MONITORING AND OUTREACH FOR MATERNAL SAFETY POSTPARTUM (MOMS POSTPARTUM)

STUDY PROTOCOL

1R43MD019206-01

FEBRUARY 3, 2025

KDH RESEARCH & COMMUNICATION
RESEARCH PROTOCOL FOR ENCORE 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 Effective Newborn Community-Outreach Recovery Engagement (ENCORE). In the NIH proposal, KDHRC named the course ENCORE. During course development, KDHRC consulted experts and CHWs to determine the extent to which ENCORE was an appropriate name for the course. Based on feedback, KDHRC renamed the course "Monitoring and Outreach for Maternal Safety Postpartum (MOMS Postpartum)." Therefore, all external facing materials (e.g., consent forms, surveys, flyers) will only use the name MOMS Postpartum, and we use that name in the remainder of the IRB documents enclosed.[1]

MOMS Postpartum is an online professional development course that aims to prepare community health workers (CHWs[2]), trusted community members familiar with their communities' needs and resources, to provide optimal care and resources to child-bearing minority women during the postpartum period.

Terminology
- CBO: Community-based organizations serving minority women
- Potential participants: CHWs referred through CBOs and the KDHRC CHW Panel
- Participants: CHWs with completed consent forms

In Phase I, KDHRC created the prototype which includes four lessons:

- Lesson 1. Welcome and Introduction
- Lesson 2. Health Disparities Experienced by Minority Mothers
- Lesson 3. CHWs' Role in Supporting Maternal Health
- Lesson 4. Working with Maternal Health Professionals

Each lesson will take 20 – 30 minutes to complete and includes content reviewed by advisory panels of subject matter experts and CHW experts.

KDHRC will conduct a two-group, randomized pretest/posttest feasibility evaluation study (henceforth, study) to explore the extent to which the prototype changes CHWs' knowledge, skills, attitudes, self-efficacy, and intentions to provide optimal care and resources to postpartum minority mothers. The study will consist of pretest and posttest surveys and videos with four lessons (treatment) or a waitlist control (control), pending Institutional Review Board (IRB) approval. The participants in the study are CHWs. KDHRC has contracted with community-based organizations (CBOs) to assist with CHW referral to the study.

[1] KDHRC internal files will introduce the course as ENCORE, then include a note about the name change.
[2] 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 project. Nicole Wanty, KDHRC senior research scientist, is the project director. Elizabeth Phelps and Laura Pfeiffer, KDHRC research assistants, will program online surveys, send communications to participants, and track participants through the study.

Specifically, KDHRC will:

- Contract and share study materials with CBOs (referral subcontractors) to refer participants.
- Share study materials with KDHRC's CHW Panel. The Panel includes CHWs who have signed up to receive notifications about research study opportunities.
- Program and manage the online screener, 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 has contracted with CBOs with CHWs who serve minority women to be the referral 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 referral materials with their network of CHWs.
(3) At least one active program that conducts health outreach minority women 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 IRB-approved study materials with each CBO, KDHRC will share a study kick-off video and manual with each CBO POC. In the video and manual, 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 referral materials (e.g., flyer, email template) with potential participants.

RESEARCH DESIGN

Goal

The goal of the study is to explore the research question: "To what extent does exposure to the prototype increase CHWs' knowledge, skills, attitudes, self-efficacy, and intentions to provide support to postpartum minority women?"

Approach

The study will use a two-group, pretest/posttest design. KDHRC will program the screener and consent forms, pretest survey, and posttest surveys in Alchemer, a secure online survey platform.

CBOs with signed contracts to participate in the study will designate a POC who will be responsible for sharing referral materials with potential participants at their respective CBO. KDHRC will require each CBO POC to review a study kick-off video and manual. In the video and manual, KDHRC will briefly explain the study and provide an overview of the study requirements, time commitment, and consent process. After reviewing the video and manual, each CBO POC will be required to sign and return the certification form that states that the CBO POC understands the study referral process and will follow the procedures outlined in the video. KDHRC will send the certification form via email or DocuSign. The CBO POC must return the signed form prior to receipt of the referral 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 refer potential participants in their networks, including potential participants within their CBOs, by sharing KDHRC-developed and IRB-approved referral materials (e.g., email template, flyer) through email (e.g., listservs) and message boards. KDHRC will also share study materials with KDHRC's CHW Panel. The referral materials will contain the link to the screener, information on the time commitment, and instructions to contact KDHRC with questions. The study will include up to 160 CHWs nationwide (80 treatment, 80 control) from up to 12 CBOs and the KDHRC CHW Panel. Although CBOs will refer 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, and that his or her participation is no way tied to his or her position at and/or relationship with the CBO that shared referral 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 (CHW).
- Must live in the United States.
- Must conduct outreach to minority women.
- 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 lessons and/or online surveys.

CHWs will be referred to the study through the CBOs or via KDHRC's CHW Panel. Materials will direct interested CHWs to an online link for screening and informed consent. KDHRC will share receive referral links with participants to refer colleagues who may be interested in research studies. Each referral link will include a specific code that links to the referring CHW. Only KDHRC researchers will have access to this code. Referring CHWs will not know if referred CHWs access and complete the referral link. Referred CHWs information will be kept confidential. Referral links will open in a separate form for referred CHWs to sign up for the KDHRC CHW Panel. Depending upon the referral completion timeline, referred CHWs may receive information about the MOMS Postpartum study via CHW Panel communications.

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 the prototype. Specifically, the participants in the treatment group will receive a link to a KDHRC Teachable School[3] where they will access the lessons. Participants can access the lessons by computer or smart phone. The control group will receive no intervention. Each participant will receive the posttest survey no more than two weeks after completing the pretest survey.

Participants 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). Participants in the treatment group will receive an additional $25 incentive for completing the prototype lessons. KDHRC calculated this amount based on the length of the surveys and amount of time required to review the treatment and control materials. This incentive amount is comparable to incentives KDHRC has successfully used for feasibility evaluation studies. Inadequate compensation for time spent participating in a study may result in a difficult and lengthy recruitment process and/or participants who agree to participate and then drop out early. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate, but also respects that they may have other responsibilities such as childcare or employment.

Upon completing and submitting the screener, participants will receive the link to the consent form via email. A KDHRC researcher will send approximately three reminders (email, phone, text) per week for up to two weeks to each eligible participant to complete the consent form.

[3] Teachable is a secure online learning platform. Users will sign up for a free account from Teachable and then receive free access to the MOMS Postpartum lessons.

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 up to one week 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 the lessons. When each participant accesses the lessons for the first time, the participant will be prompted to create a user ID and password. Participants in the treatment group will have up to two weeks to complete the lessons. Participants in the control group receive no intervention. 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 modules; remind control participants of the date when they will receive their posttest survey).

Then, no more than two weeks after pretest completion, KDHRC will email all participants the links and instructions for posttest survey completion. Each participant will have up to one week to complete the posttest survey. A KDHRC researcher will send approximately three reminders (email, phone, text) per week to each consented participant with a completed pretest survey 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 30 minutes to complete.

Analysis

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 prototype increases CHWs' knowledge, skills, attitudes, self-efficacy, and intentions to provide support to postpartum minority women.

Timeline

The study will begin immediately upon obtaining IRB approval. All data collection will conclude by April 30, 2025.

DATA COLLECTION

KDHRC will collect quantitative data from up to 160 CHWs (80 CHWs per group) through online surveys only. If KDHRC encounters low participant numbers and/or high attrition rates, then KDHRC will contract with additional CBOs and utilize additional referral 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 refer 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."[4] 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 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. 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 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 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 process. 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:

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

- 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 conclusion of 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 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 acknowledge 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:

- CBOs are promotional and referral partners and will not directly refer participants. Although CBOs 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 CBO 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 CBOs.
- CBOs must adhere to the following rules to avoid coercion:
    - Send general announcements with the promotional materials to his/her full network of contacts.
    - Not approach 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 CBOs 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 CBO 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.