GUARDIANS RECEIVING INFORMATION THROUGH NAVIGATORS (GRIN)
STUDY PROTOCOL
NCT05511935
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KDH RESEARCH & COMMUNICATION
RESEARCH PROTOCOL FOR GRIN FEASIBILITY EVALUATION
EVALUATION STUDY

BACKGROUND

Purpose of Research

KDH Research & Communication (KDHRC) received funding from the National Institutes of Health (NIH) National Institute on Minority Health and Health Disparities (NIMHD) to develop and evaluate Guardians Receiving Information through Navigators (GRIN). GRIN is an online professional development course that aims to prepare community health workers (CHWs[1]), trusted community members familiar with their communities' needs and resources, to provide oral health outreach to low-income Black guardians of children and adolescents (henceforth, Black guardians).

Terminology

- CBO: Community-based organizations serving low-income Black guardians (e.g., National Association of Community Health Workers)
- Potential participants: CHWs recruited through CBOs
- Participants: CBO-recruited CHWs with completed consent forms

In Phase I, KDHRC will convene a steering committee to inform an architecture plan that includes the full course content outline, video storyboards, and virtual interactive learning experience storyboards. Then, KDHRC will develop the GRIN prototype with two full course modules with text, video animatics, and rough-cut virtual client experiences. Finally, KDHRC will conduct a feasibility evaluation study (henceforth, study) to explore changes in CHWs' knowledge, attitudes, beliefs, perceived self-efficacy, and intentions to conduct oral health outreach to low-income Black guardians of children and adolescents after exposure to the GRIN prototype. This study will provide insight for future GRIN expansion, finalization, and randomized control trial (RCT) evaluation to measure behavior change among CHWs and guardians in a small business innovation research (SBIR) Phase II project.

Specifically, KDHRC proposes to conduct a two-group, randomized pretest/posttest feasibility study to evaluate the extent to which the GRIN protytype increases CHWs' knowledge, attitudes and beliefs, perceived self-efficacy, and intentions to conduct oral health care outreach to low-income Black guardians. KDHRC will conduct the study with CHWs nationwide.

The study will consist of pretest and posttest surveys and a virtual education session with two GRIN modules (treatment) or no intervention (control), pending Institutional Review Board (IRB) approval. The participants in the study are CHWs. KDHRC will partner with community-based organizations (CBOs) to assist with CHW recruitment.

[1] CHWs include community health workers (CHWs), community health representatives (CHRs), lay health workers, and other titles.

This protocol describes the procedures for the study.

Responsible Parties

Dexter Cooper, MPH, is the Principal Investigator with oversite of the GRIN project. Nicole Wanty, KDHRC's senior research associate, is the Project Director. Morgan Fleming, a KDHRC researcher, will manage the study.

Specifically, KDHRC will:

- Contract and share study materials with CBOs (recruitment subcontractors) to recruit participants
- Program and manage the online eligibility and consent forms, pretest survey, and posttest survey
- Send follow-up communications to consented participants
- Manage, clean, and analyze data
- Manage incentive distribution
- Report on study findings

KDHRC will contract with CBOs serving low-income Black guardians to be the recruitment subcontractors. To be eligible, each CBO must demonstrate organization stability and their capacity to participate in the study by having:

(1) Federal nonprofit tax-exempt status under Section 501(c)(3) of the Internal Revenue Code
(2) Internet access to share the recruitment materials with their network of CHWs
(3) At least one active program that conducts health care outreach to low-income Black clients with a minimum of 15 active CHWs on staff (paid or volunteer)
(4) A dedicated point of contact (POC) who will participate in a kick-off call with KDHRC and oversee the study at their CBO

Prior to sharing the study materials with each CBO, KDHRC will schedule a kick-off call with each CBO POC. During each kick-off call, KDHRC will briefly explain the study and provide an overview of the study requirements, time commitment, and consent process.

Each CBO will share the KDHRC-developed and IRB approved recruitment materials (e.g., flyer, email template) with potential participants.

RESEARCH DESIGN

Goal

The goal of the GRIN study is to examine the impact of the GRIN online professional development course prototype. Specifically, the study aims to address the following research question: "To what extent does the GRIN prototype increase CHWs' knowledge, attitudes and beliefs, perceived self-efficacy, and intentions to conduct oral health care outreach to low-income Black guardians of children and adolescents?"

Approach

The study will use a two-group, pretest/posttest design. KDHRC will program the eligibility and consent forms, pretest survey and posttest surveys in Alchemer (formerly SurveyGizmo), a

secure online survey platform. This Phase I SBIR requires KDHRC to create content for two modules only: "Tooth decay impact on children and adolescents" and "Preventive oral health care." Each module will be 20 – 30 minutes to complete and cover several expert-approved and reviewed topics. The participants in the intervention group will be sent a link to a KDHRC webpage where they will access the videos. Participants will access the videos by computer or cell phone to begin their virtual education session.

CHWs will be recruited through the CBOs and directed to an online link for eligibility screening and informed consent. KDHRC will confirm consent for each participant and after confirming consent, KDHRC will randomize each participant with completed consent into the treatment or control group using a 1:1 randomization. KDHRC will alternate assigning each participant with completed consent to the treatment group or the control group. Then, KDHRC will send each participant the link to the online pretest survey. After completing the pretest survey, each treatment group participant will receive access to a virtual education session with two GRIN modules. The control group will not receive an intervention. Each participant will receive the posttest survey two weeks after completing the pretest survey.

Participants and recruitment

CBOs with signed contracts to participate in the study will designate a POC who will be responsible for sharing recruitment materials with potential participants at their respective CBO. KDHRC will require each CBO to participate in a kick-off call with KDHRC staff during which time KDHRC staff will review the study protocol and answer additional questions. After the call, each CBO will be required to sign and return the certification form (see **Attachment X**) that states that the CBO POC understands the process and will follow the procedures outlined during the kick-off call. KDHRC will send the certification form via email or DocuSign to the CBO POC to sign prior to the CBO receiving the recruitment materials. If the CBO POC fails to follow the provisions of the certification form, the CBO will be removed from the study and will not receive full compensation.

CBOs will recruit potential participants in their networks, including potential participants within their CBOs, by sharing KDHRC-developed and IRB-approved recruitment materials (e.g., email template, flyer) thru email (e.g., listervs) and message boards. The recruitment materials will contain the link to the eligibility form, information on the time commitment, and instructions to contact KDHRC with questions. The study will include up to 120 CHWs nationwide (60 treatment, 60 control) from up to 16 CBOs. Although CBOs will recruit participants and may have access to potential participant information (e.g., name, email address) from their listservs, CBOs will not have knowledge of who actually serves as study participants and will not have access to enrolled participants' data. KDHRC will remind participants that participation in the study is completely voluntary, that the CBO that shared recruitment materials with the participant will not have knowledge of who actually serves as study participants, and that his or her participation is no way tied to his or her position at and/or relationship with the CBO that shared recruitment materials with him or her.

Eligibility criteria for CHWs include:

- Must be at least 18 years old
- Must self-identify as a community health worker

- Must conduct outreach to Black clients
- Must have six months of field experience. KDHRC defines "field experience" as conducting outreach activities in their community, for example, working with clients in a clinic, conducting home visits, or educating clients at health fairs or community events
- Must be an active CHW. KDHRC defines "active" as conducting outreach activities, such as working with clients in a clinic, conducting home visits, or educating clients at health fairs or community events, in the last six months
- Must have Internet access either at home or at work to access the GRIN virtual education session and/or online surveys.

Each participant in both the treatment group and the control group will receive a $25 e-gift card (Amazon or Walmart) incentive after completing the pretest survey, and a $25 e-gift card (Amazon or Walmart) incentive after completing the posttest survey for a total of up to $50 in e-gift card incentives (Amazon or Walmart). Each participant in the treatment group will receive an additional $25 incentive for completing the virtual education session with two GRIN modules.[2]

Methods

Upon completing and submitting the consent form to participate, each participant will be randomly assigned to either the treatment group or the control group. Then, KDHRC will send each participant the link to the online pretest survey. Participants will have two weeks to complete the pretest survey. A KDHRC researcher will send approximately three reminders (email, phone, text) per week to each consented participant to complete the pretest survey.

KDHRC will email the treatment group participants the information to access a virtual education session. When each participant accesses the virtual education session for the first time, each participant will be prompted to create a user ID and password and provide the last two letters of his or her last name, his or her three letter initials, and his or her year of birth, to access the virtual education session. Participants in the treatment group will have two weeks to complete the virtual education session. Participants in the control group will not receive an intervention for the two weeks between surveys. KDHRC will send one reminder (email or phone) per week to participants to promote continued engagement with the study (e.g., remind treatment participants to complete the virtual education session; remind control participants of the date when they will receive their posttest survey).

Then, two-weeks after pretest completion, KDHRC will email all participants the links and instructions for posttest survey completion. Each participant will have two weeks to complete the posttest survey. A KDHRC researcher will send approximately three reminders (email, phone, text) per week to each consented participant to complete the posttest survey.

The links to the pretest and posttest surveys will be used to collect participant data, therefore only KDHRC staff will have access to raw data. Each survey will take no more than 45 minutes to complete.

[2] We provide an additional incentive for treatment participants because treatment participants will access a virtual education session with two GRIN modules while the control group does not have to access anything.

Analysis

KDHRC will program the eligibility and consent forms, pretest survey, and posttest surveys in Alchemer, a secure online survey platform. After completion of the study, KDHRC will download the raw data from Alchemer into encrypted Excel spreadsheets.

KDHRC will import the data into STATA, a quantitative statistical software, to analyze and assess the extent to which the GRIN prototype increases CHWs' knowledge, attitudes and beliefs, perceived self-efficacy, and intentions to conduct oral health care outreach to low-income Black guardians.

Timeline

The study will begin immediately upon obtaining IRB approval. All data collection will conclude by June 30, 2022.

DATA COLLECTION

KDHRC will collect quantitative data from up to 120 CHWs (60 CHWs per group) through online surveys only. If KDHRC encounters low recruitment numbers and/or high attrition rates, then KDHRC will contract with additional CBOs and utilize additional recruitment methods (e.g., social media) to reach additional participants. This will not impact the rights of or risk to study participants.

Identifying Information

CBOs will not have access to enrolled participants' survey responses. Although CBOs will recruit participants and may have access to potential participant information (e.g., name, email address) from their listservs, CBOs will not have knowledge of who actually serves as study participants and will not have access to enrolled participants' data.

KDHRC will not share consented participants' names or contact information with CBOs. KDHRC will collect participants' names, email addresses, and phone numbers to share study information and send reminders. KDHRC will not link names or other identifying information to the responses. Each participant will create an ID number based on several survey questions (last two letters of his or her last name, his or her three letter initials, and his or her year of birth). KDHRC will collect this information solely to match participant data.

KDHRC will use an Alchemer-developed system to match each participant's pretest and posttest survey responses using URL redirects and a "gateway survey."[3] When participants click the KDHRC-provided link to access the pretest survey, participants will first be directed to a separate page (the "gateway survey") where they will be prompted to enter their ID number and select that they need to complete the pretest survey. The participant will then automatically be redirected to the pretest survey questions. After the two-week intervention period, KDHRC will email participants the same link that directs participants to the "gateway survey." Participants will enter the same ID number and select that they have already completed the pretest survey two weeks prior. Participants will automatically be redirected to the posttest survey questions. Alchemer, the secure online survey platform, will automatically match each participant's pretest and posttest survey question responses and create one composite complete, matched pretest and

[3] Create a Pre-Test and Post-Test Survey | Alchemer Help

posttest dataset per participant. Although each participant's ID number will be collected in the back end of the online survey platform, participants will not enter their ID number on the pretest survey questions or the posttest survey questions. Full names will not be recorded on surveys and participants will not provide other identifying information to researchers through the surveys.

KDHRC will save all raw data on KDHRC's secure server in a project specific, password protected folder. KDHRC will destroy all raw data and related forms one year after the end of data analysis.

Assurance of Confidentiality

Confidentiality is crucial to the protection of human subjects. Therefore, KDHRC will strictly follow its established procedures on the protection of confidential information. Moreover, all KDHRC staff who have access to these data will sign confidentiality pledges. Only links to the pretest and posttest surveys will be used to collect participant data, therefore only KDHRC staff will have access to raw data. KDHRC will keep information that participants provide private and confidential. KDHRC will offer to share the research report with CBOs at the conclusion of the study. KDHRC will inform participants prior to their participation that their responses are confidential. KDHRC will also advise participants of the nature of the activity, the length of time it will require, and that participation is purely voluntary and that they can stop at any time. KDHRC will assure participants that no penalties will occur if they wish not to respond, either to the information collected as a whole or to specific questions.

As a further confidentiality guarantee, KDHRC will present data in reports in aggregate form only and will not preserve links to individuals. KDHRC will track consent electronically and collect data through Alchemer, the online platform that is only accessible with the KDHRC username and password. Further, KDHRC will store participant responses in a password-protected files on the KDHRC server.