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

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 (course) that aims to prepare community health workers (CHWs[1]), trusted community lay health workers familiar with their communities' needs and resources, to provide oral health outreach to low-income Black guardians of children and adolescents (henceforth, Black guardians).

In Phase II, KDHRC finalized the GRIN course with eight full course lessons with text, video vignettes, and artificial intelligence (AI) avatar simulations. KDHRC proposes to conduct a randomized controlled trial (RCT) to evaluate the extent to which the GRIN course 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, posttest, and 3-month follow-up surveys. CHWs will be assigned to the treatment condition (up to eight lessons) or the control condition (pages from the American Dental Association (ADA) website). Participants may complete the study completely virtually (e.g., receive all links and reminders via email and phone/text communication) or during an in-person event (e.g., receive all links via flyers and verbal reminders during the event).

This protocol describes the procedures for the study.

Responsible Parties

Dexter Cooper, MPH, is the Principal Investigator of the GRIN project. Nicole Wanty, KDHRC's senior research scientist, is the Project Director. Elizabeth Phelps, a KDHRC researcher, will manage the study.

Specifically, KDHRC will:

- Contract with a recruitment contractor to share study materials with referral partners, share the study with the KDHRC CHW Panel[2], and conduct evaluation sessions at CHW conferences to recruit participants.
- Program and manage the online eligibility and consent forms, pretest survey, posttest

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

[2] The KDHRC CHW Panel is a list of CHWs who have opted-in to receive communications about program development and study opportunities.

survey, and 3-month follow-up survey.
- Send follow-up communications to consented participants.
- Manage, clean, and analyze data.
- Manage incentive distribution.
- Report on study findings.

KDHRC will use a multi-pronged recruitment strategy to recruit up to 320 CHWs to participate in the study, including:

1. Hiring a contractor to manage recruitment of CHWs
    a. The contractor will briefly explain the research study and provide an overview of the study requirements, time commitment, and consent process to participating sites (e.g., community-based organization (CBO) and other CHW organizations).
2. Sharing the opportunity with the KDHRC CHW panel. The CHW panel includes CHWs who have voluntarily signed up to be notified about future research opportunities.
3. Attending the National Association of Community Health Workers (NACHW) Annual Conference, the Southeast Community Health Worker Network Summit, and other CHW conferences
4. Recruiting participants via social media or through another recruitment panel provider

For approach #1, KDHRC will begin work with the contractor by scheduling a kick-off call, during which KDHRC will briefly explain the study and provide an overview of the study requirements, time commitment, and consent process. The Contractor will then share the KDHRC-developed and IRB approved referral materials (e.g., flyer, email template) with participating sites.

RESEARCH DESIGN

Goal

The goal of the GRIN study is to examine the impact of the GRIN online professional development course. Specifically, the study aims to explore the following research question: "To what extent does the GRIN course 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 treatment/control, pretest/posttest/follow-up design. KDHRC will program the eligibility and consent forms, and the pretest /posttest/follow-up surveys in Alchemer, a secure online survey platform.

The study will include up to 320 CHWs nationwide (160 treatment groups, 160 control groups). After referral to the study, CHWs will access an online link for eligibility screening and informed consent form. Across all approaches named above, information about the study will be shared with potential participants through KDHRC-developed and IRB-approved referral materials (e.g., email template, flyer, social media posts). The referral materials will contain the link to the eligibility form, information on the time commitment, and instructions for contacting KDHRC with questions. KDHRC will also share the study opportunity with the KDHRC CHW

panel and at CHW conferences, like the National Association of CHWs Annual Conference and the Southeast Community Health Worker Network Summit.

Eligibility criteria for CHWs include:

- Must be at least 18 years old.
- 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/health educator/individual who conducts health outreach. 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 (or at in-person session).

These criteria will be assessed through the eligibility screener, after which each eligible participant will see a consent form. 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. KDHRC will alternate assigning each participant with completed consent to the treatment or the control groups. Then, KDHRC will provide each participant with the link to the online pretest survey. After completing the pretest survey, each treatment group participant will receive access to the GRIN course (up to eight lessons). The control group will be directed to ADA webpages.

Virtual-only

Virtual-only participants will complete the above eligibility, consent, and pretest steps independently via computer, tablet, or phone. After completing the pretest, KDHRC will email the participant access to the appropriate treatment or control links. Treatment and control participants will have up to three weeks to review their assigned materials. KDHRC will send at least one reminder (email or phone) per week to participants to promote continued engagement with the study (e.g., remind treatment participants to complete the GRIN lessons; remind control participants of the date when they will receive their posttest survey). After reviewing the assigned materials, participants will receive the link to the online posttest survey. Then, three months after the posttest survey, KDHRC will send the link to the online follow-up survey (treatment group only).

In-person

KDHRC may host in-person sessions at CHW conferences and meetings. For in-person sessions, KDHRC will divide the treatment and control participants into separate rooms to prevent potential crosstalk. Participants who complete the study in-person will receive food and refreshments during the session, which will last approximately 2.5 hours. In-person session participants will receive links to complete all eligibility, consent, and surveys during the session.

KDHRC will distribute a flyer with the link and QR code to access GRIN lessons (treatment) or control materials (ADA webpages). After reviewing the assigned materials, KDHRC will provide participants with a flyer with the link to the posttest survey. Then, three months after the

posttest survey, KDHRC will send the link to the online follow-up survey (treatment group only).

Incentives

Each participant in both the treatment groups and the control groups will receive a $25 Amazon gift card incentive for completing the pretest survey, and a $50 Amazon gift card incentive for completing the posttest survey for a total of up to $50 in card incentives. Treatment participants will receive an additional $50 Amazon gift card incentive for reviewing the full GRIN course and a $25 Amazon gift card for completing the follow-up survey.

Participants who complete the study virtually will receive an e-gift card incentive. In-person session participants will receive their physical gift card upon completion of the posttest survey and prior to exiting the session. Participants who complete the session in-person will also receive food and refreshments during the session.

The links to the pretest, posttest, and follow-up surveys will be used to collect participant data and access to the secure survey platform responses is restricted to KDHRC research staff. Therefore, only KDHRC research staff will have access to raw data. Each survey will take no more than 30 minutes to complete.

Analysis

KDHRC will program the eligibility and consent forms, pretest/posttest/follow-up 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 course 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 March 31, 2026.

DATA COLLECTION

KDHRC will collect quantitative data from up to 320 CHWs (160 CHWs per treatment groups, 160 per control groups) through online surveys. If KDHRC encounters low referral numbers and/or high attrition rates, then KDHRC will utilize additional referral methods (e.g., social media, recruitment vendor/panel) to reach additional participants. This will not impact on the rights of or risk to study participants.

Identifying Information

The recruitment contractor and sites will not have access to enrolled participants' survey responses. Although the recruitment contract and sites may have access to potential participant information (e.g., name, email address) from their listservs, they will not have knowledge of who truly participates as study participants and will not have access to enrolled participants' data.

KDHRC will not share consented participants' names or contact information. 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 survey questions at the start of each survey (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. Although each participant's ID number will be collected at the start of each survey, participants will not enter full names or provide other identifying information to researchers through the surveys.

KDHRC will save all raw data on KDHRC's secure server in project specific, password protected files. KDHRC will not share personal information (participant name, phone number, email address) regarding participants with any third party without the participant's written permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or other legal processes. Data will remain stored on a password-protected computer or in a locked cabinet accessible only by KDHRC, as outlined in Table 1.

KDHRC will submit de-identified data from this study to a public access repository, such as OpenICPSR (Inter-university Consortium for Political and Social Research). It is a requirement of the study's federal funding to share the data to a repository to make data accessible and useful for the American public, businesses, and researchers. The goal of data sharing is to improve the use of data for decision-making and accountability for the Federal Government, thereby increasing transparency and reproducibility. For more information, please see the National Institutes of Health Data Management and Sharing Policy (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html).

To protect research participants, before data sharing in the repository KDHRC will:

- Remove any personal information from the shared data that could identify a specific person (like name, birthdate, age, gender, address including zip code, etc.).
- Assign each participant's data a code number to distinguish one study participant from another.

De-identified data from this study will be made publicly available (e.g., on the OpenICPSR website). Anyone can use information from a public access repository for any purpose in the future. There are no more than minimal risks to participants in the study as a result of this data sharing requirement.

Table 1. Data Retention

DATA TYPE	DELETION TIMELINE	STORAGE LOCATION	DELETION METHOD
Screener contact information listing all potential participants that have screened into the feasibility study.	*One month* after the end of data collection to allow time for incentive delivery.	Stored on a password-protected computer or a locked cabinet accessible only by KDHRC.	Destroyed by permanently deleting from the computer and shredding documents.

Quantitative screener data	*3 years* after data analysis ends.	Stored on a password-protected computer or a locked cabinet accessible only by KDHRC.	Destroyed by permanently deleting from the computer and shredding documents.
Participant consent forms	*3 years* after data collection ends.	Stored on a password-protected computer or a locked cabinet accessible only by KDHRC.	Destroyed by permanently deleting from the computer and shredding documents.
Participant survey responses	*3 years* after data analysis ends.	Stored on a password-protected computer or a locked cabinet accessible only by KDHRC.	Destroyed by permanently deleting from the computer and shredding documents.
De-identified survey responses	*Will not be deleted,* shared to public access repository after data analysis ends.	Maintained by repository (e.g., on the OpenICPSR website).	N/A

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. Online 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 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 password-protected files on the KDHRC cloud-based server. As noted above, KDHRC will submit de-identified data from this study to a public access repository, such as OpenICPSR (Inter-university Consortium for Political and Social Research).

Mitigation of Potential Risks

KDHRC acknowledges that the referral approach introduces the potential for coercion into the study. KDHRC has carefully crafted several safeguards against coercion given this potential which is outlined below:

- The recruitment contract will work with sites (e.g., CBOs and other CHW organizations) who are promotional and referral partners and will not directly refer participants. Although sites will promote participation to potential participants and may have access to potential participant information (e.g., name, email address) from listservs at their respective organizations, no site will have knowledge of who ultimately participates in

the study and will never have access to enrolled participants' data. KDHRC will not share participant names with sites.

- The recruitment contractor and sites must adhere to the following rules to avoid coercion:
    - Send general announcements with the promotional materials to his/her full network of contacts. Not approaching CHWs individually about participating in the study. This includes sending individual emails to CHWs about the study, talking one-on-one with CHWs about the study, and/or calling CHWs individually about the study. All promotional activities must be done on a group-wide basis.
    - Never ask CHWs if they enrolled in and/or completed the study.
    - Never communicate or imply that CHWs "must" or "should" participate in the study. Participation must be presented as optional and discretionary.
- KDHRC will remind participants that participation in the study is completely voluntary, that the sites that shared promotional materials with the participant will not have knowledge of who 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 site that shared promotional materials with him or her. These tenets are clearly stated in the study consent form.

Assessment and Reporting of Protocol Deviations and Adverse Events

KDHRC's IRB is listed on the consent form if participants have questions about their rights as research subjects.

The PI and project director will ensure that there are appropriate oversight systems in place to monitor all research activities and identify any adverse events or deviations from the study protocol. Upon discovery of an adverse event, the PI is responsible for reporting protocol deviations to the IRB using a standard reporting form. Any protocol deviations will be reviewed by the PI to assess whether participant safety or study integrity has been affected by the deviation and to what extent the deviation has affected the project. If the deviation meets the threshold for a protocol violation, appropriate measures will be taken to address the occurrence, which may include the development of a corrective action plan. Any protocol violations and corrective action plans will be reported to KDHRC IRB. In addition, corrective actions that lead to a change in the protocol shall be submitted to and approved by KDHRC IRB as an amendment to the protocol prior to implementation.

Subject privacy and data confidentiality breaches are serious risks and will be **reported within one hour of discovery** to NIH and the KDHRC IRB (etwombly@7research.org).

The following will be communicated in an initial notification to the NIH and KDHRC IRB (etwombly@7research.org) **as soon as possible (generally within 24 hours) with a full report submitted within 10 days.**

- **Serious Adverse Event:** An adverse health event that is life-threatening or results in death, initial or prolonged hospitalization, disability or permanent damage, congenital anomaly, or birth defect, or requires medical or surgical intervention to prevent one of the other outcomes.
- **Unexpected Adverse Event:** An adverse health event that was not identified in nature, severity, or frequency in the research protocol/informed permission documents.

- **Unanticipated Problem:** Any incident, experience, or outcome that meets all the following criteria:
    1. Unexpected (in terms of nature, severity, or frequency) given a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed permission document; and b) the characteristics of the subject population being studied;
    2. Related or possibly related to the subject's participation in the research; and
    3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.
- **Protocol Violation:** Any change, divergence, or departure from the study design or procedures of a research protocol that affects the subject's rights, safety, or wellbeing and/or the completeness, accuracy, and reliability of the study data.

The following will be communicated on a routine non-urgent basis but no less than annually:

- **Expected Adverse Events:** Those health effects and other risks that are listed in the protocol and informed consent forms as being likely to occur or as a result of participation in the study.
- **Minor Protocol Deviation:** Any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the IRB and that DOES NOT have a major impact on the subject's rights, safety, or well-being, or the completeness, accuracy, and reliability of the study data.