Utilizing Technology for Diet and Exercise Change in Complex Chronic Conditions Across Diverse Environments (U-DECIDE): Feasibility Randomised Controlled Trial

Online Supplementary Material

Contents

Supplementary Material 1: Serious adverse events and adverse events of special interest

Table S1.1 List of serious adverse events and adverse events of special interest recorded and monitored during the study period

Serious adverse event categories
• Death • Life-threatening event • Hospitalisation, including planned and unplanned admissions • Event resulting in persistent or significant disability or incapacity • Important medical event (eg. adverse drug reaction) • Pregnancy
Adverse event of special interest categories
• Hypoglycaemic episode requiring assistance from another individual • Fall • Musculoskeletal injury requiring medical or allied health attention • Hyperkalaemia (newly diagnosed or requiring intervention) • Episode of low blood pressure requiring medical attention • Chest pain requiring medical attention • Covid infection during study period

Supplementary Material 2: Dietary topics discussed during dietitian review appointments

Food based education included topics such as healthy protein sources, fruit and vegetables, healthy fat sources, whole grains and cereals, healthy snacks, alcohol, herbs and spices, healthy dairy foods, healthy drink choices / water, discretionary foods & multicultural foods

Diet pattern-based education included topics such as recommended serve sizes of food groups, recommended food portions within plated meals, Mediterranean diet, Australian Guide to Healthy Eating / core food groups, regular meals/avoid skipping meals & heart healthy diet.

Nutrient / disease specific based education included topics such as weight management, fibre, dietary electrolytes (sodium, potassium, phosphate and/or mercury), fluid management, diet for kidney disease, diet for high cholesterol, diet for gastritis, nutrition support, FODMAPS, disease specific protein targets, diet for high blood pressure, diet for nausea & food safety after transplant.

Behavioural strategies included topics such as goal setting and monitoring goals, meal planning / recipes, practical food ideas / swaps, mindful eating, eating out, food monitoring diary / apps, social events, pre-prepared meals, support systems & label reading.

Physical activity education was general in nature and not prescribed to individual needs.

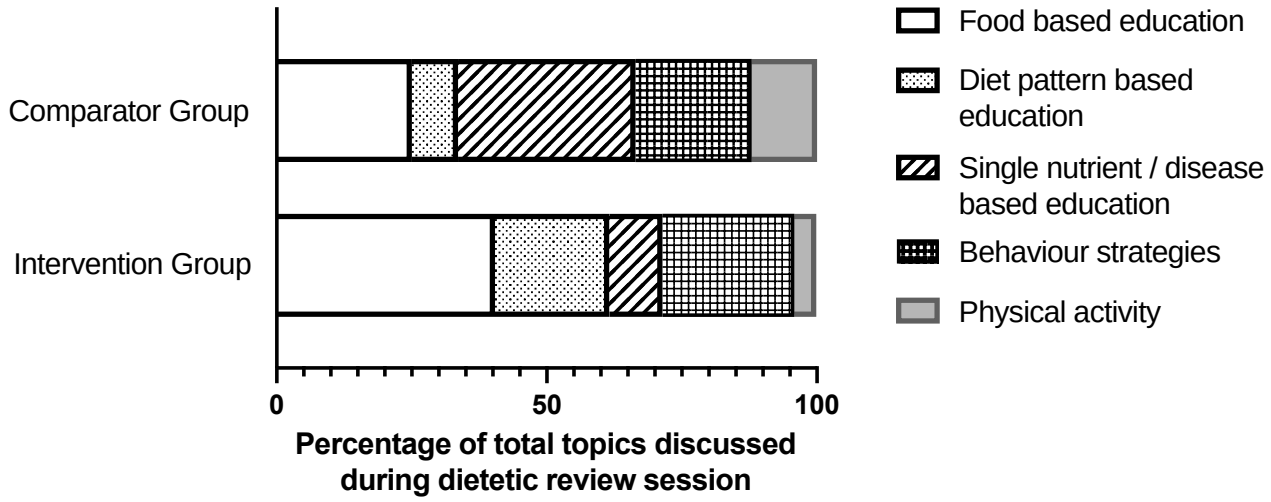

Figure S2.1 Topics discussed within dietitian review appointments in the intervention and comparator groups.

$p<0.0001$ (chi-squared test)

Supplementary Material 3: Nutrition app engagement

All fact sheets were accessible to any participants in the intervention group who chose to engage with the nutrition app, despite some fact sheets being tailored to specific conditions (e.g. eating well for kidney disease). Participants were able to access the app as they desired. The platform provided quarterly key metrics including: number of active users, date and frequency of engagement per session, the type of device used, and the pages accessed.

Each of the following platform components were measured for engagement (i.e., at least one click): 1) 'Welcome to the program' page; 2) 'Program tool kit' page; 3) 'Recipe hub' page or 4) any of the fact sheet pages. For each participant who selected access to the nutrition app, engagement data was guided by the Frequency, Intensity, Time and Type (FITT) principle)[1]. Frequency was determined by number of sessions engaged each month, number of participants who accessed each fact sheet, total number of sessions for the duration of the study. Intensity was determined by the proportion of eligible participants who engaged or did not engage with the app. Time was calculated as the time participants engaged with app material (days from first to last session using online duration calculator) and time between engagement sessions (total days between first to last engagement/number of times between engagements). Type was described as the type of device used to engage with the app (mobile phone, personal computer or combination of both).

Supplemental Material 3 references:

[1] Short CE, DeSmet A, Woods C, Williams SL, Maher C, Middelweerd A, et al. Measuring Engagement in eHealth and mHealth Behavior Change Interventions: Viewpoint of Methodologies. J Med Internet Res. 2018;20(11):e292.

Supplementary Material 4: Metabolic Syndrome Severity Score (MetSSS) calculation

Algorithm description for the metabolic syndrome severity score (MetSSS)

Adapted from: Wiley JF, Carrington MJ. A metabolic syndrome severity score: A tool to quantify cardio-metabolic risk factors. *Prev Med*. 2016; 88:189-195.

Steps to calculate the MetSSS:

1. Censor: set all biomarker values for each individual case that are below the clinical threshold to the clinical threshold shown in Table S2
2. Centre: subtract relevant clinical threshold from each biomarker value
3. Standardise: divide each censored and censored biomarker value by the matching standard deviation shown in Table S3.
4. Orthogonalise: post-multiply the normalised data matrix by the component loading matrix shown in Table S4
5. Standardise: post-multiply by a diagonal matrix comprised of the inverse of the standard deviations of the principal components shown in Table S5
6. Square: square each individual value
7. Sum: take the sum of the squared values for each individual row
8. Square root: take the square root of the sum of the squared values

Table S4.1 Sex-specific clinical thresholds for classification of metabolic syndrome[1]

	Women	**Men**
Waist circumference, cm	≥80	≥94
Triglycerides, mmol/L	≥1.7	
High-density lipoprotein cholesterol, mmol/L	≤1.3	≤1.0
Systolic blood pressure, mmHg	≥130	
Diastolic blood pressure, mmHg	≥85	
Blood glucose, mmol/L	≥5.6	

Table S4.2 Standard deviations (SD) for each biomarker value in the MetS

	SD
Systolic blood pressure, mmHg	13.28
Diastolic blood pressure, mmHg	3.14
Triglycerides, mmol/L	0.30
High-density lipoprotein cholesterol, mmol/L	0.17
Waist circumference, cm	8.60
Blood glucose, mmol/L	0.13

Table S4.3 Principal Component Analysis component loading matrix

	C1	**C2**	**C3**	**C4**	**C5**	**C6**
Systolic blood pressure, mmHg	0.58	0.36	-0.01	0.00	-0.12	0.72
Diastolic blood pressure, mmHg	0.55	0.40	-0.07	-0.06	-0.25	-0.68
Triglycerides, mmol/L	0.36	-0.41	-0.02	-0.74	0.40	-0.02
High-density lipoprotein cholesterol, mmol/L	0.17	-0.62	-0.31	0.05	-0.70	0.06
Waist circumference, cm	0.41	-0.32	-0.18	0.66	0.51	-0.08

Blood glucose, mmol/L	0.19	-0.25	0.93	0.12	-0.15	-0.04

Table S4.4 Standard deviations (SD) of the six principal components

	SD
C1	1.31
C2	1.12
C3	0.98
C4	0.90
C5	0.87
C6	0.69

Formula for the MetSSS

Let **C** be an n × 6 matrix containing the appropriate threshold for each individual case for each biomarker. Let $\mathbf{S_1}$ be a 6 × 6 diagonal matrix containing the inverse of the standard deviation for each biomarker (shown in Table S3). Let **L** be a 6 × 6 matrix containing the principal component loadings (shown in Table S4). Let $\mathbf{S_2}$ be a 6 × 6 diagonal matrix containing the inverse of the standard deviations of each component (shown in Table S5). Let **X** be an n × 6 matrix where each row represents an individual case and each column contains the values for a biomarker of the MetS, where any values below threshold are censored at the threshold. Then the MetSSS for the *i*th individual case can be calculated using the following formula:

$$Y_i = \sqrt{\sum_{j=1}^{6} (\big((X - C)S_1\big)LS_2)_{i,j}^{2}}.$$

Supplemental Material 4 references:

[1] Alberti KG, Eckel RH, Grundy SM, et al. Harmonizing the metabolic syndrome: a joint interim statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. *Circulation*. 2009; 120(16):1640-1645.

Supplementary Material 5: IPAQ-SF Physical Activity Classification

Table S5.1 International Physical Activity Questionnaire Short-Form (IPAQ-SF) physical activity categorical scoring[1, 2]

Physical activity level	Description	
Low	If not moderate or vigorous	
Moderate	i)	Three or more days of vigorous-intensity activity of at least 20 minutes per day OR
	ii)	Five or more days of moderate-intensity activity and/or walking of at least 30 minutes per day OR
	iii)	Five or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum total physical activity of at least 600 MET-minutes/week
High	i)	Vigorous-intensity activity on at least three days (20 minute minimum) achieving a minimum total physical activity of at least 1500 MET-minutes/week OR
	ii)	Seven days of any combination of walking, moderate-intensity activity or vigorous-intensity activities achieving a minimum total physical activity of at least 3000 MET-minutes/week

Abbreviations: MET, metabolic equivalent

Supplemental Material 5 references:

[1] IPAQ Group. Guidelines for Data Processing and Analysis of the International Physical Activity Questionnaire (IPAQ) – Short and Long Forms. IPAQ Group, 2005.

[2] Cheng, HL. A simple, easy-to-use spreadsheet for automatic scoring of the International Physical Activity Questionnaire (IPAQ) Short Form (updated November 2016). ResearchGate, 2016.

Supplementary Material 6: Attendance data

Table S6.1 Attendance rate of video consultations with Dietitian (offered monthly) and Exercise Physiologist (offered weekly). Video consultations were all pre-booked in advance at baseline for the remainder of the study if this digital health option was chosen by the participant.

Attendance	Dietitian video consultations attended (total of 125 pre-booked)	Exercise video consultations attended (total of 676 pre-booked)
Attended	54 sessions (43%)	284 (42%)
Did not attend	71 sessions (57%)	392 (58%)

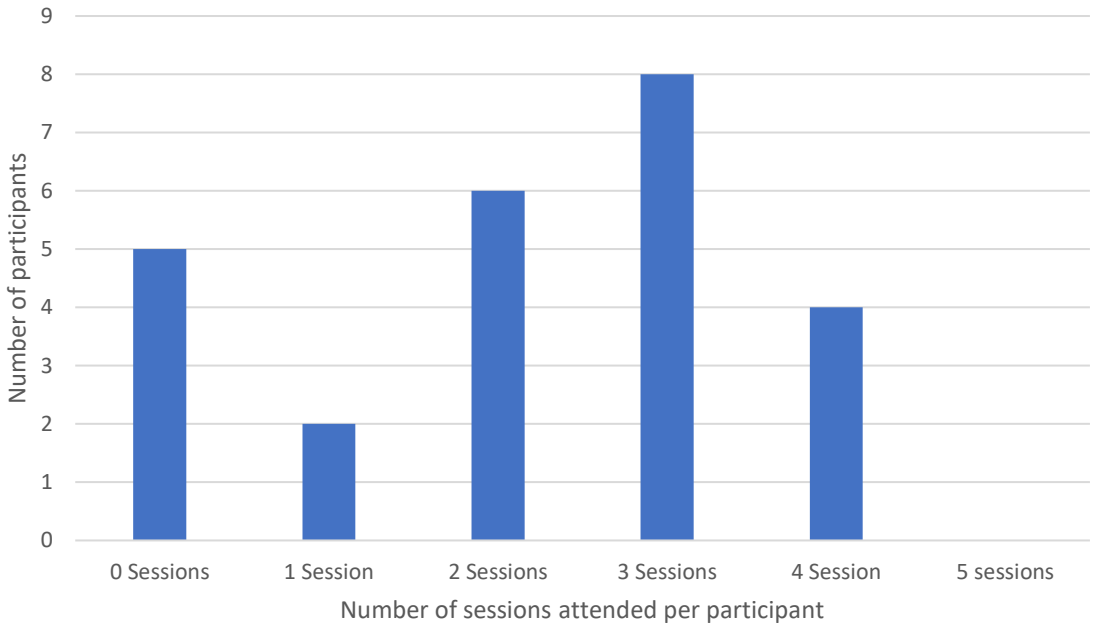

Figure S7.1 Breakdown of number of dietitian telehealth sessions attended per participant

Supplementary Material 7: Nutrition fact sheet access

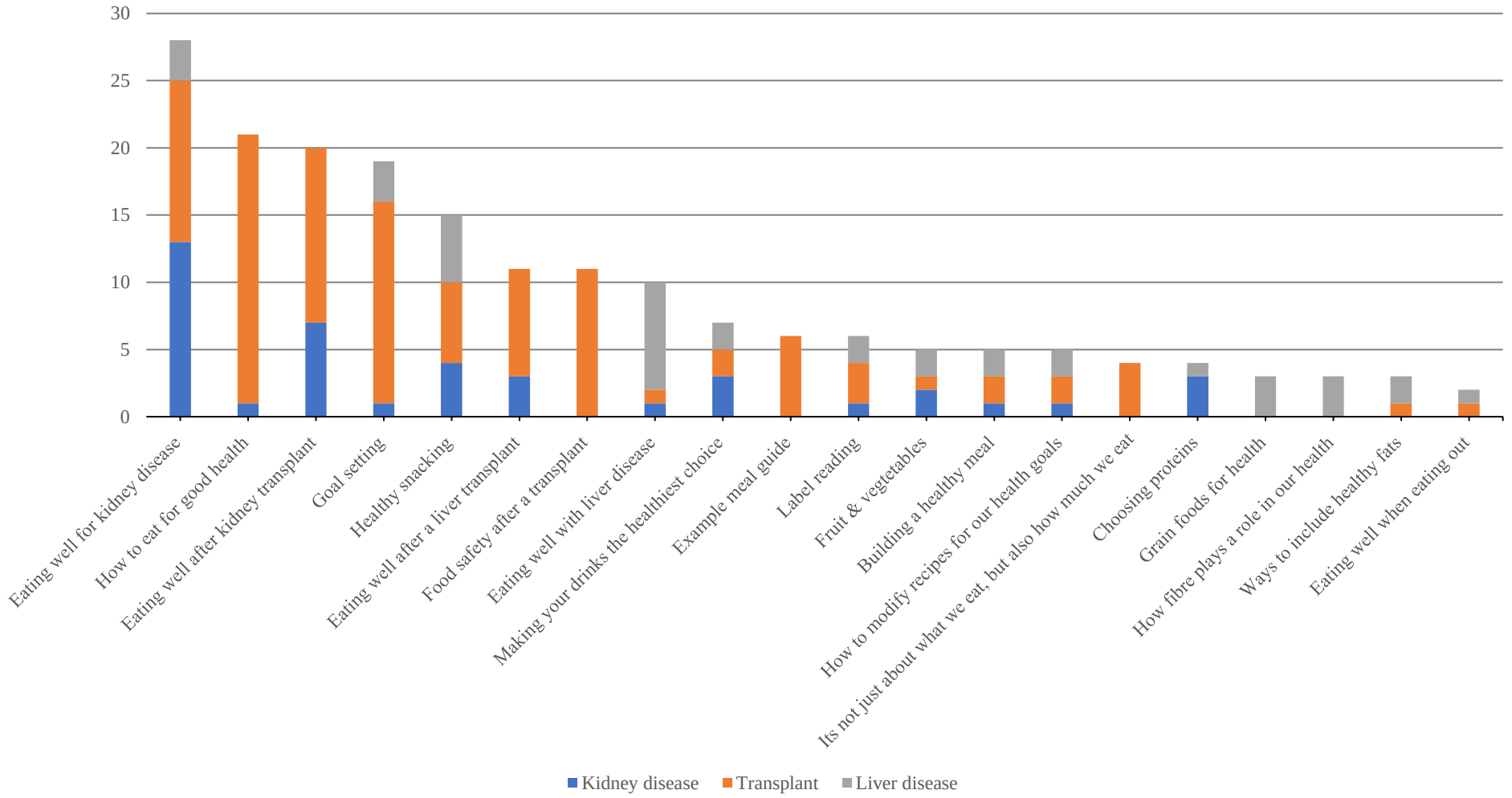

Figure S7.1 Frequency of access for each fact sheet available via the nutrition app

Supplementary Material 8: Missing data details
Table S8.1 Missing data rates for secondary outcomes

	Missing data, n (%)	
Measurement	**Baseline (n=67)**	**26-week assessments**
Systolic blood pressure	0 (0%)	11 (16.4%)
Diastolic blood pressure	0 (0%)	11 (16.4%)
Waist circumference	0 (0%)	21 (31.3%)
Triglycerides	12 (17.9%)	20 (29.8%)
High-density lipoprotein cholesterol	13 (19.4%)	21 (31.3%)
Fasting blood glucose	1 (1.5%)	9 (13.4%)
Diet record[#]	7 (10.4%)	23 (34.3%)
International Physical Activity Questionnaire	0 (0%)	15 (22.4%)
6-minute walk test	0 (0%)	27 (40.3%)
Repeated chair stand test (5xSTS)	2 (2.9%)	25 (37.3%)
Modified Nordic Musculoskeletal Questionnaire	0 (0%)	16 (23.8%)
European Quality of Life Five Dimension Five Level Scale	0 (0%)	15 (22.4%)
Functional Assessment of Chronic Illness Fatigue Scale	0 (0%)	16 (23.8%)
Pittsburgh Sleep Quality Index	0 (0%)	16 (23.8%)

[#] There were no differences in sex, age, BMI, education level, or disease stratification between participants who had complete versus incomplete diet record data. The proportion of participants with completed diet records tended to be lower among those who were full-, part-time or self-employed versus not employed (55% versus 74%, p=0.11) and in those with CKD versus those with liver disease or who had received a kidney or liver transplant (50% versus, 71% and 78% respectively, p=0.15).

Supplementary Material 9: Additional nutrient intake variables and analysis

Table S9.1 Changes in additional nutrient intake variables between groups via ANCOVA

	INT (n=24)		COM (n=20)				
Variable (intake /day)	**Baseline**	**Change (Week 26)**	**Baseline**	**Change (Week 26)**	**Adjusted Mean Difference in Change Score INT – COM (95%CI)**	**Effect Size (η^2) (p-value)**	**Magnitude of between-group effect**
Macronutrients							
Protein (g)	97.7 ± 33.1	-1.5 ± 37.8	94.4 ± 30.3	-4.2 ± 38.0	4.5 (-16.4 to 25.4)	0.00 (*p*=0.66)	negligible
Protein (%E)	19.8 ± 6.2	0.1 ± 6.1	20.0 ± 4.6	1.4 ± 4.8	-1.5 (-4.0 to 1.0)	0.02 (*p*=0.23)	small
Carbohydrates (g)^	211.4 [159.4 to 279.3]	-14.3 [-81.3 to 46.0]	197.1 [149.1 to 222.6]	-20.9 [-66.8 to 11.6]	n.a.	0.84# (*p*=0.36)	n.a.
Carbohydrates (%E)	42.5 ± 9.3	-0.1 ± 11.5	40.1 ± 7.1	0.1 ± 7.6	1.7 (-3.1 to 6.4)	0.01 (*p*=0.48)	small
Fat (g)^	79.3 [55.7 to 97.5]	-8.6 [-19.0 to 19.4]	71.9 [59.2 to 55.7]	-15.9 [-43.1 to 13.7]	n.a.	0.15# (*p*=0.22)	n.a.
Fat (%E)	34.0 ± 6.8	0.1 ± 7.8	36.5 ± 6.3	-2.4 ± 6.8	0.7 (-2.7 to 4.2)	0.00 (*p*=0.67)	negligible
SFA (g)	33.2 ± 12.6	-5.2 ± 9.0	30.7 ± 12.0	-3.5 ± 15.0	-1.0 (-8.2 to 6.2)	0.00 (*p*=0.78)	negligible
SFA (%E)^	15.0 [13.5 to 17.5]	-2.1 [-3.6 to 0.7]	15.5 [11.2 to 18.3]	-0.8 [-2.6 to 2.6]	n.a.	1.34# (*p*=0.25)	n.a.
MUFA (g)^	28.4 [23.1 to 35.5]	-3.2 [-8.8 to 14.6]	27.6 [23.8 to 38.7]	-7.3 [-14.6 to 5.1]	n.a.	2.35# (*p*=0.13)	n.a.
MUFA (%E)^	13.2 [11.1 to 15.7]	-0.2 [-1.4 to 2.9]	15.1 [12.6 to 17.7]	-1.5 [-4.8 to 1.8]	n.a.	0.23# (*p*=0.63)	n.a.

PUFA (g)	10.8 ± 4.3	1.3 ± 4.2	12.1 ± 6.0	-1.9 ± 6.4	2.7 (-0.4 to 5.7)	0.06 (*p*=0.09)	small/moderate
PUFA (%E)	5.1 ± 1.7	0.6 ± 1.8	5.9 ± 1.9	-0.3 ± 2.3	0.4 (-0.5 to 1.3)	0.01 (*p*=0.42)	small
Micronutrients							
Sodium (mg)	2771.9 ± 899.5	-375.5 ± 903.7	2320.8 ± 761.8	-136.5 ± 995.0	-73.8 (-647.7 to 500.2)	0.00 (*p*=0.80)	negligible
Potassium (mg)	3162.1 ± 1074.3	-102.8 ± 1188.3	3006.7 ± 1108.4	-16.7 ± 1134.7	18.4 (-615.1 to 651.8)	0.00 (*p*=0.95)	negligible
Phosphorus (mg)	1530.1 ± 583.4	8.2 ± 63.6	1530.2 ± 482.9	-63.6 ± 517.1	71.7 (-245.5 to 389.0)	0.00 (*p*=0.65)	negligible
Iron (mg)^	10.4 [8.5 to 13.9]	-2.1 [-3.3 to 1.6]	9.9 [7.4 to 12.9]	-1.7 [-4.4 to 1.9]	n.a.	0.50# (*p*=0.48)	n.a.
Calcium (mg)^	757.5 [582.8 to 1119.7]	-70.3 [-204.9 to 282.4]	772.0 [582.8 to 1112.4]	-106.9 [-238.4 to 91.8]	n.a.	0.72# (*p*=0.40)	n.a.
Folate (DFE in ug)	618.9 ± 247.5	-66.6 ± 274.8	694.1 ± 379.4	-105.2 ± 248.8	-3.1 (-126.4 to 120.1)	0.00 (*p*=0.96)	negligible
Linoleic acid (g)	8.89 ± 3.57	1.41 ± 4.16	10.48 ± 5.74	-1.99 ± 5.96	2.5 (-0.2 to 5.3)	0.06 (*p*=0.07)	small/moderate
ALA (g)^	1.3 [0.9 to 1.6]	0.0 [-0.2 to 0.5]	1.3 [0.9 to 2.0]	-0.3 [-0.6 to 0.0]	n.a.	**4.54# (*p*=0.04)**	n.a.
Very long chain omega-3 (g)^	0.2 [0.1 to 0.6]	0.0 [-0.1 to 0.3]	0.1 [0.1 to 0.2]	0.0 [-0.1 to 0.1]	n.a.	0.90# (*p*=0.35)	n.a.

Data presented in mean ± SD. ^Median [IQR]. #*F* statistic generated by quades nonparametric ANCOVA.

Abbreviations: INT, intervention; COM, comparator; n, number; η^2, eta-squared; CI, confidence interval; n.a., Not available due to variable not being generated by quades nonparametric ANCOVA; %E, percentage contribution to total energy intake; SFA, saturated fatty acids; MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids; DFE, dietary folate equivalents; ALA, alpha-linolenic acid

Supplementary Material 10: Economic analysis

Table S10.1. Itemised costs, cost offsets, net benefit and return on investment for the intervention and usual care from the perspective of the health service for the 6-month trial.

	Intervention totals (min – max range)	**Usual care totals (min – max range)**
Costs		
Initial dietitian appointment	$56.61	$56.61
Follow-up group appointment dietitian (range for 1-3 appointments)	$84.91 ($56.61 to $169.82)	$56.61 ($0.00 to $169.82)
Dietitian app set-up consultation	$5.76	$0.00
Exercise physiology group exercise sessions (range for 1.1-26 appointments)	$129.64 ($49.36 to $1,166.72)	$0.00 (not offered)
Administration support for consultation booking (range 4.1-29 appointments)	$206.92 ($144.06 to $1,018.97)	$70.27
Dietetics app Sophus©	$178.57 ($178.57 to $454.55)	$0.00 (not offered)
Exercise app PhysiApp©	$107.94	$0.00 (not offered)
Fitbit Inspire HR	$165.00	$0.00 ($0.00 - $165.00) (offered in study comparator group for research purposes but not offered typically in usual care)
Physical resources (rooms etc), and technology for VC and phone. All resources pre-existing.	$0.00 (pre-existing)	$0.00 (pre-existing)
Total costs (range for variation in the number of appointments)	**$935.34 ($758.15 to $3,139.60)**	**$183.49 ($126.88 to $461.71)**
Cost offsets		
Remuneration initial dietetics appointment	$163.00	$163.00
Remuneration follow-up dietetics appointment (range 1-3 and 0-2 appointments)	$246.00 ($164.00 to $492.00)	$110.00 ($0.00 to $219.00)
Remuneration group exercise physiology VC (range for 1.1-26 appointments)	$1,360.00 ($0.00 to $4,160.00)	$0.00
Total cost offsets (range)	**$1,769.00 ($327.00 to $4,815.00)**	**$273.00 ($163.00 to $382.00)**
Net benefit (range)	**$833.66 (-$431.15 to $1,675.40)**	**$89.01 ($36.12 to $79.71)**
ROI (range)	**$1.89 ($0.43 to $1.53)**	**$1.49 ($1.28 to $0.83)**

Abbreviations: *VC*, Video consultation; *ROI*, Return on investment.