A Study of *CKM-EMPOWER:*

Empowering Medical Professionals on CKM with Educational Resources

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Principal Investigator: Susan P.Y. Wong, MD

Protocol

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Abstract

Objective(s) and Hypotheses:
Conservative kidney management (CKM) is an important therapeutic alternative for patients who do not wish to pursue dialysis for their advanced chronic kidney disease (CKD). Despite a growing body of evidence and clinical services to support patients who do not wish to pursue dialysis, nephrologists receive very limited training in CKM. This study aims to test the efficacy of a series of just-in-time educational videos on topics related to CKM (CKM-EMPOWER) in improving nephrology providers ability to provide CKM. The investigators hypothesize that the CKM-EMPOWER will improve nephrology fellows' knowledge and confidence with delivering key elements of CKM.

Research Design:
This is a randomized trial of nephrology fellows that utilizes surveys to assess their change in knowledge, confidence and practice of providing CKM with receipt of CKM-EMPOWER.

Methodology
126 nephrology fellows will be recruited from around US fellowship programs and randomize participants in a 1:1 fashion to either receipt of the CKM-EMPOWER or non-receipt. Participants will complete web-based surverys to assess knowledge and confidence with providing CKM between groups.

Relevance
An important step to towards helping patients receive treatment for kidney failure that is right for them is expanding access to a range of positive therapeutic options. The proposed study has the potential to lead to improved access and delivery of CKM and ensuring that patients who prefer CKM are able to receive the care that they desire.

List of Abbreviations

CKD: chronic kidney disease

Conservative Kidney Management: CKM

UW: University of Washington, Seattle WA

KRI: Kidney Research Institute, University of Washington, Seattle WA

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1.0 Study Personnel

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2.0 Introduction

Chronic kidney disease (CKD) afflicts 1 in 7 Americans. Although dialysis is commonly regarded as a life-prolonging therapy for advanced CKD, there is growing recognition that dialysis is not always beneficial. Decisions about dialysis often involve difficult trade-offs between the potential gains in longevity and symptom management and the burdens of treatment including the substantial time spent on dialysis, complications related to treatment, frequent interaction with the healthcare system and loss of independence.

Conservative kidney management (CKM) is an important option for patients who choose not to pursue dialysis that focuses on slowing the decline in renal function, active symptom management, advance care planning and the provision of appropriate palliative care. Conservatively managed patients can survive several years after their decision to pursue CKM

and experience sustained quality of life until late in the course of illness.[1] For adults aged ≥75 years with significant comorbidity and functional impairment, dialysis might not improve survival[2-7] and quality of life[8-10] beyond what can be achieved with a more conservative approach for advanced CKD. Conservatively managed patients also spend less time in the hospital,[6,11-13] less often experience burdensome procedures,[6,13] and less often die in the hospital setting than patients treated with dialysis.[3,13-16]

Despite a growing body of evidence and clinical services to support patients who do not wish to pursue dialysis,[17,18] nephrology providers receive very limited training in CKM. Thus, it is not suprising that many providers find it difficult or are reluctant to discuss conservative options for advanced CKD.[19,20] Qualitative interviews with providers indicate that many feel ill- equipped to provide CKM or worry that to not pursue dialysis might be perceived as "no care" or "giving up."[17,19]

The current application is to support a randomized controlled trial to test the efficacy of a series of just-in-time educational videos on CKM (CKM-EMPOWER) with nephrology fellows that was created by a research team led by the principal investigator (PI, Wong). CKM-EMPOWER has the potential to be a cost-effective, time-saving and scalable intervention to improve provider education on CKM and delivery of CKM to patients with advanced CKD.

3.0 Objectives

The investigators aim to conduct a randomized controlled trial to test the efficacy of CKM-EMPOWER in improving nephrology fellows' knowledge of CKM*,* and explore preliminary outcomes, including confidence in managing health concerns of patients opting for CKM, challenges in caring for patients who opt for CKM, and changes in practice with caring for patients who opt for CKM. The investigators hypothesize that CKM-EMPOWER will improve nephrology fellows' knowledge of CKM.

4.0 Study sites

Nephrology fellows will be recruited from US fellowship programs. Fellowship programs will be purposively sampled to reflect of range of geographic locations, academic and community teaching sites, and size. All recruitment, data collection and data analyses will occur at UW.

5.0 Study Design

The investigators will conduct a randomized controlled trial to test the efficacy of CKM-EMPOWER among nephrology fellows.

5.1 Study arms

Participants will be randomized in a 1:1 fashion using REDCap auto-randomizer to either 1 of 2 groups, receipt of CKM-EMPOWER (intervention group) or non-receipt of CKM-EMPOWER (control group).

CKM-EMPOWER (intervention group)
CKM-EMPOWER is a series of 11 just-in-time educational videos on topics related to caring for patients who opt for CKM: CKM overview, dysgeusia, fatigue, restless leg syndrome, uremic pruiritis, cramping, pain, volume overload, electrolyte abnormalities, anticipatory grief, and actively dying patient. Videos are approximately 5-10 minutes in length and intended to provide learners with a brief overiew on the definition of each issue, impact of the issue on a patient, assessment of the issue, and approaches to addressing the issue. Videos conclude with references to additional resources on each topic for more in-depth self-study. CKM-EMPOWER was created by a team comprised of a health educator, the principal investigator (nephrologist), a geriatrician and a physician dually trained in nephrology and palliative care and with feedback from a geriatric pharmacist and members of a national professional interest workgroup in kidney palliative care. CKM-EMPOWER videos will be made available on an unlisted Youtube channel.

Control group

Participants randomized to the control group will not receive CKM-EMPOWER until after the study is completed.

5.2 Potential Risks and Benefits

Anticipated risks:
The principal risk posed to patients is the potential *loss of confidentiality*. The proposed work requires the collection of personal information to identify and recruit eligible subjects and contact and maintain follow up. To minimize this risk, investigators have outlined steps below to safeguard confidentiality. These include restricting data analyses to only de-identified data files, keeping separate a crosswalk file linking study ID with personal identifiers and data analysis files, storage of data on password-protected secure servers accessible to only study team members who have completed training in the protection of human subjects, and the aggregation of study data for presentations and publications in order to conceal the subjects' identities.

Potential Benefits:
Subjects may benefit from this research directly and indirectly. This study will provide education to subjects on a topic that they may know little about, potentially improving their knowledge and ability to care for patients opting for CKM.

With the measures outlined, investigators believe that the potential risks associated with the proposed work will be mitigated and will not outweigh the potential benefit to study subjects and the greater CKD population.

5.3 Recruitment Methods

Investigators aim to enroll 126 nephrology fellows. Using email, investigators will contact the program directors of nephrology fellowship programs from around the US to request their permission to disseminate an email invitation to circulate among their program fellows to participate in the study. Fellowship programs will be purposively sampled to represent a diverse range of geographic regions and academic and non-academic settings. Investigators will send no more than 2 follow-up emails to program directors requesting their assistance to circulate our email invitation.

5.3 Informed Consent Procedures

Embedded in the email invitation will be a hyperlink to an online consent form hosted on *REDCap* (https://redcap.link/CKM-EMPOWER). The consent form describes the study procedures, risks, and benefits, and information on what to do and expect if they decide not to participate. A copy of the consent form can also be downloaded from the webpage.

Fellows will be informed that participation is fully voluntary and that their decision regarding participation will be kept confidential from their fellowship program and program directors.

5.4 Inclusion/Exclusion Criteria

Inclusion

- Matriculated in a US nephrology program

Exclusion

- None

5.5 Study Evaluations

The date of study enrollment will be the date that a subject's consent is obtained.

Participants will complete the following surveys at enrollment. Participants randomized to the control group will have 2 weeks to complete the surveys Participants randomized to the intervention will have 2 weeks to review CKM-EMPOWER videos and complete the surveys. All surveys will be administered through REDCap. Each survey will take approximately of 15 to 30 minutes to complete. Investigators will send up to 3 reminder emails to participants around the time of each study visit to complete the surveys. Investigators will give participants a $5 e-gift card to participants randomized to the control group and $10 e-gift card to participants randomized to the intervention group due to the additional time spent reviewing videos.

Demographic questions: Participants will be asked their gender, age, race, ethnicity, whether they are a US or international medical school graduate, years since graduating medical degree, current year in nephrology fellowship, and whether they have completed fellowship in a subspecialty other than nephrology.

Experience with CKM: Participants will be asked the total number of clinic patients with CKD stage 4-5 who have chosen to forgo dialysis whom they have cared for.

Comfort with providing CKM: Participants will be asked to rate their level of comfort with managing patients who have chosen CKM; dysgeusia, fatigue, restless leg syndrome, uremic pruiritis, cramping, pain, volume overload, electrolyte abnormalities, and anticipatory grief in patients who have chosen CKM; and, patients who have chosen CKM and are actively dying.

Knowledge of CKM: Participants will be asked 11 multiple choice questions about managing patients who have chosen CKM; dysgeusia, fatigue, restless leg syndrome, uremic pruiritis, cramping, pain, volume overload, electrolyte abnormalities, and anticipatory grief in patients who

have chosen CKM; and, patients who have chosen CKM and are actively dying. Each knowledge questions has 4 answers of which more than one can be correct.

Challenges with CKM: Participants who are randomized to the control group will be asked what they find more challenging with managing patients who have chosen CKM; dysgeusia, fatigue, restless leg syndrome, uremic pruiritis, cramping, pain, volume overload, electrolyte abnormalities, and anticipatory grief in patients who have chosen CKM; and, patients who have chosen CKM and are actively dying.

Change in CKM practice: Participants who are randomized to the intervention group will be asked what they have learned from the intervention that they intend to apply in their practice in managing patients who have chosen CKM; dysgeusia, fatigue, restless leg syndrome, uremic pruiritis, cramping, pain, volume overload, electrolyte abnormalities, and anticipatory grief in patients who have chosen CKM; and, patients who have chosen CKM and are actively dying.

5.6 Data Analysis

Change in CKM knowledge: As the primary analysis, investigators will compare the mean number of knowledge questions (total 44) answered correctly between arms using a two-sample t-test. The target sample size (n=126) is estimated to provide 80% power (two tailed, α=0.05) to detect an absolute difference of 27 or more questions answered correctly between the intervention and control groups assuming a baseline knowledge rate of 22/44 and standard deviation of 10. In case of drop-out, investigators will continue to recruit participants until the target sample size who have completed both study visits has been achieved.

As a pre-specified analysis, investigators will compare the mean number of questions in each category (total 11) answered correctly between study arm groups. Differences for which $p<0.005$ will be considered statistically significant (Bonferonni correction).

Confidence with CKM: As a secondary outcome, investigators will compare confidence scores between study arms for each topic using two-tailed t-tests.

Exploratory outcomes: Using thematic analysis, investigators will assess self-reported challenges with each topic among participants randomized to the control arm and self-reported change in CKM practice with each topic among participants randomized to the intervention arm.

5.7 Withdrawal of Subjects

There are no anticipated circumstances under which subjects will be withdrawn from the research without their consent. There are no anticipated consequences of a subject's decision to withdraw from the research.

5.0 Reporting

Investigators do not anticipate any adverse events that might occur. However, any and all unanticipated problems, serious adverse events and protocol deviations will be recorded and reported immediately to the study Principal Investigator. Any serious adverse events and/or serious problems will be reported to the IRB within 5 business days. Additionally, the ISO and Privacy Officer will be notified within one hour of any improper use or disclosure of study data. The Principal Investigator will be the monitoring entity responsible for ensuring that all measures related to data security and protection of subject privacy and confidentiality are being followed.

Subjects will be informed to contact the PI for all urgent and non-urgent questions and concerns at the following: Susan Wong, Phone: 206-277-3012.

6.0 Privacy and Confidentiality

The proposed work will use protected health information. All study personnel who will have access to protected health information and/or will be involved in obtaining subject consent will be required to complete all necessary training in the protection of human subjects and privacy. All study personnel who have access to study and participant data have been approved by the UW.

All subjects will be given a unique study ID, and data collected for this study will be associated with study IDs only. A separate crosswalk file linking study IDs with personal identifiers will be kept separate from data analysis files. Data analysis files will not contain personal identifiers.

Study data will be aggregated for presentations or publications related to the study in order to conceal the identities of subjects.

7.0 Communication Plan

The Head of the Division of Nephrology at each medical center will be notified of any adverse events or changes to the study protocol.

9.0 Information Security and Data Storage/Movement

Participant data, including recruitment information and survey responses will be stored at the KRI in secure study folders.

Survey study data will be assembled using structured forms designed in Microsoft Excel and saved in secure study folders. Data will be associated with study IDs only.

Only approved study team members will be authorized to access the study folders
After all data are analyzed and manuscripts summarizing study findings are published (estimated 2029), all identifiable and crosswalk files will be destroyed.

Data Sharing Plan:

Partial restrictions to the data and/or materials apply: anonymized data for the study will be made available to interested parties upon written request and submission of a formal written research proposal that has undergone human subjects review.

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