PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for a hybrid effectiveness-implementation clinical trial evaluating video-assisted electronic consent vs standard consent for patients initiating and continuing haemodialysis in Australia (eConsent HD)
AUTHORS	Franca Gois, Pedro Henrique; Saunderson, Rebecca B.; Wainstein, Marina; Li, Chenlei; Damasiewicz, Matthew J; Miao, Vera Y.; Wolley, Martin; Hepburn, Kirsten; Mutatiri, Clyson; Chacko, Bobby; Bonner, Ann; Healy, Helen

VERSION 1 – REVIEW

REVIEWER	Molnar, Amber McMaster University, Faculty of Health Sciences
REVIEW RETURNED	13-Dec-2023

GENERAL COMMENTS	Gois et al. present a protocol for a study that will design a video-assisted electronic consent for patients receiving HD and test the impact of this intervention. The study overall is clearly described. Minor comments: 1. Could another term rather than consumer be selected? What about patient, caregiver or substitute decision maker? 2. I am confused by the exclusion criteria of patients who previously provided consent for HD. If patients who have previously provided consented for HD are excluded, would this not by nature exclude all prevalent patients? 3. For the data analysis plan for aim 1. Repeated measures are mentioned. It is unclear what variables will be determined at more than one time point for this aim. 4. With respect to the exclusion of patients who lack capacity or have significant vision/hearing impairment, are these not the individuals who could potentially have the greatest benefit from the intervention, i.e. at greatest risk of not understanding information delivered as per usual care and having inappropriate decisions made? Are there not adaptations that could be made to account for these impairments? Could the intervention be delivered to their substitute decision maker/caregiver? The exclusion of these individuals is an important limitation of the study. 5. With respect to the DSMB, what are some adverse events that will be monitored for? What specifically will the DSMB be reporting on? The intervention seems pretty low risk. 6. Are the authors able to provide a list of questions that will be asked of study participants for aim 1?

	7. The authors declare that there is no grant/funding specifically for this study. This is an RCT that will require considerable resources. How is the work being funded?

VERSION 1 – AUTHOR RESPONSE

Reviewer: Dr. Amber Molnar, McMaster University

Comments to the Author: Gois et al. present a protocol for a study that will design a video-assisted electronic consent for patients receiving HD and test the impact of this intervention. The study overall is clearly described.

Minor comments:

1. Could another term rather than consumer be selected? What about patient, caregiver or substitute decision maker?

Response: We have utilized the term 'Consumers' and 'Consumer Engagement' in accordance with the definitions outlined in the NHMRC guidelines (accessible at: https://www.nhmrc.gov.au/guidelinesforguidelines/plan/consumer-involvement), which define consumers as 'people who have lived experience of a health issue. They might receive health care or advice, or otherwise use health care services. They include patients, their friends, families, carers, and members of the general public.'

In our study, we intend to engage with consumers in its broader sense as outlined in this definition, encompassing patients, carers, and other individuals involved in healthcare decisions.

2. I am confused by the exclusion criteria of patients who previously provided consent for HD. If patients who have previously provided consented for HD are excluded, would this not by nature exclude all prevalent patients?

Response: Thank you for bringing up this important point. We are excluding both incident and prevalent HD patients who previously provided consent for HD to mitigate the potential bias stemming from prior exposure to information provided during the consent process. It's important to note that this exclusion does not encompass all prevalent patients. In certain participating centres, informed consent is currently not formally obtained prior to HD initiation, and instead, it may be verbal or implied by the patient's attendance at HD sessions. The manuscript has been amended to provide more clarity. Pg 11, 3-27.

3. For the data analysis plan for aim 1. Repeated measures are mentioned. It is unclear what variables will be determined at more than one time point for this aim.

Response: Thank you for seeking clarification on the data analysis plan for aim 1. In Phase 3, aim 1, which serves as a pilot study for the RCT described in Aim 2, we will not assess any data in different time points. We amended our data analysis plan accordingly.

4. With respect to the exclusion of patients who lack capacity or have significant vision/hearing impairment, are these not the individuals who could potentially have the greatest benefit from the intervention, i.e. at greatest risk of not understanding information delivered as per usual care and having

inappropriate decisions made? Are there not adaptations that could be made to account for these impairments? Could the intervention be delivered to their substitute decision maker/caregiver? The exclusion of these individuals is an important limitation of the study.

Response: Thank you for highlighting this important concern. We acknowledge that individuals lacking capacity or experiencing significant vision/hearing impairments may indeed represent a population with potentially the greatest need for an intervention at informed consent. However, we made the decision to exclude these individuals from our study due to several considerations. Firstly, Australian guardianship legislation (which varies between each state jurisdiction) mandates that substitute decision makers make decisions in the best interests of the represented person. Including substitute decision makers could introduce a significant source of bias into our RCT. Additionally, while adaptations could potentially be made to deliver the intervention to substitute decision makers or caregivers, we were concerned about introducing additional biases into our study design. Furthermore, while individuals with vision and hearing impairments may benefit from augmented forms of informed consent, we were hesitant to introduce potential confounding factors that could affect the effectiveness of our intervention. We acknowledge that this exclusion represents a limitation of our study (stated in 'Strengths and Limitations'), and we are committed to exploring interventions tailored to these specific populations in future research endeavours. This discussion will be further addressed within our collaborative group to ensure comprehensive consideration of these important issues.

5. With respect to the DSMB, what are some adverse events that will be monitored for? What specifically will the DSMB be reporting on? The intervention seems pretty low risk.
Response: Thank you for your inquiry. While the intervention itself is considered low risk, we will still monitor for any adverse events that may arise during the study period (Pg 21, 42-53). These could include but are not limited to:

- Psychological distress or anxiety experienced by participants due to the content of the digital platform.

- Technical issues or difficulties encountered by participants while navigating the online platform.

- Any unintended consequences or misunderstandings resulting from the intervention that may impact patient decision-making or outcomes.

6. Are the authors able to provide a list of questions that will be asked of study participants for aim 1?

Response: Please find additional information in the supplementary file. Pg 56-57.

7. The authors declare that there is no grant/funding specifically for this study. This is an RCT that will require considerable resources. How is the work being funded?

Response: At the time of submission to BMJ Open, there was no grant or funding specifically allocated for this study. However, we would like to clarify that this research program has been submitted to various funding schemes, and subsequent to our submission, we have secured funding to partially support our work. We have now updated our funding statement accordingly to reflect this change. Pg 26, 45-55.