PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Feasibility and acceptability of e-PROMs data capture and feedback among patients receiving haemodialysis in the Symptom monitoring WIth Feedback Trial (SWIFT) pilot: protocol for a qualitative study in Australia
AUTHORS	Duncanson, Emily; Bennett, Paul; Viecelli, Andrea; Dansie, Kathryn; Handke, William; Tong, Allison; Palmer, Suetonia; Jesudason, Shilpanjali; McDonald, Stephen; Morton, Rachael

VERSION 1 – REVIEW

REVIEWER	Fredric Finkelstein Yale University USA
REVIEW RETURNED	13-Apr-2020

GENERAL COMMENTS	This is an important area of research and the project is well described. My only concern is how the patients will be selected to participate and whether the n of 24 is sufficient to capture the heterogeneity of dialysis patients in terms of ethnic, socio-economic, and medical backgrounds. In terms of patient selection, this needs to be more clearly defined to make sure than the patients reflect the diversity of patients.

REVIEWER	Federica Picariello King's College London, UK
REVIEW RETURNED	14-Apr-2020

GENERAL COMMENTS	Thank you for inviting me to review this manuscript. This is a protocol of a qualitative study nested in a pilot cluster randomised controlled trial (SWIFT) with a focus on exploring the feasibility, acceptability, and implementation potential of e-PROMs to capture symptoms and quality of life among haemodialysis patients. Embedding and utilising patient-reported outcomes within big registries, in addition to clinical data, is valuable and much needed in this setting, as the authors very elegantly articulated in the introduction. This is a very well-written protocol, with strong methodology and inclusion of PPI. Below are a couple of issues I would like the authors to consider that would strengthen the manuscript further. 1. Normalisation Process Theory is mentioned as part of the analysis; however, it would be valuable for this to be further elaborated in the introduction first to ground the importance of understanding the context of delivery for an e-PROMs system to be rolled out across services.

	2. Because this qualitative study is embedded in a randomised-controlled trial, it would be valuable to acknowledge that the data collected on implementation would not necessarily truly reflect routine care. 3. It is great that service users will be involved in data analysis, will they receive or have they received any training for this? Please specify this in that section. 4. Please specify and define more clearly the research questions this qualitative study will address. 5. Please specify the timeframe in which this study will be conducted. Data collection will commence in April 2020, when do you anticipate it to end? 6. Further elaboration is necessary on how the data will be analysed. Will thematic analysis be exclusively deductive based on NPT or a combination of deductive and inductive analysis? Will comparisons be drawn between narratives of nurses and nephrologists for example using framework analysis (Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology, 13(1), 117)? 7. The selected sample size targets for each group have not been justified. The concept of data saturation has been widely criticised. Please see (Clarke, V., & Braun, V. (2020). To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales. Qualitative Research in Sport, Exercise and Health. and Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., ... & Jinks, C. (2018). Saturation in qualitative research: exploring its conceptualization and operationalization. Quality & Quantity, 52(4), 1893-1907). 8. In the interviews with nurses and nephrologists, it would be important to capture what would motivate them to facilitate the adoption and implementation of e-PROMs in routine care? What is the buy-in for them, beyond patient benefit? (see Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., Hinder, S., ... & Shaw, S. (2017). Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. Journal of Medical Internet Research, 19(11), e367) 9. Why “consumers” and not “service users”? 10. In Figure 1, a linear process is displayed from data collection to analysis to review of findings. A more iterative approach, commencing analysis while data collection is on-going, would allow you to explore interesting preliminary themes emerging from the analysis further in subsequent interviews. 11. In the SWIFT intervention, patients will not have access to their scores, is there a justification for this? Could sharing these data with patients be valuable? 12. It would be valuable to acknowledge that although attention to symptoms in consultations is needed, this will only translate into tangible patient benefit if treatment pathways for various symptoms actually exist in the services.

REVIEWER	Nicola Anderson University of Birmingham United Kingdom
REVIEW RETURNED	29-Apr-2020

GENERAL COMMENTS	Thank you to the Editors and the Authors for the opportunity to review this well written and thought-provoking study protocol manuscript. Whilst I would recommend acceptance of this manuscript, there are some points of minor revision and clarification: 1. Supplementary reporting – no checklist attached but authors intend to use the COREQ checklist for reporting, trial registration included but funding source is not immediately clear? NHMRC 2. It would be beneficial to have the location of the study in the title. 3. Strengths and limitations of study – no strengths are listed. Focus is on symptom monitoring and feedback for in-centre HD patients – with the growing importance of home therapies, is there transferability to patients on Home HD? Could a further limitation be the fact that participants must be able to speak English? Carers role within the process to collect ePROMs is also not captured. 4. Page 8, line 47 refers to the pilot study being conducted in 5 Australian dialysis centres – but elsewhere in the manuscript there is reference to 6 centres 5. Page 9, line 21 is the word 'populations' missing after socioeconomic? 6. Centre-based consent – please clarify this is for the main SWIFT trial 7. SWIFT PROMs data collection to complete by April 2020 – have these timeframes been affected by the COVID-19 pandemic and healthcare system responses? 8. EQ-5D-5L and IPOS-Renal are measures used within this study – it would be useful for a brief explanation of why and how these particular measures were chosen. 9. Will the emails carrying IPOS-Renal scores be generated automatically or will the nurse unit managers need to generate these manually after triage? Will these emails link up with patient electronic records systems? Aware that feedback mechanisms are being explored through this research but was a little unclear as to the process currently in place during the pilot. 10. Purposive sampling strategies are outlined to include a range of ethnicity's and linguistic backgrounds; however, it is also stated that participants will be English speaking – will this effect transferability of findings? 11. Conflicting information regarding sample size in body of text and study schema (figure 1) – n=24 and n=20 12. Research team and reflexivity: there is no information within the protocol manuscript on the occupations of those undertaking data collection, experience and training, and possible relationships with the participant's and their effects on the data/analysis and how this will be mitigated.

	13. Are there travel expenses available for participants attending interviews/focus groups, including staff who attend on days off? 14. Please clarify whether you will be analysing each group separately (nephrologists/nurses/patients) and will cease recruitment when data saturation achieved for each group. 15. Are you using the NPT deductively following inductive thematic analysis of the transcripts? Would appreciate a little further detail within the protocol manuscript on the methodological orientation and theoretical underpinnings of this qualitative component of this mixed methods programme. 16. Will participant checking be undertaken by all participants or a proportion of each group? 17. Topic guide for nursing staff – would it be beneficial to include questions around health literacy and preparedness/training to deal with symptom management?

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1
Reviewer Name
Fredric Finkelstein

Institution and Country
Yale University
USA

This is an important area of research and the project is well described. My only concern is how the patients will be selected to participate and whether the n of 24 is sufficient to capture the heterogeneity of dialysis patients in terms of ethnic, socio-economic, and medical backgrounds. In terms of patient selection, this needs to be more clearly defined to make sure than the patients reflect the diversity of patients.

Response: Purposive sampling will be undertaken among the HD units to achieve diversity in age, gender, ethnicity, symptom burden and years on dialysis. This is clearly described on page 9, paragraph 2 of the marked copy: “A purposive sampling strategy will be applied to capture a diverse range of patient experiences and perspectives in focus groups and interviews, based on demographic (sex, age, ethnicity and linguistic background) and clinical factors (time since haemodialysis commencement and symptom burden severity).”

Based on prior studies, we estimate that n=24 will be adequate for capturing a wide range of demographic and clinical characteristics. (See systematic review of qualitative studies – Table 1, characteristics of included studies for sample size Walker RC, Hanson CS, Palmer SC, et al. Patient and caregiver perspectives on home hemodialysis: a systematic review. Am J Kidney Dis. 2015;65(3):451-463).

As suggested, we have now clarified: “As interviews are being completed, we will monitor the

demographic and clinical characteristics to ensure to target recruitment to include any “missing” characteristics.” (Page 9, paragraph 3 – marked copy)

Reviewer: 2
Reviewer Name
Federica Picariello

Institution and Country
King's College London, UK

Thank you for inviting me to review this manuscript.

This is a protocol of a qualitative study nested in a pilot cluster randomised controlled trial (SWIFT) with a focus on exploring the feasibility, acceptability, and implementation potential of e-PROMs to capture symptoms and quality of life among haemodialysis patients. Embedding and utilising patient-reported outcomes within big registries, in addition to clinical data, is valuable and much needed in this setting, as the authors very elegantly articulated in the introduction. This is a very well-written protocol, with strong methodology and inclusion of PPI. Below are a couple of issues I would like the authors to consider that would strengthen the manuscript further.
1. Normalisation Process Theory is mentioned as part of the analysis; however, it would be valuable for this to be further elaborated in the introduction first to ground the importance of understanding the context of delivery for an e-PROMs system to be rolled out across services.

Response: We agree and have added several sentences describing the benefit of using this theory to the Introduction section, see page 6, paragraph 3. In brief, NPT is an approach that provides a focus on factors that facilitate and inhibit the incorporation of interventions into clinical practice. NPT encourages analysis to follow the four constructs of coherence, cognitive participation, collective action and reflexive monitoring to help understand how e-PROMs become normalised in dialysis clinics. (Ref: Jones CH, Glogowska M, Locock L, Lasserson DS. Embedding new technologies in practice - a normalization process theory study of point of care testing. BMC Health Serv Res. 2016;16(1):591).

2. Because this qualitative study is embedded in a randomised-controlled trial, it would be valuable to acknowledge that the data collected on implementation would not necessarily truly reflect routine care.
Response: We agree and have added a sentence to the Discussion section. “We acknowledge that our data collected on implementation of e-PROMs capture and feedback within the context of a randomised trial, may not necessarily reflect routine care.” See page 14, paragraph 3.

3. It is great that service users will be involved in data analysis, will they receive or have they received any training for this? Please specify this in that section.

Response: The BEATCKD “Consumers In research Program” will train the consumers with additional support provided through the Australian Clinical Trials Alliance (ACTA) Consumer and Community Involvement workshop (https://clinicaltrialsalliance.org.au/events-forums/consumer-community-involvement-in-clinical-trials-acta-training-workshop-3/). This has been added to page 13, paragraph 3.
We will also provide specific and individual training and mentorship in the analysis of qualitative data by qualitative researchers on the investigator team.

4. Please specify and define more clearly the research questions this qualitative study will address.

Response: We have added the research questions to the Introduction section on page 7, paragraph 1. Specifically we address the questions of how acceptable and feasible it is to collect, interpret and act upon electronic-PROMs (e-PROMs) including quality of life and symptoms; and why (or why not) the provision of symptom information changes clinician-patient conversations and care.

5. Please specify the timeframe in which this study will be conducted. Data collection will commence in April 2020, when do you anticipate it to end?

Response: We anticipate the data collection will be completed by July 2020 and analysis completed by October 2020. See addition of this point on page 10, paragraph 3.

6. Further elaboration is necessary on how the data will be analysed. Will thematic analysis be exclusively deductive based on NPT or a combination of deductive and inductive analysis? Will comparisons be drawn between narratives of nurses and nephrologists for example using framework analysis (Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology, 13(1), 117)?

Response: Clarification of the data analysis process has been provided on Page 12, paragraph 2. Interview transcripts will be coded through inductive and deductive methods by two researchers, using NPT constructs as a map where applicable. Additional themes related to the perceived impact of e-PROMs collection and feedback on patient care and outcomes will also be identified inductively. Codes will be grouped into themes and sub-themes, and relationships among them identified. Derived themes will be reviewed by other members of the research team throughout the analysis, as researcher triangulation and to ensure the full range and depth of data are reflected in the findings(18). Comparisons will be drawn between nurse, nephrologist and patient responses. Preliminary themes will be provided to participants for comment and feedback to ensure their views are captured and accurately reflected in final analysis and reporting of results.

7. The selected sample size targets for each group have not been justified. The concept of data saturation has been widely criticised. Please see (Clarke, V., & Braun, V. (2020). To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales. Qualitative Research in Sport, Exercise and Health. and Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., ... & Jinks, C. (2018). Saturation in qualitative research: exploring its conceptualization and operationalization. Quality & Quantity, 52(4), 1893-1907).

Response: This valid critique of data saturation analysis has informed this study and we have reviewed our protocol and revised this process. We have removed the sentence statement on page 12, paragraph 2: “Recruitment for interviews will cease at theoretical saturation (when no new emerging themes are obtained from the data)” and added, “We anticipate this will require at least twenty participants, 10 from the intervention arm and 10 from the control arm (page 12)”.
The current research team agrees that one strength of this pilot study is the sampling of the three stakeholder groups: patients, nurses and nephrologists. Using these methods of interview and focus groups, will provide sufficient data to elicit each group’s experiences and perspectives regarding the intervention process, acceptability and feasibility and perceived impacts on patient care and outcomes in order to inform the main trial.

8. In the interviews with nurses and nephrologists, it would be important to capture what would motivate them to facilitate the adoption and implementation of e-PROMs in routine care? What is the buy-in for them, beyond patient benefit? (see Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., Hinder, S., ... & Shaw, S. (2017). Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. Journal of Medical Internet Research, 19(11), e367)

Response: Included in the semi-structured interview are questions that aim to capture facilitators, barriers and motivators for e-PROM integration into routine care.

9. Why “consumers” and not “service users”?

Response: In Australia, the term ‘consumers’ is widely used and understood to include patients and carers. Our study may include informal carers of people on haemodialysis.
Stated below is the definition by the Australian National Health and Medical Research Council (2014):
‘Consumers’ are 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. Consumers can also be people who represent the views and interests of a consumer organisation, a community or a wider constituency (Kelson, Akl et al. 2012).
https://www.nhmrc.gov.au/guidelinesforguidelines/plan/consumer-involvement

10. In Figure 1, a linear process is displayed from data collection to analysis to review of findings. A more iterative approach, commencing analysis while data collection is on-going, would allow you to explore interesting preliminary themes emerging from the analysis further in subsequent interviews.

Response: We agree and have slightly modified our methods to include the following statement: “Data collection and analysis will involve an interactive process, whereby initial transcripts will be reviewed by other members of the research team, and modifications and additions to some questions made.’ This is described on page 10, paragraph 3.

11. In the SWIFT intervention, patients will not have access to their scores, is there a justification for this? Could sharing these data with patients be valuable?

Response: This is a good point, and we agree sharing these data with patients is beneficial. We are considering how to do this for the main trial protocol; however this is not part of the protocol for the pilot study.

12. It would be valuable to acknowledge that although attention to symptoms in consultations is needed, this will only translate into tangible patient benefit if treatment pathways for various symptoms actually exist in the services.

Response: We agree and that is why we have in place, evidence-based symptom management guidelines for clinicians, which forms part of the intervention. Many pharmacological and non-pharmacological treatments exist for common symptoms. (Ref: Davison SN, Jassal SV Supportive Care: Integration of Patient-Centered Kidney Care to Manage Symptoms and Geriatric Syndromes. Clin J Am Soc Nephrol 11: 1882–1891, 2016.) Through our qualitative interviewing we will assess the translation factors required for a change in treatment.

Reviewer: 3

Reviewer Name
Nicola Anderson

Institution and Country
University of Birmingham
United Kingdom

Thank you to the Editors and the Authors for the opportunity to review this well written and thought-provoking study protocol manuscript.

Whilst I would recommend acceptance of this manuscript, there are some points of minor revision and clarification:
1. Supplementary reporting – no checklist attached but authors intend to use the COREQ checklist for reporting, trial registration included but funding source is not immediately clear? NHMRC

Response: Funding for the pilot study was obtained from Kidney Health Australia, and funding for the main trial obtained from the Australian NHMRC. This has been added to page 17.

2. It would be beneficial to have the location of the study in the title.

Response: We are happy to add the location to the title. The amended tile now reads: "Feasibility and acceptability of e-PROMs data capture and feedback among patients receiving haemodialysis in the Symptom monitoring WIth Feedback Trial (SWIFT) pilot: protocol for a qualitative study in Australia." See page 1.

3. Strengths and limitations of study – no strengths are listed. Focus is on symptom monitoring and feedback for in-centre HD patients – with the growing importance of home therapies, is there transferability to patients on Home HD? Could a further limitation be the fact that participants must be able to speak English? Carers role within the process to collect ePROMs is also not captured.

Response: We have added a key strength of our study to the manuscript - see page 4.
Despite the growing focus on home therapies, the majority of patients on dialysis in Australia are managed through in-centre (facility) based HD. We know that symptom burden in this group is high. We chose the in-centre population for this complex intervention due to the regular contact with health professionals (i.e. 3-days every week) and the ability for dialysis nursing to act on the symptoms quickly.
Patients who did not speak English were not excluded if they had access to an interpreter.
We will ask whether people needed help and if so who provided that help to complete the PROMs (e.g. nursing staff, carers, family). – See Semi-structured interview guide – Patients, in the Supplementary file.

4. Page 8, line 47 refers to the pilot study being conducted in 5 Australian dialysis centres – but elsewhere in the manuscript there is reference to 6 centres

Response: Thank you – this is an error and is now corrected. 6 centres were invited to participate.(Page 7)

5. Page 9, line 21 is the word ‘populations’ missing after socioeconomic?

Response: Corrected, see page 7, paragraph 3.

6. Centre-based consent – please clarify this is for the main SWIFT trial

Response: Centre-based consent was for the pilot study. This has been added to page 8, paragraph 1.

7. SWIFT PROMs data collection to complete by April 2020 – have these timeframes been affected by the COVID-19 pandemic and healthcare system responses?

Response: There have been some delays. However, fortunately to date, we have had very few cases of COVID-19 in Australian dialysis patients and only two of our centres have been affected. The revised timelines for study recruitment and analysis are reported on page 10, paragraph 4 (see response to reviewer 2, point 5).

8. EQ-5D-5L and IPOS-Renal are measures used within this study – it would be useful for a brief explanation of why and how these particular measures were chosen.

Response: Following a national audit conducted in 2018, we identified that renal centres in Australia were familiar with these instruments from their Supportive Care, or Conservative Care clinics. (The Integrated Palliative Outcome Scale-Renal (IPOS-Renal) was the most commonly reported instrument to measure symptoms (40% of units) and the Euro-Qol 5 dimensions 5 levels (EQ-5D-5L) for the assessment of quality of life (24%), as reported in our national audit, see page 8, paragraph 2. Furthermore, IPOS-Renal is validated in Australia for use in patients on HD. (Ref: Raj R, Ahuja K, Frandsen M, Murtagh FEM, Jose M. Validation of the IPOS-Renal Symptom Survey in Advanced Kidney Disease: A Cross-sectional Study. J Pain Symptom Manage. 2018;56(2):281-287). The EQ-5D -5L is responsive to symptoms and quick and easy to administer, and acceptable to patients – therefore suitable for a registry.(Ref: Breckenridge K, Bekker HL, Gibbons E, et al. How to routinely collect data on patient-reported outcome and experience measures in renal registries in Europe: an expert consensus meeting. Nephrol Dial Transplant. 2015;30(10):1605-1614.) See page 8 paragraph 2.

9. Will the emails carrying IPOS-Renal scores be generated automatically or will the nurse unit managers need to generate these manually after triage? Will these emails link up with patient electronic records systems? Aware that feedback mechanisms are being explored through this research but was a little unclear as to the process currently in place during the pilot.

Response: These emails are generated by the ANZDATA registry staff, and tailored to the treating nephrologist and dialysis nurse unit manager. Emails were not linked with patient electronic record systems due to the control of these records being an internal process at each site which was outside the jurisdiction of the research team, however integrating the feedback into usual care/practice was strongly encouraged. See page 8, paragraph 4.

10. Purposive sampling strategies are outlined to include a range of ethnicity's and linguistic backgrounds; however, it is also stated that participants will be English speaking – will this effect transferability of findings?

Response: Participants from non-English speaking backgrounds will not be excluded from the study, if locally available translation or interpreter services are available at the study site. See amended text on page 9, paragraph 3.

11. Conflicting information regarding sample size in body of text and study schema (figure 1) – n=24 and n=20

Response: Thank you for bringing this to our attention. We have corrected the number in Figure 1.

12. Research team and reflexivity: there is no information within the protocol manuscript on the occupations of those undertaking data collection, experience and training, and possible relationships with the participant's and their effects on the data/analysis and how this will be mitigated.

Response: Thank you. Participants will self-complete the PROMs using a tablet computer. This collection process will be facilitated by clinical dialysis nurses involved in the patients care, (i.e. the tablet will be passed from one patient to the next, and nursing staff will identify the correct QR code and survey. Patients will be encouraged to complete the questions honestly and without input from others. All dialysis nursing staff will have attended 1-2 training sessions giving information about the study, the purpose of collecting PROMs, and for those in the intervention arm, the process for interpreting IPOS-Renal symptom scores. This has been clarified on page 8, paragraph 3.

13. Are there travel expenses available for participants attending interviews/focus groups, including staff who attend on days off?

Response: Patients will be reimbursed with a gift card to the value of $50. No reimbursement will be provided to health professionals. See page 10, paragraph 3.

14. Please clarify whether you will be analysing each group separately (nephrologists/nurses/patients) and will cease recruitment when data saturation achieved for each group.

Response: Yes, each group will be analysed separately, until no new themes emerge from each group. The Data Collection section of the protocol manuscript has been revised. See page 12, paragraph 2. Also refer to our response to Reviewer #2, Point 7.

15. Are you using the NPT deductively following inductive thematic analysis of the transcripts? Would appreciate a little further detail within the protocol manuscript on the methodological orientation and theoretical underpinnings of this qualitative component of this mixed methods programme.

Response: We confirm that we will commence by indicatively coding and grouping, and when we get closer to actual analysis/synthesis we will apply (deductively) the NPT constructs if/where applicable to our data. See a detailed explanation of our process on page 12, paragraph 3.

16. Will participant checking be undertaken by all participants or a proportion of each group?

Response: Yes we will provide summaries back to all focus group and interview participants for member checking. See page 13, paragraph 3.

17. Topic guide for nursing staff – would it be beneficial to include questions around health literacy and preparedness/training to deal with symptom management?

Response: One of the purposes of the pilot is to understand the impact of many patient characteristics on the barriers and facilitators to implementation. Health literacy for patients is one factor that is likely to be brought up in the section on "General questions about implementation of ePROMs data capture and feedback", see page 3 of the Supplementary file.

VERSION 2 – REVIEW

REVIEWER	Federica Picariello King's College London, UK
REVIEW RETURNED	24-Aug-2020

GENERAL COMMENTS	All my comments, queries, and suggestions have been addressed. The authors provided clear and detailed explanations. I do not have any further feedback. I look forward to the findings of the study.

REVIEWER	Nicola Anderson University of Birmingham
REVIEW RETURNED	09-Sep-2020

GENERAL COMMENTS	Many thanks to the Editors and Authors for the opportunity to review this revised manuscript. All comments have been comprehensively addressed by the research team in this well written manuscript and I wish them good luck with the pilot and look forward to having the opportunity to read their results and conclusions in the future.