PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Targeted, structured text messaging to improve dietary and lifestyle behaviours for people on maintenance haemodialysis (KIDNEYTEXT): study protocol for a randomised controlled trial
AUTHORS	Stevenson, Jessica; Campbell, Katrina; Brown, Mark; Craig, Jonathan; Howard, Kirsten; Howell, Martin; Khalid, Rabia; Sud, Kamal; Teixeira-Pinto, Armando; Thiagalingam, Aravinda; Tong, Allison; Chow, Clara; Lee, Vincent

VERSION 1 - REVIEW

REVIEWER	Deborah Kerr School of Public Health, Curtin University, Australia
REVIEW RETURNED	04-Jun-2018

GENERAL COMMENTS	Overall comments: 1. Providing text messaging support in patients with kidney disease has potential to provide valuable support and information, that may improve patient outcomes. This project will evaluate the feasibility and effectiveness of a semi-personalised mobile phone text messaging system. The challenge with text messaging interventions is to ensure the messages are salient and appropriate for the recipients. Whist technology has made it easier to deliver messages, it's critical that researchers get the content and frequency of delivery right. This includes being clear in the purpose of the messages (e.g. provide instruction, build skills, awareness raising, feedback on performance). This is where I think the manuscript could be improved. 2. The authors have referred to the taxonomy of behaviour change framework by Abraham and Michie (ref 25) but it is not clear how the theories referred to (eg page 12 theory of reasoned action, theory of planned behaviour, social cognitive theory) link to the messages developed. The theoretical framework and linking to the message needs to be more clearly articulated. This is articulated in the Abraham and Michie paper. 3. The title includes the terms "personalised, structured". This doesn't seem to be consistent with the aim of "semi-personalised" text messages. This suggests the messages are to be personalised or tailored but it is not clear in the manuscript exactly how this will be done. From my reading, it suggests the messages are "targeted messages" rather than "personalised or tailored". I

	refer the authors to the paper by Schmid K.L. (Mark Health Serv. 2008 ; 28(1): 32–37.) 'Targeting or Tailoring? Maximizing Resources to Create Effective Health Communications': a. "Two methods to customize health messages are particularly prominent in health communication research. Message targeting customizes messages to shared characteristics of population subgroups, such as lifestyle factors like recent college graduates in emerging careers in small cities or physically active retirees living in the suburbs. Message tailoring, in contrast, fits messages to individual characteristics, such as personality factors like coping styles or preferences for thinking extensively about choices." Common strategies to personalise the message include 'identification', 'raising expectation' and 'contextualisation' (RP Hawkins et al Health Education Research 23, pp 454-466, 2008). Personalising the message can include identifying the participant by name. Will the messages do this? Will participants receive any feedback on their performance? Specific comments: P6, line 23 – in text citation for reference P7, line 11-12 – what is meant by "step-wise education"? P7, line 26 – can the authors provide Australian rates for mobile phone use? P7, line 49 – the discussion on ehealth – the intervention proposed is an mhealth intervention so isn't your point more about mhealth? The evidence gap point could be clearer here. P9, line 53 – why are the texts unidirectional? Is this correct as later in the manuscript the authors say participants can respond. The respondents will receive 3 texts per week – please clarify the basis for this. P10, line 13 – it is stated that participants will receive messages based on exceeding the guidelines. It isn't clear what data will be used for this? Will this come from the baseline values? The time points used are not clear eg "2 or 3 periods" over what time? Table 1 – as outlined above will the messages be personalised? Will they receive feedback on their levels? If a participant is meeting the guidelines ie, doing well will they receive this message? P 12, line 52 – as outlined above this section is not clear how the theories link to the messages. What are the techniques (theoretical framework) that will be used? P13, line 6 & line 28 – how many people reviewed the messages? P13, line 53 – "participant satisfaction" – from your table 2 this is not really participant satisfaction you are interested in – isn't it more about knowledge, attitudes and behaviour? P14, line 4-8 – 24-hour pass methodology – the authors need to clarify how they will conduct a 24-hour recall. Will this be done in person or by telephone? Will aids for portion size estimation be used? Why an average of 2 days intake? Will these be consecutive days? How will the data be analysed? Table 2 – state when the semi-structured interviews will take place. P15, line 16 – how will participants "self-monitor"? P15 - Australian Healthy Eating Index – this is based on a food frequency questionnaire to assess diet quality. Will participants be completing a food frequency in addition to the 24-hour recall? Is the Australian HEI relevant to this population eg as scoring is based on fruit, vegetable intake that is often restricted in kidney patients?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1:

1. The authors have referred to the taxonomy of behaviour change framework by Abraham and Michie (ref 25) but it is not clear how the theories referred to (eg page 12 theory of reasoned action, theory of planned behaviour, social cognitive theory) link to the messages developed. The theoretical framework and linking to the message needs to be more clearly articulated. This is articulated in the Abraham and Michie paper.

We have now included an additional table that outlines behaviour change frameworks and examples of text messages used in KIDNEYTEXT. (page 13).

2. The title includes the terms "personalised, structured". This doesn't seem to be consistent with the aim of "semi-personalised" text messages. This suggests the messages are to be personalised or tailored but it is not clear in the manuscript exactly how this will be done. From my reading, it suggests the messages are "targeted messages" rather than "personalised or tailored". I refer the authors to the paper by Schmid K.L. (Mark Health Serv. 2008 ; 28(1): 32–37.) 'Targeting or Tailoring? Maximizing Resources to Create Effective Health Communications':

a. "Two methods to customize health messages are particularly prominent in health communication research. Message targeting customizes messages to shared characteristics of population subgroups, such as lifestyle factors like recent college graduates in emerging careers in small cities or physically active retirees living in the suburbs. Message tailoring, in contrast, fits messages to individual characteristics, such as personality factors like coping styles or preferences for thinking extensively about choices."

Common strategies to personalise the message include 'identification', 'raising expectation' and 'contextualisation' (RP Hawkins et al Health Education Research 23, pp 454-466, 2008). Personalising the message can include identifying the participant by name.

Will the messages do this? Will participants receive any feedback on their performance?

The messages are targeted to participants' baseline dietary intake and clinical variables (serum potassium, serum phosphate, interdialytic weight gains). There will be some personalisation by using the participant's name in one third of messages. As suggested we have amended the term personalised and semi-personalised to targeted. Our title is now: "Targeted, structured text messaging to improve dietary and lifestyle behaviours for people on maintenance haemodialysis (KIDNEYTEXT): study protocol for a randomised controlled trial"

Participants will not be receiving feedback on their performance. Current practice in haemodialysis units is for nursing staff and doctors to provide this feedback. This usual care will be continued.

P6, line 23 – in text citation for reference

The correct referencing style has now been amended.

P7, line 11-12 – what is meant by "step-wise education"?

Step-wise education refers to progressive education, starting from simple to more complex information. We have amended this sentence to more clearly reflect this: "Patient-centred interventions that are individualised and provide progressively simple to more complex education over time to support and engage patients may help to improve outcomes in this population." (page 7, line 11-12)

P7, line 26 – can the authors provide Australian rates for mobile phone use?

As suggested we have included the rate of mobile phone usage in Australia.

“Australia has one of the highest rates of mobile phone ownership, with 88% of Australians owning a smart phone (14).” (page 7, paragraph 2)

P7, line 49 – the discussion on ehealth – the intervention proposed is an mhealth intervention so isn’t your point more about mhealth? The evidence gap point could be clearer here.

Throughout our manuscript we have used eHealth as an overarching term that also encompasses mHealth. As suggested we have tried to improve the clarity of the evidence gap.

“There is a paucity of research using eHealth interventions, particularly interventions utilising mobile phone technologies, to target diet and lifestyle in the haemodialysis population (22). There is some indication that using electronic self-monitoring apps with additional dietary counselling may improve dietary sodium intake (23, 24) in haemodialysis and peritoneal dialysis populations, however these studies were small and of short duration.” (Page 7)

P9, line 53 – why are the texts unidirectional? Is this correct as later in the manuscript the authors say participants can respond.

The text messages are unidirectional. Participants are able to respond to messages if they want to cease the intervention as described on page 12 paragraph 2 “Participants will have the opportunity to withdraw via a text…”. Participants were advised that any messages they sent would not be responded to by text message.

The respondents will receive 3 texts per week – please clarify the basis for this.

Frequency of text messages (i.e. three messages a week) was chosen based on consumer feedback in the development of KIDNEYTEXT. We have added the following to improve clarity:

“Additionally we sought patients’ input regarding the optimal timing and frequency of text messages.” (page 13, paragraph 2).

P10, line 13 – it is stated that participants will receive messages based on exceeding the guidelines. It isn’t clear what data will be used for this? Will this come from the baseline values? The time points used are not clear eg “2 or 3 periods” over what time?

As suggested we have improved the clarity of the guidelines used. We have added the following:

“Baseline dietary intake exceeds…”

“Baseline blood values will be based on the previous 3 routine dialysis blood tests.”

Table 1 – as outlined above will the messages be personalised? Will they receive feedback on their levels? If a participant is meeting the guidelines ie, doing well will they receive this message?

Personalised feedback on their blood tests will not be provided as part of this trial. This level of care will be continued as per current dialysis unit protocols.

P 12, line 52 – as outlined above this section is not clear how the theories link to the messages. What are the techniques (theoretical framework) that will be used?

As suggested we have added an additional table to more clearly outline the frameworks used to develop text messages. Please refer to Table 2.

P13, line 6 & line 28 – how many people reviewed the messages?

As outlined on page 13, line 32, “each message was reviewed by at least three consumers…”.

Page 13, line 28 we have added in the following: “We conducted semi-structured interviews with 35 patients on haemodialysis to elicit their perspectives regarding the use of eHealth”

P13, line 53 – “participant satisfaction” – from your table 2 this is not really participant satisfaction you are interested in – isn’t it more about knowledge, attitudes and behaviour?

As suggested we have amended to include changes to dietary knowledge, attitudes and behaviours.

“Feasibility will be assessed as a composite outcome of: recruitment rate, retention rate, adherence to renal dietary recommendations, participant satisfaction and changes in dietary knowledge, attitude and behaviours” (Page 13, paragraph 3)

P14, line 4-8 – 24-hour pass methodology – the authors need to clarify how they will conduct a 24-hour recall. Will this be done in person or by telephone? Will aids for portion size estimation be used? Why an average of 2 days intake? Will these be consecutive days? How will the data be analysed?

As suggested the following has been added to improve clarity around dietary recall processes:

Dietary recalls will be conducted in-person, or if this is not possible, on the telephone with food models to assist with portion size estimations. Dietary intake will be assessed using an average of 2 days intake, including a dialysis day and a non-dialysis day to ensure we are capturing any differences in dietary intake on these days. Dietary intake will be assessed at baseline, three months and six months, and will be taken assessed within two weeks a participant’s scheduled review. Dietary intake data will be analysed using Xyris Software Foodworks version 9 Pty Ltd.” (page 13, paragraph 1).

Table 2 – state when the semi-structured interviews will take place.

As suggested we have added the following to table 3. “Interviews will be conducted in-person or on the telephone within 8 weeks of participants completing the trial.”

P15, line 16 – how will participants “self-monitor”?

Some of the text messages encourage participants to monitor their dietary and fluid intake, for example counting their fluid intake or recording their dietary intake in a diary. The interviews will explore whether such techniques were used.

P15 - Australian Healthy Eating Index – this is based on a food frequency questionnaire to assess diet quality. Will participants be completing a food frequency in addition to the 24-hour recall? Is the Australian HEI relevant to this population eg as scoring is based on fruit, vegetable intake that is often restricted in kidney patients?

The healthy eating index was chosen as a surrogate measure of healthful dietary choices as there is no equivalent measure developed for people on dialysis. Whilst there are restrictions on diet in haemodialysis general healthy eating principles, such as wholegrains, inclusion of fruits and vegetables, minimisation of fats and sugars are still promoted. No additional dietary intake measure (i.e. food frequency questionnaire) will be used, only the 24-hour recall will be used to code for the healthy eating index.

VERSION 2 – REVIEW

REVIEWER	Deborah Kerr Curtin University, Australia
REVIEW RETURNED	04-Nov-2018

GENERAL COMMENTS	The authors have addressed the majority of the issues raised in their response. The inclusion on Table 2 has improved the clarity of the behaviour change framework and how it will be used in the intervention. Some of the other issues raised have been answered in the author's response, but these changes haven't been carried over into the revised manuscript. The following points need to be clarified: 1. Details of the messages and the rationale. The response to "if participants receive any feedback on performance" needs to be inserted into the manuscript to make this clearer. 2. Page 9, line 53 – "why are the text unidirectional?" The authors have made no changes to the manuscript to provide further details. I am still not clear why the texts are unidirectional? The value of text messaging systems available now is that participants are able to respond. If the authors are not planning to allow this they need to state why and justify their decision. Later in the manuscript the authors have stated "A record of any text messages received from participants will be kept…". This conflicts with the above statement. Are the authors only referring to being able to reply "STOP"?. 3. P14 – 24 hour pass – This section is still not clear to me. "Dietary intake will be assessed using an average of 2 days intake". I am unclear why the authors would use an average of 2 days unless it's a food record not a recall? Are the authors planning to do repeat 24-hour recalls? If so what is the time frame between? It would be clearer to say "Dietary intake will be assessed using a 24-hour recall….". 4. "Dietary intake will be analysed using Xyris Software …". This is the software package but doesn't indicate what nutrient database will be selected e.g AUSNUT 2011–13 is the most recent survey database: http://www.foodstandards.gov.au/science/monitoringnutrients/ausnut/foodnutrient/Pages/default.aspx

VERSION 2 – AUTHOR RESPONSE

Reviewer 1:

1. Details of the messages and the rationale. The response to "if participants receive any feedback on performance" needs to be inserted into the manuscript to make this clearer.

As suggested, we have included the following statement: "Feedback regarding participants' biochemical and clinical parameters will continue to be provided as per the standard care of each dialysis unit (e.g. via nursing and medical staff)." (page 10, paragraph 2 – marked copy)

2. Page 9, line 53 – "why are the text unidirectional?" The authors have made no changes to the manuscript to provide further details. I am still not clear why the texts are unidirectional? The value of text messaging systems available now is that participants are able to respond. If the authors are not

planning to allow this they need to state why and justify their decision. Later in the manuscript the authors have stated “A record of any text messages received from participants will be kept…”. This conflicts with the above statement. Are the authors only referring to being able to reply “STOP”?.

To improve clarity regarding the unidirectionality of the text message intervention we have added in the following: “Text messages will be unidirectional, (i.e. one-way with no response required from participants), as they are intended to function as reminders and reinforcements of various dietary components. Unidirectional text messages have improved dietary and lifestyle behaviours in patients with coronary heart disease (22) and are more time and cost effective compared with in person interventions.” (page 9, paragraph 1 – marked copy)

“Whilst participants are asked not to respond to text messages, a record of any text messages received from participants will be kept and managed by a researcher who is not involved in recruitment or outcome assessment.” (page 11, paragraph 2 – marked copy)

3. P14 – 24 hour pass – This section is still not clear to me. “Dietary intake will be assessed using an average of 2 days intake”. I am unclear why the authors would use an average of 2 days unless it’s a food record not a recall? Are the authors planning to do repeat 24-hour recalls? If so what is the time frame between? It would be clearer to say “Dietary intake will be assessed using a 24-hour recall….”.

We have amended this to improve clarity: “Dietary intake will be assessed using a 24-hour recall, of both a dialysis day and a non-dialysis day, to ensure that we capture any differences in dietary intake on these days.” (page 15 paragraph 1)

4. “Dietary intake will be analysed using Xyris Software …”. This is the software package but doesn’t indicate what nutrient database will be selected e.g AUSNUT 2011–13 is the most recent survey database:
http://www.foodstandards.gov.au/science/monitoringnutrients/ausnut/foodnutrient/Pages/default.aspx

As suggested, we have now included the food databases that used: “Dietary intake data will be analysed using Xyris Software Foodworks version 9 Pty Ltd (using food databases AUSNUT 2011-2013, Aus Foods 2017, Aus Brands 2017)”. (page 15, paragraph 1 – marked copy)