Document Coversheet

Study Title: Enhancing the Diabetes Prevention Program to Promote Weight Loss Among Nonresponders in a Community-Based Lifestyle Intervention

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	7/30/2025
NCT Number:	NCT04757519
IRB Number	58766
Coversheet created:	11/18/2025

IRB Approval
7/30/2025
IRB # 58766
IRB6

IMPORTANT NOTE:

If you accidentally select the wrong IRB type or "Protocol Process Type" while your Initial Review (IR) application is in draft form (unsubmitted), you may change your selections. Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions regarding your selections *prior* to submitting your Initial Review application.

If your **submitted IR application has been returned to you for requested revisions or additional information,** to streamline the review process **do not make changes** to your selections here **unless instructed to do so by the ORI/IRB.**

Changes to this section cannot be made after initial approval has been issued (the option is not available for MR or CR).

For guidance, see:

- Which IRB should review my research?
- Which Protocol Process Type?
- "Getting Started"

Which IRB

- (•) Medical ( ) NonMedical

Protocol Process Type

- ( ) Exemption
- ( ) Expedited (Must be risk level 1)
- (•) Full

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

MODIFICATION REQUEST SECTION

0 unresolved comment(s)

***** If this modification changes the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

Select One:

- (•) This modification does not increase risk to study participants.
- ( ) This modification may or will increase risk to study participants.

Is this modification request due to an Unanticipated Problem/Adverse Event, or Protocol Violation?

- ( ) Yes (•) No

In your professional opinion, does this modification involve information that might relate to a subject's willingness to continue to take part in the research?

- ( ) Yes (•) No

If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.):

For each proposed modification, include a justification.

Example: Jane Doe, MD, is being added as co-investigator because she has expertise with the subjects on this protocol. She has completed human subject protections training, and is authorized to obtain consent.

Attached under the research description is the minor amendment cover letter.

58766

PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

Enhancing the Diabetes Prevention Program to Promote Weight Loss among Non-responders in a Community-Based Lifestyle intervention.

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

Enhanced DPP-GLB

Anticipated Ending Date of Research Project: 6/30/2026

Maximum number of human subjects (or records/specimens to be reviewed) 500

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? ◉ Yes ○ No

Are you requesting that the UK IRB serve as the lead IRB for a multi-site study, **OR** that the UK IRB defer review to another IRB? [Click here for "IRB Reliance" help]
○ Yes ◉ No
If "Yes," before completing your IRB application, fill out the Reliance Request Form and submit it to irbreliance@uky.edu.

PI CONTACT INFORMATION

0 unresolved comment(s)

Principal Investigator (PI) role for E-IRB access
The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be listed as PI here.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to myUK and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a 'Name Change Form' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the HR Benefits Office for additional information.

The Principal Investigator's (PI) contact information is filled in automatically based on who logged in to create the application.

If you are not the Principal Investigator, do NOT add yourself as study personnel.
To change the PI contact information on an application in Researcher edit status:

- click "Change Principal Investigator";
- search for the PI's name using the search feature;
- click "Select" by the name of the Principal Investigator, then "Save Contact Information".

You will automatically be added as study personnel with editing permissions to continue editing the application.

Change Principal Investigator:

First Name:	Lovoria	Room# & Bldg:	751 Rose Street
Last Name:	Williams	Speed Sort#:	40536
Middle Name	Breckley		
Department:	Nursing Instruction - 7E100	Dept Code:	7E100
PI's Employee/Student ID#:	12314742	Rank:	Associate Professor
PI's Telephone #:	859-323-5579	Degree:	PhD, FNP-BC, FAANP
PI's e-mail address:	LBWI234@uky.edu	PI's FAX Number:	859 3231079
PI is R.N.	◉ Yes ○ No	HSP Trained:	Yes
		HSP Trained Date:	3/6/2024
		RCR Trained:	Yes

Do you, the PI/researcher, have a significant financial interest related to your responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2)?

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

- ○ (Risk Level 1) Not greater than minimal risk
- ◉ (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ○ (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ○ (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Refer to UK's guidance document on assessing the research risk for additional information.

SUBJECT DEMOGRAPHICS **0 unresolved comment(s)**

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc.) 18 to 80

Study Population:

Describe the characteristics of the subject population, including age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider this FDA Guidance on Enrollment of Participants from Underrepresented Populations in Clinical Studies

The study population includes 500 participants, self-described as Black males and females that are nested in 20 community settings, which are primarily churches and community recreation centers. Ten sites will be randomized to the standard intervention and ten to the enhanced intervention, participants (500) will receive the intervention assigned to their site. The date of the first participant enrollment is anticipated Feb 2021 and last enrollment July, 2024.

Inclusion criteria:
Self-described Blacks; 18 years or older; nondiabetic;Body Mass Index BMI greater than 25; CDC diabetes risk assessment greater than or equal to 5 or pre-diabetes diagnosis or a previous history of gestational diabetes, live within driving distance of participating church/site.

Non-Hispanic Blacks suffer a disproportionate burden of type 2 diabetes that is a 50% higher morbidity and mortality than non-Hispanic Whites and are at substantially higher risk of diabetes-related complications than the general population.

Exclusion criteria:
- Diagnosed Type 1 or 2 diabetes, pregnant or planning pregnancy during the study period, contraindications to moderate-level of physical activity or serious medical condition that contradicts weight loss, e.g. terminal illness.
- Are not Black or African American
- Individuals that indicate contraindications to physical activity during the medical history, such as chest pain, shortness of breath or severe joint pain, will be asked to provide medical clearance from their healthcare provider prior to starting the physical activity portion of the intervention (week 4).

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Kentucky State Census, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:	0	0		
Asian:	0	0		
Black/African American:	100	400		
Latinx:	0	0		
Native Hawaiian/Pacific Islander:	0	0		
White:	0	0		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:	0	0		

If unknown, please explain why:

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking (translated long or short form)
- ☐ International Citizens
- ☑ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☐ Patients
- ☐ Appalachian Population

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see also the E-IRB Research Description section on this same topic]
- International Citizens [DoD SOP may apply]
- Military Personnel and/or DoD Civilian Employees

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

Does this study focus on adult subjects with any conditions that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

For creating your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and edit to match your research project.

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- If another site is serving as the IRB for the project, attach the form as a "Reliance Consent Form" so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
  Document Types that do NOT get an IRB approval stamp are:
  - "Highlighted Changes",
  - "Phone Script", and
  - "Reliance Consent Form",
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) check the box for at least one of the consent items and/or check mark one of the waivers

2. If applicable attach each corresponding document(s) **as a read-only PDF.**
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Check All That Apply

- [x] Informed Consent Form (and/or Parental Permission Form and/or translated short form)
- [ ] Assent Form
- [ ] Cover Letter (for survey/questionnaire research)
- [ ] Phone Script
- [ ] Informed Consent/HIPAA Combined Form
- [ ] Debriefing and/or Permission to Use Data Form
- [ ] Reliance Consent Form
- [ ] Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- [ ] Stamped Consent Doc(s) Not Needed

Attachments

Attach Type	File Name
Informed Consent/Parental Permission	Informed Consent clean.pdf

Informed Consent Process:

Using active voice, in the text box below, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)
- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

Will electronic consent form/process be utilized on-site or remotely for this study?

◉ Yes ○ No

If yes, in addition to addressing the above bullet points, describe the e-consent method and platform, including any hyperlinks, videos, or enhancements used to convey information, if applicable. Attach a representation of the e-consent with signature fields. For guidance, see the ORI E-Consent web page.

Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.
- *Research Repositories*
  If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template.

Consent will be conducted online using REDCap. All team members who conduct informed consent will undergo REDCap consent training. After screening potential participants and determining eligibility and interest (see above Recruitment section), the IRB approved research team members will contact potential participants by phone or email and schedule a UK-Zoom appointment to conduct REDCap consent. Prior to the consenting appointment, the team members will email the IRB approved consent document to the potential participant and ask them to read it. In addition, the team members will determine if the potential participant prefers a hard copy or electronic version of the ICD In the event that a potential participant desires to consent by paper team members will provide two copies of the consent document to the potential participant in advance via U.S. mail. Team members will call the potential participant to schedule an appointment to complete the informed consent process by telephone or UK-Zoom. During the appointment, the team member will discuss the research study, answer questions and obtain informed consent over the phone or via UK-Zoom. With a copy of the consent document in front of him/her, the team member will review the informed consent document and answer all questions. Once all questions are answered, the potential participant will be asked to sign and date both copies of the hard copy consent document. The participant will return one of the signed consent documents via fax, scanned PDF or photographic image of the signed consent sent by fax or email to the research team member. The research personnel will store all consents collected in the Office of Nursing Research (UK CON, office 509) in a locked file cabinet that is only accessible to the research personnel. The participant will be advised to retain the remaining copy for their records.

For ease and logistics, we will encourage the participant to use the electronic version (REDCap) and we will schedule a group informed consent event on UK-Zoom. Given our knowledge of this participant population, we expect most will select REDCap.We will provide each prospective participant with a copy of the consent document. We will explain the scope of the group-based weight and diabetes prevention program. We will review the document with them, provide time for questions and use the "talk back" method to ensure that the participant understand the interventions and how we will use the data collected. Time will be provided for participants to read the document in its entirety. We then will review each page and use the “talk back” method to ask the participants questions regarding each page of the consent document; clarification will be provided to the participants if they do not respond with the appropriate answer. Participants will be encouraged to ask questions. At the completion of the review of each page the research staff will state, “Are there any questions?” and will answer the participants’ questions. At the last page, the research staff will state “Are there any questions regarding any information on any page of this document, if not, then you may sign and date the document.” An individual consent form link will be sent through REDCap. The participant will then sign and date the document. Each participant will receive a copy of the REDCap generated consent form. Team members will remain on the UK-Zoom to confirm that the participant has received the fully executed ICD.
In case of any questions or concerns about their rights as a volunteer in this research study, participants will be provided with contact information of the University of Kentucky Office of Research Integrity and the Principal Investigator contact number and email address. Participants will be provided with copies of the signed consent forms. The PI and research staff will ensure all complaints will be handled in a timely manner.

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting a waiver of the requirement for the informed consent process.

☐ I am requesting an alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered and/or omitted, and justify the alteration.

SECTION 2.

Explain how each condition applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are “identifiable” if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

☐ Request for Waiver of Signatures

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (e.g., a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to the subject, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study.

*If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the **Cover Letter Template** as a guide. There is an English and a Spanish version.*

○ **Option 1**

Describe how your study meets these criteria:

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

○ **Option 2**

Describe how your study meets these criteria:

a) The research presents no more than minimal risk to the participant:

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

○ **Option 3**

Describe how your study meets these criteria:

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

STUDY PERSONNEL **0 unresolved comment(s)**

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button.

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below. ***Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual as a contact with an editor role (DP).***
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature:

- Search for personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Home page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	A C	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Abu Farsakh	Bassema Mahyoub Mahmoud	Project Assistance/Support	SP	Y	N		S	Y	10/18/2024	Y	N	09/12/2023	N	Y
Adimoha	Love	Recruitment	SP	N	N		N	Y	03/03/3000		N	08/21/2023	N	Y
Adu-Peasah	Cathy	Recruitment	SP	N	N		N	Y	03/03/3000		N	11/30/2021	N	Y
Afolayan	Victor	Project Assistance/Support	SP	Y	N		P	Y	06/02/2024	Y	N	06/27/2023	N	Y
Akomah Donkor	Amanda	Data Collection	SP	Y	N		P	Y	08/23/2022	Y	N	01/21/2021	N	N
Alsada	Fatema	Project Assistance/Support	SP	N	N		P	Y	02/15/2023	Y	N	07/05/2023	N	Y
Ashford	Kristin	Consultant/Advisor	SP	N	N	PhD	P	Y	07/13/2024	Y	N	06/15/2020	N	N
Baughman	Phyllis	Recruitment	SP	N	N		N	Y	03/03/3000		N	11/30/2021	N	Y
Bojang	Joko	Project Assistance/Support	SP	N	N		N	Y	03/03/3000		N	01/19/2023	N	Y
Boyd	Felice	Recruitment	SP	N	N		N	Y	03/03/3000		N	11/30/2021	N	Y
Brooks	Maranda	Recruitment	SP	N	N		P	Y	10/31/2023	Y	N	08/21/2023	N	Y
Brooks	Tina	Recruitment	SP	N	N		N	Y	03/03/3000		N	08/21/2023	N	Y
Browder	Rondale	Recruitment	SP	N	N		N	Y	03/03/3000		N	06/10/2022	N	Y
Brown-Patterson	Turquoise	Recruitment	SP	N	N		N	Y	03/03/3000		N	01/18/2023	N	Y
Bush	Joshua	Co-Investigator	SP	N	N		P	Y	02/19/2025	Y	N	08/21/2023	N	Y
Butler	Donna	Recruitment	SP	N	N		N	Y	03/03/3000		N	01/18/2023	N	Y
Carter	Carla	Recruitment	SP	N	N		P	Y	08/07/2023	Y	N	08/21/2023	N	Y
Churchill	Kalyn	Recruitment	SP	N	N		N	Y	03/03/3000		N	07/29/2024	N	Y
Coulter	Payton-Ann	Project Assistance/Support	SP	N	N		S	Y	09/12/2024	Y	N	10/01/2024	N	Y
Cozart	Destiny	Recruitment	SP	Y	N		P	Y	03/07/2024	Y	N	01/15/2021	N	Y
Crumbie	Lynsey	Recruitment	SP	N	N		N	Y	03/03/3000		N	07/29/2024	N	Y
Crumbie	Martha	Recruitment	SP	N	N		N	Y	03/03/3000		N	07/29/2024	N	Y
Davis	Billy	Recruitment	SP	N	N		N	Y	03/03/3000		N	08/21/2023	N	Y
Davis	Connie	Recruitment	SP	N	N		N	Y	03/03/3000		N	01/18/2023	N	Y
Ebikwo	Favour	Recruitment	SP	N	N		N	Y	03/03/3000		N	08/21/2023	N	Y
Ebikwo	Treasure Unekwu Enyo Ojo	Project Assistance/Support	SP	Y	N		P	Y	08/30/2023	Y	N	09/12/2023	N	N
Foster	Aline	Recruitment	SP	N	N		N	Y	03/03/3000		N	07/29/2024	N	Y

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Gustafson	Alison	Co-Investigator	SP	Y	N	PhD	P	Y	11/30/2024	Y	N	06/15/2020	N	Y
Hatchett	Angela	Recruitment	SP	N	N		N	Y	03/03/3000		N	07/29/2024	N	Y
Hyung	Somang	Project Assistance/Support	SP	N	N		P	Y	04/03/2023	Y	N	07/05/2023	N	Y
Jackson	Charles	Recruitment	SP	N	N		N	Y	03/03/3000		N	01/18/2023	N	Y
Jinwright	Emma	Project Assistance/Support	SP	N	N		N	Y	03/03/3000		N	07/05/2023	N	Y
Karle	Erika	Study Coordinator	DP	Y	Y	MS	P	Y	08/27/2024	Y	N	01/10/2022	N	Y
Kinkead	Conley	Project Assistance/Support	SP	N	N		P	Y	05/24/2023	Y	N	07/05/2023	N	Y
Kovacs	Debbonnaire	Recruitment	SP	N	N		N	Y	03/03/3000		N	11/30/2021	N	Y
Lang	Juan	Data Collection	SP	N	N		P	Y	09/28/2023	Y	N	02/02/2021	N	Y
Magee	Tamera	Recruitment	SP	N	N		N	Y	03/03/3000		N	07/29/2024	N	Y
Mangino	Anthony	Data Analysis/Processing	SP	N	N		P	Y	11/01/2022	Y	N	01/10/2022	N	Y
Moser	Debra	Co-Investigator	SP	Y	N	PhD	P	Y	04/05/2023	Y	N	06/15/2020	N	N
Nakinoja	Daniela	Project Assistance/Support	SP	N	N		S	Y	09/14/2023	Y	N	01/31/2022	N	N
Nichols	Brayden	Project Assistance/Support	SP	N	N		P	Y	08/30/2023	Y	N	09/12/2023	N	Y
Okeyo	Hilda	Data Collection	SP	Y	N		P	Y	12/01/2024	Y	N	09/03/2021	N	Y
Poyntz	Heather	Recruitment	SP	N	N		N	Y	03/03/3000		N	01/18/2023	N	Y
Ray	Erin	Recruitment	SP	N	N		N	Y	03/03/3000		N	06/10/2022	N	Y
Rayens	Mary Kay	Co-Investigator	SP	Y	N	PhD	P	Y	03/06/2025	Y	N	06/15/2020	N	Y
Rice	Brittany	Project Assistance/Support	SP	N	N		P	Y	06/24/2025	Y	N	07/05/2023	N	Y
Small	Hattie	Recruitment	SP	N	N		N	Y	03/03/3000		N	11/30/2021	N	Y
Stigall	Barbara	Recruitment	SP	N	N		N	Y	03/03/3000		N	06/10/2022	N	Y
Thaxton Wiggins	Amanda	Consultant/Advisor	SP	N	N	PhD	P	Y	08/05/2024	Y	N	06/15/2020	N	Y
Thompson	Marcella	Recruitment	SP	N	N		N	Y	03/03/3000		N	06/10/2022	N	Y
Thurman	Lisa	Recruitment	SP	N	N		N	Y	03/03/3000		N	06/10/2022	N	Y
Waters	Teresa	Co-Investigator	SP	Y	N	PhD	P	Y	04/11/2023	Y	N	06/15/2020	N	N
Webster	Levangela	Recruitment	SP	N	N		N	Y	03/03/3000		N	01/18/2023	N	Y
Westneat	Susan	Data Analysis/Processing	SP	N	N	MA	P	Y	07/05/2023	Y	N	09/14/2020	N	Y
Whitlock	Kathy	Recruitment	SP	N	N		N	Y	03/03/3000		N	01/18/2023	N	Y
Wilder	Janisha	Recruitment	SP	N	N		N	Y	03/03/3000		N	01/18/2023	N	Y
Akakpo	Carolyn	Project Assistance/Support	SP	Y	N		P	N	09/18/2019	Y	Y	03/29/2023	N	N
Bowman	Hannah	Project Assistance/Support	SP	N	N		P	N	01/27/2020	Y	Y	01/10/2022	N	N
Dempsey	Tara	Recruitment	SP	N	N			N	03/01/2021		Y	12/06/2024	N	N
Dugan	Adam	Project Assistance/Support	SP	N	N		P	N	04/30/2020	Y	Y	01/18/2024	N	N
Gilliam-Avery	Monique	Recruitment	SP	N	N		N	N	06/09/2021		Y	12/06/2024	N	Y
Gomez	Maria	Study Coordinator	DP	Y	Y	DrPH, MPH	P	Y	12/01/2024	N	Y	03/09/2021	N	Y
Hairston	Taquay	Recruitment	SP	N	N		N	N	03/03/2021		Y	12/06/2024	N	Y
Hieronymus	Laura	Consultant/Advisor	SP	N	N	DNP	P	Y	01/04/2024	Y	Y	03/29/2023	N	Y
Keck	James	Consultant/Advisor	SP	N	N	MD	P	N	07/28/2020	Y	Y	01/18/2024	N	N
King	Toni	Recruitment	SP	N	N		N	N	06/17/2021		Y	12/06/2024	N	Y
Manz	Karina	Project Assistance/Support	SP	N	N	MPH	P	N	08/17/2020		Y	03/09/2021	N	N
McFalls	Xavier	Recruitment	SP	N	N		N	N	06/14/2021		Y	12/06/2024	N	Y
McFarland	Falon	Recruitment	SP	N	N		N	N	06/17/2021		Y	12/06/2024	N	Y
Meadows	Erika	Recruitment	SP	N	N		N	N	03/01/2021		Y	12/06/2024	N	Y

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Nance	Aaron	Recruitment	SP	N	N		N	N	06/21/2021		Y	12/06/2024	N	Y
Nelson	Nadja	Data Collection	SP	N	N		S	N	12/03/2020		Y	01/10/2022	N	N
Ousley	Lateisha	Project Assistance/Support	SP	Y	N		P	N	12/03/2018		Y	01/10/2022	N	N
Patel	Nidhiben	Data Collection	SP	N	N		P	N	10/16/2020	Y	Y	01/10/2022	N	Y
Patton	Michelle	Recruitment	SP	N	N		N	N	06/08/2021		Y	12/06/2024	N	Y
Pea	Jharonee	Recruitment	SP	N	N		N	N	06/16/2021		Y	12/06/2024	N	Y
Sanford	Nataliah	Recruitment	SP	N	N		N	N	03/03/2021		Y	12/06/2024	N	Y
Smarr	Edwina	Recruitment	SP	N	N		N	N	06/17/2021		Y	12/06/2024	N	Y
Taylor	Alisia	Project Assistance/Support	SP	N	N		P	Y	01/08/2025	Y	Y	12/06/2024	N	Y
White	Elisabeth	Data Collection	SP	Y	N		P	N	06/02/2021		Y	01/10/2022	N	N

RESEARCH DESCRIPTION

0 unresolved comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

Pro Tips:

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section or under the Additional Information section to include supplemental information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background

Include a brief review of existing literature in the area of your research. You should identify gaps in knowledge that should be addressed and explain how your research will address those gaps or contribute to existing knowledge in this area. For interventional research, search PubMed and ClinicalTrials.gov for duplicative ongoing and completed trials with same condition and intervention(s).

Obesity is the number one and most preventable Type 2 diabetes (T2D) risk factor, yet despite a $20 billion annual expenditure on diet and weight loss efforts, 87% of US adults are overweight or obese. Racial/ethnic disparities exist, with Non-Hispanic Black adults almost two times more likely than non-Hispanic Whites to have a T2D diagnosis (13.4% and 7.3% respectively). Blacks compared to Whites have a 50% higher morbidity and mortality and are at substantially higher risk of diabetes-related complications such as end stage renal disease and amputations. Evidenced-based lifestyle interventions (LIs) to prevent T2D are available and demonstrate that weight loss as small as 5% is clinically meaningful, however 40-60% of intervention participants do not achieve the intervention weight loss goal. The original clinic-based Diabetes Prevention Program (DPP) LI clearly demonstrated that a LI that focused on a 7% weight reduction through changing behavior related to nutrition and increasing moderate intensity physical activity (PA) to 150 minutes weekly reduced incident diabetes by 58% among high-risk adults. The DPP used an intense one-on-one delivery model and included a "toolbox" of personalized strategies for use with individuals who were challenged with reaching the 7% weight loss goal. One on one approaches are not practical for public dissemination, thus upon translation and subsequent national dissemination of the DPP as the National DPP (NDPP), the paradigm has shifted among LIs to a group-based delivery model. Group based delivery is more cost effective than more resource intense one-on-one approaches, but with group-based delivery, all participants receive the same intervention regardless of their weight loss response. This "one size fits all" model is problematic because it does not account for heterogeneity in treatment response among participants. Previous research has translated the DPP to a variety of "real world" settings such as community centers, senior center and military bases to address issues of access and public health. Churches have been among these settings and the effectiveness of churchbased health promotion interventions support previous research regarding the importance of providing contextual and culturally adapted interventions to racial/ethnic minority populations. This study seeks to establish the efficacy of identifying weight loss nonresponders early in a Diabetes Prevention Program (DPP) intervention in 20 community settings (primarily churches and community centers) and providing them with individual-level, enhanced treatment through telephone contacts and access to additional resources. We characterize nonresponse as a weight loss of less than or equal to 1% by week four of the intense phase of the intervention. Additionally, we will examine potential mediators and moderators of the relationship between intervention status and weight loss response at 6 months in both nonresponders and responders and lastly we conduct a cost effectiveness analysis to evaluate the cost of the intervention arm by comparing the incremental cost and weight loss with the active control arm. This study addresses key gaps in the literature about the weight loss effects of identifying nonresponders early and characterizing individuals who need more intense personalized strategies. We hypothesize that changes between baseline and 3 months will be more pronounced among the nonresponders in the intervention group compared to the nonresponders in the active control group.

Objectives

List your research objectives. Please include a summary of intended research objectives in the box below.

The objectives of this pilot study are:
1) To evaluate differences over time in the primary outcome of weight, and secondary outcomes (i.e., PA level, blood pressure, and dietary behaviors) between
nonresponders in the intervention group compared to nonresponders in the active control group.
pressure) that offers additional support to nonresponders through weekly telephone personalized assistance to help them to overcome barriers to
adhere to program goals.
2) To examine potential mediators and moderators of the relationship between intervention status and weight loss response at 6 months in both nonresponders and responders
3) Conduct a cost effectiveness analysis to evaluate the cost of the intervention arm by comparing the incremental cost and weight loss with the active control arm

Study Design

Describe and explain the study design (e.g., observational, secondary analysis, single/double blind, parallel, crossover, deception, etc.).

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *Community-Based Participatory Research*: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

This study is a two-group cluster randomized design to enroll and follow-up 500 participants over a period of 6 months.
Participants will be randomized by site assigned to:
1) DPP-GLB standard intervention (n=250)
2) DPP-GLB enhanced intervention (n=250)
We will involve our established Community Advisory Board through all stages of the intervention, from recommending community sites to engage in the project, to assisting with identifying Community Health Workers and reviewing project results prior to publication and presentations.

Attachments

Attach Type	File Name
StudyDesign	amendment_cover_minor amendment 3-4-2025.pdf
StudyDesign	amendment_cover_minor amendment 7-23-2024.pdf
StudyDesign	amendment_cover_minor amendment 8-21-23.pdf
StudyDesign	amendment_cover_minor amendment 7-5-23.pdf
StudyDesign	amendment_cover_minor amendment 1-26-23.pdf
StudyDesign	amendment_cover_minor amendment 6-14-22.pdf
StudyDesign	amendment_cover_minor amendment 1-10-22.pdf
StudyDesign	amendment_cover_minor amendment 1-31-22.pdf
StudyDesign	amendment_cover_letter 7.22.2021.pdf
StudyDesign	amendment_cover_letter 2.25.2021.pdf
StudyDesign	amendment_cover_letter.pdf
StudyDesign	amendment_cover_letter 6.4.2021.pdf
StudyDesign	amendment_cover_letter 6.7.2021.pdf
StudyDesign	amendment_cover_letter 6.28.2021.pdf
StudyDesign	amendment_cover_letter 7.14.2021.pdf
StudyDesign	amendment_cover_letter 9.3.2021.pdf
StudyDesign	amendment_cover_minor amendment 9-13-21.pdf
StudyDesign	amendment_cover_minor amendment 11-29-21.pdf
StudyDesign	amendment_cover_minor amendment 12-15-21.pdf
StudyDesign	amendment_cover_minor amendment 6-22-23.pdf
StudyDesign	amendment_cover_minor amendment 9-12-23.pdf
StudyDesign	amendment_cover_minor amendment 9-21-23.pdf
StudyDesign	amendment_cover_minor amendment 10-1-24.pdf
StudyDesign	amendment_cover_minor amendment 7-29-25.pdf

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

We will recruit 500 adult participants from twenty community sites (primarily churches) with predominant Black membership lead by pastors/administrators willing to support the study. We will submit letter of support/church registration forms from the sites once they are identified. We will target enrollment of 25 participants per site, however we anticipate lower enrollment in the smaller sites, thus to

reach target enrollment, we will allow up to 50 participants in the larger sites. Four weeks prior to intervention, we will begin recruiting participants using pastor announcement/script, investigator-developed flyers, and team member presence through online congregation session. During recruitment period and prior to the enrollment date, we will hold a virtual Information Q & A session (PDF of Information Session attached) about the study. The research team will review the background and purpose of the research study, the study design, inclusion criteria, a detailed explanation of what is expected of participants, and the study benefits and risks. We will explain the components of the intervention as well as the risk factors for diabetes. Given that the participating sites are not currently meeting in person, the pastor/church leaders will instruct members who are interested in participating to contact the Community Health Workers by phone, email or church messenger. Or they will contact the PI or Program Manager. Afterward a team member will contact the potential participant to assess eligibility, if eligible the team member will schedule a time for completion of the informed consent process (explained below).
The research team will use investigator-developed IRB- approved flyers and scripted church announcement. Both have been revised to reflect current protocol changes related to virtual format and are awaiting approval by UK Public Relations (will submit by amendment once received).

We will also recruit through a YouTube video clip (will submit after developed and once it is approved by UK-PR); additionally the investigators will discuss the research during media interviews such as radio, TV, podcast and newspapers, during these media encounters, the direct recruitment will be limited to providing the investigators contact information for additional information.

We will utilize the UK Center for Clinical and Translational Science (CCTS) Participant Recruitment Services to assist us with marketing services to promote the study to the potential participants using numerous venues.
Print Advertisements. This study will recruit subjects through IRB approved, Research Spotlights, advertisements placed on campus and in the participating community sites.

Advertisement in the Internet and Social Media: This study will be advertised on recruitment internet webpages in digital or video form n(e.g., ResearchMatch.org, CCTS and may utilize Google Adwords). The study will be promoted via social media, including Facebook boost advertisements, UK, CCTS Facebook page, UK-CCTS Twitter, UK-CCTS Instagram, UK and UK Health Care and them participating community sites' social media (scripts attached

Attachments

Attach Type	File Name
Advertising	NURS-127C flyer[2] PR edit STAMPED.pdf
Advertising	NURS-127D flyer STAMPED.pdf
Advertising	Pastor Script 1 21.2021.pdf
Advertising	Pastor Script Tracked Changes.pdf
Advertising	Fit and Faithful Video Feb 2021 PR STAMPED.pdf
Advertising	Social Media script.pdf
Advertising	Williams_radioadvertisementscript-STAMPED.pdf

Research Procedures

Describe how the research will be conducted.

- What experience will study participants have?
- What will study participants be expected to do?
- How long will the study last?
- Outline the schedule and timing of study procedures.
- Provide visit-by-visit listing of all procedures that will take place.
- Identify all procedures that will be carried out with each group of participants.
- Describe deception and debrief procedures if deception is involved.

Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project. List medications that are explicitly forbidden or permitted during study participation.

After recruiting the sites, the statistician will randomize them for their nonresponders to receive either the DPP-GLB (standard) or the DPP-GLB plus telephone support to deliver individual-level enhanced strategies for nonresponders (enhanced intervention).
Given the COVID-19 pandemic the intervention will be delivered online e.g. UK-Zoom. Participants will receive a private UK-Zoom link that requires a password.
1) Diabetes Prevention Program Group Lifestyle Balance (DPP-GLB) Intervention Program (standard)

The intervention is based upon the 2017 version of the University of Pittsburgh DPP Group Lifestyle Balance Program (DPP-GLB). The DPP-GLB is a CDC-recognized curriculum and is a direct adaptation of the DPP curriculum for use in the public health arena. The original DPP was developed with Social Cognitive Theory (SCT). SCT is a behavioral theory that explains how an individual's thoughts and actions continually interact to change their behavior. The theory is well aligned with the proposed enhanced strategies which focus on reinforcing the intervention content to improve the participants' behavioral capability and self-efficacy to adhere to the intervention.

All participants in both groups will receive the DPP-GLB once per week for 12 weeks, then twice monthly for 12 weeks (18 sessions total). The sessions will be delivered by trained community members online eg. UK-Zoom and each session will last 1 hour. The Community Health Workers (CHWs) will be adult community members with at least a high school education. They will receive 16 hours of training on intervention delivery and on human subjects research with materials from the
Community Involvement in Research Training (CIRT) developed by the University of Illinois at Chicago Center for Clinical and Translational Science. The CHWs will be added as Study Personnel in this protocol as they are identified and trained.

The intervention is was developed by the University of Pittsburgh Diabetes Prevention Support Center (DPSC) which is periodically updated to reflect current dietary and PA recommendations.The DPP-GLB maintains the DPP program goals to achieve a 7% weight loss and to progress participants to 150 minutes per week of moderately intense PA by 6 months. The entire DPP-GLB program and related materials are accessible online through the University of Pittsburgh DPSC (Diabetes Prevention Support Center) and has been approved by the CDC for application to the CDC Diabetes Prevention Recognition Program. The manual and materials are available to the general public and available at the University of Pittsburgh website; www.diabetesprevention.pitt.edu/index.php/group-lifestylebalance-materials/

The DPP-GLB program has been rigorously tested in diverse community settings, including by the PI in churches, and shown to lead to clinically meaningful weight loss.For the purpose of this study and the focus on early loss weight response adherence we will deliver the intervention online e.g.UK-Zoom in 18 sessions (1 weekly x 12 weeks then twice monthly x 12 weeks) with the goal of losing 5% of body weight from baseline up to 3 months and to increase physical activity to 150 minutes per week. Participants in both groups will receive the same dose of the intervention (18 sessions) in 1-hour long group-based sessions delivered online eg. UK-Zoom once weekly for 12 weeks followed by six group-based sessions delivered twice monthly for 1 hour. The participants will receive supportive materials such as a weekly food diary and a FitBit/pedometer. Team members will deliver all participant study materials to the church/site for distribution to each participant.

Overview of DPP-GLB Intervention:

Schedule Participant Handouts and Leader Guides
Month 1
Session 1: Welcome to the Diabetes Prevention Program Group Lifestyle Balance
Session 2: Be a Calorie Detective
Session 3: Healthy Eating
Session 4: Move Those Muscles

Month 2
Session 5: Tip the Calorie Balance
Session 6: Take Charge of What's Around You
Session 7: Problem Solving
Session 8: Step Up Your Physical Activity Plan

Month 3
Session 9: Manage Slips and Self-defeating Thoughts
Session 10: Four Keys to Healthy Eating Out

Session 11: Make Social Cues Work for You
Session 12: Ways to Stay Motivate
Sessions 13-18 will reinforce content introduced in sessions 1-12.

After the participants have attended four sessions, we will identify nonresponders (defined as less than or equal to 1% weight loss) by weighing all participants. Both groups including the nonresponders will continue with the group sessions, however additionally, the nonresponders in the enhanced intervention sites will receive the individual-level enhanced intervention for the duration of the intervention which includes weekly telephone support.

2) DPP-GLB Enhanced Intervention Program (including telephone support)

2.a. Identification of Nonresponders:
At session four, the research data collector team member will weigh participants and calculate the percentage of weight loss. We will use percentage of weight loss rather than pounds because percentage is more applicable to a wide weight range and is consistent with the recommendations of the Obesity Society clinical guidelines. Participants who have lost less than or equal to 1% of their weight by 4 weeks will be defined as nonresponders and will remain nonresponders regardless of subsequent weight response. The nonresponders in both groups will continue with the standard DPP-GLB group-based intervention, however the nonreponders at the intervention sites will also receive the enhanced intervention delivered through weekly telephone support.

2.b. Enhanced Intervention Calls:
The enhanced intervention will be delivered through weekly phone calls to the nonresponders. In addition to the nonresponders continued attendance at the DPP-GLB group sessions, beginning at week 5 the Community Health Worker will call each nonresponder weekly. During the brief call, the CHWs will use telephone scripts to guide the discussion with the nonresponder. Each script will begin with an open-ended question to assess the nonresponder's perspective of their progress and/or their weight loss barriers. The content of the script will align with the topic of the previous group session and guide the CHW in asking open-ended questions to elicit participant responses. We anticipate each call lasting ~15 minutes. During the call, the CHW will review the participant's self-monitoring log that each participant submits during the sessions and use motivational interviewing techniques to provide social support, assess the participants' barriers, resolve ambivalence regarding behavior change and to support the participant in developing their own strategies to overcome personal barriers. The content of the telephone script is under development and will be submitted to the IRB by amendment.

2.c Tailoring of enhanced intervention
Based on the contents of the self-monitoring log and the MI discussion during the weekly phone calls, the CHW will tailor the intervention by sending the participant relevant videos that are available on the CDC National NDPP website https://www.cdc.gov/diabetes/prevention/resources/personal-success-modules.html. The CHW will send the video link by text or email.

The videos are brief (~10 min) accessible by smartphone, tablet or computer.

3) Fit & Faithful Weight Re-Check
3.a. Fit & Faithful participants who accept the invitation to participate in the Fit & Faithful weight re-check will be asked to come to a data collection site. To accommodate the participants, we will hold two data collections at each of two centrally located churches, one in Lexington and one in Louisville (four data collections total).

Attachments

Attach Type	File Name
ResearchProcedures	Community Health Worker Semi-structured Interview Guide.pdf
ResearchProcedures	Community Health Worker Investigators Invitation Email.pdf
ResearchProcedures	Non Responders Enhanced Intervention Script Final.pdf
ResearchProcedures	Williams-Info session 1-20-2021 DC-lbw.pdf

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

After completion of informed consent, participants will receive the REDCap link to the surveys listed below. All data will be collected by IRB-approved research team members. Given the COVID-19 pandemic until the University resumes Phase 4 research activities and the community sites resume in person activities all data will be collected remotely by REDCap survey (attached) and by telephone, afterward, data will be collected in person. We will collect data at baseline, 12 weeks, and 6 months.

Please see Table 1 with time point outline for outcome assessment.
We will utilize the following instruments to collect the following measures: (see attachments when applicable).

a. American Diabetes Association-CDC Prediabetes Screening Test. CDC recently updated its Prediabetes Screening Test to ensure

that CDC and the American Diabetes Association provide the same risk test. Scores =5 indicates high risk for diabetes. The test is available online through the CDC (see attachment).
b. Investigator developed demographic . We will use the tool to assess demographics e.g. socioeconomic status, age, gender, sexual orientation, marital status, employment (attached) and obtain a brief medical history survey.
c. Weight-Height-BMI. We will measure with participant barefoot, wearing lightweight clothing with a calibrated, digital medical scale recorded to the nearest 0.1 kg. Height measured with portable stadiometer, participant standing erect, barefoot in center of scale; recorded to nearest 0.1 cm.
The height and weight will be used to calculate BMI [Wt. in kg/Ht in meters squared (kg/m2)].
d. Blood Pressure. We will measure blood pressure twice, one minute apart with calibrated automated blood pressure monitor after an initial 5 minute sit time. We will record both readings and average them.
e. Physical Activity. We will use the Modifiable Activity Questionnaire (MAQ) which has been developed to assess activity in the DPP. The MAQ has shown both reliability and validity for adults
f. Weight Efficacy Lifestyle Questionnaire
g. Perceived Stressh.
Social support for diet and physical activity
i. Treatment self-regulation questionnaire
j. Process measures- session attendance
k. IWQOL-Lite - Impact of Weight on Quality of Life Questionnaire.
l. Cost survey

Table 1: Outline for outcome assessment:
Measure Baseline 4wks. 12wks. 6 months
Demographic X
Weight X X X X
Height X
Blood Pressure X X X
Physical Activity X X X
Dietary Intake X X
Wt. Efficacy X
Quality of Life-Lite x X
Perceived Stress X
Motivation X
Social Support X
Treatment Reg X
Cost X X
To facilitate remote data collection we will provide all participants with a BodyTrace cellular scale and an automated blood pressure monitor. During the Phase 3 research activities, the participants will self measure height and blood pressure. Team members will contact the participants by telephone to obtain the height and blood pressure readings.

None of the health data collected will be added to a participant's UK HealthCare medical record.

Attachments

Attach Type	File Name
DataCollection	NotHumanResearchNHRDeterminant.pdf
DataCollection	FitAndFaithfulEnhancedDPP PDF.pdf
DataCollection	cost_data_collection_final_ version.pdf
DataCollection	ADA-CDC Prediabetes-Risk-Test-Final.pdf
DataCollection	Demographic Form - DPP-GLB.docx
DataCollection	MAQ _Physical Activity FINAL.docx
DataCollection	IWQOL-Lite English-US-Review-Only.pdf
DataCollection	DSMB Charter Final.pdf
DataCollection	Key Personnel and DSMB Members 5-22-2020.pdf
DataCollection	Data Safety Monitoring Plan Final.pdf
DataCollection	Weight Efficacy Life-Style Questionnaire.pdf
DataCollection	Perceived Stress Scale.pdf
DataCollection	Treatment Self Regulation.pdf
DataCollection	Sallis_SocialSupport_diet-exercise.pdf

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

We have all the resources required for completion of this research which include access to population of interest, trained research personnel, UK iPads and UK desktop computers with software for data entry and analysis. The desktop computers are password protected. The iPads are encrypted. The desktop computers are located in the office of the PI and in the office of the research personnel in the College of Nursing Building and the office of Nursing Research, 5th floor, suite 509-K. The office of Nursing Research has a secured entry allowed only to staff working in this office.

Participants will be recruited from 20 sites, primarily churches and community centers, in central Kentucky. The weekly class sessions will take place online e.g. UK-Zoom. We will submit letter of support/church registration forms by amendment from the sites once they are identified.The intervention will be taught by trained Community Health Workers. In the event of any unanticipated problem involving safety or risks to participants we will call for an emergency meeting of our Data Safety Monitoring Board, submit an official report to the IRB and the NIH-NIDDK within the specified timeline.

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychological or emotional, learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

The risks to participants are minimal. During the eligibility call we will will assess for high risk for physical activity. Participants identified as high risk will be required to obtain clearance from their healthcare provider prior to week five, which is the start of the physical activity portion of the intervention. Participants may experience some discomfort especially if they are new to exercising. Therefore, while engaging in moderate physical activity such as walking, they could twist an ankle, pull a muscle, or break a bone. They may feel uncomfortable answering questions for the study in group or individual sessions. There is no promise that fellow church members will keep what they share during the group meetings confidential. The NIH-approved DSMP and DSMB Charter with names of DSMB members are attached.
The participants will benefit by attending the intervention sessions and obtaining knowledge of keeping a healthy lifestyle, how to improve healthy eating, nutrition information, to stay physically active, health tips, and having a support team to reduce weight which ultimately will reduce the risks of diabetes, obesity, and other chronic diseases such as cardiovascular disease. The risks of participant harm are minimal.

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

Should participants decide not to participate, they can obtain information of how to improve their lifestyle habits and decrease the chance of developing type 2 diabetes from their regular health care provider.

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Records, Privacy, and Confidentiality

Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Specify who will have access to the data/specimens and why they need access.

Describe how data will be managed after the study is complete:

- If data/specimens will be maintained, specify whether identifiers will be removed from the maintained information/material.
- If identifiers will not be removed, provide justification for retaining them and describe how you will protect confidentiality.
- If the data/specimens will be destroyed, verify that this will not violate retention policies and will adhere to applicable facility requirements.

If this study will use de-identified data from another source, describe what measures will be taken to ensure that subject identifiers are

not given to the investigator.

If applicable, describe procedures for sharing data/specimens with collaborators not affiliated with UK.

For additional considerations:
Return of Research Results or Incidental Research Findings
HIPAA policies
FERPA policies
Procedures for Transfer agreements
Information regarding multi-site studies
NIH Genomic Data Sharing (GDS) Policy
Digital Data

We will not collect human specimens and will not access participants' medical records or obtain data beyond the sociodemographic, validated surveys, anthropometric and physiologic data. The collected data is necessary to describe the sample and to assess for efficacy of the intervention.
We will use online eg. UK-Zoom and REDCap software to obtain informed consent, and to record socio-demographic, anthropometric, validated survey and physiological information from participants.Each participant will be assigned a unique participant identification number (PID). The list that connects the participant with the de-identified PID will be saved on the PI or study coordinator password-protected computer. Research team members will enter the data into REDCap by using password protected laptop or iPad. Only research staff who have been certified in human subjects' research and who are listed as study personnel with the University of Kentucky IRB will be allowed access to participants' data. We will keep all identifiable data and consent forms for six years. After six years the data that includes the participant identifiers and that links the PID to the data will be destroyed, thereby resulting in completely confidential data set. The confidential data set will be retained on the UK secured drive indefinitely. The potential risk to participants is breach of confidentiality of personal information. To minimize this risk, the statistician will provide the research team with an enrollment list that has participant identification (PID) numbers. Each participant will be assigned a PID number. The PID list will be stored in a password protected computer program in the office of the PI or the study coordinator. All data collected at the sites including consent forms will be placed in a sealed envelope and transported within a locked mobile file cabinet by IRBapproved research staff to UK College of Nursing. The research team will store all consents and data collected in the limited access UK Center for Nursing Research (College of Nursing Building office 509 located at 751 Rose Street, Lexington KY 40536) in a locked file cabinet that is only accessible to the investigators.

☑ **UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Check this item to confirm that you will retain all IRB-related records for a minimum of 6 years after study closure.**

Payment

Describe the incentives (monetary or other) being offered to subjects for their participation. If monetary compensation is offered, indicate the amount and describe the terms and schedule of payment. Please review this guidance for more information on payments to subjects, including restrictions and expectations.

Each participant will receive compensation for their time valued at $10 at enrollment (in the form of t-shirt/or gift card from national retail chain) face mask, carry bag; $25 gift card at 12 weeks and $35 at 24 week in the form of a gift card from a national retail chain. Additionally, participants will receive a FitBit/pedometer to track physical activity and a blood pressure monitor. At the end of the intervention (24 weeks), each non-responder participants of the 10 churches randomized to receive the weekly enhanced telephone delivered intervention will receive an additional incentive of $5 for each completed telephone call (maximum 20 calls) in the form of a gift card with a maximum value of $100. Additionally, participants attending 80% or more of the sessions will be entered into a drawing at the end of the program for a health & wellness gift basket valued up to $100.

Costs to Subjects

Include a list of services and/or tests that will not be paid for by the sponsor and/or the study (e.g., MRI, HIV). Keep in mind that a subject will not know what is "standard" – and thus not covered by the sponsor/study – unless you tell them.

There is no cost to participate in this study.

Data and Safety Monitoring

The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research or NIH-funded/FDA-regulated clinical investigations.

- If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.
- If this is a non-sponsored investigator-initiated protocol considered greater than minimal risk research, and if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

NIDDK-approved Data Safety Monitoring Plan and Data Safety Monitoring Board Attached

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Future Use and Sharing of Material (e.g., Data/Specimens/Information)

If the material collected for this study will be used by members of the research team or shared with other researchers for future studies, please address the following:

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research
- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

Your information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name or date of birth.

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone who is willing to serve as the cultural consultant to the IRB.

- This person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.
- The consultant should not be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations
- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board, attach a copy in the "Additional Information/Materials" section. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?

○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Initiated FDA-Regulated Research

Is this an investigator-initiated study that:

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?

○ Yes ○ No

If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ○ Yes ◉ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

I have attached a HIPAA Waiver of Authorization. ○ Yes ◉ No

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

Drugs are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize Investigational Drug Service (IDS) pharmacies (Oncology or Non-Oncology). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

See FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Expanded Access SOP.

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

Medical devices are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals.

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer "no" above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor's authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition [FDA's PDF] of Significant Risk (SR) device?

- Yes. Device(s) being tested in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices being tested in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Complete and attach the required Study Device Form, picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.

Attachments

RESEARCH SITES

0 unresolved comment(s)

To complete this section, ensure the responses are accurate then click "SAVE".

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☐ UK Classroom(s)/Lab(s)
- ☐ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☐ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky (UK) or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page), including:

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.
- Supportive documentation, including letters of support, can be attached below. When attaching reliance documents, please ensure that you select the correct 'Document Type' from the drop-down menu. See below for the "**Document Types**" in bold, followed by examples of reliance documents for each type:
  - **Individual Investigator Agreement (IIA)**
    - A completed Individual Investigator Agreement

- IRB Approval (Non-UK)
- A Letter of Approval from a Non-UK IRB

- IRB Authorization Agreement (IAA)
- A SMART IRB Agreement
- An OHRP Agreement
- A DoD Agreement
- An IREx Reliance Notification
- Any Reliance Agreement

- Letter of Support & Local Context
- A Letter of Support from an organization at which some research activities are occurring
- Communications Plan
- Local Context Form

Please reach out to IRBReliance@uky.edu if you have any questions or concerns.

- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

List all other non-UK owned/operated locations where the research will be conducted:

The research will occur in churches and community centers located in Kentucky. Once we have identified the sites we will submit the Letters of Support/church registration forms by amendment.

Describe the role of any non-UK site(s) or non-UK personnel who will be participating in your research.

Please describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites:

Attachments

Attach Type	File Name
-Individual Investigator Agreement	Nataliah Sanford-2020 Individual Investigator Agreement.pdf
-Individual Investigator Agreement	Erika Meadows- Individual Investigator Agreement.pdf
-Individual Investigator Agreement	Taquay Hairston Individual Investigator Agreement.pdf
-Individual Investigator Agreement	Individual Investigator Agreement Tara Dempsey.pdf
-Individual Investigator Agreement	IIA_ Falon McFarland_VPR_Approved.pdf
-Individual Investigator Agreement	IIA_ Xavier McFalls_VPR_Approved.pdf
-Individual Investigator Agreement	IIA_Aaron Nance_VPR_approved.pdf
-Individual Investigator Agreement	IIA_Edwina A Smarr_VPR_Approved.pdf
-Individual Investigator Agreement	IIA_Jharonee Pea_VPR_Approved.pdf
-Individual Investigator Agreement	IIA_Michelle Patton_VPR_Approved.pdf
-Individual Investigator Agreement	IIA_Toni King_VPR_Approved.pdf
-Individual Investigator Agreement	Individual Investigator Agreement Monique Gilliam..pdf
-Individual Investigator Agreement	IIA for Adu Peasah.pdf
-Individual Investigator Agreement	IIA for Baughman.pdf
-Individual Investigator Agreement	IIA for Boyd.pdf
-Individual Investigator Agreement	IIA for Kovacs.pdf
-Individual Investigator Agreement	IIA for Small.pdf
-Individual Investigator Agreement	IRB 58766_IIA_Thurman.pdf
-Individual Investigator Agreement	IRB 58766_IIA_Thompson_.pdf
-Individual Investigator Agreement	IRB 58766_IIA_Stigall.pdf
-Individual Investigator Agreement	IRB 58766_IIA_Ray.pdf
-Individual Investigator Agreement	IRB 58766_IIA_Browder_.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Brown-Patterson.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Butler.pdf

-Individual Investigator Agreement	UKY IRB 58766_IIA_Davis.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Jackson.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Poyntz.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Webster.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Whitlock.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Wilder.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Kinkead.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Hyung.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_ALsada.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Jinwright.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Rice.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Bojang.pdf
-Individual Investigator Agreement	UKY IRB 58766 IIA Maranda Brooks.pdf
-Individual Investigator Agreement	UKY IRB 58766 IIA_Billy Davis.pdf
-Individual Investigator Agreement	UKY IRB 58766 IIA_Carla Carter.pdf
-Individual Investigator Agreement	UKY IRB 58766 IIA_Favour Ebikwo.pdf
-Individual Investigator Agreement	UKY IRB 58766 IIA_Love Awah.pdf
-Individual Investigator Agreement	UKY IRB58766 IIA_Tina Brooks.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Churchill.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Crumbie.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Foster.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Hatchett.pdf
-Individual Investigator Agreement	UKY IRB 58766_IIA_Magee.pdf
-Individual Investigator Agreement	Individual Investigator Agreement_Crumbie.pdf
-Letter of Support & Local Context	Greate Galilee CDC.pdf
-Letter of Support & Local Context	Kingdom Fellowship Registration Form.pdf
-Letter of Support & Local Context	Marnel C. Moorman Family Life Center Registration Form.pdf
-Letter of Support & Local Context	New Mt Zion Registration Form.pdf
-Letter of Support & Local Context	Spirit Filled Registration.pdf
-Letter of Support & Local Context	Shiloh Baptists Church Letter of Support.pdf
-Letter of Support & Local Context	Redeeming Christian Church Letter of Support.pdf
-Letter of Support & Local Context	First Corinthian (Frankfort).pdf
-Letter of Support & Local Context	HOC Church Registration .pdf
-Letter of Support & Local Context	Burnette Ave. BC.pdf
-Letter of Support & Local Context	Historic Calvary.pdf
-Letter of Support & Local Context	St. Stephen Baptist Church.pdf
-Letter of Support & Local Context	Bates Memorial Baptist Church.pdf
-Letter of Support & Local Context	CBC Church Registration Form.pdf
-Letter of Support & Local Context	FB Bracktown.pdf
-Letter of Support & Local Context	FB Winchester.pdf
-Letter of Support & Local Context	Forest Baptist Church.pdf
-Letter of Support & Local Context	Historic St. Paul AME Church.pdf
-Letter of Support & Local Context	Pilgrim Baptist Church Form.pdf
-Letter of Support & Local Context	First African Baptist Church.pdf
-Letter of Support & Local Context	Lima Drive Church.pdf

B) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Instructions: For various reasons, it is necessary to determine whether your research activities meet the definition of clinical research and/or a clinical trial. Your responses to the next series of questions will make that determination. For more details on the definitions, go to ORI's clinical research vs. clinical trial web page or visit NIH's decision tree for the NIH Clinical Trial definition.

Contact the Clinical Research Support Office (CRSO) if your study provides clinical services (e.g., labs, biopsies, tissue samples, physical exams, PT, counseling) regardless of payer (grant, federal, UK, industry)), utilizes UKHC space, or meets the NIH definition of a clinical trial (thereby requiring registry with CT.gov) as your study will need to be entered in OnCore to ensure appropriate regulatory tracking and billing. Visit CRSO FAQs for more information; requests for CCTS/CRSO services can be submitted via their service request form. For other questions, you can contact the CRSO Director, Jessica Heskel, at jhesk2@uky.edu.

My research activities include one or more of the following:

Patient-oriented research regarding mechanisms of human disease, therapeutic interventions, clinical studies, or development of new technologies
○ Yes ◉ No

Material of human origin (such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects
○ Yes ◉ No

Epidemiologic or Behavioral Studies
○ Yes ◉ No

Outcomes Research or Health Services Research
○ Yes ◉ No

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

☐ Academic Degree/Required Research
☐ Alcohol/Drug/Substance Abuse Research
☐ Biological Specimen Bank Creation (for sharing)
☐ Cancer Research
☐ CCTS-Center for Clinical & Translational Science
☐ Certificate of Confidentiality
☐ Collection of Biological Specimens for banking and use
☑ Community-Based Participatory Research
☐ Deception
☐ Educational/Student Records (e.g., GPA, test scores)
☐ Emergency Use (Single Patient)
☐ Gene Transfer
☐ Genetic Research
☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
☐ Treatment with Human Cells, Tissues, and Cellular and Tissue Based Products
☐ Individual Expanded Access or Compassionate Use

For additional requirements and information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial
- Collection of Biological Specimens for Banking (look up "Banks, Repositories, Registries...")
- Collection of Biological Specimens (look up "Repositories, Registries, Specimen/Tissue Banks...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

  *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach

- ☐ International Research
- ☐ Planned Emergency Research Involving Exception from Informed Consent
- ☐ Recombinant DNA
- ☐ Registry or data repository creation
- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☐ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

Emergency Use Checklist] (PDF)

- Genetic Research (look up "Banks, Repositories, ...Genetic/Genomic Data Sharing...")
- Gene Transfer

*For gene transfer research, also go to the E-IRB Application Other Review Committees section, and checkmark Institutional Biosafety Committee

- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Exception to Informed Consent*

*For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Use, storage and disposal of radioactive material and radiation producing devices

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

- ☑ Grant application pending
- ☑ (HHS) Dept. of Health & Human Services
  - ☑ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Click applicable listing(s) for additional requirements and information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info-look up "Does the IRB Charge a Fee..."]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

Other:

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

National Institute of Diabetes Digestion and Kidney (NIDDK)

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP and DoD Summary for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

Assurance/Certification Attachments

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC) - Attach required IBC materials
- Radiation Safety Committee (RSC) - For applicability, see instructions
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

Do you want specific information inserted into your approval letter? ○ Yes ◉ No

Approval Letter Details:

If you wish to have specific language included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type that language in the box below exactly as it should appear in the letter. The text you enter will automatically appear at the top of all approval letters, identical to how you typed it, until you update it. Don't include instructions or questions to ORI staff as those will appear in your approval letter. **If these details need to be changed for any reason, you are responsible for updating the content of this field.**

Additional Materials:

If you have other materials you would like to include for the IRB's consideration, check all that apply and attach the corresponding documents using the Attachments button below.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Other Documents

Protocol/Other Attachments

NOTE: Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

To view the materials currently attached to your application, click “All Attachments” on the left menu bar.

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

For a detailed illustration of how to complete this section, please review the short online video tutorial "Signatures (Assurance) Section - How to Complete." Otherwise, follow the steps below.

Required Signatures:

Individuals chosen as signees may remove the application from their Inbox without signing the Assurance Statement by clicking "Return to PI" with a comment about why it is being returned (e.g., specific edits are deemed necessary).

The PI, and personnel chosen as a contact, will receive an email notification that edits are needed, and can find the draft application in both the "Draft" folder and the "Signatures Status" folder located in the menu in the left margin of the default Inbox page. The researcher does not have a 'reply' option to the signee's comments and must make the requested edits directly in the application, or communicate outside the E-IRB system as to why not. Once the response is finalized, the researcher must re-visit the "Assurances Required" section to click the "Return to Signee" button for their re-consideration; the signee will receive an email notification at that time.

Hover your mouse cursor here for additional instructions.

First Name	Last Name	Role	Department	Signee Return Comment	Date Signed	
Thomas	Kelly	Department Authorization	Behavioral Science		04/02/2020 02:28 PM	View/Sign
Lovoria	Williams	Principal Investigator	Nursing Instruction		04/02/2020 02:46 PM	View/Sign

Department Authorization

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator has been notified of the additional regulatory requirements of the sponsor and by signing the principal investigator Assurance Statement, confirms he/she can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

**IF APPLICABLE FOR RELIANCE: I attest that the principal investigator has been notified of the regulatory requirements of both the Reviewing and Relying IRBs, according to the information provided in the E-IRB application. The attached Reliance Assurance Statement, signed by the principal investigator, confirms that he/she can comply with both sets of IRB requirements.

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☑ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.
- If applying for an Abbreviated Application (AA) to rely on an external IRB, I understand that certain items above (1, 3, 4, 7-8) may not apply, or may be altered due to external institutional/IRB policies. I document my agreement with the Principal Investigator Reliance Assurance Statement by digitally signing this application.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Once all Assurance Statement signatures have been acquired, return to this section to submit your application to ORI.

SUBMISSION INFORMATION

0 unresolved comment(s)

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed. Otherwise your submission for IRB review and approval cannot be sent to the Office of Research Integrity/IRB.

If applicable, remember to update the Approval Letter Details text box under the Additional Information section

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and you will receive a message to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Your protocol has been submitted.

CT Gov analysis plan

We analyzed study data descriptively, via means and standard deviations (SD) or frequency distributions, both as a summary of variables at each time point and as a check for missing and out-of-range values. We used T-tests and Chi Square tests of association to make baseline demographic comparisons between the treatment and comparison groups and between those who completed the study and those who were retained in the analytic sample but were missing one or both follow-up weights at 12 and 24 weeks. We evaluated means, SD, and Pearson product moment correlations among the variables indicating percent weight loss at 4, 12, and 24 weeks, with percentage of classes attended, and for the treatment group nonresponders the number of completed CHW calls.

We accounted for the cluster-randomized design and used repeated measures mixed modeling to evaluate the percent decrease in weight over *Time* (timepoints of 4 weeks, 12 weeks, and 24 weeks, relative to weight at baseline), between *Intervention Conditions* (Treatment vs. Comparison), and by *Response status* (responder vs. nonresponse). In addition to these main effects, we included the two- and three-way interaction terms. We included covariates that had the largest observed differences between the Treatment vs. Comparison group and/or those who completed the study versus those who missed one or both 12 and 24-week data collections. We evaluated post-hoc pairwise differences using Fisher's least significant difference procedure for pre-planned comparisons. The data analysis was done using SAS, v. 9.4; an alpha level of .05 was used for inferential testing.

For the cost effectiveness analysis we evaluated the cost of the intervention arm by comparing the incremental cost and weight loss with the active control arm (Aim 3). *We* compared the cost and outcomes associated with the intervention arm relative to the active control arm by calculating ICERs. An ICER is the ratio of the incremental change in costs divided by the incremental change in outcomes. Our primary cost effectiveness analysis focused on incremental cost per kilogram (kg) lost.