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Document:
IN-HOME Study Protocol and Statistical Analysis Plan

Official Study Title:
Testing Preliminary Effectiveness of a Community Health Worker (CHW) Training Program to Support African American and Latino Male Caregivers of Older Adults

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IN-HOME feasibility evaluation

I. Original proposal narrative

The Phase 1 feasibility evaluation, a RCT with a two-group pre–post design with 87 CHWs will explore the following question: To what extent is IN-HOME exposure (treatment) associated with greater CHW knowledge, skills, and perceived self-efficacy to conduct outreach to reduce caregiver burden for African American and Latino male informal caregivers of older adults compare to CHWs reviewing caregiver information from AARP's English "Care at Home" resource page (control)? What is the relation between demographic characteristics (e.g., age and race/ethnicity) and experimental differences in knowledge, skills, and perceived self-efficacy? What is the extent of difference in outcomes between treatment and control participants?

We will enroll 60 CHWs per arm. Eligible participants will (1) be at least 18 years old, (2) self-identify as a CHW, (3) live in the United States, (4) conduct outreach, to African American and Latino male informal caregivers, (5) have at least six months of field experience and (6) be an active CHW within the last six months.

We will randomly assign participants to the treatment and control conditions. Any stratification based on potentially confounding factors will be done by using covariates in the full analyses. Treatment participants will complete a pretest before and a posttest after viewing the IN-HOME prototype. Control participants will complete a pretest before and a posttest after reviewing caregiver information from AARP's English "Care at Home" resource page.

IN-HOME is feasible if the treatment group shows statistically significant higher mean scores in knowledge, skills, and perceived self-efficacy at posttest compared to the control group. We will use covariate-adjusted ANCOVA to control for group differences (e.g., received caregiver training before) that may confound outcomes. We will use two-tailed tests to identify potential iatrogenic effects.

II. IN-HOME study research questions

1. To what extent is IN-HOME exposure (treatment) associated with greater CHW knowledge, skills, and perceived self-efficacy to conduct outreach to reduce caregiver burden for African American and Latino male informal caregivers of older adults compare to CHWs reviewing caregiver information from an online resource (control)?
    - What is the relation between demographic characteristics (e.g., age and race/ethnicity) and experimental differences in knowledge, skills, and perceived self-efficacy?
2. What is the extent of difference in outcomes between treatment and control participants?
    - What is the relation between demographic characteristics (e.g., age and race/ethnicity) and experimental differences in knowledge, skills, and perceived self-efficacy?

3. To what extent do CHWs exposed to IN-HOME show greater gains in knowledge compared to the control group?
    - What is the relation between demographic characteristics (e.g., age and race/ethnicity) and experimental differences in knowledge, skills, and perceived self-efficacy?
4. To what extent do CHWs exposed to IN-HOME are more prepared to provide support to male caregivers compared to the control group?
    - What is the relation between demographic characteristics (e.g., age and race/ethnicity) and experimental differences in knowledge, skills, and perceived self-efficacy?

For specific hypotheses, see the research question and hypotheses document, located here: S:\Projects\IN-HOME\Feasibility evaluation\Methods and analysis

III. IN-HOME study summary

Study design: Randomized controlled trial with a two-group online pretest/posttest design.

Study population and sites: The study population will include active CHWs. The study will be conducted online and include participants recruited by six CHW organizations in Alabama, Georgia, Florida, Virginia, Illinois, and Texas.

Treatment regimen: Treatment group participants will view the IN-HOME prototype. Control group participants will view materials from AARP's English "Care at Home" resource page.

Randomization: The research assistant will randomly assign participants to the control or treatment group after they consent to the study.

Institutional Review Board (IRB): KDHRC received approval for pilot testing materials on May 2, 2023 IRB # 00005850.

The final approved IRB package can be found at: S:\IRB\Reviews\Reviews - general\2023\2023-02-01 - 2023-0213 - In Home\12 - Amended approval packet

IV. Pre-launch survey review

KDHRC conducted a pre-launch review of the survey instrument to ensure its clarity, reliability, and validity before full-scale use. Internal staff tested the eligibility, consent, pretest, and posttest links to confirm that the surveys were ready to launch. After reviewing the survey questions and testing the survey, we submitted an amendment request to the IRB for modifications and additions. Staff retested the links.

The amendment request can be found here: S:\IRB\Reviews\Reviews - general\2023\2023-02-01 - 2023-0213 - In Home\10 - Amendment request

V. Recruitment

We contracted with six sites with CHW-related programs. All sites received a brief training video to explain IN-HOME and provide an overview of the study requirements, time commitment, and consent process. After completing the training call, sites will begin recruitment using KDHRC-developed and IRB-approved recruitment materials. Sites shared the recruitment materials with their CHWs via email, newsletter, fliers, in-office communications (e.g., Slack) and social media posts. The recruitment period began upon receiving IRB approval, and ended when we received enough participants for power for analysis.

The recruitment period for IN-HOME lasted from May 15, 2023 to August 16, 2023.

IV. Data collection

- Recruitment numbers (aimed): 123 CHWs
- Recruitment numbers (actual): 123 CHWs consented [52 control; 55 treatment]
- Dates: May 15, 2023 – August 16, 2023

V. Data cleaning

1. Make changes in Alchemer (if required)

2. Download pretest and posttest from Alchemer and save in the "raw data" folder – do not make any changes to this data.
    - Location (control group): S:\Projects\IN-HOME\Feasibility evaluation\Raw data\Control\Final control group raw data
    - Location (intervention group): S:\Projects\IN-HOME\Feasibility evaluation\Raw data\Treatment\Final treatment group raw data
    - File is password protected with standard data protection password. See Dexter for password.

3. Copy the raw data file exported from Alchemer into the "Manipulated data folder"
    - Location: S:\Projects\IN-HOME\Feasibility evaluation\Manipulated data

4. Merge the posttest treatment and posttest control surveys together to form a single posttest file.
    - Archive separate posttest treatment and posttest control surveys.
    - Save combined posttest survey files as _COMBINED.

5. Merge pretest and posttest data by matching pre- and posttest responses by participant ID.

- Compare participant ID (last-initials-state) between pre and posttest responses.
- If the participant matches, merge the pre and posttest variables.
- Archive pretest and posttest survey files.
- Save merged survey files as _MERGED.

6. Delete observations, if applicable.

7. Clean data in preparation for data analysis.

VI. Data analysis

1. Create dichotomous variables for incorrect and correct answers
    a. For the knowledge and skills variables, we will code correct answers as '1' and incorrect answers as '0'.
    b. The new variable name will use "_correct" (e.g. q1_t1_correct).
2. Create a dummy variable for treatment.
    a. For all participants in the treatment group, we will code the variable "treatment" with a '1' and control group participants with a '0'.
3. Create composite variables for the knowledge, skills, and self-efficacy questions.
    a. Create composite variables for each participant that sums all their answers for each outcome and divides them by the total number of questions to create composite scores, ranging from 0 to 100 (e.g., a composite knowledge score of 100 means that a participant correctly answered all knowledge questions on the pretest).
    b. The new variable names will be "know_comp_t1," "know_comp_t2," "att_comp_t1," "att_comp_t2," "se_comp_t1," "se_comp_t2," "int_comp_t1," and "int_comp_t2."
4. Create "gain" or "differences" score for the composite variables.
    a. Subtract the t1 composite variables from the t2 composite variables to get the change in composite score from pretest to posttest for each outcome area.
    b. The new variable names will be "know_comp_diff," "att_comp_diff," "se_comp_diff," and "int_comp_diff."

Methods

- Between groups t-tests on each outcome's composite score at pretest and posttest.
- Within group t-tests between each outcome's pretest and posttest composite scores.

- Regression analyses using each primary outcome's posttest composite score as the dependent variable and group assignment as the primary independent variable, while controlling for participant characteristics at baseline including race, ethnicity, age, sex, education, time as CHW, paid/volunteer status, having over 16hrs of training, number of usual topics outreach is conducted on, and whether participants had been trained previously in older adult care.