

MOVE: MOTiVational Strategies to Empower African Americans to Improve Dialysis Adherence

Ebele M. Umeukeje MD, MPH

Division of Nephrology, Department of Medicine
Vanderbilt University Medical Center
1161 21st Avenue South S-3223 MCN
Nashville, TN 37232 USA

Table of Contents:

| | |
|-------------|---|
| | Study Schema |
| 1.0 | Background |
| 2.0 | Rationale and Specific Aims |
| 3.0 | Inclusion/Exclusion Criteria |
| 4.0 | Enrollment/Randomization |
| 5.0 | Study Procedures |
| 6.0 | Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others |
| 7.0 | Study Withdrawal/Discontinuation |
| 8.0 | Statistical Considerations |
| 9.0 | Privacy/Confidentiality Issues |
| 10.0 | Follow-up and Record Retention |

1.0 Background

End stage kidney disease (ESKD) is a public health concern. High morbidity from ESKD accounts for more than 30% of the \$30 billion Medicare ESKD budget and contributes to excessive ESKD-related hospitalizations. Higher hospitalization risk is observed in African Americans receiving hemodialysis, who have a four-fold higher prevalence of ESKD. Among ESKD patients, 35.4% are rehospitalized within 30 days compared to 15.3% of Medicare beneficiaries without kidney disease. African Americans constitute the highest proportion (36.2%) of this group. Non-adherence to dialysis treatment is key to increased risk of these outcomes. Compared to Whites, African Americans have a four-fold higher odds of hospitalization and higher dialysis treatment non-adherence rate. Psychosocial factors impact adherence behaviors in ESKD and associate with readmissions in patients receiving hemodialysis. Yet, interventions to reduce readmissions fail to focus on psychosocial factors. Optimal dialysis adherence behavior warrants evaluation of novel motivation-related psychosocial factors, such as optimism, apathy and autonomy. Optimism is a trait-like attitude which associates with health behaviors and predicts health outcomes. Apathy is a lack of motivation, which leads to a negative impact on goal-directed behavior. Autonomy is an essential factor for achieving durable behavior change.

The hypothesis of this study is that culturally tailored motivational interviewing is feasible, acceptable, and will show preliminary efficacy in improving autonomy, apathy, optimism, and dialysis treatment adherence. This study will provide additional critical and timely information to reduce the excessive re-hospitalizations in end-stage kidney disease (ESKD) by intervening upon dialysis treatment non-adherence. It will address the need to rigorously advance the science and understanding of the development, feasibility, acceptability and adoption of novel culturally-sensitive motivational strategies to improve dialysis treatment adherence among African Americans with ESKD. This study is significant because it aligns with research priorities in dialysis care identified by the World Health Organization, the American Society of Nephrology, the Center for Medicare and Medicaid Services and patients with end-stage kidney disease.

2.0 Rationale and Specific Aims

This study addresses the need to rigorously advance the science and understanding of the development, feasibility, acceptability and adoption of novel culturally-sensitive motivational strategies to improve dialysis treatment adherence among African Americans with ESKD. This study specifically aims to:

- 1) Gain advanced skills in the development and implementation of novel culturally sensitive motivational strategies
- 2) Acquire critical preliminary data for an R01-funded phase II efficacy trial testing the use of these motivational strategies to improve dialysis treatment adherence.

3.0 Inclusion/Exclusion Criteria

Inclusion Criteria:

- African American
- Receiving hemodialysis treatments
- Been on hemodialysis for more than 30 days
- 18 years of age and older
- Within a 3-month look back at the time of screening, patients who have missed at least one dialysis session or shortened at least one dialysis session by 15 minutes.

Exclusion Criteria:

- Not self-identified as African American
- Impaired mental status or severe illness
- Non-English speaking
- No documented evidence of dialysis treatment non-adherence
- Missed or shortened treatments due to hospitalizations or excused travel
- Terminal condition
- Living in a nursing home/rehab
- Planned transplant within the next 3 months
- Planned conversion to peritoneal dialysis within the next 3 months

4.0 Enrollment/Randomization

1. Obtain consent by email from attending physicians to approach their hemodialysis patients (in person or over the phone) for study inclusion. Provide the Attending Physicians with pertinent details of the study and encourage them to share this information with their patients.
2. With the permission of the Attending Physicians, review the dialysis clinic schedules/census to identify patients currently receiving hemodialysis therapy.
 - a. Dialysis clinic locations
 - i. Vanderbilt Dialysis Clinic:
2906 Foster Creighton Drive Ste 200, Nashville, TN 37204
 - ii. Vanderbilt Dialysis Clinic East:
20 Rachel Drive, Nashville TN 37214
3. Approach patient in person in the dialysis clinics or via phone to discuss and invite participation (see subject participation script and phone recruitment script). In addition to information which the patients may have received from their Attending Physicians, answer any questions that they may have regarding the study, assess their interest in the study and do an initial screening.

4. The randomization schedule will be generated and uploaded to Redcap by the biostatistician, and personnel will be masked until after enrollment. Personnel will be masked to patients' randomization status until after enrollment. After baseline enrollment into the study, participants as well as study personnel will no longer be blinded to participants' treatment assignments. Patients will be randomized to the intervention group (Arm 1) or to usual care (Arm 2) using a block randomization scheme.

5.0 Study Procedures

1. See #4.0 above for enrollment procedures.
2. Obtain signed informed consent in person, via phone or eConsent (see attached eConsent).
 - a. Phone consent - If consent is taken over the phone a consent form will be mailed to the participant to obtain their signature with a request to mail it back in a self-addressed stamped envelope.
 - b. eConsent- participant will be called, if they agree to participate and have capability, the REDCap link for eConsent will be emailed to the participant.
3. Give copy of signed consent to patient in person or by mail and place copy of signed consent in dialysis medical record
4. Administer surveys to all the subjects either orally, by phone, on paper, or electronically using mobile device depending upon the subject's preference
 - a. Patient Demographics Survey*
 - b. Brief Health Literacy Screening (BHLS)*
 - c. Social Desirability Scale (SDS)*
 - d. Chronic Hemodialysis Knowledge Scale (CHeKS)*
 - e. Perceived Kidney Knowledge Survey (PiKS)*
 - f. Autonomous Regulation (AR) Scale
 - g. Healthcare Climate Questionnaire (HCCQ)
 - h. Perceived Kidney Disease Self-Management Scale (PKDSMS)
 - i. Apathy Evaluation Scale (AES)
 - j. Perceived Expectancies Index (PEI)
 - k. Life Orientation Test-Revised (LOT-R)
 - l. Adherence to Refills and Medication Scale (ARMS)
 - m. Cook-Medley Subscale Baseline Questionnaire
 - n. Center for Epidemiologic Studies Depression Scale (CES-D 10)
 - o. Trust in Physician Scale (TPS)
 - p. Readiness Ruler
 - q. Time to Recover after Dialysis

Surveys with an asterisk* are administered at Baseline ONLY.

5. Administer surveys at three different time points: Baseline, week 8-9, and week 12/closeout.
6. Abstract medical records at baseline, week 8, and week 12.
7. Administer motivational interviewing session to subjects in the intervention arm of the study (as determined using a block randomization scheme)
 - a. Motivational interviewing sessions will either be done face-to-face or virtually given challenges imposed by coronavirus disease-19 (COVID-19) pandemic. Face-to-face sessions will be audio recorded. Virtual motivational interviewing will be done using a Health Insurance Portability and Accountability Act (HIPAA)-protected Zoom account. Initial session will take about 30 to 45 minutes. Follow up sessions will likely last less than 30 minutes.
 - b. 10% of the motivational interviewing sessions will be coded by MI expert using the Motivational Interviewing Treatment Integrity Scale (MITI).
 - c. The motivational interviewing script is attached separately.
 - d. MI sessions will be conducted by certified health coaches. In preparation for the study, we will use standardized patients to assess the motivational interviewing skills of the health coaches.
8. Provide subject with a \$25 gift card as compensation for completing surveys at baseline, week 8-9, and week 12/closeout; \$25 gift card as compensation for completion of each motivational interviewing session: weekly for the 1st 4 weeks, week 6, and week 8; and \$25 gift card for completion of post-intervention exit interviews (applicable to subjects in the intervention arm).
9. Complete payment form each time subjects are compensated for MI visits and/or completion of surveys, and complete payment form for the post-intervention exit interviews.
10. Summary of study activities and timeline:

| Procedure/Activity | Frequency |
|--|---|
| Survey completion | 3 time points |
| Motivational interviewing (for intervention arm) | 6 time points |
| Exit interviews (for patients in intervention arm) | 1 time point |
| Medical record abstraction | 3 time points |
| Dialysis adherence record abstraction | From 3 months prior to enrollment to end of study |

| Variables | 3M prior | W1 | W2 | W3 | W4 | W5 | W6 | W7 | W8 | W9 | W10 | W11 | W12 |
|------------------------------|----------|----|----|----|----|----|----|----|----|----|-----|-----|-----|
| Autonomous regulation | | X | | | | | | | X | | | | X |
| Autonomy support | | X | | | | | | | X | | | | X |
| Perceived competence | | X | | | | | | | X | | | | X |
| Apathy | | X | | | | | | | X | | | | X |
| Optimism | | X | | | | | | | X | | | | X |
| Intervention | | | | | | | | | | | | | |
| MI | | X | X | X | X | | X | | X | | | | |
| Clinical Outcome/ EMR | | | | | | | | | | | | | |
| Dialysis adherence | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Medical record abstraction | | X | | | | | | | X | | | | X |
| Logistical Outcomes | | | | | | | | | | | | | |
| Screening - enrollment ratio | | X | | | | | | | | | | | |
| Attendance to MI | | X | X | X | X | | X | | X | | | | |
| Drop-out rates | | X | X | X | X | | X | | X | | | | |
| Compensation | | | | | | | | | | | | | |
| MI visits | | X | X | X | X | | X | | X | | | | |
| Surveys | | X | | | | | | | X | | | | X |
| Exit Interviews | | | | | | | | | X | | | | |

M – month, W – week, MI – motivational interviewing

Brief exit semi-structured interviews with patients who receive MI

The goal is to understand the perceptions, enablers and nurturers of the adoption of the culturally tailored motivational interviewing protocol to improve hemodialysis adherence.

a. Exclusion criteria:

- I. African American hemodialysis patients who are not currently enrolled in this study
- II. African American hemodialysis patients who are not in the intervention arm of this study

b. Clinic locations

- i. Vanderbilt Dialysis Clinic
- ii. Vanderbilt dialysis East clinic

1. The facilitator guide for the semi-structured interviews is a separate attachment.

6.0 Reporting of Adverse Events or Unanticipated Problems Involving Risk to Participants or Others

The PI and all the research personnel will adhere to the required IRB policies. All the subjects will be closely monitored for any and all AEs related to either the study survey administration or the motivational interviewing sessions. These will be reported upon incident to the IRB within 7 calendar days as per IRB policy. In addition, the health coaches are to notify the PI and/or Research Coordinators if any concerning information comes up during the motivational interviewing session. The PI will be responsible for communicating any such information to the dialysis unit staff immediately.

7.0 Study Withdrawal/Discontinuation

If the study participant decides to withdraw from the study, no additional information will be collected from them. This will have no impact on the care that they receive from their doctor. They are allowing us to use their information from this study for as long as we want. If they decide to withdraw permission, all they need to do is to let Dr. Umeukeje know. A decision to not participate in this research will not affect their treatment.

8.0 Statistical Considerations

This study is a pilot test of a culturally tailored motivational interviewing intervention. Thus, the main focus of the statistical analyses is simply to generate estimates of treatment effects and variation and to evaluate feasibility outcomes and acceptability of a culturally tailored motivational interviewing intervention compared to usual hemodialysis care.

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. Data collection process will be assessed for completeness and accuracy and operating procedures for data collection will be developed to minimize missing data in the confirmatory clinical trial.

The Vanderbilt Qualitative Research Core will provide qualitative analyses of the brief exit interviews done in this study. All interviews will be recorded and transcribed verbatim and analyzed using HyperRESEARCH software (version 3.5.2; Research Ware Inc., Randolph, MA). Open coding will be performed, and themes and sub-themes will be assigned to each idea fragment. The unit of data analysis will be the codes. Any discrepancies will be reconciled among coders. Themes will be categorized into the three domains of the PEN-3 model: Cultural identity; Cultural empowerment; Relationships and Expectations.

9.0 Privacy/Confidentiality Issues

All measures will be taken to ensure participant confidentiality during all phases of data collection, storage, and management. All patient data will be assigned a study ID number at the time of collection. Until the medical chart abstraction has been completed for all patients, a master key that contains patients name and date of birth or medical record number will be maintained on the secure VUMC server, in a password protected folder to which only the PI and mentors and approved study personnel have access. Once all data is collected for each individual participant, the linking information and their entry on the master key will be destroyed. The PI will subsequently maintain all de-identified data that is collected in this study. Hard copies will be kept separately in a locked file cabinet in the PI's or research coordinator's office. All materials will have a study ID number and no identifying information will be attached to any data (i.e., no names, address, phone number, medical record, social security number, or date of birth). A database will be created with the de-identified data and maintained by the PI in a password-protected folder on the Vanderbilt Redcap database. All video/audio recordings will be stored on the secure VUMC server. Only the KSP included in this IRB application will have access to the research information. This project will utilize the REDCap platform for data collection and management. This includes the ability for project team members listed as Key Study Personnel with existing electronic health record (EHR) system access rights to make use of REDCap Clinical Data Interoperability Services (CDIS) tools. These tools are designed to enable transfer of relevant study-related data from the Vanderbilt Research Derivative and/or directly from the EHR into REDCap.

10.0 Follow-up and Record Retention

Study duration is 2 years. Once all data is collected for each individual participant, the linking information and their entry on the master key will be destroyed. The raw data will be stored for 10 years after the close of the study.