PEER REVIEW HISTORY

This paper was submitted to a another journal from BMJ but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

(This paper received three reviews from its previous journal but only two reviewers agreed to published their review.)

ARTICLE DETAILS

TITLE (PROVISIONAL)	Feasibility and Acceptability of a Telehealth Coaching to Promote Healthy Eating in Chronic Kidney Disease: A Mixed Methods Process Evaluation
AUTHORS	Kelly, Jaimon Terence; Warner, Molly M; Conley, Marguerite; Reidlinger, Dianne Patricia; Hoffmann, Tammy; Craig, Jonathan; Tong, Allison; Reeves, Marina; Johnson, David; Palmer, Suetonia; Campbell, Katrina L

VERSION 1 – REVIEW

REVIEWER	Suzanne Morony Sydney School of Public Health, The University of Sydney, Australia
REVIEW RETURNED	24-Jul-2018

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. It is a well-written manuscript describing a carefully designed feasibility study using telehealth to assist people with CKD to better manage their diet. The results indicate the program is feasible and acceptable to those who participated. Participants tended to be well-educated and of higher socioeconomic status. Although retention was excellent, uptake was low, and there is little information about the people who declined to participate. Given that the study is designed to assess feasibility, my main concern is the low uptake. There is insufficient detail about recruitment processes and characteristics of those who declined. For example, it is not clear whether the relatively high socioeconomic status of the participating sample is simply a demographic characteristic of the participating hospitals, or if more disadvantaged people elected not to participate. Are the age/sex and other demographic characteristics of the recruited sample in line with population estimates? It may also be useful to collect data on household/living situation and responsibilities for food shopping/preparation. There is limited consideration to the important role of health literacy in CKD and self-management, which could be improved by reference to the literature in this area. People with lower health literacy tend to be less receptive to self-management (http://dx.doi.org/10.1080/10810730.2015.1080329) and have poorer outcomes. Previous work (http://dx.doi.org/10.1093/ndt/gfs371) suggests 20-25% of people with CKD have low health literacy, yet in this study it was 10% or

	less. Although socioeconomic status was generally high, education level was roughly spilt between tertiary educated and lower than 10th grade. It is not uncommon for people with poor literacy to attempt to conceal this – could estimates of health literacy proceed by the SILS be inflated in this sample due to socially desirable responding? An alternative measure is the Newest Vital Sign (NVS), which is skills-based and has face validity for this study (see https://doi.org/10.3928/24748307-20180530-02). It can be challenging to recruit research participants with lower health literacy, yet by failing to do so there is a risk of widening existing health inequalities for people who miss out on interventions that can help them. The authors acknowledge the poor uptake, and low representation of people with low health literacy, but do not consider what the reasons may be or how they might address them. The high retention is impressive, especially considering that high attrition is common in studies of this nature, (p19); but perhaps less so if your sample is not representative of the wide population of people with CKD. Such considerations would add value to this manuscript and others that follow. The study is identified as a feasibility study in the abstract and later in text, but not in the title. The attached CONSORT checklist is for RCT, rather than the extension for pilot and feasibility studies. The extension adds several relevant items. In particular, "Implications for progression from pilot to future definitive trial, including any proposed amendments" is missing. An example of "dietary complexity and competing demands of self-management" (p4 line 22) would be useful. P6 line 52 –telehealth modalities are effective at supporting behaviour change to reduce chronic disease risk P19 line 14 clarify that this refers to "intervention participants" – the control group were also participants in this pilot

REVIEWER	Donald Hilty VANCHCS, USA
REVIEW RETURNED	11-Aug-2018

GENERAL COMMENTS	General comments 1. Interesting study, overall program impressive and grant-funded. 2. Design issues, terminology and presentation approach: had difficulty 'seeing' what was done and not done. a. Seems odd that a feasibility study is done by adding texts to deliver coaching methods – outright, yes, they are delivered, so there is no mystery that it is feasible? So, not surprisingly, the "Retention was 93% and 98% in the intervention and control groups, respectively, and 96% of all planned intervention calls were completed." b. What is the intervention? One place says tailored vs. non-tailored and the outcome is usefulness – that is rather obvious result, too? Another place says the texts were added on and the controls got nothing? c. Should the title have "feasibility" – if this is what it is – or a more specific term or too (i.e., tailored and non-tailored messaging). d. Then, looking at Table 2, it is even more confusing as to what was done? e. Then, there is much data and information in the Tables that is not specific to this study (e.g., the outcomes). f. My guess is that a general study write-up was used and not exactly crafted for this submission, leading to confusion.

	Specific comments Abstract. 1. Need overall clearer picture to comment specifically on this section. Introduction. 1. Very nice. Methods. 1. Unclear as stated above. 2. Each paper – representing only a portion of the bigger study – needs to be clearer, customized and easy to read. Results. 1. Need overall clearer picture to comment specifically on this section. Discussion. 1. Very good. 2. Need overall clearer picture to comment specifically see how these findings link with others' findings and more fully grasp the implications. 3. Limitations are good, pending clarification of the Methods issues. Tables/Figures 1. Good, just probably do not need all the information included – as a lot of it is not reviewed in the prose and it is distracting (though interesting). References 1. Good.

REVIEWER	Kathy L. Rush University of British Columbia, Canada
REVIEW RETURNED	24-Aug-2018

GENERAL COMMENTS	This study describes a mixed-methods process evaluation embedded in an RCT. It describes a thorough and rigorous process evaluation that makes an important contribution to the use of telehealth in promoting healthy eating with people with CKD. There are a few areas that would strengthen the manuscript. Introduction The background to, and context of your study could be strengthened from an organizational and content perspective. Particularly weak is attention to the population of CKD in making the case. It isn't readily apparent from the development of your argument, why alternative modalities are needed to determine whether increasing diet quality attenuates CKD progression and elevated CV risk? You seem to be suggesting that whole food-based dietary pattern is effective but traditional modalities may be as effective as alternative modalities in promoting adherence. Is there evidence suggesting traditional modalities are ineffective? There is need for more logical development of your argument. For example, you refer to barriers to health care service access but very generically

	and your argument would be strengthened if you could relate it to the CKD population, which is the focus of your study. You extol the value of telehealth modalities in work with populations with chronic disease. It isn't until the last paragraph of the Introduction that we learn about limitations that your study is seeking to address. You mention the need for quantifying coaching but not in relation to a telehealth delivery modality. The background needs much more clarification and focus to support the need for your study. Even though you were using the intervention to improve self-management to reduce dietary sodium intake (and increase dietary quality), there is no mention of self-management or dietary sodium intake in your background? Tailoring the intervention was important to your telehealth coaching but again the importance of a tailored approach and the evidence base to support it could strengthen the argument. Pg. 6 Last sentence of first paragraph, it isn't clear what "overcoming these barriers to implementation of sustained dietary change" is referring to. Barriers haven't been highlighted in the opening paragraph. Materials and Methods Overall the methods are well described. There are few areas for clarification. Typically, the word data requires a plural verb. You have used it with a singular and plural verb. (e.g., Pg. 7 line 38-39). Please be consistent. Pg. 7 Design: you indicate the dietary intervention was designed using social cognitive theory. In your supplementary Table 2 you outline the SCT construct and the parallel text message type in operationalizing the constructs. It would be helpful in the text when you introduce SCT to indicate the two constructs you used: outcome expectations and self-regulation. Recruitment: You indicate that participants were recruited from three tertiary nephrology units in Queensland, Australia over a six-month period. Why were these tertiary units selected? Were there contact people at each site inviting eligible patients? Were nephrologists involved in recruitment as one of your exclusion criteria is "deemed unfit to participate by their treating nephrologist" (pg. 8, 23-25. More details about recruitment would be helpful. Eligible participants were randomized on a 1:1 ratio into one of two groups (stratified by recruiting site and diabetes status). The stratification could benefit from greater detail. Re the text message library and the tailoring of messages you state, - The text message library was imported into the software platform, which was designed to tailor text messages based on: participant's name; individual goals; barriers to achieving goals; and, participant-identified solutions to overcoming those barriers. Was the information for this tailoring collected during the coaching telephone call? If so it would be helpful to clarify with the addition of this information. Currently you note that coaches logged the following information - goal setting, implementation intentions, self-

	monitoring tools, call attempts and durations, and text message preferences. On pg. 9 you indicate that intervention group participants received 2-8 text messages with the actual number and time of day determined by each participant. It is assumed that this is part of the tailoring of the intervention. Was there any concern that variability in the number of text messages not be expected to affect outcomes or was the number of lesser importance than the tailoring of the messages? Pg. 11 You note under Data Collection that clinical objective data were collected at baseline, 3- and 6-months. Even though the clinical data is not reported, a couple of examples of the data would be helpful to include. Pg. 12 You assessed consistency on 10% of coaching calls – what were you looking for in the way of the consistency. Also, you note the fidelity data that were collected by coaches but since there was variability in the "dosage" of text messages, it isn't entirely clear what fidelity indicators you were looking for. Pg. 12 and Intervention adherence, line 21 –data "was" should be "were" if you intend to consistently use the plural verb" Results The results are well presented and supplemented with excellent tables and figures. On pg. 15 you state that randomization was effective at distributing all measured demographic characteristics. Is this another way of saying the groups were equivalent at the outset? On pg. 17 and utility and acceptability results you report in the last sentence of this section, that acceptability of the text messages was assessed as highly acceptable with 78% of participants reporting that the characteristics of the text messages were satisfactory. Please add for intervention participants. On pg. 17-18 and Attributes of Feasibility and Acceptability you note the categories for both acceptability and feasibility. You note under feasibility, variability in degrees of usefulness of text messages – briefly what were the main areas of variability? Discussion Pg. 19, 1st paragraph, you note the tailored telephone calls and text messages were acceptable to participants in this pilot but was variable for those in the non-tailored control group. You provide more interpretation of this finding in paragraph 4 of the Discussion and perhaps this aspect could be combined with paragraph 1. Pg. 19 2nd paragraph – you note "The successful recruitment and retention of participants in the ENTICE trial demonstrated feasibility." While you note that recruitment occurred in the anticipated 6-months, discussion could be enhanced with more elaboration of what your recruitment targets were for this study and how it compares to other similar studies? You note later in the

	discussion (paragraph 3), Blakeman et al's (2014) recruitment rate of 69%. Could you comment on between study differences that might account for your study having about half their recruitment rate over the same timeframe? In this same paragraph, you note the problem with attrition in the CKD population and its reduction of the "certainty of findings." It would be helpful to replace "certainty" with more precise language. Pg. 21 In the 2nd full paragraph you use the term "uncertain" in a couple of places. Perhaps "unknown" is a more appropriate term? Pg. 21, 1st full paragraph, the last 2 sentences could be strengthened grammatically. The ENTICE-CKD intervention …was dedicated to an individual topic and was tailored …." These attributes …observed in the acceptability of the intervention compared…. Pg. 21 Limitations are addressed. Wrt to your low recruitment rate, you may want to add that it compromises representativeness.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1 (Suzanne Morony)

1. **Although retention was excellent, uptake was low, and there is little information about the people who declined to participate. Given that the study is designed to assess feasibility, my main concern is the low uptake. There is insufficient detail about recruitment processes and characteristics of those who declined.**

   We have provided additional details regarding the reasons for refusal further in Figure 1 (file 1) and in text (pg. 16). We are unable to provide more detail regarding the characteristics of those who declined to participate. We have also added a section on pg. 9 (addressing reviewer 3, comment 9) further detailing the recruitment process.

   > *"Of the 146 individuals who declined to participate, "not interested" was the most frequently stated reason for non-participation (36%), followed by perceived excessive time commitment (16%), having other medical conditions taking priority (13%), travel burden to make study visits (11%), and already feeling healthy (10%). Other reasons for non-participation included already seeing a dietitian (6%), believed the intervention did not fit their current lifestyle (6%) or preferred not to use technology (1%). A further two individuals (1%) consented to the study but did not attend a baseline visit and were therefore not randomized to a treatment group."*

2. **For example, it is not clear whether the relatively high socioeconomic status of the participating sample is simply a demographic characteristic of the participating hospitals, or if more disadvantaged people elected not to participate. Are the age/sex and other demographic characteristics of the recruited sample in line with population estimates? It may also be useful to collect data on household/living situation and responsibilities for food shopping/preparation.**

   We are unable to provide comparison to household/living situation and responsibilities for food shopping/preparation, as this information was not collected during the trial.

   In line with this suggestion, we have compared our demographics to data reported in national and international cohorts[1-3], which we have now included in our discussion (pg. 22).

   > *"other demographics of the people who participated in the ENTICE-CKD study were broadly representative of the CKD demographic reported in international comparisons*[1-3]*"* citing the following studies:
   >
   > Hill NR, Fatoba ST, Oke JL, et al. Global Prevalence of Chronic Kidney Disease – A Systematic Review and Meta-Analysis. *PLoS ONE* 2016;11(7):e0158765. doi: 10.1371/journal.pone.0158765

Yang W, Xie D, Anderson AH, et al. Association of Kidney Disease Outcomes With Risk Factors for CKD: Findings From the Chronic Renal Insufficiency Cohort (CRIC) Study. *American journal of kidney diseases : the official journal of the National Kidney Foundation* 2014;63(2):236-43. doi: 10.1053/j.ajkd.2013.08.028

Mahmood U, Healy HG, Kark A, et al. Spectrum (characteristics) of patients with chronic kidney disease (CKD) with increasing age in a major metropolitan renal service. *BMC Nephrology* 2017;18:372. doi: 10.1186/s12882-017-0781-5

With respect to local cohort data, we were only able to locate local data for stage of CKD; specifically, the proportions of participants with stage 3 and 4 CKD in our study were 75% and 25%, respectively, comparable to the 70% and 30% reported in an Australian dataset.[3] In international comparisons, are broadly comparable in terms of age, gender, BMI, diabetes and hypertension.[2] The following studies are cited:

Yang W, Xie D, Anderson AH, et al. Association of Kidney Disease Outcomes With Risk Factors for CKD: Findings From the Chronic Renal Insufficiency Cohort (CRIC) Study. *American journal of kidney diseases : the official journal of the National Kidney Foundation* 2014;63(2):236-43. doi: 10.1053/j.ajkd.2013.08.028

Mahmood U, Healy HG, Kark A, et al. Spectrum (characteristics) of patients with chronic kidney disease (CKD) with increasing age in a major metropolitan renal service. *BMC Nephrology* 2017;18:372. doi: 10.1186/s12882-017-0781-5

2. **There is limited consideration to the important role of health literacy in CKD and self-management, which could be improved by reference to the literature in this area. People with lower health literacy tend to be less receptive to self-management (http://dx.doi.org/10.1080/10810730.2015.1080329) and have poorer outcomes. Previous work (http://dx.doi.org/10.1093/ndt/gfs371) suggests 20-25% of people with CKD have low health literacy, yet in this study it was 10% or less. Although socioeconomic status was generally high, education level was roughly spilt between tertiary educated and lower than 10th grade. It is not uncommon for people with poor literacy to attempt to conceal this – could estimates of health literacy proceed by the SILS be inflated in this sample due to socially desirable responding? An alternative measure is the Newest Vital Sign (NVS), which is skills-based and has face validity for this study (see https://doi.org/10.3928/24748307-20180530-02).**

We have expanded our limitation section (pg. 22) of our manuscript to include the selected citations detailing your points raised above.

> *"Furthermore, the baseline health literacy was 'good' in over 90 percent of our participants, which is likely greater than the health literacy of the wider CKD population.[4] While other demographics of the people who participated in the ENTICE-CKD study were broadly representative of the CKD demographic reported in international comparisons,[1] we note that previous work has shown that approximately 20-25% have low health literacy,[5] while only 10% of our study's participants had low health literacy. We speculate that it is possible that our estimate of health literacy may be inflated due to the single-item questionnaire having poorer sensitivity for people with marginal reading ability.[6] Future studies should consider the use of a skill-based health literacy questionnaire, such as the Newest Vital Sign, which might better detect poor levels of health literacy in this population.[7]"*

We have included the following citations in this revision:

> Hill NR, Fatoba ST, Oke JL, et al. Global Prevalence of Chronic Kidney Disease – A Systematic Review and Meta-Analysis. *PLoS ONE* 2016;11(7):e0158765. doi: 10.1371/journal.pone.0158765

Wright Nunes JA, Wallston KA, Eden SK, et al. Associations among perceived and objective disease knowledge and satisfaction with physician communication in patients with chronic kidney disease. *Kidney Int* 2011;80(12):1344-51. doi: 10.1038/ki.2011.240 [published Online First: 2011/08/13]
Fraser SD, Roderick PJ, Casey M, et al. Prevalence and associations of limited health literacy in chronic kidney disease: a systematic review. *Nephrology Dialysis Transplantation* 2012;28(1):129-37.

Morris NS, MacLean CD, Chew LD, et al. The Single Item Literacy Screener: Evaluation of a brief instrument to identify limited reading ability. *BMC family practice* 2006;7(1):21. doi: 10.1186/1471-2296-7-21

Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the newest vital sign. *The Annals of Family Medicine* 2005;3(6):514-22.

3. **It can be challenging to recruit research participants with lower health literacy, yet by failing to do so there is a risk of widening existing health inequalities for people who miss out on interventions that can help them. The authors acknowledge the poor uptake, and low representation of people with low health literacy, but do not consider what the reasons may be or how they might address them. The high retention is impressive, especially considering that high attrition is common in studies of this nature, (p19); but perhaps less so if your sample is not representative of the wide population of people with CKD. Such considerations would add value to this manuscript and others that follow.**

   As a pilot feasibility study, we did not design the study to specifically recruit people with low health literacy. However, we have now expanded the limitation section to address this (as per response to comment 4 above).

4. **The study is identified as a feasibility study in the abstract and later in text, but not in the title. The attached CONSORT checklist is for RCT, rather than the extension for pilot and feasibility studies. The extension adds several relevant items. In particular, "Implications for progression from pilot to future definitive trial, including any proposed amendments" is missing.**

   We have now used the CONSORT extension for pilot and feasibility studies. In addition to the expanded limitation section, we have added a paragraph to address other future implications for a larger trial on page 23.

   > *"There are several adaptions which should be considered for a future trial based on the findings of this feasibility and acceptability study. Firstly, the generalizability of the study sample could be improved by recruiting participants from primary care (including general practices) and public and private nephrology units. This may improve the recruitment rate, targeting people who are potentially more motivated to change their diets compared to those who have been in the nephrology service for many years. There is also more opportunity for people to consult with a dietitian in specialized nephrology services, evident by 6% of people who declined to participate doing so because they were already seeing a dietitian. Secondly, the number and structure of the coaching calls could be modified. All participants who completed call 1 went on to complete at least 4 calls, however reasons for missing the final two calls did vary and these calls were most commonly used for check-in and review of participant goals only. This could therefore be done at the participant's discretion and to give participants more flexibility, which was a key reason for the ENTICE-CKD program's acceptability. Lastly, due to the unexpectedly large volume of over 1,000 'unrecognized' text messages sent by participants, a larger trial would be required to adapt the program to provide an automated response in these instances."*

5. **An example of "dietary complexity and competing demands of self-management" (p4 line 22) would be useful.**

   We have included "other medical and lifestyle" to this sentence for clarity.

6. **P6 line 52 –telehealth modalities are effective at supporting behaviour change to reduce chronic disease risk**

Thank you we have added “at supporting behaviour change” to this sentence as suggested.

7. **P19 line 14 clarify that this refers to “intervention participants” – the control group were also participants in this pilot**

   Thank you, this has been added.

Reviewer: 2 (Donald Hilty)

1. **Design issues, terminology and presentation approach: had difficulty ‘seeing’ what was done and not done.**

   We have now updated our reporting checklist to comply with the CONSORT extension for pilot and feasibility studies for transparency, as per editorial and reviewer 1 requests.

2. **Seems odd that a feasibility study is done by adding texts to deliver coaching methods – outright, yes, they are delivered, so there is no mystery that it is feasible? So, not surprisingly, the “Retention was 93% and 98% in the intervention and control groups, respectively, and 96% of all planned intervention calls were completed.”**

   Feasibility was assessed by a range of measures including recruitment, non-participation and retention rates, intervention fidelity, and participant adherence. Retention of participants is a major issue that threatens external validity in CKD dietary trials. We therefore aimed to simplify intervention delivery and maximize participant engagement through a scalable dietary intervention.

3. **What is the intervention? One place says tailored vs. non-tailored and the outcome is usefulness – that is rather obvious result, too? Another place says the texts were added on and the controls got nothing?**

   The study had two distinct phases, across two study groups (reported on page 10-12). The intervention group received a tailored intervention in both phases (phase 1, routine coaching calls and tailored text messages for 3 months, and phase 2 tailored text messages for a further 3 months).

   The comparison group was not tailored, receiving usual care for 3 months (phase 1), followed by 3 months of non-tailored, information-only text messages (phase 2). We have now added a clarifying sentence on page 12.

   > “*Participants in the control group received non-tailored education-only text messages (described in Supplementary Table 1) at the commencement of phase 2 of the trial. This intervention was additional to the usual care participants in the control group were receiving in phase 1.”*

   We have also produced a new Supplementary Table 1 – which details every aspect of the intervention, according to the TIDieR checklist (Supplementary Material and page 9) to help the readers comprehend the complex intervention used in this study.

   > *“*The ENTICE-CKD program was completed in two three-month phases in both the intervention and control group of the study as outlined in Supplementary Figure 1 and the details of the intervention according to the TIDieR items (1-10)[25] is described in Supplementary Table 1. Details about the intervention fidelity TIDieR items (11 and 12) is described and reported throughout this paper and is not summarised in Supplemental Table 1.*”*

   Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. The British Medical Journal. 2014;348.

4. **Should the title have “feasibility” – if this is what it is – or a more specific term or too (i.e., tailored and non-tailored messaging).**

   We have now added ‘Feasibility and Acceptability’ into the title.

5. **Then, looking at Table 2, it is even more confusing as to what was done? Then, there is much data and information in the Tables that is not specific to this study (e.g., the outcomes).**

   We believe the tables provide the necessary data relating to the specific aims of this pilot feasibility and acceptability study. We reported the outcomes using these tables due to the large amount of feasibility (recruitment, non-participation and retention rates, intervention

fidelity, and participant adherence) and acceptability (questionnaire and semi-structured interviews) data.

6. **My guess is that a general study write-up was used and not exactly crafted for this submission, leading to confusion.**

   We have now updated our reporting checklist to comply with the CONSORT extension for pilot and feasibility studies for transparency, as per editorial and reviewer 1 requests. We believe that updating this checklist has now improved the clarity around the study design.

7. **Abstract: Need overall clearer picture to comment specifically on this section.**

   The abstract adheres to the BMJ Open author guidelines. As per response to comment 6, we trust that updating our reporting checklist to comply with the CONSORT extension for pilot and feasibility studies, and other requested amendments, will provide the necessary clarity.

8. **Methods: Unclear as stated above.**

   As per response to comment 3, we have now produced a new Supplementary Table 1 – which details every aspect of the intervention, according to the TIDieR checklist (Supplementary Material and page 9) to help the readers comprehend the complex intervention used in this study.

   As per response to comment 6, we have now updated our reporting checklist to comply with the CONSORT extension for pilot and feasibility studies for transparency. We believe that updating this checklist has now improved the clarity around the study design. We have also removed the section of the method which alludes to clinical outcome data, as these are not reported in this study which should reduce reader confusion.

9. **Each paper – representing only a portion of the bigger study – needs to be clearer, customized and easy to read.**

   We confirm that this is one manuscript of a single study with the aim of evaluating the feasibility and acceptability of a personalized telehealth intervention to support dietary self-management in adults with stage 3-4 CKD. These are the primary outcomes for this trial as registered (ACTRN12616001212448).

   Our manuscript reports the results a mixed methods process evaluation of an intervention, in which two distinct data collection methods, including quantitative and qualitative data, are used to enhance the understanding of the feasibility and acceptability of the intervention.

10. **Results: Need overall clearer picture to comment specifically on this section.**

    In addition to clarifying the context of the study in response to comments 1-9, we have also made minor amendments to the results section of our manuscript. We would like to also clarify that each section of the results is structured according to the key elements of the feasibility (recruitment, non-participation and retention rates, intervention fidelity, and participant adherence) and acceptability (questionnaire and semi-structured interviews) of data collection.

11. **Discussion: Need overall clearer picture to comment specifically see how these findings link with others' findings and more fully grasp the implications.**

    Thank you for your suggestion, we have made a number of changes to the discussion to improve the clarity, flow and generalizability. Please see marked changes throughout the discussion (pg. 20-24).

12. **Tables/Figures: Good, just probably do not need all the information included – as a lot of it is not reviewed in the prose and it is distracting (though interesting).**

    In addition to the details provided in response to comment 14, we confirm that all the information reported provides the necessary data relating to the specific aims of this pilot feasibility and acceptability study. We agree that there is a large volume of data, however, to ensure transparency full evaluation of all of the pre-specified feasibility (recruitment, non-participation and retention rates, intervention fidelity, and participant adherence) and acceptability (questionnaire and semi-structured interviews) data, we feel this information is needed.

<u>Reviewer 3: (Kathy L. Rush)</u>

1. **Introduction: The background to, and context of your study could be strengthened from an organizational and content perspective. Particularly weak is attention to the population of CKD in making the case.**

   We have added sentences following the opening topic sentence (pg. 6) of the introduction to expand on the importance of dietary intervention in the CKD population.

   > *"Chronic kidney disease (CKD) is a progressive condition affecting over 10% of the population worldwide.[8] The management of CKD is burdensome for patients, families and the healthcare system. With the incidence of end stage kidney disease (ESKD) growing, there is a pressing need for preventative action.[9] This includes the provision of pragmatic, person-centred interventions to support dietary behaviour change."*

2. **It isn't readily apparent from the development of your argument, why alternative modalities are needed to determine whether increasing diet quality attenuates CKD progression and elevated CV risk? You seem to be suggesting that whole food-based dietary pattern is effective but traditional modalities may be as effective as alternative modalities in promoting adherence. Is there evidence suggesting traditional modalities are ineffective?**

   We have revised this description to improve the clarity; each reference specifically relates to CKD literature (pg. 6).

   > *"Typical dietary advice given to people with CKD includes restricting individual nutrients, such as sodium, protein, potassium and phosphate. However, there is little evidence regarding the adherence to, and efficacy of, nutrient-specific dietary advice in CKD populations.[10] Recent evidence suggests that following a healthy dietary pattern, as a whole food-based dietary pattern is associated with a reduced risk of death in people with CKD.[11]"*

3. **There is need for more logical development of your argument. For example, you refer to barriers to health care service access but very generically and your argument would be strengthened if you could relate it to the CKD population, which is the focus of your study. You extol the value of telehealth modalities in work with populations with chronic disease. It isn't until the last paragraph of the Introduction that we learn about limitations that your study is seeking to address. You mention the need for quantifying coaching but not in relation to a telehealth delivery modality. The background needs much more clarification and focus to support the need for your study.**

   As advised, we have added more context into the introduction (pg. 6-7):

   > *"Telehealth interventions may facilitate an increased frequency and quality of contact between the patient and healthcare professional,[12 13] which may improve acceptability, uptake and adherence to interventions[14] and better align with a patient-centred model of care and reflect the needs of people with CKD.[15] While clinical trials of telehealth-delivered dietary interventions conducted specifically in CKD are lacking, trials conducted in the broader chronic disease population have shown telehealth-delivered dietary interventions are effective at supporting behaviour change to reduce chronic disease risk, including improving diet quality, fruit and vegetable consumption and reducing dietary sodium intake, compared to face-to-face modalities.[12] This may be due to the flexibility that both telephone and text messaging interventions provide in time and location, and the opportunity to offer more intensive dietary coaching that may not be feasible with traditional care models.[16-18]"*

4. **Even though you were using the intervention to improve self-management to reduce dietary sodium intake (and increase dietary quality), there is no mention of self-management or dietary sodium intake in your background?**

   The aim of the intervention is to support self-management to improve overall dietary quality. Although the intervention advised for lower sodium intake within the overall healthy dietary pattern (through adherence to the Australia Dietary Guidelines), it was not a single strategy and therefore is not included in the background literature.

5. **Tailoring the intervention was important to your telehealth coaching but again the importance of a tailored approach and the evidence base to support it could strengthen the argument.**

   As suggested, we have added some references to non-CKD literature on page 7 which outlines the evidence for varied levels of text-messaging tailoring and the absence of evidence for this in CKD.

"While dietary patterns aligned with a higher diet quality are associated with lower mortality in CKD,[11] the level of tailoring and individualized coaching required to achieve and support dietary self-management is unknown. Non-CKD trials have demonstrated effectiveness for minimally tailored text messages,[19] information-only text messages and tailored interactive text messages.[20] However, no approach has been shown to be superior and no study has investigated such questions in the CKD population. To determine the level of tailoring, and the delivery method that is most feasible and acceptable for patients with CKD, this pilot study aimed to evaluate the feasibility and acceptability of telehealth-delivered dietary coaching to support dietary self-management in stage 3-4 CKD."

6. **Pg. 6 Last sentence of first paragraph, it isn't clear what "overcoming these barriers to implementation of sustained dietary change" is referring to. Barriers haven't been highlighted in the opening paragraph.**

We have changed the word 'barriers' to 'challenges', which are discussed in the previous sentence.

7. Materials and Methods: Overall the methods are well described. There are few areas for clarification. Typically, the word data requires a plural verb. You have used it with a singular and plural verb. (e.g., Pg. 7 line 38-39). Please be consistent.

This has been corrected, thank you.

8. Pg. 7 Design: you indicate the dietary intervention was designed using social cognitive theory. In your supplementary Table 2 you outline the SCT construct and the parallel text message type in operationalizing the constructs. It would be helpful in the text when you introduce SCT to indicate the two constructs you used: outcome expectations and self-regulation.

We have added a sentence following this section in the manuscript to signpost the construct of the SCT utilized (pg. 8).

"The constructs of the social cognitive theory most utilized were outcome expectation (through education text messages and calls), self-regulation (through goal-setting, self-monitoring, coaches' feedback during calls and text-message goal-check replies), and self-efficacy (through setting and celebrating goals, encouraging self-monitoring and problem solving in calls and text messages)."

9. Recruitment: You indicate that participants were recruited from three tertiary nephrology units in Queensland, Australia over a six-month period. Why were these tertiary units selected? Were there contact people at each site inviting eligible patients? Were nephrologists involved in recruitment as one of your exclusion criteria is "deemed unfit to participate by their treating nephrologist" (pg. 8, 23-25. More details about recruitment would be helpful.

The tertiary units were determined as the sites with collaborating investigators. As suggested, we have added more detail regarding recruitment method.

"Potential participants were screened for eligibility by a local site investigator or research nurse from daily outpatient appointment lists and relevant hospital databases. Following discussion with their treating nephrologist, people were approached and invited to participate. If people were unable to be contacted at their outpatient appointment, they were mailed a written invitation to participate with a phone number to contact if they were interested."

10. Eligible participants were randomized on a 1:1 ratio into one of two groups (stratified by recruiting site and diabetes status). The stratification could benefit from greater detail.

We have added clarification to the stratification;

"Simple stratification by recruiting site (Site A, B, C) and presence of diabetes (Yes, No) in blocks of 8" to page 9.

11. Re the text message library and the tailoring of messages you state, - The text message library was imported into the software platform, which was designed to tailor text messages based on: participant's name; individual goals; barriers to achieving goals; and, participant-identified solutions to overcoming those barriers. Was the information for this tailoring collected during the coaching telephone call? If so it would be helpful to clarify

with the addition of this information. Currently you note that coaches logged the following information - goal setting, implementation intentions, self-monitoring tools, call attempts and durations, and text message preferences.

Page 11 documents the tailoring variables and outlines that the coaches were responsible for making adjustments as required. We have now added a minor clarification to this sentence.

> *"These tailoring variables were collected and modified as required by the coaches following the initial and subsequent coaching calls."*
>
> *"At three months, participants in the intervention group completed a tailoring telephone call with their coach to determine individual preferences for the timing and frequency of text messages for phase 2."*

12. **On pg. 9 you indicate that intervention group participants received 2-8 text messages with the actual number and time of day determined by each participant. It is assumed that this is part of the tailoring of the intervention. Was there any concern that variability in the number of text messages not be expected to affect outcomes or was the number of lesser importance than the tailoring of the messages?**

    The tailoring of the messages was deemed of greater importance than the overall number of text messages for this feasibility study. The study was designed to be pragmatic and tailored to participants preferences, permitting text messages choices were within the set protocol (as detailed in table Supplemental Table 2).

13. **Pg. 11 You note under Data Collection that clinical objective data were collected at baseline, 3- and 6-months. Even though the clinical data is not reported, a couple of examples of the data would be helpful to include.**

    We have now removed the first paragraph of data collection because it is not relevant to this process evaluation.

14. **Pg. 12 You assessed consistency on 10% of coaching calls – what were you looking for in the way of the consistency. Also, you note the fidelity data that were collected by coaches but since there was variability in the "dosage" of text messages, it isn't entirely clear what fidelity indicators you were looking for.**

    Fidelity data included the number, duration and content of telephone calls to ensure the tailored telephone calls were as standardized as possible. This data was captured by coach's database for every call. However, 10% of recordings were analysed by an external party and appraised for consistency to the pre-defined call scripts, capturing deviation from the call scripts and reasons for why this occurred. The following has been clarified on page 12.

    > *"All coaching calls were audio recorded, from which 10% were assessed for consistency by peer-review by an individual external to the project. Consistency considered the pre-defined call scripts and potential deviation from the call scripts with reasons for why this occurred. The following fidelity data were also collected and stored in a Microsoft Excel[21] database throughout the trial: number, duration and content of coaching telephone calls; number and type of text messages delivered; number and type of text message responses; and time spent by coaches for each interaction."*

15. **Pg. 12 and Intervention adherence, line 21 –data "was" should be "were" if you intend to consistently use the plural verb"**

    Thank you, this has been corrected.

16. **On pg. 15 you state that randomization was effective at distributing all measured demographic**
    characteristics. Is this another way of saying the groups were equivalent at the outset?

    Yes, that is correct. We have revised this sentence to

    > "Baseline characteristics were well balanced across the two groups, suggesting randomisation was effective" on page 16 to improve clarity for readers.

17. **On pg. 17 and utility and acceptability results you report in the last sentence of this section, that acceptability of the text messages was assessed as highly acceptable with 78% of participants reporting that the characteristics of the text messages were satisfactory. Please add for intervention participants.**

This is an aggregate percentage across all intervention and control participants. We have adjusted this sentence to make this clearer on page 18.

> *"Acceptability of the text messages was assessed as high with 78% of all intervention and control participants reporting that the characteristics of the text messages (language, frequency, program length, time of delivery) were satisfactory".*

18. **On pg. 17-18 and Attributes of Feasibility and Acceptability you note the categories for both acceptability and feasibility. You note under feasibility, variability in degrees of usefulness of text messages – briefly what were the main areas of variability?**

    The majority of participants found the text messages useful, and all participants who completed the utility and acceptability survey (Table 4) agreed that the text messages were useful. However, in the individual interviews, a few participants did not find the text messages useful, predictably because they did not use text messages in their usual day-to-day lives. We have added one sentence on page 19 to clarify

    > "*They appreciated the personable, bidirectional conversation of the telephone calls. The degree of usefulness of text messages was rated with some variability, although no participants described the content or delivery of text messages negatively in the semi-structured interviews. The only areas of variability were noted in the small number of participants who were not familiar with using text messaging in their everyday life*."

19. **Discussion: Pg. 19, 1st paragraph, you note the tailored telephone calls and text messages were acceptable to participants in this pilot but was variable for those in the non-tailored control group. You provide more interpretation of this finding in paragraph 4 of the Discussion and perhaps this aspect could be combined with paragraph 1.**

    We have made this amendment as requested.

20. **Pg. 19 2nd paragraph – you note "The successful recruitment and retention of participants in the ENTICE trial demonstrated feasibility." While you note that recruitment occurred in the anticipated 6-months, discussion could be enhanced with more elaboration of what your recruitment targets were for this study and how it compares to other similar studies? You note later in the discussion (paragraph 3), Blakeman et al's (2014) recruitment rate of 69%. Could you comment on between study differences that might account for your study having about half their recruitment rate over the same timeframe? In this same paragraph, you note the problem with attrition in the CKD population and its reduction of the "certainty of findings." It would be helpful to replace "certainty" with more precise language.**

    Thank you for this helpful suggestion. We have added a possible explanation as to why the difference in recruitment rates in Blakeman and our current study may have occurred (pg. 21). We have also changed 'certainty' to 'generalizability'.

    > *"The major difference between the study conducted by Blakeman and colleagues[22] and the ENTICE-CKD study was that recruitment occurred in general practices compared in tertiary hospitals in our study. Our patient-engagement work highlighted the desire of people with CKD for preventative diet and lifestyle advice in the early stages of CKD, before it became a clinical issue.[15] This possibly explains the higher recruitment rate in the primary care study by Blakeman and colleagues (69%) compared to our study in the tertiary hospital setting (35%)."*

21. **Pg. 21 In the 2nd full paragraph you use the term "uncertain" in a couple of places. Perhaps "unknown" is a more appropriate term?**

    We have replaced 'uncertain' with 'unknown' throughout these passages.

22. **Pg. 21, 1st full paragraph, the last 2 sentences could be strengthened grammatically. The ENTICE-CKD intervention …was dedicated to an individual topic and was tailored …." These attributes …observed in the acceptability of the intervention compared….**

    We have revised in passage of the discussion and made the following marked changes to page 22.

    > *"The ENTICE-CKD program was designed to foster incremental dietary advice, with each individual call being dedicated to a separate topic. Each call was also tailored and flexible to participants' goals for dietary change. These attributes may also help*

explain the difference observed in the acceptability compared to the non-tailored education only (control) intervention."

23. **Pg. 21 Limitations are addressed. Wrt to your low recruitment rate, you may want to add that it compromises representativeness.**

    This has been included as suggested.