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Peers empowering peers

Submission date
04/02/2024

Recruitment status
No longer recruiting

Registration date
07/02/2024

Overall study status
Completed

Last Edited
07/02/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
African American (AA) grandmothers are the most revered members of the AA community, serving as a source of heritage and wisdom. Almost 30% of AA grandmothers living with grandchildren serve as primary caregivers compared to 9% of the general population. While most AA grandmothers describe caring for their grandchildren as a rewarding experience, emotional stress from financial constraints, inadequate social support and managing a household often lead to unhealthy coping behaviors like overeating. About 80% of AA grandmother caregivers are overweight or obese, increasing their risk of diabetes, heart disease, and other obesity-related complications. Grandmothers also play an important role in the formation of food habits and preferences of their grandchildren by modeling their own eating behaviors and food preferences. Overweight or obese AA grandmothers who are caregivers for their grandchildren may benefit from interventions to reduce obesity and prevent diabetes, and improvements in their lifestyles may translate to benefits in reducing the alarming obesity trend among African American grandchildren.
The Diabetes Prevention Program (DPP) is an evidence-based, lifestyle change program that has been shown to decrease the risk of diabetes through weight loss among all participants, including African Americans. However, suboptimal weight loss outcomes have been reported among AAs, particularly older women who participated in DPP translations in 'real world' settings. High attrition and low attendance may have contributed to these outcomes, indicating additional enhancements are needed to optimize outcomes for AAs, particularly AA grandmothers. In an earlier study, AA grandmothers who were the sole economic and parenting providers within the home reported that peer support provided a positive sense of accountability and confidence to make lifestyle changes that result in weight loss.
In this study the researchers propose augmenting the DPP with an novel peer support program, Healthy Outcomes through Peer Educators (HOPE), where grandmothers serve as peers to other grandmothers who are enrolled in the DPP. HOPE uses peer support to build self-efficacy and provide needed encouragement and positive reinforcement essential for successful sustainable health behaviors regarding diet and exercise within a low resource environment. HOPE may increase retention and participation in DPP, allowing grandmothers to fully benefit from the program. The researchers are planning a future large trial to evaluate the effects of HOPE + DPP to reduce diabetes risk factors among overweight and obese AA grandmothers with prediabetes and the 'spillover' effect on their grandchildren. To do so, the researchers must be able to provide preliminary data to demonstrate their ability to carry out the proposed research intervention focusing primarily on grandmother caregivers. Building on previous studies and

strong community relationships the researchers are prepared to conduct a study that will evaluate the practicality of HOPE, a peer-led, culturally grounded, lifestyle intervention that is accessible to AA grandmothers living in underserved communities.

Who can participate?
Women 40 years of age or older who self-identify as African American, care for their grandchild (ren) on a regular basis and are at risk for developing diabetes.

What does the study involve?
Participants are randomly allocated to a DPP group or a DPP + HOPE group. In addition, five grandmothers (plus two alternates) will be recruited and trained to serve as peer educators. Each peer educator will be paired with six grandmothers assigned to DPP + HOPE and will offer ongoing support during DPP + HOPE sessions, in-person meetings, and weekly phone calls. The goals are to:
1. Evaluate the feasibility (number of potential versus recruited participants, intervention adherence, attrition, missing data) of the DPP + HOPE intervention.
2. Describe the acceptability of the DPP + HOPE intervention using structured interviews conducted in person or by telephone at study completion or at the time of dropout from the program (1 year) in a subsample.
3. Determine the preliminary impact of DPP + HOPE by comparing the intervention and active comparator group (DPP alone) on weight loss, physical activity (assessed with a Fitbit device) and hemoglobin A1C measured at the start of the study and months 6 and 12.

What are the possible benefits and risks of participating?
The long-term goal is to improve health outcomes for AA grandmothers who participate in the DPP. This peer support program is specifically aimed at educating and equipping AA grandmothers with the practical and sustained support needed to work toward better health for themselves and their grandchildren. In terms of public health impact, if effective, DPP +HOPE will be the first evidence-based culturally adapted healthy lifestyle intervention for AA grandmothers that improves behaviors and reduces inappropriate weight gain and the development of diabetes.

Where is the study run from?
University of Wisconsin–Madison (USA)

When is the study starting and how long is it expected to run for?
February 2021 to May 2024

Who is funding the study?
The American Diabetes Association (USA)

Who is the main contact?
Eva Vivian, eva.vivian@wisc.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
11-21-ICTSHD-48

Study information

Scientific Title
Healthy Outcomes through Peer Educators (HOPE)

Acronym
HOPE

Study objectives
The central hypothesis is that HOPE will increase retention and participation in the diabetes prevention program (DPP), allowing grandmothers to fully benefit from the program.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/12/2021, Minimal Risk Institutional Review Board (800 University Bay Drive, Madison, 53705, United States of America; +1 (0)608 263 2362; AskTheIRB@hsirb.wisc.edu), ref: 2021-1504

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of diabetes in patients with obesity and prediabetes

Interventions
All grandmothers will participate in 16 Diabetes Prevention Program (DPP) group sessions over the first 6 months (once a week for months 1-2, then every other month for months 3-6), and 8 sessions during months 7 to 12. The sessions will be offered virtually to increase accessibility and address participant safety concerns about travelling alone in the evenings. The DPP sessions will be led by a trained certified diabetes care and education specialist, dietitian, exercise physiologist, and trained peer educators using materials from the Diabetes Prevention Program (DPP). The goal of the educational group sessions is to bring the grandmothers together so they can offer each other support by sharing their experiences and knowledge with each other. The sessions are designed to empower participants to improve health and reduce diabetes risk through healthy behaviors. This message will be reinforced throughout the program where grandmothers will be encouraged to appreciate various aspects of health in a comprehensive manner. Nutritional education with a focus on the development of healthy eating behaviors that are sustainable throughout life is a key aspect of DPP. Rather than promoting caloric restriction, the nutrition sessions will focus on the importance of eating breakfast, increasing fruit and vegetable consumption, reducing calories from fat and added sugar, portion control, and healthy snacking.

Grandmothers will be allocated in a 2:1 ratio to the Diabetes Prevention Program (DPP) (active comparator) or DPP + HOPE (intervention) to account for anticipated attrition in the DPP arm. Grandmothers assigned to the DPP + HOPE intervention will be assigned a peer educator who will meet with them in person or by phone weekly during the 1-year study to provide support and guidance.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility assessed using the number of potential participants versus the number successfully recruited, screened, consented and completing the 12-month study
2. Intervention adherence assessed using attendance and active participation at sessions
3. The acceptability of the intervention assessed using virtual focus group interviews at study completion (1 year) in a subsample of the study group

Key secondary outcome(s))
Measured at baseline and months 6 and 12:
1. Body weight measured without shoes and in light clothing to the nearest 0.1 kg. Each measurement will be done twice and the mean of the two measurements will be used.
2. Physical activity assessed with a Fitbit One physical activity tracker watch
3. Hemoglobin A1C measured using the A1cNow+ system

Completion date
30/05/2024

Eligibility

Key inclusion criteria

1. 40 years of age or older
2. Primary caregiver of one or more grandchildren, defined as “one who provides instrumental and expressive care to a grandchild on a daily basis for an indefinite period of time”
3. Meet DPP eligibility requirements at the time of enrollment in the study, which includes:
3.1. Having overweight or obesity (BMI greater than or equal to 25 kg/m2)
3.2. No previous diagnosis of diabetes
3.3. A glycosylated hemoglobin A1C (A1C) between 5.7 % to 6.4 % (39 mmol/mol-46 mmol/mol) measured using a finger stick test at the time of enrollment

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
90 years

Sex
Female

Total final enrolment
50

Key exclusion criteria
Grandmothers were excluded if they were pregnant or had diseases that would limit their life span and ability to participate in the study

Date of first enrolment
01/07/2022

Date of final enrolment
30/05/2023

Locations

Countries of recruitment
United States of America

Study participating centre
McGovern Park Senior Center
4500 West Custer St

Milwaukee
United States of America
53218

Sponsor information

Organisation
University of Wisconsin–Madison

ROR
https://ror.org/01y2jtd41

Funder(s)

Funder type
Charity

Funder Name
American Diabetes Association

Alternative Name(s)
American Diabetes Association, Inc., American Diabetes Assn, AmDiabetesAssn, American Diabetes Association Inc, Asociación Americana de la Diabetes, ADA

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Eva Vivian PharmD, PhD (eva.vivian@wisc.edu).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes