ISRCTN24274245 https://doi.org/10.1186/ISRCTN24274245

Generations Health Project: Promoting Child Health in Out-of-School and Home Settings

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
23/04/2018

Overall study status
Completed

Last Edited
02/08/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Obesity rates are much higher among rural children than non-rural children in the United States, and high among rural minority children, particularly American Indian children. Novel health promotion strategies are needed for children and minorities living in rural areas that encompass the cultural and contextual strengths of rural communities and engage parents. Poverty is particularly acute among rural children, and residents often lack access to healthy foods and physical activity (PA) opportunities compared with urban residents. Despite these challenges, rural residents often have strong social ties and common values for well-being and health. Leveraging the strengths unique to rural communities may ensure responsive and effective strategies to improve child health in rural environments. A recent review of obesity research targeting children and minority populations living in underserved communities show that very few trials intervene at multiple levels or factors (e.g., home, school, out-of-school, local policies). More than 10 million children in the United States participate in out-of-school programs (OOSPs) with rural and low-income children, and children of color participating at higher rates. Engaging children in out-of-school program activities that support and encourage more healthful behaviors holds promise for achieving and maintaining a healthy weight throughout life. However, this support and encouragement must translate to home environments, so supporting parents to make changes in the home environment for food and PA is critical. Generations Health starts with OOSPs as the launching intervention implementation point that moves out to multiple settings (e.g., parents at home, local policies) for changing rural children's health behaviors. This study assessed the feasibility and behavioral and health-related outcomes of the Generations Health program in a rural, OOSP on an American Indian reservation. Knowledge of this information sets the foundation for future effectiveness studies that extend the reach of the intervention into multiple rural communities with a high proportion of American Indians.

Who can participate?
Children, age 6-9 years old, who attend one out-of-school program on a rural, American Indian Reservation at least three times per week during the school year, and their parent, caregiver or guardian who make most of the food and activity decisions in the household.

What does the study involve?
Participants are randomized to one of two groups. Children in the Generations Health treatment

group receive activities every day the OOSP is in session. These daily, 60-minute activities focus on increasing physical activity and reducing TV/screen time, and improving healthy eating and sleep. Each week parents in the Generations Health group receive three take-home toolkits with materials and resources that support the Generations Health activities children take part in when they are at the OOSP. Parents also receive a weekly text message to remind them of project activities. Families in the Generations Health group attend three, 90-minute family nights with cooking, physical activity and healthy lifestyles hands-on activities during each month of the study. Children in the comparison group receive the usual out-of-school program activities at the OOSP site, which include chances for physical activity. There are no activities for parents in the comparison group, except to complete pre- and posttest measures.

What are the possible benefits and risks of participating?
All participants receive information about ways to encourage physical activity and healthy eating at home at the end of the study. Participants randomized to the Generations Health group are given resources to complete the intervention activities. These resources include food items for making healthy meals and snacks at home, pedometers, and other items to encourage physical activity, healthy eating, sleep quality and turning off TV and screens at home. There are no risks of physical injury or harm or health risks in participants taking part in the study. To avoid any risk of embarrassment in collecting health and behavioral study measures in participants, project staff perform measurement collection in a private room at the OOSP site.

Where is the study run from?
The University of Montana in Missoula Montana, Salish-Kootenai College in Pablo, Montana, and the Flathead and Lake County Boys and Girls Club in Ronan, Montana (United States).

When did the study start and how long did it run for?
April 2015 to December 2015

Who funded the study?
National Institute of General Medical Sciences of the National Institutes of Health under Award Number P20GM10347

Who is the main contact?
Dr Blakely Brown (Scientific)
blakely.brown@umontana.edu

Contact information

Type(s)
Public

Contact name
Dr Blakely Brown

ORCID ID
http://orcid.org/0000-0001-9036-9562

Contact details
206 McGill Hall
32 Campus Drive
The University of Montana

Missoula
United States of America
58912
+1 (0)406 243 6524
blakely.brown@umontana.edu

Type(s)
Scientific

Contact name
Dr Blakely Brown

Contact details
206 McGill Hall
32 Campus Drive
The University of Montana
Missoula
United States of America
59812
+1 (0)406 243 6524
blakely.brown@umontana.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1001

Study information

Scientific Title
Determining the feasibility of an out-of-school and home-based obesity prevention intervention for children living on a rural American Indian reservation: a two-group, randomized, controlled pilot study

Study objectives
Hypothesis 1: The 11-week Generations Health pilot study will show high recruitment, participation and program satisfaction rates. These outcomes demonstrate strong feasibility for a full-scale trial of the Generations Health child obesity prevention intervention.
Hypothesis 2: At 11 weeks, children in the Generations Health condition will have healthier weight status (primary outcome child zBMI), and improved changes physical activity, healthy eating, sleep, TV/screen time compared to children in the comparison condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board at Salish-Kootenai College, Pablo Montana, USA, 03/04/2015, ref: protocol #2014_19

Study design
Two-group randomized feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Childhood overweight/obesity

Interventions
Participants were Native American (NA) and non-Native American children and their parents at one out-of-school program located on a rural American Indian reservation. Children (n=23, ages 6-9, 52% NA) were randomized to receive the Generations Health intervention or comparison condition. The Generations Health group received daily activities focused on physical activity, nutrition, sleep, and reducing TV/screen time. The Generations Health activities frequently engaged parents. The comparison group received usual out-of-school program activities.

The Generations Health intervention program components promote dynamic, integrated activities for increasing PA, reducing TV/screen time, improving sleep, preferring and consuming healthy foods in children, and engaging parents to support these behaviours in their child. Each Generations Health OOSP session begins with 40-minutes of moderate-to vigorous physical activity (MVPA) that is followed by 20-minutes of nutrition, reducing sedentary behaviours including TV/screen time, and improving sleep activities. The intervention targets for nutrition and PA are based on previous studies in out-of-school program (OOSP) settings and national recommendations. Project staff encourage children to participate in the Generations Health activities at least 3 times per week on days of their choice while they attend the OOSP.
The physical activity portion of the program is designed to engage children in activities such as aerobic dance, jump rope, hula-hoop and kickball by increasing their activity in incremental steps and in ways that are intended to be enjoyable. All activities are game-like and non-competitive. These strategies are designed to increase a child’s sense of self-efficacy and keep children active at a moderate to vigorous level.
The nutrition portion of the program is designed to build skills that make it easy and fun to consume a diet that delivers a balanced array of nutrients from fruits and vegetables, whole grains, lean meats, legumes, and foods and beverages low in sodium and added sugars. Sessions use hands-on activities for understanding portion size, calorie and nutrient content on food labels, and limiting unhealthy snacks. The sleep portion of the program is designed to improve

sleep by having children role play bedtime routines and engage in stories and conversations about sleep. The reducing sedentary behaviors portion of the program is designed to reduce the amount of time children spend watching TV or screens. Sessions use games that challenge children to turn off TVs and electronic devices and play active games instead, and hands on activities comparing heart rates during sedentary and active behaviors with discussions of the differences.

Parents of children in the Generations Health program receive take-home toolkit materials and activities 3 times per week from program staff when they pick up their child(ren) at the OOSP. Each toolkit contains interactive, hands-on learning activities and healthy lifestyle reinforcers such as cooking supplies (e.g., coolers with foods their child made during the program for the family to taste at home, recipes, food coupons, fruit challenge games, family activities that repeat concepts from OOSP sessions), exercise equipment (e.g., jump ropes with jumping songs, flex bands and exercises), bedtime routine activities (e.g., stories about children living in rural areas, bedtime routine check-off list games) and turn off the TV/screen time interactive challenge activities. Parents also participate in monthly family nights. Each family night begins with families eating a healthy dinner together (i.e. stew made with bison meat and vegetables and salad). Then families rotate through stations where they engage in dynamic hands-on activities that repeat concepts from the Generations Health sessions. For example, at a “Make a tasty snack” station, families select from raw nuts and dried fruit to make a healthy trail-mix snack. At a “Family fun games!” station, families play a relay race and giant tic tac toe games. At a “Is there caffeine in there?” station, families create a list of non-caffeinated drinks that can be enjoyed closer to bedtime. Many of the Generations Health activities are tailored to be culturally- and contextually relevant for children and families living in the Northern Plains rural communities.

Generations Health group activities for children were offered every day the OOSP was in session (48 days) over an 11-week period. These activities took place at a different location than the OOSP and children took a 5-minute van ride to this location. Each week parents received three take-home toolkits (n=33) with associated materials (e.g., coolers with recipe ingredients, strength and flexibility bands, pedometers, etc.) when they picked up their child(ren) at the OOSP. In addition, project staff hosted three family nights for all family members in this group, and a 1-hour informational session during the first two weeks of the study. At this session, project staff talked more in-depth with parents of children in this group about the various intervention components such as the take-home toolkits, returning toolkit prize tickets to the OOSP, reminding parents of upcoming schedules for family nights and measurement outcomes, and answered questions about the study. Project staff sent parents text messages to remind them of key events, such as upcoming family nights. All project staff (n=5) attended a day-long training session on delivering the Generations Health components 3 weeks before the study began.

Children in the comparison group received the usual Club activities at the OOSP site, which routinely included opportunities for physical activity. There were no activities for parents in the comparison group, except to complete pre- and posttest measures.

Randomization procedure

This was a randomized, pretest to posttest two-group feasibility study of the Generations Health intervention. The study was 11-weeks in duration and there were two data collection periods: baseline (September 2015) and final assessment (December 2015); data were analyzed in April 2016. The study took place at an existing Boys and Girls Club OOSP site in a small, rural town on an American Indian (AI) reservation (population 29,000) comprised of 33% AI and 66% non-AI people.

Randomization to the Generations Health treatment group or the usual OOSP activities group (from this point on referred to as the comparison group) occurred after parents and children

completed all baseline measures. Project staff opened an envelope that contained pre-determined group assignments (Generations Health or comparison group); families were assigned to the group indicated in the envelope. Immediately following randomization, participants were handed a letter informing them of their group assignment and describing the activities associated with that group. To assure equal allocation, the randomization scheme was constructed using permuted block sizes of 4. Only the Co-Investigator (Harris) had access to allocation codes before randomization. As this was a feasibility study, no stratification was used.

Intervention Type
Behavioural

Primary outcome measure
Intervention feasibility outcomes:
1. Recruitment is measured by recording the number of children who express interest in participating in the study and who meet initial eligibility criteria, during the 22 days before baseline
2. Intervention participation is measured by recording whether or not each child in the Generations Health group attend the daily intervention sessions at the out-of-school program site, during the 48 days of the intervention period (Weeks 1 to 11).
3. Measurement participation is measured by recording whether or not the child and parent in the study completed each outcome measure at baseline (pretest) and at the end of the 11-week intervention (posttest).
4. Participation in the take-home activities is measured by the number of tear-off portions of the take-home cards, signed by their parent, that a child in the Generations group returns to the out-of-school program site during the 48 days of the intervention period (Weeks 1 to 11).
5. Program satisfaction is measured by parents in the Generations Group rating their overall satisfaction with the Generations Health program and the family nights on Likert scale ranging from 1 (not at all) to 5 (very high) and parent responses to open ended questions about the “best part” and “recommended changes” to the project, at posttest.

Secondary outcome measures
Behavioural and health outcomes:
1. Height is measured using a portable stadiometer and weight is measured using an electronic scale, at baseline (pretest) and at the end of the 11-week intervention (posttest).
2. Kilocalorie intake and Healthy Eating Index scores are measured using the online National Cancer Institute’s ASA24TM-2014 system, at baseline (pretest) and at the end of the 11-week intervention (posttest).
3. Physical activity and sleep efficiency is measured using 7-day wrist-worn activity monitors, at baseline (pretest) and at the end of the 11-week intervention (posttest).
4. TV/screen time is measured by three questions that ask children to self-report the number of hours per day they spent watching TV, playing video games, and using a computer for non-school related activities. Responses are summed across the three questions to estimate the number of hours screen time viewed per day across a 7-day period, at baseline (pretest) and at the end of the 11-week intervention (posttest).
5. Children’s knowledge of nutrition is assessed by asking children to indicate which of twelve paired foods are “better for your health.” Number of correct responses are summed and ranged from 0 to 12, at baseline (pretest) and at the end of the 11-week intervention (posttest).

Overall study start date
01/04/2015

Completion date
20/12/2015

Eligibility

Key inclusion criteria
Native American (NA) and non-Native American children, age 6 - 9 years old enrolled at an out-of-school program located on a rural American Indian reservation, and the child's primary parent /caregiver. Eligibility criteria for the children included being 6-9 years old, attending the out-of-school program at least 3 times per week, and planned to attend the out-of-school program throughout the study period.

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
23 child/parent dyads

Key exclusion criteria
1. Children not between the ages of 6-9 years old
2. Attended the out-of-school program less than 3 times per week, or planned to not to attend the out-of-school program throughout the study period

Date of first enrolment
15/08/2015

Date of final enrolment
10/09/2015

Locations

Countries of recruitment
United States of America

Study participating centre
Boys and Girls Club of the Flathead Reservation and Lake County
United States of America
59864

Sponsor information

Organisation
University of Montana Office of Research and Sponsored Programs

Sponsor details
101 Main Hall
32 Campus Drive
The University of Montana
Missoula
United States of America
59812

Sponsor type
University/education

ROR
https://ror.org/0078xmk34

Funder(s)

Funder type
Government

Funder Name
National Institute of General Medical Sciences Award Number P20GM103474.

Alternative Name(s)
U.S. National Institute of General Medical Sciences, NIGMS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date. The partnership that conducted the study (e.g. University of Montana, The Flathead Boys and Girls Club, Salish-Kootenai College) are in the process of formalizing a data sharing and access plan. The trialists hope to make this protocol public in on or before January 1, 2019. Please contact the lead author (Brown) for further details.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/07/2018		Yes	No