Document Coversheet

Study Title: Clinic to Community Navigation to Improve Diabetes Outcomes

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	3/29/2024
NCT Number:	NCT03474731
IRB Number	43766
Coversheet created:	7/3/2024

PROTOCOL TYPE (VERSION 4)

IRB Approval
3/29/2024
IRB # 43766
IRB6
CLOSED

IMPORTANT NOTE: You will not be able to change your selections for "Which IRB" and "Protocol Process Type" after saving this section. If you select the wrong IRB or Protocol Process Type, you may need to create a new application.

For guidance, see:

- Which IRB?
- Which Protocol Process Type?
- "Getting Started"

Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions prior to saving your selections.

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.

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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

UK/O Clinic to Community Navigation to Improve Diabetes Outcomes

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.

A1C

Anticipated Ending Date of Research Project: 1/1/2024

Maximum number of human subjects (or records/specimens to be reviewed) 1400

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.

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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.

For Expedited and Exempt Applications, the research activities must be Risk Level 1 (no more than minimal risk to human subjects).

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

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

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

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 these resources:
NIH Diversity Policy
FDA Diversity Guidance

Adults (age 18+); Appalachian residence, no plans to relocate out of the area in the next 18 months, willingness and ability to participate (i.e., no major cognitive impairment) and HbA1c levels at least 6.5%.

Individuals interested and potentially eligible will be asked to complete human subject protection protocol and verify their blood sugar through HbA1c screening. With the high prevalence of undetected T2DM, interested individuals at elevated risk of T2DM (as determined by the American Diabetes Association Risk Test, with a score of = 2) who have not received a T2DM diagnosis, will be offered HbA1c screening and will be considered eligible if they meet the above criteria. More than one member of a household may participate. We will note such arrangements.

We also will need to recruit health clinics who will allow us to partner with them. We would ask them to allow us to work with their receptionists, or other designated staff member, to help schedule appointments for our participants and receive permission to access participants' EMR. Generally, clinics will be paid $500 for their participation. We will include clinics that serve our specific participants.

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, 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:	10	15		
Asian:	5	10		
Black/African American:	60	70		
Latinx:	5	10		
Native Hawaiian/Pacific Islander:				
White:	515	690		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:	5	5		

If unknown, please explain why:

Adults (age 18+); Appalachian residence, no plans to relocate out of the area in the next 18 months, willingness and ability to participate (i.e., no major cognitive impairment) and HbA1c levels at least 6.5%.

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Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depend
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

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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

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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

- ☐ 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/HIPAA Combined Form	Informed Consent Clean 818.pdf
Informed Consent/HIPAA Combined Form	72601_Stamped Consent Form_551584.pdf
Informed Consent/HIPAA Combined Form	clean consent 53023.pdf
Phone Script	Phone Consent clean.pdf

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Informed Consent Process:

Using active voice, 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

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.

Patient Navigation Arm: Clinic staff will work to identify current diabetic patients who are not compliant with the diabetic standard of care, defined as not having had an appointment with their primary care provider (PCP) within the last 3 months. Clinic staff will contact these patients to inform them of the UK- Faith Moves Mountains Diabetes Research Project. If a patients indicates interest in the program, the clinic staff will inform our research staff. All patients who are interested will be invited to attend a scheduled health screening event. Project staff will administer the informed consent document. Study personnel for all phases of the project will provide a clear explanation of the project and invite questions. Our informed consent forms are written in a basic language. Interested participants will be asked to provide their signature on the informed consent forms. A copy of the signed consent will be provided for all participants. All forms will be read to participants to allay concerns about limited literacy. No non-English speaking or cognitively impaired participants will be recruited.
For the additional interrview with a subset of CCN participants (n=30), We will contact previous CCN participants who have given us permission to recontact them about participation in future related studies. During these conversations, we will use the attached phone script for consent to explain all aspects of participation in the interview and invite the participant to enroll in the study. Throughout this process, participants will be encouraged to ask questions and reminded of their right to discontinue participation at any time. After completing the consent process, participants will be invited to schedule a 60-minute interview.

Clinic Site will work with FMM Project Staff to verify appointments made and/or kept by participants at the conclusion of the 6- week intervention and again at the 3-month milestone. Clinic Site will identify a point of contact/representative for FMM Staff to reach out to in order to verify this information.
If needed, Clinic Site will identify a point of contact/representative for FMM Staff to reach out for scheduling facility usage for the intervention and follow-up sessions.
Participants will be asked to contact the investigator, Dr. Nancy Schoenberg at 859-323-8175 should they have any complaints. If they have any questions about their rights as a volunteer in this research, they will be asked to contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428.

☐ 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 ju
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.

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.

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).

: Appalachian residents maintain disproportionately high rates of Type 2 Diabetes Mellitus (T2DM) and suffer tremendous burdens from diabetic complications. The main challenges to stemming adverse outcomes from T2DM involve ensuring optimal clinical care and self-management. Because the prevalence of diabetes has tripled since 2005, the already low supply of primary care physicians combined with this tremendous chronic disease burden places huge demands on providers in rural Appalachia. Enhancing the quality and efficiency of these practices by linking to community health workers has the potential of mitigating the adverse effects of these shortages.
Patient navigation, particularly a clinic to community navigation (CCN) model offers an innovative approach to address these inequities. Patient navigation has been implemented almost exclusively in the cancer setting, despite being promising for chronic disease management. The proposed project is, to our knowledge, the first to test a hybrid model of clinic (health promotion professional) plus community (community health worker) navigation among rural residents.
Clinical patient navigation has been shown to facilitate appointment setting and return visits, improve goal setting, and enhance some adherence (medication taking, blood glucose testing). It does not however, address some key psychosocial (self-efficacy, patient activation) and practical concerns (transportation, childcare, self-management) challenges. Community-based navigation programs have been shown to enhance self-efficacy, decrease community barriers to care (e.g., transportation), and improved self-management, but may be less effective in ensuring return visits and working collaboratively with the doctor.

Objectives

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

Objectives: We aim to test a CCN program that may improve the most salient influences on diabetes outcomes and self-management, the health care context, and the patient's home context. Specifically, we will (1) recruit 1280 individuals with T2DM and HbA1c levels between over 6.5% and randomize them to one of three arms: (1) the Diabetes Empowerment Education Program (DEEP) (2) tailored patient navigation; and (3) a combination of the two arms, called community-to-clinic navigation. We will administer three quantitative assessments. All activities will take place in Appalachia. Outcomes include physiologic data (waist circumference, HbA1C levels, blood pressure, and BMI); quantitative data collection of self-management (medication taking, blood glucose, appointment adherence, diet, physical activity, foot and eye care obtained by interviewer); and psychosocial variables (self-efficacy, patient activation) obtained by interviewer. (3) We are proposing to conduct one additional interview with a subset of CCN participants (n=30). The in-depth interview will explore the influence of social support on Appalachian adults' diabetes self-management strategies.

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.

Behavioral randomized controlled trial, single blind design.

Attachments

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

For all data collection and intervention protocols, participants will be recruited through churches and community centers in several KY counties in Appalachian Kentucky, primarily in Letcher and Harlan Counties. Community-centered recruitment offers advantages (over clinical recruitment) such as : enrolling hard to reach individuals with impeded access to clinics; avoiding selection bias of healthier participants better able to access clinics; increasing comfort and trust of participants; and insuring that the facilities are accessible to participants after hours, when we may need to conduct classes. We will contact a diverse array of churches and community organizations to determine their interest in participating in this diabetes project. Once the minister or organization director has agreed to work with our team, we will conduct an information session about our project at their site and invite potentially eligible and interested individuals to talk with us after the presentation. At least two team members should attend each event, with one doing the eligibility testing and the other recording the contact information.
For the one additional interview with a subset of CCN participants (n=30). We will contact previous CCN participants who have given us permission to re-contact them about participation in future related studies. During these conversations, we will explain all aspects of participation in the interview and invite the participant to enroll in the study. Throughout this process, participants will be encouraged to ask questions and reminded of their right to discontinue participation at any time. After giving verbal consent, participants will be invited to schedule a 60-minute interview. The interview will be conducted in person at a mutually acceptable time and location.

Patient Navigation Arm:
UK's community based research organization, Faith Moves Mountains' (FMM) staff will work to identify potential clinical partners to assist with facilitating the Patient Navigation arm of the study.
An official Memorandum of Understanding will be signed by each participating clinic. Clinic staff will work to identify current diabetic patients who are not compliant with the diabetic standard of care, defined as not having had an appointment with their primary care provider (PCP) within the last 3 months. Clinic staff will contact these patients to inform them of the UK- Faith Moves Mountains Diabetes Research Project. If a patients indicates interest in the program, the clinic staff will inform our research staff. All patients who are interested will be invited to attend a scheduled health screening event to determine project eligibility.
It is critical for potential participants to be contacted by our project staff for several reasons: (1) As a community-based research organization that has been operating in the counties for over 15 years, our FMM staff have earned a reputation as trustworthy and non-threatening; (2) Given that the very reason we are providing patient navigation to their appointment is that they have not been to their primary care provider as recommended, being contacted by clinic staff likely would be more intimidating and less successful than by our trained and CITI-certified staff; (3) clinic staff are extremely busy and may not fully understand or be able to take the time to explain the research protocol. Our staff, on the other hand, will take all the time needed to explain every component of the intervention and fully answer all questions.
The Faith Moves Mountains- Appalachians In Control (AIC) Project Staff will use advertising to help enhance public awareness and participation in the research screening, interventions, and post-tests via traditional media (radio, TV, newspapers); community outreach (events, festivals) and social media (Facebook). UK PR approved flyer will be used for all advertisement. The approved flyer would be provided to serve as the advertisement and the script. Local radio, newspaper and TV stations may be sent flyers for community and public service announcements about upcoming Eligibility Screening Events. Local radio personalities often post such information on their business social media outlet once the station receives notification. Project Staff will supply participating sites with digital and hard copies of their event flyer for distribution. Please be advised that site contacts may also share the flyer on their own personal social media sites and tag members of their congregation to aid in recruitment efforts.
Social Media
Project Staff will work with UK PR to have an approved Facebook Page for the Faith Moves Mountains –UK Research Project. Social Media will be used to help aid in recruitment efforts by posting approved flyers of upcoming Eligibility Screening Events. The Project Staff will likely share or post upcoming Eligibility Screening Flyers to their personal Facebook pages to help spread the reach in the local communities in which they work. In additions, project team members such as Community Health Workers will be tagged in such post due to their overall connection to the community where these events are taking place.
Project Staff may share Eligibility Screening flyers with on social media with groups that are labeled as community sites for sharing and dissemination of public information. The approved flyer would be posted on this page.
The FMM Social Media page will also be used for project staff to share general diabetes knowledge and project office work such as health education information and tips.
We are aware that use of social media may open up room for complaints. The Project Manager, Tiffany Scott, will regularly monitor the site to ensure identification of any complaint comments which will be addressed and reported to the IRB. Ms. Scott will also monitor for any individuals post private information and in that event will take those comments down.

FMM has worked with Roxane Poskin, Participant Recruitment Senior Specialist, University of Kentucky' Center for Clinical and Translational Science to develop a short video that may be used on social media or shared with potential recruitment sites. Link : https://nam04.safelinks.protection.outlook.com/?
url=https%3A%2F%2Fyoutu.be%2FCHfk6qLceVg&data=05%7C01%7CJennifer.Malan%40uky.edu%7C9be3531f0a52408ac66f08da592ff49f%7C2b30530b69b64457b818481cb53d42ae%7C0%7C0%7C637920359779298800%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=KFGO%2BbOI%2FvCE4%2FS5gX3n26AZN%2Fw5KiGz4U9yri2Of1I%3D&reserved=0

Attachments

Attach Type	File Name
Advertising	HealthScreeningEvent LUNCH MP Edits APPROVED.pdf
Advertising	HealthScreeningEvent MP Edits APPROVED.pdf
Advertising	Schoenberg2_062822_Clean.pdf
Advertising	Schoenberg2_062822_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.

The consort diagram attachment provides an estimation and visual description of the timing and structure of the research and intervention. (a) Once informed consent documents are completed, participants (N=1280) will undergo the baseline assessment. Baseline and posttest assessments will consist of the same measures highlighted in the Table below. (b) All churches and organizations participating will receive the DEEP, Diabetes self-management classes. Some sites will be randomized to receive the classes immediately and others will receive them after a 3 month delayed period.
Step 1. Health Screening Event
Step 2. Church or Organization Randomized to DEEP or Delayed
Step 3. Baseline Interviews Conducted (Within 2 weeks following event)
Step 4. DEEP Intervention Begins For Those Randomized To DEEP (Within 2 weeks following Baseline Interviews)
Step 5. 3 Month PostTest For All
Step 6. DEEP Intervention Begins For Those Randomized To Delayed
Step 7. 6 Month Out PostTest For All
Step 8. 9 Month Out PostTest For All

(c) Patient Navigation Arm:Once a patient agrees to participate in the research study, FMM project staff will inform them about the eligibility screening and determine a time to administer informed consent and then collect baseline biometric data including AIC Test, Height, Weight, BMI, Mini Cognitive Brain Screener, and Blood Pressure as well as a baseline interview. For the intervention, FMM personnel will provide each participant with a tailored Patient Navigation (PN) intervention. The team of trained Patient Navigators will work one-on-one with the participants to help increase their clinic attendance and reduce barriers that stand in their way of keeping their medical appointments. This process involves problem solving, active listening, and motivational interviewing techniques. At the end of the 6-week PN intervention. FMM staff will then offer all participants a 6- Week diabetes self-management course. Some clinic sites will be randomized to receive the classes immediately following the 6-week Patient Navigation and others will receive the classes after a 3 month delayed period. FMM Interviewers will follow up with participants at the 3, 6, and 9-month mark. FMM staff will conduct another interview at each milestone and the biometric data will be repeated. FMM will compensate each participant $35 per interview. Clinic Site will work with FMM Project Staff to verify appointments made and/or kept by participants at the conclusion of the 6- week intervention and again at the 3-month milestone. Clinic Site will identify a point of contact/representative for FMM Staff to reach out to in order to verify this information. At the conclusion of the 9-month mark data collection, project staff will provide the clinical representative with a report of all of the clinic's participating patients and their biometric data reports.
Step 1. Clinic Randomized to DEEP or Delayed
Step 2. Health Screening Event
Step 3. Baseline Interviews Conducted (Within 2 weeks following event)
Step 4. PN Intervention Begins For All (Within 2 weeks following Baseline Interviews)
Step 5. 3 Month Out PostTest For All
Step 6. DEEP Intervention Begins For Those Randomized To DEEP
Step 7. 3 Month Out PostTest For All
Step 8. DEEP Intervention Begins For Those Randomized To Delayed
Step 9. 3 Month Out PostTest For All

d) 30 participants who chose to participate in the social support survey will complete the one time survey and be compensated $35 each.

Attachments

Attach Type	File Name
ResearchProcedures	Patient Navigation Encounter Packet.pdf
ResearchProcedures	AIC- Patient Navigation Process & Dialogue.pdf
ResearchProcedures	consort diagram.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.

We will administer three quantitative assessments. All activities will take place in Appalachia. Outcomes include physiologic data (waist circumference, HbA1C levels, blood pressure, and BMI); quantitative data collection of self-management (medication taking, blood glucose, appointment adherence, diet, physical activity, foot and eye care obtained by interviewer); and psychosocial variables (self-efficacy, patient activation) obtained by interviewer.

For the social support sub-study 30 participants will be consented separately and complete a one time assessment of psychosocial variables.

Attachments

Attach Type	File Name
DataCollection	Stress, Social influences and T2DMManagement Interview GuideJune2021.pdf
DataCollection	a1c questionnaire as in redcap 02_04_21.docx

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.

The research and intervention activities will be conducted in participants' homes, community sites, Mountain Comprehensive Health Corporation (MCHC), or other clinics.

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 potential risks from participating in the study are very small. Some risk of psychological upset could result from responding to interview questions or the emotional distress from questions about diabetes management. Some risk may be associated with a finger prick for A1C. The most significant risk involves any threat to confidentiality. However, all project staff will be human subjects trained and have extensive experience maintaining participant confidentiality. HIPAA protocols will also be in place and will follow MCHC's protocols.
Participation in the study involves little risk for subjects in comparison to the potential benefits of adopting improving diabetes outcomes. Participants in all three arms of the project will receive diabetes programming at no cost. Given the disproportionate diabetes burden experienced by Appalachian populations, implementing and evaluating this novel, theory based intervention has the potential to save many lives while advancing intervention science.

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).

Participants will be randomized to one of three the intervention arms. No other alternative treatments are available.

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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

Two sources of data will be collected: biometric data (HbA1C levels, waist circumference, blood pressure, and BMI) from trained project staff and quantitative assessments (surveys). The table below highlights the specific data to be collected.

Table 1: Variables Data sources and collector
Main outcomes
HbA1C, blood pressure, waist circumference, BMI Project staff
Additional outcomes: Self-management outcomes
Medication taking, blood glucose testing, appointment adherence, diet, physical activity, foot and eye care Project staff
Diabetes Empowerment Scale (self-efficacy),27 patient activation28 , other psychosocial questions Project staff
Sociodemographic, self-perceived health status, depression, sleep scale, other health data Project staff
Confidentiality of all data will be maintained by never linking paper or computer copy of data with the participants' names. A sheet with the participant's name, address, telephone number, and identification number will be kept by the Project Director and Principal Investigator separately in a locked file. Only staff members who are authorized to review files will be permitted access to the data. As part of our training, each community health worker and interviewer will be asked to sign a confidentiality pledge promising never to reveal, alter, or falsify survey data. This pledge is especially important in small, tight-knit rural communities. Data are held in password-protected computers and secure servers at University of Kentucky which have extensive firewalls and security measures. We will keep all records (tapes, informed consent documents, and other records like completed questionnaires) for a minimum of six years after the completion of the study.
In each stage of the research, we will make every effort to provide protection against risks. Study personnel will provide a clear explanation of the project and invite questions during enrollment. In the rare event that a participant experiences psychological distress resulting from the interview questions or from the intervention or discomfort stemming from the finger prick, our staff will contact Dr. Van Breeding, internal medicine physician at MCHC. Dr. Breeding will consult with the participant, debrief and discuss the participant's concerns, and refer participants to any additional support.

UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Do you confirm that you will retain all IRB-related records for a minimum of 6 years after study closure?
(•) Yes ( ) No

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.

Participants will be offered $35 for each assessment (survey). There will be three assessments over the course of their participation, participants will receive their payment for each assessment.

Participants in the social support sub-study will be consented separately and compensated $35 for the one time survey.

Patient Navigation Arm: FMM will compensate the clinical site in an amount to be negotiated with each site for their participation in the project. A maximum amount will be determined. This amount will reflect a percentage of the designated staff person's salary for the duration of project participation. This amount is to help offset the time spent of that employee working to obtain Consent for the Faith Moves Mountain Referrals.

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.

N/A

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.

Data will be stored such that no participants will be identified other than on the initial participation sheet that will be kept separately by the Principal Investigator in a locked file.

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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

• list the biological specimens and/or information that will be kept: no biological specimens will be kept
• briefly describe the types, categories and/or purposes of the future research: de-deidentified secondary data set may be used, with permission of the PI and research team, for additional psychsocial and behavioral analyses.
• describe any risks of the additional use: none
• describe privacy/confidentiality protections that will be put into place: all data are de-identified and run no risk of confidentiality breeches.
• describe the period of time specimens/information may be used: n/a for specimens; data will be kept for a minimum of six years
• describe procedures for sharing specimens/information with secondary researchers: A data use request should be filed with the data coordinator and the PI indicating the proposed analysis, the intended variables to be used for the analyses, and the intended site for dissemination (conferences, journal articles, etc). Requests will be considered on a rolling basis and the requesting researcher will be informed.
• describe the process for, and limitations to, withdrawal of specimens/data: n/a

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

Multilevel linear mixed effects models are used for the continuous outcomes. Models incorporate fixed effects corresponding to trial arm, categorical time, and their interaction, with primary interests described in the next paragraph. To further account for the study design, models incorporate random site effects, random household effects within sites, and an unstructured covariance matrix for repeated measures over time from the same subject. Standard error estimates and degrees of freedom are calculated using the approach of Kenward and Roger (1997).

Analyses are based on intention-to-treat, and utilize all available data. Tests are two-sided at the 5% significance level. Analyses are conducted in SAS Version 9.4 (SAS Institute, Cary, NC).