PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Integrating conservative kidney management options and advance care planning education (COPE) into routine CKD care: a protocol for a pilot randomized controlled trial
AUTHORS	Stallings, Taylor; Temel, Jennifer; Klaiman, Tamar; Paasche-Orlow, Michael; Alegria, M; O'Hare, Ann; O'Connor, Nina; Dember, Laura; Halpern, SD; Eneanya, Nwamaka

VERSION 1 – REVIEW

REVIEWER	Rachael Morton University of Sydney, Australia
REVIEW RETURNED	27-Aug-2020

GENERAL COMMENTS	Thank you for the opportunity to review this pilot trial protocol "Integrating conservative kidney management options and advance care planning education (COPE) into routine CKD care." The trial is registered on ClinicalTrials.gov and has not started recruitment. The manuscript could be strengthened with attention to the following minor points: 1) Provide further detail about the intervention education sessions - will they include or exclude the patients' family members / close persons? 2) Is there information provided in the intervention about ACP being a 'process' of conversations rather than a one-off consult resulting in the completion of an Advanced Directive / Not For Resuscitation order? 3) Patients/family members and clinicians can need reassurance that those managed conservatively will not be "abandoned" by the renal unit. What content is provided in the intervention or usual care about this? 4) Will you be capturing any health system resource use or patient out of pocket costs alongside this study? ACP / conservative care can save acute care costs as well as align with patients goals and an RCT is an excellent study design to include this as an outcome. 5) Can you opportunistically include a COVID-19 related question about preferences for in-hospital versus home-based conservative treatment? 6) Suggest using the new KDIGO nomenclature. e.g. "Kidney failure rather than ESRD" 7) The analysis related to racial disparities is a strength. Consider also any intervention generated inequalities from the intervention associated other factors of social disadvantage such as income or health literacy. Good luck with it!

REVIEWER	Dr Claire A Douglas NHS Tayside Scotland, UK
REVIEW RETURNED	13-Sep-2020

GENERAL COMMENTS	1. Good pilot study design and question. 2. Have made some suggest changes via comments - see attached file. 3. Would be better to replace some of the terminology - ie ESRD with kidney failure, renal replacement therapy with kidney replacement therapy as per the recommendations by KDIGO - reference in comments integrated into file. 5. How are the EoL preferences going to be measured? Will the authors be asking about preferred place of care, preferred place of death, etc? The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name

Rachael Morton

Thank you for the opportunity to review this pilot trial protocol "Integrating conservative kidney management options and advance care planning education (COPE) into routine CKD care." The trial is registered on ClinicalTrials.gov and has not started recruitment.

The manuscript could be strengthened with attention to the following minor points:

1. Provide further detail about the intervention education sessions - will they include or exclude the patients' family members / close persons?

We have updated the details of the intervention to reflect how patient's family members and close persons will be invited to attend sessions. However, all survey items will be provided to patient participants only.

2. Is there information provided in the intervention about ACP being a 'process' of conversations rather than a one-off consult resulting in the completion of an Advanced Directive / Not For Resuscitation order?

The primary goal of this one-time intervention is to educate patients about treatment options and initiate ACP discussions. The interventionist will counsel patients about the importance of ACP and also walk them through state-specific advance directives. We have included a section to specify these details further under "Intervention".

3. Patients/family members and clinicians can need reassurance that those managed conservatively will not be "abandoned" by the renal unit. What content is provided in the intervention or usual care about this?

Thank you for this comment. This very important topic is included in the intervention guide.

4. Will you be capturing any health system resource use or patient out of pocket costs alongside this study? ACP / conservative care can save acute care costs as well as align with patients' goals and an RCT is an excellent study design to include this as an outcome.

Although we considered important outcomes such as health system and patient-related costs, we chose to focus on patient-reported outcomes in this trial given how the infrastructure of our conservative care clinic continues to evolve.

5. Can you opportunistically include a COVID-19 related question about preferences for in-hospital versus home-based conservative treatment?

Thank you for this innovative suggestion. When we elicit reasons for treatment preferences, we will include COVID-19 concerns as an option for patients to choose.

6. Suggest using the new KDIGO nomenclature. e.g. "Kidney failure rather than ESRD"

Thank you for this suggestion. We have changed "ESRD" to "kidney failure" throughout the manuscript.

7) The analysis related to racial disparities is a strength. Consider also any intervention generated inequalities from the intervention associated other factors of social disadvantage such as income or health literacy.

Thank you for this comment. Our intervention brochure has been created to specifically target patients of lower health literacy levels. We will also collect demographic information such as income and educational level as well as health literacy screens (using REALM) to include in the secondary adjusted analyses.

Reviewer: 2

Reviewer Name

Dr Claire A Douglas

Institution and Country

NHS Tayside

Scotland, UK

Please state any competing interests or state 'None declared':

None declared

Please leave your comments for the authors below

1. Good pilot study design and question.

Thank you for this feedback.

2. Have made some suggest changes via comments - see attached file.

Thank you for your suggestions. We have addressed the comments in the attached file including:

a.” Suggest adding reference - Douglas C et al. The impact of a renal supportive care service on symptom control, advance care planning and place of death for patients with advanced chronic kidney disease managed without dialysis. BJRM 2019;24(3):60-65”
We have added this reference
b. “Add as their health deteriorates and / or if they were to become incapacitated” on page 7, line 47.”
We have made this edit.
c.” Replace renal replacement therapy with kidney replacement therapy (KRT) as per KDIGO recommendations
We have made this edit.
d. “How will the treatment decision and ACP be communicated to all professionals involved in the patient's care? By paper or electronic means?”
Patients who receive the intervention will have an email sent to their primary care physician and nephrologists notifying them of study enrollment. Study preferences will not be shared with treating physicians in this study,
e. “Suggest adding to table 1 - lives alone or with someone, plus record of any formal social support”.
Thank you for this suggestion. We have added the Multidimensional Scale of Perceived Support to ascertain social support for all study participants.

3. Would be better to replace some of the terminology - ie ESRD with kidney failure, renal replacement therapy with kidney replacement therapy as per the recommendations by KDIGO - reference in comments integrated into file.

Thank you for this suggestion. We have changed “ESRD” to “kidney failure” throughout the manuscript.

4. How are the EoL preferences going to be measured? Will the authors be asking about preferred place of care, preferred place of death, etc?

We will use questions from the SUPPORT Trial (*JAMA* 1995) to assess EOL preferences (e.g. resuscitation, place of death, etc).