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Randomised trial of Mentored 'Planning to be Active+Family' [MPBA+F] for Appalachian youth at risk for diabetes: virtual delivery protocol

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ABSTRACT

Introduction Obesity (OB) in children remains a national epidemic. This trial targets children suffering from overweight (OW) and OB living in rural Appalachia. Rural Appalachia is fraught with unhealthy behaviours, high rates of OB, pre-diabetes and type 2 diabetes among children. Diabetes prevalence in Appalachia is nearly double that of other regions. The prevalence of Appalachian children suffering from OB and extreme obesity (EO) increases the severity of diabetes.

Methods and analysis We will conduct a stratified randomised-controlled trial to evaluate *Mentored Planning to be Active+Family (MPBA+F)* among seventh grade children with OW/OB/EO from rural Appalachian counties. Based on the Social Cognitive Theory, *MPBA+F* curriculum is a self-regulation approach to physical activity (PA) developed at The Ohio State University and successfully tested for feasibility in rural Appalachian middle schools. *MPBA+F* (a) incorporates active skill-building activities; (b) reinforces self-regulating activities; (c) engages in individual and group PA; (d) builds the link between PA, hydration and physical health and (e) actively supports weekly PA goals. Weekly skills are incorporated into reinforcement assignments verified at the beginning the following week. The primary outcome is the average daily minutes of moderate-vigorous PA. We will stratify by sex assigned at birth and conduct intent-to-treat analysis. We use descriptive statistics to summarise cohort and group (*MPBA+F*or comparison) baseline characteristics and examine variable distributions. Bivariate tests examine the balance of baseline characteristics by intervention groups. Mixed-effects linear modelling will be our more primary regression strategy. A potential problem is loss of curricular integrity. Our process assessment, structured mentor training and Instructor's Guide reduce this concern. Another concern may be the lack of reliable broadband access. Participating counties exceed 75% broadband access. Those who lose internet access may have materials mailed to their home or accessed on the study website.

Ethics and dissemination This study was reviewed and approved by the American Diabetes Association Grants Review Committee (Grant number 11-22-ICTSN-30), the host institution's Social and Behavioral Human Subjects Review Committee (Protocol 2022B0149) and is registered on ClinicalTrials.gov (Protocol NCT05758441). All data that can be shared without compromising human subject protections will be shared to an approved open data repository within six months of publication or 18 months of the conclusion of the funding period (November 2025) if the study remains unpublished. Dissemination to families and stakeholders is by project newsletters. Public presentation of findings will be shared at the Annual Appalachian Translational Research Network and local health department meetings.

Trial registration number NCT05758441.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Appalachians die more frequently and at younger ages from obesity-related conditions than those living elsewhere. Diabetes mortality in Appalachia rate is 11% higher than the national rate.

WHAT THIS STUDY ADDS

⇒ This clinical trial tests the effects of the Mentored Planning to be Active+Family intervention on physical activity (PA) and body composition among rural Appalachian middle school aged youth suffering from overweight or obesity.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Peer mentored guidance shifts PA intervention research away from teacher led initiatives to a sustainable model with broader community engagement and reach. Local peer mentors, mentees and parents are empowered to tailor and implement a health curriculum for self-regulation skills to increase PA.

INTRODUCTION

Obesity (OB) in children remains a national epidemic. Rural Appalachia is a low resource

area fraught with unhealthy behaviours, high rates of OB, pre-diabetes and type 2 diabetes among children.[1–6] This clinical trial targets children suffering from overweight (OW) and OB living in rural Appalachia. Appalachians die more frequently and at younger ages from OB-related conditions than those living elsewhere.[7] High prevalence of children suffering from OW, OB and extreme obesity (EO) in Appalachia increases the severity of diabetes.[2–6] In Appalachia, diabetes prevalence is nearly double that of non-Appalachian regions, and diabetes mortality rate is 11% higher than the national rate.[6–9]

Guided by Social Cognitive Theory and Developmental Mentoring Principles, *Mentored Planning to be Active plus Family (MPBA+F*) includes two components delivered over 9 months: (1) 10 peer mentoring sessions (1 day/week for 45 min each week) for youth to become more physically active (eg, aerobic activity, muscle strength and bone strength) at home. *MPBA+F*also promotes water for hydration. With content delivered by Project Leaders (PLs) coupled with peer mentoring to provide guidance, feedback and support, mentoring sessions are delivered virtually with no greater than 1:2 mentor/mentee ratios; (2) a 6-month family reinforcement component provides a home-based, parent-guided programme to support physical activity (PA) adherence, promote water for hydration and reinforce self-regulation skills. The structured family programme helps parents identify family PA needs, strengths and resources for daily PA.

Through promoting daily moderate-vigorous PA (MVPA), the long-term goal is to reduce the high rates of OW, OB/EO contributing to type 2 diabetes in rural Appalachia youth. The trial tests the effects of the *MPBA+F* intervention on PA outcomes ((MVPA, exercise 'bouts', sedentary behaviour) and body composition (body mass index (BMI), body fat, % body fat, weight) among rural Appalachian middle school aged youth suffering from OW, OB or EO. We posit that having local teen mentors increasing social support, self-efficacy and self-regulation skills through *MPBA+F* sustains PA and will improve body composition as children enter high school.

MPBA+F engages parents in supporting their child's PA by modifying home environments, family-centred PA and serving as role models. Residents (eg, peer mentors, mentees and parents) are empowered to tailor and implement a health curriculum for self-regulation skills to increase PA. Children set personally tailored PA goals and apply self-regulation skills to reach goals. They adapt the home environment to support their PA goals. Peer mentored guidance of *MPBA* shifts PA intervention research away from teacher led initiatives to a sustainable model with broader community engagement and reach. This study allows reach to home-schooled children and their families. Home-schooled children are underrepresented in research targeting health behaviours such as PA. Many studies targeting health behaviours rely on school-based samples.

METHODS AND ANALYSIS

Our primary aim (Aim 1) is to determine the effectiveness of *MPBA+F* compared with '*Tracking Health & Fitness',* 10 self-paced, self-guided modules developed by the Ohio State University Extension, on average daily minutes of MVPA. With a parent helper, *Tracking Health and Fitness* consists of 30-min learning modules focused on: defining health and fitness; measuring heart rate, measures of fitness, body temperature, benefits of PA on emotional health, why steps matter, reviewing fitness data and creating fitness goals. Secondary PA outcomes are numbers of exercise 'bouts' and average minutes of sedentary behaviour. We hypothesise that compared with the *Tracking Health & Fitness* group, children in the *MPBA+F* group will demonstrate greater improvements in daily PA outcomes.

A secondary aim (Aim 2) is to determine the effectiveness of *MPBA+F* compared with '*Tracking Health and Fitness*' on body composition (eg, BMI for age and gender, weight, body fat and body fat percentage). We hypothesise that compared with the *Tracking Health & Fitness* group, children in the *MPBA+F* group will demonstrate greater improvements in body composition outcomes. An exploratory aim (Aim 3) tests whether the intervention effects on outcomes differ by subgroups including sessions attended (child and reinforcement), sex assigned at birth and parent perceptions of child outcomes (eg, PA, health, social support).

Overall approach

Funded by the American Diabetes Association (Grant number 11-22-ICTSN-30), the study launched in February 2023 and will conclude in November 2025. We will conduct a stratified randomised controlled clinical trial. We stratify by biological sex at birth to have equal numbers of males and females in each group.

Sample

Rural Appalachian children suffering from OW, OB or EO in seventh grade (n=288) from one of 14 targeted counties will be recruited. Half of the children (n=144) are randomised to receive *MPBA+F;* the other half (n=144) receive '*Tracking your Health and Fitness'* mailed to their home. By following participants for 9 months (baseline) through the end of the family reinforcement programme, longer-term effects on PA outcomes and body composition can be determined. A subset of parents (72 parents from each condition) provide child assessments of perceived PA behaviours and perceived child health. Parent participants are recruited at the same time as their children. Tenth or eleventh grade (n=72) students from the same rural Appalachian counties are recruited to serve as peer mentors. Two doctoral students serve as PLs guiding the *MPBA* curricular content delivery to mentees.

Intervention

The '*Mentored Planning* to *be Active*' (MPBA) curriculum is a theory based self-regulation approach to PA[10–12]

successfully tested for feasibility in rural Appalachian middle schools. *MPBA* (a) incorporates active skill-building activities; (b) reinforces self-regulating activities; (c) engages in individual and group PA; (d) builds the link between PA, hydration and physical health and (e) actively supports weekly PA goals. *MPBA+F* incorporates content on water for hydration and reducing sugary drinks to enhance readiness for PA. Weekly skills are incorporated into homework (reinforcement) assignments verified by weekly checks at the beginning the following week. *MPBA+F* empowers children to develop a personally tailored approach to health behaviour change that is experience-based.

Each week, mentees consider ways to incorporate daily PA into their discretionary time, choose water for hydration and drink with less sugar. Personal goal setting and weekly plans tailor behaviours to each person's preferences, interests and environment. The approach empowers mentees to plan, regulate and evaluate their personal lifestyle. Parents are actively engaged in a structured 6-month, family reinforcement programme to strengthen engagement and support.

For the first phase, 10 peer-mentoring sessions (1 day/week for 45 min each week) are delivered virtually with a PL, peer mentors and mentees adhering to at least 1:2 mentor/mentee ratios. Each session consists of 10–15 min of content followed by 20–30 min of guided practice, social support, feedback and setting goals for the following week in mentor/mentee 'break-out' rooms (see box 1). Mentees track activities and efforts towards meeting their personal goals on weekly 'trackers'. Mentees review their efforts at achieving the prior week's goal with mentors. A project website used by the parents, mentees and peer mentors contains: (a) programme overview, (b) weekly structured session plans, activities and trackers (c) content cues and prompts, (d) session summaries, (e) forms and handouts, (f) study personnel contact information and (g) and *Mentor Discussion Guides* that outline the message(s) and social support provided during 'break-out' rooms.

Instructions for each module, contact information and options to submit 'Tracker' forms are on the project website. Parents are contacted every week by text or phone to check on progress in completing the modules. Parents receive a $5.00 incentive each for the monthly return of completed 'Tracker' forms.

The reinforcement component of *MPBA+F* is a guided, parent-directed 6-module (once a month for 6 months) programme to further support the child's home-based PA. The *MPBA+F* modules strengthen family-based support, encourage weekly family-based PA, provide community specific resources for PA and reinforce the PA skills learnt through the *MPBA* programme (see box 2). The comparison group participate in a 6-month rewards-based programme to encourage sustainability of weekly.

Box 1 Curricular topics for MPBA programme

Lesson curricula

1. Program overview, expectations, physical activity, water, 'and Pop' trackers
2. Review of activity trackers, SMART activity goals, everyday activities to reach goals
3. Benefits of water, how much water do you need? Water for exercise
4. Benefits of water for hydration and less sugary drinks for exercise
5. Exercise myths, find your comfort zone, measure pulse, tailoring activities
6. Tailor your activity plans, barriers & motivators for PA, plans to overcome barriers
7. Friends and family for social support, how to help one another
8. Ways to track progress, finding what I like. Using cellphone apps, journals, calendars
9. Time management for success. How to find time to exercise
10. Plan for long-term success: tracking, goal setting and personal choices to keep going

Box 2 Curricular topics for +F program

Lesson curricular topic

1. Family and PA, importance of PA, role of family in support of PA, health benefits
2. SMART activity goals, daily activities to reach goals, how to tailor activities, exercise myths
3. Put into action: tailor your activity plans, barriers & motivators for PA, overcoming barriers
4. Benefits of water: water for exercise - water trackers for success/drink less sugary drinks
5. Friends, family, & others for social support, helping one another-resources for exercise and activities to do. Find what works for you to track progress (apps, journals, calendars)
6. Long-term success: tracking, goal setting, support from others, managing time & choices

Eligibility

Using Centers for Disease Control and Prevention (CDC) guidelines for age and gender to classify BMI, OW status is classified at the 85th percentile (%) to less than the 95th%; OB is at or above the 95th%.[13] EO is having a BMI 120% of the 95th% or an absolute BMI at 35 kg/m^2, whichever is lower based on age and sex assigned at birth.[14] An absolute BMI threshold (35 kg/m^2) aligns with the paediatric definition of class II OB in adults, a high-risk category of OB associated with early adult mortality.[15] Children are eligible if they are: (a) enrolled in seventh grade at the start of the study, (b) have a BMI of the 85th% or greater, (c) not under medical care for OB or type 1 diabetes, (d) have reliable internet connection at home, (e) have access to a computer, laptop or tablet at home and (f) not expected to move from a participating county before the study concludes. Parents are eligible to participate if they can read at a fifth grade-level, speak English, have a home-mailing address (not PO box), have a working telephone number and are not expected to move from a participating county before study conclusion. Targeted counties exceed 75% of high-speed internet access.

High school students are eligible to participate as peer mentors if they: (a) are in either tenth or eleventh grade, (b) reside in a targeted county, (c) are interested in working with peers, supporting others and striving to cultivate their own health-supportive behaviours, (d) have reliable internet connection at home, (e) have access to a computer, laptop or tablet at home, (f) are not expected to move before the intervention ends, (g) speak English and (h) are recommended by a teacher, school advisor or counsellor. Teens interested in serving as a peer mentor complete an application form; selection is based on study needs, motivation to serve and recommendations.

Power analysis

Sample size is based on the intervention effect on average daily MVPA (the primary PA outcome). The power analysis suggests that we will need to recruit 288 seventh grade children to have 80% power to detect a between-group difference in change from baseline with a small-to-medium effect size (Cohen's *d* of 0.40) at final follow-up. This effect size is translated to a between-group difference of 30 min in weekly MVPA, assuming the corresponding SD of 75 min based on the pilot data.

The power analysis used mixed-effects linear modelling with a two-sided alpha of 0.05, assuming a correlation of 0.7 between measures of two time points and an attrition rate of 20% at follow-up. All assumptions were based on pilot data. Similarly, this sample size provides 80% power for the between-group differences of $d \geq 0.40$ in the change of other PA outcomes (exercise bouts and sedentary behaviours) for Aim 1 and body composition for Aim 2. Power analyses were not conducted for Aim 3 due to its exploratory nature.

Recruitment

A multiphased recruitment strategy is planned. First, referrals from 29 school nurses at partner schools will be sought. Second, we avail our institution's physical presence in every targeted county through local extension offices to advertise for the study with flyers and ads on local websites. Home schooling families under-represented in studies frequently use local extension programmes for health-related programming. Our third phase of recruitment is social media advertisements on Facebook and Instagram. Each advertisement describes the study and provides a link to an eligibility screening survey on Qualtrics. Advertisements run for 4 weeks. Results from each Qualtrics survey will be assessed weekly. Those eligible for the study will be contacted by email to arrange for consent, assent and baseline data collection.

Randomisation

A computerised randomisation module was created to assign enrolled children to *MPBA+F*versus comparison group. We employ stratified randomisation by biological sex at birth (male vs female). Children in each sex stratum will be randomly allocated 1:1 to *MPBA+F*versus comparison group using permuted block randomisation with varying block sizes of 2 or 4.

Training

PLs are trained on the delivery of the *MPBA* curricular content and management of the Zoom platform for virtual delivery. Peer mentor trainings are held 'virtually' via the Zoom meeting platform. Peer-mentor training follows the *Developmental Mentoring Training Methods*[16] adapted (with permission) for use with this project.[17] Training stresses the provision of tailored support using both didactic and experiential methods such as role-play, demonstration, guidance and feedback for skill-building. Peer mentor training includes mentoring responsibilities, sharing points of view, working with different points of view, role-playing and motivating mentees. Training also includes engaging and offering support to younger mentees in a virtual environment, use of the Zoom platform and the 'breakout room' feature. These training and debriefing approaches have been successfully used in preliminary studies.[18–21]

Data collection training and procedures

Undergraduate students serve as research assistants (RAs, trained in data-collection procedures and blinded to study conditions) to conduct data collection. Measurement teams (blinded, RAs) perform only functions for which they are certified. Prior to baseline data collection, a series of training sessions are held for data collection staff including using *ActiGraph GT3X+* accelerometers[22] and *Tanita 430-DCU Analyzers*[23] as well as administration of the data-collection instruments.

To assure standardisation and quality of data collection, training includes a review of the eligibility criteria and consent procedures; overview of the measurement protocols; demonstration of the measurement methods and an opportunity to have each measurement team mock data collect on several subjects and gain expert feedback on their ability to follow protocol. This training occurs prior to each data-collection time-period at baseline (T1), the conclusion of the 10-session mentoring or comparison programme (T2) and following the 6-month reinforcement programme (T3). Informed consent and written child assent are documented on tracking forms to link the participant to their study identification number. For subsequent data collection, the identification number are used.

Data are collected at community sites such as libraries and local extension field offices over a 3-week data collection time-period. Data are obtained from the parent (if applicable) and child at the same time. Child anthropometric data are obtained in a private room at the site. No data will be saved on the laptop or other portable devices. Data are entered into a secure, encrypted and password protected database server within 72 hours of data collection. The server is backed up at least every 24 hours. Access to these data will be limited to approved project staff.

Outcomes and procedures

Physical activity

ActiGraph GT3X+ accelerometers measure PA. Child PA data are measured at baseline, midpoint before family reinforcement programme begins and at the end of family reinforcement programme. Cut points for counts per minute are above 3962=vigorous PA; 1535–3961=moderate PA; 100–1534=light PA and 0–100=sedentary activity.[22 24 25] Two or more continuous hours of zero counts suggests that the device was not worn and are excluded from sedentary analysis. Exercise 'bouts' counts above 1535/min for 10 or more continuous minutes.[24 25]

The device is distributed with written and verbal instructions on how to wear the device to both parent and child. A demonstration of the correct right iliac crest placement of the monitor using a belt provided is given. Each child receives a belt to allow for the correct placement of the device. Written directions assure correct placement of the device in subsequent days. Collection of the PA variable requires that the device be worn for 24 hours/day for 7 days. A text or email reminder will be sent to the parent every other day during the monitoring period to ensure child participants are adhering to instructions. Instructions are provided on how and when to return the device by prepaid mail. Parents will be provided study team contact information to answer any questions during accelerometer data collection.

Child participants will receive a $20 incentive at each of the three data collection time-points for a total of $60.00. Child incentives are provided when the assigned accelerometer is returned. Parents will receive $25.00 incentive during each of two data collection time-points for a total of $50.00.

Body composition

RAs collect anthropometric (body composition) data using the *Tanita 430-DCU Body Composition Analyzer*. Standard measurement is used to obtain the most reliable results.[26 27] Anthropometric data are collected individually and away from other data collection areas. First, children remove outer clothing such as coats and sweatshirts. Height is obtained by standing without shoes on a portable stadiometer while facing forward. Next, the child's age, gender and height are entered into the analyzer. Third, children stand on the analyzer without shoes or socks having their feet on the measuring pad and hands directed down the sides of their legs. *BMI for age and gender* is calculated by the analyzer as: weight Ob)/[height (in)]2×703. Using standard body fat ranges, *body fat percentage* is as the amount of body fat as a proportion of body weight by the analyzer. *Fat mass* is the actual weight of fat in the child's body. *Raw weight* will be measured in kilograms.

Parent perceptions of PA behaviors and health

Using 5-point Likert scales, the 8-item *PROMIS Physical Activity* measures parent's perceptions of their child's performance of PA over the past 7 days.[28 29] Physical actions reflect bodily movement ranging from simple static behaviours with minimal muscle activity to more complex activities requiring dynamic or sustained muscle activity and greater movement of the body. Scoring is specified in the *Users' Guide*[26] The 7-item *PROMIS Global Health* measures parent perceptions of their child's overall general health, physical health, mental health, social health and quality of life. Scoring is specified in the *Users'* Guide.[30]

Parent perceptions of child's social support

Parents rate the support they think their child receives from family and peers for PA over the past month on a 3-point scale ranging from 1 (none) to 3 (many times). Items are averaged to create scores for each subscale (eg, positive family, negative family, positive peer and negative peer support for PA).[31]

Sessions attended (dose effects)

The number of sessions attended by mentees is calculated. The total number of returned module forms by parents of children in the usual care group will be calculated. The number of completed tracking sheets from family reinforcement programmes returned from each group will be calculated. The total number of sessions will be calculated by summing all for a total score. Analysis will include separate effects and combined effects.

Data analysis

Congruent with the stratified-RCT (randomized controlled trial) design, we will conduct intent-to-treat analysis. First, descriptive statistics summarise cohort and group (*MPBA+F*or comparison) baseline characteristics and examine variable distributions. Bivariate tests (eg, t-tests or χ^2 tests) examine the balance of baseline characteristics by intervention groups. We will identify unbalanced baseline characteristics as those having a between-group standardised (Z) difference score of 0.2 or higher. The advantage of Z-difference score is that it is a unified approach for both continuous and categorical variables. As balanced characteristics at the beginning of the trial may become unbalanced due to attrition, we will repeat the above-described balance checking at each time point. Following the recommendations from Altman and Senn,[32 33] we will adjust for baseline imbalance identified at any time point (T1, T2 and T3) as covariates in the subsequent regression models. Altman illustrated that even small imbalance in baseline covariates may introduce bias in treatment effect estimates.[32] Therefore, we chose a Z-difference score cut-off of 0.2 (small but not trivial effect size)[34] to identify and adjust for baseline imbalance. Mixed-effects linear modelling is the primary regression strategy. The primary aim is to determine the effectiveness of *MPBA+F* compared with *Tracking Health & Fitness* delivered by self-guided modules on PA outcomes (eg, MVPA (the primary outcome), exercise 'bouts' and sedentary behaviour). Descriptive statistics and trend

plots summarise and visually compare each outcome across time for each group.

Next, mixed-effects linear modelling models each outcome as a linear function of the fixed effects of treatment (MPBA+F vs comparison), time (Tl vs T2 vs T3) and the treatment by time interaction as well as the subject-specific random intercepts. It is reasonable to assume higher correlations between outcomes that are close together than those that are far apart in time. Therefore, the first-order auto-regressive [AR(1)] covariance structure will be the primary choice. Other covariance structure will be chosen if it significantly improves the model fit indicated by lower Akaike's information criterion and Bayesian information criterion compared with the AR(1) model. Restricted maximum likelihood will be used for parameter estimation. From the model, estimates of the effects of *MPBA+F* (between-group differences in outcome change from T1 to T2 and T3) are derived, adjusting for within-subject clustering from repeated measures and covariates (eg, sex assigned at birth, un-balanced baseline characteristics if any and baseline characteristics associated with attrition). For exercise bouts, we will use generalised linear mixed-effects model (eg, mixed-effects Poisson regression or mixed-effects negative binormal regression).

A secondary aim determines the effectiveness of *MPBA+F* compared with *Tracking Health & Fitness* on body composition (eg, BMI for age and gender, weight, body fat and body fat percentage). The same analytical methods as Aim 1 (descriptive statistics, trend plots and followed by mixed-effects linear modelling) estimate MPBA+F effects on each body composition measure.

An exploratory aim tests whether the intervention effects differ by sessions attended (child and reinforcement), sex assigned at birth or parent perceptions of child outcomes (PA, health, social support). This aim tests the moderating effects of each factor. First, visual plot means estimate each outcome (Y) at different levels of both X (intervention) and W (eg, biological sex). Two lines to represent the effect of X on Y on the two values of W are created. For continuous measures, the low and high values are chosen as one SD below and above the mean, respectively. Moderating effect is suggested if the two lines are not parallel to each other. The significance of the moderating effect by including the interaction term of X and W in the mixed-effects regression models is tested. A significant interaction between X and W suggests that the effect of X on Y changes at different levels of W.

Point estimates, the variability of the estimates (eg, SD, 95% CI) and effect sizes in addition to statistical significance are reported. These estimates along with their clinical significance guide the interpretation of study findings and intermediate decision making in the process of data analysis.

We will examine missing data and compare those with and without missing at baseline and follow-ups. Appropriate multiple imputation using Markov Chain Monte Carlo algorithm with 20 imputations for each intervention group if the expected 20% attrition holds will be performed for missing at random.[35 36]

Mixed-effects regression modelling accommodates data missing at random and is robust by including auxiliary variable associated with missingness. We will repeat analyses before and after multiple imputation. If missing not at random exists, pattern mixture modelling will be used.[37 38] Sensitivity analysis will examine the robustness of study findings from analyses before and after multiple imputation or under pattern mixture modelling.

Patient and public involvement

Parents and community stakeholders identify OB and early-onset diabetes as a leading health concern in rural Appalachia. Through personal interviews, community representatives stressed the need to focus intervention efforts on youth. Because schools are focused on meeting the core academic needs of students, a flexible intervention not reliant on school time or use of school resources was developed. Teachers assisted in the virtual-delivery design. Parent participants provided information needed for scheduling such as planned holidays, best time of day and best day of week for mentoring sessions. High school students provided input on how peer mentoring could be delivered in a virtual format.

The intervention burden was assessed by local peer mentors, parents and teachers. A weekly session lasting 40–45 min was determined to be the best plan. This community-driven intervention has trained high school students serve as peer mentors to the younger mentees and parents assessing goal achievement. The peer mentors deliver mentoring sessions, provide guidance and support mentees. Parents complete weekly trackers that assess their child's efforts each week. Results are disseminated to family participants and interested schools through project newsletters. Public presentation of findings will be offered through the Annual Appalachian Translational Research Network and local health department meetings.

Ethics and dissemination plan

This study was reviewed and funded by the American Diabetes Association Grants Review Committee (Grant: 11-22-ICTSN-30). The study is approved by the host institutions' Social and Behavioural Human Subjects Review Committee (Protocol: 2022B0149) and is registered on ClinicalTrials.gov. Study data are securely stored. All data resulting that can be shared without compromising human subject protections will be available on approved open data repository within 6 months of publication or 18 months of the conclusion of the funding period (November 2025) if the study remains unpublished.

Study-related data will be anonymised, catalogued and stored per federal guidelines and policies at the host institution. Resources developed will be made available to the broader scientific community.

A public-use, de-identified data set will be available to qualified researchers on request and after analyses of the study's aims are completed with findings published. Interested parties must make a request in writing with a statement of intended use. Data will be securely shared via the most cost-effective means agreed on by both parties. Requirements for sharing include acknowledgement of funding source for publications and study authors. Research findings will be shared through publications and presentations at scholarly research meetings. At the conclusion of the study, curricular materials will be available at no charge.

Contributors LHS is the lead author and principal investigator of the study. LHS wrote all sections of the paper. LHS is responsible for overall content as guarantor. As such, LHS is responsible for the work, has access to the data, and controlled publication decisions. RLP is the co-author and co-investigator. RLP wrote descriptions of physical activity measures, including measurement and analysis of accelerometry data. RLP co-wrote the intervention content. AT is the co-author, co-investigator and statistician. AT co-wrote the power analysis section and overall data analysis plan. SS is the co-author and project director. SS contributed to the introduction and background sections. She contributed to the description of the intervention delivery procedures. YP is the co-author and project director. YP contributed to the introduction and background sections. He also contributed to the randomisation procedure and discussion section.

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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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