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Document: Study Protocol and Statistical Plan

Official Study Title: Racial inequities in end-of-life healthcare: how perceived discrimination affects communication and decision-making during serious illness

NCT Number: NCT04915079

Document Date: December 7, 2022

Research Protocol for PRISM pilot RCT

Final Draft: December 7, 2022

Goal:

Original Aim: Conduct a pilot randomized trial of 60 patients to test the feasibility, acceptability, and preliminary efficacy of a patient-centered intervention to cultivate resilience and improve patient-clinician communication and shared decision-making in seriously ill patients who have experienced healthcare discrimination. I will utilize a version of an established intervention to improve resilience and empower patients to effectively communicate with clinicians.

Hypothesis: This pilot RCT will establish feasibility and acceptability and show preliminary efficacy in improving resilience and quality of communication.

PRISM Pilot RCT Phases	
Pre-Study	<ul style="list-style-type: none">• IRB approval obtained• Study surveys developed<ul style="list-style-type: none">○ Enrollment○ 1-month○ 3-month• PRISM manual finalized• Provider script finalized• Patient interview script• Provider interview script• RedCap database created
Phase 1: Planning	<ul style="list-style-type: none">• Goal enrollment: 60 participants<ul style="list-style-type: none">○ 30 PRISM arm○ 30 usual care• Research question• Inclusion/Exclusion criteria
Phase 2: Conducting	<ul style="list-style-type: none">• Data extraction: EHR, survey results• Data synthesis: RedCap, DeDoose
Phase 3: Reporting	<ul style="list-style-type: none">• Dissemination of results

1. Getting Started:

- Phase 1 should be completed

2. Selecting Cases:

- Patients will be screened in the EHR. Eligible patients will be
 - Black
 - Diagnosed with serious illness with median expected survival of two years or less
 - English-speaking
 - Age 18 years and older
 - No cognitive impairment.

3. Instruments:

- Participants will complete three surveys upon
 - A) enrollment
 - B) 1-month post-randomization
 - and C) 3-months post randomization
- They will receive \$20 gift cards with each survey
- At enrollment, they will complete:
 - Demographic information
 - DMS
 - MHCS
 - GBMM
 - CD-RISC
 - HADS
- PRISM participants will also complete a post-PRISM qualitative interview
- At 1-month and 3-months post-enrollment, participants will complete
 - CD-RISC
 - HADS

4. Entering the Field

- Patients will continue to be enrolled in the ongoing cohort, but will also be approached regarding participating in a pilot RCT.
- Study goals will be explained and consent obtained prior to enrollment in the RCT.
- Note that patients will need to be consented for both the cohort and the RCT each.
- Participants will be randomized 1:1 to either PRISM or usual care using a random number generator (range 1-100; odd=usual care; even=PRISM)
- PRISM RCT participants will be tracked in RedCap and will include:
 - Enrollment survey results
 - 1-month survey results
 - 3-month survey results
 - Contact information including address, phone number, and email
- Provide patients with dates of follow up surveys upon enrollment.

- Participants will receive reminder phone-calls and emails 1 week before each survey, and in-person check-ins if they are readmitted or have an upcoming clinic visit during a 2-week window around each survey.
- If surveys are not completed within 1 week, participants will receive a phone call and email to remind them and assess willingness to continue participation

5. Analyzing Data

- Primary outcome: Differences in CD-RISC scores in PRISM vs usual care group at 1- and 3- months post randomization
- Statistical Analysis: My primary outcome is resilience, measured by the CD-RISC. I will use the intention-to-treat principle for analysis and use linear regression to evaluate differences in mean resilience at 3 months between the two study arms. I will adjust for baseline CD-RISC scores since I anticipate resilience at randomization and 3 months later will be highly correlated. For secondary analyses, I will adjust for age, sex, race/ethnicity, marital status, and diagnosis. I will also jointly model resilience scores at all time points (randomization, and 1- and 3-months) using a mixed model approach to evaluate trends in resilience scores. This approach accommodates missing outcomes, assuming data are missing at random. I will use a similar approach for my secondary, continuous outcomes. I will use logistic regression for dichotomous outcomes.
- Power: To calculate sample size, I used the difference in mean change in resilience scores, due to anticipated correlations between scores over time (Table 4). The standard deviation of change in the 10-item CD-RISC scores over 6 months (4.2 points) was available from a prior trial.⁵⁵ With 30 participants per arm, I will have 80% power at a 0.05 two-sided significance level to detect a mean change in CD-RISC scores over 3 months of 3 points (Table 4). I expect power to be similar or greater after adjusting for baseline resilience scores. I anticipate $\geq 70\%$ complete data and will randomize 43 patients per arm to achieve 30 patients with complete data. With 80% completion, I will have 80% power to detect a change of 2.8 points at the same significance level.
- Anticipated papers:
 - PRISM RCT
 - Clinician interviews
 - Patient interviews
 - Experience/feedback on racial healing/medical racism session?