

HOPE for grandmother caregivers enrolled in a diabetes prevention program

Submission date 20/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/02/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

Study website
<https://pharmacy.wisc.edu/faculty/vivian-research-group/>

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Eva Vivian

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

12/03/2021

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

Age group

Adult

Lower age limit

40 Years

Upper age limit

100 Years

Sex

Female

Target number of participants

80

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

Sponsor details

2451 Crystal Drive, Suite 900
Arlington
United States of America
22202
+1 800-342-2383
askADA@diabetes.org

Sponsor type

Research organisation

Website

<http://www.diabetes.org/>

ROR

<https://ror.org/04f6cgz95>

Funder(s)**Funder type**

Research organisation

Funder Name

American Diabetes Association

Alternative Name(s)

Asociación Americana de la Diabetes, American Diabetes Association, Inc., American Diabetes Assn, AmDiabetesAssn, ADA

Funding Body Type

Government organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United States of America

Results and Publications**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

Intention to publish date

01/03/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Eva Vivian, eva.vivian@wisc.edu

IPD sharing plan summary

Available on request