Online Supplemental Material

This Online Supplemental Material has been provided by the authors to provide more detail regarding the ENTICE-CKD study.

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Supplemental Table 1. Description of data collection methods for the exploratory outcomes in the ENTICE-CKD study.

Exploratory outcome measure	Data collection method
Diet quality – food groups and nutrients	Exploratory measures of dietary quality and nutrient intake were measured by the Australian Eating Survey, including the (i) energy intake from the core food groups as per dietary guidelines in Australia and the US (fruit, vegetables, meats and meat alternatives, dairy, and grains and cereals); (ii) fruit intake; (iii) vegetable intake; (iv) fiber intake; (v) sodium intake; (vi) energy and (vii) protein intake.
Antihypertensive medication requirements, n (%)	Changes in antihypertensive medication requirements (total number, dose, class) were collected from participants and verified from patient records at each study visit. The change in antihypertensive pill counts was determined by substracting the total pill counts at each time point from the baseline pill count.
Body mass, Kg; cm	Body weight (rounded to the nearest 0.1kg) and waist circumference (rounded to the nearest 0.1cm) were collected to a standard protocol. ¹
Quality of Life, AQol- 4D	Quality of life was measured using the 'Assessment of Quality of Life' questionnaire (AQoL-4D), which was used to calculate quality adjusted life years (QALYs). ²
Risk markers of kidney disease progression	Risk markers of kidney disease progression were collected as the estimated glomerular filtration rate (GFR) from blood serum pathology and albuminuria on mid-stream urine samples.
Economic evaluation	Costs of the study included the total program and participant costs. Total costs included the intervention development (including programming of the software and technical staffing), intervention delivery costs (training, call duration, call attempts, phone call cost, text-messages, overheads), cost of the automated text-message system (subscription fee, staff time, and software required). We also collected an estimate of participant's individual daily food expenditures by matching dietary intake data from the FFQ with local supermarket costs and reported shopping habits based on the method described by Monsivais et al. ³ Healthcare costs captured downstream healthcare use over the duration of the trial using a patient-reported calendar approach, which captured a) visits to any healthcare providers (e.g. general practitioner, specialist and allied health providers), b) visits to hospital (including length-of-stay), and c) pathology costs collected outside of the trial. Quality-adjusted life years (QALYs) were calculated from the AQoL-4D and the proportion of participants achieving a 5-point improvement in diet quality was determined from the AHEI. The incremental cost per QALY gained, and the incremental cost per additional patient achieving a meaningful improvement in diet quality were calculated.

Abbreviations: kg: kilogram, cm: centimeter, AQoL-4D: Assessment of Quality of Life' questionnaire, QALY: Quality-adjusted life years, GFR: glomerular filtration rate, FFQ: Food frequency questionnaire, AHEI: Alternate Health Eating Index.

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Supplemental Table 2. Exploratory dietary and clinical outcomes in the ENTICE-CKD study

		3 months			6 months	
	Intervention	Control	N/	Intervention	Control	D/I
Evoloratory outcome	n=38	n=37	Mean Difference	n=35	n=36	Mean Difference
Exploratory outcome	11=36	11=37	Difference	11=35	11=30	Difference
Nutrient intake						
Fiber, grams/day	5.0 (2.9, 7.1)***	-1.3 (-3.3, 0.7)	6.1 (3.2, 8.9)***	1.5 (0.4, 3.5)	-0.2 (-2.9, 2.6)	1.1 (-2.0, 4.1)
		-420.1 (-				
	-321.9 (-625.5, -	689.8, -	162 (-170.5,	-466.2 (-803.4, -	-395.2 (-723.5,	-22.5 (-329.8,
Sodium, mg/day	18.3)*	150.5)*	495.3)	128.9)*	-66.8)*	284.8)
		-1196.5 (-			-1124.8 (-	
	-549.5 (-1540.1,	1954.2, -	622.7 (-401.6,	-1199.7 (-2344.4, -	2094.4, -	-267.3 (-
Energy, kj ^a	441.1)	438.9)*	1647.0)	55.1)*	155.1)*	1325.3, 790.7)
		-14.8 (-23.8, -			-13.8 (-25.2, -	-1.1 (-13.5,
Energy, kj/kg/day ^b	-1.6 (-11.6, 8.3)	5.7)*	10.8 (-0.9, 22.6)	-9.5 (-21.9, 2.8)	2.4)*	11.2)
		-0.1 (-0.3, -			-0.2 (-0.3, -	3.0 (-10.5,
Protein, g ^a	0.0 (-0.1, 0.1)	0.0)*	7.2 (-4.7, 19.1)	0.0 (-0.2, 0.2)	0.1)*	16.4)
		-11.6 (-21.3, -			-15.0 (-25.9, -	
Protein, g/kg/day ^b	-1.6 (-13.1, 9.9)	1.8)*	0.1 (-0.0, 0.3)	-3.7 (-18.9, 11.5)	4.2)*	0.0 (-0.1, 0.2)
Clinical outcomes						
Body mass						
Weight, kg ^c	-1.9 (-2.8, -0.9)***	0.1 (-1.1, 1.2)	-1.9 (-3.3, -0.4)*	-1.6 (-3.0, -0.2)*	-0.1 (-1.3, 1.2)	-1.5 (-3.5, 0.4)
Weight, % loss	-2.0 (3.0)	0.0 (3.4)	-1.9 (-3.4, -0.4)*	-1.5 (4.4)	-0.1 (3.8)	-1.5 (-3.4, 0.5)

Waist circumference, cm ^d	-2.0 (-3.2, -0.8)*	-0.9 (-2.7, 0.9)	-0.7 (-2.8, 1.4)	-2.9 (-4.8, -0.9)*	-1.1 (-3.6, 1.4)	-0.8 (-3.4, 1.8)
Kidney function						
		0.02 (-0.10,	-0.08 (-0.24,		0.02 (-0.17,	-0.08 (-0.30,
Serum creatinine, mg/dL	-0.06 (-0.16, 0.50)	0.14)	0.08)	-0.04 (-0.15, 0.06)	0.22)	0.13)
		·		· · · · · · · · · · · · · · · · · · ·	·	<u> </u>
eGFR, mL/min ^e	1 (-2, 3)	2 (-1, 4)	-1 (-5, 2)	2 (-1, 4)	3 (-0, 6)	-1 (-5, 2)
Albuminuria,						_
% change from baseline ^{f,g}	-47.0 (95.6)	-4.4 (89.7)	-	-18.1 (80.4)	8.5 (118.3)	-
Albuminuria, mg/L	0.1 (0.1, 0.4)	0.0 (0.1, 0.2)	0.1 (0.4 0.2)			0.2 (0.2 0.2)
$(Log\text{-}transformed)^g$	0.1 (-0.1, 0.4)	0.0 (-0.1, 0.2)	-0.1 (-0.4, 0.2)	0.0 (-0.2, 0.2)	0.0 (-0.1, 0.1)	0.3 (-0.2, 0.3)
Dose of anti-HTN medications						
Increase dosage, n (%)	1 (3)	9 (23)	- φ=0.33*	6 (16)	11 (29)	- φ=0.19
			ψ 0.55			ψ 0.17
Decreased dosage, n (%)	5 (13)	2 (5)		1 (3)	0 (0)	
Quality of life						
		-0.02 (-0.06,	0.03 (-0.02,		0.00 (-0.03,	0.01 (-0.03,
Independent-living ^h	0.03 (-0.01, 0.07)	0.02)	0.08)	0.01 (-0.02, 0.03)	0.02)	0.04)
		0.02 (-0.03,	0.01 (-0.06,		0.01 (-0.03,	0.01 (-0.06,
Relationships ^h	0.03 (-0.03, 0.09)	0.07)	0.07)	0.02 (-0.04, 0.09)	0.05)	0.07)
		0.00 (-0.02,	0.02 (-0.01,		0.02 (0.00,	0.00 (-0.03,
Senses ^h	0.01 (-0.02, 0.04)	0.02)	0.05)	0.01 (-0.02, 0.04)	0.04)	0.03)
		0.04 (-0.01,			0.04 (-0.02,	0.03 (-0.03,
Mental health ^h	0.05 (0.01, 0.10)*	0.08)	0.05 (0.01, 0.09)	0.04 (0.00, 0.09)*	0.10)	0.08)
		0.03 (-0.03,	0.70 (-0.01,		0.05 (-0.01,	0.02 (-0.06,
Overall QOL ^h	0.10 (0.03, 0.16)*	0.09)	0.15)	0.07 (0.01, 0.14)*	0.12)	0.10)
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			0.01 (-0.01,			0.02 (-0.02,
QALYS gained ⁱ	0.16 (0.04)	0.15 (0.06)	0.03)	0.33 (0.09)	0.31 (0.11)	0.07)

^a Sample size at 3 months (n=38 for intervention; n=37 for control). Sample size at 6 months (n=35 for intervention; n=36 for control).

^b Sample size at 3 months (n=37 for intervention; n=37 for control). Sample size at 6 months (n=35 for intervention; n=36 for control).

^{c.} Sample size at 6 months (n=37 for intervention)

d. Sample size at 3 months (n=36 for intervention; n=35 for control). Sample size at 6 months (n=32 for intervention; n=34 for control).

^{e.} Sample size at 6 months (n=37 for intervention).

f. Albuminuria is reported as median and interquartile range and is the absolute value for each time point. No between group differences calculated.

g. Sample size at 3 months (n=33 for intervention; n=36 for control). Sample size at 6 months (n=33 for intervention; n=35 for control).

h. Sample size at 3 months (n=37 for intervention; n=36 for control). Sample size at 6 months (n=38 for intervention; n=36 for control).

i. 3- and 6-month data is reported as mean (SD) as within group changes cannot be analyzed.

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Supplemental Table 3. Cost-effectiveness of the tailored intervention (Phase 1 (0-3 months): workbook, telephone coaching with tailored text messages; Phase 2 (3-6 months) tailored text messages only) versus non-tailored intervention (Phase 1 (0-3 months) usual care plus workbook; Phase 2 (3-6 months) non-tailored text messages).*

	0-3 months			
	Intervention	Control		
	n=38	n=38		
Health Outcomes				
Proportion of patients achieving a meaningful change in dietary	19 (50.0)	14 (36.8)		
quality, n (%)	0.1.1.0.0.0	2.17 (2.2)		
QALYs	0.16 (0.05)	0.15 (0.06)		
Costs, AUD				
Program cost (as delivered, per participant)	\$250.19	\$8.99		
Healthcare costs#				
Mean ± SD	\$511.97 (1,626.60)	\$801.04 (2,915.70)		
Participant food costs				
Mean ± SD	\$1,046.25 (278.04)	\$1,034.14 (270.89)		
Total costs (per participant) including participant food cost				
Mean ± SD	\$1,780.88 (1,665.25)	\$1,789.74 (2,850.51)		
Median (IQR)	\$1,498.74 (1191.44, 1749.59)	\$1,202.85 (1001.87, 1421.18)		
Incremental cost per additional patient achieving a meaningful	T. (
change in diet quality (including food costs)	intervention is less costly and m	ore effective at 3 months (dominant)		
Incremental cost per QALY gained (including food costs)	Intervention is less costly and m	ore effective at 3 months (dominant)		
Sensitivity analysis 1: excluding participant food costs				
Total costs (per participant) excluding participant food				
Mean ± SD	\$762.16 (1626.60)	\$810.03 (2915.70)		
Median (IQR)	\$382.42 (321.05, 481.68)	\$182.13 (46.04, 273.07)		
Incremental cost per additional patient achieving a meaningful				
change in diet quality (excluding food costs)	Intervention is less costly and more effective at 3 months (dominant)			
Incremental cost per QALY gained (excluding food costs)	Intervention is less costly and more effective at 3 months (dominant)			

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Sensitivity analysis 2 excluding outliers (>3 SD total costs)			
Total cost (per participant) including participant food cost			
Mean ± SD	\$1,525.87 (557.87)	\$1,349.89 (891.71)	
Median (IQR)	\$1,494.74 (1187.26, 1743.21)	\$1,194.05 (992.36, 1402.19)	
Incremental cost per additional patient achieving a meaningful change in diet quality	\$1,337.44 per additional patient achieving a meaningful change in diet quality at 3 months		
Incremental cost per QALY gained	\$16,328.71 per additional QALY gained at 3 months		

^{*} We were unable to analyze the 6 month cost-effectiveness of the ENTICE-CKD program, as the tailored telehealth intervention was delivered in 2 phases, both of which had different interventions (in both the intervention and control).

Abbreviations: QALY: Quality-adjusted life year, SD: standard deviation, IQR: Interquartile range. AUD: All data is reported in Australia Dollars.

[#] There was no significant difference in healthcare costs between the groups at 3 months.

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		Screening and recruitment					
		Randomization					
		✓ >					
	Week	Intervention group Control group					
		Baseline Visit					
		Outcome	s				
		Demographics					
		• Health l	•				
			intake (FFQ)				
		_	eight and waist circumfer	rence			
		Blood p Medicat	ressure tion requirement				
		• Quality					
Phase 1			athology (including electr	rolytes (Potassium) and			
Thase T			ne (to assess eGFR))				
		• Urinary	albumin-creatinine ratio				
	2						
	4		ghtly telephone calls +	Usual Care			
	6	tailo	ored text messages	(workbook only)			
	8		+ workbook	(3222 2 22 2 22)			
	10						
	12		*	+ telephone call			
		Outcomes					
		Dietary intake (FFQ)Body weight and waist circumference					
		Blood pressure					
			Medication requirement				
3-month vis	sit	• Quality of Life					
			Safety				
			Blood Pathology (incl				
				tinine (to assess eGFR))			
			 Urinary albumin-creat Adverse events 	tinine ratio			
	14						
	16	Taile	ored text messages				
Phase 2	18	,	Telephone call	Educational text messages			
Tildse 2	20 22		ored text messages				
	24	End-point visit					
	Outcomes						
		• Dietary intake (FFQ)					
			Body weight and waist circumference				
Blood pressure							
6-month vis	6-month visit		Medication requirement				
o monur visit			• Safety				
		Blood Pathology (including electrolytes (Potagainum) and Creatining (to aggree a CEPD))					
		(Potassium) and Creatinine (to assess eGFR)) • Urinary albumin-creatinine ratio					
		Adverse events					

Supplemental Figure 1. Summary of ENTICE-CKD program delivery

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References

- National Health Medical Research Council. Clinical practice guidelines for the management of overweight obesity in adults, adolescents and children in Australia.
 In: National Health and Medical Research Council Melbourne; 2013.
- 2. Hawthorne G, Richardson J, Osborne R. The Assessment of Quality of Life (AQoL) instrument: a psychometric measure of Health-Related Quality of Life. *Quality of life research*. 1999;8(3):209-224.
- 3. Monsivais P, Perrigue M, Adams S, Drewnowski A. Measuring diet cost at the individual level: a comparison of three methods. *Eur J Clin Nutr.* 2013;67(11):1220-1225.