Redesigning Pediatric Primary Care Obesity Treatment: Virtual House Calls

NCT06078774

09.19.2023

PROTOCOL

The Virtual HouseCalls model is designed to augment existing primary care approaches for management of childhood obesity preventing progression to severe obesity. This approach will leverage existing, widely accessible telehealth technologies to improve reach to populations with disparities in obesity prevalence. The goal is to develop an evidence-based intervention that could be widely integrated into pediatric patient-centered medical homes. The study question is to establish the feasibility of this intervention and support a future application.

STUDY AIMS:
Aim 1: To test the feasibility and preliminary efficacy of the Virtual HouseCalls intervention.

Aim 2: To test the preliminary efficacy of Virtual HouseCalls on BMI and secondary outcomes of parenting, child diet and physical activity, sleep and home food environment.

RECRUITMENT:
We plan to recruit 50 parent-child dyads using established strategies. Eligible families will be invited to an informed consent discussion virtually (Zoom) or in person, in which study procedures will be detailed, eligibility confirmed, and consent/assent obtained. Consented participants will receive detailed instructions for completing baseline assessments.

INTERVENTION:
Parents will attend a 60-minute orientation at the start of the intervention to review study logistics: telehealth visit setup, prioritizing modules, and setting study expectations. Week 1, dyads will attend a meeting with their health coach to launch the program that will last up to 60 minutes. Dyads will then attend weekly 30-minute sessions with their coach weeks 2-12 (intensive phase) and bi-weekly 30-minute sessions with their coach weeks 13-24 (maintenance phase). During the intensive phase, all dyads will receive the same 12 modules; however, during the maintenance phase, dyads will select the topics of their choice for each session (see Session Outline document). Sessions follow a behavior therapy approach, including guided goal-setting, self-monitoring, identifying barriers and solutions, contingency management, stimulus control, dealing with setbacks, maintenance and relapse prevention. Weight is assessed weekly by coaches, with MI-consistent, autonomy-supportive feedback provided. Weeks 2-4, parents will have one, 60-minute visit with their coach; this will occur again during weeks 12-15. These individual parent sessions will focus on ways to support their child's weight management. Dyads will also be sent weekly exercise videos (1x/week for 30 min) and be encouraged to participate in them. All sessions will be conducted virtually utilizing Zoom or EPIC.

Participants will be provided scales to be used for weekly self-weighing and will be provided guidance on self-regulation by their coach.

ASSESSMENTS:
All assessments will occur at baseline, 3-, and 6-months (primary) unless otherwise noted.

CHILD:

- Trained staff measure height and weight to the nearest 0.1cm and 0.1kg using a precision stadiometer and digital scale, respectively. BMI will be calculated (kg/m2).
- Children will complete the following psychosocial measures via REDCap:
    - The Authoritative Parenting Index (Jackson et al, 1998) will assess child report of parenting style
    - A subset of questions from Project Eat (Neumark-Sztainer, 2002 et al) will be used to assess eating and weight-related habits
    - 2 item physical activity scale (Prochaska et al., 2001) assessing weekly engagement in physical activity.
    - Children's Eating Disorder Examination Questionnaire (Kliem et al, 2017) will assess eating disorders.
- Children will complete the Automated Self-Administered 24-Hour (ASA24®) from NCI that assesses dietary intake.

PARENT:

- Trained staff measure height and weight to the nearest 0.1cm and 0.1kg using a precision stadiometer and digital scale, respectively. BMI will be calculated (kg/m2).

- Parents will complete the following psychosocial measures via REDCap:
    - Demographics (baseline only) will assess household income, family structure, weight management treatments
    - Food insecurity (USDA, 2012) will be assessed
    - Home Food Inventory (Fulkerson et al, 2008) will assess what food is available in the home
    - The Standardized Screening Tool for Health (Billioux et al, 2017) will assess health-related social needs that negatively impact health
    - Parenting Style Dimension Questionnaire short version, authoritative parenting subscale (Robinson et al, 2001) will assess parent report of parenting style
    - 2 item physical activity scale (Prochaska et al., 2001) assessing weekly engagement in physical activity.
    - A subset of questions from the Family Mealtime Environment (Berge et al 2016) questionnaire will assess the household environment during family meals
    - Modified NHANES sleep time questions (Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Data. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention) will assess

Attendance and adherence will be monitored. At the 6-month assessment only, all participants will complete an Exit Survey assessing: intervention likes/dislikes; perceived benefits and barriers to implementing intervention goals; overall satisfaction; and suggestions for improvement.

STATISTICAL ANALYSIS:

A proposed sample size of 50 dyads, or parent-child pairs, will allow investigators to establish feasibility and proof of concept. Primary outcomes will be determined with percentage calculations ([actual/target]*100) to determine percent recruited, percent retained, and percent satisfied. Secondary outcomes will be examined using descriptive statistics to calculate scale means and standard deviations at assessment time points. Paired samples t-tests will be used to examine changes in secondary outcomes over the course of the 6-month intervention.