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HOPE for grandmother caregivers enrolled in a diabetes prevention program

Submission date
20/02/2025

Recruitment status
No longer recruiting

Registration date
21/02/2025

Overall study status
Completed

Last Edited
21/02/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
African American (AA) grandmothers play a vital role in their families, often serving as primary caregivers for their grandchildren. Many of these grandmothers are overweight or obese, which can affect their health and the health of their grandchildren. The Healthy Outcomes through Peer Educators (HOPE) study aims to help AA grandmother caregivers make healthier lifestyle choices and positively influence their grandchildren's health. The study tests a community-based, peer support diabetes prevention program (DPP) where grandmothers support each other in making these changes.

Who can participate?
AA grandmothers who are 40 years or older and serve as primary caregivers for their grandchildren can participate. They must also meet certain health criteria, including being overweight or obese and being at risk for diabetes.

What does the study involve? (for participants)
Participants will be assigned to one of two groups: the DPP group or the DPP plus HOPE group. The DPP plus HOPE group will receive additional support from a peer educator who will meet with them in person or by phone every week for one year. The study aims to help participants eat healthier, become more active, lose weight, and set a good example for their families.

What are the possible benefits and risks of participating?
Participants may benefit from improved health, weight loss, and better lifestyle habits. They may also positively influence their grandchildren's health. Risks could include the time commitment required for the program and potential challenges in making lifestyle changes.

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?
March 2021 to January 2025

Who is funding the study?
American Diabetes Association

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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
11-21-ICTSHD-48

Study information

Scientific Title
Healthy Outcomes through Peer Educators

Acronym
HOPE

Study objectives
Grandmother caregivers at risk for diabetes who received ongoing support from peers are more likely to successfully complete the Diabetes Prevention Program and model healthy behaviors that influence the health behaviors of family members particularly their grandchildren.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/03/2021, Social Sciences Human Subjects Protection Committee (University Bay Office Building Suite 105 800 University Bay Drive, Madison, 53705, United States of America; +1 608-263-2362; AskTheIRB@hsirb.wisc.edu), ref: 2021-1504

Study design
Prospective randomized feasibility study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of diabetes in grandmother caregivers with prediabetes

Interventions
This is a prospective randomized study to assess feasibility of diabetes prevention program (DPP) + HOPE relative to the active comparator (DPP only).

Grandmother caregivers were randomized in a 2:1 ratio to DPP (active comparator) or DPP plus HOPE (intervention). DPP + HOPE incorporated support from a peer educator who met with participants in person or by phone every week during the one-year intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Outcome assessment, and intervention adherence rates assessed quantitatively
2. Grandchildren’s perspective of impact of grandmother’s health behaviors on their own health will be assessed (measured) using semi-structured interviews conducted at the end of the 12-month study

Key secondary outcome(s))
1. Changes in physical activity (steps per day) measured using Fitbit watch at end of 12 month study
2. Body weight (kg) measured at months 0, 6 and 12

Completion date
30/01/2025

Eligibility

Key inclusion criteria
1. 40 years of age or older and the primary caregiver of one or more grandchildren. A primary caregiver was defined as “one who provides instrumental and expressive care to a grandchild on

a daily basis for an indefinite period of time."
2. Grandmothers were also required to meet DPP eligibility requirements at the time of enrollment in the study, which includes:
2.1. Having overweight or obesity (BMI greater than or equal to 25 kg/m²).
2.2. No previous diagnosis of diabetes.
2.3. 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
100 years

Sex
Female

Total final enrolment
71

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
01/06/2022

Date of final enrolment
01/03/2024

Locations

Countries of recruitment
United States of America

Study participating centre
World Outreach Center
3410 West Silversprings Drive

Milwaukee
United States of America
53209

Study participating centre
McGovern Park Senior Center
4500 West Custer Avenue
Milwaukee
United States of America
53218

Study participating centre
Northside Church of God
4858 N 19th St
Milwaukee
United States of America
53209

Study participating centre
Foundation of Black Womens Wellness
6601 Grand Teton Plaza Suite A2
Madison
United States of America
53719

Sponsor information

Organisation
American Diabetes Association

ROR
https://ror.org/04f6cgz95

Funder(s)

Funder type
Research organisation

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 analyzes during the current study will be available upon request from Eva Vivian, eva.vivian@wisc.edu

IPD sharing plan summary
Available on request

Study outputs

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