A Self-Affirmation Intervention to Enhance Patient Outreach for Health System-based Lifestyle Programs for Diabetes Prevention

Study Protocol and Statistical Analysis Plan

August 29, 2018

National Clinical Trial (NCT) Identified Number: NCT03550066
Unique protocol ID: CN-14-1871-H

Principal Investigator: Susan D. Brown, PhD

Sponsor: National Institutes of Health

Human Subjects Approval: Kaiser Foundation Research Institute

I. Study Overview

This pilot study examines the acceptability of a values affirmation intervention, which prompts participants to reflect on important personal values, embedded within a health outreach message encouraging participation in healthcare services for diabetes prevention (e.g., a lifestyle program for reduction of diabetes risk factors). This study tests whether an outreach message containing the values affirmation intervention is as acceptable as (non-inferior to) a standard outreach message without the values affirmation. Participants will be sampled from a multi-lingual, ethnically diverse population of women who face high risk for type 2 diabetes due to having a history of gestational diabetes mellitus (GDM) and elevated body mass index (BMI). This study extends prior research by including English- and Spanish-speaking women from African-American and Latina racial/ethnic backgrounds. The overall objective is to develop theory-based health messaging that is acceptable to diverse women who may benefit from diabetes prevention programs.

II. Study design and methods

Two-arm, parallel-group, randomized trial among English- and Spanish-speaking minority women with prior GDM and elevated BMI in a healthcare system.

III. Hypothesis and Outcomes

We hypothesize that an outreach message containing a values affirmation will be as acceptable to participants as an outreach message that does not contain a values affirmation.

Primary outcome: Acceptability of the message, as assessed by its perceived persuasiveness (e.g., perceiving the message as helpful, respectful, personally relevant). Persuasiveness is assessed using a 7-point self-report scale, with higher mean scores corresponding to greater perceived persuasiveness.

Secondary outcomes: Whether women a) seek health information on diabetes prevention, and b) either seek information about or intend to join a preventive program.

IV. Recruitment

Potential participants will be recruited from Kaiser Permanente Northern California, a large integrated healthcare delivery system. Eligibility criteria include:

- Age ≥ 18 years
- History of gestational diabetes mellitus within the past 4 years
- Elevated body mass index (≥ 25 kg/m^2)
- Hispanic or Black race/ethnicity

Exclusion criteria include current pregnancy and current diabetes. Participants already participating in a lifestyle program for diabetes prevention will be excluded from analyses.

V. Informed Consent

Informed consent is obtained from each participant at entry into the study by the following process:

1. Participants are invited to complete the study online via a secure website. On the website, participants are first asked to review the study consent form.
2. A toll-free phone number and study email address are provided so that research staff can answer any questions that participants might have.

3. Participants agree to participate in the study with an electronic signature. Participants will not be able to proceed to the survey unless they have agreed to consent.
4. Participants are able to save and print out a copy of the consent.

VI. Procedure

Study participation involves completing a single online survey. Within the survey, participants are assigned to read an outreach message promoting an existing preventive program that contains either a values affirmation (intervention condition) or no affirmation (control condition). Participants complete survey items before and after being exposed to the outreach message in their assigned condition. Participants receive a $10 gift card upon completion of the survey.

VII. Adherence statement

The Data and Safety Monitoring Plan (DSMP) outlined below for CN-14-1871-H will adhere to the protocol approved by the Kaiser Permanente Northern California IRB.

VIII. Adverse Events

A. Adverse event assessment

Few risks are expected in the present study, with little to no risk of serious adverse events or mortality. Risks include the potential for participants to find the survey questions and outreach materials upsetting. Risks are addressed in the consent form. Steps taken to minimize risks include using materials based on existing, publicly available health education materials or based on established research instruments used in prior studies which, to our knowledge, no studies have found to be more than minimally upsetting. Additionally, participants are explicitly advised in the consent form that they may skip any questions that make them feel uncomfortable. The consent form reminds participants that they may seek medical care as needed as members of the Kaiser Foundation Health Plan. Participants are provided with study contact information to report any concerns regarding their safety and welfare.

B. Adverse event reporting

Applicable events reported by participants to either the principal investigator or the designated research associates will be documented. For each adverse event, a report will be generated including, at a minimum, a description of the event, when and how it was reported, and determinations of attribution (related or unrelated to the study) and severity. Recipients of the adverse event report will include the IRB in accordance with institutional policies for timeliness of reporting. Any action resulting in a temporary or permanent suspension of this study will be immediately reported to the appropriate NIDDK program official.

IX. Safety Review Plan and Monitoring

A. Justification of sample size

The primary goal of the study is to examine the acceptability of a self-affirmation intervention embedded within an outreach message promoting patient uptake of health services for type 2 diabetes prevention. A sample size of 70 participants (35 per condition) for this early-stage pilot and feasibility project will provide adequate power to determine that there is no difference in acceptability between conditions (see Statistical Design and Power, below).

B. Safety and study progress review

The PI will review study progress, e.g., recruitment, retention, and protocol adherence, on a weekly basis (and more frequently if needed). The PI will review adverse events at least monthly. No formal stopping points will be included.

X. Data Quality and Management

Study staff will review all data collection forms for completeness, accuracy, and protocol compliance on an ongoing basis during active data collection, and again upon completion of data collection.

Measures taken to ensure data integrity and protection of databases: Data verification will be performed by study staff. The PI has consulted with Kaiser Permanente Division of Research (DOR) IT Development and Application Services to offer the data collection survey online. An authentication process will be used to ensure the privacy of user accounts. Access to survey data will be provided to the research team in a secure web console requiring authentication.

XI. Confidentiality

Risks to confidentiality will be mitigated by extensive provisions to safeguard participants' confidential information. No data collection forms will have identifying information on them except for a unique study participant identification (ID) number. Any physical data (paper copies) will be kept in locked file cabinets with access limited to the study team on a need-to-know basis. The list that links study identification numbers with participants' names will be maintained electronically in a password-protected folder on our secure sever, to which only study staff will have access on a need-to-know basis. Access to computerized patient tracking systems and data files will be restricted to the study staff by the use of a password. No individual-level data will be included in any report or publication related to any study. All data will be reported in the aggregate.

XII. Statistical Analysis and Power

The primary goal of the study is to examine the acceptability of a self-affirmation intervention embedded within an outreach message promoting patient uptake of health services for type 2 diabetes prevention. The primary hypothesis is that acceptability of an outreach message that includes self-affirmation (experimental condition) will be non-inferior to the acceptability of a standard outreach message without self-affirmation (no-affirmation control condition). The target sample size is 70 participants (35 per condition) for this early-stage pilot and feasibility project. This sample size provides 80% power to determine that there is no difference in acceptability between conditions above a non-inferiority limit of d=.6. The primary outcome of acceptability will be examined using t-tests. Outcomes will be assessed by modified intent-to-treat analyses (excluding participants who already have diabetes or who are already participating in a lifestyle program for diabetes prevention).