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Telehealth Coaching to Promote Healthy Eating in Chronic Kidney Disease: A Mixed Methods Process Evaluation

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Conflict of interest

The authors declare that they have no conflicts of interest.

Author contributions

JK wrote the first draft of the manuscript and takes responsibility for the integrity of the data. JK, KC, DJ, MR and SP assisted in the conceptualization of the trial design. MW & DR were

responsible for the qualitative data collection and analysis, assisted in the conceptualization of the qualitative research methods. MW wrote the qualitative results section of the manuscript. JK & MC designed the intervention materials and were responsible for the management of the trial at their respective sites. TH, JC and AT provided methodological expertise and revised drafts of the manuscript. All authors contributed to revisions of the manuscript and approved the final version for submission. Jaimon Kelly is the guarantor and affirms that the manuscript is an honest, accurate, and transparent account of the study being reported.

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ABSTRACT

Objective: To evaluate the feasibility and acceptability of a personalized telehealth intervention to support dietary self-management in adults with stage 3-4 CKD.

Design: Mixed-methods process evaluation embedded in a randomized controlled trial.

Participants: People with stage 3-4 CKD (eGFR 15-60mL/min/1.73m^2).

Setting: Participants were recruited from three hospitals in Australia and completed the intervention in ambulatory community settings.

Intervention: The intervention group received one telephone call per fortnight and 2-8 tailored text messages for three months, and then 4-12 tailored text messages for three months without telephone calls. The control group received usual care for three months then non-tailored education-only text messages for three months.

***Main outcome measures*:** Feasibility (recruitment, non-participation and retention rates, intervention fidelity, and participant adherence) and acceptability (questionnaire and semi-structured interviews).

Statistical analyses performed: Descriptive statistics and qualitative content analysis.

Results: Overall, 80/230 (35%) eligible patients who were approached consented to participate (mean±SD age 61.5±12.6 years). Retention was 93% and 98% in the intervention and control groups, respectively, and 96% of all planned intervention calls were completed. All participants in the intervention arm identified the tailored text messages as useful in supporting dietary self-management. In the control group, 27 (69%) reported the non-tailored text messages were useful in supporting change. Intervention group participants reported that the telehealth program delivery methods were practical and able to be integrated into their lifestyle. Participants viewed the intervention as an acceptable, personalized alternative to face-face clinic consultations, and were satisfied with the frequency of contact.

Conclusions: This telehealth-delivered dietary coaching program is an acceptable intervention which appears feasible for supporting dietary self-management in stage 3-4 CKD. A larger-scale randomized controlled trial is needed to evaluate the efficacy of the coaching program on clinical and patient-reported outcomes.

***Trial registration*:** Prospectively registered (ACTRN12616001212448)

Article Summary

- This study utilized a pragmatic design which enhanced its feasibility.
- Mixed methods captured both quantitative and qualitative data to determine multiple aspects of feasibility and acceptability.
- Interview data to determine the intervention's acceptability were not captured in control group participants.

INTRODUCTION

Chronic kidney disease (CKD) is a progressive condition affecting over 10% of the population worldwide.[1] Diet is a modifiable risk factor for the progression of CKD to end-stage kidney disease (ESKD).[2,3] Typical dietary advice 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.[4] 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 established CKD.[5] A focus on foods rather than single nutrients may also facilitate increased adherence to dietary change in CKD[5,6] which is otherwise challenging due to dietary complexity and competing demands of self-management.[7] Overcoming these barriers to implementation of sustained dietary change are necessary to test whether improving diet quality alters patient-centered outcomes.

Providing regular and individualized dietary support required for those with CKD comes with geographical, time and financial barriers.[8] To determine whether increasing diet quality (through dietary pattern) may attenuate the progression of CKD and elevated cardiovascular risk on a sufficient scale for a randomized controlled trial (RCT), alternative modalities that are effective in supporting dietary management are needed. Telehealth modalities, particularly telephone-based and text message coaching, present an opportunity to overcome barriers and challenges that people with CKD encounter in accessing health care services.[7,9] Telehealth interventions may facilitate an increased frequency and quality of contact between the patient and healthcare professional,[10,11] which may improve acceptability, uptake and adherence to interventions[12] and better align with a patient-centered model of care.[9] Compared to face-to-face consultations,[11] telehealth modalities are effective in reducing chronic disease risk, including improving diet quality, fruit and vegetable consumption and reducing dietary sodium intake.[10] Text messaging has been utilized to 'extend contact' after an intervention and has been shown to maintain clinical outcomes and minimize

intervention decay.[13,14] A systematic review of text message health interventions highlighted the need for better evidence on the relative effectiveness of text-based interventions including message delivery (incorporating frequency and timing), level of interaction (i.e. response and feedback) and impact of additional interventions (such as a combination with telephone, face-to-face, video or internet).[15]

While dietary patterns aligned with a higher diet quality are associated with improved lower mortality in CKD,[5] the level of coaching required to achieve and support dietary self-management is largely unknown. Furthermore, evidence to support the level of tailoring, and the delivery method that is most feasible and acceptable for patients with CKD, is lacking. Therefore, 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.

MATERIALS AND METHODS

We used a mixed methods design, whereby qualitative data on the patient experiences were embedded within quantitative data relating to participants recruited into the Evaluation of iNdividualized Telehealth Intensive Coaching to promote healthy Eating and lifestyle in Chronic Kidney Disease (ENTICE-CKD) program. All data was prospectively collected. This pilot randomized controlled trial was prospectively registered (ACTRN12616001212448) and reported based on the extension of the CONSORT statement for feasibility and pilot studies.[16] This trial was approved by the Metro South Health Service District Human Research Ethics Committee (EC00167) and Bond University Human Research Ethics Committee (EC00357).

Design

This mixed-methods process evaluation was embedded in a randomized controlled trial, conducted from November 2016 to November 2017. The dietary intervention was designed using the social cognitive theory,[17] with a patient-centered focus on improving self-management to reduce dietary

sodium intake (<2300mg/day) and increase dietary quality in accordance with the Australian Dietary Guidelines (see Supplementary Table 1 for intervention guidance).[18] Interventions were adjunct to usual nephrology care from treating physician(s) and renal team members, including ad hoc referrals to allied health practitioners during the study.

Participants

Participants were recruited from three tertiary nephrology units in Queensland, Australia over a six month period. Inclusion criteria were: adults over 18 years of age; stage 3-4 CKD (eGFR 15-60mL/min/1.73m^2); and access to a mobile device capable of receiving text messages and telephone calls. Exclusion criteria were: anticipated dialysis commencement or kidney transplant within the following 12 months; pregnancy; non-English speaking; cognitively impaired; or deemed unfit to participate by their treating nephrologist.

Eligible participants were randomized on a 1:1 ratio into one of two groups (stratified by recruiting site and diabetes status). Randomization was completed by computer-generated random numbers carried out by an independent statistician not involved in the study.

Study treatment

The ENTICE-CKD program was completed in two three-month phases in both the intervention and control group of the study as detailed in Supplementary Figure 1. Each participant was involved in the trial for six consecutive months. All participants were provided with an ENTICE-CKD workbook at the baseline visit. The 90-page workbook included information on setting *specific, measurable, achievable, realistic, and time-bound* (SMART) goals; eating well for kidneys (based on the Australian Dietary Guidelines);[18] active living (based on the Australian Physical Activity Guidelines);[19] role of diet in kidney disease, strategies for planning, self-monitoring checklists, and a list of useful websites, apps, and recipes for further reference.

Telehealth coaches

Each participant was assigned to one of two telehealth coaches at baseline. The participant had the same coach for the duration of the program. Both telehealth coaches were registered dietitians (Australian equivalent) with additional training in renal nutrition, behavior change and motivational interviewing; were external to the recruiting sites and had never met the participants; and were not involved in any outcome data collection.

Phase 1

The participants in the intervention group received six fortnightly telephone calls in phase 1 which were scheduled on weekdays at a time of the participants choosing (from 7am to 7pm). The first call was scheduled for 45 minutes and five subsequent for approximately 30 minutes. Each call was based on established protocols and call scripts. The telephone call content was guided by the workbook topics, structured according to the 5A's framework (Assess, Advise, Agree, Assist, Arrange),[20] and individually tailored to participants using relevant educational strategies, and in consideration of the participant goals and co-morbidities. Where required, 24-hour dietary recalls were undertaken during coaching calls to track adherence and progress with goals. Coaches used Microsoft Excel[21] to document progress of each call and log information including goal setting, implementation intentions, self-monitoring tools, call attempts and durations, and text message preferences.

In addition, participants in the intervention group received two to eight text messages scheduled between coaching calls with the actual number and time of day determined by each participant's preference. Text categories included: educational; self-monitoring; and goal setting. The schedule of text messages for the intervention and control group in phase 1 and 2 is detailed in Supplementary Table 2. The text messages were sent using a web-based, semi-automated text message management platform (Propelo, www.propelo.com.au), developed and administered by

The University of Queensland's School of Public Health.[22] The investigators, in consultation with local nephrologists, dietitians and evidence-based practice guidelines, designed the library of text messages, which were then reviewed for comprehension by a group of patients, nephrologists and members of the investigator team. 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. These tailoring variables were modified as required following each coaching call.

As shown in Supplementary Table 2, participants in the intervention group could receive one 'goal check' per goal (total 2 goal checks) per fortnight in phase 1 and up to 2 goal checks per goal (total 2 to 4 goal checks) per fortnight in phase 2. These goal checks required the participant to respond to the text with a "yes" or "no" which prompted the software to send a pre-determined response. An incoming text reply outside protocol (i.e. not a "yes" or "no" response) was classified as an 'unrecognized response'. This triggered an email to the participant's coach and was only responded to where participants expressed considerable risk to their health (e.g. symptoms needing medical attention).

Participants in the control group received no coaching or text messages between the baseline visit and three months (phase 1). The control group continued to receive standard care under their treating nephrologist (typically 1 clinic visit every 3 months) and were encouraged to work through the ENTICE-CKD workbook at their own pace.

Phase 2

At three months, participants in the intervention group completed a tailoring telephone call to determine individual preferences for the timing and frequency of text messages for phase 2. At 18 weeks (i.e. half way through phase 2), participants received a second tailoring call where they could

modify the timing and frequency of text messages and could update their goals. Intervention group participants chose text message frequencies (four to 12 text messages per fortnight) for the same types of texts that they received in phase 1 (educational tips, self-monitoring, goal checks). Participants in the control group received non-tailored education-only text messages (described in Supplementary Table 2).

Data collection

Each participant attended a baseline, three-month (mid-point), and six-month (end-point) visit with a local site investigator (nurse or dietitian blinded to group assignments) at their study site to collect all clinical objective data (not reported here). All participants' study visits were scheduled on separate days or hours apart to avoid risk of contamination bias. Basic demographic data (including participant's age and gender) were recorded at baseline. Socio-economic status was estimated from participants' postcodes, according to the Index of Relative Socio-economic Advantage and Disadvantage (IRSAD).[23] Baseline health literacy was collected using the single item Literacy Screener which classifies health literacy as good or limited based on the single question, "How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?".[24]

Reach and retention

The sample size was determined for the purpose of informing a future study. Therefore, a target of 30-40 participants per arm was set to allow for meaningful and reliable data, which could be used to power future trials.[25] Recruitment and non-participation rates were captured across the three recruitment sites, with a goal to achieve the target sample size of 80 participants in the six month recruitment time frame. Retention rate was measured at three and six months in both study groups, with successful retention defined 80% at the six-month study end.

Intervention delivery

Individual cases were discussed fortnightly between the coaches and the lead investigator to support consistent intervention delivery. All coaching calls were audio recorded, from which 10% were assessed for consistency by peer-review by an individual external to the project. The following fidelity data were 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.

Intervention adherence

Adherence was defined as successfully completing five of the six telephone calls for the intervention group. Data was also collected on individual participant adherence to the dietary intervention, collected by coaches in each telephone call using a call log template in Microsoft Excel.[21] In the call logs, coaches described evidence of the participant's overall progress, evidence of self-monitoring, goals set and implementation intentions (behaviours implemented to achieve goals) during each call, which was quantified in counts to capture participant adherence.

Acceptability

A utility and acceptability survey of the text message component of the ENTICE-CKD trial was collected from all participants at the six-month end of study visit (Supplementary Table 3). The survey included 13 items, developed specifically for the study, with five items asking participants to rate on a 5-point Likert scale from 1 'strongly disagree' to 5 'strongly agree', four items asking participants yes/no questions, and four multiple choice questions, based on previous methodology in cardiac patients.[26] In addition to this, during the sixth telephone call (three-month study mid-point; for intervention participants only), coaches obtained verbal consent of participants to be approached to complete an interview relating to their experiences of the intervention.

Semi-structured interviews were conducted in-person and by telephone. Participants were recruited based on consecutive sampling of completing participants until data saturation was achieved. The

interviews were conducted by investigator (MW), who had not previously met the participants and was not involved in the planning of the intervention. The interview guide included questions on: barriers and facilitators of program adherence; telehealth delivery methods and frequency of contact; usability of the program; goal setting, self-monitoring, behavior change; and experiences (Supplementary Table 4). Modification of the interview guide occurred after each interview to broaden scope of the data collected. Interviews were audio-recorded and transcribed verbatim.

Patient involvement

The study was designed in collaboration with similar participants as those recruited for this study. This patient engagement was conducted as a qualitative study, reported elsewhere by the investigators[9] and details the patient reported burden associated with following dietary recommendations that were considered while developing this trial. All intervention materials, including the workbook and text messages, were reviewed by people with CKD with feedback forms which were used to revise all the material before production. No patients were involved in the recruitment or data collection of this process evaluation study. A summary of the main results will be mailed out to participants. The burden of the trial has been evaluated in semi-structured interviews (unpublished data in preparation).

Data analysis

Quantitative data were analyzed using simple descriptive statistics (counts and percentages). To determine the difference in the utility and acceptability between the two study groups, a standard Chi square test was used with a significance level determined as $p< 0.05$. Statistics were conducted in SPSS Statistics for Windows (version 22.0. Chicago: SPSS Inc.) and Microsoft Excel.[21]

Inductive content analysis[27] of the semi-structured interview transcripts regarding acceptability of the intervention was conducted researcher (MW) who was not involved in quantitative data planning, collection and analysis. After familiarization with the data, an open coding approach was adopted to identify, develop and finalize categories and subcategories within the data. A dietitian

and qualitative researcher (DR) familiar with the data then finalized and confirmed emerging categories that were relevant to the process evaluation. Verbatim quotes were collected and used to represent attributes demonstrated for both the feasibility and acceptability of the ENTICE-CKD program. Microsoft Word[28] was used to facilitate data management (tables) and basic content analysis (comments relating to attributes demonstrating feasibility and acceptability) of data.

RESULTS

Characteristics of participants

The baseline characteristics of the participants are reported in Table 1. Of the 80 participants who completed their baseline visit, 64% were men and had a mean age of 62 years. The stage of CKD varied within the sample, with 31% stage 3a (eGFR 45-59ml/min/1.73m^2), 44% stage 3b (eGFR 30-44ml/min/1.73m^2) and 25% stage 4 (eGFR 15-29ml/min/1.73m^2). The most common comorbidities were hypertension (81%) and diabetes (39%) (Table 1). Baseline health literacy was good in over 90% of all participants. Randomization was effective at distributing all measured demographic characteristics.

Reach and retention

Participants were recruited between November 2016 and May 2017, from Gold Coast (43%), Sunshine Coast (31%) and Brisbane (26%) hospitals. The flow of participants through the ENTICE-CKD study is shown in Figure 1. A total of 230 potentially eligible individuals were approached and invited to participate, of whom 80 participants (35%) were recruited to the ENTICE-CKD trial. Of the 146 individuals who declined to participate, "not interested/other" were the most commonly stated reasons for non-participation (49%) with reasons documented in Figure 1. 'Other' reasons for non-participation included: already feeling healthy (5%), already seeing a dietitian (5%), believed the intervention did not fit their current lifestyle (3%) or preferred not to use technology (1%). A further two individuals consented to the study but did not attend a baseline visit and were therefore not randomized to a treatment group.

Seventy-six (95%) of all randomly allocated participants completed the six-month telehealth program. A total of four (5%) participants withdrew from the study. All the withdrawals occurred in the first three months of the program. Three of the four participants who withdrew were from the intervention group (two were unable to be contacted and therefore did not commence the program,

and one participant was unable to continue due to a family illness). The sole participant who withdrew from the control group did not report a reason for doing so. There were no appreciable differences in the demographics of those participants who dropped out compared to those remaining in the trial.

Intervention delivery

Table 2 shows the adherence to the planned delivery of the telephone and text message components of the ENTICE-CKD intervention. The delivery of the scheduled telephone calls was conducted according to protocol with 90% of planned calls being completed as scheduled. The mean duration of the first intervention call was 45.5±10 minutes (range 28 to 75 minutes). The mean length of the subsequent five calls was 24±10 minutes (range 2 to 62 minutes).

A total of 4,985 intervention text messages were sent to ENTICE participants. The median number of text messages sent to participants was within protocol for both groups, with intervention participants receiving a median of four text messages per fortnight in phase 1 and seven per fortnight in phase 2. Control participants received a median of six non-tailored education-only text messages per fortnight in phase 2 (Table 2). The total number of incoming text messages (replies from participants) was 1,100 (Table 2), 36% (n=400) triggered the appropriate goal-check reply, 3% (n=31) required the dietitian coach to send a tailored text message to address the concern raised by the sender and 61% (n=669) required no reply.

Intervention adherence

A total of 38 participants (95%) completed at least five calls, and 36 (90%) completed all six calls. Two participants (5%) never received a telephone call. Goal setting was completed by all participants in the first call as planned, with 95% of the participants setting two or more goals. The coaches' call logs showed that, throughout the program, participants continued setting new goals with 10 (26%) updating at least one goal in call two and 22 (61%) updating at least one goal

throughout the remaining four calls (Table 3). A total of 29 (76%) participants showed evidence of self-monitoring by the second call, which was sustained throughout phase 1 of the intervention. Evidence of implementation intentions indicated that the majority of participants (82%) needed at least two calls to begin putting planned dietary intentions in place. This number continued to rise over the next four calls to 97% by the end of phase 1 of the intervention.

Acceptability

Utility and acceptability

There were several differences in ratings for utility and acceptability between the intervention (tailored-text) group compared to the non-tailored education-only text message (control) group (Table 4). Participants agreed (responses for 'agree' and 'strongly agree') that the text message component: supported their dietary self-management (intervention 100%; 69% control, p=0.003); provided motivation to change their diet (intervention 75%, control 50%; p=0.03); and led them to a healthier diet (intervention 81%, control 61%, p=0.06). There were no other differences observed in the utility of the text messages between the groups. The majority of text messages were saved and not deleted (77% overall), and 62% were shared with family, friends or health care providers across the two study groups. Acceptability of the text messages was assessed as highly acceptable with 78% of participants reporting that the characteristics of the text messages (language, frequency, program length, time of delivery) were satisfactory.

Attributes of feasibility and acceptability

Twenty one intervention participants were interviewed upon completion of phase 1, either by telephone (n=20) or face-to-face (n=1). Interviews ranged from 20 to 96 minutes (mean 49 min). Overall, participants had positive experiences with the ENTICE-CKD trial. Attributes of the discussions are described in nine categories within components of acceptability and feasibility (Table 5). The acceptability categories discussed by participants were: acceptable alternative to

clinic, preference for voice communication, regular contact via text message, and personalized messages valued. The categories described under feasibility were: program integrated into lifestyle, diverse delivery modes, social accountability, responding to dietary advice, and infeasible elements beyond intervention. Participants emphasized the importance of social accountability; all participants expressed benefit from the relationship built with their coach. Participants identified benefits from telehealth delivery of the intervention, with the majority expressing preference for telehealth over face-to-face interventions. They appreciated the personable, bidirectional conversation of the telephone calls. The degree of usefulness of text messages was rated variably by different participants, although no participants described the content or delivery of text messages negatively. Messages that were perceived to be personalized were preferred for both calls and text messages. Participants felt that receiving information via more than one delivery mode was helpful for making diet changes. Some participants discussed challenges which were not addressed by the ENTICE-CKD intervention, such as participants not being easily able to implement routine dietary behaviors whilst travelling, or those lacking social support outside of the program.

DISCUSSION

This mixed methods process evaluation study within a randomized controlled trial evaluated the feasibility and acceptability of the ENTICE-CKD telehealth coaching program to promote healthy eating among people with moderate CKD. The ENTICE-CKD program was a feasible intervention that was delivered according to protocol and enabled participant adherence. The tailored telephone calls and text messages were acceptable to participants in this pilot. In contrast, the acceptability varied for those in the non-tailored education-only text message (control) group.

The successful recruitment and retention of participants enrolled in the ENTICE trial demonstrated feasibility. Although it is important to consider the trial only had a 35% recruitment rate, the feasibility was strengthened by the successful recruitment in the anticipated six-month recruitment period and very low attrition rate (5%) at six-months. Attrition is a common problem in studies of self-management in CKD, which is reported as between 11 to 39%, and which reduces the certainty of findings, particularly given the often underpowered sample sizes of trials of lifestyle interventions in CKD.[29]

The intensive coaching intervention had a high call completion rate (90%) and high intervention adherence. This is similar to the 90% call completion rates reported in other telehealth studies in weight management,[30] breast cancer,[31] younger adults in the general population,[32] and CKD studies.[33] A study involving 436 participants with CKD in the UK, who received a combination of interactive web-based resources and telephone follow-up demonstrated successful recruitment, retention and intervention satisfaction.[33] There was no specific dietary education provided to participants in that study, however the community support intervention, provided through a workbook, online portal, and telephone follow-up demonstrated a 69% recruitment rate, and had 85% retention at the six-month follow up. Participants reported over 80% usefulness for the workbook, 62% for the telephone calls and 23% for the interactive website.[33] Considering the

limited evidence on lifestyle interventions in CKD specifically, the findings from this trial support the feasibility of using telehealth coaching to support dietary self-management of CKD.

The ENTICE-CKD program made participants feel supported and motivated for dietary self-management. However, this was more strongly indicated by participants who received the tailored intervention program, as opposed to the control group who received non-tailored education-only text messages. These results suggest that a tailored approach to text messaging may be important to people with CKD, as it may facilitate the support and regular interaction for dietary changes.[7] Participants felt that the frequent contact via calls and text messages reinforced rapport and built a supportive relationship between participant and coach, which in turn, enabled stronger social accountability and progressive dietary change.

Overall, there is limited evidence on the acceptability of telehealth dietary interventions in CKD.[34] A pilot study in 47 CKD participants demonstrated over 80% user adherence and satisfaction with a smart-phone self-management support program to support the self-monitoring of blood pressure, medications, symptom recognition, and biochemistry.[35] In contrast, another study found that text-message based interventions were the least preferred telehealth intervention for medication monitoring by CKD participants, compared with web-based or personal digital assistant-based applications.[36] The Effects of Sodium Modification on Outcome (ESMO) study, a three-month self-management intervention in 138 adults with CKD which provided one-to-one sessions and telephone support, demonstrated relatively high (63%) satisfaction from participants. It has been postulated that a key factor for the high acceptability of the ESMO intervention was the patient-engagement utilized in the design of the trial.[37] This was an approach also taken in the ENTICE-CKD study. We have previously found that patients with CKD have been confused by dietary advice and need more frequent contact to support dietary change.[9] They were willing to participate in telephone calls and receive text messages, as these were viewed within their comfort zone and

levels of digital literacy, [9] but also raised concerns about the credibility, safety, and lack of personalization in mobile apps and internet modalities. The ENTICE-CKD program was developed from the key results in this focus group study, which assured a patient-centered approach.[38]

Previous thematic synthesis has shown that people with CKD experience many challenges in relation to achieving their dietary and fluid recommendations. People express a preference for regular coaching, feedback and monitoring to help them understand dietary information and become confident in their ability to self-monitor and manage such changes.[7] The ENTICE-CKD intervention fostered incremental dietary change advice, where each call was dedicated to an individual topic, as well as being tailored and flexible for participants' goals for change. These attributes may also explain the difference observed in the acceptability compared to the non-tailored education only (control) intervention.

There are limitations to this study. As we had a 35% recruitment rate, the feasibility and acceptability only relate to the participants enrolled in this pilot, thus the feasibility for the uptake of the program in clinical practice is uncertain. 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,[39] therefore the generalizability of the results to people with lower health literacy is uncertain. We also acknowledge that we captured the individual participant adherence to the intervention using qualitative methods rather than validated surveys. However, given the primary outcome of feasibility, qualitative methods were used to minimize the over-use of self-report surveys and participant burden and this was an exploratory measure of intervention adherence only. Using this method, we were able to capture to reasons for adherence (and non-adherence). We also did not recruit children into the ENTICE-CKD study, so our results are not generalizable to children with CKD. Finally, we did not interview participants in the non-tailored education-only (control)

group, and thus could not ascertain the reasons for lower acceptability compared with the intervention group.

In conclusion, the ENTICE-CKD dietary coaching program is a feasible and acceptable intervention for adults with stage 3-4 CKD. The program facilitated self-monitoring and encouraged the adoption of goal setting throughout the intensive coaching period. Findings from this study are promising for the use of telehealth to modify dietary practices in future clinical practice and research. However, longer-term studies are needed to determine the safety, clinical effectiveness, and sustainability before the wider implementation of the ENTICE-CKD program is appropriate. This process evaluation can be used by clinicians to inform frequent and structured contact through telephone-based and text message platforms to support the complex dietary self-management required for people with CKD.

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LIST OF TABLES FIGURES

Figure 1. Consort flow diagram showing the flow of participants through the ENTICE-CKD study.

Table 1. Demographics of participants whom completed the six month ENTICE-CKD pilot study.

Characteristic	**Intervention group** (n=41)	**Control group** (n=39)
Male, n (%)	**26 (63%)**	**25 (64%)**
Age (years)	**62.0 ± 12.0**	**61.1 ± 13.3**
Stage of chronic kidney disease		
3a	10 (25%)	15 (38%)
3b	19 (46%)	16 (41%)
4	12 (29%)	8 (21%)
Body Mass Index, kg/m^2	33.4 ± 6.7	31.0 ± 6.4
Hypertension	34 (83%)	31 (80%)
Diabetes	15 (37%)	16 (41%)
Active smoker status	21 (51%)	16 (41%)
Ethnicity		
Asian	2 (5%)	1 (3%)
Caucasian/European	37 (91%)	32 (82%)
Indigenous	1 (2%)	0
Other	1 (2%)	6 (15%)
Education		
Lower than 10th grade	17 (42%)	12 (32%)
Up to 12th grade	4 (10%)	10 (26%)
Tertiary educated	20 (47%)	16 (41%)
Socio-economic status		
High	27 (66%)	25 (64%)
Health Literacy		
Good	37 (90%)	36 (92%)

Table 2. Delivery and response of fortnightly telephone calls and text messages in ENTICE-CKD.

	Intervention group		Control group
TELEPHONE CALLS	Phase 1	Phase 2	Phase 2
Planned	234	-	-
Actual	225	-	-
Call attempts	290	-	-
Missed calls, n (%)	9 (3)	-	-
Duration of initial calls, mins (mean± SD)	45±10	-	-
Duration of follow up calls, mins (mean ± SD)	24±10	-	-
Call scheduling text messages outgoing	245	57	0
TEXT MESSAGES – outgoing			
Total intervention texts sent, per fortnight	1371	1980	1634
Educational[a], median(range)	2(0-6)	4(0-8)	6(0-13)
Goal check[b], median(range)	2(0-4)	3(0-5)	-
Self-monitoring[c], median(range)	0(0-2)	2(0-5)	-
TEXT MESSAGES – incoming			
Total text responses	437	608	55
Recognized goal check responses, n (%)	174 (39.8)	226 (37.2)	0
Unrecognized responses	263	382	55
Requiring tailored text reply from coach, n (%)	7 (2.7)	18 (4.7)	2 (3.6)

[a] Outcome expectations (providing information on consequence)
[b] Self-regulation
[c] Self-regulation (facilitate planned behavior change)

Table 3. Participant adherence to the ENTICE intervention[a].

Adherence	Call 1	Call 2	Call 3-6
Total planned calls	39	39	156
Calls delivered, n (%)	39 (100)	38 (97)	148 (95)
Number of missed calls, n (%)	0	1 (3)	8 (5)
Due to withdrawal from trial			2 (1)
Due to travel			2 (1)
Other[b]		1 (3)	4 (3)
Goal setting, n (%)	38 (100)	10 (26)	23 (61)
1 goal	2 (5)	8 (21)	12 (32)
2 goals	36 (95)	2 (5)	7 (18)
3 goals	N/A[c]	N/A[c]	1 (3)
4 goals	N/A[c]	N/A[c]	3 (8)
Self-monitoring, n (%)	22/38 (58)	29/38 (76%)	29/38 (76)
Implementation intentions, n (%)	14 (37)[d]	31 (82)	37 (97)
Yes	24 (63)[d]	7 (18)	1 (3)
No			

[a] – Data are presented as *n (%)*.

[b] – 1 participant decided to get tailored text messages only following call 1

[c] - In each call only 2 goals could be set or updated.

[d] - Implementation intentions were not expected to be evident in the first call

Table 4. Utility and acceptability of ENTICE-CKD text messages by participant group[a].

Characteristic	Tailored text messages	Non-tailored text-messages
Usefulness and understanding		
Q1 - Useful in supporting dietary change	100%	69%**
Q2 - Messages were easy to understand	100%	100%
Influence on motivation and behavior change		
Q3 - Messages motivated change	75%	50%**
Q4 - Healthier diet due to messages	81%	61%
Q5 - Exercise increased due to messages	38%	33%
Message saving and sharing		
Q6 - Percent of messages read	100%	100%
Q7 - Saved messages	81%	72%
Q8 - Shared messages	56%	67%
Family member	71%	74%
Friend	12%	10%
Health provider	12%	10%
Appropriate message characteristics		
Q9 - Suitable language	100%	100%
Q10 - Texts were not too regular	94%	86%
Q11 - Program length (six months)	88%	78%
Q12 - Appropriate time of the day/night	100%	94%

[a] - Response rate for this survey was 73 out of 80 participants (91%), tailored text messages (n=43), non-tailored text messages (n=39).

** - $p<0.01$ between groups

Table 5. Acceptability and feasibility of ENTICE-CKD program at completion of phase 1 (intervention group): qualitative content analysis of semi-structured interviews (n=21)

Category	Attributes	Quote
Acceptability		
Acceptable alternative to clinic	- Overcomes clinic wait times, transport logistics - Flexibility of phone call appointment times - Preferred talking from a familiar environment and not feeling rushed - No identified disadvantages of telehealth communication vs face-to-face - Building rapport with coach	*"At home I'm more relaxed and I have the book in front of me and I was able to jot down anything that was important, if I was at the hospital there's so many people around and you don't feel very relaxed, you feel like everyone is listening to your conversation, so you don't say personal information"* Female, 69
Preference for voice communication	- More benefit from voice calls - Frequency of fortnightly phone calls	*"I found the calls better than the texts … they were more personable and kept me on track"* Female, 68
Regular contact via text message	- Text messages were an acceptable mode of communicating information - Preference for receiving text messages with personal encouragement *and* general tips - All text messages were acceptable	*"We solved a lot of my little issues, and it's given me a lot better understanding, and you know the more you think about it and communicate about it, ah the better it is"* Male, 71
Personalized messages valued	- Health professional expertise - Usefulness of coordinated nutrition advice - Removal of multiple conflicting nutrition recommendations	*"It's given me simple tasks, simple methods, or methodologies, to improve the situation, and they're not a whole lot of gobbledygook, just basic stuff that we can understand." Male, 65*
Feasibility		
Program integrated into lifestyle	- Length of phone calls easily accommodated - 12-week telephone intervention enough time for change - Self-monitoring the behavior of choice	*"As long as you're getting information backwards and forwards, that's the more important thing than the length of the call, it's what you're getting out of it"* Male, 78
Diverse delivery modes	- Active learning from a range of understandable delivery modes - Hard copy workbook as reference tool - Receiving explanations develops understanding and awareness of reasons for dietary change - Quantifiable dietary recommendations (food groups, "good vs bad" foods, portion sizes, sodium levels)	*"You've got to eat these foods, food groups and that, but you don't actually know the right quantities … this program shows it to you and it's like, it's teaching someone how to walk again"* Male, 46 *"The book I think was brilliant, because you've got that to go back through all the time, well any time you're doubtful you've got thoughts, you just look at the book, I did, I still do it"* Male, 64

Category	Attributes	Quote
Social accountability	- Supportive relationship with one coach allows progressive dietary change - Frequent reminders and reinforcing goals - Interaction with coach via text messages	*"If I didn't have the phone calls from* [my coach] *once a fortnight I probably wouldn't have taken it as serious as I have"* Male, 65 "*The support, even just texting and that, it's still, you know someone's doing it. It's, it just makes you feel better as a person, to know someone cares*" Male, 64
Responding to dietary advice	- Small changes at a time - Practical strategies, manipulating environment to support behaviors, skill development (label reading) - Setting goals and finding satisfaction in quantifiable outcomes (e.g. portion sizes, food group servings)	*"The program is delivered in segments, you're just having a bit of information at a time, so it's not overwhelming"* Female, 68 *"I was astounded at the salt content of it all, so when I read that I immediately stopped all salt that I put on my plate … I've not had salt since, so that was 3 months ago"* Male, 65
Infeasible elements beyond intervention	- Physical comorbidities a barrier for lifestyle component of program - Lack of support from others with poor understanding or low interest - Unstable or unsupportive environment for creating healthy habits	*"I have just been moving around a lot more and not in a stable environment of being in familiar surroundings, being unable to replicate … the menus … due to my transient nature of where I am presently"* Male, 46

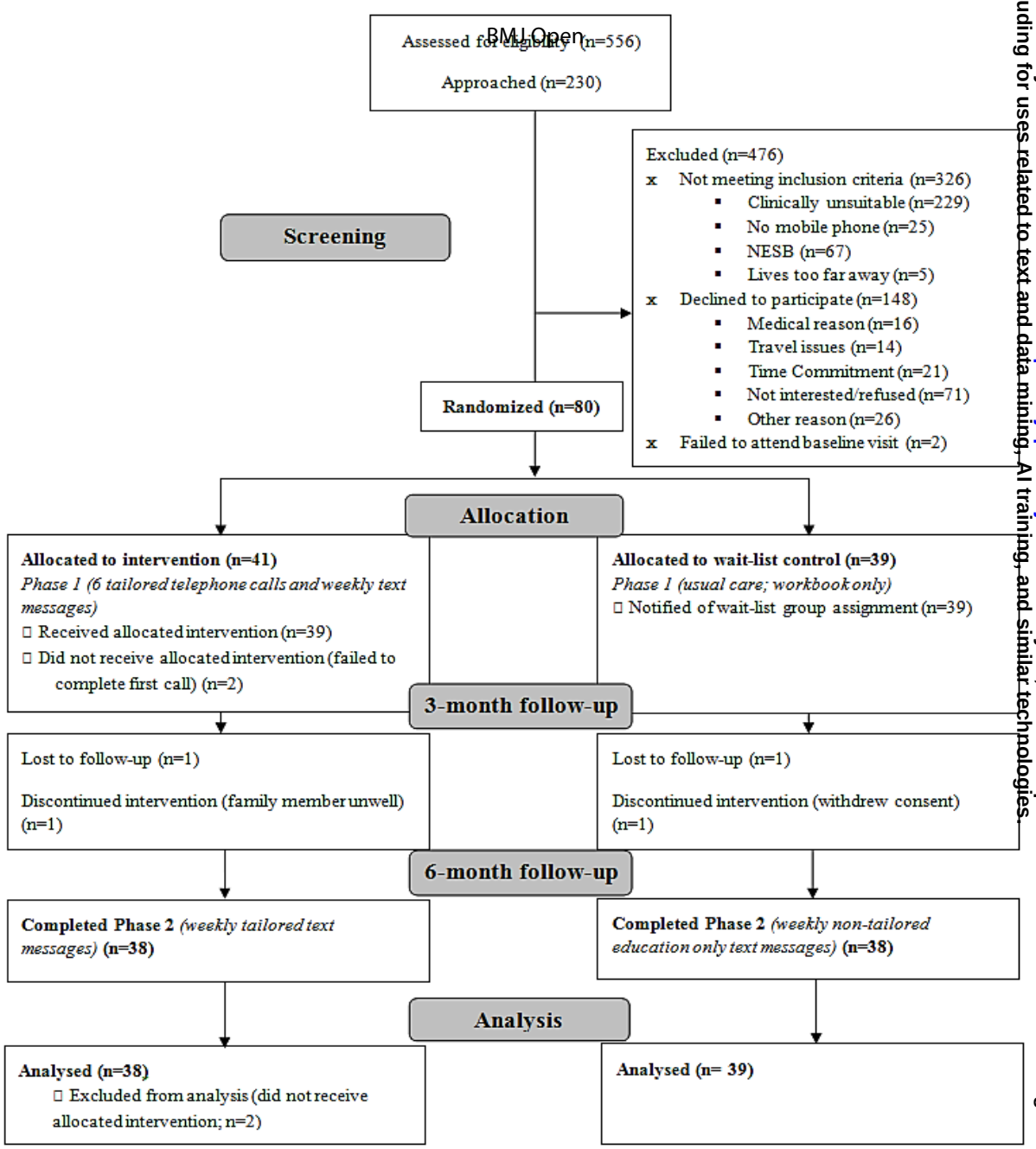

Figure 1. Consort flow diagram showing the flow of participants through the ENTICE-CKD study.

SUPPLEMENTARY MATERIALS

Supplementary Table 1. Dietary targets encouraged in the ENTICE-CKD intervention workbook, telephone calls and text messages[1,2].

Food group	**Dietary target** (serves/day)	**Considerations**
Grains/cereals	3-6 (>50% whole grain)	Replacing refined carbohydrates for wholegrain
Vegetables and fruit	5-7	Low potassium alternatives as appropriate
Low fat dairy	2	250mL milk, 40g cheese, 200g yoghurt
Lean meat, poultry and fish	<2 (130-200g)	Modified for protein (aiming for 1.0 g/kg/day)
Fats and oils	20 to 40g	Emphasise healthy oils
Dietary sodium	<100mmol/day (6g salt)	Replace takeaway and processed foods for fresh food and healthy cooking methods
Added sugars	<10% total calorie intake	
Discretionary choices	<2	Limit where possible

Abbreviations – g: grams, kg: kilogram, mL: millilitre.

Supplementary Table 2. Text messaging framework and related social cognitive theory constructs in the six month ENTICE-CKD trial.

			Schedule of Text Messages			
Text message type	**SCT construct** [a]	**Example text** [a]	Intervention group [b]		Control group [b]	
			Phase 1	Phase 2	Phase 1	Phase 2
Educational	Outcome expectations (providing information on consequence)	Dietary fibre intake reduces ur cholesterol levels and controls ur blood sugar. Include wholegrain breads & cereals, fruits & veg regularly	2-6	1-4	NA[c]	6-8
Self-monitoring	Self-regulation Assist with perceived impediments and facilitators of behavior	Hi [name], are you keeping track of ur fruit/vegetable intake every day? Remember ur goal to meet at least 5 serves this week	0-2	1-4	NA	NA
Goal check of behavioral goals	Self-regulation	Hi [name], did you reach ur goal to eat 5 fruits/vegetables 4 times this week? Text me back yes or no to let me know	2	2-4	NA	NA
Educational Permutations (Safety protocol)	Low potassium diet	Choose high fibre, low potassium breakfast cereals. Good choices are Multigrain Weetbix, Rolled Oats, Guardian, Oatbritz, Special K	0-2 [d]	0-2 [d]	NA	0-2 [d]

[a] Abbreviations: SCT: Social Cognitive Theory; Each text message utilized common abbreviations to reduce character counts. For example 'ur' refers to 'your', 'u' refers to 'you'.
[b] Phase 1 was from baseline to three months. Phase 2 was from three months to the six month study end-point
[c] NA = not applicable
[d] Educational permutations were only available for coaches to use if a participant experienced hyperkalaemia or hyperphosphataemia

Supplement Table 3. Utility and acceptability questionnaire completed at six months.

Thinking about the text message component of the ENTICE intervention; please answer the following questions (part A).
1. The text messages sent to me were useful in supporting me make a dietary change? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
2. The text messages sent to me were easy to understand? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
3. The text messages sent to me motivated me to change my diet ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
4. The text messages sent to me made me eat healthier? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
5. The text messages sent to me made me exercise more? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
6. How many of the text messages sent to you did you read? ○ All ○ Approximately three quarters ○ Approximately one half ○ Approximately one quarter ○ None
7. What did you do after receiving the text message? ○ Ignore it ○ Read and saved ○ Read and deleted

Thinking about the text message component of the ENTICE intervention; please answer the following questions (part B)
8. Did you share your text messages with family friends or your health care providers? ○ No ○ Yes; (please specify) ○ Spouse ○ Other family member ○ Doctor ○ Nurse ○ Other Health Care Professional
9. The text messages sent to me where worded in a suitable language ○ Yes ○ No
10. The text messages sent to me were too regular ○ Yes ○ No
11. The text message program (over 6 months) was long enough? ○ Yes ○ No
12. The text messages sent to me were at an appropriate time of the day/night? ○ Yes ○ No

Supplement Table 4. Semi-structured Interview Schedule.

Focus Point	*Key questions and prompts*
1. Warm Up, rapport building, experiences	I'm interested to hear about your story with a kidney condition. Would you be able to tell me about your story from when you first found out, how you felt and your journey up until now? - Can you tell me how you felt, or your initial reactions, when you were first diagnosed? - What was your experience with the healthcare system and dietitians before the ENTICE program? Can you talk me through how you got involved in the program? What happened? - How and why did you sign up? (Motivation? Knowledge? Priorities?) - Who influenced your decision to take part in the program? How? Why? - Did your doctor recommend the program? Did they have an influence on your decision to take part? (Support/pressure? Influence of medical professionals?) What happened after you signed up for the program? - Did you meet with a dietitian? How did you find that?
2. Barriers and facilitators of adherence to program	Before ENTICE, did you have any needs, challenges, concerns about diet? Could you briefly tell me about that? To what degree does the ENTICE program meet your needs or address what you want? How? Why? What do you like most/least about being involved in the program - why? What were some of the things that made the program easy/difficult to take part in? What are your thoughts on being in familiar surroundings while you're talking to [JK/MC]?
3. Telehealth delivery methods and frequency of contact	Let's move on to your experiences with the phone calls. - What did you expect from the calls and did they meet your expectations? - What are your thoughts on never having seen [JK/MC] and building a relationship with them? - How do you think using the telephone is different to seeing someone in person? Feel any different being in a familiar environment compared to a clinic? - Can you share some things that made the phone calls easier/harder than seeing [JK/MC] in person? - Were you able to make the calls at a suitable time - how? - What do you think about the frequency of the calls? – why? - How did you feel about the length of the calls? Did you feel you were rushed during the calls? - Do you have anything more to add about the phone calls? Let's talk about the text messages now, what did you think about getting the text messages from [JK/MC]? - Can you give me an example of a text message that you liked the most/least? - Do you think the text messages were necessary - why? - What do you think about how frequently you got the text messages? Why? - Do you have anything more to add about the text messages? You got a workbook at the start of the program. - What are your thoughts on the information in the workbook? – why? - Can you give me an example of something from the workbook that had an impact on you? (Why? Motivation? Knowledge?) - Did you have any difficulties understanding the information in the workbook? - Did you show the workbook to anyone? Who? Why? What did they think? - Do you have anything more to add about the workbook?
4. Usability of the program	Can you think of an example recommendation that [JK/MC] gave you about your diet or your lifestyle? - What are some things that helped you/made it hard for you to follow recommendations? – why?
5. Goal setting and self-monitoring	What are your thoughts on setting health goals? - How do you feel about goal setting? - Can you tell me about your experience with goal setting before the program? - Did you set goals in the program? When? Are you able to tell me about one of your goals? - Do you think ENTICE helped you to achieve your goals - why? One of the aims of ENTICE is to improve self monitoring –do you know what self-monitoring

	means? (Stuff you'll do without people reminding you, like writing down or taking note of what you eat or how active you've been) - Do you find you do that? Why? - What impact do you think the program has had on your self-monitoring? (The way you go about it? How often?) - How confident do you feel with monitoring your diet? Why?
6. Behaviour change	You have made some changes to your lifestyle in order to meet your goals [example] - Will these changes be something that you'll continue to do? – how? why? - Can you tell me about your motivation to make changes before the program? - How and why did your motivation change during the program? - How do you feel about keeping motivated after the program? Do you feel like your daily activities have changed since before the program? How? (Eating behaviour? Purchasing of foods? How physically active you are?)
7. Experiences	- Did you feel that the recommendations from [JK/MC] were specific to you and nobody else? - Can you give an example of when you felt this way? - Were the recommendations clear? How? Why? - Do you understand why the advice was given to you? - Do you think the program and the telephone sessions were suited to your culture? - Did you share your experiences with the program with anybody else? Family, friends, other health professionals? How? Why? Did you find it helpful? Imagine you became director of the hospital and you had the power to improve the services for people with kidney disease. What would be the top 2 changes you would make to improve the care and support for people with kidney disease?
8. Closing	We would like you to help us evaluate the program to help improve it and the difference it makes to patients. Is there anything that you think would be important to mention that we haven't covered?

Screening and recruitment

↓

Randomization

↙ ↘

	Week	**Intervention group**	**Control group**
Phase 1	1	Baseline Visit	
	2	6x fortnightly telephone calls + tailored text messages + workbook	Usual Care (workbook only)
	4		
	6		
	8		
	10		
	12	Mid-point visit + telephone call	
Phase 2	14	Tailored text messages	Educational non-tailored text messages
	16		
	18	Telephone call	
	20	Tailored text messages	
	22		
	24	End-point visit	

Supplementary Figure 1. Summary of ENTICE-CKD program delivery.

References for supplementary material

1. Pollock C, Voss D, Hodson E, Crompton C, Caring for Australasians with Renal Impairment. The CARI guidelines. Nutrition and growth in kidney disease. *Nephrology*. 2005;10 Suppl 5(2005 Dec):S177.
2. NHMRC. Australian Dietary Guidelines. In. Canberra: National Health and Medical Research Council, Department of Health and Ageing; 2013.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	NA; abstract and method
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4-5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6-7
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7-8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	11
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8-12
	11b	If relevant, description of the similarity of interventions	8-11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13-14
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	15-16
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Results and tables
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	NA
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21-22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	21-22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-22
Other information			
Registration	23	Registration number and name of trial registry	5 & 7
Protocol	24	Where the full trial protocol can be accessed, if available	5 & 7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title page

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Feasibility and Acceptability of a Telehealth Coaching to Promote Healthy Eating in Chronic Kidney Disease: A Mixed Methods Process Evaluation

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Feasibility and Acceptability of a Telehealth Coaching to Promote Healthy Eating in Chronic Kidney Disease: A Mixed Methods Process Evaluation

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Conflict of interest

The authors declare that they have no conflicts of interest.

Author contributions

JK wrote the first draft of the manuscript and takes responsibility for the integrity of the data. JK, KC, DJ, MR and SP assisted in the conceptualization of the trial design. MW & DR were responsible

for the qualitative data collection and analysis, assisted in the conceptualization of the qualitative research methods. MW wrote the qualitative results section of the manuscript. JK & MC designed the intervention materials and were responsible for the management of the trial at their respective sites. TH, JC and AT provided methodological expertise and revised drafts of the manuscript. All authors contributed to revisions of the manuscript and approved the final version for submission. Jaimon Kelly is the guarantor and affirms that the manuscript is an honest, accurate, and transparent account of the study being reported.

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ABSTRACT

Objective: To evaluate the feasibility and acceptability of a personalized telehealth intervention to support dietary self-management in adults with stage 3-4 CKD.

Design: Mixed-methods process evaluation embedded in a randomized controlled trial.

Participants: People with stage 3-4 CKD (eGFR 15-60mL/min/1.73m^2).

Setting: Participants were recruited from three hospitals in Australia and completed the intervention in ambulatory community settings.

Intervention: The intervention group received one telephone call per fortnight and 2-8 tailored text messages for three months, and then 4-12 tailored text messages for three months without telephone calls. The control group received usual care for three months then non-tailored education-only text messages for three months.

***Main outcome measures*:** Feasibility (recruitment, non-participation and retention rates, intervention fidelity, and participant adherence) and acceptability (questionnaire and semi-structured interviews).

Statistical analyses performed: Descriptive statistics and qualitative content analysis.

Results: Overall, 80/230 (35%) eligible patients who were approached consented to participate (mean±SD age 61.5±12.6 years). Retention was 93% and 98% in the intervention and control groups, respectively, and 96% of all planned intervention calls were completed. All participants in the intervention arm identified the tailored text messages as useful in supporting dietary self-management. In the control group, 27 (69%) reported the non-tailored text messages were useful in supporting change. Intervention group participants reported that the telehealth program delivery methods were practical and able to be integrated into their lifestyle. Participants viewed the intervention as an acceptable, personalized alternative to face-face clinic consultations, and were satisfied with the frequency of contact.

Conclusions: This telehealth-delivered dietary coaching program is an acceptable intervention which appears feasible for supporting dietary self-management in stage 3-4 CKD. A larger-scale

randomized controlled trial is needed to evaluate the efficacy of the coaching program on clinical and patient-reported outcomes.

***Trial registration*:** Prospectively registered (ACTRN12616001212448)

Article Summary

- This study utilized a pragmatic design which enhanced its feasibility.
- Mixed methods captured both quantitative and qualitative data to determine multiple aspects of feasibility and acceptability.
- Interview data to determine the intervention's acceptability were not captured in control group participants.

INTRODUCTION

Chronic kidney disease (CKD) is a progressive condition affecting over 10% of the population worldwide.[1] 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.[2] This includes the provision of pragmatic, person-centred interventions to support dietary behaviour change.

Diet is a modifiable risk factor for the progression of CKD to end-stage kidney disease (ESKD).[3 4] 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.[5] 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.[6] A focus on foods rather than single nutrients may also facilitate increased adherence to dietary change in people with CKD[6 7] which is otherwise challenging due to dietary complexity and competing demands of other medical and lifestyle self-management.[8] Overcoming these challenges to implementing sustained dietary change is necessary to test whether improving diet quality alters patient-centred outcomes.

Providing regular and individualized dietary support required for those with CKD comes with geographical, time and financial barriers.[9] Furthermore, addressing diet quality requires more frequent and repetitive support that most health services are unable to provide. To determine whether increasing diet quality (through dietary pattern) may attenuate the progression of CKD and elevated cardiovascular risk on a sufficient scale for a randomized controlled trial (RCT), alternative modalities that are effective in supporting dietary management are needed. Telehealth modalities, particularly telephone-based and text message coaching, present an opportunity to overcome barriers and challenges that people with CKD encounter in accessing health care services.[8 10] Telehealth

interventions may facilitate an increased frequency and quality of contact between the patient and healthcare professional,[11] [12] which may improve acceptability, uptake and adherence to interventions[13] and better align with a patient-centred model of care and reflect the needs of people with CKD.[10] 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.[11] 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.[14-16] Text messaging has been utilized to 'extend contact' after an intervention and has been shown to maintain clinical outcomes and minimize intervention decay.[17] [18] A systematic review of text message health interventions highlighted the need for better evidence on the relative effectiveness of text-based interventions including the level of tailoring of text message delivery (incorporating frequency and timing), level of interaction (i.e. response and feedback) and impact of additional interventions (such as a combination with telephone, face-to-face, video or internet).[19]

While dietary patterns aligned with a higher diet quality are associated with lower mortality in CKD,[6] the level of tailoring and individualised coaching required to achieve and support dietary self-management is unknown. Non-CKD trials have demonstrated effectiveness for minimally tailored text messages,[20] information-only text messages and tailored interactive text messages.[21] 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.

MATERIALS AND METHODS

We used a mixed-methods design in this pilot study, whereby qualitative data on the patient experiences were embedded within quantitative data relating to participants recruited into the Evaluation of iNdividualized Telehealth Intensive Coaching to promote healthy Eating and lifestyle in Chronic Kidney Disease (ENTICE-CKD) program. All data were prospectively collected. This pilot randomized controlled trial was prospectively registered (ACTRN12616001212448) and reported based on the extension of the CONSORT statement for feasibility and pilot studies.[22] This trial was approved by the Metro South Health Service District Human Research Ethics Committee (EC00167) and Bond University Human Research Ethics Committee (EC00357).

Design

This mixed-methods process evaluation was embedded in a randomized controlled trial, conducted from November 2016 to November 2017. The dietary intervention was designed using the social cognitive theory,[23] with a patient-centred focus on improving self-management to reduce dietary sodium intake (<2300mg/day) and increase dietary quality in accordance with the Australian Dietary Guidelines (see Supplementary Table 1 for intervention guidance).[24] The constructs of the social cognitive theory most utilised 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 small, achievable goals, celebrating success, encouraging self-monitoring and prompting problem solving in calls and text messages). Interventions were adjunct to usual nephrology care from treating physician(s) and renal team members, including ad hoc referrals to allied health practitioners during the study.

Participants

Participants were recruited from three tertiary nephrology units in Queensland, Australia over a six month period. Inclusion criteria were: adults over 18 years of age; stage 3-4 CKD (eGFR 15-60mL/min/1.73m^2); and access to a mobile device capable of receiving text messages and telephone calls. Exclusion criteria were: anticipated dialysis commencement or kidney transplant within the

following 12 months; pregnancy; non-English speaking; cognitively impaired; or deemed unfit to participate by their treating nephrologist.

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.

Eligible participants were randomized on a 1:1 ratio into one of two groups (stratified by recruiting site (site A, B, C) and presence of diabetes (Yes, No) in blocks of 8's). Randomization was completed by computer-generated random numbers carried out by an independent statistician not involved in the study.

Study treatment

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 2. Details about the intervention fidelity TIDieR items (11 and 12) is described and reported throughout this paper and is not summarised in Supplemental Table 2. Each participant was involved in the trial for six consecutive months. All participants were provided with an ENTICE-CKD workbook at the baseline visit. The 90-page workbook included information on setting *specific, measurable, achievable, realistic, and time-bound* (SMART) goals; eating well for kidneys (based on the Australian Dietary Guidelines [Supplementary Table 1]);[24] active living (based on the Australian Physical Activity Guidelines);[26] role of diet in kidney disease, strategies for planning, self-monitoring checklists, and a list of useful websites, apps, and recipes for further reference.

Telehealth coaches

Each participant was assigned to one of two telehealth coaches at baseline. The participant had the same coach for the duration of the program. Both telehealth coaches were registered dietitians (Australian equivalent) with additional training in renal nutrition, behaviour change and motivational interviewing; were external to the recruiting sites and had never met the participants; and were not involved in any outcome data collection.

Phase 1

The participants in the intervention group received six fortnightly telephone calls in phase 1 which were scheduled on weekdays at a time of the participants choosing (from 7am to 7pm). The first call was scheduled for 45 minutes and five subsequent for approximately 30 minutes. Each call was based on established protocols and call scripts. The telephone call content was guided by the workbook topics, structured according to the 5A's framework (Assess, Advise, Agree, Assist, Arrange),[27] and individually tailored to participants using relevant educational strategies, and in consideration of the participant goals and co-morbidities. Where required, 24-hour dietary recalls were undertaken during coaching calls to track adherence and progress with goals. Coaches used Microsoft Excel[28] to document progress of each call and log information including goal setting, implementation intentions, self-monitoring tools, call attempts and durations, and text message preferences.

In addition, participants in the intervention group received two to eight text messages scheduled between coaching calls with the actual number and time of day determined by each participant's preference. Text categories included: educational; self-monitoring; and goal setting. The schedule of text messages for the intervention and control group in phase 1 and 2 is detailed in Supplementary Table 2. The text messages were sent using a web-based, semi-automated text message management platform (Propelo, www.propelo.com.au), developed and administered by The University of Queensland's School of Public Health.[29] The investigators, in consultation with local nephrologists, dietitians and evidence-based practice guidelines, designed the library of text messages, which were

then reviewed for comprehension by a group of patients, nephrologists and members of the investigator team. 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. These tailoring variables were collected and modified as required by the coaches following the initial and subsequent coaching calls.

As shown in Supplementary Table 2, participants in the intervention group could receive one 'goal check' per goal (total 2 goal checks) per fortnight in phase 1 and up to 2 goal checks per goal (total 2 to 4 goal checks) per fortnight in phase 2. These goal checks required the participant to respond to the text with a "yes" or "no" which prompted the software to send a pre-determined response. An incoming text reply outside protocol (i.e. not a "yes" or "no" response) was classified as an 'unrecognized response'. This triggered an email to the participant's coach and was only responded to where participants expressed considerable risk to their health (e.g. symptoms needing medical attention).

Participants in the control group received no coaching or text messages between the baseline visit and three months (phase 1). The control group continued to receive standard care under their treating nephrologist (typically 1 clinic visit every 3 months) and were encouraged to work through the ENTICE-CKD workbook at their own pace.

Phase 2

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. At 18 weeks (i.e. half way through phase 2), participants received a second tailoring call where they could modify the timing and frequency of text messages and could update their goals. Intervention

group participants chose text message frequencies (four to 12 text messages per fortnight) for the same types of texts that they received in phase 1 (educational tips, self-monitoring, goal checks). Participants in the control group received non-tailored education-only text messages (described in Supplementary Table 2) 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.

Data collection

Basic demographic data (including participant's age and gender) were recorded at baseline. Socio-economic status was estimated from participants' postcodes, according to the Index of Relative Socio-economic Advantage and Disadvantage (IRSAD).[30] Baseline health literacy was collected using the single item Literacy Screener which classifies health literacy as good or limited based on the single question, "How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?".[31]

Reach and retention

The sample size was determined for the purpose of informing a future study. Therefore, a target of 30-40 participants per arm was set to allow for meaningful and reliable data, which could be used to power future trials.[32] Recruitment and non-participation rates were captured across the three recruitment sites, with a goal to achieve the target sample size of 80 participants in the six month recruitment time frame. Retention rate was measured at three and six months in both study groups, with successful retention defined 80% at the six-month study end.

Intervention delivery

Individual cases were discussed fortnightly between the coaches and the lead investigator to support consistent intervention delivery. 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[28] 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.

Intervention adherence

Adherence was defined as successfully completing five of the six telephone calls for the intervention group. Data were also collected on individual participant adherence to the dietary intervention, collected by coaches in each telephone call using a call log template in Microsoft Excel.[28] In the call logs, coaches described evidence of the participant's overall progress, evidence of self-monitoring, goals set and implementation intentions (behaviours implemented to achieve goals) during each call, which was quantified in counts to capture participant adherence.

Acceptability

A utility and acceptability survey of the text message component of the ENTICE-CKD trial was collected from all participants at the six-month end of study visit (Supplementary Table 3). The survey included 13 items, developed specifically for the study, with five items asking participants to rate on a 5-point Likert scale from 1 'strongly disagree' to 5 'strongly agree', four items asking participants yes/no questions, and four multiple choice questions, based on previous methodology in cardiac patients.[20] In addition to this, during the sixth telephone call (three-month study mid-point; for intervention participants only), coaches obtained verbal consent of participants to be approached to complete an interview relating to their experiences of the intervention.

Semi-structured interviews were conducted in-person and by telephone. Participants were recruited based on consecutive sampling of completing participants until data saturation was achieved. The interviews were conducted by investigator (MW), who had not previously met the participants and was not involved in the planning of the intervention. The interview guide included questions on:

barriers and facilitators of program adherence; telehealth delivery methods and frequency of contact; usability of the program; goal setting, self-monitoring, behaviour change; and experiences (Supplementary Table 4). Modification of the interview guide occurred after each interview to broaden scope of the data collected. Interviews were audio-recorded and transcribed verbatim.

Patient involvement

The study was designed in collaboration with similar participants as those recruited for this study. This patient engagement was conducted as a qualitative study, reported elsewhere by the investigators[10] and details the patient reported burden associated with following dietary recommendations that were considered while developing this trial. All intervention materials, including the workbook and text messages, were reviewed by people with CKD with feedback forms which were used to revise all the material before production. No patients were involved in the recruitment or data collection of this process evaluation study. A summary of the main results will be mailed out to participants. The burden of the trial has been evaluated in semi-structured interviews (Warner et al, patients' experiences and perspectives of the acceptability of telehealth coaching to improve diet quality in chronic kidney disease: a qualitative interview study).

Data analysis

Quantitative data were analysed using simple descriptive statistics (counts and percentages). To determine the difference in the utility and acceptability between the two study groups, a standard Chi square test was used with a significance level determined as $p< 0.05$. Statistics were conducted in SPSS Statistics for Windows (version 22.0. Chicago: SPSS Inc.) and Microsoft Excel.[28]

Inductive content analysis[33] of the semi-structured interview transcripts regarding acceptability of the intervention was conducted researcher (MW) who was not involved in quantitative data planning, collection and analysis. After familiarization with the data, an open coding approach was adopted to identify, develop and finalize categories and subcategories within the data. A dietitian and qualitative researcher (DR) familiar with the data then finalized and confirmed emerging categories that were

relevant to the process evaluation. Verbatim quotes were collected and used to represent attributes demonstrated for both the feasibility and acceptability of the ENTICE-CKD program. Microsoft Word[34] was used to facilitate data management (tables) and basic content analysis (comments relating to attributes demonstrating feasibility and acceptability) of data.

RESULTS

Characteristics of participants

The baseline characteristics of the participants are reported in Table 1. Of the 80 participants who completed their baseline visit, 64% were men and had a mean age of 62 years. The stage of CKD varied within the sample, with 31% stage 3a (eGFR 45-59ml/min/1.73m^2), 44% stage 3b (eGFR 30-44ml/min/1.73m^2) and 25% stage 4 (eGFR 15-29ml/min/1.73m^2). The most common comorbidities were hypertension (81%) and diabetes (39%) (Table 1). Baseline health literacy was good in over 90% of all participants. Baseline characteristics were well balanced across the two groups, suggesting randomisation was effective.

Reach and retention

Participants were recruited between November 2016 and May 2017, from Gold Coast (43%), Sunshine Coast (31%) and Brisbane (26%) hospitals. The flow of participants through the ENTICE-CKD study is shown in Figure 1. A total of 230 potentially eligible individuals were approached and invited to participate, of whom 80 participants (35%) were recruited to the ENTICE-CKD trial. Of the 146 individuals who declined to participate, "not interested" was the most commonly stated reasons for non-participation (36%) followed by perceived excessive time commitment (16%), having other medical conditions which are 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.

Seventy-six (95%) of all randomly allocated participants completed the six-month telehealth program. A total of four (5%) participants withdrew from the study. All the withdrawals occurred in the first three months of the program. Three of the four participants who withdrew were from the

intervention group (two were unable to be contacted and therefore did not commence the program, and one participant was unable to continue due to a family illness). The sole participant who withdrew from the control group did not report a reason for doing so. There were no appreciable differences in the demographics of those participants who dropped out compared to those remaining in the trial.

Intervention delivery

Table 2 shows the adherence to the planned delivery of the telephone and text message components of the ENTICE-CKD intervention. The delivery of the scheduled telephone calls was conducted according to protocol with 90% of planned calls being completed as scheduled. The mean duration of the first intervention call was 45.5±10 minutes (range 28 to 75 minutes). The mean length of the subsequent five calls was 24±10 minutes (range 2 to 62 minutes).

A total of 4,985 intervention text messages were sent to ENTICE participants. The median number of text messages sent to participants was within protocol for both groups, with intervention participants receiving a median of four text messages per fortnight in phase 1 and seven per fortnight in phase 2. Control participants received a median of six non-tailored education-only text messages per fortnight in phase 2 (Table 2). The total number of incoming text messages (replies from participants) was 1,100 (Table 2), 36% (n=400) triggered the appropriate goal-check reply, 3% (n=31) required the dietitian coach to send a tailored text message to address the concern raised by the sender and 61% (n=669) required no reply.

Intervention adherence

A total of 38 participants (95%) completed at least five calls, and 36 (90%) completed all six calls. Two participants (5%) never received a telephone call. Goal setting was completed by all participants in the first call as planned, with 95% of the participants setting two or more goals. The coaches' call logs showed that, throughout the program, participants continued setting new goals with 10 (26%) updating at least one goal in call two and 22 (61%) updating at least one goal throughout the

remaining four calls (Table 3). A total of 29 (76%) participants showed evidence of self-monitoring by the second call, which was sustained throughout phase 1 of the intervention. Evidence of implementation intentions indicated that the majority of participants (82%) needed at least two calls to begin putting planned dietary intentions in place. This number continued to rise over the next four calls to 97% by the end of phase 1 of the intervention.

Acceptability

Utility and acceptability

There were several differences in ratings for utility and acceptability between the intervention (tailored-text) group compared to the non-tailored education-only text message (control) group (Table 4). Participants agreed (responses for 'agree' and 'strongly agree') that the text message component: supported their dietary self-management (intervention 100%; 69% control, p=0.003); provided motivation to change their diet (intervention 75%, control 50%; p=0.03); and led them to a healthier diet (intervention 81%, control 61%, p=0.06). There were no other differences observed in the utility of the text messages between the groups. The majority of text messages were saved and not deleted (77% overall), and 62% were shared with family, friends or health care providers across the two study groups. 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.

Attributes of feasibility and acceptability

Twenty one intervention participants were interviewed upon completion of phase 1, either by telephone (n=20) or face-to-face (n=1). Interviews ranged from 20 to 96 minutes (mean 49 min). Overall, participants had positive experiences with the ENTICE-CKD trial. Attributes of the discussions are described in nine categories within components of acceptability and feasibility (Table 5). The acceptability categories discussed by participants were: acceptable alternative to clinic,

preference for voice communication, regular contact via text message, and personalized messages valued. The categories described under feasibility were: program integrated into lifestyle, diverse delivery modes, social accountability, responding to dietary advice, and infeasible elements beyond intervention. Participants emphasized the importance of social accountability; all participants expressed benefit from the relationship built with their coach. Participants identified benefits from telehealth delivery of the intervention, with the majority expressing preference for telehealth over face-to-face interventions. 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. Messages that were perceived to be personalized were preferred for both calls and text messages. Participants felt that receiving information via more than one delivery mode was helpful for making diet changes. Some participants discussed challenges which were not addressed by the ENTICE-CKD intervention, such as participants not being easily able to implement routine dietary behaviours whilst travelling, or those lacking social support outside of the program.

DISCUSSION

This mixed methods process evaluation study within a randomized controlled trial evaluated the feasibility and acceptability of the ENTICE-CKD telehealth coaching program to promote healthy eating among people with moderate CKD. The ENTICE-CKD program was a feasible intervention that was delivered according to protocol and enabled participant adherence. The tailored telephone calls and text messages were acceptable to intervention participants in this pilot. In contrast, the acceptability varied for those in the non-tailored education-only text message (control) group. The ENTICE-CKD program made participants feel supported and motivated for dietary self-management. However, this was more strongly indicated by participants who received the tailored intervention program, as opposed to the control group who received non-tailored education-only text messages. These results suggest that a tailored approach to text messaging may be important to people with CKD, as it may facilitate the support and regular interaction for dietary changes[8] Participants felt that the frequent contact via calls and text messages reinforced rapport and built a supportive relationship between participant and coach, which in turn, enabled stronger social accountability and progressive dietary change.

The successful recruitment and retention of participants enrolled in the ENTICE trial demonstrated feasibility. Although it is important to consider the trial only had a 35% recruitment rate, the feasibility was strengthened by the successful recruitment in the anticipated six-month recruitment period and very low attrition rate (5%) at six-months. Attrition is a common problem in studies of self-management in CKD, which is reported as between 11 to 39%, and which reduces the generalizability of findings, particularly given the often underpowered sample sizes of trials of lifestyle interventions in CKD.[35]

The intensive coaching intervention had a high call completion rate (90%) and high intervention adherence. This is similar to the 90% call completion rates reported in other telehealth studies in

weight management,[36] breast cancer,[37] younger adults in the general population,[38] and CKD studies.[39] A study involving 436 participants with CKD in the UK, who received a combination of interactive web-based resources and telephone follow-up demonstrated successful recruitment, retention and intervention satisfaction.[39] There was no specific dietary education provided to participants in that study, however the community support intervention, provided through a workbook, online portal, and telephone follow-up demonstrated a 69% recruitment rate, and had 85% retention at the six-month follow up. Participants reported over 80% usefulness for the workbook, 62% for the telephone calls and 23% for the interactive website.[39] Considering the limited evidence on lifestyle interventions in CKD specifically, the findings from this trial support the feasibility of using telehealth coaching to support dietary self-management of CKD. The major difference between the study conducted by Blakeman and colleagues[39] and the ENTICE-CKD study was that recruitment occurred in general practices compared to 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.[10] 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%).

Overall, there is limited evidence on the acceptability of telehealth dietary interventions in CKD.[40] A pilot study in 47 CKD participants demonstrated over 80% user adherence and satisfaction with a smart-phone self-management support program to support the self-monitoring of blood pressure, medications, symptom recognition, and biochemistry.[41] In contrast, another study found that text-message based interventions were the least preferred telehealth intervention for medication monitoring by CKD participants, compared with web-based or personal digital assistant-based applications.[42] The Effects of Sodium Modification on Outcome (ESMO) study, a three-month self-management intervention in 138 adults with CKD which provided one-to-one sessions and telephone support, demonstrated relatively high (63%) satisfaction from participants. It has been postulated that a key factor for the high acceptability of the ESMO intervention was the patient-engagement utilized

in the design of the trial.[43] This was an approach also taken in the ENTICE-CKD study. We have previously found that patients with CKD have been confused by dietary advice and need more frequent contact to support dietary change.[10] They were willing to participate in telephone calls and receive text messages, as these were viewed within their comfort zone and levels of digital literacy,[10] but also raised concerns about the credibility, safety, and lack of personalization in mobile apps and internet modalities. The ENTICE-CKD program was developed from the key results in this focus group study, which assured a patient-centred approach.[44]

Previous thematic synthesis has shown that people with CKD experience many challenges in relation to achieving their dietary and fluid recommendations. People express a preference for regular coaching, feedback and monitoring to help them understand dietary information and become confident in their ability to self-monitor and manage such changes.[8] 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.

There are limitations to this study. As we had a 35% recruitment rate, the feasibility and acceptability only relate to the participants enrolled in this pilot, thus the feasibility for the uptake of the program and its generalizability in clinical practice are unknown. 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.[45] While other demographics of the people who participated in the ENTICE-CKD study were broadly representative of the CKD demographic reported in international comparisons,[46-48] we note that previous work has shown that approximately 20-25% have low health literacy,[49] 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.[50] 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.[51] We also acknowledge that we captured the individual participant adherence to the intervention using qualitative methods rather than validated surveys. However, given the primary outcome of feasibility, qualitative methods were used to minimize the over-use of self-report surveys and participant burden and this was an exploratory measure of intervention adherence only. Using this method, we were able to capture to reasons for adherence (and non-adherence). We also did not recruit children into the ENTICE-CKD study, so our results are not generalizable to children with CKD. Finally, we did not interview participants in the non-tailored education-only (control) group, and thus could not ascertain the reasons for lower acceptability compared with the intervention group.

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.

In conclusion, the ENTICE-CKD dietary coaching program is a feasible and acceptable intervention for adults with stage 3-4 CKD. The program facilitated self-monitoring and encouraged the adoption of goal setting throughout the intensive coaching period. Findings from this study are promising for the use of telehealth to modify dietary practices in future clinical practice and research. However, longer-term studies are needed to determine the safety, clinical effectiveness, and sustainability before the wider implementation of the ENTICE-CKD program is appropriate. This process evaluation can be used by clinicians to inform frequent and structured contact through telephone-based and text message platforms to support the complex dietary self-management required for people with CKD.

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Table 1. Demographics of participants whom completed the six month ENTICE-CKD pilot study.

Characteristic	**Intervention group** (n=41)	**Control group** (n=39)
Male, n (%)	**26 (63%)**	**25 (64%)**
Age (years)	**62.0 ± 12.0**	**61.1 ± 13.3**
Stage of chronic kidney disease		
3a	10 (25%)	15 (38%)
3b	19 (46%)	16 (41%)
4	12 (29%)	8 (21%)
Body Mass Index, kg/m^2	33.4 ± 6.7	31.0 ± 6.4
Hypertension	34 (83%)	31 (80%)
Diabetes	15 (37%)	16 (41%)
Active smoker status	21 (51%)	16 (41%)
Ethnicity		
Asian	2 (5%)	1 (3%)
Caucasian/European	37 (91%)	32 (82%)
Indigenous	1 (2%)	0
Other	1 (2%)	6 (15%)
Education		
Lower than 10th grade	17 (42%)	12 (32%)
Up to 12th grade	4 (10%)	10 (26%)
Tertiary educated	20 (47%)	16 (41%)
Socio-economic status		
High	27 (66%)	25 (64%)
Health Literacy		
Good	37 (90%)	36 (92%)

Table 2. Delivery and response of fortnightly telephone calls and text messages in ENTICE-CKD.

	Intervention group		Control group
TELEPHONE CALLS	Phase 1	Phase 2	Phase 2
Planned	234	-	-
Actual	225	-	-
Call attempts	290	-	-
Missed calls, n (%)	9 (3)	-	-
Duration of initial calls, mins (mean± SD)	45±10	-	-
Duration of follow up calls, mins (mean ± SD)	24±10	-	-
Call scheduling text messages outgoing	245	57	0
TEXT MESSAGES – outgoing			
Total intervention texts sent, per fortnight	1371	1980	1634
Educational[a], median(range)	2(0-6)	4(0-8)	6(0-13)
Goal check[b], median(range)	2(0-4)	3(0-5)	-
Self-monitoring[c], median(range)	0(0-2)	2(0-5)	-
TEXT MESSAGES – incoming			
Total text responses	437	608	55
Recognized goal check responses, n (%)	174 (39.8)	226 (37.2)	0
Unrecognized responses	263	382	55
Requiring tailored text reply from coach, n (%)	7 (2.7)	18 (4.7)	2 (3.6)

[a] Outcome expectations (providing information on consequence)
[b] Self-regulation
[c] Self-regulation (facilitate planned behaviour change)

Table 3. Participant adherence to the ENTICE intervention[a].

Adherence	Call 1	Call 2	Call 3-6
Total planned calls	39	39	156
Calls delivered, n (%)	39 (100)	38 (97)	148 (95)
Number of missed calls, n (%)	0	1 (3)	8 (5)
Due to withdrawal from trial			2 (1)
Due to travel			2 (1)
Other[b]		1 (3)	4 (3)
Goal setting, n (%)	38 (100)	10 (26)	23 (61)
1 goal	2 (5)	8 (21)	12 (32)
2 goals	36 (95)	2 (5)	7 (18)
3 goals	N/A[c]	N/A[c]	1 (3)
4 goals	N/A[c]	N/A[c]	3 (8)
Self-monitoring, n (%)	22/38 (58)	29/38 (76%)	29/38 (76)
Implementation intentions, n (%)	14 (37)[d]	31 (82)	37 (97)
Yes	24 (63)[d]	7 (18)	1 (3)
No			

[a] – Data are presented as *n (%)*.

[b] – 1 participant decided to get tailored text messages only following call 1

[c] - In each call only 2 goals could be set or updated.

[d] - Implementation intentions were not expected to be evident in the first call

Table 4. Utility and acceptability of ENTICE-CKD text messages by participant group[a].

Characteristic	Tailored text messages	Non-tailored text-messages
Usefulness and understanding		
Q1 - Useful in supporting dietary change	100%	69%**
Q2 - Messages were easy to understand	100%	100%
Influence on motivation and behaviour change		
Q3 - Messages motivated change	75%	50%**
Q4 - Healthier diet due to messages	81%	61%
Q5 - Exercise increased due to messages	38%	33%
Message saving and sharing		
Q6 - Percent of messages read	100%	100%
Q7 - Saved messages	81%	72%
Q8 - Shared messages	56%	67%
Family member	71%	74%
Friend	12%	10%
Health provider	12%	10%
Appropriate message characteristics		
Q9 - Suitable language	100%	100%
Q10 - Texts were not too regular	94%	86%
Q11 - Program length (six months)	88%	78%
Q12 - Appropriate time of the day/night	100%	94%

[a] - Response rate for this survey was 73 out of 80 participants (91%), tailored text messages (n=43), non-tailored text messages (n=39).

** - $p<0.01$ between groups

Table 5. Acceptability and feasibility of ENTICE-CKD program at completion of phase 1 (intervention group): qualitative content analysis of semi-structured interviews (n=21)

Category	Attributes	Quote
Acceptability		
Acceptable alternative to clinic	- Overcomes clinic wait times, transport logistics - Flexibility of phone call appointment times - Preferred talking from a familiar environment and not feeling rushed - No identified disadvantages of telehealth communication vs face-to-face - Building rapport with coach	*"At home I'm more relaxed and I have the book in front of me and I was able to jot down anything that was important, if I was at the hospital there's so many people around and you don't feel very relaxed, you feel like everyone is listening to your conversation, so you don't say personal information"* Female, 69
Preference for voice communication	- More benefit from voice calls - Frequency of fortnightly phone calls	*"I found the calls better than the texts ... they were more personable and kept me on track"* Female, 68
Regular contact via text message	- Text messages were an acceptable mode of communicating information - Preference for receiving text messages with personal encouragement *and* general tips - All text messages were acceptable	*"We solved a lot of my little issues, and it's given me a lot better understanding, and you know the more you think about it and communicate about it, ah the better it is"* Male, 71
Personalized messages valued	- Health professional expertise - Usefulness of coordinated nutrition advice - Removal of multiple conflicting nutrition recommendations	*"It's given me simple tasks, simple methods, or methodologies, to improve the situation, and they're not a whole lot of gobbledygook, just basic stuff that we can understand." Male, 65*
Feasibility		
Program integrated into lifestyle	- Length of phone calls easily accommodated - 12-week telephone intervention enough time for change - Self-monitoring the behavior of choice	*"As long as you're getting information backwards and forwards, that's the more important thing than the length of the call, it's what you're getting out of it"* Male, 78
Diverse delivery modes	- Active learning from a range of understandable delivery modes - Hard copy workbook as reference tool - Receiving explanations develops understanding and awareness of reasons for dietary change - Quantifiable dietary recommendations (food groups, "good vs bad" foods, portion sizes, sodium levels)	*"You've got to eat these foods, food groups and that, but you don't actually know the right quantities ... this program shows it to you and it's like, it's teaching someone how to walk again"* Male, 46 *"The book I think was brilliant, because you've got that to go back through all the time, well any time you're doubtful you've got thoughts, you just look at the book, I did, I still do it"* Male, 64

Category	Attributes	Quote
Social accountability	- Supportive relationship with one coach allows progressive dietary change - Frequent reminders and reinforcing goals - Interaction with coach via text messages	*"If I didn't have the phone calls from* [my coach] *once a fortnight I probably wouldn't have taken it as serious as I have"* Male, 65 "*The support, even just texting and that, it's still, you know someone's doing it. It's, it just makes you feel better as a person, to know someone cares*" Male, 64
Responding to dietary advice	- Small changes at a time - Practical strategies, manipulating environment to support behaviors, skill development (label reading) - Setting goals and finding satisfaction in quantifiable outcomes (e.g. portion sizes, food group servings)	*"The program is delivered in segments, you're just having a bit of information at a time, so it's not overwhelming"* Female, 68 *"I was astounded at the salt content of it all, so when I read that I immediately stopped all salt that I put on my plate … I've not had salt since, so that was 3 months ago"* Male, 65
Infeasible elements beyond intervention	- Physical comorbidities a barrier for lifestyle component of program - Lack of support from others with poor understanding or low interest - Unstable or unsupportive environment for creating healthy habits	*"I have just been moving around a lot more and not in a stable environment of being in familiar surroundings, being unable to replicate … the menus … due to my transient nature of where I am presently"* Male, 46

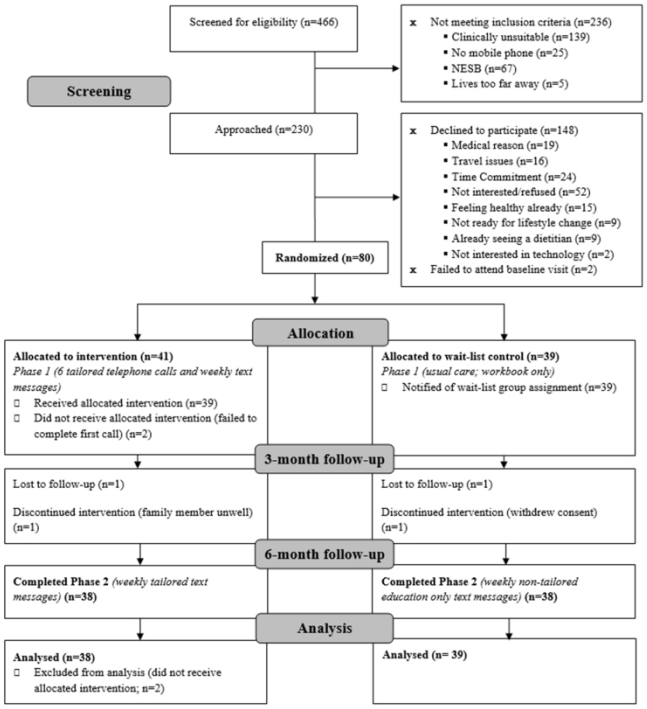

Figure 1. Consort flow diagram showing the flow of participants through the ENTICE-CKD study.

Figure 1

254x190mm (300 x 300 DPI)

SUPPLEMENTARY MATERIALS

Supplementary Table 1. Dietary targets adopted in the ENTICE-CKD intervention workbook, telephone calls and text messages[1].

Food group	**Dietary target** (serves/day)	**Considerations**
Grains/cereals	3-6 (>50% whole grain)	Replacing refined carbohydrates for wholegrains
Vegetables and fruit	5-7	Low potassium alternatives as appropriate
Low fat dairy	2	250mL milk, 40g cheese, 200g yoghurt
Lean meat, poultry and fish	<2 (130-200g)	Modified for protein (aiming for 1.0 g/kg/day)
Fats and oils	20 to 40g	Emphasise healthy oils
Dietary sodium	<100mmol/day (6g salt)	Replace takeaway and processed foods for fresh food and healthy cooking methods
Added sugars	<10% total calorie intake	
Discretionary choices	<2	Limit where possible

Abbreviations – g: grams, kg: kilogram, mL: millilitre.

Supplementary Table 2. Description of the intervention according to the TIDieR checklist.[2]

Item Name/Number	Item Description
Item 1: Brief name	
ENTICE-CKD	
Item 2: Why	
Telehealth intervention may support patients with stage 3-4 CKD to improve their diet quality through access to education, coaching and regular contact with a health professional. Improving access to dietary education may assist people with stage 3-4 CKD reduce their dietary sodium intake <100mmol/day and improve their overall diet quality in line with the Australian Dietary Guidelines.[1] These dietary changes are complex and different levels of telehealth tailoring and intensity may be needed to support and sustain dietary behavior change.	
Item 3: What	
ENTICE-CKD program workbook	
About ENTICE	Introduction page "The focus of the ENTICE program is to help you make gradual changes to your eating and physical activity habits that work for YOU – changes that become lifelong."
Section 1: Setting your goals and keeping track	"Use the following steps every time you set a SMART goal…"
Section 2: Eating well for healthy kidneys	"The ENTICE program will help you to gradually make changes to your diet to meet the daily recommended serves of fruit, vegetables and wholegrain breads/cereals."
Section 3: Active living	"Participating in regular physical activity and reducing sitting time is very important for your health and well-being."
Section 4: Why is healthy eating important for my kidneys?	Did you know? "Less than 4% of the Australians meet the recommended daily intake for vegetables. Research has shown that increasing your intake of vegetables by as little as ONE serve per day can help you live longer and stronger."
Section 5: Plan for success	"There are a number of things that affect what we eat and our overall energy intake. It is important to be aware of, pay attention to and plan for: How you eat; Where/why you eat?
Section 6: Self-monitoring and setting goals	Smart snacking Reflections Tracking my food intake
Section 7: Additional healthy eating resources	Useful websites; Healthy recipes Useful apps for mobiles or tablets High/low potassium/phosphate foods (if required) Healthier verse unhealthy takeaway options
Item 4: What – procedures	
Phase 1: Intensive coaching using telephone calls and tailored text messages. Each call was designed to align with each section of the workbook, and structured based on the 5As framework (Assess, Advise, Agree, Assist, Arrange).[3] The overall sequence of calls had the purpose of aligning participants' diets with a reduced dietary sodium intake to <100mmol/day and improving their overall diet quality in line with the Australian Dietary Guidelines.[1] **Intervention calls** **Call 1** • Welcome to ENTICE-CKD • Information about the program • Feedback on baseline outcome measures • Complete Section 1 – goal setting • Discuss section 6 – self monitoring • Begin section 2 - introduction the five food groups **Call 2** • Revisit goals	

- Recap Australia Guide to Healthy Eating – answer any questions
- Continue section 2 – (plate model, snacks, salt, label reading, potassium and phosphate)

Call 3

- Revisit goals
- Answer any questions on healthy eating
- Complete section 3 – Active living

Call 4

- Revisit goals
- Revisit any questions about active living/ healthy eating
- Complete section 4 – Why is healthy eating important for my kidneys
- Complete section 5 - planning for success - how why and where you eat and managing slips

Call 5

- Revisit goals
- Answer any dietary or Active living questions
- Discuss section 7 - additional information / resources

Call 6

- Revisit goals
- Revisit any questions participant may have
- Discuss where to from here
- Adjust text message frequency if desired

Text message component

Text message type	**SCT**	**Example text**	Intervention		Control	
			Phase 1	Phase 2	Phase 1	Phase 2
Education	Outcome expectations	Dietary fibre intake reduces ur cholesterol levels and controls ur blood sugar. Include wholegrain breads & cereals, fruits & veg regularly	2-6	1-4	NA[a]	6-8
Self-monitor	Self-regulation	Hi [name], are u keeping track of ur fruit/vegetable intake every day? Remember ur goal to have 5 serves this week	0-2	1-4	NA	NA
Goal check	Self-regulation	Hi [name], did you reach ur goal to eat 5 fruits/vegetables 4 times this week? Text me back yes or no to let me know	2	2-4	NA	NA
Education (Safety protocol)	Low potassium diet	Choose high fibre, low potassium breakfast cereals. Good choices are Multigrain Weetbix, Rolled Oats, Guardian, Oatbritz, Special K	0-2[a]	0-2[a]	NA	0-2 [a]

Phase 2: Extended contact using tailored text messages only.

At the end of phase 1 (3 month study mid-point), participants completed their final coaching call and discussed their preferences for the timing and frequency of the phase 2 text messages. At 18 weeks, participants received another tailoring call (no dietary coaching) to make individualized adjustments to their text message timing and frequency for the remaining 6 weeks of the intervention.

Item 5: Provider

Two accredited practicing dietitians (RD equivalent) with additional training in behavior change, motivational interviewing and renal nutrition. Each participant in the intervention was assigned to one dietitian for the duration of the intervention.

Item 6: How

Phase 1 (month 0-3)	Intervention: One-to-one coaching provided through 6 fortnightly phone calls, and tailored text messages at a frequency requested by the participant (TIDieR item 4 – Text message component).
Phase 2 (month 3-6)	Intervention: Tailored text messages at a frequency requested by the participant (TIDieR item 4 – Text message component).

Item 7: Where

Participants were in locations of their choosing as the intervention was delivered by telephone/mobile.

Item 8: When and How Much

Phone calls: Intervention group participants received fortnightly phone calls for 3 months

Text messages: Intervention participants received fortnightly text messages for 6 months. Control group participants received text messages for 3 months (TIDieR item 4 – Text message component).

Item 9: Tailoring

Phone calls: Coaches could tailor the dietary guidelines to participants' individual comorbidities and goals.

Coaches documented any tailoring to the intervention in call logs. Text messages: Tailored text messages were tailored to participants' names, set goals and barriers to achieving each goal (examples can be seen under TIDieR item 4 – Text message component).
Item 10: Modifications
Some participants who replied to the goal check text messages in a way the system could not recognize (i.e. not a yes/no response) were giving a tailored goal check reply message instead of the automatic system generated reply. No other modifications were made to the intervention during the course of the study.

[a] Abbreviations: SCT: Social Cognitive Theory; Each text message utilized common abbreviations to reduce character counts. For example 'ur' refers to 'your', 'u' refers to 'you'.

[b] Phase 1 was from baseline to three months. Phase 2 was from three months to the six month study end-point

[c] NA = not applicable

[d] Educational permutations were only available for coaches to use if a participant experienced hyperkalaemia or hyperphosphataemia

Supplement Table 3. Utility and acceptability questionnaire completed at 6 months.

Thinking about the text message component of the ENTICE intervention; please answer the following questions (part A).
1. The text messages sent to me were useful in supporting me make a dietary change? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
2. The text messages sent to me were easy to understand? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
3. The text messages sent to me motivated me to change my diet ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
4. The text messages sent to me made me eat healthier? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
5. The text messages sent to me made me exercise more? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
6. How many of the text messages sent to you did you read? ○ All ○ Approximately three quarters ○ Approximately one half ○ Approximately one quarter ○ None
7. What did you do after receiving the text message? ○ Ignore it ○ Read and saved ○ Read and deleted

Thinking about the text message component of the ENTICE intervention; please answer the following questions (part B)
8. Did you share your text messages with family friends or your health care providers? ○ No ○ Yes; (please specify) ○ Spouse ○ Other family member ○ Doctor ○ Nurse ○ Other Health Care Professional
9. The text messages sent to me where worded in a suitable language ○ Yes ○ No
10. The text messages sent to me were too regular ○ Yes ○ No
11. The text message program (over 6 months) was long enough? ○ Yes ○ No
12. The text messages sent to me were at an appropriate time of the day/night? ○ Yes ○ No

Supplement Table 4. Semi-structured Interview Schedule.

Focus Point	*Key questions and prompts*
1. Warm Up, rapport building, experiences	I'm interested to hear about your story with a kidney condition. Would you be able to tell me about your story from when you first found out, how you felt and your journey up until now? - Can you tell me how you felt, or your initial reactions, when you were first diagnosed? - What was your experience with the healthcare system and dietitians before the ENTICE program? Can you talk me through how you got involved in the program? What happened? - How and why did you sign up? (Motivation? Knowledge? Priorities?) - Who influenced your decision to take part in the program? How? Why? - Did your doctor recommend the program? Did they have an influence on your decision to take part? (Support/pressure? Influence of medical professionals?) What happened after you signed up for the program? - Did you meet with a dietitian? How did you find that?
2. Barriers and facilitators of adherence to program	Before ENTICE, did you have any needs, challenges, concerns about diet? Could you briefly tell me about that? To what degree does the ENTICE program meet your needs or address what you want? How? Why? What do you like most/least about being involved in the program - why? What were some of the things that made the program easy/difficult to take part in? What are your thoughts on being in familiar surroundings while you're talking to [JK/MC]?
3. Telehealth delivery methods and frequency of contact	Let's move on to your experiences with the phone calls. - What did you expect from the calls and did they meet your expectations? - What are your thoughts on never having seen [JK/MC] and building a relationship with them? - How do you think using the telephone is different to seeing someone in person? Feel any different being in a familiar environment compared to a clinic? - Can you share some things that made the phone calls easier/harder than seeing [JK/MC] in person? - Were you able to make the calls at a suitable time - how? - What do you think about the frequency of the calls? – why? - How did you feel about the length of the calls? Did you feel you were rushed during the calls? - Do you have anything more to add about the phone calls? Let's talk about the text messages now, what did you think about getting the text messages from [JK/MC]? - Can you give me an example of a text message that you liked the most/least? - Do you think the text messages were necessary - why? - What do you think about how frequently you got the text messages? Why? - Do you have anything more to add about the text messages? You got a workbook at the start of the program. - What are your thoughts on the information in the workbook? – why? - Can you give me an example of something from the workbook that had an impact on you? (Why? Motivation? Knowledge?) - Did you have any difficulties understanding the information in the workbook? - Did you show the workbook to anyone? Who? Why? What did they think? - Do you have anything more to add about the workbook?
4. Usability of the program	Can you think of an example recommendation that [JK/MC] gave you about your diet or your lifestyle? - What are some things that helped you/made it hard for you to follow recommendations? – why?
5. Goal setting and self-monitoring	What are your thoughts on setting health goals? - How do you feel about goal setting? - Can you tell me about your experience with goal setting before the program? - Did you set goals in the program? When? Are you able to tell me about one of your goals? - Do you think ENTICE helped you to achieve your goals - why? One of the aims of ENTICE is to improve self monitoring –do you know what self-monitoring

	means? (Stuff you'll do without people reminding you, like writing down or taking note of what you eat or how active you've been) - Do you find you do that? Why? - What impact do you think the program has had on your self-monitoring? (The way you go about it? How often?) - How confident do you feel with monitoring your diet? Why?
6. Behaviour change	You have made some changes to your lifestyle in order to meet your goals [example] - Will these changes be something that you'll continue to do? – how? why? - Can you tell me about your motivation to make changes before the program? - How and why did your motivation change during the program? - How do you feel about keeping motivated after the program? Do you feel like your daily activities have changed since before the program? How? (Eating behaviour? Purchasing of foods? How physically active you are?)
7. Experiences	- Did you feel that the recommendations from [JK/MC] were specific to you and nobody else? - Can you give an example of when you felt this way? - Were the recommendations clear? How? Why? - Do you understand why the advice was given to you? - Do you think the program and the telephone sessions were suited to your culture? - Did you share your experiences with the program with anybody else? Family, friends, other health professionals? How? Why? Did you find it helpful? Imagine you became director of the hospital and you had the power to improve the services for people with kidney disease. What would be the top 2 changes you would make to improve the care and support for people with kidney disease?
8. Closing	We would like you to help us evaluate the program to help improve it and the difference it makes to patients. Is there anything that you think would be important to mention that we haven't covered?

Screening and recruitment

↓

Randomization

↙ ↘

	Week	**Intervention group**	**Control group**
Phase 1	1	Baseline Visit	
	2	6x fortnightly telephone calls + tailored text messages + workbook	Usual Care (workbook only)
	4		
	6		
	8		
	10		
	12	Mid-point visit + telephone call	
Phase 2	14	Tailored text messages	Educational text messages
	16		
	18	Telephone call	
	20	Tailored text messages	
	22		
	24	End-point visit	

Supplementary Figure 1. Summary of ENTICE-CKD program delivery.

References for supplementary material

1. NHMRC. Australian Dietary Guidelines. In. Canberra: National Health and Medical Research Council, Department of Health and Ageing; 2013.
2. 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.
3. Whitlock EP, Orleans CT, Pender N, Allan J. Evaluating primary care behavioral counseling interventions: An evidence-based approach 1 1The full text of this article is available via AJPM Online at www. ajpm-online. net. *American journal of preventive medicine*. 2002;22(4):267-284.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	4-5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6-7
	2b	Specific objectives or research questions for pilot trial	7
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	8-9
	4b	Settings and locations where the data were collected	12
	4c	How participants were identified and consented	9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-12
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	12-15
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with a future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9-12
	11b	If relevant, description of the similarity of interventions	8-11
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	14-15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	15-16
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Results and tables
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	22-23
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	22-23
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	19-23
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	22-24
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	8
Protocol	24	Where the pilot trial protocol can be accessed, if available	8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title page
	26	Ethical approval or approval by research review committee, confirmed with reference number	8

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.