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Study protocol for clinical trial of the FIT Families multicomponent obesity intervention for African American adolescents and their caregivers: Next step from the ORBIT initiative

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ABSTRACT

Introduction This study will test the effectiveness of FIT Families (FIT), a multicomponent family-based behavioural intervention, against a credible attention control condition, Home-Based Family Support (HBFS). This protocol paper describes the design of a randomised clinical trial testing the efficacy of the FIT intervention. The protocol will assess the efficacy of FIT to improve health status in African American adolescents with obesity (AAAO) and their primary caregivers on primary (percent body fat) and secondary (physical activity, metabolic control, weight loss) outcomes and its cost-effectiveness.

Methods 180 youth/caregiver dyads are randomised into FIT or HBFS, stratified by age, gender and baseline per cent overweight. The proposed study follows a two condition (FIT, HBFS) by four assessment time points. Tests will be conducted to identify potential relationship of baseline demographic and clinical variables to our dependent variables and see whether they are balanced between groups. It is hypothesised that youth/caregiver dyads randomised to FIT will show significantly greater reductions in percent body fat over a 12-month follow-up period compared with AAAO receiving HBFS. Preliminary findings are expected by November 2023.

Ethics This protocol received IRB approval from the Medical University of South Carolina (Pro00106021; see 'MUSC IRB 106021 Main Approval.doxc' in online supplemental materials).

Dissemination Dissemination activities will include summary documents designed for distribution to the broader medical community/family audience and submission of manuscripts, based on study results, to relevant peer-reviewed scientific high-impact journals.

Trial registration number NCT04974554.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Our FIT Families trial will provide innovative and significant data that will help elucidate the effectiveness of this intervention, which is designed to address weight issues in a youth and parent, concurrently.
⇒ The approach is highly novel and will generate data that may inform the next generation of obesity interventions for young people and their families from health disparate populations.
⇒ The project has high significance in terms of potential public health impact and reduction in obesity-related healthcare costs.
⇒ Because of our focus on reducing obesity in African American adolescents, our results will have limited generalisability across obese adolescent populations.
⇒ There may be some study drop-out, which will impact longitudinal analysis.

INTRODUCTION

Obesity in the USA has reached alarming prevalence rates generally, and particularly among ethnic minorities. According to the Centers for Disease Control and Prevention (CDC), non-Hispanic African American (AA) adults (49.9%) have the highest age-adjusted prevalence of obesity, followed by Hispanic adults (45.6%), non-Hispanic White adults (41.4%) and non-Hispanic Asian adults (16.1%).[1] Similarly, although the prevalence of adolescent obesity has increased broadly, ethnic minority adolescents, especially AAs, are disproportionately likely to be obese (24.88%) relative to their non-Hispanic White adolescent counterparts (16.66%).[1] South Carolina (SC), the site of the described study, has the 9th highest obesity rate among US children at 20.0%[2 3] and the 11th highest obesity rate among US adults at 36.2%.[4] Obese AAs living in the South are at high risk of deleterious and costly outcomes related to cardiometabolic complications such as hypertension, insulin resistance, type 2 diabetes, pre-diabetes[5] and some forms of cancer.[6–8]

This project focuses on AA families for several reasons. First, extensive evidence supports the critical role families play in the etiology, maintenance and treatment of childhood obesity.[9–13] African American adolescents with obesity (AAAO) are likely to have caregivers who are also overweight and suffer from obesity-related diseases (e.g., type 2 diabetes and metabolic syndrome), which increases their chances of becoming obese as adults.[14–21] Parents have a powerful influence on their child's behaviour, not only through their control of food in the home, but also through the impact of modelling appropriate choices regarding physical activity (PA) and diet. Parental involvement is associated with the effectiveness of weight loss interventions for obese children. Second, developing effective interventions targeting AAs has proven difficult as few studies target AAs, and almost every major randomised clinical trial targeting AAs has achieved little to no weight loss.[22–24] Furthermore, intervention studies targeting AAs have reported attrition rates ranging from 27% to 55%.[22 25] Contributing to these unfavourable findings include practical barriers such as travel distance and scheduling,[26] but also a lack of motivation to adhere to evidence-based weight management skills.[23] Thus, it is not surprising that clinical practice guidelines highlight the importance of parent involvement in youth obesity treatment.

The need to involve parents in obesity treatment, and motivational factors among AAAO and their caregivers that interfere with adherence to evidence-based weight loss guidelines[27 28] influenced our decision to incorporate motivational interviewing (MI)[29 30] into the design of FIT Families (FIT), a multicomponent family-based behavioural intervention that was culturally tailored to meet the unique needs of AAAO and their caregivers. FIT Families grew out of a programmatic effort that used the ORBIT model[31] of behavioural intervention development and an NHLBI centre grant (U01HL097899; Naar/Jen, MPIs). ORBIT phases I and II for FIT were completed in the aforementioned centre grant based on the science of intrinsic (MI) and extrinsic (contingency management; CM) motivation and cognitive behavioural skills training (CBST) that were culturally tailored using communication science methodologies.[32–36] FIT components were pilot tested in a multiple baseline design[36] and optimised based on findings from a 'proof-of-concept' study[36] and a sequential multiple assignment randomised trial (SMART[37]) in a large Mid-Western city. This SMART design tested several behavioural strategies (ie, home-based delivery, CM, MI, CBST[37]) that used evidence-based skill acquisition procedures (i.e., modelling, guided practice and performance feedback) during twice weekly treatment sessions.[38–40]

Although FIT was shown to be acceptable to AAAO and their caregivers, and MI, CM and CBST components showed some efficacy,[41] there was sufficient variability in outcomes associated with its components that highlighted several areas where the intervention could be further optimised for use in the proposed study, including (1) Adolescents who reported higher skill utilisation reduced their percent overweight by almost fivefold that of adolescents reporting lower skill utilisation (5.77% vs 1.22%, respectively); (2) Qualitative interviews[41–43] revealed that caregiver active involvement with adolescents in cognitive skills building differentiated the top 10% from the bottom 10% of weight loss[43]; (3) CM for adolescent weight loss was only effective above CBST if caregivers attended sessions, and (4) CM increased parental session attendance, but significant weight loss was only achieved among adolescents with more PA and higher executive functioning.[41 44] Reinforcing caregivers for attendance resulted in higher attendance, but not other caregiver behaviours known to influence adolescent weight loss (e.g., self-monitoring (SM) of food and exercise, environmental control). (5) Qualitative analysis revealed that families specifically requested more supervised PA and suggested ways to refine FIT by focusing on the skills most critical to weight loss, and (6) community health worker (CHW) use of MI-based open-ended questioning was associated with greater use of change talk and commitment language[29 45] among both youth and caregivers. This finding is important because these MI components have been shown to be precursors to actual behaviour change.[35 45] Also, CHW reflections of change talk and commitment language predicted more of the same during sessions.[33] In summary, given the 5% reduction we achieved in percent overweight in our previous developmental SMART,[41] communication science studies of sessions elucidated the most relevant MI strategies for AAAO and their caregivers, allowing us to tailor MI for the next trial, presented here. This trial has one primary aim and two secondary aims:

1. The primary aim of the study is to test the efficacy of FIT Families to improve weight status in AAAO. Primary hypothesis: AAAO and their caregivers randomised to FIT Families will show significantly greater reductions in % body fat over a 12-month follow-up period compared with AAAO receiving Home-Based Family Support (HBFS).
2. Secondary aim 1 is to test the efficacy of FIT Families on secondary outcomes of PA (step counts) and fitness measures, improved metabolic syndrome symptoms and SM of diet/PA (log completion) in youth and caregiver as well as caregiver weight loss.
3. Secondary aim 2 is to assess cost-effectiveness of FIT Families using a decision-analytical Markov model that accounts for changes in health status and obesity-related costs over 1 and 5 years using mathematical models that estimate downstream effects on costs and benefits.

METHODS

Study design

Because of the intensity of the intervention and the high rates of obesity or overweight status in AA adults living in SC, we are focusing our relatively intensive intervention

on AAAO with an overweight or obese caregiver. Because of the high rates of obesity and cardiometabolic diseases in AA families, we redesigned the parent component beyond just session attendance by adding CM for caregiver's modelling of health behaviours and monitoring their adolescent's behaviours.

The trial is registered with the US National Library of Medicine Clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT04974554). This randomised clinical trial (HL155793; Clinical Trial of the Fit Families Multicomponent Obesity Intervention for African American Adolescents and Their Caregivers: Next Step from the ORBIT Initiative (NCT04974554); Cunningham/Naar, MPIs), submitted in response to PAR-19-328,[46] employs reproducible and rigorous methods testing the effectiveness of FIT compared with HBFS, a credible attention control condition. The study follows a two-condition (FIT, HBFS)×four assessments (baseline (T1), 3-month mid-treatment [T2], 6-month end of treatment (T3) and 12-month follow-up (T4)), with random assignment of 180 caregivers/youths to one of the two treatment conditions. Repeated measures of caregiver and youth percent body fat (primary outcome) and PA (secondary outcome) are collected at baseline and each of the three postrandomisation time points (T2–T4).

Participants and recruitment

We plan to recruit 180 AAAO and their primary caregiver who also meet criteria for overweight or obese (maAttention-deficit/hyperactivity disordery include biological parent, grandparent, extended family member, etc). We define adolescent obesity as a body mass index (BMI)≥95th percentile for age and gender (https://www.nhlbi.nih.gov/health/overweight-and-obesity/childhood-obesity). Primary caregiver overweight is defined as a BMI 25.0–29.9 kg/m^2 and obesity defined as a BMI≥30 kg/m^2 (https://www.nhlbi.nih.gov/files/docs/guidelines/prctgd_c.pdf#page=15). Human subjects research will be conducted at the Medical University of SC and the homes of participating families. Adolescents with obesity were chosen as the target population because adolescents are at greater risk for obesity than any other paediatric age group. Families from AA backgrounds were selected given the persistence of obesity disparities among youth and adults from minority backgrounds. Finally, we chose to include only adolescents with a primary caregiver because, with a majority of caregivers also struggling with weight, parental involvement also has added cost-effective benefits by influencing caregiver health, and, potentially that of other family members.

In addition to meeting criteria for being obese, to be eligible, adolescent participants must be between 12 and 17 years of age, self-identify as AA, have a primary caregiver who is either overweight or obese and willing to participate in treatment, and reside primarily with a primary caregiver within 50 miles of the Medical University of SC. Exclusion criteria for youth include obesity secondary to medication use for another medical condition (eg, steroids, antipsychotics) or secondary to a chronic condition (eg, Down syndrome, Prader-Willi syndrome and Cushing's syndrome). Exclusion criteria that apply to both adolescents and caregivers include pregnancy, thought disorder (eg, schizophrenia or other psychosis), suicidal, homicidal or serious cognitive impairment (eg, inability to complete questionnaires). To increase external validity of study findings, caregivers and adolescents are included regardless of co-morbid mental health problems (i.e., Attention-deficit/hyperactivity disorder, conduct disorder, depression and anxiety disorder), with the exception of thought disorder (i.e., schizophrenia, autism), suicidality or intellectual disability. Youth and caregivers with mild intellectual disability may be included if they are capable of reading and understanding study measures; youth/caregivers with more serious cognitive impairments are excluded. Youth and caregivers will also be excluded if they are pregnant or have a medical condition where weight loss is contraindicated. Participants will be required to speak and understand spoken English. Literacy is not a requirement as questionnaires can be read to families.

Participants are recruited from South Carolina Pediatric Practice Research Network (SCPPRN) practices. SCPPRN research staff will use IRB-approved recruitment procedures that have been used successfully in previous SCPPRN studies.[47 48] Participants for SCPPRN collaborative studies are recruited primarily through paediatric practices that are part of this research network that have agreed to participate in recruitment. Previous SCPPRN collaborative studies have relied on two IRB provided recruitment strategies-retrospective recruitment and traditional as described below.

When using the retrospective recruitment method, each practice generates a list of patients who have been seen over the previous 12 months at the participating clinic and meet study eligibility criteria. Clinic staff at each participating practice search the clinic's electronic medical records and/or billing software to develop a list of AA patients who are 12–17 years old with BMIs>or equal to the 95th% and seen consecutively, over the previous 12 months by clinicians in the practice. Each practice provides SCPPRN research staff with patient-visit data. The list unduplicated by patient and then sorted from the most recent clinic visits to the oldest visit. Prior to active recruitment, an opt-out letter is sent to the family of potentially eligible participants describing the FIT Families study and explains that participation is optional and will not affect their care at the clinic. This letter provides an opt-out option from the clinic and signed by each potential participant's primary care provider. Any opt-out letters received will result in removal of the child's name from the recruitment list/database. Two weeks after the opt-out letters are sent, SCPPRN staff begins contacting potential participants using procedures previously approved by Medical University of South Carolina (MUSC's) IRB. Using a phone script developed by the research team, SCPPRN staff then

contact families by phone to provide more information about the study and participant requirements and to complete the initial eligibility screening. If the adolescent and caregiver meet eligibility requirements and caregiver is interested, SCPPRN staff will explain the study, conduct an online consent appointment or schedule a time for a research assistant (RA) to conduct a home visit to review the informed consent and assent with HIPPA document.

Each participating practice will also use traditional IRB-approved recruitment methods that have been used in a number of SCPPRN-associated randomised clinical trials.[47 48] These include advertisements and flyers where patients can self-refer to the study and/or to the study team. In addition, practices may directly refer their patients to the study. Researchers provide SCPPRN staff a menu of options from which participating practices can choose from including IRB-approved recruitment flyers that can be placed in prominent locations within each practice or provided to patients at check-in; project newsletters; email blasts to practice patients; and other means that families can contact study research staff directly. Participants may also be directly referred from their paediatrician. For potential participants who contact the clinic for FIT Families, clinic staff will provide: basic study information, project flyers, brochures or newsletters; and provide contact information for the potential participant to contact research staff.

Regardless of which method is used to recruit the participants, caregiver consent and youth assent forms emphasise that the family is entitled to receive services from their respective clinic regardless of their participation in the research. The RA then schedules a 1.5-hour interview at a time convenient to the family to complete research instruments.

Ethics approval

All procedures and materials were reviewed and approved by the Institutional Review Board at the MUSC (see 'MUSC IRB 106021 Main Approval.doxc' in online supplemental material). In addition, a data and safety monitoring board reviewed all procedures for the study and provide oversight of participants' safety throughout the study. All procedures will follow guidelines as outlined in 45 CFR Part 46 Subpart D for research involving children. The research is permitted as it falls under the category of 'Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject' (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc).

Patient and public involvement

Patients were involved in the design and conduct of this research. Beginning with our SMART,[41] adolescent and their caregivers participated in semistructured qualitative exit interviews, results of which were used to inform the design of the current trial. During the R61 Phase (pilot) of the current trial, informed by the results from the aforementioned semistructured exit interviews, research protocols and intervention components were pilot tested to determine their feasibility and acceptability with AAAO and their caregivers residing in SC. Following treatment, all 18 families who participated in the R61 Phase, provided feedback that was used to adapt and finalise intervention and research protocols for this randomised clinical trial. Following completion of the clinical trial and publication of its results, family and SCPPRN practices will be informed of the study's results via a newsletter.

Treatment conditions

FIT Families

FIT is a 6-month, home-based multicomponent intervention for AAAO and their adult caregivers. FIT components include MI, CM, CBST and an option for supervised PA (FLEX). Using an MI foundation, CHWs deliver FIT in participants' home twice weekly for the first 3 months and weekly for the second 3 months of Fit intervention. However, families are given an option to have one longer session each week that combines both FIT and FLEX (described below). Table 1 lists prescribed intervention components that are planned for each week.

Motivational interviewing

Originally developed for adults with substance abuse disorders,[49 50] MI is an evidence-based behaviour change intervention that uses client-centred, directive methods for enhancing intrinsic motivation and self-efficacy.[29] MI has been used to improve health behaviours including to promote health behaviour change in youth with HIV infection,[51 52] and by members of our research team to promote weight loss or adherence to weight loss recommendations in adolescents with obesity.[33 35–37 41 53] MI has been tested alone and in combination with other weight loss skill building interventions.[54 55]

Cognitive Behaviour Skills Training

CBST is used to address individual, family, peer and school factors that contribute directly or indirectly to youth and caregivers' poor adherence to body fat loss and PA recommendations. Each home-based CBST session includes the following components: (1) assessment of attendance, body fat lost, youth and caregiver SM of Food and Water Intake logs, PA steps, caregiver's monitoring of youth's steps and completion of Food and Water Intake logs and administration of CM to caregiver and youth. (2) Barriers and supports to PA change, fat loss and completion of homework are assessed; (3) An agenda is set based on results of the assessment; (4) To address barriers for skill deficits, CBST uses the following format: (a) discussion of rationale, (b) modelling of skill, (c) caregiver and teen behavioural rehearsal of skill, (d) feedback and (e) caregiver and teen develop implementation plans for between session skills practice.

Optional supervised PA

Optional supervised PA (FLEX): FLEX combines MI, which increases motivation, with personal fitness training.

Table 1 FIT sessions description

FIT phases	Weeks in Treatment	Session 1	Session 2
Phase 1	Week 1	Motivation and CM	Introduction to FLEX Session (optional)
	Week 2	Physical Activity Education+CM	Family FLEX Session (optional)
	Week 3	Nutrition Education 1+CM	Family FLEX Session (optional)
	Week 4	Nutrition Education 2+CM	Family FLEX Session (optional)
	Week 5	Self-Monitoring of PA and Nutrition+CM	Family FLEX Session (optional)
	Week 6	Managing Hunger	Family FLEX Session (optional)
Phase 2	Week 7	Foundation Module: Managing Hunger	Family FLEX Session (optional)
	Week 8	Foundation Module: Managing Cravings	Family FLEX Session (optional)
	Week 9	Foundation Module: Environmental Control of Nutrition and Physical Activity	Family FLEX Session (optional)
	Week 10	Foundational Module: Parenting Session	Family FLEX Session (optional)
	Week 11	Transitional Session: *Functional Analysis	Family FLEX Session (optional)
	Week 12	Functional Analysis	Family FLEX Session (optional)
Phase 3	Weeks 13–24 (Tailored Activities†)	Planning and Organisation Skills	Phone Check In
	Week 14	To Be Determined (TBD)	Phone Check In
	Week 15	TBD	
	Week 16	TBD	Phone Check In
	Week 17	TBD	Phone Check In
	Week 18	TBD	Phone Check In
	Week 19	TBD	Phone Check In
	Week 20	TBD	Phone Check In
	Week 21	TBD	
	Week 22	Maintenance Module Values and Commitment	Phone Check In
	Week 23	Module: Managing Slips with Think Plan	Phone Check In
	Week 24	Module: Termination	Phone Check In

*As families transition into phase 3, CHWs conduct a functional analyses to determine what factors (e.g., antecedents, behaviours, consequences) that can maintain or undermine healthy lifestyle changes (e.g., decreased sedentary behaviour, increased physical activity) achieved during FIT.
†Tailored activities: Based on the results of the functional analysis, the following modules represent activities that may be selected during weeks 13–24 based on a family's needs including Planning and Organisation Skill; Managing Thoughts (Teen or Caregiver); Managing Emotional Eating and Refusal Skills.
CHWs, community health workers; CM, contingency management; FIT, FIT Families.

Each optional home-based session includes: (1) five minutes of warm-up; (2) 20 min of high intensity interval training that targets cardiovascular fitness with intensity being based on baseline fitness levels; (3) 20 min of resistance band and body weight resistance training; (4) 5 min of cooling down with yoga stretches, and (5) 10 min of MI-based goal setting to determine an additional PA for participants to complete on their own. Participants are guided via an MI approach to add to supervised PA with their own independent PA. The goal here is to have participants increase adherence to PA guidelines and to create PA routines and habits. Participants are given a set of resistance bands to use for their workouts after 2 weeks of the FIT programme. The CHW screens participants for any abnormal physical symptoms and ensures participants' heart rates are within normal range prior to each weekly workout. CHWs are trained by an expert in home-based supervised PA programmes with minority youth (certified personal trainer and a member of the MI network of trainers). As part of their initial training, each CHW receives feedback from the Flex expert as they practice implementing FLEX. As part of their ongoing training and supervision, to ensure Flex fidelity, quarterly each FIT CHW submits a randomly selected FLEX session video to the Flex expert for review and corrective feedback.

Contingency management

During our SMART,[37] CM was designed to increase parental session attendance, but not other caregiver behaviours known to influence adolescent weight loss (e.g., SM of food and exercise, environmental control)–behaviours

the proposed study target. In this study, adolescents and their caregivers can both earn incentives for completing a series of target behaviours described below.

Adolescent CM

Prize incentives are used to encourage attendance, PA, dietary SM and body fat loss. Across 24 weeks, adolescents can earn up to US$1643 in prizes if they meet all behavioural targets.

CM for attendance

Adolescents can earn prizes in the first 4 weeks for attending sessions. Each week, adolescents can earn five spins for attendance for a maximum of 20 draws/spins.

CM for PA

Starting the second week, adolescents can earn prize spins for engaging in PA. Each week, CHW and adolescent will set a new personalised step goal using the adolescent's FitBit. Each week, the step goal will increase by 10%, so that the adolescent increases the duration of his or her PA. CHW will meet with adolescent weekly for 24 weeks to review FitBit goals and to provide prize spins. Adolescents will receive 1 prize spin for each day FitBit step goal is achieved. Thus, if the adolescent achieves FitBit goal for all 7 days, she/he would receive 7 spins. The adolescent can also get bonus spins for weeks that she/he completes step goals on at least 6 out of 7 days. Bonus spins will begin with 3 for week 1, and will increase by 3 with each week in a row the bonus target is met up to a maximum of 15 bonus spins during any week. If the adolescent does not meet FitBit step goal, no prize spins will be earned for that day and the bonus spins available at the next weekly session will be re-set to 3. Resets will not happen if there is a valid reason for not completing the behavioural activity (e.g., illness, FitBit malfunction). Adolescents can earn up to 530 prize spins for completing all FitBit step goals across treatment weeks.

Diet/exercise SM component

Starting in week 5, the adolescent can earn prize spins for completing forms that help him/her monitor his/her daily food quality and water intake. The adolescent will enter these logs online in REDCap or complete them on paper. The adolescent will also rate all exercise and PA on a log, including how long the adolescent did the activity, and how intense it was. The adolescent will receive 1 prize spin each day s/he submits a completed food and exercise log up to 7 spins per week. Adolescents can earn up to 140 prize spins for completing all logs across 24 weeks.

Bonus draws for body fat loss

Starting week 8 of the Fit intervention, adolescents can earn bonus spins for body fat reduction. For every 4 weeks in a row that the adolescent has at least a one-point-per-month body fat percentage reduction (averaged across the 4 weeks), she/he will receive 10 bonus spins. Thus, if the adolescent lost at least one percentage point per month across all weeks of the Fit treatment, adolescent could earn up to 50 body fat reduction bonus spins.

The prize wheel or bowl

The CM prize wheel has various landing options; 50% of the spins will not result in a prize but will have a positive message ('Good Job'); 41.8% will yield a small prize (worth US$1); 8% a large prize (worth US$20); and 0.2% a jumbo prize (worth US$100). An adolescent who adheres to attendance, PA, SM and body fat loss targets for a period of 24 weeks may earn up to US$1643 in prizes. However, on average, participants will likely earn substantially less. Based on previous studies investigating single behavioural targets, we estimate that adolescent participants will earn approximately US$500 on average.

Caregiver CM

Caregivers will undergo the same procedures as adolescents and receive the same number of spins on the same time frames as adolescents for attendance, PA, SM and body loss. Additionally, caregivers will receive spins for monitoring and reviewing with their adolescent daily nutrition/exercise SM logs and PA. Caregivers will complete a form online each day, which will consist of the following: (1) an overview of their adolescent SM and PA goals; (2) an assessment of whether adolescent met/completed SM and PA, and (3) if adolescent failed to complete SM and PA, the caregiver will provide a brief action plan to assist the adolescent in meeting SM and PA goals. The caregiver will receive 1 prize spin for each day she/he submits a completed assessment and can earn up to 7 spins per week for a maximum number 168 spins.

FIT Families training and treatment fidelity

Session digital audio recordings are used to assess treatment adherence. Experts in FIT and prize-based CM procedures provide training and ongoing quality assurance support for CHWs with protocols developed and used successfully in other studies.[56] Manualised MI, CM, CBST and supervised PA training plans will be used to train CHWs. Training will include CHWs completing role play tests with 100% of components completed on fidelity checklists for FIT components and no less than beginner MI competency on an MI Coach Rating Scale. This rating scale was developed using item response theory item development methods in our original Fit trial[37] and is currently used in a multicity National Institute of Health (NIH)/Health Resources and Services Adminstration-funded MI implementation project. FIT supervisors will listen to a CHWs audio sessions and will complete 12 items about the quality of implementation based on a 4-point scale (i.e., 1=poor, 2=fair, 3=good, 4=excellent). Sessions will be randomly selected monthly for ongoing fidelity coding. Paperwork is reviewed weekly for fidelity to other components of the intervention. Quarterly booster training will ensure that fidelity is maintained.

CHWs receive CM training based on procedures from an NIH-funded study designed to train community clinicians

to effectively administer CM.[57 58] Prize-based CM Expert (David Ledgerwood [LR] and Jeff Randall [JR]) will conduct trainings. Trainings will include didactic instruction on CM, demonstration of procedures for monitoring and tracking target behaviours, practice role-play exercises, and developing homework and clinical tasks for caregivers to complete. Before and after completing CM training, CHWs will complete a 20-item test that assesses general knowledge about CM and behaviour therapy principles.[59] After completing CM training, CHWs will complete an additional multiple choice test on the specific protocol procedures of this study. The CHWs are required to successfully complete role-play tests with either JR or DL to ensure he/she can administer CM effectively. RAs will rate audio sessions of the role-plays using the Contingency Management Competence Scale (CMCS).[59] CHWs have to obtain scores of at least 80% on relevant objective tests and minimum average scores of 4/7 on the role-play tests before being eligible to treat study participants. RAs rate 25% of all audiorecorded CM sessions for fidelity using the CMCS observational rating system.[59] If a CHW's ratings fall below a minimum average score of 4/7, the CHW will receive additional training until ratings have reached an acceptable level.

Weekly supervision will include reviewing participants' progress and barriers to success related to body fat loss and completion of steps and physical activities. JR will review and address fidelity deficits in any CHWs' implementation of FIT. JR will also provide quarterly 1-day booster trainings for CHWs in areas identified as presenting difficulties in adherence or achieving clinical outcomes. A registered dietitian (Ms. Janet Carter) will provide consultation on dietary issues. Mr. Bulls will provide telephone and video consultation to CHWs in designing each participant's PA programme and its safety. These calls focus on promoting adherence to the supervised PA component and developing solutions to PA implementation problems.

Control condition: HBFS

Control participants will receive HBFS, which meets the requirements for a comparison treatment for testing behavioural interventions, and has been used in other health behaviour change studies (e.g., asthma).[60] HBFS employs a client-centred, non-directive manualised counselling[61] approach to providing information and emotional support for both adolescents and caregivers regarding choices about nutrition and PA to promote weight loss. The HBFS intervention emphasises use of open-ended questions, empathic and reflective listening, and general affirmations to facilitate healthier choices about nutrition and PA that stem from within the individual. Weekly sessions are 45 min in duration with adolescent-caregiver in the home, with a second phone check-in per week during the first 3 months to match for treatment condition dose. HBFS sessions involve: (a) basic education in nutrition and/or PA recommendations for adolescent and adult obesity (sessions 1–4); (b) brief review of effort/progress with healthy nutrition and PA (sessions 2—final); (c) discussion of barriers or challenges with steps towards healthier nutrition and PA (sessions 2—final), and (d) an invitation for adolescent and caregiver to consider solutions to those barriers/challenges (sessions 2—final). Session 1 involves orienting adolescent and caregiver to the HBFS intervention and discussion of their thoughts about current weight, previous attempts at weight loss, and other domains associated with adolescent's psychosocial well-being (e.g., peers, family, school, hobbies/interests). Subsequent sessions involve psychoeducation about nutrition including discussion of portion size, food groups and tips for improving nutrition and creating healthy meals (session 2), discussion of calories and practice with reading food nutrition facts labels (session 3) and psychoeducation about PA and discussion of recommended guidelines on the amount, variety and intensity of PA for adolescents and adults (session 4). Review and discussion of effort/progress with healthy nutrition and PA continue throughout the remaining sessions with opportunity to revisit basic nutrition and PA material from initial sessions as well as discussion of other health-related concerns or non-weight-related difficulties (e.g., general family, school/work, peer adjustment) identified by the adolescent and/or caregiver. At the conclusion of HBFS sessions, the adolescent and caregiver are invited to consider how they might use the information on healthy nutrition/PA discussed in session to assist them in managing a healthier weight during the upcoming week.

HBFS training, fidelity and ongoing supervision

Bachelors-level CHWs conduct sessions after completing a 2-day training (17 hours) conducted by a doctoral-level clinician with expertise in client-centred counselling. Training includes a review of client-centred counselling skills such as open-ended questions, reflective listening and general affirmations, session-by-session review of HBFS protocol and role-play of HBFS sessions. However, there is no training on MI-specific strategies such as eliciting and reinforcing change talk, selective reflection, supporting autonomy and managing counter change talk and discord. All sessions are audiorecorded. The HBFS clinical supervisor, a doctoral-level clinician with expertise in client-centred counselling, reviews one randomly selected session once per month for each CHW. On a quarterly basis, one randomly selected session is coded for each CHW according to the MI-CRS and CBST checklists from intervention condition to ensure the unique components of FIT are not present. Feedback on selected HBFS sessions as well as progress and challenges with scheduling and general HBFS protocol implementation are reviewed with CHWs during weekly (60 min) group supervision sessions.

Procedures

Data collection and data management

All data collection and treatment sessions will take place at a time and location convenient to the family, usually the family's home. Data collection is conducted on laptop computers using Research Electronic Data Capture (REDCap).[62 63] REDCap is a software toolset and workflow methodology for electronic collection and management of clinical trial data, which will be used for data capture and management. Direct data entry increases the efficiency of data management by reducing data entry burden and decreases missing data and data entry errors associated with paper and pencil assessments. Data collected by means other than questionnaires (ie, height and weight measurements, SM logbook data, and metabolic syndrome symptom data which include laboratory results and blood pressure measurements) are collected using case report forms (CRFs). A second data capture system has been established for RAs to enter CRFs. Detailed data entry guidelines and data dictionaries have been developed for each study measure/variable to support data collection and RA entry (where applicable) processes. Accelerometer data are captured using the manufacturer's cloud-based software (Fitabase). Fitabase washes the data using Fitbit's proprietary machine learning algorithms and results in the number of accelerometer-recorded steps taken each day. All electronic data will be identified using research identification numbers only. RAs will download data from the electronic data capture systems every 2 weeks to a spreadsheet programme (i.e., Excel or SPSS) and save it to a secure MUSC server. MUSC RAs will conduct a preliminary review of all data to ensure that data are deidentified prior to sharing data files with non-MUSC investigators. Data quality will be examined before statistical analysis can be conducted, including examination of missing data, assessment of distributional assumptions and identification of outliers. The psychometric properties of the instruments will be examined. Missing data will be estimated using multiple regression or full-information maximum likelihood procedures where appropriate. If necessary, transformations to normality will be applied.

Randomisation

The study biostatistician conducts the randomisation of 180 subjects, 90 subjects in each level of treatment (FIT vs HBFS) using a 1:1 allocation ratio. He will block randomise to reduce the probability that a disproportionate number of subjects is randomised to one group. Because youth gender, age and baseline percent overweight may be related to obesity treatment outcomes the block randomisation procedure will balance these potential confounding variables across the two conditions; these variables will not be used as moderators/factors in the design. The master randomisation chart will be kept in a safe place and only accessible by the study's' biostatistician and data manager. RAs collecting data will be kept blind to participants' randomisation status to the extent possible in a behavioural clinical trial.

Measures

Primary outcome measures

Percent of body fat

Percent body fat will be measured using bioelectrical impedance analysis (BIA, RJL Systems, Clinton Township, Michigan, USA). In BIA measurement, a very weak electronic current is passed through the body by means of four electrodes placed on the dorsal surface of the hand and foot. The participant cannot feel the current. The body's resistance to this current is measured by the instrument and reflects the amount of fat and cell membranes that oppose the current. Studies have demonstrated that BIA estimation of body composition in AA females is comparable to that estimated by dual-energy X-ray absorptiometry (DEXA),[64] often considered the gold standard in measuring fat mass. Researchers[65] have developed a special BIA equation that considers race, based on data obtained from DEXA methodology for adolescent girls. As such, BIA will provide us with a reliable, accurate, and easily obtainable body composition data to estimate change in body composition.

Secondary outcome measures

Percent overweight

Percent overweight will be calculated as the percentage BMI above the CDC's median BMI for age and gender. BMI in kg/m^2 will subsequently be calculated and converted to BMI percentile using age and gender norms from the CDC. BMI in kg/m^2 is calculated from in-home weight and height measurements. Weight is measured using a portable digital scale with the capacity to reliably obtain weights up to 600 pounds. Height is obtained using a portable stadiometer.

Physical activity

Physical activity is assessed using the compact FitBit Inspire 2 accelerometer, which uses a tri-axial accelerometer and digital filtering proprietary machine-learning algorithms to analyse and estimate human movement patterns. Fitabase (Fitbit cloud-based software application) provides details of specific PA components including energy expenditure, step counts, sedentary time, distance travelled, and PA intensity. The Inspire 2 is a waterproof device; therefore, we will require participants to wear the Inspire 2 at all times, including showering and swimming. Data will be downloaded directly from Fitabase.

Symptoms of metabolic syndrome

Blood samples are obtained at the baseline (T1), 7-month end of treatment (T3) and 18-month postbaseline (T4)) assessments for measurement of plasma glucose, high-density lipoprotein cholesterol and triglyceride levels. Blood glucose and lipid levels are measured using the Alere Cholestech LDX, a psychometrically sound point

of care analyser[66–69] which requires only one drop of whole blood. Blood pressure is measured with a sphygmomanometer three times, with the second and third measurement averaged for analysis. We will obtain waist, hip, mid-arm and mid-thigh circumferences. We will also measure caregivers' weight and height and to derive a BMI.

Haemoglobin A1c

Haemoglobin A1c is obtained during the T1, T3 and T4 assessments using the Accubase A1c test kit,[70] a FDA-approved test that uses a capillary tube blood collection method instead of venipuncture. This collection technique makes it appropriate for home-based data collection by non-phlebotomists.

Moderators, cognition and mental health measures

Executive functioning

To assess executive functioning, we will administer the NIH Toolbox objective subtests measuring attention and executive functioning (Flanker Task), working memory (List Sorting Test) and cognitive flexibility (Dimensional Change Card Sort).

Delayed discounting

Preference for immediate over delayed rewards will be assessed using the Delayed Reward Discounting Task taken from NIDA's PhenX Toolkit.[71]

Cognitive functioning

Self-report about concerns about cognitive functioning over the previous week is assessed using the NEURO-QOL (Quality of Life in Neurological Disorders[72]), a set of NINDS-sponsored 'common currency' measures of health-related quality of life. The NEURO-QOL is psychometrically sound and designed to be completed in approximately 1 min.

Mental health functioning

Caregiver psychological symptoms will be measured using the Patient Health Questionnaire at T1, T2, T3 and T4 assessments. Adolescents' depressive symptoms are assessed using the 8-item Patient-Reported Outcomes Measurement Information System (PROMIS)—Paediatric Short Form V.1.0—Depressive Symptoms,[73] and adolescents' anxiety symptoms using the PROMIS—Paediatric Short Form V.1.0—Anxiety Symptoms.[73]

Control measures

Therapeutic alliance

To control for the quality of the relationship between participant and CHW as a potential confound, caregiver and teen participants will complete the 36-item Working Alliance Inventory[74] after their first treatment session and then at the T2 and T3 assessments. To assess and control for other services the youth may receive besides treatment conditions (FIT or HBFS), the caregiver is asked to complete the Service Utilisation Questionnaire at each assessment.

Family functioning

The Conflict Behaviour Questionnaire (CBQ[75]) is a 20-item true/false scale that assesses general conflict between parents and their children. The CBQ is administered at T1, T2, T3 and T4 assessments. The CBQ is completed by both caregivers and adolescents. The CBQ has been used extensively in the literature and has adequate internal consistency and has been found to discriminate between distressed and non-distressed families.[75]

Importance of weight loss

The importance ruler[76] is completed by the caregiver and adolescent assesses how important different behaviours are to youth weight loss, will also be administered at all four time points.

Readiness to change

The confidence rulers administered at all four time points to the caregiver and adolescent assesses their readiness to improve their behaviours towards healthier lifestyles.

Service utilisation

To assess and control for other services (psychotherapy, medications), the youth may receive besides treatment conditions (FIT or HBFS) and the caregiver will be asked to complete a Service Utilisation Questionnaire at each assessment.

Statistical analyses

The data analysis will have two parts. In the first part, we will do exploratory data analysis[77] using descriptive statistics to ensure underlying distributions for the second part are satisfied. We will examine the distribution of each variable. We will then check for out-of-range values, outliers, and abnormal values using graphical methods (e.g., boxplots and histograms) and descriptive summaries to ensure that all values are within expected ranges. Transformations will be used when distributional assumptions are not fulfilled for inferential tests. Tests will be conducted to identify the potential relationship between baseline demographic and clinical variables (eg, attention and executive functioning (Flanker task), working memory (List Sorting test), delayed discounting (Delayed Reward Discounting Task), impulsivity (Dimensional Change Card Sort), cognitive functioning (NEURO-QOL), psychopathology (Brief Symptom Inventory), depression (Beck Depression Inventory and PROMIS) and anxiety (PROMIS)) to our dependent variables and to see whether they are balanced between groups. If a baseline variable is not balanced between groups (i.e., is a potential confounder) and is correlated with the dependent variable ($r>0.30$), we will include this variable as a covariate in subsequent analyses. Inclusion of potential confounding variable(s) will enable us to control for them and prevent spurious effects (if any). Since we propose to test more than one primary hypothesis, the Hochberg step-down multiplicity adjustment will be used with a two-tailed family-wise alpha level of 0.05.[78] All other tests described below will each

have a two-tailed alpha level of 0.05. Outcome analyses will be based on the principle of intention to treat.[79]

Our analysis of the primary outcome is based on a mixed-effect model. This will be specified using Singer and Willett's[80] model building approach to mixed-effects regression models (MRMs) for repeated measure data. The research design leads to two levels of data, with four repeated measurements of adolescent percent overweight (level 1, subject) nested within the subject (level 2, within-subject). The MRMs will address variability in the number and spacing of measurements across participants, continuous and discrete outcome distributions, and curvilinear patterns of change. First, a fully unconditional model will estimate the proportion of outcome variance attributable to time (i.e., within-subject) and attributable to the subject (i.e., between-youth/caregiver). Second, and informed by the spaghetti plots, growth terms will be added to model the pattern of change over time. These terms will be computed using actual assessment dates, tailoring them to the observed spacing of measurements. Third, a dichotomous, uncentred indicator will be added (intervention vs control group), along with a cross-level interaction term between this indicator and the growth terms. This group effect will be treated as fixed effect and subjects' specific effect within a group will be treated as random effect. The resulting formulation will test for differences in baseline status and the rate of change over time (slopes) between intervention and control groups (this test will be obtained as a primary test for planned comparison). Prior to estimating the final model, systematic differences across treatment providers will be evaluated, and ultimately controlled, using fixed effects. With four repeated measurements, it is possible to specify fixed and random effects for a linear (i.e., straight-line) pattern of change over time, along with a fixed effect for a quadratic pattern of change. This combination allows the initial rate of change to vary randomly from subject to subject, with the acceleration of change over time (i.e., the speeding up or slowing down of the trajectory) being the same across subjects. Based on the model building results, an alternative formulation would be to include indicators to differentiate the three assessment occasions. This would compare the intervention and control conditions on their mean BMI at each occasion and in the amount of change occurring from occasion to occasion. Since more than one primary hypothesis is proposed (aims 1 and 2), the Hochberg step-down multiplicity adjustment[81] will be used for the coprimary hypotheses with a two-tailed family-wise alpha level of 0.05 across the two hypotheses. The decision rule for each primary hypothesis calls for the rejection of H_0 if the group×time interaction is statistically significant using the Hochberg adjustment. The models will be performed by using SAS (V.9.4) and SPSS V.24 (IBM). Significance tests for variance components will be based on the likelihood ratio test, tests for fixed effects will be based on the Wald test (ie, β/SE), and 95% CIs will be computed to reflect the magnitude and precision of the estimated effects.

Sample size

The sample size was determined based on statistical power analyses to detect clinically meaningful group differences for the primary hypotheses. This represents the differential course for the two intervention arms over time. Statistical power was estimated in a simulation study by using SAS V.9.3 PROC MIXED. The sample size for the study was based on the N needed to detect the two-way interaction (group×time). As stated above, because two primary hypotheses have been proposed, the Hochberg alpha adjustment will be used in hypothesis testing. The smaller of those sequential alpha levels of 0.025 (=0.05/2) was used in our estimates of the multiplicity-adjusted sample size. Based on the results, the protocol proposes the recruitment of 170 participants (85/cell). Our simulation is based on the statistical power to detect standardised interaction effects of various magnitudes (0.40–0.50) for the proposed sample size and a two-tailed alpha level of 0.025. (The magnitude of interactions is expressed as standardised differences at 12 months post-treatment that would be seen with differential slopes.) The intraclass correlation coefficient varied (ICC: 0.30, 0.40, 0.50, 0.60, based on pilot SMART data); and in an effort to account for attrition, the number of observations per participant was specified as 4. For each combination of simulation specifications, we generated 1000 data sets. We had observed ≤15% attrition in our pilot SMART study; however, the assessment schedule was less frequent in that study, which necessitates some adjustment in the final sample size per group. After accounting for about 10% for attrition, the proposed sample size of 90/group (N=180 total) provides the sufficient statistical power to detect differences in slopes that results in endpoint differences of ≥0.40 SD units with ICC=0.30 or 0.40 and ≥0.45 SD units with ICC=0.50 or 0.60. Based on our pilot data, these effects correspond to group differences that are feasible and clinically relevant.

Current status

The research protocol R01 R33HL155793 (Cunningham/Naar, MPIs) was funded by the NHLBI for the period 1 May 2022–30 April 2026. Notice of award was received on 5 May 2022. Enrolment began in November 2022 and will continue through January 2025. As of November 2023, 97 families have been consented and enrolled. The final proposed sample is N=180 families. This research protocol received Institutional Review Board for Human Research (IRB) of the MUSC approval in December 2020. We expect collection and data analyses to be completed by January 2025. Preliminary findings are expected to be published by June 2024.

Lessons learnt

Consistent with the biphasic (R61/R33) milestones-driven mechanism (PAR-19-328[46]) and the ORBIT model, the R61 Phase of the 'Clinical Trial of the FIT Families Multicomponent Obesity Intervention for African American Adolescents and Their

Caregivers: Next Step from the ORBIT Initiative' (R61 HL144895) was conducted to determine the feasibility and acceptability of study protocols with AAAO and their caregivers residing in SC to support transition to the R33 Phase,[46] which was approved in March 2022 (R33 HL155793). During the R61 phase, we were able to adapt and pilot test project organisation and management plans, finalise research and intervention protocols, develop a manual of operations, and obtain IRB approval (Pro00106021) and establish an independent Data and Safety Monitoring Board. We recruited a small sample of youth/caregiver dyads (n=18) from the recruitment sites and pilot tested our recruitment procedures. Based on our experience during the R61 Phase, we requested and received approval for a Change in Scope during the R33 Phase, to change our primary outcome from reductions in 'percent overweight' (ie, BMI) to reductions in 'percent body fat'. The rationale for this change was threefold. First, with advances in research on body fat percentage in recent years, this measurement provides a better picture of an individual's overall health and fitness, and risk of obesity-related diseases than BMI. Second, a major drawback of BMI is that it does not take into account how much weight is muscle and how much weight is fat, and as such, is considered a poor indicator for obesity, especially in adolescent athletes.[82] Conversely, percent body fat can distinguish between trained athletes who are overweight versus overfat (e.g., football players seen during our R61 Phase). Finally, it is widely accepted by nutritionists, dieticians, and physicians that weight loss (i.e., change in BMI) can be misleading and potentially detrimental to health, due to doing so can result in substantive reductions in lean body mass as often occurs when individuals focus on weight loss.[83] As a result of this change in scope, we changed our stratification variables from gender, age and baseline percent overweight to gender, age and baseline percent body fat. We conducted a power analysis with our new outcome variable 'percent body fat'. Originally, we proposed to power the study with a standardised effect size of 0.4 ('percent overweight', i.e., BMI) and a sample size of N=180. With our new outcome variable, 'percent body fat', we propose to achieve the same standardised effect size (0.4) which clinically translates to a reduction in body fat by 3 units in 6 months' time. All other statistical quantities (i.e., primary endpoint, 80% power, attrition rate) remain unchanged. From our prior experience with this population, this is a very achievable and feasible goal. Thus, we expect that this change in our primary outcome variable from BMI to percent body fat will have no significant effect on sample size and power calculation, and yet we will still be able to detect clinically meaningful group differences.

DISCUSSION

AAAO are likely to have caregivers who are overweight, which increases their chances of becoming obese as adults.[84–88] In treatment studies of obese youth, parents' own weight problems are associated with less weight loss.[84–88] Moreover, parental involvement is associated with the effectiveness of weight loss interventions for children with obesity.[87] As a result, researchers[89 90] as well as practice guidelines highlight the importance of parent involvement in youth obesity treatment. This study is designed to test the efficacy of FIT Families, a promising multicomponent behavioural intervention designed to treat AAAO, by increasing caregivers' participation through monitoring their child's implementation of evidence-based cognitive behavioural skills and PA, and modelling the use of these same skills by SM their own diet and exercise, and increasing their own PA. Our primary hypothesis is that AAAO and their caregivers randomised to FIT Families will show significantly greater reductions in percent body fat over a 12-month follow-up period (18 months postrandomisation) compared with AAAO receiving HBFS. Furthermore, it is expected that FIT participants will show significantly greater reductions in percent overweight, and significantly greater improvements in physical activities, SM of diet and exercise, and metabolic syndrome symptoms than families randomised to the control condition.

Health disparities in obesity among ethnic minority adolescents, especially AA, are a significant public health problem. Unfortunately, AAAO are likely to have caregivers who are also obese or overweight. This is not surprising as social determinants of health research suggest that home environments can substantially influence obesogenic lifestyles (e.g., high caloric intake, inadequate PA) often modelled by caregivers.[91–94] This protocol paper describes the design of a clinical trial testing the efficacy of the FIT Families intervention that was informed by the results from an NHLBI/NICHD centre grant ('FIT Families Project,' U01HL097889) that followed the NHLBI, ORBIT model[31] for developing behavioural interventions. Consistent with the Orbit Model of intervention development,[31] the 5% reduction we achieved in percent overweight in our developmental SMART,[41] and the health benefits of this reduction in a population that has shown little response to weight-lost treatments, coupled with culturally tailoring and optimisation of FIT and each of its evidence-based behavioural components (home-based services, CM, MI, CBST, skill acquisition), is expected to provide even further benefit and warrants further testing in the current trial. Our FIT Families trial will provide innovative and significant data that will help elucidate the effectiveness of this intervention, which is designed to address weight issues in a youth and parent, concurrently. This approach is highly novel and will generate data that may inform the next generation of obesity interventions for young people and their families from health disparate populations. Thus, this project has high significance in terms of potential public

health impact and reduction in obesity-related healthcare costs.

Data statement

At the expiration of the study locked data files and variable and scale dictionaries will be made available to the NIH for archiving and sharing with other researchers, in accordance with NIH policies. The PI (PC) will ensure that all datasets provided will be prepared in accordance with NIH requirements for data repository and associated documentation for submission to the Biological Specimen and Data Repository Information Coordinating Centre; NIH Policy for Data Sharing from basic research, survey, clinical trials, epidemiological and other types of research; and NIH Guidelines for Data Set Preparation. Results from the proposed study will be presented in required reports to NIH. Additionally, results will be presented to clinical researchers, clinical treatment organisations, and state and national legislative bodies as requested. Within 1 year of completion of the study and publication of the main study findings, we will make available the datasets publicly.

Furthermore, the data set, coding instructions and all other key study materials (i.e., data collection tools) will be made available in electronic form at the conclusion of the study as well as after the first major data paper is accepted for publication. We prioritise the privacy of all participants and will check to make certain that all identifying information has been removed, including information that could be combined that may identify an individual. Even though all data will be deidentified, we will provide an even greater level of human subjects' protection by making the data and associated documentation exclusively available to users under a data-sharing agreement that provides for:

1. A commitment to using the data only for research purposes and to avoid the identification of any individual participant.
2. A commitment to securing the data using appropriate computer technology.
3. A commitment to removing or returning the data after analyses is completed.

The dataset will be made available in a timely manner (i.e., no later than the acceptance of the main study papers for publication) and include data collected from all instruments, devices, and assessments. The documentation of the data will clearly describe each variable in the dataset, which instrument supplied that variable, and what each code for each variable represents. Copies of the instruments will also be made available. The documentation will also include explanatory notes regarding the collection of the data and any special codes used for missing data. It will also include all relevant references to publications which are based on the data. Data will be provided to any interested researcher or policy analyst or graduate student. We will be available to answer data-related questions as they arise from the recipients.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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