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A Text Messaging Intervention for Dietary Behaviors for People Receiving Maintenance Hemodialysis: A Feasibility Study of KIDNEYTEXT

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ABSTRACT

Rationale and Objective: An important component of hemodialysis management involves delivery of complex dietary recommendations. The aim of this study was to determine the feasibility of a mobile phone text message intervention to improve dietary behavior in people on hemodialysis.

Study design: Six-month randomized feasibility study.

Setting and participants: Patients receiving maintenance hemodialysis across two health districts in Sydney, Australia.

Interventions: Participants randomized to the intervention received three text messages per week, in addition to standard dietary care, for six months. The usual care group received standard dietary care.

Outcomes: The primary outcomes were feasibility, measured using recruitment and retention rates, acceptability of the intervention, and adherence to dietary recommendations. Secondary exploratory outcomes included information on certain clinical parameters related to dietary management of patients receiving maintenance hemodialysis.

Results: 130 people were recruited. 48% (130/272) of eligible patients consented to participate and 88% (115/130) completed the study. Semi-structured interviews evaluating acceptability identified five themes: *clear and comprehensive, engaging with consistent and relevant content, maintaining attention with timely reminders, sustaining interest through ongoing care and generic messages inadequate to prompt dietary change*. There was no difference in adherence to dietary recommendations across treatment groups (odds ratio: 1.21, 95% CI 0.55, 2.72, p=0.6). Secondary exploratory analyses suggested reductions in dietary intake of single nutrients

(potassium, phosphorus, sodium, protein), interdialytic weight gains, and phosphate binder usage among intervention participants compared to participants assigned to standard of care.

Limitations: Our feasibility study was of short duration. Adherence was based on self-reported data. Generalizability to populations receiving maintenance hemodialysis outside of an urban, Australian setting is unknown.

Conclusions: A simple mobile phone text messaging intervention was feasible and acceptable to patients. Further investigation of the impact on patient-reported and clinical outcomes is warranted.

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Trial Registration: ACTRN12617001084370

Key words: nutrition, diet, hemodialysis, mobile phone, technology, randomized controlled trial

PLAIN LANGUAGE SUMMARY

Dietary management is a central component of care for people receiving hemodialysis. Mobile phone text messaging is widely used in the population and offers a potential avenue to enhance current nutritional care. KIDNEYTEXT was a 6-month randomised controlled study that evaluated the feasibility and acceptability of text messages to alter dietary behaviors. This intervention was feasible and acceptable. It showed promise at improving dietary parameters and may impact other clinically important outcomes, such as fluid management. Larger trials are needed to evaluate the effectiveness of this intervention.

INTRODUCTION

Chronic kidney disease (CKD) affects approximately 13% of the population^{1,2}. Dietary management plays an important role in preventing the progression of CKD, managing complications such as high blood pressure, reducing symptom burden and managing electrolyte abnormalities. Patients with CKD have identified nutrition and lifestyle interventions as high priorities for research³.

Dietary management for people receiving hemodialysis is particularly challenging because patients have to integrate general healthy eating recommendations with additional complex and restrictive dietary requirements such as modifying protein, fluid, sodium, potassium, and phosphorus intake⁴. People receiving hemodialysis report that they lack the confidence and the skills to make dietary choices⁵⁻⁷. Whilst dietary self-management may be most effectively achieved through frequent, individualized education with a dietitian^{8,9}, access to renal dietitians is variable, and may be limited^{10,11,12}. Furthermore, one off didactic education sessions can be overwhelming and difficult to comprehend, particularly at the time of diagnosis^{6,7}.

Given the high use of mobile phones and the internet, there is increasing interest in utilising these technologies to enhance nutritional care. In chronic disease populations, interventions using telehealth¹³ and mobile phone text messaging¹⁴ have led to improvements in dietary behaviors (e.g. increased fruit and vegetable intake and a reduction in sodium intake) and other clinical outcomes such as reductions in blood pressure, cholesterol levels and weight. The aim of

this study was to evaluate the feasibility of a mobile phone text message intervention to improve dietary behavior in patients receiving hemodialysis.

METHODS

Study design

A detailed study protocol has been published¹⁵. In brief, we conducted a six-month randomized feasibility study, with a 2:1 allocation ratio. Outcome assessors were two external research dietitians who were blinded to allocation until the end of the study and who were not involved in any aspect of the participant's clinical care. The design and development of KIDNEYTEXT was underpinned by considerations for the development of complex interventions¹⁶ and a range of behavior change frameworks¹⁷ (Item S1). This study was approved by the Western Sydney Local Health District Human Research Ethics Committee and was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12617001084370). Written and informed consent was obtained from all participants prior to their enrolment in the study.

Study Setting

The study was conducted in six dialysis units across two local health districts (Western Sydney and South-Eastern Sydney) Sydney, Australia. The dialysis units were included in the study serve socio-economically and culturally diverse populations.

Participants

Eligibility criteria (Item S2) included end-stage kidney disease on maintenance hemodialysis for at least 90 days, age 18 years and over, having sufficient English language skills to read and understand text messages, and having access to a mobile phone throughout the duration of the study. Participants were randomly allocated using a computerized randomization program to either intervention or usual care (2:1), stratified by geographical location of the dialysis units (Western Sydney, South Eastern Sydney). Allocation was concealed from outcome assessors until the completion of the study. Participants were notified of their allocation via text message and were asked not to disclose their allocation to study personnel throughout the study.

Intervention

The usual care group continued to receive standard care provided by the dialysis unit. The intervention group received standard care plus three text messages per week over a 6-month period. Text messages were unidirectional, (i.e. one-way with no response required from participants). Unidirectional messages were chosen as these have been shown to improve dietary and lifestyle behaviors¹⁴ and are more time and cost-effective compared with in-person interventions. Content of the messages included advice, information, motivation and support to improve renal dietary behaviors (related to potassium, phosphorus, sodium, fluid) and general healthy eating and lifestyle behaviors. Text messages were semi-personalised based on baseline dietary intake and clinical parameters (Item S3) from baseline to 3 months. All intervention

participants received general healthy eating and lifestyle messages from 4 months to 6 months. All participants had the opportunity to withdraw at any time via text message.

Primary Outcomes

The primary outcomes were feasibility, acceptability and adherence to dietary recommendations (Item S-4). Feasibility was measured using recruitment rate and retention rate. Adherence to dietary recommendations was defined as participants meeting three of the four dietary guideline recommendations with respect to protein, potassium, phosphorus, and sodium (Item S4).

Dietitians who served as outcome assessors and were blinded to participants' allocation and not involved with the clinical care of the participants assessed dietary intake, using the validated 24-hour dietary recall methodology¹⁸. Prior to 3 and 6 month reviews participants were sent a text message reminding them not to reveal their allocation to the outcome assessors. Dietary recalls were conducted in-person or via telephone with food models to assist with portion size estimations, of both a dialysis day and a non-dialysis day, assessed at baseline, three months and six months. Dietary recalls included the intake of nutritional supplements. Dietary intake data was then analysed using Xyris Software Foodworks version 9 Pty Ltd (using food databases AUSNUT 2011-2013, Aus Foods 2017, Aus Brands 2017).

To determine acceptability and to undertake a process evaluation¹⁹ of the KIDNEYTEXT intervention we conducted semi-structured interviews with 25 participants sampled from the intervention group after completion of the 6 month follow-up. The process evaluation will be published separately. We undertook purposive sampling to achieve broad diversity of

demographic and clinical characteristics. As we recruited participants, we monitored the characteristics and targeted recruitment of patients based on the demographic or clinical characteristics as required to obtain wide variability of responses. All interviews were audio-recorded and transcribed verbatim. Using principles of grounded theory and thematic analysis, J.S. coded the transcripts using HyperRESEARCH software (ResearchWare Inc. United States. Version 3.3) and inductively identified concepts. Investigator triangulation was undertaken whereby another investigator (A.Tong.) read the transcripts and discussed the preliminary themes to ensure these reflected the full range and depth of the data collected. Similar concepts were grouped into themes.

Secondary exploratory outcomes

Secondary exploratory outcomes (Item S4) included measurements at baseline, 3 months and 6 months of: mean change in renal-specific dietary nutrients, serum potassium, serum phosphate, interdialytic weight gain, dietary quality (measured using the Healthy Eating Index - HEI²⁰), nutritional status, quality of life, blood pressure and additional serum markers (bicarbonate, urea, albumin, parathyroid hormone and for diabetics glycated hemoglobin), healthcare utilization (i.e. number of consultations with dietitian) and medication usage (Sodium Polystyrene Sulfonate, phosphate binders, diuretics, anti-hypertensives).

Statistical analysis

A sample size of 129 participants, 86 in the intervention arm and 43 in the usual care arm, provided 80% power to detect an increase from 25% to 50% (odds ratio of 3) or 90% power for an increase from 10% to 35% (odds ratio of 4.85) on adherence to renal dietary recommendations, using a chi-square test, with a significance level of 0.05. Dietary adherence at

6 months, was compared across the two groups with a logistic regression, adjusting for the stratification variable, local health district.

The secondary exploratory continuous outcomes were analysed as changes from baseline at 3 and 6 months, using linear models (separate models for each time period) and adjusting for the stratification variable - health district. For categorical variables, we have presented the adjusted odds ratios and the adjusted proportions for baseline status using the *margins* command from Stata²¹. An additional analysis, presented as supplementary material (Item S5), analysed these outcomes longitudinally (baseline, 3 months, 6 months) through a linear mixed model with a random intercept for each participant and an interaction between time and trial arm. For secondary categorical outcomes, we used logistic models for each time point, adjusting for the baseline measurement and adjusted for the stratification variable. Similarly to the continuous variables, an additional analysis modelled these outcomes longitudinally (baseline, 3 months and 6 months), using a logistic mixed model with a participant-specific random intercept, adjusting for the stratification variable and including the interaction involving time and trial arm to compare the changes in the outcomes over time, between the two groups.

The 95% confidence intervals for means, proportions and odds ratios are model bases, unless stated otherwise. Missing data were not imputed and a complete case analysis was performed. The analysis was conducted in R software and SPSS. Dichotomous variables are summarized as numbers and percentages, continuous variables are presented as means and standard deviation (SD), or medians and 25th and 75th percentiles, according to their distribution.

RESULTS

Feasibility

A total of 462 individuals were screened, of whom 128 (28%) were not eligible, 142 (31%) declined to participate, 62 (13%) were unable to be contacted or followed up and 130 (28%) were recruited into the study from six centres between December 2017 and April 2018 (Figure 1). Reasons for being ineligible included not having access to a mobile phone (24, 19%), not having sufficient English (51, 40%), having significant cognitive impairment (14, 11%) and other (39, 30%). Reasons for declining to participate included not being interested (62, 43.5%), satisfied with current dietary care (7, 5%) and other, including non-disclosure of reason (73, 51.5%).

Of the eligible patients, 48% (130/272) consented to participate. The rate of consent for each dialysis unit was between 32% to 58%. Eighty-seven were randomized to receive the intervention and 43 randomized to usual care (Table 1). Among individuals who consented to participate, 88% (115/130) completed the study. Three intervention participants (3%) requested text messages to be paused, reasons given included being too busy to read messages and having enough information. Nine participants in the intervention group (11%) and six participants in the usual care group (14%) did not complete the study. Reasons for not completing the study are shown in figure 1.

Adherence to renal dietary guidelines

At baseline, 28 intervention (34%) and 18 usual care (46%) participants were adherent with 3 or more dietary guidelines. At 6-months, 35 participants (45%) were adherent in the intervention group compared with 15 (41%) in the usual care arm (odds ratio: 1.21, 95% CI 0.55, 2.72, p=0.6)

(Table 2, Figure 2). The result was the same when looking at the longitudinal measures of adherence (baseline, 3 months, and 6 months) in the logistic mixed model, adjusting for the stratification factor ($p = 0.1$ for the interaction between time and allocation).

Acceptability

Semi-structured interviews were conducted with 25 intervention arm participants at the completion of the study. Five themes were identified.

Clear and comprehensive

Participants found the text messages “informative” and “simple”. The amount of repetition in the messages was deemed acceptable. Overall, they thought the messages covered a comprehensive range of dietary and lifestyle topics.

Engaging with consistent and relevant content

Participants felt that information in the text messages was relevant and reinforced previous educations. Text messages provided participants with a wider range of options of foods that they could include in their diet –*“most of the information I’d been given previously...but there were a couple I didn’t know...for example I didn’t realise cottage cheese was preferred...(I have now) incorporated this”* (Male, 80s, community dialysis).

Maintaining attention with timely reminders

Participants appreciated having regular reminders about their diet to “keep them on track”. Three messages per week was thought to be “just right” to keep them engaged with the messages

without becoming burdensome. Participants did not have a preference for what time of day, or day of the week the text messages were received. However, some preferred receiving the text messages while on dialysis or on a “dialysis day” - “*Getting the messages while I was doing dialysis clicked off something in the back of my mind... If I had have got them on a (non-dialysis day) I don't think I would have taken any notice of them.*” (Male, 50s, in-centre).

Sustaining interest through ongoing care

Participants received text messages over a six-month period, which they perceived was adequate, and “*looked forward to what (text message) was going to come up next*” (Male, 60s, home dialysis). Some participants felt that receiving these messages when first commencing dialysis would have been helpful – “*it would have been better because obviously it was all new to me*” (Male, 80s, community dialysis).

Generic messages inadequate to prompt diet change

Some participants felt the messages were “too generic” and needed more individualised information to prompt them to “break their routines” and alter their diet. Ongoing consultation with renal dietitians was considered important by participants to receive more personalised information.

Secondary exploratory outcomes

Dietary intake: Dietary intake outcomes are summarized in Table 3 and Item S5. The intervention arm had a mean reduction in potassium intake of 7.4mmol (95% CI -12.8, -2)

compared to a slight increase in the usual care arm of 2.9mmol (95% CI -4.5, 10.3) to 59mmol (p=0.01). There was a mean reduction in dietary phosphorus intake in the intervention arm of 168mg (95% CI -277, -58), and a slight increase in the usual care arm of 85mg (95% CI -64, 235) (p=0.003). There was a mean reduction in sodium intake in the intervention arm of -417mg (95% CI -622, -210.6), with the usual care arm having a smaller mean reduction of 29mg (95% CI -310, 252) (p=0.03). Mean protein intake declined in the intervention arm by 11g (95% CI -18.7, -4.8) and remained stable in the usual care arm (1.1g, 95% CI -8.4, 10.5) (p=0.01). There was no difference in HEI score between the groups (p=0.3) (Table 3).

Biochemical parameters: There was no difference or clinical meaningful change between intervention and usual care arms with respect to serum potassium, albumin, urea, bicarbonate, parathyroid hormone or HbA1c (Table 3, Item S5). Whilst there was no statistical difference in mean serum phosphate or the proportion of participants meeting serum phosphate guidelines, there was a clinically meaningful reduction in serum phosphate in the intervention arm by -0.19mmol/L (95% CI -0.32, -0.06). (Table 3, Item S5).

Interdialytic weight gain: Participants receiving the intervention were significantly more likely to meet IDWG guidelines (OR 6.23, 95% CI 2.12, 20.43, p=0.001). There was a significant improvement in IDWG in the intervention arm (-0.06 kg, 95% CI -0.29, 0.18) compared to usual care participants (0.37 kg, 95% CI 0.04, 0.69) (p=0.022).

Quality of life: The quality of life at 6 months as measured by the EQ-5D utility score was lower in the intervention group with a mean reduction of 0.04 (95% CI -0.10, 0.02) compared to usual

care mean improving by 0.06 (95% CI -0.02, 0.15) ($p=0.03$). The variation in utility scores from baseline to 6 months was such that there was no difference in quality adjusted life years (QALYs) between the intervention (0.39 years, 95% CI 0.35, 0.5) and usual care groups (0.42 years, 0.41, 0.5) ($p=0.4$) (Table 3).

Additional exploratory outcomes: There was a reduction in the mean number of phosphate binder medications in the intervention arm by 0.49 tablets (95% CI -1.19, 0.22) and an increase in mean number of phosphate binder in the usual care arm by 0.71 tablets (95% CI -0.22, 1.64) ($p=0.03$) (Table 3). There was no difference or clinically relevant change in nutritional status, the usage of other medications (Sodium Polystyrene Sulfonate, diuretics, anti-hypertensives), blood pressure or number of dietetic consultations (Table 3). A detailed health economics evaluation will be published elsewhere.

DISCUSSION

A simple mobile phone text intervention targeting dietary behaviors is feasible. There was a high rate of recruitment and retention, with 48% of eligible people consenting to be involved in the study, 88% of participants completed the study, with only 2% asking to be withdrawn from the study and 2% requesting text messages to be paused. Participants reported the intervention to be acceptable and were satisfied and engaged with the text messages.

The most significant barriers to recruitment into the study included not having access to a mobile phone, having insufficient English to read and understand text messages, not being interested in participating in research. These barriers are generally consistent with the literature regarding

challenges of recruitment into nephrology studies²². Potential methods in which to improve recruitment in a future trial could be to design an adaptive, cluster (by dialysis unit) randomized study with the intervention embedded into current renal nutrition services to promote buy-in from clinicians and enrolling patients through trusted clinicians and enhancing the participation of dialysis staff in the development and implementation of the intervention²²⁻²⁴.

KIDNEYTEXT was deemed acceptable by participants with self-reported high levels of satisfaction and engagement. This has been reflected in another trial conducted in CKD, that used a combination of telephone consultations and mobile phone text messages (ENTICE)²⁵. In both our study and ENTICE, participants reported the interventions to prompt dietary behavior change, and found the frequency of text messages and length of intervention satisfactory, with text message content being relevant and comprehensible. KIDNEYTEXT had a recruitment rate of 48% and a low withdrawal rate of 2%. Similar findings have been reported in other studies using eHealth interventions to alter dietary behaviors, with 35% recruitment rate²⁵ and 5% withdrawal rates^{25,26}. These findings indicate a good uptake and acceptance of eHealth interventions in CKD and hemodialysis populations, and justifies the conduct of larger and longer duration trials to establish effects on long term outcomes.

The adherence definition in KIDNEYTEXT did not reach statistical significance. Our finding is in contrast to results from a prior study, TEXTME, which was a 6-month RCT conducted in coronary heart disease.¹⁴ TEXTME demonstrated significant improvements in dietary intake with use of a one-way mobile phone text messaging intervention. This study demonstrated significantly more intervention participants (93%) adhered to 4 or more (out of 8) dietary

guidelines, compared to usual care participants (75%).²⁷ There was no data available to guide a sample size calculation for dietary adherence for the KIDNEYTEXT study. The sample size calculation underestimated adherence to dietary guidelines in usual care. The KIDNEYTEXT study has provided useful data for future studies when considering dietary intake and dietary adherence as a primary end-point.

We detected some promising signals in secondary exploratory outcomes of KIDNEYTEXT that will need to be evaluated in future trials. The intervention group showed a progressive reduction in dietary sodium intake from baseline to 6 months. Consistent with these results, KIDNEYTEXT demonstrated a significant improvement in fluid management in intervention participants. There was a significant difference in average IDWG and the proportion of participants meeting IDWG targets at 6 months. Our findings are supported by results from prior studies. Interventions using digital self-monitoring tools, with or without individualised dietary counselling have been conducted in dialysis populations^{26, 28} and showed modest reduction in average daily sodium intake of 197mg sodium daily (95% CI -540.76 to 116.85mg/d) at 4-months²⁹, however the strength of this evidence was considered to be low.

A meta-analysis that demonstrated reduction of IDWG by an average of 0.13kg per day (95% CI -0.27 to 0.01) in hemodialysis populations through self-monitoring eHealth interventions, however the evidence was considered to be of low quality²⁹.

In KIDNEYTEXT, we noted an unintended decline in protein intake, with intervention participants reducing their protein intake and usual care participants maintaining their protein intake. Given the significant reduction in dietary phosphorus intake, this result is not unexpected

as there is a large overlap in foods containing both protein and phosphorus. Whilst there was a significant reduction in protein intake in the intervention group there was no change in nutritional status in either study arm.

The quality of life in the KIDNEYTEXT group was not anticipated to be different to that of the usual care group given the short time frame of the study. Quality adjusted life years, collected for economic evaluations, accounts for the change in quality of life over follow-up of the study was the same between the two groups. The EQ-5D utility values in both the KIDNEYTEXT (0.7) and usual care (0.8) groups were higher than values commonly reported for people receiving hemodialysis³⁰.

The strengths of KIDNEYTEXT include its randomized design that focused on feasibility evaluation of a simple mobile phone text messaging intervention to alter dietary behaviors in the hemodialysis population. There are some limitations to our study. Firstly, this was a small study of short duration. This study was designed to confirm feasibility, with our results indicating that text messages can produce dietary change and justifies the need for a larger study to confirm results and long-term acceptability and outcomes. Whilst participants were asked not to share messages, it is unknown whether participants shared text messages with patients who were in the control group that may have led to unintended change in behaviours (i.e. contamination). However, should this have occurred, the differences in dietary behaviors would likely be diluted. Additionally, dietary intake data was measured using patients' self-report. Self-reported dietary intake may not accurately reflect an individual's actual intake, however we used validated 24-hour dietary recall methodology to standardise dietary intake assessment and minimise bias.

Finally, generalizability to hemodialysis populations outside of an Australian, urban setting may vary depending upon the availability of specialist dietitians. Future trials should include measures to determine the impact on these outcomes.

Whilst further evaluation is needed confirm our findings, this study indicates that mobile phone text messaging is feasible and acceptable. This simple intervention has the potential to be used in everyday practice by dietitians and renal units to enhance current nutritional care, particularly in settings where access to renal dietitians is limited. Further evaluation of the impact of mobile phone text messaging in other CKD groups, (i.e. chronic kidney disease stages 3-5, conservative management, peritoneal dialysis and transplantation) is required. Our results suggest that phosphate and fluid management (assessed using IDWG) may be best targeted with supportive dietary text messages. KIDNEYTEXT indicated an improvement in the proportion of intervention participants meeting phosphate and IDWG guidelines by 15% and 17% respectively. This approaches the threshold of a 25% improvement in adherence that was determined to be clinically significant. Recommendations for the design of a larger clinical trial in hemodialysis are outlined in table 4.

Traditional (e.g. face-to-face) interventions to alter behaviors, such as dietary sodium intake³¹⁻³³ and fluid management³⁴ are resource-intensive, requiring frequent (e., g. weekly or fortnightly) contact with practitioners. In practice, access to renal dietitians may be limited, with dietitians citing a lack of resources to being able to provide adequate support and counselling¹⁰⁻¹². In our study, at baseline less than 70% of participants had seen a dietitian in the past year and only half had seen a dietitian during the 6-month follow up. A simple, feasible and acceptable mobile

phone text messaging intervention aimed at improving dietary behaviors in a hemodialysis population may be a useful interim measure used in conjunction with individualised face-to-face counselling. Our feasibility study justifies a larger RCT to evaluate the impact of a mobile phone text messaging intervention on important patient-centred and clinical outcomes in hemodialysis.

SUPPLEMENTARY MATERIAL

Item S1: Behavioural frameworks used to develop text messages

Item S2: Eligibility criteria

Item S3: Text message allocation (baseline to 3 months)

Item S4: Primary and secondary exploratory outcome measures

Item S5: Secondary exploratory outcomes longitudinally analysed from baseline to 6 months

ARTICLE INFORMATION

Authors' Contributions: principal investigators who designed study: VWL, KLC, JCC, ATong, JD; substantial contributions to the conception and design of the project: CKC, AThiagalingam, MAB, KH, MH, KS; developed the software for use in the study: AThiagalingam; collected data: JD, RK; performed statistical analysis: AT-P. Each author contributed important intellectual content during manuscript drafting or revision and agrees to be personally accountable for the individual's own contributions and to ensure that questions pertaining to the accuracy or integrity of any portion of the work, even one in which the author was not directly involved, are appropriately investigated and resolved, including with documentation in the literature if appropriate.

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Data Sharing: Individual participant data that underlie the results reported in this article, after de-identification will be made available beginning 9 months and ending 36 months following article publication. The study protocol has been published in detail¹⁵ and the statistical analysis plan uploaded to ANZCTR (www.anzctr.org.au). Investigators who provide a methodologically sound proposal and have gained ethical clearance may use the de-identified individual data as per the proposal. Proposals may be submitted up to 36 months following article publication by contacting vincent.lee@sydney.edu.au. Requestors will need to sign a data access agreement. After 36 months the data will be available in our Universities data warehouse but without investigator support other than deposited metadata.

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Table 1: Baseline characteristics

Characteristics	Intervention n=87	Usual Care n=43
Sex (Male)	50 (57.5)	29 (67.4)
Age, mean (SD)	64.4 (13.2)	65.2 (14.5)
Cause of ESKD, n(%)		
Diabetes	42 (48.3)	17 (39.5)
Hypertension	5 (5.7)	9 (20.9)
Interstitial Nephritis	0	0
Polycystic Kidney Disease	6 (6.9)	1 (2.3)
Obstructive Nephropathy	0	1 (2.3)
Reflux Nephropathy	1 (1.1)	0
Autoimmune	16 (18.4)	8 (18.6)
Other	11 (12.6)	4 (9.3)
Undetermined	6 (6.9)	3 (7)
Dialysis Vintage (years), mean (SD)	3.2 (3)	2.8 (2.9)
Dialysis Location, n(%)		
Western Sydney	56 (64.4)	27 (62.8)
South East Sydney	31 (35.6)	16 (37.2)
Dialysis Unit, n(%)		
Auburn Hospital	9 (10)	5 (12)
Blacktown Hospital	22 (25)	11 (26)
Nepean Hospital	19 (22)	8 (19)
St George Hospital	20 (23)	11 (26)
Sutherland Hospital	11 (13)	5 (12)
Westmead Hospital	6 (7)	2 (5)
Dialysis Type, n(%)		
In-center	15 (17.2)	5 (11.6)
Community-based	66 (75.9)	34 (79.1)
Home	6 (6.9)	4 (9.3)
Previous RRT, n(%)		
None	71 (81.6)	36 (83.7)
Kidney transplant	9 (10.3)	0
Peritoneal Dialysis	7 (8)	7 (16.3)
Number of co-morbidities, n(%)		
Less than 3	52 (59.8)	24 (55.8)
3 or more	35 (40.2)	19 (44.2)
Cultural Background, n(%)		
Australia, New Zealand	38 (43.7)	29 (46.5)
Aboriginal, Torres Strait Island	5 (5.7)	1 (2.3)
Pacific Islands	20 (23)	5 (11.6)
European	11 (12.6)	2 (4.7)
North American	1 (1.1)	0
South and Central Asian	3 (3.4)	2 (4.7)
North-Eastern Asian	0	1 (2.3)
South-East Asian	4 (4.6)	2 (4.7)
Middle East, North Africa	5 (5.7)	8 (18.6)
Sub-Saharan Africa	0	2 (4.7)
Country of Birth, n(%)		
Australia	46 (52.9)	19 (44.2)
Other	41 (47.1)	24 (55.8)
Primary language, n(%)		
English	67 (77)	23 (53.5)
Other	20 (23)	20 (46.5)
Seen a dietitian prior to intervention, n(%)	58 (66.6)	30 (69.7)

Table 2: Proportion of participants adhering to renal dietary recommendations for hemodialysis

	Baseline		3 months		6 months	
	Intervention n=87	Usual care n=43	Intervention n=84	Usual care n=39	Intervention n=78	Usual care n=37
Protein	37 (43%) (32%, 53%)	15 (35%) (20%, 50%)	30 (36%) (26%, 47%)	20 (51%) (35%, 68%)	18 (23%) (14%, 33%)	17 (46%) (29%, 63%)
Potassium	61 (70%) (60%, 80%)	32 (74%) (61%, 81%)	62 (74%) (65%, 84%)	29 (74%) (60%, 89%)	65 (83%) (75%, 92%)	27 (73%) (58%, 88%)
Phosphorus	25 (29%) (19%, 38%)	16 (37%) (22%, 52%)	22 (26%) (17%, 36%)	10 (26%) (11%, 40%)	32 (41%) (30%, 52%)	11 (30%) (14%, 45%)
Sodium	61 (70%) (64%, 83%)	29 (67%) (60%, 89%)	61 (73%) (64%, 83%)	29 (74%) (60%, 89%)	63 (81%) (72%, 90%)	27 (73%) (58%, 88%)
Adherent with ≥ 3 renal dietary guidelines**	28 (32%) (23%, 44%)	18 (42%) (30%, 63%)	30 (36%) (26%, 47%)	16 (41%) (25%, 57%)	35 (45%)* (34%, 56%)	15 (41%)* (24%, 57%)

Data is presented as n(%) (95% confidence intervals)

* p=0.6 for the comparison between the two arms, adjusting for geographical location of dialysis unit (stratification variable), using a logistic regression,

** p=0.1 for interaction of time and allocation, in the longitudinal analysis (secondary analysis), adjusting for local health district (stratification variable)

Table 3: Secondary exploratory outcomes. Changes from baseline to three and six months

		3 months		6 months	
		Intervention, n=84	Usual Care, n=39	Intervention, n=78	Usual Care, n=37
		Change from baseline (95% CI)	p-value	Change from baseline 95% CI	p-value
Adjusted Protein (g/kg IBW/d)	Intervention Usual Care	-0.07 (-0.17; 0.03) 0.03 (-0.11; 0.16)	0.2	-0.15 (-0.24; -0.05) 0.01 (-0.12; 0.14)	0.03
Total Protein (g/d)	Intervention Usual Care	-5.8 (-12.6; 1.0) 1.7 (-7.7; 11.1)	0.2	-11.3 (-18.7; -4.8) 1.1 (-8.4; 10.5)	0.02
Potassium (mmol/d)	Intervention Usual Care	-5.4 (-10.7; -0.2) 2.7 (-4.6; 9.9)	0.05	-7.4 (-12.8; -2.0) 2.9 (-4.5; 10.3)	0.01
Phosphate (mg/d)	Intervention Usual Care	-128 (-234; -22) 48 (-98; 195)	0.03	-168 (-277; -58) 85 (-64; 235)	0.003
Sodium (mg/d)	Intervention Usual Care	-344 (-536; -153) 25 (-240; 290)	0.02	-417 (-622; -210.6) -29 (-310; 252)	0.02
Healthy eating Index (HEI)	Intervention Usual Care	0.5 (-1.7; 2.8) 0.7 (-2.3; 3.8)	0.9	1.7 (-0.5; 3.9) -0.1 (-3.2; 2.9)	0.3
Serum potassium (mmol/L)	Intervention Usual Care	-0.13 (-0.30; 0.05) -0.17 (-0.42; 0.07)	0.7	0.01 (-0.20; 0.23) 0.18 (-0.12; 0.47)	0.3
Meeting serum potassium guidelines (%)	Intervention Usual Care	0.87 (0.80; 0.93) 0.86 (0.75; 0.96)	0.9	0.86 (0.78; 0.93) 0.81 (0.69; 0.94)	0.5
Serum phosphate (mmol/L)	Intervention Usual Care	-0.09 (-0.21; 0.03) -0.21 (-0.38; -0.05)	0.2	-0.19 (-0.32; -0.06) -0.05 (-0.23; 0.12)	0.2
Meeting serum phosphate guidelines (%)	Intervention Usual Care	0.67 (0.59; 0.78) 0.75 (0.62; 0.88)	0.4	0.71 (0.62; 0.81) 0.60 (0.45; 0.75)	0.2
Interdialytic weight gain (kg/session)	Intervention Usual Care	0.03 (-0.19; 0.26) 0.22 (-0.09; 0.53)	0.3	-0.06 (-0.29; 0.18) 0.37 (0.04; 0.69)	0.02
Meeting interdialytic weight gain guidelines (%)	Intervention Usual Care	0.78 (0.70; 0.87) 0.73 (0.60; 0.86)	0.5	0.89 (0.82; 0.96) 0.62 (0.47; 0.77)	0.001
Nutritional status, well nourished (PG-SGA)	Intervention Usual Care	N/A N/A		0.88 (0.81; 0.95) 0.92 (0.84; 1.00)	0.5
Prescribed Sodium Polystyrene Sulfonate (%)	Intervention Usual Care	0.91 (0.86; 0.96) 0.90 (0.82; 0.97)	0.7	0.84 (0.72; 0.97) 0.81 (0.63; 0.98)	0.8
Number of phosphate binders	Intervention Usual Care	-0.05 (-0.69; 0.58) 1.13 (0.28; 1.98)	0.01	-0.49 (-1.19; 0.22) 0.71 (-0.22; 1.64)	0.03
Prescribed diuretic (%)	Intervention Usual Care	0.80 (0.75; 0.86) 0.68 (0.57; 0.80)	0.05	0.80 (0.73; 0.86) 0.75 (0.65; 0.86)	0.5
Number of anti-hypertensive medications	Intervention Usual Care	-0.08 (-0.28; 0.11) 0.03 (-0.23; 0.29)	0.5	-0.05 (-0.29; 0.20) -0.13 (-0.46; 0.20)	0.7
Number of other medications	Intervention Usual Care	0.19 (-0.36; 0.74) 0.28 (-0.46; 1.01)	0.8	-0.10 (-0.84; 0.65) 0.16 (-0.83; 1.14)	0.6
EQ-5D (utility)	Intervention Usual Care	0.00 (-0.06; 0.06) -0.004 (-0.09; 0.08)	0.9	-0.04 (-0.10; 0.02) 0.06 (-0.02; 0.15)	0.03
Quality Adjusted Life Years (no baseline value)	Intervention Usual Care	N/A N/A		0.39 (0.35; 0.5) 0.42 (0.41; 0.5)	0.4
Serum Urea (mmol/L)	Intervention Usual Care	N/A N/A		-1.3 (-2.8; 0.2) -0.7 (-2.7; 1.3)	0.6

Serum albumin (g/L)	Intervention	N/A		0.9 (-0.3; 2.1)	0.6
	Usual Care	N/A		1.4 (-0.3; 3.0)	
Serum bicarbonate (mmol/L)	Intervention	N/A		0.9 (0.1; 1.7)	0.8
	Usual Care	N/A		1.0 (0; 2.1)	
Parathyroid Hormone (pg/ml)	Intervention	N/A		5.7 (-3.3; 14.7)	0.9
	Usual Care	N/A		5.1 (-6.9; 17.0)	
HbA1c (diabetics only)	Intervention	N/A		0.01 (-0.36; 0.55)	0.2
	Usual Care	N/A		-0.37 (-1.13; 0.38)	
Pre-dialysis systolic BP (mmHg)	Intervention	N/A		0.9 (-4.0; 5.8)	0.9
	Usual Care	N/A		1.5 (-5.0; 8.1)	
Pre-dialysis diastolic BP (mmHg)	Intervention	N/A		-0.7 (-3.5; 2.1)	0.6
	Usual Care	N/A		0.34 (-3.40; 4.08)	
Post-dialysis systolic BP (mmHg)	Intervention	N/A		-2.0 (-7.5; 3.6)	0.7
	Usual Care	N/A		-0.4 (-7.8; 7.0)	
Post-dialysis diastolic BP (mmHg)	Intervention	N/A		-3.4 (-6.0; -0.8)	0.3
	Usual Care	N/A		-1.3 (-4.7; 2.2)	
Having ≥ 1 consultation with dietitian during study (OR)	Intervention	0.69 (0.55; 0.83)	0.7	0.79 (0.67; 0.92)	0.6
	Usual Care	0.74 (0.55; 0.93)		0.73 (0.54; 0.93)	

CI – confidence interval; effect – mean change from baseline, adjusted for health district (stratification variable) or percentage adjusted baseline status and health district; N/A: for data that was only collected at baseline and 6 months

Table 4: Recommendations for development of Phase 2b trial of KIDNEYTEXT

Design	Adaptive, cluster randomization by dialysis unit ²²
Potential recruitment strategies	<ul style="list-style-type: none">• Pragmatic study design that is embedded within current renal nutritional care^{22, 23}• Consent process facilitated through renal clinicians (i.e. dietitians, nurses, nephrologists), rather than specific research staff^{22, 24}• Additional online portal patients can opt into without clinicians²²• Use of a care givers' mobile phone if necessary or preferred by the patient
Follow-up	6 month intervention with 3 month of follow-up
Blinding	Outcome assessors to be blinded
Interventions	Three mobile phone text messages per week for 6 months. Enhancement of personalisation of text messages by: <ul style="list-style-type: none">• participants being able to change the text message topics they receive throughout the intervention, or• having two-way communication with a dietitian or trained health professional.
Primary outcome	Dietary related markers of cardiovascular disease risk. Such as: <ul style="list-style-type: none">• potassium management (i.e. serum targets and use of medications)• phosphate management (i.e. serum targets and use of medications) and• fluid management (i.e. interdialytic weight gain)

Figure 1: Study flow diagram

Figure 2: Proportion of participants adhering to ≥ 3 renal dietary guidelines (non-adjusted) with 95% confidence intervals.



