatshirt, or jacket over their shirt, ask them to remove it to reduce excess weight.]*

WEIGHT MEASUREMENT:

Now I will take your weight.
[Weight: start by tapping the scale to turn it on. When it shows zero (0.0), say:]
Please stand with your feet evenly spaced over the center of the scale. Make sure your weight is balanced between your two feet. Keep your hands at your sides and look straight ahead [at the sticker or poster on the wall].
[Record weight after it stabilizes.]

Okay, you may step off the scale.

HEIGHT MEASUREMENT

Now we are going to measure your height.

[If the child has a hair accessory or their hair is up, please ask them to remove it. If it would be too difficult to remove or if they refuse, Follow the instructions in Section 9.2 – "Measuring height with inflexible hairdos" and write in the comments on the form "inflexible hairdo."]

Please step back onto the height board until some part of your body (heels, upper back, buttocks) touches the board and bring your feet together until your ankles or knees touch, whichever touch first. Stand straight up against the board. Your arms should be straight down at your sides, palms facing in. *[check that they are properly aligned, both from front and from left side.]*

Now, I am going to position your head.
[Position head so an imaginary horizontal line can be drawn between the bottom of eye socket and the opening of the ear.]

Please don't move your head until we finish. Now, hold your head still, keep your feet flat, and take a deep breath and hold it; stand up tall.
[Verify body is properly aligned and head position did not shift with deep breath. Move the headboard onto the head with sufficient pressure to compress hair. Record the height on the form.]

WAIST MEASUREMENT:

Take the measuring tape in hand and say: **Now we will measure you waist size. Is that OK?** If "Yes", **Can I touch your hip bones?** If "Yes", continue; if "No" stop here and note on data sheet.

Please lift your shirt up so that I can see your belly-button. Please lower the waist of your pants so I can see your hip bones. Now stand straight, cross your arms with your hands on opposite shoulders, and relax you stomach, while I find your hip bones.

Now I am going to put a small mark on the top of your hip bones. Now I am placing the measuring tape around your waist. *Check that the tape sits parallel to the floor and lies snug but does not compress the skin.* **Please breathe normally while I get the measurement.** *Take the measurement at the end of normal expiration*

Got it! Thanks.

All done. Thanks!

APPENDIX 8. ANTHROPOMETRIC STATION SCRIPTS

WEIGHT & HEIGHT STATION SCRIPT

Weight

1. **Welcome! I am going to take your weight and height at this station. May I see your data collection form?**

2. **Before we get started, I am going to ask you to please remove everything from your pockets and any large or heavy jewelry and put them in this basket. Also, please remove your shoes.**

   [While they are removing their items, locate their participant ID number on the data collection form and open the correct file on REDCap for the Body Composition tool. On the REDCap tool, enter the Collection Date, Collection Start Time, and your name for Data Collector.]

3. **Okay, will you please step onto the scale? Place your feet side by side in a way that is comfortable for you. You will need to be in the center of the scale with your feet placed evenly on either side.**

4. **Make sure that your arms are relaxed and at the sides of your body. Please stand up straight, look forward, and hold as still as possible, while I take this measurement.**

[Take the weight measurement to the nearest .1kg and record it in the appropriate place on the Body Composition tool on REDCap. Verify against the range check chart if this falls into the correct range.]

5. **Okay, you may relax now and step off the scale. Good job!**
   [Collect the weight measurement for both adult and child before taking height.]

Height

1. **Now, I am going to take your height.**
   [If necessary] **Will you please remove your glasses?**
   [If necessary] **Will you please take down your hair? We will need to take the measurement flat against your head.**
   [If they cannot take down their hair, follow the instructions for inflexible hair – proceed with the height measurement.]

2. **Okay, will you please step in front of the height board? Back up against it until some part of your body touches it (heels, back, bottom). Once you're touching it, bring your feet together until your ankles or knees touch, whichever touch first.**

3. **Stand up as straight as possible with your arms at your sides, palms facing inward.**
   [Check that they are properly aligned - both from front and from left side.]

4. **Now, I am going to position your head.**

   [Position their head so an imaginary horizontal line can be drawn between the bottom of eye socket and the opening of the ear.]

5. **Please don't move your head until we finish. Now, hold your head still, keep your feet flat, and take a deep breath and hold it; stand up tall.**

   [Verify body is properly aligned and head position did not shift with deep breath. Move the headboard onto the head with sufficient pressure to compress hair. Record the height on the REDCap Body Composition tool to the nearest .1cm. Verify against the range check chart if this falls into the correct range.]

6. **Great job!**
   [If first measurement or second measurement and a third is required] **Now, we will take these measurements again.**
   [If the final measurement] **You are finished. Let me sign your data collection form to show you have completed these stations. Thank you!**

   [Be sure to select the completion time on the REDCap tool, when you are finished with all measurements for a parent/child pair.]

WAIST CIRCIMFERENCE STATION SCRIPT

Waist Circumference

1. **Welcome! I am going to take your waist circumference measurements at this station. May I see your data collection form?**

   [Locate their participant ID number on the data collection form and open the correct file on REDCap for the Waist Circumference tool. On the REDCap tool, enter the Collection Date, Collection Start Time, and your name for Data Collector.]

2. **I need to ask you a few questions before we begin.**
   [Adults only] **What is your gender?**
   [If female] **Are you or could you possibly be pregnant?**

   [If yes, then do not continue with the measurement. If no, then continue. Be sure to note the answers in the correct locations on the REDCap data collection tool.]

3. **Now, I am going to measure your waist size, is that okay?**
   [If yes] **Can I touch your hip bones?**

   [If yes, continue with the measurement. If no, stop and record this information in the Comments section on the data collection tool.]

4. **Now, please lift your shirt up, so I can see your belly-button. Please lower the waist of your pants, so I can see your hip bones.**

5. **Now, stand straight with your arms at your side and relax your stomach, while I find your hip bones.**

6. **I am going to put a small mark on the top of your hip bones. Now, I am placing the measuring tape around your waist.**

   [Check that the tape sits parallel to the floor and lies snug but does not compress the skin.]

7. **Breathe in and out.**

   [Take the weight measurement at the end of normal expiration to the nearest .1 cm and record it in the appropriate place on the Waist Circumference tool on REDCap. Verify against the range check chart if this falls into the correct range.]

8. **Okay, you may relax now. Good job!**
   [Repeat the waist circumference measurement for both adult and child.]

[If the final measurement] **You are finished. Let me sign your data collection form to show you have completed these stations. Thank you!**

[Be sure to select the completion time on the REDCap tool, when you are finished with all measurements for a parent/child pair.]

APPENDIX 9. FREQUENTLY ASKED QUESTIONS

What do the checkboxes on the Anthropometric Data Collection Form stand for?

Out of range – valid	The measurement is out of range. However, the data collector confirmed that protocol was followed properly and the measurements were recorded accurately. The data collector's visual examination agrees with the range check indicating that the value is particularly high or low.
Refusal	Participant refused one or more of the expected measurements for this measure.
Cast	The participant was wearing a cast, which affected this specific measurement or prevented measurement from being taken.
Measurement exceeds capacity	The measurement exceeds equipment capacity and no other equipment (e.g. second scale) was available to take the measurement.
Unreliable	The data collector has any other concern about the measure being unreliable and will indicate a reason for this concern.

What do I do if the participant weighs more than the scales allows?

If two scales are available, put them side-by-side and have the person stand on both. Be sure their weight is evenly distributed and take the measurements from both scales and add them together to get the weight. Note this on the data form. If two scales are not available, note on the form that the subject's weight was off the scales.

What to do if the person (adult) is unable have their anthropometrics measured due to being in wheelchair?

Complete the anthropometric form for the person but check the box "unreliable" and write the reason why the person was not measured.

If the quality control measurement and the data collector (1st) measurement are outside the pre-defined limits, which measurement is used in the analysis?

The first data collection staff's measurements will be used in the analysis.

If the quality control measurement and the data collector (1st) measurement are outside the pre-defined limits can the data collector re-do their set of measurements?

To be acceptable, the absolute difference between the calculated values by the two data collectors must be less than 0.5 cm for height, 0.3 kg for body mass, and 1 cm for waist.

If the protocol and procedures were not followed during the data collection process, then the 1st data collector should repeat their set of measurements.

When does the data collector require re-training?

If a data collection staff's agreement of a measurement (height, weight, or waist circumference) is outside this range in more than two out of ten individuals, then he/she must complete retraining. This retraining can be completed immediately if circumstances allow the Master Trainer to observe the data collection staff taking measurements and apply corrective instruction. These practice measurements can be taken on the Master Trainer or on other data collection staff. The data collection staff can reinitiate data collection when approved by the Master Trainer, but complete certification exercises are not necessary, unless deemed needed by the Master Trainer.

Recollecting BMI

Baseline BMI data must be collected ≤ 30 days (from anthropometry collection day) in order to randomize. Randomization must occur within 37 days. Data should not be collected between Days 31 and 37 unless extenuating circumstances warrant data collection during this period (must be PI approved; PI will determine if BMI must be recollected). If randomization occurs outside of the 37 day window, ALL data must be recollected.

APPENDIX 10. ANTHROPOMETRIC RANGE CHECKS

Based on NHANES data (2003-2010). All anthropometrics were log transformed. Used +/- 2.4 SD

	Weight		Height		Waist	
Age	Lower (-2.4 sd)	Upper (+2.4sd)	Lower (-2.4 sd)	Upper (+2.4sd)	Lower (-2.4 sd)	Upper (+2.4sd)
Boys						
2	9.8	17.7	81.5	106.1	40.8	56.4
3	10.7	24.3	87.0	114.0	40.9	62.2
4	11.6	30.9	92.5	121.9	41.0	68.1
5	12.5	37.5	98.0	129.9	41.2	73.9
6	13.5	44.2	103.5	137.8	41.3	79.7
7	14.4	50.8	109.0	145.7	41.4	85.6
8	15.3	57.4	114.5	153.7	41.5	91.4
Girls						
2	9.4	14.7	78.2	107.5	40.4	54.8
3	10.2	22.9	84.1	115.3	40.3	62.0
4	11.0	31.0	89.9	123.1	40.1	69.2
5	11.8	39.2	95.8	131.0	40.0	76.3
6	12.6	47.3	101.7	138.8	39.9	83.5
7	13.4	55.5	107.5	146.6	39.7	90.6
8	14.2	63.6	113.4	154.5	39.6	97.8

Table 3. Adults

	Weight			Height			Waist	
Gender	0.25th %tile	99.75th %tile		0.25th %tile	99.75th %tile		0.25th %tile	99.75th %tile
Males	47.7	175.2		152.9	196.8		66.5	155.7
Females	39.5	164.5		140.9	180.7		63.2	151.1

APPENDIX 11 – PARTICIPANT DATA COLLECTION FORM

COACH Participant Data Collection Form

Participant Study ID:_____ **Date:**_____

Station		Complete?		Data Collector
Consent				
Survey				
Adverse Events				
Measurements	Weight	Child	Parent	
	Height			
	Waist			
Check-Out Station	Gift Card			

Thank you for your time!

If you have a stamp for every station, you are finished! Congratulations! You may now go to the check-out station to receive your compensation. Thank you for your time!

COACH

COMPETENCY BASED APPROACHES TO COMMUNITY HEALTH

VANDERBILT UNIVERSITY MEDICAL CENTER

MANUAL OF PROCEDURES

QUESTIONNAIRES

PROCEDURES MANUAL
QUESTIONNAIRES
Table of Contents

1. INTRODUCTION

The purpose of this procedure manual is to provide explicit and detailed instruction on how to collect questionnaires for Vanderbilt University's COACH Trial. Vanderbilt will be collecting specific questionnaire items at predetermined time points throughout the 1-year RCT - baseline, 15 weeks, 6 months and 12 months. All data collection will occur between May 2017 and August 2018.

The survey is administered to parents/primary caregivers of the participating child. Table 1 summarizes the administration format.

Table 1. Characteristics of questionnaire administration

Administration Location	Participant Home
Administration Format	Interviewer administered
Data collection format	Computer
Languages	English and Spanish
Respondent	Parent or primary adult caregiver

2. TERMINOLOGY TO DESCRIBE RELEVENT INDIVIDUALS

Index child: A child who meets eligibility criteria and is randomized to a study arm with the intention that his or her BMI data will be included in the primary outcome analysis.

Parent: The participating index parent as the index child's legal guardian who identifies that she/he spends the majority of time with that child at home.

Master Trainer: The person (or persons) that trains and supervises certification of other data collectors or research associates.

Measurement Coordinator: The person (or persons) that organizes data collection activities. This person may or may not be a master trainer.

Research Associate/data collection staff: Personnel who collect the measurement data.

Trainee: The person receiving training and seeking certification to participate as a Research Associate.

3. DATA COLLECTORS

Data collectors must be separate from intervention staff unless data are collected prior to randomization. All data collection procedures need to be performed by personnel who have completed the appropriate training and certification procedures referred to in this manual.

4. CONFIDENTIALITY CONSIDERATIONS

Each index child and/or parent completing the questionnaires has the right to confidentiality. No form is identified with a participant's name. The staff should be pleasant and respectful to each person who participates in the study and make the experience a positive one. The staff introduce themselves to the participants, explain all procedures to them, and obtain the participant's approval before giving them the questionnaires. The data collector is available to answer any question that the index child or parent may have.

Survey data will be handled according to the confidentiality procedures described in the protocol. This confidentiality protects privacy and confidentiality of participant data.

5. EQUIPMENT

Equipment needed for survey administration includes:

- Laptops with wireless capability for survey administration
- Mobile hotspot devices
- Paper copy of the survey for backup
- Pencils / pens
- Visual aids (e.g. hard copies of question response categories for interviewer-administered surveys)

6. TRAINING AND CERTIFICATION REQUIREMENTS

A "train the trainer" model is used to prepare staff to collect questionnaire data. Vanderbilt designated two "Master Trainers" who have been Master Trainers in the GROW program. These Master Trainers are responsible for training and certifying the data collection staff. To be certified, a Master Trainer candidate should have significant prior experience collecting questionnaires and has read the protocol and MOP. The data collectors are certified by a Master Trainer who describes the data collection process, insures that the manual of procedures is read and observes the questionnaire being administered to a volunteer.

To be certified, the Master Trainer candidate attends the training session conducted by the Master Trainer, reads the protocol and MOP, and is observed administering the questionnaire to a volunteer.

All survey data collection staff must be certified prior to administering questionnaires. A Questionnaire Certification Training Log (Appendix 4) will be updated each time a new certification has been added.

7. SURVEY QUESTIONS

Please see Appendix 1 for the full survey.

8. PREPARATION FOR ADMINISTRATION

Laptop computers will be set up at tables with the data collector on one side and the participant on the other. All survey questions will be asked by the trained data collector and responses entered directly into the computer database, REDCap. The data collectors will be trained to enter data correctly into this database in order to reduce error. Branching logic and calculation fields exist in the online REDCap forms to ensure accurate data capture.

9. ADMINISTRATION OF THE SURVEY

Generally, surveys may be conducted on any day of the week. The questions do not have to be asked in the order they are provided on the questionnaire form (Appendix

1). Appendix 2 includes an example of a general introductory survey administration staff script. Appendix 3 includes standard answers to frequently asked general questions and to common mediator and moderator questions.

- Log into REDCap.
- Select the "My Projects" tab and click the appropriate project.
- Click "Data Entry" on the left toolbar.
- Select the Study ID associated with the participant in the dropdown menu.
- Select the Data Collection Instrument under the appropriate time/event
    - A green dot indicates that the measurement has been completed. A red dot indicates that the measurement is incomplete.
- If applicable, click "Today" for Date of Survey and "Now" for Start Time
- Administer survey items
- Click "Now" for "Completion Time"
- Select "Complete" in the "Complete?" field dropdown menu
- Select Save Record

10. QUALITY CONTROL

The office will monitor for missing values in the surveys upon completion.

All data collection staff will be trained and certified prior to administering the questionnaires to participants.

Branching logic and calculation fields exist in the online REDCap forms to ensure accurate data capture.

11. DATA MANAGEMENT

All collected questionnaire data should be reviewed for completeness by each data collector and then checked by the data manager.

APPENDIX 1. QUESTIONNAIRE

COACH

Please complete the survey below.

Once complete, you will be directed to a form asking for your mailing address. This is so we can send you a gift card as a token of appreciation for taking the time to complete the survey.

Thank you!

Start Time:

The first set of questions asks some basic questions about you and your family.

Including you, how many people live in your household most of the time?

- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7+

How many persons less than 18 years of age usually live in your home?

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7+

Now we would like to ask a few more questions about you.

What is your marital status?

- ○ Now Married
- ○ Living with a partner / significant other
- ○ Widowed
- ○ Divorced
- ○ Separated
- ○ Never Married
- ○ Prefer not to answer

Gender

- ○ Female
- ○ Male
- ○ Not listed here
- ○

Prefer not to answer

What is your age?

- ○ 18-24 years old
- ○ 25-34 years old
- ○ 35-44 years old
- ○ 45-54 years old
- ○ 55-64 years old
- ○ 65-74 years old
- ○ 75 years or older

Preschool-Caregiver's Feeding Styles Questionnaire

In the following, please respond 1-5, with 1 being never and 5 representing always.

1. How often do you physically struggle with your child to get him or her to eat (for example, physically putting your child in the chair so he or she will eat)?

   Never 1 2 3 4 5 Always

2. How often do you ask your child questions about the food during dinner?

   Never 1 2 3 4 5 Always

3. How often do you reason with your child to get him or her to eat (for example, "Milk is good for your health because it will make you strong")?

   Never 1 2 3 4 5 Always

4. How often do you allow your child to choose the foods he or she wants to eat for dinner from foods already prepared?

   Never 1 2 3 4 5 Always

5. How often do you compliment your child for eating food (for example, "What a good boy! You're eating your beans")?

   Never 1 2 3 4 5 Always

6. How often do you warn your child that you will take away something **other than food** if he or she doesn't eat (for example, "If you don't finish your meat, there will be no play time after dinner")?

   Never 1 2 3 4 5 Always

7. How often do you tell your child to eat something on the plate (for example, "Eat your beans")?

   Never 1 2 3 4 5 Always

8. How often do you help your child to eat dinner (for example, cutting the food into smaller pieces)?

   Never 1 2 3 4 5 Always

9. How often do you encourage your child to eat something by using food as a reward (for example, "If you finish your vegetables, you will get some fruit")?

   Never 1 2 3 4 5 Always

10. How often do you beg your child to eat dinner?

    Never 1 2 3 4 5 Always

Sleep Duration Survey

The following questions ask about you and your child's sleeping patterns.

How often does this child nap daily?

- ◯ 0 times
- ◯ 1 time
- ◯ 2 times
- ◯ 3 times

What is the average length of a daily nap for this child? (minutes)

(Please respond in half hour increments.)

What is this child's usual bedtime?

What is this child's usual wake time?

The following question asks how often your family eats together. By eating together, we mean there's at least one adult who sits down with the child or children in your household.

During the past 7 days, how many times did all, or most, of your family living in your house eat dinner together?

- ◯ 0 times
- ◯ 1-2 times
- ◯ 3-4 times
- ◯ 5-6 times
- ◯ 7 or more times

Media Use Survey

The following questions ask about media use or what we call MEDIA SCREEN and includes tablets, iPads, smart phones, TVs, computers, video games, and other media devices found in your household that your child may use.

In the past 7 days, how many DAYS did your child eat in front of a media screen? (This includes both meals and snacks)

- ◯ 0
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7

((Media screen includes tablets, iPads, smart phones, TVs, computers, video games, and other media devices found in your household that your child may use))

Is there a media screen in the room where this child sleeps?

- ◯ Yes
- ◯ No

((Media screen includes tablets, iPads, smart phones, TVs, computers, video games, and other media devices found in your household that your child may use))

On an average WEEK day, how many hours does this child engage with a media screen?	◯ None ◯ Less than 1 hour per day ◯ 1 hour per day ◯ 2 hours per day ◯ 3 hours per day ◯ 4 hours per day ◯ 5 hours or more per day ((Media screen includes tablets, iPads, smart phones, TVs, computers, video games, and other media devices found in your household that your child may use))
On an average WEEKEND day, how many hoursdoes this child engage with a media screen?	◯ None ◯ Less than 1 hour per day ◯ 1 hour per day ◯ 2 hours per day ◯ 3 hours per day ◯ 4 hours per day ◯ 5 hours or more per day ((Media screen includes tablets, iPads, smart phones, TVs, computers, video games, and other media devices found in your household that your child may use))
On an average day, how many hours does this child engage with a media screen?	◯ None ◯ Less than 1 hour per day ◯ 1 hour per day ◯ 2 hours per day ◯ 3 hours per day ◯ 4 hours per day ◯ 5 hours or more per day ((Media screen includes tablets, iPads, smart phones, TVs, computers, video games, and other media devices found in your household that your child may use))
How often do you monitor your child's media screen time?	◯ Never ◯ Rarely ◯ Sometimes ◯ Often ◯ Always ((Media screen includes tablets, iPads, smart phones, TVs, computers, video games, and other media devices found in your household that your child may use))

Goal-Setting and Monitoring Survey

The following questions ask about the goals you have set for you and your family.

In the past 7 days, did you make aSPECIFIC and REALISTIC physical activity goal for your family? Your goal is SPECIFIC if everyone involved can understand it, not just you. Other words that means specific are detailed, or clear. Your goal is REALISTIC if you have what you need to meet the goal.	◯ Yes ◯ No

In the past 7 days, how many DAYS did you monitor (e.g. write down your progress) your family physical activity goal?

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7

In the past 7 days, how many DAYS did you meet your family physical activity goal?

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7

In the past 7 days, did you make a SPECIFIC and REALISTIC nutrition goal for your family? Your goal is SPECIFIC if everyone involved can understand it, not just you. Other words that means specific are detailed, or clear. Your goal is REALISTIC if you have what you need to meet the goal.

- ○ Yes
- ○ No

In the past 7 days, how many DAYS did you monitor (e.g. write down your progress) your family nutrition goal?

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7

In the past 7 days, how many DAYS did you meet your family nutrition goal?

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7

Nutrition Survey

CDC

These questions will ask you about your eating habits.

ese questions will ask you about your eating habits.

These questions will ask you about your eating habits.

'o each of the fol lowi g gro ps of foods , ell us ow of en yo u ea t each one:

	ever:	Raro y l	So elimes o ce a we k o more, ut not v -y day	Often: one a o	ay o
'ast food o pizza	0	0	0	0	
)esserts, candy, cookies weets, or salty s acks	0	0	0	0	
'e getab les and/o vegeta le ice s	0	0	0	0	
'r i s					
glass , can, or bottle of: so nks, · sweet ea o er swee ened dri s	0	0	0	0	

Duri g he pas t 3 mon s, mow oft €:n d i d yow:

		1 lirne i mo.nlll'l o les:s	2-3 mes p m on!	1 llimes a 'IY88,k	4 B Um 13,s a 'IY8 8 .k	1 O or e time;:s per lta •
) vereat u11till you fel stuffecl o r too f w l l?	0	0	0	0	0	0
Eat u planne d snacks tha y ou wish y ou hadn't?	0	0	0	0	0	0
Make poo r food chorces th a you wishi youl a / 1 'l?	0	0	0	0	0	0
Eat as a 11;•ay to ro pe wi"h e gative fe eling s like a ger , unhiap p in ess, stress or de pressi'on ?	0	0	0	0	0	0

W rnich of the folto wi g behavim s describes whe yo wl eat?

		A few times a week	fl ai 'I
Breakfa st	0	0	
) Lunch	0	0	
)			
Diri er	0	0	
) Snacks	0	0	
)			

Cognitive Tools

While shopping for groceries, how often do you look at the food label for sugar content of the foods you choose?

- ◯ Very rarely
- ◯ Rarely
- ◯ Occasionally
- ◯ Very frequently
- ◯ I do not purchase foods with a food label.

While shopping for groceries, how often do you look at the food label for fiber content in the foods you choose?

- ◯ Very rarely
- ◯ Rarely
- ◯ Occasionally
- ◯ Very frequently
- ◯ I do not purchase foods with a food label.

Before going to the grocery store, how often do you make a list of what to buy?

- ◯ Very rarely
- ◯ Rarely
- ◯ Occasionally
- ◯ Very frequently

During the past 7 days at mealtime, about how much of your child's plate was made up of fruits and vegetables?

- ◯ 0%
- ◯ 25%
- ◯ 50%
- ◯ More than 50%

In the past 7 days, how many DAYS did you portion out food before you put it on your child's plate?

- ◯ 0
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7

In the past 7 days, how many DAYS did you choose snacks with 100 calories or less?

- ◯ 0
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7
- ◯ Don't Know

In the past 7 days, how many DAYS did your child drink fruit juice, sports drinks, or soda?

- ◯ 0
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7

Physical Activity Survey

PHYSICAL ACTIVITY PARENTING PRACTICES

Please choose the best answer for how often **you** do each of the following with **your 3-5 year old child**.

	How often do you...	1 Never	2 Rarely	3 Sometimes	4 Often	5 Always
1	Take your child to sport practice or game in which he/she is enrolled?	☐	☐	☐	☐	☐
2	set an example for your child by exercising in front of him/her?	☐	☐	☐	☐	☐
3	play active games with your child (such as playing ball or racing)?	☐	☐	☐	☐	☐
4	NOT let your child play actively for fear of him/her getting dirty?	☐	☐	☐	☐	☐
5	take your child to the park?	☐	☐	☐	☐	☐
6	tell your child he/she is not good enough at sports or active games?	☐	☐	☐	☐	☐
7	go on a walk with your child?	☐	☐	☐	☐	☐
10	allow your child to watch TV for long periods of time?	☐	☐	☐	☐	☐
11	find age appropriate games that get your child moving?	☐	☐	☐	☐	☐
12	say positive things to motivate your child to be more active?	☐	☐	☐	☐	☐
13	carry your child because he/she does not want to walk?	☐	☐	☐	☐	☐
14	teach your child new and different ways to be active?	☐	☐	☐	☐	☐
15	play a sport or active game together as a family?	☐	☐	☐	☐	☐
16	give your child choices of what physical activities to do?	☐	☐	☐	☐	☐
19	Set aside time for active play?	☐	☐	☐	☐	☐
20	drive your child, when it was easy to walk?	☐	☐	☐	☐	☐
21	allow your child to pick an active game to do together?	☐	☐	☐	☐	☐
23	allow your child to play a lot of videogames?	☐	☐	☐	☐	☐
24	dance with your child?	☐	☐	☐	☐	☐
25	tell your child he/she will get hurt if he/she plays actively?	☐	☐	☐	☐	☐

26	play sports games with your child (such as soccer or baseball)?	☐	☐	☐	☐	☐
27	discipline your child for being too active?	☐	☐	☐	☐	☐
28	NOT register your child for sports or dance due to lack of money?	☐	☐	☐	☐	☐
29	~~keep your child inside your home all day?~~	☐	☐	☐	☐	☐
30	not let your child play outside because you are worried about traffic?	☐	☐	☐	☐	☐
31	push your child in a stroller instead of letting him/her walk?	☐	☐	☐	☐	☐
32	let your child go outside to play around your home?	☐	☐	☐	☐	☐
33	teach your child that being active is good for his/her health?	☐	☐	☐	☐	☐
34	reward your child for being still?	☐	☐	☐	☐	☐
35	have outdoor toys available for your child?	☐	☐	☐	☐	☐
36	NOT let your child play outside because you are worried about crime?	☐	☐	☐	☐	☐
37	NOT let your child play outside because you are worried about strangers?	☐	☐	☐	☐	☐
38	keep your child occupied by letting him/her watch TV?	☐	☐	☐	☐	☐

Acculturation

In general, which languages to you use while reading and speaking?

1 = only Spanish
2 = more Spanish than English
3 = both equally
4 = more English than Spanish
5 = only English.

In general, which languages to you use while speaking in your house?

1 = only Spanish
2 = more Spanish than English
3 = both equally
4 = more English than Spanish

5 = only English.

In general, which languages do you think in?

1 = only Spanish
2 = more Spanish than English
3 = both equally
4 = more English than Spanish
5 = only English.

In general, which languages do you use to you talk to your friends?

1 = only Spanish
2 = more Spanish than English
3 = both equally
4 = more English than Spanish
5 = only English.

Self-efficacy

Please find the self-efficacy scales below. There are 4 items (questions) per behavior in the tables below. I presented the 4-item version in the published paper. I used 5 items (questions) per behavior in my pilot study, however. The 5th item is below the table in (**). The 5-item version has good psychometrics as well.

Sugary Drinks

How sure you are that you could limit your child to 1 serving per week of sugary drinks in the following situations?

- **1 serving** equal to 8oz ounces or 3/4 can or a Small restaurant size.
- **Sugary drinks** include regular soda, sport drinks, fruit drinks, punches, Kool-aid, Sunny-D, Tampico, Capri-sun, sweet teas, sugar flavored waters, and similar drinks with added sugar.

How sure are you in the following situations?	Not Sure	Some-what Sure	Sure	Very Sure	Extremely Sure
1. When other members of my house drink it	1	2	3	4	5
2. When it's cheap to buy	1	2	3	4	5

3. When we eat at a restaurant	1	2	3	4	5
4. When everyone else in the neighborhood drinks it	1	2	3	4	5

(* When the water tastes bad*)

Fruit Juice

100% fruit juice is pure juice with no added sugar, such as orange, apple, grape or Juicy Juice.

How sure you are that you could limit your child's juice intake to no more than 6 ounces of 100% fruit juice each day in the following situations...

How sure are you in the following situations....	Not sure	Somewhat sure	Sure	Very Sure	Extremely Sure
1. When other family members demand it	1	2	3	4	5
2. When I feel tired	1	2	3	4	5
3. When other members of my house drink it	1	2	3	4	5
4. When my child won't drink milk	1	2	3	4	5

(*When my child demands it*)

Physical Activity

- Moderate intensity physical activity is any activity that raises your child's heart rate and breathing rate.
- Moderate intensity physical activities include playing tag, kickball, hopscotch, jumping rope and other similar games, running, basketball, soccer, dancing and other energetic games or sports.

How sure you are that you could help your child get 1 hour of moderate intensity physical activity **every day**?

How sure are you in the following situations?	Not Sure	Somewhat Sure	Sure	Very Sure	Extremely Sure
When there are too many other things to worry about	1	2	3	4	5
When money is tight	1	2	3	4	5
When you do not like to exercise or play	1	2	3	4	5
When your child is tired	1	2	3	4	5

(* When the weather is bad)

Fruit and vegetable

The recommended amount of fruits and vegetables for a child is 5 servings per day.

5 servings of fruits and vegetables is about 1 1/2 cups of fruit and 2 cups of vegetables and includes all fresh, frozen and canned choices.

How sure are you that you could provide your child with 5 servings of fruits and vegetables everyday in the following situations?

How sure are you in the following situations?	Not at all sure	a little sure	sure	very sure	Extremely Sure
1. When you are too tired to make them	1	2	3	4	5
2. When your store doesn't have a good selection	1	2	3	4	5
3. When your family wants to eat junk food instead of fruits and vegetables	1	2	3	4	5
4. When you are eating out at a restaurant	1	2	3	4	5

(* When you feel they are too expensive)

Perceived Stress

Circle the description that best represents how often you have felt or thought that way during the last month.

1) Been upset because of something that happened unexpectedly?	Never	Almost Never	Sometimes	Fairly Often	Very Often
2) Felt that you were unable to control the important things in your life?	Never	Almost Never	Sometimes	Fairly Often	Very Often
3) Felt nervous and — "stressed"?	Never	Almost Never	Sometimes	Fairly Often	Very Often
4) Felt confident about your ability to handle your personal problems?	Never	Almost Never	Sometimes	Fairly Often	Very Often

5) Felt that things were going your way?	Never	Almost Never	Sometimes	Fairly Often	Very Often
6) Found that you could not cope with all the things that you had to do?	Never	Almost Never	Sometimes	Fairly Often	Very Often
7) Been able to control irritations in your life?	Never	Almost Never	Sometimes	Fairly Often	Very Often
8) Felt that you were on top of things?	Never	Almost Never	Sometimes	Fairly Often	Very Often
9) Been angered because of things that were outside of your control?	Never	Almost Never	Sometimes	Fairly Often	Very Often
10) Felt difficulties were piling up so high that you could not overcome them?	Never	Almost Never	Sometimes	Fairly Often	Very Often

The last set of questions ask additional questions about you.

Are you currently:

- ☐ Employed (full-time, part-time, or self-employed)
- ☐ Unemployed (looking for a job)
- ☐ Homemaker / stay at home parent or caregiver Full-time
- ☐ student
- ☐ Retired
- ☐ Unable to work (disabled)

What is the highest level of school you have completed?

- ☐ 8th grade orless
- ☐ Some high school, but did not graduate
- ☐ High school graduate or GED
- ☐ Some college or 2-year degree
- ☐ College graduate
- ☐ More than a college degree
- ☐ Prefer not to answer

We would like to ask you about your household income.
One of the things we're trying to understand is how people's income may affect their use of recreation centers and food choices.

Which category best describes your annual household income?

- ☐ less than $10,000
- ☐ $10,000 to $19,999
- ☐ $20,000 to $34,999
- ☐ $35,000 to $49,999
- ☐ $50,000 to $74,999
- ☐ $75,000 to $99,999
- ☐ $100,000 or more
- ☐ Don't know / Not sure
- ☐ Prefer not to answer

Race

- ☐ Black/African-American (non-Hispanic)
- ☐ Caucasian/White (non-Hispanic)
- ☐ Hispanic/Latino

Asian/Pacific Islander
Native American Indian/Native Alaskan
Not listed here
Prefer not to answer

Please complete the address information form so we can mail you a token of appreciation for taking the time to complete the survey. Your name and mailing address is kept confidential and not linked to your surveyanswers.

First name Last name _____

Home address line 1 _____

Home address line 2 _____

City _____

State or province name _____

Zip/Postal Code _____

Country _____

May our research team contact you regarding future studies that you are eligible for? ○ Yes ○ No

What is your preferred method to be contacted for future studies? ☐ Mail ☐ Phone ☐ Email (Check all that apply)

Phone Number _____

Email address _____

Date of Approval: 05/02/2017

Institutional Review Board

VANDERBILT

APPENDIX 2. SURVEY ADMINISTRATION SCRIPT

As part of the COACH study at Vanderbilt, we are collecting information about each family's background, household and lifestyles. These questions include information about you and your family's education, income, racial and ethnic background, living situation, activities, eating patterns, rules, and parenting styles.

Please keep in mind that all of your answers are confidential and will not be shared with anyone outside the research project. There are some researchers who are outside of Vanderbilt that are a part of the larger research group that we will share some information with. We will take off your name and any other identifying information. The survey is voluntary, so you are free to decide not to answer any question that you do not want to answer. However, the study will be helped if you are able to answer all of the questions as completely as you can.

At any time, if you have questions, please feel free to ask me for help.

Please keep in mind that there are no right or wrong answers. Please answer the questions as honestly as you can.

Do you have any questions before we begin?

APPENDIX 3: FREQUENTLY ASKED QUESTIONS

1. What does [WORD] mean?
NOTE: If the person is asking for a translation from English to another language or vice versa, the translator can provide. The possible acceptable translations should be written in advance.

If the person is asking about defining a word in English and is an English speaker, the data collector's response is "Whatever [WORD] means to you."

2. How do I answer if [PARTICIPANT DESCRIBES A SCENARIO]
Answer as best as you can. Choose the response that seems to best show your answer.

3. What is the reason you are asking about X?
"It helps us with the research project."
"It helps us learn about how different families respond to the program/research project."

4. I don't understand the question.

NOTE: If the person is asking for a translation from English to another language or vice versa, the translator can provide. The possible acceptable translations should be written in advance.

If the person is an English speaker and is asking the data collector to interpret or rephrase a question:
"Answer as best as you can. Choose the response that seems to best show your answer."

APPENDIX 4. QUESTIONNAIRE TRAINING CERTIFICATION LOG

Name	Training Date(s)	Certification Date	Certified by

COACH

COMPETENCY BASED APPROACHES TO COMMUNITY HEALTH

VANDERBILT UNIVERSITY MEDICAL CENTER

STATISTICAL

ANALYSIS

NCT03141151

Baseline characteristics were reported as mean (SD) or number (%) for categorical variables. The analysis used an intention-to-treat approach designed to test the difference in the BMI growth trajectory between children in the intervention and control groups. As specified a priori, BMI trajectory was modeled using a linear and a quadratic term, given the non-linear nature of early child growth. The original analysis used a longitudinal mixed-effects regression model with 2 levels (time nested within child), three random effects (intercept, linear, and quadratic), and an unstructured variance-covariance matrix.[32] BMI data were assumed to be missing at random, and the model used a maximum likelihood procedure to handle missing outcome data (approximately 10% missing BMI data across all time points).[33] Measurement time varied individually and was measured continuously as years since baseline data collection. Child gender was a covariate for the intercept. Child age and intervention condition were covariates for the intercept, linear, and quadratic terms. Intervention effectiveness was evaluated by a likelihood ratio test to determine whether the linear and quadratic intervention effects were jointly equal to zero (df=2; 0.05 level). However, because the linear term alone might be sufficient to adequately capture child BMI trajectory in this relatively short one-year timeframe, the original quadratic model fit was compared to an otherwise identical nested linear model using a likelihood ratio test and the AIC and BIC statistics. Baseline parent education, BMI, and age were then added to the final linear model as covariates for the intercept and linear terms.

Secondary and post-hoc outcomes were analyzed using ordinary least squares regression when residual diagnostics did not confirm violation of distributional assumptions. The child diet items were analyzed as non-integer count variables using Poisson regression with robust standard errors to control for mild assumption violation,[34] and goodness-of-fit was evaluated using tests of both the deviance and Pearson statistics.[35] The child and parent physical activity outcomes were analyzed using negative binomial regression because their distributions were severely overdispersed (variance vastly exceeded the mean). Models were prespecified and adjusted for covariates hypothesized to be associated with each outcome. All secondary models included the baseline outcome as a covariate. The child outcome models (child diet and child physical activity) also adjusted for baseline child age, child gender, and parent education, while the parent outcome models (BMI, diet practices, physical activity, self-efficacy, and parenting practices relating to child physical activity) adjusted for baseline parent age and education.
In post-hoc analyses, we used ordinary least squares multivariable regression to test the relationship between attendance at sessions (dose) and child BMI-Z at 7 and 12-month followup.

A separate model was conducted for each dose modality (i.e., the number of intensive phase in-person contacts delivered, and the number of maintenance phone calls completed). A third model tested the interaction of the two dose modalities by including each of the main effects and their interaction. To evaluate for a potential non-linear relationship between dose and BMI-Z, we repeated the linear regression using two different approaches: 1) restricted cubic splines, and 2) a categorical dose variable (0-5 sessions [ref] vs. 6-10 sessions vs. 11-15 sessions). Because interpretation of diagnostic plots and the model with restricted cubic splines provided no evidence for non-linearity, we present the model treating dose categorically for ease of interpretation. The control group was included and had zero dose for all models in the dose analysis. All models adjusted for baseline child age and gender.

Statistical analyses were conducted using Stata version 15.1 (StataCorp). Statistical significance

was defined using a two-sided test with □=0.05.