MOTIVATIONAL STRATEGIES TO EMPOWER AFRICAN AMERICANS TO IMPROVE DIALYSIS ADHERENCE

NCT05003115

02/22/2024

MoVE R03 Pilot Study Analysis Plan
for Aim 2A

The primary aim of this study were to gather feasibility metrics for a larger trial. However, Aim 2A included an estimates of treatment effects, acknowledging these will be underpowered in this pilot study. **Aim 2A: To generate estimates of treatment effects and variation of a culturally tailored motivational interviewing protocol as compared to usual dialysis care and to evaluate feasibility outcomes and acceptability.**

Study Design and Setting: A three-month randomized pilot feasibility trial. I will enroll N=30 patients from the VUMC-owned dialysis unit of over 300 patients, 60 to 70% of whom self-identify as African American.
Inclusion Criteria*:* English-speaking African American receiving hemodialysis who are ≥ 18 years of age who have missed more than one dialysis session per month in any of the three-months prior to enrollment or who have shortened their dialysis session by over ten minutes per month. Participants with missed treatments due to hospitalizations or excused travel, with alternate arrangements for dialysis will not be included.
Exclusion Criteria: Non-English speaking; known diagnosis of dementia or psychotic illness; severe medical illness; no documented evidence of hemodialysis treatment non-adherence.
Randomization & Masking*:* Randomization will be performed within the REDCap online, secure, data management platform, and personnel will be masked until after enrollment. Patients will be randomized to receive Culturally Tailored Motivational Interviewing (Arm 1) or to Usual Care (Arm 2) using a block randomization scheme. Personnel collecting surveys will be masked to the assignment.
Outcomes: In this pilot feasibility trial, emphasis will be placed on assessing preliminary operational feasibility. Study outcomes will include assessing screening to enrollment ratio; attendance to motivational interviewing sessions; motivational interviewing fidelity, and drop-out rates. Outcomes will also include imprecise measures of variation in hemodialysis treatment adherence and motivation-related factors including the following: *autonomous regulation, autonomy support,* and *perceived competence* using the Autonomous Regulation (AR) scale[81]; Health Care Climate Questionnaire (HCC)[82] and Perceived Competence (PC) scales,[50] respectively. Apathy and optimism will be assessed with the Apathy Evaluation scale (AES)[22] (range 0-4) and the optimism subscale[68] of the Perceived Expectancies index (PEI)[69] (range 0-5).
Analysis Plan: Descriptive measures of autonomy, apathy, optimism, and dialysis treatment adherence will be calculated, including sample means, standard deviations, and quantiles. Estimated distributions of these variables will guide study design and power for a follow-up confirmatory clinical trial. Graphical displays of univariate and bivariate data will be created to generate hypotheses for the follow-up study. Preliminary estimates of treatment effect sizes will be calculated via multivariate linear regressions adjusting for the baseline measure of the outcome, i.e. Y_8wks ~ treatment + f(Y_0wks), where f() is a 3rd degree polynomial when adjusting for baseline adherence and a linear fit when adjusting for other baseline measures. We will report 95% Wald confidence intervals for the treatment effect.