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Effect of interdisciplinary care on weight loss in chronic disease management: a randomized controlled trial.

Objective: To determine the effectiveness of a novel interdisciplinary treatment compared with usual care on weight loss in overweight and obese adult volunteers.

Design: Single-blinded controlled trial. Participants randomly assigned to usual care (C, general guideline-based diet and exercise advice), intervention (I, interdisciplinary protocol) or intervention+ a healthy food supplement (30g walnuts/d) (IW).

Setting: Community based study, Illawarra region, south of Sydney, Australia.

Participants: Generally well volunteer adult residents, 25-54y, BMI 25-40kgm^{-2} were eligible. At baseline 439 were assessed, 377 were randomised, 298 completed the 3mo intensive phase and 178 completed the 12mo follow up.

Interventions: Treatment was provided at clinic visits intensively (0,1,2,3mo) then quarterly to 12mo. Support phone calls were quarterly. All participants underwent blinded assessments for diet, exercise, and psychological status.

Primary and secondary measures: The primary outcome was difference in weight loss between baseline and 12mo (clinically relevant target 5% loss). Secondary outcomes were changes in blood pressure, fasting blood glucose and lipids, and changes in diet, exercise and psychological parameters.

Results: At 12mo, differences in weight loss were identified (P<0.001). The I group lost more than controls at 3mo (-1.11[-2.23,-0.00], P<0.05) and the IW more than controls at 3mo (-1.25 [-2.35,-0.15], P<0.05) and 6mo (-2.20[-3.90,-0.49], P<0.01). The proportion achieving

5% weight loss was significantly different at 3,6 and 9mo (P=0.04, 0.03, 0.03), due to fewer controls on target at 3,6 and 9mo and more IW participants at 6mo. Reductions in secondary outcomes (systolic bold pressure, blood glucose/lipid parameters, and lifestyle measures) followed the pattern of weight loss.

Conclusions: An interdisciplinary intervention produced greater and more clinically significant and sustained weight loss compared to usual care. The intensive phase was sufficient to reach clinically relevant targets, but long term management plans may be required.

Trial registration: Australian New Zealand Clinical Trials Registry ANZCTRN 12614000581662, www.anzctr.org.au

Strengths and limitations of this study

- The study was closely aligned to practice and protocols tested could be readily translated into primary care services
- Although this was a single centre study, substantial controls were applied to provided quality evidence of effects
- The study demonstrated the breadth of behavioural influences integral to achieving weight loss and clinical outcomes
- Rigorous statistical analyses were applied to the evaluation of primary outcomes, including a sensitivity analysis to confirm effects.
- As practice oriented research, retention strategies were not applied, with higher than anticipated loss to follow up following the intensive phase.

INTRODUCTION

The prevention and management of chronic non-communicable disease (CNCD) is a challenge for health services[1].Given the links to disease pathology, identifying overweight as a problem is an important first step[2]. Primary Care is an ideal setting for the clinical management of obesity, yet relevant studies are scarce[3], and measuring or recording weight in this setting appears sub optimal[4]. In addition, weight management may require a more shared sense of decision making[5], and a broader approach, including the expertise of relevant allied health professionals[6]. For example, dietitians may provide expertise on nutritional factors other than dietary energy that influence weight loss and chronic disease risk factors[7], such as dietary patterns[8], significant foods[9], and nutrients such as fibre[10], fatty acids[11], and sodium[12].

Health behaviours that can significantly lower disease risk are central to the management of chronic disease[13]. There is convincing evidence that focusing on diet, physical activity and behaviour will have the best effects on overweight[14]. Obese individuals who lose just 5% of their body weight (the target for American College of Cardiology/American Heart Association clinical guidelines[2]) have significant improvements in risk factors for type 2 diabetes and cardiovascular disease, including improved insulin sensitivity and reduced fat in the liver[15]. However, there are underlying metabolic problems and weight regain invariably follows[16 17]. This suggests obesity itself is a chronic condition requiring acute effective treatments repeated at intervals[16] with the provision of consistent positive reinforcement to address associated complex psychological factors[18]. There is little research on holistic treatments that integrate diet, exercise and psychological support[19] and research is needed to test novel protocols in this area[20 21]. In a feasibility trial comparing usual care with an interdisciplinary model, we found high eligibility (83%) and completion (87%) rates and a

preliminary effect of -3.98kg greater weight loss over 3mo (95%CI 6.17-1.79, P=0.002)[22]. In the current trial we hypothesised that a model of care with physician oversight that integrates the expertise of dietitians, with exercise physiologists and psychologists will be more effective than general advice provided by a practice nurse (usual care). Further, the provision of a supplement of a significant healthy food may enhance this effect and influence the overall diet.

METHODS

Study oversight and ethics

The study was approved by the University of Wollongong/Illawarra Shoalhaven Local Health District Human Research Ethics Committee (Health and Medical) (HE 13/189) and conducted in compliance with the Principles of the Declaration of Helsinki. The trial is registered with the Australian and New Zealand Clinical Trial Registry (ANZCTRN12614000581662). Study oversight was provided by the senior clinical investigative team.

Study participants

Recruitment was conducted through communications and advertising in the local media. Respondents who were permanent residents of the Illawarra region, aged 25-54 years, community dwelling, and with a BMI 25-40kg/m^2 were included. Exclusion criteria were being unable to communicate in English; having severe medical conditions, having reported illegal drug use or regular alcohol intake associated with alcoholism (>50g/day); or other major impediments to participation.

Trial design

This was a community specific (single center), randomized, assessor blinded trial, comparing outcomes between intervention and control groups at 0, 3, 6, 9, 12 mo. Full details of the study protocol and baseline results are reported elsewhere[23]. Briefly, all participants attended the clinic for counselling on 7 occasions (0, 1, 2, 3, 6, 9, 12mo) and received quarterly support phone calls. Assessment and treatment protocols were devised by the research team including Physicians, Dietitians, Exercise Physiologists and Psychologists. Measurements were undertaken separately at these time points. Body weight (kg) was measured at each visit in an upright position (minimal clothing, no shoes) using scales with a bio-electrical impedance component for estimating body fat (%) (Tanita TBF-662, Wedderburn Pty Ltd, Ingleburn, NSW, Australia). Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured at 0, 3 and 12mo using the Omron BP-203RPEIII VP-1000 device (Omron Health Care, Kyoto, Japan). Measurements are collected at the end of 5 min resting period in supine position. Fasting blood lipids (cholesterol, LDL, HDL, Trig), fasting blood glucose, and serum HBA1c were assessed through a registered Pathology service (Southern IML Pathology) quarterly. For 24 hour urinary sodium assessments a 24 hour urine sample was provided at 0, 3 and 12mo. Dietary intake was assessed using a diet history interview[24] and physical activity using the International Physical Activity Questionnaire (IPAQ)[25] and via a pedometer worn for a four day period every quarter. A range of psychological assessments were applied, including the Physical and Mental Health SF-12 (12 questions)[26] and Acceptance and Action Questionnaire for Weight-related problems (11 questions) (AAQW)[27] at 0, 3 and 12mo.

Participants were randomly assigned to usual care (C, general advice), intervention (I, interdisciplinary advice) and intervention+ food supplement (IW, I+ 30g walnuts/day). Usual care involved a nurse providing general advice based on the Australian Guide to Health Eating, (AGHE)[28] and National Physical Activity Guidelines[29]. Phone contact at quarterly

intervals was also made with the by the study administrator delivering semi scripted patient centred support of short duration. In the intervention counselling session an Accredited Practising Dietitian negotiated changes in specific food choices based on a diet history assessment and materials that referred to the food groups outlined in the AGHE (vegetables, fruits, grains, protein rich foods, dairy foods, oils). This consultation included advice on exercise with categorical guidance prepared by the Exercise Physiologist. The psychologist developed a workbook for participants and trained health coaches to deliver related scripted calls of short (15 minute) duration at quarterly intervals.

Randomisation was performed remotely in randomly allocated blocks of 3, 6 or 9 by an investigator unrelated to the clinic. A computer generated randomisation sequence was used (STATA V12, StataCorp LP, College Station Tx). The randomisation was stratified according to sex and BMI (low BMI:≤30 and high BMI:>30). The randomisation list was provided to the study team who added eligible participants sequentially for each of the strata. Participants were blinded to their randomised allocation and only advised they would be seen by a health practitioner.

Effectiveness outcomes

All endpoints compared baseline data with 12mo results. The primary outcome was body weight (kg). Secondary outcomes were fasting blood lipids, glucose and HBA1c, systolic blood pressure, dietary intake, measures of physical activity and psychological wellbeing.

Statistical analysis

Outcomes were analysed using mixed models. The primary outcome variable weight was analysed using a published model building procedure[30]. Initially a simple model with main effects and a group by time interaction was considered. Initial data exploration suggested

quadratic and cubic terms may be needed and these were added in turn and tested with likelihood ratio tests to determine improvement in model fit. Random effects for both intercept and slope were included in the weight model. A similar procedure was followed for all other variables. Significant higher order interaction terms were followed up by ANCOVA to determine differences between groups at each time point with baseline value as a covariate. Gender was included as a covariate in the body composition models. As the dropout rate at the end of the follow up period (12mo) was substantial, several sensitivity analyses were performed. Firstly multiple imputation of 100 datasets was used to verify the significance of the difference between the groups at all time points. The imputation model included group, age and gender as well as weight at each time point. A complete case analysis, last observation carried forward and baseline observation carried forward were also performed. Model building was performed using LMER in the LME4 package of R (RStudio V0.99.489, RStudio Inc). Multiple Imputation was performed in SAS (V9.4 SAS Institute Inc, Cary NC) using PROC MI, PROC MIXED and MIANALYSE, for the ANCOVA. F tests for the 100 multiple imputation using PROC MIXED were combined using the package MICEADDS in R.

RESULTS

Participants

Recruitment began in May 2014 and the last participant completed in May 2016. Surveys were sent to 718 respondents, 439 of whom underwent baseline assessments. N=377 were randomised into the C (n=126), I (n=125) and IW groups (n=126). The intensive phase was completed by 298 participants (withdrawal rate 18%) and the 12mo follow up by n=178 participants (withdrawal rate 39%) (Figure 1). Screening and baseline data are reported elsewhere[23]. The sample comprised mostly obese (BMI 32 (29-35) kg/m^2), non-smoking

(98%) well educated (85% post school qualifications) females (74%) of median age 45 (37-51) years. They also suffered from anxiety (26.8%) and depression (33.7%) and were treated for hypertension (25%). Metabolic syndrome was identified in 34% of participants[31].

Participants attended the Clinical Trials Unit of the Illawarra Health and Medical Research Institute. After randomisation 67 participants withdrew, with most (75%) citing an inability to commit time and/or personal reasons. The next major withdrawal (n=49) occurred after the 3mo intensive phase for similar reasons. Attendance gradually reduced for all groups but IW participants attended more, and were more likely to complete the phone coaching calls than the I group (at quarters 2,3,4; $P<0.05$). Less than a quarter of participants were on medications for glucose, lipids, and blood pressure. There were no differences between groups for medication use ($P>0.05$) (Table 1).

Table 1: Number (%) of participants reporting medication during the HealthTrack study

Medication type	Control	Intervention	Intervention + walnuts	p-value*
Antihypertensive (n [%])				
Baseline	14 (11)	20 (16)	17 (14)	0.521
3 months	10 (10)	16 (16)	17 (17)	0.410
6 months	7 (10)	10 (15)	12 (14)	0.654
9 months	6 (10)	8 (15)	13 (17)	0.491
12 months	6 (10)	9 (20)	13 (18)	0.267
Hypoglycaemic/insulin (n [%])				
Baseline	6 (5)	4 (3)	5 (4)	0.945
3 months	6 (6)	3 (3)	5 (5)	0.584
6 months	2 (3)	2 (3)	4 (5)	0.819
9 months	1 (2)	3 (6)	3 (4)	0.563
12 months	1 (2)	3 (7)	3 (4)	0.429
Hypolipidaemic (n [%])				
Baseline	15 (12)	10 (8)	7 (6)	0.201
3 months	14 (15)	8 (8)	7 (7)	0.147
6 months	10 (14)	6 (9)	5 (6)	0.190
9 months	9 (15)	6 (11)	5 (7)	0.287
12 months	10 (16)	5 (11)	3 (4)	0.064

*Chi square test

Primary outcomes

Weight loss

After 12mo weight reduced in all groups with a significant difference between groups (P=0.0002) (Tables 2 and 3). The primary analysis model including group, gender and time, found a quadratic time by group interaction. The effect was seen with the IW group showing initial weight loss and then a gain from 6mo, while the other groups maintained their weight loss over time (Figure 2). Post hoc analysis on complete cases indicated significantly greater weight loss in I and IW compared to C at 3mo (-1.2 kg, P=0.045 I; -1.3kg, P=0.025 IW) and at 6mo for IW (-2.1kg; P=0.010). The ANCOVA compared the groups using a mixed model on the actual data and the combined estimates for 100 imputations (Table 2). A sensitivity analysis confirmed the effects (Table 3).

Table 2: Effectiveness End Points for the Intention to Treat Population

Variable		Control		Intervention		Intervention + walnuts	Group	Time	Group x time
	n	value	*n*	value	*n*	value	p-value	p-value	p-value
Body weight, mean (SD), kg							0.644	0.004(3)	<0.001
Baseline	126	91.8 (14.7)	125	91.9 (15.2)	126	91.4 (15.6)			
3mo	96	90.0 (14.1)	99	90.3 (15.3)	103	88.3 (14.7)			
12mo	61	87.8 (14.9)	45	86.5 (17.8)	72	87.9 (14.2)			
Body fat, median (IQR), %							0.599	0.070(3)	0.022
Baseline	125	41.3 (36.2 – 45.1)	125	41.4 (35.4 – 46.1)	125	41.4 (36.2 – 46.1)			
3mo	95	41.0 (35.0 – 44.6)	99	39.2 (33.8 – 45.1)	103	39.8 (34.7 – 43.0)			
12mo	61	40.7 (32.0 – 43.3)	45	37.0 (31.8 – 41.9)	72	38.2 (33.9 – 43.5)			
Systolic blood pressure, median (IQR), mmHg*							0.441	<0.001(2)	0.551
Baseline	126	123 (113 – 132)	124	124 (114 – 134)	125	123 (114 – 134)			
3mo	93	118 (109 – 129)	96	119 (109 – 131)	102	119 (110 – 127)			
12mo	61	116 (109 – 127)	45	118 (106 – 128)	71	123 (111 – 131)			
Diastolic blood pressure, median (IQR), mmHg*							0.671	<0.001(2)	0.712
Baseline	126	73 (66 – 79)	124	73 (65 - 80)	125	74 (65 – 79)			
3mo	93	69 (63 – 77)	96	70 (60 – 76)	102	70 (63 – 76)			
12mo	61	70 (63 – 77)	45	69 (61 – 77)	71	71 (63 – 77)			
Glucose, median (IQR), mmol/L							0.340	<0.001(2)	0.399
Baseline	126	5.2 (4.9 – 5.6)	124	5.2 (4.9 – 5.7)	126	5.2 (4.9 – 5.8)			
3mo	69	5.2 (5.0 – 5.5)	69	5.2 (4.9 – 5.7)	84	5.2 (4.9 – 5.6)			
12mo	52	5.5 (4.9 – 5.7)	37	5.3 (5.0 – 5.7)	64	5.3 (5.0 – 5.7)			
HbA1c, median (IQR), (%)							0.301	0.003(3)	0.407
Baseline	126	5.2 (5.0 – 5.5)	125	5.2 (4.9 – 5.4)	126	5.1 (4.9 – 5.4)			
3mo	69	5.3 (5.1 – 5.4)	69	5.2 (5.0 – 5.4)	84	5.2 (5.0 – 5.5)			

12mo	52	5.2 (5.0 – 5.4)	37	5.1 (4.9 – 5.4)	63	5.1 (4.9 – 5.4)			
Total cholesterol, median (IQR), (mmol/L)							0.193	<0.001(3)	0.135
Baseline	126	5.3 (4.7 – 6.0)	124	5.0 (4.4 – 5.8)	126	5.1 (4.6 – 5.7)			
3mo	70	5.2 (4.4 – 5.6)	69	5.0 (4.4 – 5.5)	83	4.8 (4.3 – 5.6)			
12mo	52	5.0 (4.2 – 5.6)	37	5.4 (4.5 – 6.0)	64	5.4 (4.6 – 5.8)			
Triglycerides, median (IQR), (mmol/L)							0.005	0.142	0.368
Baseline	125	1.3 (0.9 – 1.6)	124	1.1 (0.8 – 1.6)	126	1.1 (0.8 – 1.5)			
3mo	70	1.3 (0.9 – 1.6)	69	1.2 (0.9 – 1.8)	83	1.0 (0.8 – 1.4)			
12mo	52	1.3 (0.9 – 1.6)	37	1.2 (0.8 – 1.7)	64	1.1 (0.9 – 1.6)			
HDL, median (IQR), (mmol/L)							0.236	<0.001(3)	0.098
Baseline	126	1.3 (1.1 – 1.7)	124	1.4 (1.2 – 1.6)	126	1.4 (1.2 – 1.7)			
3mo	70	1.3 (1.0 – 1.6)	69	1.3 (1.1 – 1.6)	83	1.4 (1.2 – 1.8)			
12mo	52	1.3 (1.1 – 1.6)	37	1.5 (1.2 – 1.8)	64	1.5 (1.2 – 1.8)			
Cholesterol:HDL ratio, median (IQR)							0.036	<0.001	0.739
Baseline	125	3.9 (3.0 – 4.7)	124	3.5 (3.1 – 4.4)	126	3.6 (2.9 – 4.3)			
3mo	70	4.0 (3.3 – 4.8)	68	3.8 (3.1 – 4.5)	83	3.4 (2.7 – 4.1)			
12mo	52	3.8 (3.0 – 4.2)	37	3.3 (2.9 – 4.4)	64	3.5 (2.9 – 4.4)			
LDL, median (IQR), (mmol/L)							0.516	<0.001(3)	0.295
Baseline	123	3.2 (2.7 – 3.7)	123	3.0 (2.4 – 3.6)	126	3.1 (2.6 – 3.7)			
3mo	69	3.2 (2.4 – 3.8)	69	3.1 (2.5 – 3.4)	83	2.8 (2.3 – 3.5)			
12mo	52	3.1 (2.3 – 3.6)	37	3.1 (2.4 – 4.0)	64	3.2 (2.5 – 4.0)			
Steps per day, median (IQR)*									
Baseline	101	6856 (5398 – 9659)	96	7139 (5040 – 9095)	98	7419 (6058 – 9248)	0.380	0.046(3)	0.571
3mo	41	8383 (6879 – 11009)	51	8265 (5715 – 10380)	59	7747 (6133 – 11024)			
12mo	39	7790 (6052 – 10011)	29	6954 (5468 – 10126)	48	8531 (5800 – 10996)			

MET-mins/week (IPAQ), median (IQR)*									
Baseline	124	876 (396 – 1523)	123	918 (396 – 1551)	124	1040 (563 – 2329)	0.053	<0.001	0.341
3mo	92	1461 (793 – 2486)	94	1540 (842 – 2635)	102	2020 (1236 – 3125)			
12mo	61	1782 (807 – 3451)	46	2009 (924 – 3015)	77	1678 (827 – 3732)			
Energy, median (IQR), kJ/day*							0.095	<0.001(2)	0.444
Baseline	126	9400.2 (7840.5 – 11574.3)	125	8647.5 (7158.2 – 10993.8)	126	8932.9 (7458.3 – 10785.5)			
3mo	93	7443.8 (6479.0 – 9087.9)	97	6891.1 (6045.1 – 8700.3)	103	7264.4 (6239.3 – 8444.5)			
12mo	60	7864.7 (7014.0 – 9345.7)	44	7184.9 (5754.3 – 9078.2)	71	7805.5 (6622.9 – 9718.9)			
Protein, median (IQR), % energy*							0.735	<0.001(2)	0.454
Baseline	126	19.8 (17.0 – 22.6)	125	20.2 (17.8 – 22.9)	126	19.8 (17.3 – 22.9)			
3mo	93	21.2 (18.7 – 24.2)	97	22.1 (19.5 – 25.9)	103	21.7 (19.4 – 23.6)			
12mo	60	20.4 (17.9 – 23.4)	44	22.4 (20.0 – 25.3)	71	20.5 (18.5 – 22.6)			
Total fat, median (IQR), % energy*							0.937	<0.001(2)	0.397 (2)
Baseline	126	33.7 (29.9 – 38.2)	125	32.8 (28.6 – 36.3)	126	33.1 (29.6 – 36.9)			
3mo	93	31.8 (28.0 – 37.4)	97	27.3 (23.6 – 32.6)	103	33.4 (29.5 – 36.5)			
12mo	60	32.8 (28.3 - 36.7)	44	32.4 (29.1 – 35.5)	71	33.0 (27.8 – 37.3)			
Carbohydrate, median (IQR), % energy*							0.633	0.002	0.556
Baseline	126	42.0 (36.5 – 46.8)	125	41.6 (37.9 – 46.0)	126	42.1 (38.1 – 46.6)			
3mo	93	42.3 (34.3 – 47.7)	97	43.4 (38.7 – 48.8)	103	40.8 (36.6 – 43.8)			
12mo	60	41.9 (36.6 – 45.8)	44	40.5 (36.6 – 43.1)	71	40.4 (35.9 – 45.1)			
Alcohol, median (IQR), % energy*							0.500	0.012 (2)	0.624
Baseline	126	1.30 (0.00 – 3.43)	125	1.19 (0.01 – 4.42)	126	1.14 (0.01 – 4.18)			
3mo	93	1.06 (0.03 – 3.22)	97	0.79 (0.01 – 4.31)	103	1.33 (0.02 – 4.07)			

12mo	60	1.25 (0.05 – 3.53)	44	0.70 (0.02 – 4.54)	71	1.86 (0.24 – 5.68)			
Fibre, median (IQR), g/day							0.989	0.059	0.005
Baseline	126	26.1 (21.7 – 33.3)	125	25.2 (21.5 – 31.1)	126	25.0 (19.8 – 32.2)			
3mo	93	24.6 (19.1 – 30.6)	97	27.0 (22.0 – 33.1)	103	26.7 (22.2 – 32.5)			
12mo	60	22.9 (19.7 – 32.5)	44	26.8 (22.2 – 30.1)	71	26.5 (20.6 – 32.1)			
P:S ratio, median (IQR)*							<0.001	<0.001(2)	<0.001 (2)
Baseline	126	0.4 (0.3 – 0.5)	125	0.4 (0.3 – 0.5)	126	0.4 (0.3 – 0.5)			
3mo	93	0.5 (0.4 – 0.7)	97	0.5 (0.4 – 0.7)	103	1.3 (0.9 – 1.8)			
12mo	60	0.5 (0.3 – 0.6)	44	0.5 (0.4 – 0.7)	71	0.8 (0.6 – 1.1)			
Urinary sodium excretion, median (IQR), mmol/day									
Baseline	122	151 (101 – 193)	117	135 (101 – 172)	125	137 (101 – 192)	0.236	<0.001(2)	0.686
3mo	68	114 (81 – 157)	65	125 (89 – 183)	84	110 (83 – 140)			
12mo	44	138 (98 – 162)	35	130 (104 – 162)	61	129 (97 – 183)			
Quality of life (SF12), physical summary, median (IQR)									
Baseline	126	49.3 (43.1 – 54.4)	124	49.6 (45.0 – 54.1)	125	51.1 (44.8 – 55.2)	0.027	<0.001	0.660
3mo	91	51.3 (45.1 – 55.9)	96	51.0 (42.9 – 54.6)	102	53.5 (46.6 – 56.4)			
12mo	60	54.3 (48.6 – 57.4)	44	52.6 (44.2 – 57.5)	69	54.0 (51.7 – 57.4)			
Quality of life (SF12), mental summary, median (IQR)									
Baseline	126	48.7 (41.3 – 53.5)	124	48.4 (37.7 – 55.0)	125	47.5 (39.4 – 53.9)	0.772	0.002 (2)	0.788
3mo	91	51.0 (45.6 – 56.7)	96	49.9 (43.1 – 56.4)	102	51.7 (44.9 – 57.2)			
12mo	60	51.9 (41.4 – 57.1)	44	54.7 (44.5 – 56.5)	69	51.1 (42.3 – 55.2)			
DASS-21 total, median (IQR)†									
Baseline	126	13 (6 – 19)	125	11 (7 – 19)	126	11 (7 – 18)	0.469	0.002 (2)	0.677
3mo	92	9 (6 – 16)	94	8 (5 – 16)	101	7 (4 – 14)			
12mo	51	9 (4 – 18)	37	9 (5 – 15)	64	9 (5 – 13)			
AAQW, median (IQR)									
Baseline	103	84 (22)	106	85 (20)	104	85 (24)	0.8110	<0.001(2)	0.881

3mo	92	76 (21)	94	77 (21)	102	73 (20)			
12mo	51	76 (22)	37	69 (20)	65	73 (21)			

(2) quadratic term (3) cubic term *ln transformed prior to analysis †sqrt transformed prior to analysis

Table 3: Sensitivity analysis, comparison of differences in weight between groups at each time point

Method		3			6			9			12		P (Interaction)
	Control-Walnut	Control-intervention	Intervention-Walnut	Control-Walnut	Control-intervention	Intervention-Walnut	Control-Walnut	Control-intervention	Intervention-Walnut	Control-Walnut	Control-intervention	Intervention-Walnut	
Mixed	**-1.25* (-2.35,-0.15)**	**-1.11* (-2.23,-0.00)**	**-0.13 (-1.23,0.96)**	**-2.20 ** (-3.90,-0.49)**	**-1.53 (-3.36,0.30)**	**-0.67 (-2.42,1.08)**	**-1.98 (-3.95,0.00)**	**-1.67 (-3.80,0.46)**	**-0.31 (-2.32,1.71)**	**-1.91 (-4.06,0.25)**	**-1.72 (-4.15,0.71)**	**-0.19 (-2.54,2.17)**	**<0.001**
MI	-1.27** (-2.17,-0.37)	1.04* (-1.91,-0.16)	-0.23 (-1.12,0.65)	-1.82** (-3.14,-0.50)	-1.26 (-2.57,0.04)	-0.56 (-1.88,0.76)	-1.69* (-3.22,-0.16)	-1.46* (-2.92,-0.00)	-0.24 (-1.72,1.24)	-1.15 (-2.77,0.47)	-1.06 (-2.57,0.47)	-0.11 (-1.65,1.43)	0.002
Complete	-1.70** (-3.06,-0.33)	-1.14 (-2.66,0.38)	-0.56 (-1.99,0.88)	-2.30* (-4.28,-0.32)	-1.30 (-3.51,0.91)	-1.00 (-3.08,1.07)	-2.22* (-4.44,0.00)	-1.89 (-4.36,0.58)	-0.33 (-2.65,1.99)	-1.61 (-3.90,0.68)	-1.40 (-3.95,1.16)	-0.21 (-2.19,0.68)	<0.001
LOCF	-1.11* (-2.02,-0.19)	-0.95* (-1.87,-0.04)	-0.15 (-1.07,0.76)	-1.57** (-2.77,-0.36)	-1.05 (-2.26,0.16)	-0.52 (-1.73,0.69)	-1.44 (-2.74,-0.15)	-1.27 (-2.56,0.26)	-0.18 (-1.47,1.12)	-1.04 (-2.33,0.24)	-1.09 (-2.37,0.20)	0.04 (-1.24,1.33)	<0.001
BCF	-1.11* (-2.02,-0.19)	-0.95* (-1.87,-0.04)	-0.15 (-1.07,0.76)	-1.73** (-2.87,-0.59)	-0.78 (-1.92,0.36)	-0.96 (-2.09,0.19)	-1.40** (-2.53,-0.28)	-0.64 (-1.78,0.49)	-0.76 (-1.89,0.37)	-1.30* (-2.45,-0.15)	-0.46 (-1.61,0.70)	-0.84 (-2.00,0.31)	<0.001

**<0.01, *<0.05

MI= multiple imputation, using groups, age, gender and weight at each time point

Complete = complete analysis

LOCF = Last observation carried forward

BCF = baseline observation carried forward

Achievement of 5% weight loss target

Chi square analyses indicated significant differences in the proportion of participants achieving the clinically significant effect of 5% weight loss. At 3, 6, and 9mo the proportion achieving 5% weight loss in the C group was lower than expected (P=0.04, 0.03, 0.03, respectively), although there was no difference at 12mo (p=0.091). At 6mo the number in the IW group was higher than expected (P=0.03), consistent with the primary analysis. Likewise there was a group difference in change in percent body fat (interaction effect P=0.022) (Table 2).

Secondary outcomes

Clinical effects

Systolic blood pressure (SBP) decreased between baseline and 3mo but then remained unchanged (Table 2). Changes in SBP also reflected patterns of sodium excretion (a marker of dietary intake) decreasing from baseline to 3mo (P<0.001) and increasing to 12mo (P=0.002). Likewise, fasting blood glucose was lower than baseline at 3mo (P=0.040) and 6mo (P<0.001), and then remained lower than 12mo (P=0.003). HbA1c at 12mo was lower than the baseline value (P=0.031).

In keeping with this pattern of effects, total cholesterol and LDL concentrations were lowest for the sample at 3mo (P<0.001; P≤0.031 respectively) and at 6mo they remained lower than baseline (P=0.020; P=0.034 respectively). The Cholesterol: HDL ratio decreased particularly after 6mo, while HDL-C values first dropped at 3mo then returned to greater than baseline at 12mo (P≤0.021). The group effect for total cholesterol showed a lower overall mean for the IW group compared with controls (P=0.001) and I (P=0.037) (Table 2).

Behavioural effects

As with the pattern of weight change, reported energy and total fat intakes (as a percent of energy) were lower than baseline at 3mo (P<0.001) and still at 12mo (P<0.001), but they increased between 3mo and 12mo (P=0.020) (Table 2). Changes in percent energy from protein were the opposite for dietary fat. The value was higher than baseline at 3 and 12mo (P<0.001), but lower at 12mo than 3mo (P=0.04). Percent energy from carbohydrate reduced from baseline to 12mo (P=0.002), and from alcohol (P=0.012) decreased from baseline to 12mo (P=0.041). The only reported difference between groups was for the Polyunsaturated:Saturated (P:S) fatty acid ratio, where the the IW group showed a higher value over time compared to the other groups (interaction effect P<0.001).

The time effects for increased physical activity were stronger in self-reported MET-Mins/week (IPAQ) (P<0.001; significantly higher than baseline at all time points) than measurements of steps/day (P=0.046) (Table 2). The changes in diet and physical activity were accompanied by increases in scores for positive psychological parameters (Quality of Life, QoL) and decreases for negative parameters (Depression Anxiety Stress, DASS-21; Acceptance and Action for Weight Related problems, AAQW). The IW group scored highest for Quality of Life (QoL SF12) physical summary scores throughout the study period (group effect P=0.027). The QoL (SF12) mental summary score increased after 3mo, with differences from baseline to 12mo (time effect P=0.002). The DASS-21 and AAQW scores were lower at 12mo (P<0.001) but the significant decreases occurred at 3mo (P<0.001).

DISCUSSION

Main findings

Despite the same intensity of intervention and a focus on national diet and physical activity

guidelines, the interdisciplinary protocol produced greater and more clinically significant effects on weight loss than usual care (Figure 2). The statistical analysis was comprehensive and results were confirmed with sensitivity analysis (Table 2). While it is not possible to separate out the components of the interdisciplinary approach, it appears more individualized advice including a focus on specific foods may have enhanced the effect. This was especially evident with the food supplemented group who continued to produce a greater weight loss at 6 months. The size of the effect and the time taken to achievement are also highly relevant to practice. Without unusual retention strategies, we found that a 3 month commitment to an intensive treatment was feasible, and in that time the intervention protocol delivered a greater proportion with a 5% weight loss target. In Western societies, it is estimated that the adult population gains 0.45kg weight/year[32], so our effects could be interpreted as even greater.

Secondary outcomes

We confirmed the observation that a 5% weight loss can have an impact on disease risk factors[15]. Significant reductions in systolic blood pressure occurred with weight loss, as expected, but this also occurred with increased physical activity, improved mental health scores and a reduction in urinary sodium, a dietary factor known to be associated with blood pressure[33]. The latter implies that the dietary changes went beyond that of energy restriction. As the national dietary guidelines were a reference point for all groups, differences in sodium intakes were not observed in this intention to treat analysis. Per protocol analyses may be able to detect whether greater changes occurred in the groups with the dietitian (I and IW) confirming effects seen in other primary care studies[34]. Similarly the improvements in blood glucose parameters occurred with weight loss in the presence of increased physical activity and a reduced carbohydrate load for the study cohort. Further research on the types of carbohydrate-rich foods may be informative in detecting more specific differences between

groups.

The changes in blood lipids were as expected with changes in weight. The lower overall mean for total cholesterol for the IW group occurred in the presence of a significantly different dietary P:S ratio. We have previously shown that integrating walnuts in an energy controlled diet can change the dietary P:S ratio with concomitant effects on lipids (31). Given that walnuts are a fat-rich food, their inclusion in the dietary modelling for the IW group would be expected to influence the overall diet profile.

Implications for practice

Practice involves an integration of evidence on many factors, and in this research we examined a number of components. We confirmed that changes in disease risk factors occurred alongside changes in body weight, physical activity, mental health scores and dietary factors known to have an impact on disease risk such as dietary sodium, fibre, and fatty acid profile[10 12 16 35]. In this trial the dietitian provided the face-to-face counseling with participants. Being more specific about actual foods to consume may be more effective and providing a significant healthy food (walnuts) emphasized this point. While the effects of walnuts in the diet can be found in the literature[36 37], there may have been synergistic effects with psychological factors in our trial. The reduced psychological avoidance of weight related issues (AAQW scores) was particularly relevant and further analyses of our data may clarify the effects of health coaching when integrated into diet and physical activity advice. In addition, and based on our previous research[38], the greater initial weight loss achieved by the IW group may have influenced retention, and this may have also resulted in the higher QoL scores, but it is difficult to determine if the provision of the food supplement alone acted as the main incentive[39]. The greater attendance at phone coaching sessions by the IW group,

which targeted skills in mindfulness and acceptance, also may have helped deal with the stress associated with achieving health goals[18]. It is difficult to tease out any singular effect as there is so much interdependence between behavioral factors, but this study has helped expose significant elements. The pattern of weight loss reflected reduced energy intake and increased physical activity (Table 2), providing evidence for applying expertise in both diet and exercise[40 41]. As sources of nutrients, the food choices drove nutritional changes underpinned by the involvement of dietitians[42 43].

Strengths and limitations

The sample comprising volunteers from the community attending a single clinic was a limitation, but as a case study in planning services, this gave us an indication of who might attend for these types of treatment. The study was testing an approach applicable to primary care, so the analysis was conducted on an intention to treat basis rather than on compliance to treatment. In addition there was a high level of control of potential confounding variables. The design where all groups received the same intensity of intervention with dietary advice referring to foods in the Australian Guide to Healthy Eating (AGHE)[28] may have masked our ability to show true effects. In similar highly controlled circumstances it has been argued that for every kg increase in weight loss by controls, treatment effects may be reduced by about 0.3kg[44].

While weight loss was observed, the lack of between group differences in reported energy intakes may reflect inaccuracies in dietary reporting and limitations in databases for estimating food energy. For example, the available energy from walnuts has been measured as 20% less than conventional estimates[45], and this may relate to other whole foods[46]. The between group differences in weight loss are plausible from the literature[8 47]. Like other

research in this area[8 48], this study confirms the benefit of thinking beyond energy restriction, where other dietary factors act in synergy to influence outcomes.

The trial was aligned to translation to practice, so we did not employ enhanced retention strategies, but we know that early weight loss and age > 50yrs may predict retention[38]. In the evaluation survey of the trial, participants indicated general approval of the approach and the three most listed positive features were individual attention, the health practitioner and the education provided (data not shown). Research indicates that, as part of chronic disease management, avoidance of weight gain may reduce health care costs in the long term[49]. Four visits within the 3mo model of care could fit within the current annual Australian Medicare arrangements[50], albeit with considerations for eligibility, and possible co-payments. These aspects all require confirmatory research. Research is also needed on whether attending for 3mo would be sufficient to achieve this initial target, acknowledging that a 'flattening' of effects after 6mo is typical and reflects metabolic and behavioural adaptions[16 17].

This study addressed a research gap providing evidence for developing effective healthcare teams in chronic disease management[20 21]. Further analyses will be able to examine motivation and commitment barriers that both participants and health care teams must face. It is acknowledged that addressing long term behaviour change is difficult in primary care[51], and that a lack of motivation and incentives may hinder trials on novel lifestyle interventions[52]. Our trial recruited from the community, but medical supervision and communications with primary care physicians was part of the safety management, and provided insights into translation.

Conclusion

The primary care context provides many opportunities for dealing seriously with weight

management as a health issue. Excess body weight is linked to the pathology of major non-communicable chronic disease, and is influenced by both physiological and behavioral factors. More research with greater consolidation of interdisciplinary expertise, and establishing greater integration with medical and nursing practices will assist translation into primary care. Familiarity in standards of operation for the various professions building a full appreciation of knowledge and skills is required. Promoting opportunities to collaborate and providing guidelines[53] are a start to developing long term plans.

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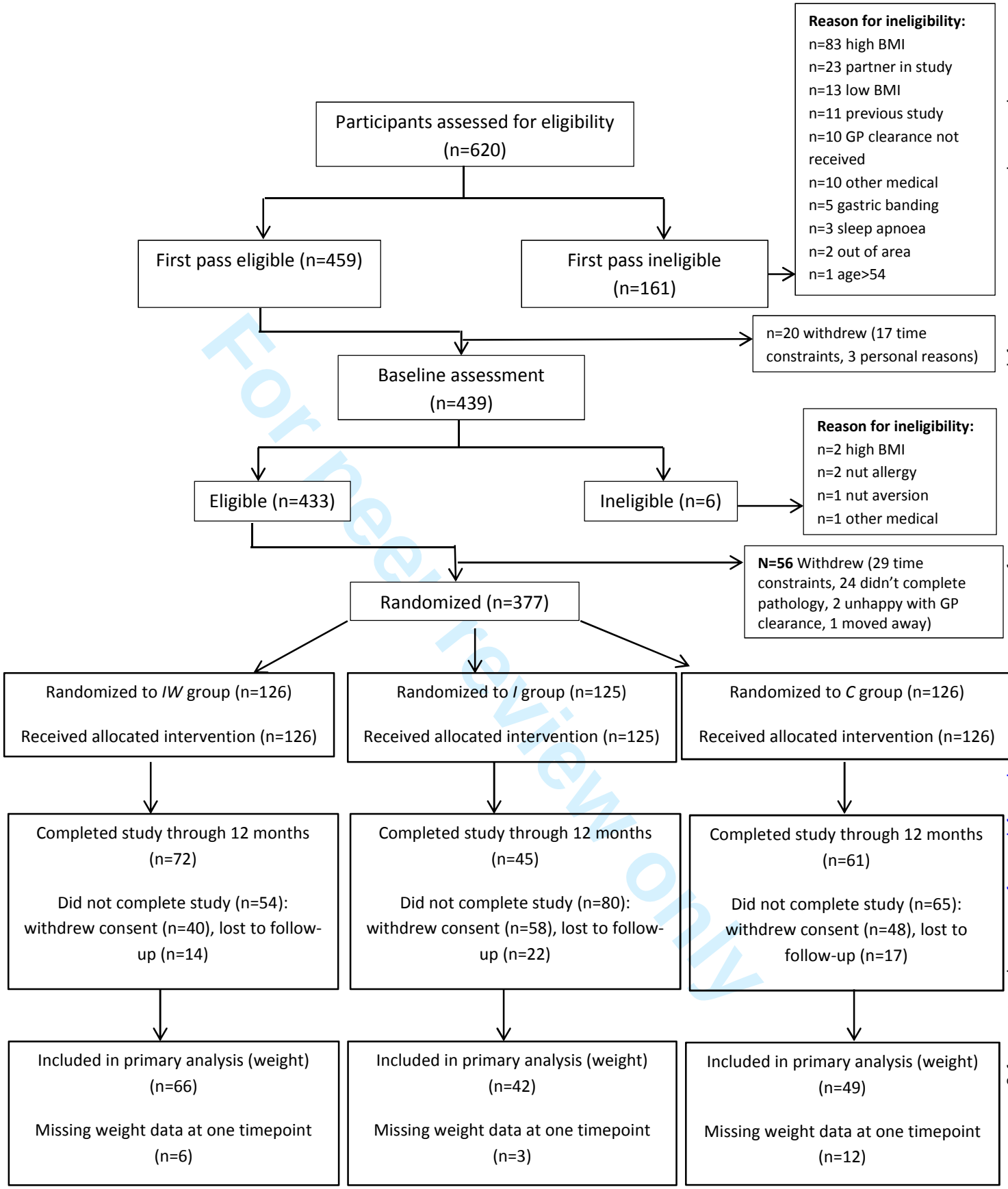

Figure 1: Participant flow in the HealthTrack randomised controlled trial

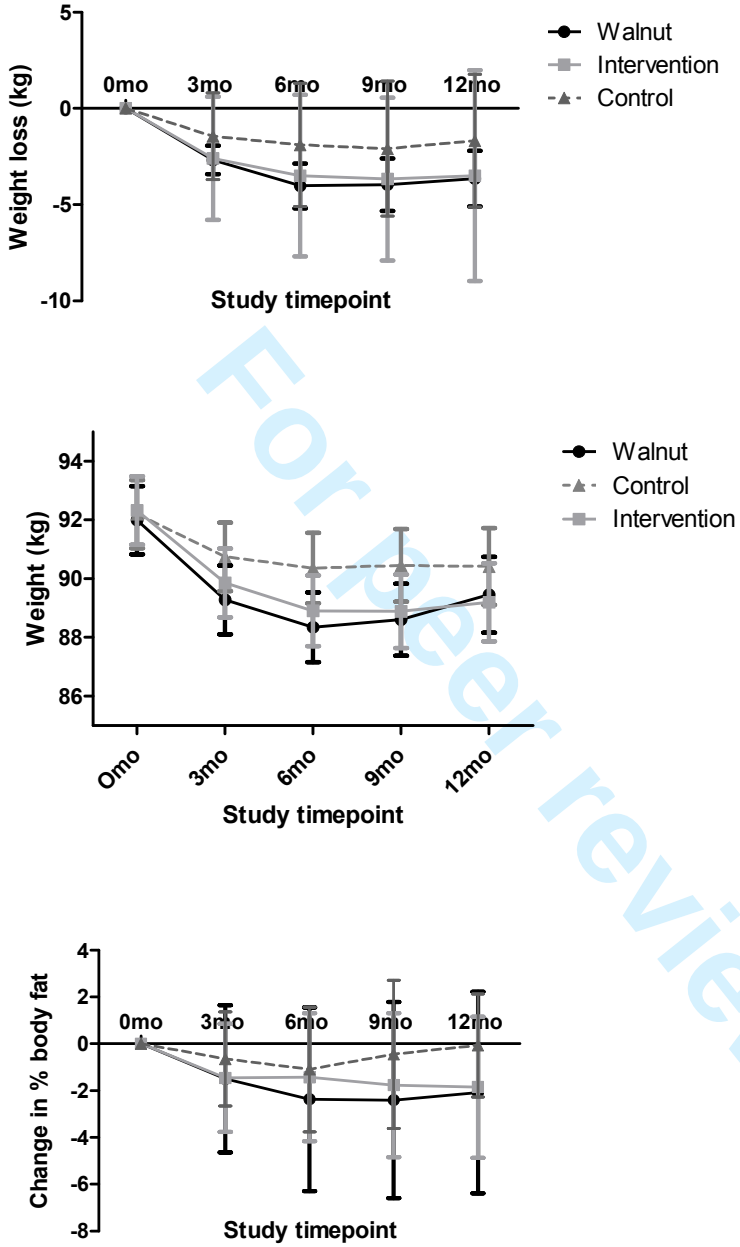

Figure 2: Difference in change in weight, weight change, and % body fat over time

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	3
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
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	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	7,10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7,8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	Protocol paper
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
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	7,8
	11b	If relevant, description of the similarity of interventions	7,8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8,9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8,9
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	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	9
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 2
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)	Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Table 3
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	24,25
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	24,25
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21 - 25
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	29

*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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Health Track Study Protocol V34

Table of Contents

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Background

Chronic disease in the Illawarra region:

Chronic lifestyle related disease such as cardiovascular disease (CVD) and type 2 diabetes are major public health concerns throughout Australia, and indeed most parts of the first world. Being overweight is strongly associated with the development of various chronic diseases, and overweight itself contributes to 7.5% of the national disease burden [1]. Health status data indicates 60% of Australians are overweight or obese, and this figure is reflected in the Illawarra population [2-4]. The prevention of chronic disease is a primary target for public health, and body weight statistics provide a reasonable indication that much can be done to reduce obesity and hence reduce the burden of chronic disease. The Illawarra region has a defined geography and relatively stable population profile that lends itself well to research of this nature. It also has a history of community based partnerships, and strong links between the health services and the University of Wollongong.

The ISLHD services a geographical area comprising four Local Government Areas (LGAs); Wollongong, Kiama, Shellharbour and Shoalhaven. The LGAs comprise six Statistical Local Areas (SLAs), in addition to the Jervis Bay Territory (which is a Territory of the Commonwealth). The Australian Bureau of Statistics (ABS) estimates that in 2011 the resident population for the Illawarra Shoalhaven Local Health District (ISLHD) was approximately 390,000. Population projections 2016 to 2026 indicate a 9.5% growth 2011-2021 [1] p 9].

Leaders in the Illawarra health system are aware of the consequences of chronic disease development associated with being overweight, particularly in the middle and older aged sectors of the community. The (ISLHD) has a higher proportion of people aged 75 years and older at 8.0% when compared to the NSW average of 6.6% and 5.8% of children aged less than 5 years [1] p11]. The health of ISLHD residents is, on average, poorer than for other NSW residents, in terms of many indicators of current and expected future health status and system outcomes. Preventable hospitalisations are significantly higher than that found in the rest of NSW. Of chronic diseases, hospitalisations for diabetes are significantly higher than that found in NSW for three of the four LGAs in the Illawarra [1]. In particular, many people are referred for assessment of renal disease following routine screening in response to symptoms of disease. A recent cohort study in the UK found that people with chronic kidney

disease were at greater risk of myocardial infarction than those with diabetes, underlining the significance of renal impairment in monitoring chronic disease risk [5]. The study suggested that healthier diet and greater physical activity patterns were needed to achieve optimal weight. Concurrently, active renal disease screening would be of benefit as part of a population based research aimed at addressing chronic disease risk.

NHMRC policy directions for intervention

Several authoritative documents have emerged in recent years to provide direction for developing this research. The National Preventative Health Strategy (NPHS) (2009)[3], the **Clinical Practice Guidelines for Primary Care Health Professionals in the Management of Overweight and Obesity in Adults, Adolescents and Children (2013)**[6] and Australia's Health 2012 report [7]. Drawing on a defined critical appraisal of the scientific literature, the NHMRC Obesity Management Guidelines provide a number of evidence based statements and associated recommendations relevant to the HealthTrack project.

NHMRC evidence based statements for obesity management

Evidence statement

'*In adults with a BMI<35kg/m^2 multi-component interventions that incorporate a combination of diet, physical activity and a behavioural component will result in greater weight loss for at least 12 months than single component lifestyle interventions'*

(Evidence Base Level A- excellent)

Recommendation 9:

For adults who are overweight or obese, strongly recommend lifestyle change including reduced energy intake, increased physical activity and measures to support behaviour change.

Evidence statement

'*Weight loss following lifestyle changes is maximal at 6-12 months. Regardless of the degree of initial weight loss, most weight is regained within a 2 year period and by 5 years the majority of people are at their pre-intervention body weight*'. (Evidence Base Level A – excellent)

Recommendation: Strongly recommend to adults that they adopt specific strategies for long-term management that are appropriate to their individual situation'.

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In addition, the **Summary Guide for the Management of Overweight and Obesity in Primary Care** provides specific reference to approaches. (http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n57b_obesity_guidelines_summary_guide_131219.pdf)

For adults, these include:

- Measure waist circumference in addition to calculating BMI
- Discuss readiness to change lifestyle behaviours
- Convey the message that even small amounts of weight loss improve health and wellbeing
- Use multicomponent approaches — these work better than single interventions
- Refer appropriately to assist people to make lifestyle changes or for further intervention
- Support a self-management approach and provide ongoing monitoring

Recommendations and practice points are also listed as:

1. For adults who are overweight or obese, strongly recommend lifestyle change—including reduced energy intake, increased physical activity and measures to support behavioural change
2. For adults who are overweight or obese, design dietary interventions that produce a 2500 kilojoule per day energy deficit and tailor programs to the dietary preferences of the individual.
3. Current Australian dietary guidelines should be used as the basis of advice on nutrition for adults.
4. For adults who are overweight or obese, prescribe approximately 300 minutes of moderate-intensity activity, or 150 minutes of vigorous activity, or an equivalent combination of moderate-intensity and vigorous activities each week combined with reduced dietary intake
5. Current Australian physical activity guidelines should be used as the basis of advice on preventing weight gain through physical activity.
6. For adults who are overweight or obese, particularly those who are older than 40 years, there should be an individualised approach to increasing physical activity.
7. Individual or group-based psychological interventions may improve the success of weight management programs.

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Approaches to HealthCare

Under Medicare, obesity is recognised as a chronic disease condition which is usually associated with co-morbidities as the disease progresses. Currently the treatment pathway for obese patients presenting at hospitals or at their GP involves:

- Eligibility for 5 allied health visits per annum with Medicare rebates based on requirement for chronic disease management
- The patient having a BMI>30 and at least one medical condition that has been present (or is likely to be present) for at least 6 months (termed chronic) or is a medical condition that will be terminal. The GP requirement to create a GP Management Plan (GPMP) for each patient. This includes Team Care Arrangements made by a minimum of 3 professionals (one of which is the referring GP). The arrangements include referrals for up to 5 visits to allied health professionals.

In the Illawarra, Shell Cove Family Health offers a model of care with 5 allied health consultations and team care arrangements onsite. As an outcome of patient case reviews selected patients visit a dietician, exercise physiologist and/or a behavioural psychologist. The HealthTrack project takes this one step further and brings together the allied health professionals before the patient interface, offering a novel integrated model of service, with medical oversight of patient healthcare. This would have implications for developing more patient oriented, efficient and effective interventions when resources are limited.

Approaches to supportive environments

The NPHS also outlines several population-based health initiatives designed to reduce or maintain appropriate body weight, with activities supporting healthy environments [3]as can be found in the literature [8]. NSW Health has recently launched a statewide program (including the Illawarra region), based on this approach Healthy Living and Active Living Strategy (http://www.health.nsw.gov.au/obesity/Pages/nsw-healthy-eating-strategy.aspx)

The Illawarra has a history of strong collaborations between health services, university academics, the local councils, and NGOs. Significant new developments such as the

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Wollongong Healthy Communities Initiatives have been rolled out through local governments. (http://www.wollongong.nsw.gov.au/services/community/Pages/HealthyCommunitiesInitiative.aspx) This latter work has been recognised in recent NSW Health workshops and forums.

HealthTrack research framework and hypotheses

The HealthTrack essentially comprises a randomised controlled trial of an interdisciplinary lifestyle intervention, supported by analyses of data from surveys of 3 population samples (volunteers responding to advertising for the lifestyle intervention: that is, trial and non-trial participants; and the Illawarra sample of the NSW Health Survey).

The research is founded on the discipline of epidemiology yet given the complexity design elements come from a multidisciplinary framework. The proposed study contains the following elements:

- A population target group at risk of developing lifestyle related disease (adults 25-54 years)
- The collation of data profiling of 3 population samples for comparison
    - A volunteer sample responding to media advertising for inclusion in the lifestyle intervention trial
    - A selected group from the volunteer sample meeting inclusion and exclusion criteria for the lifestyle intervention trial
    - A population representative sample from the NSW Health Survey
- Direct measurement of demographic, clinical, anthropometric and behavioural data at baseline and after 1 year in the volunteer (including lifestyle intervention trial) sample with a 1 year long-term follow-up.
- Descriptions of obesity prevention initiatives occurring throughout the region during the time course of the study (such as the NSW Health *Get Healthy* campaign)
- The implementation of an individualised healthy lifestyle intervention trial based on an interdisciplinary model of healthcare, and with direct relevance to local health services.

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Primary hypothesis

A novel interdisciplinary approach to lifestyle change (diet, physical activity) will be more effective in producing sustained weight loss than usual care.

Secondary hypotheses

1. The characteristics of the full sample volunteering for the trial will not be substantively different to that generated from the NSW Health Survey
2. The subsample admitted to the trial will show greater changes in weight than those not included in the trial.
3. Improved weight and health outcomes will be observed in the population sample in the period of observation
4. The outcomes observed after one year of intervention will be sustained over a further 1 year follow-up period

HealthTrack study methods

Recruitment and surveys

Advertising: A managed advertising and recruitment campaign will be conducted in the Illawarra region, beginning the first week in May. Volunteers will be those who respond to the campaign by contacting the clinical trials team following the media campaign.

Screening survey: All respondents will be asked to complete a screening survey. The first pass inclusion criteria are those aged 25-54 years, permanent residents, living in a household in the area. Based on previous experience and enhancement of the campaign, a sample size of 1000 volunteers is anticipated. It is expected that approximately 50% of this group will be eligible for the RCT (BMI in a range of 25-40). Of those eligible it is anticipated that 360 will enrol and attend the clinic for baseline assessment and counselling. Following the initial screening contact, participants will be sent by email or SMS a unique link to the online survey with instructions on how to complete the survey. The survey will include demographic data as well as questions reflecting current health surveys applied to this population and include tailored questions targeting additional areas of concern, such as health service utilisation. As part of the survey participants will be requested to self-report their height and weight, answer questions relating to food habits in the form of short questions. The short questions provide a quick and easy alternative to a whole diet and nutrient survey.

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The questions included in this survey were selected to measure specific aspects of food habits that are relevant to overweight and obesity (Marks, short questions, 2001).Psychological questions will include Emotional eating (3 questions), Brief stigmatising (SSI brief, 10 questions), and stages of change – exercise (SOC, 4 questions),

Follow up survey: At 12 and 24 months, all those who completed the initial screening survey, that is, both trial and non-trial volunteers) will be invited to complete a second and third survey to assess changes in lifestyle factors. The data will be used to examine differences between non-trial and trial volunteers. Procedures will be developed tracking respondents and they will be contacted via email one week before the 12 and 24 month anniversary of completing the first survey to complete a second and third survey. Up to two reminders will be sent via email or SMS with links to the unique link to the online survey asking respondents to complete the survey. The 2nd and 3rd survey will include similar questions to the first screening survey to enable researchers to examine any major changes that may have affected the participant over the duration of the study.

NSW Health survey: In addition to the surveys of volunteers, data from existing NSW and national health surveys will be used to describe the health profile of the region in particular the Wollongong LGA and compared to both that obtained from non-trial and trial volunteers.

In addition, environmental and community engagements activities in the Wollongong LGA will be described. These include public awareness campaigns, private company programs and community interventions addressing healthy dietary intake, and/or promoting physical activity in the community. Information on these activities w will be collated and described and considered in the analysis.

*Analysis of survey data***:** Explanatory variables will include standard socio-demographic variables and other area level variables found to be important with multilevel modelling applied to the data. This approach can use random effects to account for area effects that have not been explained by the area level explanatory variables included in the analysis and clustering of the data at various levels, as well as the repeated nature of the longitudinal data [9]. Because the activities are not randomly allocated this is an observational study so interpretation of cause and effect

is problematic. The scale and spatial distribution of a community intervention will affect what, if anything can be determined about such effects. There will be little scope to directly detect the impact of community activities if they have been applied to a large part of the region, such as the NSW Get Healthy campaign. If the activity affects the whole of ISLHD then the study cannot give statistical evidence of its effect – in this case we would have to rely on NSW PHS and compare changes in ISLHD with other regions. The trial itself, however, will provide proof of principle of the approach in a volunteer study sample.

Trial Design

This is a 12 month single blinded parallel randomised controlled trial with 2 arms: control (usual care), intervention (multidisciplinary lifestyle support). A 3rd arm comprising intervention + 30g walnuts/day is anticipated for the first 12 months only. Participants will be randomised into a control or one of the intervention groups testing the effect of a novel versus conventional form of individualised health care targeting diet, exercise and health behaviour. There will be a 1 year long-term follow-up phase after the completion of the 12 month visit. All participants will roll-over into a single follow-up group following the intervention arm protocol and continue with quarterly visits with a health practitioner.

Trial Hypothesis:

A novel individualised lifestyle intervention program will produce a greater and sustained weight loss compared with general lifestyle advice.

It is anticipated that combining integrated diet, physical activity and behavioural support in an alliance with medical care will result in sustained weight loss along with improvements in chronic disease risk factors profiles and health behaviours

Outcome measures

Primary outcome: Body weight (kg)

Secondary outcomes: Diet quality assessed by diet score based on adherence to Australian Dietary Guidelines. Biomarkers of disease risk: fasting blood lipids, fasting blood glucose, blood pressure, micro-albuminuria, waist circumference, dietary patterns, and amount of physical activity, psychological indices, and medical intervention.

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Inclusions and exclusions

The study sample comprises men and women from the Illawarra community (adults aged 25-54 years, permanent resident, community dwelling), at higher risk of lifestyle related disease (defined by BMI). The prevalence estimate is based on secondary information from the state survey 2008 which sampled 1317 adults from the SESIAHS, showing 48% were overweight/obese [2].

***Inclusions*:** Generally physically well and Body Mass Index 25-40 kg/m2. Includes people with Type 2 diabetes and risk factors such as; hypertension, raised LDL-cholesterol, low HDL- cholesterol, and family history of coronary heart disease (CHD).

***Exclusions**:* Unable to communicate in English; severe medical conditions impairing ability to participate in study; other medical conditions thought to limit survival to 1 year; immunodeficiency; reported illegal drug use or regular alcohol intake associated with alcoholism (>50g/day); difficulties or major impediments to participating in the components of the study.

Randomisation and blinding:

A researcher independent of the participant interface will undertake the randomisation of subjects into diet groups (stratified by sex and block randomised STATA (V12 Cary NC) and the code will be kept from the researchers collecting data and delivering treatment. Different people will collect the data and provide lifestyle advice. Since individualised dietary advice will be given to the intervention group it will not be possible to blind the health practitioners but the participants will not be informed as to their group allocation. Participants will be fully informed of the study, although blinded to the type of intervention.

Power

Several power calculations were conducted using SAS PROC POWER using a range of standard deviations from 3.5 to 5. One hundred and twenty subjects were considered sufficient to detect a minimum between group weight loss difference of 2.7kg as significant with 90% power and a two tailed α of 0.025 and 0.017 (adjusted for planned contrast between control and each treatment group and a between treatments comparison). This assumes up to ~20% post randomization dropout rate and a within group weight loss standard deviation of 3.5-5kg (using available literature and our own experience).[10].

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Fig 1 Flow Diagram for Recruitment, Survey, Randomisation, and Study Finalisation

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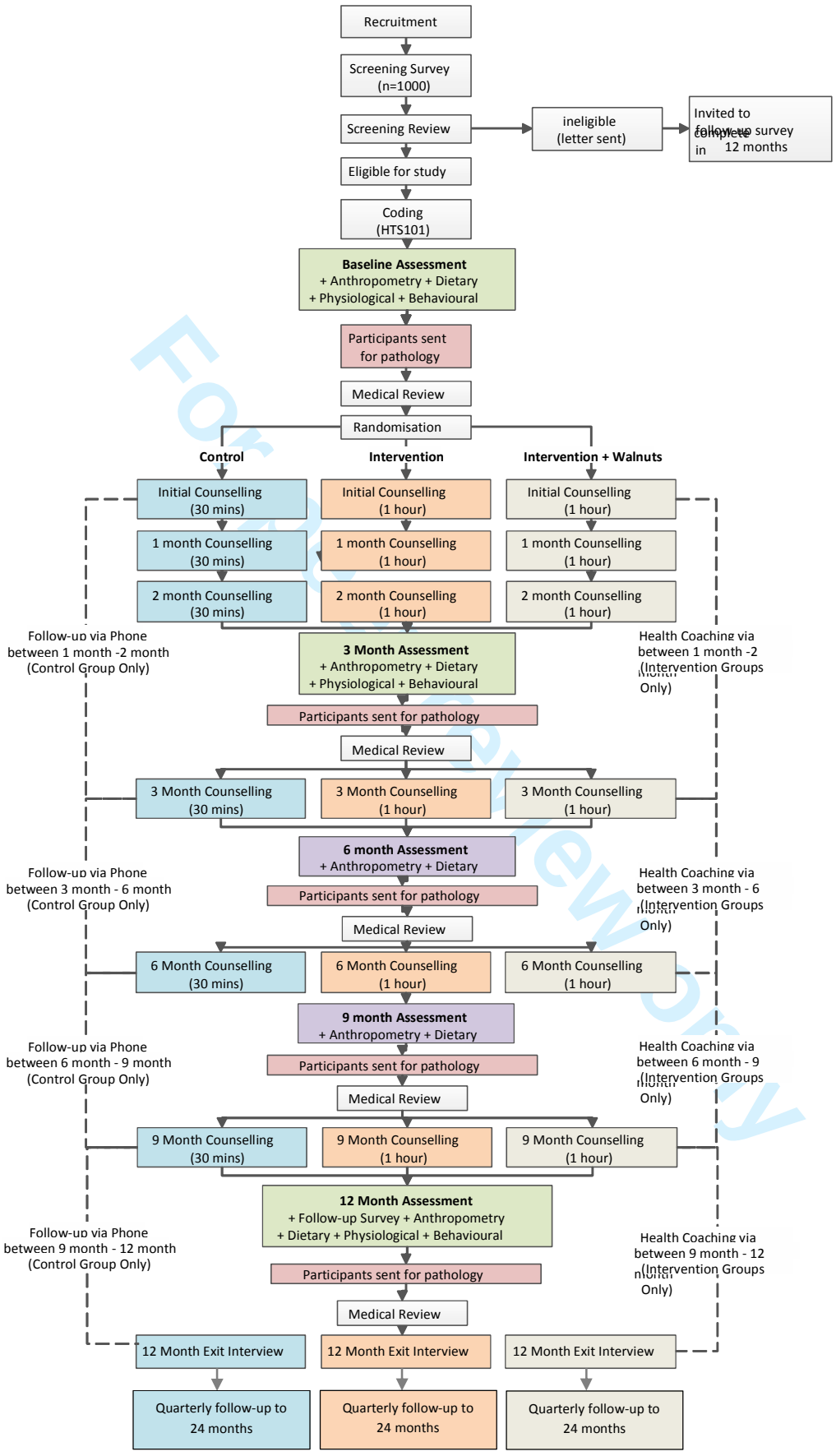

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For the 3rd arm, it is anticipated that both intervention arms will lose more weight than the control arm within the 12 month period. The approach to analysis comparing the two intervention arms is as reported in a PREDIMED paper where the effect size is compared. (See Salas-Salvadó J, et al. *Arch Intern Med* 2008;168:2249-58. Here the reduced prevalence of MetS was shown to be -2% in control, -7% in MedDiet +VOO and - 14% in Med diet + nuts – we would look at weight and diet quality score rather than MetS).

Measurements

All assessments except pathology will be performed at 0,1,2,3,6,9,12 months and then quarterly for up to a total of 24 months at the CRTU of the Illawarra Health and Medical Research Institute on the University of Wollongong campus. Table 1 and 2 summarises the assessments conducted at each study visit.

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Table 1 – 12 month visit summary

HEALTHTRACK LIFESTYLE INTERVENTION STUDY

	VISITS												
ASSESSMENTS	Screening Survey	Baseline Assessment	Baseline Counselling	W4 Counselling	W8 Counselling	W12 Assessment	W12 Counselling	W24 Assessment	W24 Counselling	W36 Assessment	W36 Counselling	W48 Assessment	W48 Counselling
Consent		X											
Survey	X											X	
Physiological Assessment		X				X						X	
Anthropometric Assessment		X		X*	X*	X		X		X		X	
Diet History & 4 Day Food Diary		X				X		X		X		X	
Psychological & Behaviour Assessment		X				X						X	
Physical Activity Assessment		X				X		X		X		X	
Blood Pathology		X				X**		X**		X**		X**	
24 hr Urine Pathology		X				X						X	
MSU		X											
Dietary/Exercise Counselling			X	X	X		X		X		X		X
Exercise Physiology Assessment (intervention arm only)		X				X		X		X			
Healthy Coaching (intervention arm only)		X				X		X		X			
Medical Review		X				X		X		X		X	

Physiological Assessment includes: Blood pressure, Queens College Step Test
Anthropometric Assessment includes: height (only at baseline), weight, BMI, % body fat, waist & hip circumference. * means only weight and body fat% measured

Psychological & Behaviour Assessment: SF12 - quality of life, BREQ, RC16, AAQ-W, DASS-21, Positive Emotional Eating

Physical Activity Assessment: IPAQ Survey, Pedometer, Accelerometer (0,3,12 only), Heart Rate Monitor (0,3,12 only)
Baseline Blood Pathology includes: EUC (electrolytes, urea, creatinine), FBC, Fasting Glucose, HbA1c, Fasting Lipids (cholesterol, triglycerides, LDL and HDL cholesterol), Urate
**3, 6, 9 & 12 month Blood Pathology includes: Fasting Glucose, HbA1c, Fasting Lipids (cholesterol, triglycerides, LDL and HDL cholesterol)

24 hour Urine includes: urate, sodium, potassium, creatinine

MSU includes: albumin:creatinine and M/C/S (inc Haematuria)

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Table 2 – 1 year follow-up visit summary

ASSESSMENTS	VISITS			
	15M Counselling	18M Counselling	21M Counselling	24M Counselling
Consent	X			
Survey				X
Physiological Assessment	X	X	X	X
Anthropometric Assessment	X	X	X	X
Diet History & 4 Day Food Diary	X	X	X	X
Psychological & Behaviour Assessment				X
Physical Activity Assessment	X	X	X	X
Blood Pathology				X
Dietary/Exercise Counselling	X	X	X	X
Medical Review	X	X	X	X

Physiological Assessment includes: Blood pressure

Anthropometric Assessment includes: weight, BMI, % body fat, waist & hip circumference

Psychological & Behaviour Assessment: SF12 - quality of life, BREQ, RC16, AAQ-W, DASS-21

Physical Activity Assessment: IPAQ Survey, Pedometer

Blood Pathology includes: Fasting Glucose, HbA1c, Fasting Lipids (cholesterol, triglycerides, LDL and HDL cholesterol)

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Blood and urine samples will be collected by nursing staff from centres managed by Southern Pathology, where they will be analysed using standard pathology procedures. A pathology form will be provided to participants to attend a laboratory in their local area for fasting blood and urine samples to be undertaken in the two weeks following acceptance into the intervention. A protocol of contact will be followed in instances of non-attendance to promote future attendance. As biomarkers of cardiovascular, diabetes and renal disease risk, blood tests will assess the following

Blood samples*:*

Lipids: Fasting blood lipids (cholesterol, LDL, HDL, Trig),

Glucose: fasting glucose and HBA1c

Renal measures: (urea, electrolytes, creatinine) (Baseline only)

Full blood count: haemoglobin, red cell count, haematocrit, white cell count, leucocyte differential, platelets

Urine samples

Microalbuminuria: status correlates with cardiovascular risk and its presence indicates end-organ damage. Tests should be mandatory in the presence of diabetes. The most accurate screening test is urinary. Spot urine samples will test albumin/creatinine ratio. Urine specimens will be taken for clinical screening (MSU - microscopy and culture if dipstick positive for blood; spot urine for microalbuminuria). (Baseline only)

Participants will be asked to collect a 24 hour urine sample (at 0, 3 and 12months) prior to their pathology visit and deliver the sample to nursing staff at Southern Pathology. A container and instruction sheet will be provided to participants at the same time as they are provided with the pathology forms. A protocol of contact will be undertaken to remind participants to complete the 24 hour urine collection. This urine sample will test urinary sodium, urate, potassium and creatinine excretion as the gold standard for sodium intake.

Anthropometric measurements

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- **Weight:** Digital scales will measure lightly clad body weight recorded to the closest 100g, in accordance with the established anthropometric protocols. [11, 12] . BMI will be calculated with standard definitions.[13];
- **Height:** A stadiometer will be used to measure height at baseline, rounded to the nearest millimetre. This procedure is in accordance with the established anthropometric protocols.[11, 12].
- **Hip and Waist Circumference:** Widest part of hip and narrowest waist circumferences will be measured for all participants. All measures will be in accordance with the reported acceptable protocols [14].
- **Body Composition:** % body fat is measured on the Tanita scales

Dietary assessment*:*

- *4 day food records* (including one weekend day) will measure usual dietary patterns prior to attending at every 3 months. Participants record all foods consumed including amounts and recipes. Food records also serve as a behavioural support for dietary change.
- *Diet history interviews* will also be taken at 3 monthly intervals. These assist the clinical interview as they enable the participant and dietician to talk through a usual day and the foods likely to be important for consideration [15]. Food patterns will be analysed to confirm extent of individual dietary change.

Physiological assessments

- *Systolic and diastolic blood pressure* will be measured in the supine position using standard techniques.
- *Resting and ankle brachial index* will be assessed to provide a measure of severity of peripheral arterial disease through measurements of resting and post exercise systolic blood pressure in arm and ankle (after skeletal muscle testing calf function test) for RCT group.
- *Sub Maximal Exercise Test:* The Queen's College Step Test will use recovery heart rate to calculate participant's physical fitness levels. It has proven validity and reliability in this context [16]. Participants will have a monitor placed around their chest for continually recording of heart rate. They will begin by resting for 5minutes and pre-exercise heart rate will be recorded. Exercise will then commence for 3minutes whereby participants continually

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step up and down onto a 41.3cm box. The step rate will be set by a metronome (men; 24 steps/ minute and women 22 steps/minute). On completion, recovery heart rate is then recorded between 3.05mins and 3.20minutes and the mean will be used in the following equations.

VO2max determination;	
○ Men	111.33 -0.42 x (recovery heart beats/minute)
○ Women	65.81 – 0.1847 x (recovery heart beats/minute)

Physical activity assessment

- *IPAQ*: a survey recall of minutes of physical activity. The International Physical Activity Questionnaire (IPAQ) short form survey questions, along with a set of questions regarding the participants' perceptions on how much physical activity is necessary for a healthy lifestyle and information on sedentary behaviour will be used in combination with the psychological survey questions.
- *Accelerometers* in a random sub group (n=30 in each group). In accordance with gold standard practice[17], participants will be assigned an accelerometer and trained in its use (placement on wrist, record keeping). They will be asked to wear the accelerometer on two week days and one weekend (to coincide with the 4 day food record). Total number of counts will be recorded for each day. Participants will then be categorised into meeting or not meeting the recommended levels of physical activity minutes per day.
- *Pedometers*: A scientific grade pedometer will be used that is accurate and reliable for counting steps and can be used to explain physical activity levels and sedentary time (cut-points)[18].

Psychological measurements:

Validated questionnaires to test for psychological flexibility, diet flexibility, and exercise motivation will be utilised at 0,3,12, and 24 months. These include items relating to

- Physical and mental health SF-12 (12 questions) [19]
- Acceptance and action (11 questions), AAQ-W[20], Positive Emotional Well-being (3 questions) [21]

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- Depression anxiety stress short form (DASS – 21; 21 questions)[22]
- Emotional eating (3 questions) [23], Rigid control of diet (R16; 16 questions)[24],
- Motivation for exercise (24 questions) [25, 26],

Medical Review and Response

The medical panel reviews all clinical data at baseline. Feedback is provided to all participants and a letter sent to participants' GPs with recommendations. Case review meetings led by the medical investigator are conducted 3 monthly to deal with adverse events and changes. Standards refer to NHMRC and Heart Foundation criteria for disease risk (hypertension, diabetes, cardiovascular disease, renal disease). [27] (http://www.heartfoundation.org.au/SiteCollectionDocuments/HypertensionGuidelines2008QRG2010Update.pdf

Hypertension	Systolic mmHg	Diastolic mmHg
Normal	<120	<80
Recheck in 2yrs (or earlier depending on absolute CV risk)		
High normal	120-139	80-89
Recheck in 1yr (or earlier depending on absolute CV risk)		
Grade 1 (mild) hypertension	140-159	90-99
Confirm within 2 mo		
Grade 2 (moderate) hypertension	160-179	100-109
Reassess or refer within 1mo		
Grade 3 (severe) hypertension	≥180	≥110
Reassess or refer within 1-7 days as necessary		
Isolated systolic hypertension	≥140	<90
As for category corresponding to systolic BP		
Isolated systolic hypertension with widened pulse pressure	≥160	≤70
As for grade 3 hypertension		

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Diabetes Risk WHO [28] and NHMRC [29]	Fasting venous plasma glucose (mmol/L)	Random venous pl gluc (mmol/L)
Normal: diabetes unlikely, retest in 3 years	up to 5.5	up to 5.5
Equivocal: impaired glucose tolerance possible, diabetes not excluded, a 75g oral glucose tolerance test recommended	5.6 to 5.9	5.6 to 11
Diabetes: diagnostic in presence of symptoms; In absence of symptoms a repeat measure (fasting in the diabetic range) on a different day diagnostic of diabetes, (OGTT unnecessary)	7 or more	11.1 or more

Cardiovascular disease risk	Risk score
High risk Treat simultaneously with lifestyle interventions and for both blood pressure and cholesterol lowering therapy, regardless of the level of these risk factors. Refer to GP	>15% risk of CV event within 5 years
Moderate risk Opportunity to reduce risk with lifestyle change; drug therapy considered if risk not reduced in 3-6 mo or if specific additional factors present	10-15% risk of CV event within 5 years
Low risk Life style advice.	<10% risk of CV event within 5 years

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Renal disease risk	Risk score
Chronic kidney disease (CKD)	
Decreased kidney function ±kidney damage persisting at least 3mo	GFR < 60ml/minute per 1.73m^2 (kidney dysfunction) albumin –creatinine ratio of >30g/g. (kidney damage)
Kidney damage	*Glomerular Filtration Rate (GFR)*
Stage 1 CKD	≥90 mls/minute per 1.73m^2
Stage 2	≥60-89 mls/minute per 1.73m^2
Stage 3	≥30-59 mls/minute per 1.73m^2
Stage 4	≥15-29 mls/minute per 1.73m^2
Stage 5	<15 mls/minute per 1.73m^2 or kidney damage treated by dialysis or transplantation
Microalbuminuria	*Spot (am) sample Albumin creatinine ratio*
Normal	M <2.5 F <3.5 mg/mmol
Microalbuminuria	M 2.5-25 F 3.5-35 mg/mmol
Macroalbuminuria	M >25 F >35 mg/mmol

If albumin/creatinine ratio ≥ 2.0 mg/mmol (males) or ≥ 2.5 mg/mmol (females) is detected, advise repeat test to confirm. If confirmed, advise a 24-hour urine collection for accurate measurement.

Intervention

Participants will attend clinic visits at baseline 0, then 1, 2, 3, 6, 9, 12, 15, 18, 21, and 24 months (Figure 1). Medical supervision will be provided at baseline and throughout for both the intervention and control group, in collaboration with participants' General Practitioner (GP). Medical intervention will be recorded and integrated into the analysis of outcomes. Individual sessions will be conducted with health practitioners (nurse in the control and dietician in the intervention) in response

to the measures and survey responses. Dietary, physical and behavioural information and counselling will be client oriented but using different materials for advice.

Control group:

Health Practitioner: Participants will receive general health policy advice and social support from a nurse practitioner.

Dietary advice: Similar to Women's Health Initiative's Dietary Modification trial [30], participants will be given copies of the Australian Dietary Guidelines[31] plus other health related material and asked to maintain usual dietary patterns with changes.

Physical activity: The participants will receive basic and structured physical activity advice. This advice will be in line with the current National Physical Guidelines p. 23[32]. Specifically, participants will be encouraged to be physically active almost every day. When undertaking physical activity, a prescription of low to moderate intensity will be communicated as activities that make you 'at-least huff or puff'.

Psychological support: The standard 'patient centred' behavioural components in control group will include self-monitoring of food intake using estimated food records, stimulus control discussions on how to re-engineer personal environment to make health choices easier, addressing common barriers to healthy diet and exercise, support for assertive behaviour, goal setting, and relapse prevention.

Intervention groups

Health Practitioner: With the support of an exercise physiologist and a psychologist, a dietician will provide advice based on an individualised program of diet, physical activity and behavioural support for weight loss and maintenance. Usual diet and physical activity patterns will be assessed and plans negotiated to assist participants to adapt to healthier eating/exercise options targeting weight management.

Dietary advice: Participants will be given individualised dietary counselling addressing their unique patterns of food choice. Dietary modelling will be undertaken to ensure the advice given to participants matches the targeted requirements for their status. Advice will be based on the prescription of the number of food choices

from food categories, individualised based on usual food habits and energy requirements. Dietary support material on seasonal foods, recipes and shopping lists will be developed along the lines of the PREDIMED trial [33]. One arm of the experimental group (Intervention + Walnuts) will be provided with 30g of walnuts per day for the the first 12 months of the study. The walnuts will be modelled into the diet provided.

Physical activity: the intervention will target not only physical activity levels specifically, but moreover reducing the accumulative minutes of daily sedentary behaviour. The intervention will clearly communicate opportunities that arise in leisure, occupation and household activities. A 2 page hand-out will be provided to participants to assist them in understanding current national recommendations and help participants to develop and establish goals for healthy lifestyle change.

Psychological support: A 2 page hand-out and set of value cards (prepared by the senior psychologist) will be provided to participants at baseline counselling. This will support the content of the dietary advice provided by the dietitian (individual diet plan with goals). Three themes will be used to support the achievement of these (and exercise) goals

- Mindfulness
- Motivation
- Self-compassion

Behavioural support of 10 min duration will be provided by regular audio recorded phone coaching (4 times over 12 mo – between 1-3mo, 3-6mo, 6-9mo, 9-12mo). The health coaches will make appointments for phone calls and participants will be sent SMS texts to remind them of the call arriving the next day. Calls may be made out of hours. The senior psychologist will provide 10 tips and recommend use as required. The tips can be linked to study newsletters.

Statistical analysis

The analysis will address the hypothesis that the multidisciplinary lifestyle intervention (non-supplemented or supplemented with walnuts) will produce a greater and sustained weight loss compared to usual care. A combined dataset with de-identified data will be generated from the main study database. The dataset will be analysed by a bio-statistician who is blinded to the group assignment. An

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intention to treat model will be used for analysis. The analysis will be conducted using a linear mixed model. The use of the mixed model allows partial datasets incorporating all available data regardless of whether or not the subject completes the study. The planned contrasts are between the control and the intervention groups. There is no assumption a priori that a difference in weight between the two treatments groups will be detected however the study is adequately powered to show this difference exists if a clinically meaningful difference is detected.

Changes in dietary patterns would be most interesting for the walnut arm. Both intervention arms should lose more weight than the control. An approach to analysis reported in a PREDIMED paper where the effect size is compared. (See Salas-Salvadó J, et al. *Arch Intern Med* 2008;168:2249-58. Here the reduced prevalence of MetS was shown to be -2% in control, -7% in MedDiet +VOO and - 14% in Med diet + nuts – we would look at weight and diet quality score rather than MetS).

Timeframe

The RCT within the HealthTrack study was scheduled to begin recruitment in May 2014. Recruitment was completed in April 2015, the initial 12 month follow-up will be completed in April 2016. Long-term follow-up will cease in April 2017. This schedule is likely to be adjusted with contracts and resourcing.

2014

Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Ethics amendments, Advertising				Recruitment							
						Intervention					

2015

Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Recruitment cease											
Intervention											

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2016

Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Initial intervention complete				Data analysis and report writing							
				Long-term follow-up continues							

2017

Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Long term follow-up complete											

Ethics

Application: The primary ethics application was submitted to the University of Wollongong Human Research Ethics Research Committee and approved in July 2013 (HE13/189). Amendments to the ethics application were submitted for a pilot cohort study and pilot randomised controlled trial and approved in August 2013.

Adverse events: This project is a life-style intervention project where the risk of adverse events is considered minimal. However, in the unlikely case where an adverse event occurred, the participants so affected will be removed from the study and referred to medical personnel for appropriate medical attention. The Ethics Committee will be advised.

Informed consent and management of confidentiality: Participants will be fully informed of the nature of the study and be requested to sign consent to participate. A second informed consent form will be signed for participation in the long-term follow-up. They will be able to withdraw without penalty at any stage during the study, however in the event of that occurring requests will be made to utilise data to date. Each participant in this project is given a unique ID, matched to their personal identifiable information through a master code sheet. The master code sheet will be the responsibility of the Project co-ordinator and stored separately from the main

study database, where no personal identifiable information was stored except for the unique ID. Both the master code sheet and the study database will be stored in a locker in a locked office, and in the case of electronic files, they will be password protected to prevent unauthorized access to the data.

Data management

Data management will be the responsibility of the HealthTrack research fellow, who will develop and maintain the database and facilitate statistical and trial monitoring support throughout the study. This includes oversighting data entry from recruitment and follow up, the preparation of monthly reports on progress, and the assurance of quality and completeness of the data. Data will also be scrutinised for missing or inappropriate entries which may require clarification and completeness of data verified for each individual. A Manual of Operations will be written to assure quality with respect to;

- Data entry and the missing data checks
- Cross from edit checks for inconsistencies
- Audits of data and standardised edit reports

A detailed flowchart of all activities was developed during the pilot to ensure that all ethical requirements are met, that interviewers are suitably trained and that all interactions with the general public are conducted in an exemplary manner. The flowchart is provided below.

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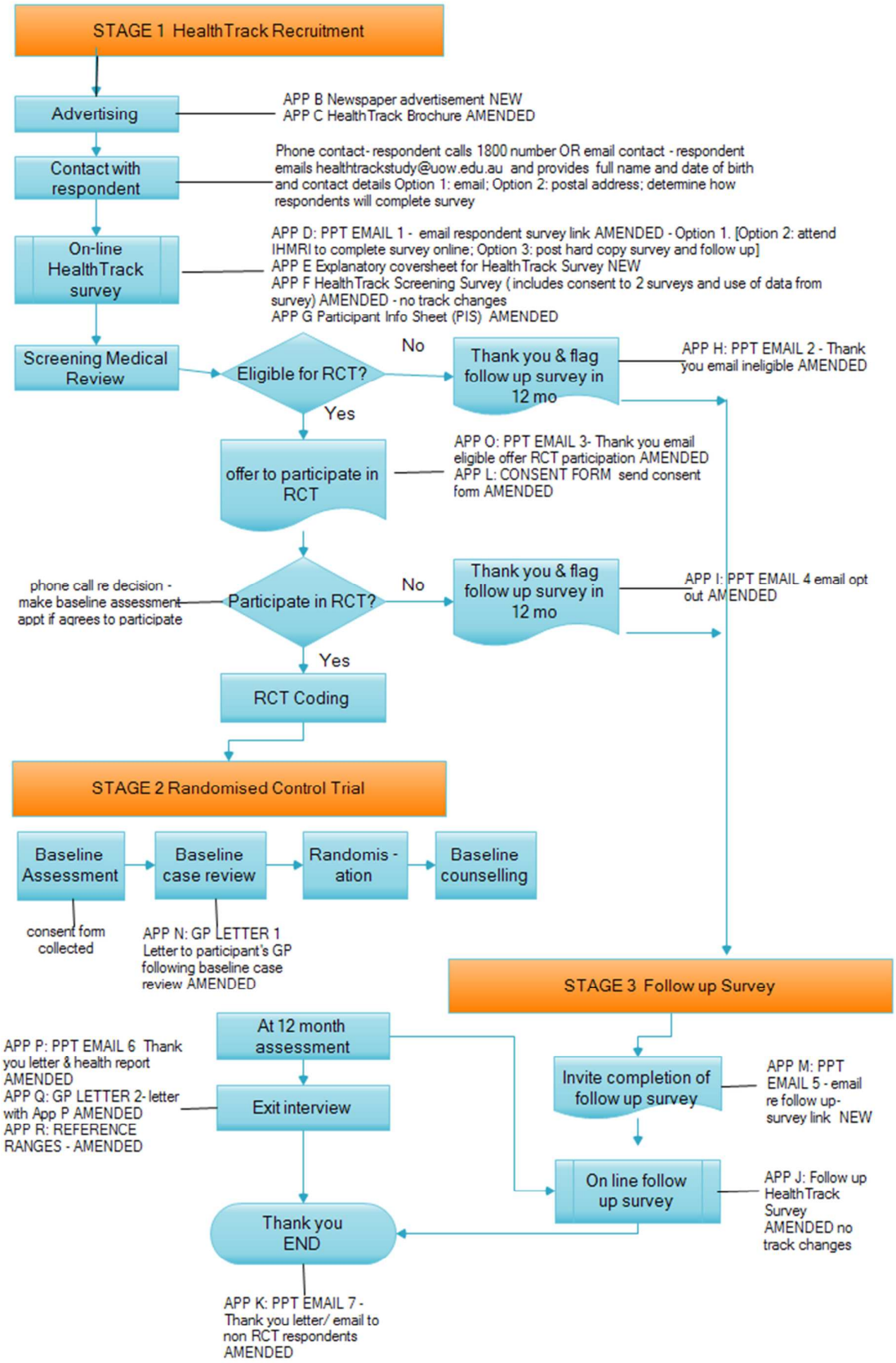

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Obtaining data: Respondent cooperation will be encouraged at each step of data collection in both the survey and the trial components of the study. Three attempts will be made to follow up participants who do not complete the initial screening survey. Where possible computer aided data collection methods will be applied. Tracking procedures will be set up to monitor progress and report to the study team and overarching committees. Standard Operating Procedures will be developed for all processes and interactions with participants and other stakeholders.

Client Record Files: Client Record Files (CRFs) will be established for all participants in the study using standardised protocols and referencing an aligned data management system utilised by IHMRI.

Database structure: A custom built, password protected tailored database will be created for this study (Clintel Specialist http://www.clintel.com.au/) that will have the ability to store and supply data for analysis. Separate tables will be created for baseline information as well as each major group of outcomes. At the end of the study, the tables will be merged using a custom built SQL query.

Data storage and access: Data will be entered and stored in the Clintel Specialist database mentioned above. The electronic copy of the database will be backed up regularly to an access restricted folder on the SHS shared drive. Only personnel authorized by the ethics committee will be provided access to the data.

Data cleaning and preparation for analysis: Steps will be taken during data collection (e.g. visual prompts on questionnaire; etc.) to minimize missing data. However should there be missing data, steps will be developed to address the gaps. Missing data of all other participants will be treated as missing or estimated using linear regression modelling where appropriate.

Data from the 4-day food records will be entered into a nutrition analysis software package FoodWorks Professional 2009 to estimate the average daily energy and nutrient intake, based on the food composition database [34]. Goldberg cut-offs [35] for specific physical activity level will be used to assess the plausibility of the 4-day food records to exclude under-and over-reporters.

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Physical activity data will be converted to METs (minutes per week) for continuous analysis and physical activity level will be used for categorical analysis.

Secondary data sources: Agreements will be sought with secondary sources of population data opportunities for example the Australian Health Services Research Institute, the Centre for Health Record Linkage [36]. NSW Health survey.

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Effect of interdisciplinary care on weight loss in chronic disease management: a randomised controlled trial.

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Effect of interdisciplinary care on weight loss in chronic disease management: a randomised controlled trial.

Objective: To determine the effectiveness of a novel interdisciplinary treatment compared with usual care on weight loss in overweight and obese adult volunteers.

Design: Single-blinded controlled trial. Participants randomly assigned to usual care (C, general guideline-based diet and exercise advice), intervention (I, interdisciplinary protocol) or intervention+ a healthy food supplement (30g walnuts/d) (IW).

Setting: Community based study, Illawarra region, south of Sydney, Australia.

Participants: Generally well volunteer adult residents, 25-54y, BMI 25-40kgm^{-2} were eligible. At baseline 439 were assessed, 377 were randomised, 298 completed the 3mo intensive phase and 178 completed the 12mo follow up.

Interventions: Treatment was provided at clinic visits intensively (0,1,2,3mo) then quarterly to 12mo. Support phone calls were quarterly. All participants underwent blinded assessments for diet, exercise, and psychological status.

Primary and secondary measures: The primary outcome was difference in weight loss between baseline and 12mo (clinically relevant target 5% loss). Secondary outcomes were changes in blood pressure, fasting blood glucose and lipids, and changes in diet, exercise and psychological parameters.

Results: At 12mo, differences in weight loss were identified (P<0.001). The I group lost more than controls at 3mo (-1.11[-2.23,-0.00], P<0.05) and the IW more than controls at 3mo (-1.25 [-2.35,-0.15], P<0.05) and 6mo (-2.20[-3.90,-0.49], P<0.01). The proportion achieving

5% weight loss was significantly different at 3,6 and 9mo (P=0.04, 0.03, 0.03), due to fewer controls on target at 3,6 and 9mo and more IW participants at 6mo. Reductions in secondary outcomes (systolic bold pressure, blood glucose/lipid parameters, and lifestyle measures) followed the pattern of weight loss.

Conclusions: An interdisciplinary intervention produced greater and more clinically significant and sustained weight loss compared to usual care. The intensive phase was sufficient to reach clinically relevant targets, but long term management plans may be required.

Trial registration: Australian New Zealand Clinical Trials Registry ANZCTRN 12614000581662, www.anzctr.org.au

Strengths and limitations of this study

- The study was closely aligned to practice and protocols tested could be readily translated into primary care services
- Although this was a single centre study, substantial controls were applied to provided quality evidence of effects
- The study demonstrated the breadth of behavioural influences integral to achieving weight loss and clinical outcomes
- Rigorous statistical analyses were applied to the evaluation of primary outcomes, including a sensitivity analysis to confirm effects.
- As practice oriented research, retention strategies were not applied, with higher than anticipated loss to follow up following the intensive phase.

INTRODUCTION

The prevention and management of chronic non-communicable disease (CNCD) is a challenge for health services[1].Given the links to disease pathology, identifying overweight as a problem is an important first step[2]. Primary Care is an ideal setting for the clinical management of obesity, yet relevant studies are scarce[3], and measuring or recording weight in this setting appears sub optimal[4]. In addition, weight management may require a more shared sense of decision making[5], and a broader approach, including the expertise of relevant allied health professionals[6]. For example, dietitians may provide expertise on nutritional factors other than dietary energy that influence weight loss and chronic disease risk factors[7], such as dietary patterns[8], significant foods[9], and nutrients such as fibre[10], fatty acids[11], and sodium[12].

Health behaviours that can significantly lower disease risk are central to the management of chronic disease[13]. There is convincing evidence that focusing on diet, physical activity and behaviour will have the best effects on overweight[14]. Obese individuals who lose just 5% of their body weight (the target for American College of Cardiology/American Heart Association clinical guidelines[2]) have significant improvements in risk factors for type 2 diabetes and cardiovascular disease, including improved insulin sensitivity and reduced fat in the liver[15]. However, there are underlying metabolic problems and weight regain invariably follows[16 17]. This suggests obesity itself is a chronic condition requiring acute effective treatments repeated at intervals[16] with the provision of consistent positive reinforcement to address associated complex psychological factors[18]. There is little research on holistic treatments that integrate diet, exercise and psychological support[19] and research is needed to test novel protocols in this area[20 21]. In a feasibility trial comparing usual care with an interdisciplinary model, we found high eligibility (83%) and completion (87%) rates and a

preliminary effect of -3.98kg greater weight loss over 3mo (95%CI 6.17-1.79, P=0.002)[22]. The next research question was whether weight loss could be achieved in a larger cohort and over a longer time period. The objective of the current trial was to determine the effectiveness of a novel interdisciplinary treatment compared with usual care on weight loss in overweight and obese adult volunteers. We hypothesised that a model of care with physician oversight that integrates the expertise of dietitians, with exercise physiologists and psychologists will be more effective than general advice provided by a practice nurse (usual care). Further, the provision of a supplement of a significant healthy food may enhance this effect and influence the overall diet.

METHODS

Study oversight and ethics

The study was approved by the University of Wollongong/Illawarra Shoalhaven Local Health District Human Research Ethics Committee (Health and Medical) (HE 13/189) and conducted in compliance with the Principles of the Declaration of Helsinki. The trial is registered with the Australian and New Zealand Clinical Trial Registry (ANZCTRN12614000581662). Study oversight was provided by the senior clinical investigative team.

Study participants

Recruitment was conducted through communications and advertising in the local media. Respondents who were permanent residents of the Illawarra region, aged 25-54 years, community dwelling, and with a BMI 25-40kg/m^2 were included. Exclusion criteria were being unable to communicate in English; having severe medical conditions impairing the ability to participate in the study or thought to limit survival to one year, having reported

illegal drug use or regular alcohol intake associated with alcoholism (>50g/day); or other major impediments to participation.

Trial design

This was a community specific (single center), randomized, assessor blinded trial, comparing outcomes between intervention and control groups at 0, 3, 6, 9, 12 mo. Full details of the study protocol and baseline results are reported elsewhere[23]. Briefly, all participants attended the clinic for counselling on 7 occasions (0, 1, 2, 3, 6, 9, 12mo) and received quarterly support phone calls. Assessment and treatment protocols were devised by the research team including Physicians, Dietitians, Exercise Physiologists and Psychologists. Measurements were undertaken separately at these time points. Body weight (kg) was measured at each visit in an upright position (minimal clothing, no shoes) using scales with a bio-electrical impedance component for estimating body fat (%) (Tanita TBF-662, Wedderburn Pty Ltd, Ingleburn, NSW, Australia). Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured at 0, 3 and 12mo using the Omron BP-203RPEIII VP-1000 device (Omron Health Care, Kyoto, Japan). Measurements are collected at the end of 5 min resting period in supine position. Fasting blood lipids (cholesterol, LDL, HDL, Trig), fasting blood glucose, and serum HBA1c were assessed through a registered Pathology service (Southern IML Pathology) quarterly. For 24 hour urinary sodium assessments a 24 hour urine sample was provided at 0, 3 and 12mo. Dietary intake was assessed using a diet history interview[24] and physical activity using the International Physical Activity Questionnaire (IPAQ)[25] and via a pedometer (Yamax Digiwalker SW200, Pedometers Australia). worn for a four day period every quarter. A range of psychological assessments were applied, including the Physical and Mental Health SF-12 (12 questions)[26], Depression Anxiety Stress Scale (short form 21 questions)[27], and Acceptance and Action Questionnaire for Weight-related problems (11 questions) (AAQW)[28] at 0, 3 and 12mo.

Participants were randomly assigned to usual care (C, general advice), intervention (I, interdisciplinary advice) and intervention+ food supplement (IW, I+ 30g walnuts/day). Usual care involved a nurse providing general advice based on the Australian Guide to Health Eating, (AGHE)[29] and National Physical Activity Guidelines[30]. Phone contact at quarterly intervals was also made with the by the study administrator delivering semi scripted patient centred support of short duration. In the intervention counselling session an Accredited Practising Dietitian negotiated changes in specific food choices based on a diet history assessment and materials that referred to the food groups outlined in the AGHE (vegetables, fruits, grains, protein rich foods, dairy foods, oils). This consultation included advice to increase physical activity and reduce sedentary behaviour by identifying opportunities in leisure, occupation and household activities, with additional categorical guidance prepared by the Exercise Physiologist following exercise assessment. The psychologist developed a workbook for participants and trained health coaches to deliver related scripted calls of short (15 minute) duration at quarterly intervals. The psychological coaching component was based on principles from Acceptance and Commitment Therapy[31] and involved clarification of underlying values to increase motivation related to weight loss, increasing mindfulness and awareness to facilitate better health choices, and self-compassion to promote continued valued-action even in the presence of setbacks.

Randomisation was performed remotely in randomly allocated blocks of 3, 6 or 9 by an investigator unrelated to the clinic. A computer generated randomisation sequence was used (STATA V12, StataCorp LP, College Station Tx). The randomisation was stratified according to sex and BMI (low BMI:≤30 and high BMI:>30). The randomisation list was provided to the study team who added eligible participants sequentially for each of the strata. Participants were blinded to their randomised allocation and only advised they would be seen by a health practitioner.

Effectiveness outcomes

All endpoints compared baseline data with 12mo results. The primary outcome was body weight (kg). Secondary outcomes were fasting blood lipids, glucose and HbA1c, systolic blood pressure, dietary intake, measures of physical activity and psychological wellbeing.

Statistical analysis

Outcomes were analysed using mixed models. The primary outcome variable weight was analysed using a published model building procedure[32]. Initially a simple model with main effects and a group by time interaction was considered. Initial data exploration suggested quadratic and cubic terms may be needed and these were added in turn and tested with likelihood ratio tests to determine improvement in model fit. Random effects for both intercept and slope were included in the weight model. A similar procedure was followed for all other variables. Significant higher order interaction terms were followed up by ANCOVA to determine differences between groups at each time point with baseline value as a covariate. Gender was included as a covariate in the body composition models. As the dropout rate at the end of the follow up period (12mo) was substantial, several sensitivity analyses were performed. Firstly multiple imputation of 100 datasets was used to verify the significance of the difference between the groups at all time points. The imputation model included group, age and gender as well as weight at each time point. A complete case analysis, last observation carried forward and baseline observation carried forward were also performed. Model building was performed using LMER in the LME4 package of R (RStudio V0.99.489, RStudio Inc). Multiple Imputation was performed in SAS (V9.4 SAS Institute Inc, Cary NC) using PROC MI, PROC MIXED and MIANALYSE, for the ANCOVA. F tests for the 100 multiple imputation using PROC MIXED were combined using the package MICEADDS in R.

RESULTS

Participants

Recruitment began in May 2014 and the last participant completed in May 2016. Surveys were sent to 718 respondents, 439 of whom underwent baseline assessments. N=377 were randomised into the C (n=126), I (n=125) and IW groups (n=126). The intensive phase was completed by 298 participants (withdrawal rate 18%) and the 12mo follow up by n=178 participants (withdrawal rate 39%) (Figure 1). Screening and baseline data are reported elsewhere[23]. The sample comprised mostly obese (BMI 32 (29-35) kg/m^2), non-smoking (98%) well educated (85% post school qualifications) females (74%) of median age 45 (37-51) years. They also suffered from anxiety (26.8%) and depression (33.7%) and were treated for hypertension (25%). Metabolic syndrome was identified in 34% of participants[33].

Participants attended the Clinical Trials Unit of the Illawarra Health and Medical Research Institute. After randomisation 67 participants withdrew, with most (75%) citing an inability to commit time and/or personal reasons. The next major withdrawal (n=49) occurred after the 3mo intensive phase for similar reasons. Attendance gradually reduced for all groups but IW participants attended more, and were more likely to complete the phone coaching calls than the I group (at quarters 2,3,4; P<0.05). Less than a quarter of participants were on medications for glucose, lipids, and blood pressure. There were no differences between groups for medication use (P>0.05) (Table 1).

Table 1: Number (%) of participants reporting medication during the HealthTrack study

Medication type	Control	Intervention	Intervention + walnuts	p-value*
Antihypertensive (n [%])				
Baseline	14 (11)	20 (16)	17 (14)	0.521
3 months	10 (10)	16 (16)	17 (17)	0.410
6 months	7 (10)	10 (15)	12 (14)	0.654
9 months	6 (10)	8 (15)	13 (17)	0.491
12 months	6 (10)	9 (20)	13 (18)	0.267
Hypoglycaemic/insulin (n [%])				
Baseline	6 (5)	4 (3)	5 (4)	0.945
3 months	6 (6)	3 (3)	5 (5)	0.584
6 months	2 (3)	2 (3)	4 (5)	0.819
9 months	1 (2)	3 (6)	3 (4)	0.563
12 months	1 (2)	3 (7)	3 (4)	0.429
Hypolipidaemic (n [%])				
Baseline	15 (12)	10 (8)	7 (6)	0.201
3 months	14 (15)	8 (8)	7 (7)	0.147
6 months	10 (14)	6 (9)	5 (6)	0.190
9 months	9 (15)	6 (11)	5 (7)	0.287
12 months	10 (16)	5 (11)	3 (4)	0.064

*Chi square test

Primary outcomes

Weight loss

After 12mo weight reduced in all groups with a significant difference between groups (P=0.0002) (Tables 2 and 3). The primary analysis model including group, gender and time, found a quadratic time by group interaction. The effect was seen with the IW group showing initial weight loss and then a gain from 6mo, while the other groups maintained their weight loss over time (Figure 2). Post hoc analysis on complete cases indicated significantly greater weight loss in I and IW compared to C at 3mo (-1.2 kg, P=0.045 I; -1.3kg, P=0.025 IW) and at 6mo for IW (-2.1kg; P=0.010). The ANCOVA compared the groups using a mixed model on the actual data and the combined estimates for 100 imputations (Table 2 and Supplementary Materials). A sensitivity analysis confirmed the effects (Table 3). An ANCOVA on complete cases for the 12 month weight change adjusted for baseline weight, gender and age showed an effect approaching significance P=0.056 reflecting a difference between the C - IW group of -2.2kg (95%CI -4.6,0.1kg P=0.068) compared with differences between the C-I groups -1.9kg (95%CI -4.5,0.7kg P=0.228) and the I and IW groups -0.3kg(95%CI -2.8,2.2kg P=1.00).

Table 2: Effectiveness End Points for the Intention to Treat Population‡

Variable		Control		Intervention		Intervention + walnuts	Group	Time	Group x time
	n	value	*n*	value	*n*	value	p-value	p-value	p-value
Body weight, mean (SD), kg							0.644	0.004(3)	<0.001
Baseline	126	91.8 (14.7)	125	91.9 (15.2)	126	91.4 (15.6)			
3mo	96	90.0 (14.1)	99	90.3 (15.3)	103	88.3 (14.7)			
12mo	61	87.8 (14.9)	45	86.5 (17.8)	72	87.9 (14.2)			
Body fat, median (IQR), %							0.599	0.070(3)	0.022
Baseline	125	41.3 (36.2 – 45.1)	125	41.4 (35.4 – 46.1)	125	41.4 (36.2 – 46.1)			
3mo	95	41.0 (35.0 – 44.6)	99	39.2 (33.8 – 45.1)	103	39.8 (34.7 – 43.0)			
12mo	61	40.7 (32.0 – 43.3)	45	37.0 (31.8 – 41.9)	72	38.2 (33.9 – 43.5)			
Systolic blood pressure, median (IQR), mmHg*							0.441	<0.001(2)	0.551
Baseline	126	123 (113 – 132)	124	124 (114 – 134)	125	123 (114 – 134)			
3mo	93	118 (109 – 129)	96	119 (109 – 131)	102	119 (110 – 127)			
12mo	61	116 (109 – 127)	45	118 (106 – 128)	71	123 (111 – 131)			
Glucose, median (IQR), mmol/L							0.340	<0.001(2)	0.399
Baseline	126	5.2 (4.9 – 5.6)	124	5.2 (4.9 – 5.7)	126	5.2 (4.9 – 5.8)			
3mo	69	5.2 (5.0 – 5.5)	69	5.2 (4.9 – 5.7)	84	5.2 (4.9 – 5.6)			
12mo	52	5.5 (4.9 – 5.7)	37	5.3 (5.0 – 5.7)	64	5.3 (5.0 – 5.7)			
HbA1c, median (IQR), (%)							0.301	0.003(3)	0.407
Baseline	126	5.2 (5.0 – 5.5)	125	5.2 (4.9 – 5.4)	126	5.1 (4.9 – 5.4)			
3mo	69	5.3 (5.1 – 5.4)	69	5.2 (5.0 – 5.4)	84	5.2 (5.0 – 5.5)			
12mo	52	5.2 (5.0 – 5.4)	37	5.1 (4.9 – 5.4)	63	5.1 (4.9 – 5.4)			
Total cholesterol, median (IQR), (mmol/L)							0.193	<0.001(3)	0.135
Baseline	126	5.3 (4.7 – 6.0)	124	5.0 (4.4 – 5.8)	126	5.1 (4.6 – 5.7)			
3mo	70	5.2 (4.4 – 5.6)	69	5.0 (4.4 – 5.5)	83	4.8 (4.3 – 5.6)			

12mo	52	5.0 (4.2 – 5.6)	37	5.4 (4.5 – 6.0)	64	5.4 (4.6 – 5.8)			
Triglycerides, median (IQR), (mmol/L)							0.005	0.142	0.368
Baseline	125	1.3 (0.9 – 1.6)	124	1.1 (0.8 – 1.6)	126	1.1 (0.8 – 1.5)			
3mo	70	1.3 (0.9 – 1.6)	69	1.2 (0.9 – 1.8)	83	1.0 (0.8 – 1.4)			
12mo	52	1.3 (0.9 – 1.6)	37	1.2 (0.8 – 1.7)	64	1.1 (0.9 – 1.6)			
HDL, median (IQR), (mmol/L)							0.236	<0.001(3)	0.098
Baseline	126	1.3 (1.1 – 1.7)	124	1.4 (1.2 – 1.6)	126	1.4 (1.2 – 1.7)			
3mo	70	1.3 (1.0 – 1.6)	69	1.3 (1.1 – 1.6)	83	1.4 (1.2 – 1.8)			
12mo	52	1.3 (1.1 – 1.6)	37	1.5 (1.2 – 1.8)	64	1.5 (1.2 – 1.8)			
Cholesterol:HDL ratio, median (IQR)							0.036	<0.001	0.739
Baseline	125	3.9 (3.0 – 4.7)	124	3.5 (3.1 – 4.4)	126	3.6 (2.9 – 4.3)			
3mo	70	4.0 (3.3 – 4.8)	68	3.8 (3.1 – 4.5)	83	3.4 (2.7 – 4.1)			
12mo	52	3.8 (3.0 – 4.2)	37	3.3 (2.9 – 4.4)	64	3.5 (2.9 – 4.4)			
LDL, median (IQR), (mmol/L)							0.516	<0.001(3)	0.295
Baseline	123	3.2 (2.7 – 3.7)	123	3.0 (2.4 – 3.6)	126	3.1 (2.6 – 3.7)			
3mo	69	3.2 (2.4 – 3.8)	69	3.1 (2.5 – 3.4)	83	2.8 (2.3 – 3.5)			
12mo	52	3.1 (2.3 – 3.6)	37	3.1 (2.4 – 4.0)	64	3.2 (2.5 – 4.0)			
MET-mins/week (IPAQ), median (IQR)*									
Baseline	124	876 (396 – 1523)	123	918 (396 – 1551)	124	1040 (563 – 2329)	0.053	<0.001	0.341
3mo	92	1461 (793 – 2486)	94	1540 (842 – 2635)	102	2020 (1236 – 3125)			
12mo	61	1782 (807 – 3451)	46	2009 (924 – 3015)	77	1678 (827 – 3732)			
Energy, median (IQR), kJ/day*							0.095	<0.001(2)	0.444
Baseline	126	9400.2 (7840.5 – 11574.3)	125	8647.5 (7158.2 – 10993.8)	126	8932.9 (7458.3 – 10785.5)			
3mo	93	7443.8 (6479.0 – 9087.9)	97	6891.1 (6045.1 – 8700.3)	103	7264.4 (6239.3 – 8444.5)			

12mo	60	7864.7 (7014.0 – 9345.7)	44	7184.9 (5754.3 – 9078.2)	71	7805.5 (6622.9 – 9718.9)			
Fibre, median (IQR), g/day							0.989	0.059	0.005
Baseline	126	26.1 (21.7 – 33.3)	125	25.2 (21.5 – 31.1)	126	25.0 (19.8 – 32.2)			
3mo	93	24.6 (19.1 – 30.6)	97	27.0 (22.0 – 33.1)	103	26.7 (22.2 – 32.5)			
12mo	60	22.9 (19.7 – 32.5)	44	26.8 (22.2 – 30.1)	71	26.5 (20.6 – 32.1)			
P:S ratio, median (IQR)*							<0.001	<0.001(2)	<0.001 (2)
Baseline	126	0.4 (0.3 – 0.5)	125	0.4 (0.3 – 0.5)	126	0.4 (0.3 – 0.5)			
3mo	93	0.5 (0.4 – 0.7)	97	0.5 (0.4 – 0.7)	103	1.3 (0.9 – 1.8)			
12mo	60	0.5 (0.3 – 0.6)	44	0.5 (0.4 – 0.7)	71	0.8 (0.6 – 1.1)			
Quality of life (SF12), physical summary, median (IQR)									
Baseline	126	49.3 (43.1 – 54.4)	124	49.6 (45.0 – 54.1)	125	51.1 (44.8 – 55.2)	0.027	<0.001	0.660
3mo	91	51.3 (45.1 – 55.9)	96	51.0 (42.9 – 54.6)	102	53.5 (46.6 – 56.4)			
12mo	60	54.3 (48.6 – 57.4)	44	52.6 (44.2 – 57.5)	69	54.0 (51.7 – 57.4)			
Quality of life (SF12), mental summary, median (IQR)									
Baseline	126	48.7 (41.3 – 53.5)	124	48.4 (37.7 – 55.0)	125	47.5 (39.4 – 53.9)	0.772	0.002 (2)	0.788
3mo	91	51.0 (45.6 – 56.7)	96	49.9 (43.1 – 56.4)	102	51.7 (44.9 – 57.2)			
12mo	60	51.9 (41.4 – 57.1)	44	54.7 (44.5 – 56.5)	69	51.1 (42.3 – 55.2)			

Mixed model. (2) quadratic term (3) cubic term *ln transformed prior to analysis †sqrt transformed prior to analysis ‡ results for the following variables are presented in Supplementary Materials: diastolic blood pressure, steps, percent energy from protein, total fat, carbohydrate, and alcohol, urinary sodium excretion, DASS-21, AAQW

Table 3: Sensitivity analysis, comparison of differences in weight between groups at each time point

Method		3			6			9			12		P (Interaction)
	Control-Walnut	Control-intervention	Intervention-Walnut	Control-Walnut	Control-intervention	Intervention-Walnut	Control-Walnut	Control-intervention	Intervention-Walnut	Control-Walnut	Control-intervention	Intervention-Walnut	
Mixed	**-1.25* (-2.35,-0.15)**	**-1.11* (-2.23,-0.00)**	**-0.13 (-1.23,0.96)**	**-2.20 ** (-3.90,-0.49)**	**-1.53 (-3.36,0.30**	**-0.67 (-2.42,1.08)**	**-1.98 (-3.95,0.00)**	**-1.67 (-3.80,0.46)**	**-0.31 (-2.32,1.71)**	**-1.91 (-4.06,0.25)**	**-1.72 (-4.15,0.71)**	**-0.19 (-2.54,2.17)**	**<0.001**

					)								
MI	-1.27** (-2.17,-0.37)	1.04* (-1.91,-0.16)	-0.23 (-1.12,0.65)	-1.82** (-3.14,-0.50)	-1.26 (-2.57,0.04)	-0.56 (-1.88,0.76)	-1.69* (-3.22,-0.16)	-1.46* (-2.92,-0.00)	-0.24 (-1.72,1.24)	-1.15 (-2.77,0.47)	-1.06 (-2.57,0.47)	-0.11 (-1.65,1.43)	0.002
Complete	-1.70** (-3.06,-0.33)	-1.14 (-2.66,0.38)	-0.56 (-1.99,0.88)	-2.30* (-4.28,-0.32)	-1.30 (-3.51,0.91)	-1.00 (-3.08,1.07)	-2.22* (-4.44,0.00)	-1.89 (-4.36,0.58)	-0.33 (-2.65,1.99)	-1.61 (-3.90,0.68)	-1.40 (-3.95,1.16)	-0.21 (-2.19,0.68)	<0.001
LOCF	-1.11* (-2.02,-0.19)	-0.95* (-1.87,-0.04)	-0.15 (-1.07,0.76)	-1.57** (-2.77,-0.36)	-1.05 (-2.26,0.16)	-0.52 (-1.73,0.69)	-1.44 (-2.74,-0.15)	-1.27 (-2.56,0.26)	-0.18 (-1.47,1.12)	-1.04 (-2.33,0.24)	-1.09 (-2.37,0.20)	0.04 (-1.24,1.33)	<0.001
BCF	-1.11* (-2.02,-0.19)	-0.95* (-1.87,-0.04)	-0.15 (-1.07,0.76)	-1.73** (-2.87,-0.59)	-0.78 (-1.92,0.36)	-0.96 (-2.09,0.19)	-1.40** (-2.53,-0.28)	-0.64 (-1.78,0.49)	-0.76 (-1.89,0.37)	-1.30* (-2.45,-0.15)	-0.46 (-1.61,0.70)	-0.84 (-2.00,0.31)	<0.001

**<0.01, *<0.05

MI= multiple imputation, using groups, age, gender and weight at each time point

Complete = complete analysis

LOCF = Last observation carried forward

BCF = baseline observation carried forward

Achievement of 5% weight loss target

Chi square analyses indicated significant differences in the proportion of participants achieving the clinically significant effect of 5% weight loss. At 3, 6, and 9mo the proportion achieving 5% weight loss in the C group was lower than expected (P=0.04, 0.03, 0.03, respectively), although there was no difference at 12mo (p=0.091) with 33% IW, 38% I and 20% C meeting the 5% target. At 6mo the number in the IW group was higher than expected (P=0.03), consistent with the primary analysis. Likewise there was a group difference in change in percent body fat (interaction effect P=0.022) (Table 2).

Secondary outcomes

Clinical effects

Systolic blood pressure (SBP) decreased between baseline and 3mo but then remained unchanged (Table 2). Changes in SBP also reflected patterns of sodium excretion (a marker of dietary intake) decreasing from baseline to 3mo (P<0.001) and increasing to 12mo (P=0.002). Likewise, fasting blood glucose was lower than baseline at 3mo (P=0.040) and 6mo (P<0.001), and then remained lower than 12mo (P=0.003). HbA1c at 12mo was lower than the baseline value (P=0.031).

In keeping with this pattern of effects, total cholesterol and LDL concentrations were lowest for the sample at 3mo (P<0.001; P≤0.031 respectively) and at 6mo they remained lower than baseline (P=0.020; P=0.034 respectively). The Cholesterol: HDL ratio decreased particularly after 6mo, while HDL-C values first dropped at 3mo then returned to greater than baseline at 12mo (P≤0.021). The group effect for total cholesterol showed a lower overall mean for the IW group compared with controls (P=0.001) and I (P=0.037) (Table 2).

Behavioural effects

As with the pattern of weight change, reported energy and total fat intakes (as a percent of energy) were lower than baseline at 3mo (P<0.001) and still at 12mo (P<0.001), but they increased between 3mo and 12mo (P=0.020) (Table 2). Changes in percent energy from protein were the opposite for dietary fat. The value was higher than baseline at 3 and 12mo (P<0.001), but lower at 12mo than 3mo (P=0.04). Percent energy from carbohydrate reduced from baseline to 12mo (P=0.002), and from alcohol (P=0.012) decreased from baseline to 12mo (P=0.041). The only reported difference between groups was for the Polyunsaturated:Saturated (P:S) fatty acid ratio, where the the IW group showed a higher value over time compared to the other groups (interaction effect P<0.001).

The time effects for increased physical activity were stronger in self-reported MET-Mins/week (IPAQ) (P<0.001; significantly higher than baseline at all time points, Table 2) than measurements of steps/day (P=0.046) (Supplementary Materials). The changes in diet and physical activity were accompanied by increases in scores for positive psychological parameters (Quality of Life, QoL, Table 2) and decreases for negative parameters (Depression Anxiety Stress, DASS-21; Acceptance and Action for Weight Related problems, AAQW, Supplementary Materials). The IW group scored highest for Quality of Life (QoL SF12) physical summary scores throughout the study period (group effect P=0.027). The QoL (SF12) mental summary score increased after 3mo, with differences from baseline to 12mo (time effect P=0.002). The DASS-21 and AAQW scores were lower at 12mo (P<0.001) but the significant decreases occurred at 3mo (P<0.001) (Supplementary Materials).

DISCUSSION

Main findings

Despite the same intensity of intervention and a focus on national diet and physical activity guidelines, the interdisciplinary protocol produced greater and more clinically significant effects on weight loss than usual care (Figure 2). The statistical analysis was comprehensive and results were confirmed with sensitivity analysis (Table 2). While it is not possible to separate out the components of the interdisciplinary approach, it appears more individualized advice including a focus on specific foods may have enhanced the effect. This was especially evident with the food supplemented group who continued to produce a greater weight loss at 6 months. The size of the effect and the time taken to achievement are also highly relevant to practice. Without unusual retention strategies, we found that a 3 month commitment to an intensive treatment was feasible, and in that time the intervention protocol delivered a greater proportion with a 5% weight loss target. In Western societies, it is estimated that the adult population gains 0.45kg weight/year[34], so our effects could be interpreted as even greater. Had we continued with monthly rather than quarterly clinic visits after 3 months we may have improved retention and study power, but that would meant greater healthcare costs. A simple sample size calculation based on the differences between groups for the completers at 12 months indicates that approximately 124 subjects per group would be required to complete the study for differences between the 3 groups to be statistically significant when adjusted for multiple comparisons.

Secondary outcomes

We confirmed the observation that a 5% weight loss can have an impact on disease risk factors[15]. Significant reductions in systolic blood pressure occurred with weight loss, as expected, but this also occurred with increased physical activity, improved mental health scores and a reduction in urinary sodium, a dietary factor known to be associated with blood pressure[35]. The latter implies that the dietary changes went beyond that of energy restriction.

As the national dietary guidelines were a reference point for all groups, differences in sodium intakes were not observed in this intention to treat analysis. Per protocol analyses may be able to detect whether greater changes occurred in the groups with the dietitian (I and IW) confirming effects seen in other primary care studies[36]. Similarly the improvements in blood glucose parameters occurred with weight loss in the presence of increased physical activity and a reduced carbohydrate load for the study cohort. Further research on the types of carbohydrate-rich foods may be informative in detecting more specific differences between groups.

The changes in blood lipids were as expected with changes in weight. The lower overall mean for total cholesterol for the IW group occurred in the presence of a significantly different dietary P:S ratio. We have previously shown that integrating walnuts in an energy controlled diet can change the dietary P:S ratio with concomitant effects on lipids (31). Given that walnuts are a fat-rich food, their inclusion in the dietary modelling for the IW group would be expected to influence the overall diet profile.

Implications for practice

Practice involves an integration of evidence on many factors, and in this research we examined a number of components. We confirmed that changes in disease risk factors occurred alongside changes in body weight, physical activity, mental health scores and dietary factors known to have an impact on disease risk such as dietary sodium, fibre, and fatty acid profile[10 12 16 37]. In this trial the dietitian provided the face-to-face counseling with participants. Being more specific about actual foods to consume may be more effective and providing a significant healthy food (walnuts) emphasized this point. While the effects of walnuts in the diet can be found in the literature[38 39], there may have been synergistic effects

with psychological factors in our trial. The reduced psychological avoidance of weight related issues (AAQW scores) was particularly relevant and further analyses of our data may clarify the effects of health coaching when integrated into diet and physical activity advice. In addition, and based on our previous research[40], the greater initial weight loss achieved by the IW group may have influenced retention, and this may have also resulted in the higher QoL scores, but it is difficult to determine if the provision of the food supplement alone acted as the main incentive[41]. The greater attendance at phone coaching sessions by the IW group, which targeted skills in mindfulness and acceptance, also may have helped deal with the stress associated with achieving health goals[18]. It is difficult to tease out any singular effect as there is so much interdependence between behavioral factors, but this study has helped expose significant elements. The pattern of weight loss reflected reduced energy intake and increased physical activity (Table 2), providing evidence for applying expertise in both diet and exercise[42 43]. As sources of nutrients, the food choices drove nutritional changes underpinned by the involvement of dietitians[44 45].

Strengths and limitations

The sample comprising volunteers from the community attending a single clinic was a limitation, but as a case study in planning services, this gave us an indication of who might attend for these types of treatment. The study was testing an approach applicable to primary care, so the analysis was conducted on an intention to treat basis rather than on compliance to treatment. In addition there was a high level of control of potential confounding variables. The design where all groups received the same intensity of intervention with dietary advice referring to foods in the Australian Guide to Healthy Eating (AGHE)[29] may have masked our ability to show true effects. In similar highly controlled circumstances it has been argued that for every kg increase in weight loss by controls, treatment effects may be reduced by about

0.3kg[46].

While weight loss was observed, the lack of between group differences in reported energy intakes may reflect inaccuracies in dietary reporting and limitations in databases for estimating food energy. For example, the available energy from walnuts has been measured as 20% less than conventional estimates[47], and this may relate to other whole foods[48]. The between group differences in weight loss are plausible from the literature[8 49]. Like other research in this area[8 50], this study confirms the benefit of thinking beyond energy restriction, where other dietary factors act in synergy to influence outcomes.

The trial was aligned to translation to practice, so we did not employ enhanced retention strategies, but we know that early weight loss and age > 50yrs may predict retention[40]. Whilst we observed considerable participant drop-out which was predominantly due to time constraints and personal reasons, participant drop-out is common in weight loss trials[51]. We also compared a number of missing data analysis techniques via sensitivity analyses[51]. Research indicates that psychological and behavioural factors appear more aligned with attrition than other background participant characteristics[52], something we aim to study further with this dataset. In the evaluation survey of the trial, participants indicated general approval of the approach and the three most listed positive features were individual attention, the health practitioner and the education provided (data not shown). Research indicates that, as part of chronic disease management, avoidance of weight gain may reduce health care costs in the long term[53]. Four visits within the 3mo model of care could fit within the current annual Australian Medicare arrangements[54], albeit with considerations for eligibility, and possible co-payments. These aspects all require confirmatory research. Research is also needed on whether attending for 3mo would be sufficient to achieve this initial target,

acknowledging that a 'flattening' of effects after 6mo is typical and reflects metabolic and behavioural adaptions[16 17].

This study addressed a research gap providing evidence for developing effective healthcare teams in chronic disease management[20 21]. Further analyses will be able to examine motivation and commitment barriers that both participants and health care teams must face. It is acknowledged that addressing long term behaviour change is difficult in primary care[55], and that a lack of motivation and incentives may hinder trials on novel lifestyle interventions[56]. Our trial recruited from the community, but medical supervision and communications with primary care physicians was part of the safety management, and provided insights into translation.

Conclusion

The primary care context provides many opportunities for dealing seriously with weight management as a health issue. Excess body weight is linked to the pathology of major non-communicable chronic disease, and is influenced by both physiological and behavioral factors. More research with greater consolidation of interdisciplinary expertise, and establishing greater integration with medical and nursing practices will assist translation into primary care. Familiarity in standards of operation for the various professions building a full appreciation of knowledge and skills is required. Promoting opportunities to collaborate and providing guidelines[57] are a start to developing long term plans.

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Author Contributions:

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Acquisition, analysis, or interpretation of data: Tapsell, Lonergan, Batterham, Deane, Peoples, Martin, Neale, Thorne

Drafting of the manuscript: Tapsell, Batterham

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Batterham

Obtained funding: Tapsell

Administrative, technical, or material support: Tapsell, Lonergan, Batterham, Deane, Peoples, Martin, Neale, Thorne

Study supervision: Tapsell, Lonergan, Martin.

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Figure legends

Figure 1: Participant flow in the HealthTrack randomised controlled trial

Figure 2: Difference in change in weight, weight change, and % body fat over time

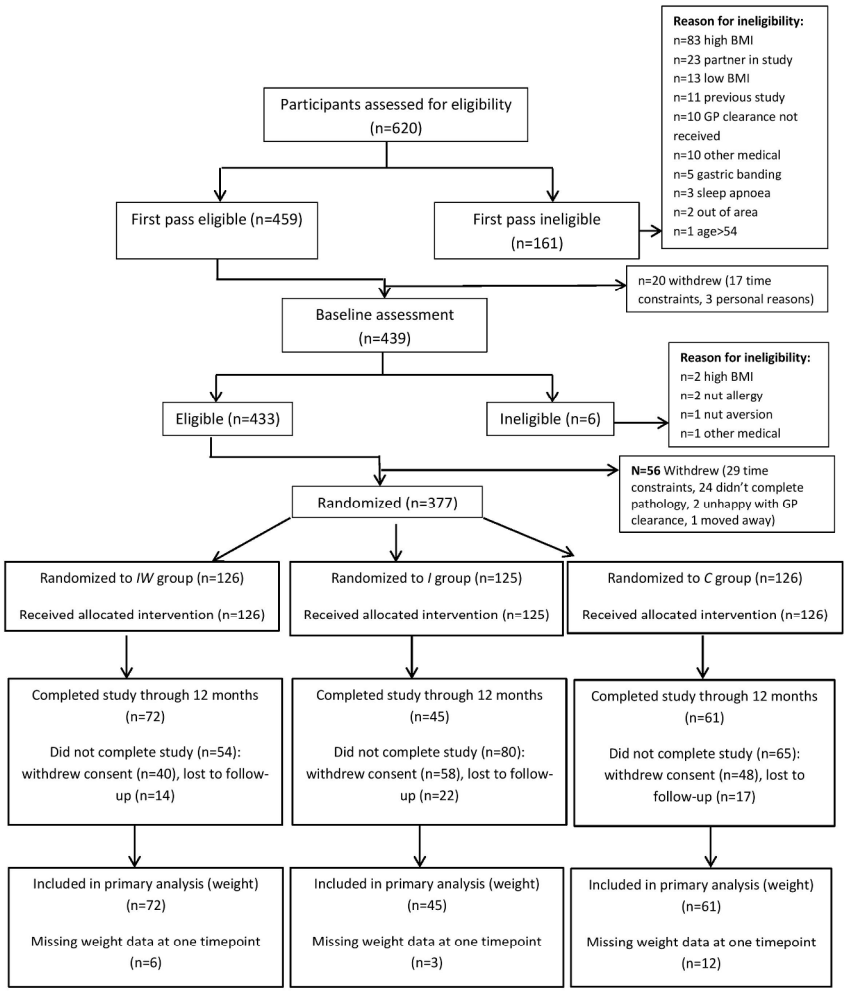

Figure 1: Participant flow in the HealthTrack randomised controlled trial

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215x279mm (300 x 300 DPI)

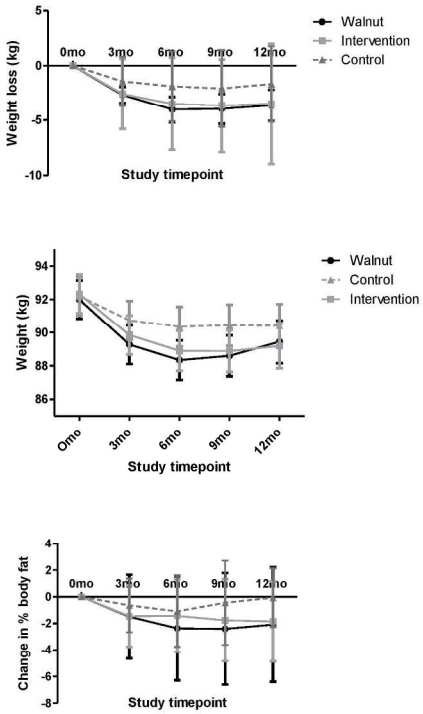

Figure 2: Difference in change in weight, weight change, and % body fat over time

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215x279mm (300 x 300 DPI)

Supplementary Appendix: Effectiveness End Points for the Intention to Treat Population

Variable		Control		Intervention		Intervention + walnuts	Group	Time	Group x time
	n	value	*n*	value	*n*	value	p-value	p-value	p-value
Diastolic blood pressure, median (IQR), mmHg*							0.671	<0.001(2)	0.712
Baseline	126	73 (66 – 79)	124	73 (65 - 80)	125	74 (65 – 79)			
3mo	93	69 (63 – 77)	96	70 (60 – 76)	102	70 (63 – 76)			
12mo	61	70 (63 – 77)	45	69 (61 – 77)	71	71 (63 – 77)			
Steps per day, median (IQR)*									
Baseline	101	6856 (5398 – 9659)	96	7139 (5040 – 9095)	98	7419 (6058 – 9248)	0.380	0.046(3)	0.571
3mo	41	8383 (6879 – 11009)	51	8265 (5715 – 10380)	59	7747 (6133 – 11024)			
12mo	39	7790 (6052 – 10011)	29	6954 (5468 – 10126)	48	8531 (5800 – 10996)			
Protein, median (IQR), % energy*							0.735	<0.001(2)	0.454
Baseline	126	19.8 (17.0 – 22.6)	125	20.2 (17.8 – 22.9)	126	19.8 (17.3 – 22.9)			
3mo	93	21.2 (18.7 – 24.2)	97	22.1 (19.5 – 25.9)	103	21.7 (19.4 – 23.6)			
12mo	60	20.4 (17.9 – 23.4)	44	22.4 (20.0 – 25.3)	71	20.5 (18.5 – 22.6)			
Total fat, median (IQR), % energy*							0.937	<0.001(2)	0.397 (2)
Baseline	126	33.7 (29.9 – 38.2)	125	32.8 (28.6 – 36.3)	126	33.1 (29.6 – 36.9)			
3mo	93	31.8 (28.0 – 37.4)	97	27.3 (23.6 – 32.6)	103	33.4 (29.5 – 36.5)			
12mo	60	32.8 (28.3 - 36.7)	44	32.4 (29.1 – 35.5)	71	33.0 (27.8 – 37.3)			
Carbohydrate, median (IQR), % energy*							0.633	0.002	0.556
Baseline	126	42.0 (36.5 – 46.8)	125	41.6 (37.9 – 46.0)	126	42.1 (38.1 – 46.6)			
3mo	93	42.3 (34.3 – 47.7)	97	43.4 (38.7 – 48.8)	103	40.8 (36.6 – 43.8)			
12mo	60	41.9 (36.6 – 45.8)	44	40.5 (36.6 – 43.1)	71	40.4 (35.9 – 45.1)			
Alcohol, median (IQR), %							0.500	0.012 (2)	0.624

energy*									
Baseline	126	1.30 (0.00 – 3.43)	125	1.19 (0.01 – 4.42)	126	1.14 (0.01 – 4.18)			
3mo	93	1.06 (0.03 – 3.22)	97	0.79 (0.01 – 4.31)	103	1.33 (0.02 – 4.07)			
12mo	60	1.25 (0.05 – 3.53)	44	0.70 (0.02 – 4.54)	71	1.86 (0.24 – 5.68)			
Urinary sodium excretion, median (IQR), mmol/day									
Baseline	122	151 (101 – 193)	117	135 (101 – 172)	125	137 (101 – 192)	0.236	<0.001(2)	0.686
3mo	68	114 (81 – 157)	65	125 (89 – 183)	84	110 (83 – 140)			
12mo	44	138 (98 – 162)	35	130 (104 – 162)	61	129 (97 – 183)			
DASS-21 total, median (IQR)†									
Baseline	126	13 (6 – 19)	125	11 (7 – 19)	126	11 (7 – 18)	0.469	0.002 (2)	0.677
3mo	92	9 (6 – 16)	94	8 (5 – 16)	101	7 (4 – 14)			
12mo	51	9 (4 – 18)	37	9 (5 – 15)	64	9 (5 – 13)			
AAQW, median (IQR)									
Baseline	103	84 (22)	106	85 (20)	104	85 (24)	0.8110	<0.001(2)	0.881
3mo	92	76 (21)	94	77 (21)	102	73 (20)			
12mo	51	76 (22)	37	69 (20)	65	73 (21)			

Mixed model. (2) quadratic term (3) cubic term *ln transformed prior to analysis †sqrt transformed prior to analysis

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	3
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
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	N/A
Participants	4a	Eligibility criteria for participants	6 -7
	4b	Settings and locations where the data were collected	7,10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7,8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7,9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	Protocol paper
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
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	7,8
	11b	If relevant, description of the similarity of interventions	7,8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8,9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8,9
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	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	10
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2 and sup materials
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 2 and sup materials
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)	Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Table 3
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	24,25
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	24 , 25, 26
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21 - 26
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	29

*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.

BMJ Open

Effect of interdisciplinary care on weight loss: a randomised controlled trial.

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Title: Effect of interdisciplinary care on weight loss: a randomised controlled trial.

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Effect of interdisciplinary care on weight loss: a randomised controlled trial.

Objective: To determine the effectiveness of a novel interdisciplinary treatment compared with usual care on weight loss in overweight and obese adult volunteers.

Design: Single-blinded controlled trial. Participants randomly assigned to usual care (C, general guideline-based diet and exercise advice), intervention (I, interdisciplinary protocol) or intervention+ a healthy food supplement (30g walnuts/d) (IW).

Setting: Community based study, Illawarra region, south of Sydney, Australia.

Participants: Generally well volunteer adult residents, 25-54y, BMI 25-40kgm^{-2} were eligible. At baseline 439 were assessed, 377 were randomised, 298 completed the 3mo intensive phase and 178 completed the 12mo follow up.

Interventions: Treatment was provided at clinic visits intensively (0,1,2,3mo) then quarterly to 12mo. Support phone calls were quarterly. All participants underwent blinded assessments for diet, exercise, and psychological status.

Primary and secondary measures: The primary outcome was difference in weight loss between baseline and 12mo (clinically relevant target 5% loss). Secondary outcomes were changes in blood pressure, fasting blood glucose and lipids, and changes in diet, exercise and psychological parameters.

Results: At 12mo, differences in weight loss were identified (P<0.001). The I group lost more than controls at 3mo (-1.11[-2.23,-0.00], P<0.05) and the IW more than controls at 3mo (-1.25 [-2.35,-0.15], P<0.05) and 6mo (-2.20[-3.90,-0.49], P<0.01). The proportion achieving 5% weight loss was significantly different at 3,6 and 9mo (P=0.04, 0.03, 0.03), due to fewer controls on target at 3,6 and 9mo and more IW participants at 6mo. Reductions in secondary outcomes (systolic bold pressure, blood glucose/lipid parameters, and lifestyle measures) followed the pattern of weight loss.

Conclusions: An interdisciplinary intervention produced greater and more clinically significant and sustained weight loss compared to usual care. The intensive phase was sufficient to reach clinically relevant targets, but long term management plans may be required.

Trial registration: Australian New Zealand Clinical Trials Registry ANZCTRN 12614000581662, www.anzctr.org.au

Strengths and limitations of this study

- The study was closely aligned to practice and protocols tested could be readily translated into primary care services
- Although this was a single centre study, substantial controls were applied to provided quality evidence of effects
- The study demonstrated the breadth of behavioural influences integral to achieving weight loss and clinical outcomes
- Rigorous statistical analyses were applied to the evaluation of primary outcomes, including a sensitivity analysis to confirm effects.
- As practice oriented research, retention strategies were not applied, with higher than anticipated loss to follow up following the intensive phase.

INTRODUCTION

The prevention and management of chronic non-communicable disease (CNCD) is a challenge for health services[1].Given the links to disease pathology, identifying overweight as a problem is an important first step[2]. Primary Care is an ideal setting for the clinical management of obesity, yet relevant studies are scarce[3], and measuring or recording weight in this setting appears sub optimal[4]. In addition, weight management may require a more shared sense of decision making[5], and a broader approach, including the expertise of relevant allied health professionals[6]. For example, dietitians may provide expertise on nutritional factors other than dietary energy that influence weight loss and chronic disease risk factors[7], such as dietary patterns[8], significant foods[9], and nutrients such as fibre[10], fatty acids[11], and sodium[12].

Health behaviours that can significantly lower disease risk are central to the management of chronic disease[13]. There is convincing evidence that focusing on diet, physical activity and behaviour will have the best effects on overweight[14]. Obese individuals who lose just 5% of their body weight (the target for American College of Cardiology/American Heart Association clinical guidelines[2]) have significant improvements in risk factors for type 2 diabetes and cardiovascular disease, including improved insulin sensitivity and reduced fat in the liver[15]. However, there are underlying metabolic problems and weight regain invariably follows[16 17]. This suggests obesity itself is a chronic condition requiring acute effective treatments repeated at intervals[16] with the provision of consistent positive reinforcement to address associated complex psychological factors[18]. There is little research on holistic treatments that integrate diet, exercise and psychological support[19] and research is needed to test novel protocols in this area[20 21]. In a feasibility trial comparing usual care with an interdisciplinary model, we found high eligibility (83%) and completion (87%) rates and a

preliminary effect of -3.98kg greater weight loss over 3mo (95%CI 6.17-1.79, P=0.002)[22]. The next research question was whether weight loss could be achieved in a larger cohort and over a longer time period. The objective of the current trial was to determine the effectiveness of a novel interdisciplinary treatment compared with usual care on weight loss in overweight and obese adult volunteers. We hypothesised that a model of care with physician oversight that integrates the expertise of dietitians, with exercise physiologists and psychologists will be more effective than general advice provided by a practice nurse (usual care). Further, the provision of a supplement of a significant healthy food may enhance this effect and influence the overall diet.

METHODS

Study oversight and ethics

The study was approved by the University of Wollongong/Illawarra Shoalhaven Local Health District Human Research Ethics Committee (Health and Medical) (HE 13/189) and conducted in compliance with the Principles of the Declaration of Helsinki. The trial is registered with the Australian and New Zealand Clinical Trial Registry (ANZCTRN12614000581662). Study oversight was provided by the senior clinical investigative team.

Study participants

Recruitment was conducted through communications and advertising in the local media. Respondents who were permanent residents of the Illawarra region, aged 25-54 years, community dwelling, and with a BMI 25-40kg/m^2 were included. Exclusion criteria were being unable to communicate in English; having severe medical conditions impairing the ability to participate in the study or thought to limit survival to one year, having reported

illegal drug use or regular alcohol intake associated with alcoholism (>50g/day); or other major impediments to participation.

Trial design

This was a community specific (single center), randomized, assessor blinded trial, comparing outcomes between intervention and control groups at 0, 3, 6, 9, 12 mo. Full details of the study protocol and baseline results are reported elsewhere[23]. Briefly, all participants attended the clinic for counselling on 7 occasions (0, 1, 2, 3, 6, 9, 12mo) and received quarterly support phone calls. Assessment and treatment protocols were devised by the research team including Physicians, Dietitians, Exercise Physiologists and Psychologists. Measurements were undertaken separately at these time points. Body weight (kg) was measured at each visit in an upright position (minimal clothing, no shoes) using scales with a bio-electrical impedance component for estimating body fat (%) (Tanita TBF-662, Wedderburn Pty Ltd, Ingleburn, NSW, Australia). Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured at 0, 3 and 12mo using the Omron BP-203RPEIII VP-1000 device (Omron Health Care, Kyoto, Japan). Measurements are collected at the end of 5 min resting period in supine position. Fasting blood lipids (cholesterol, LDL, HDL, Trig), fasting blood glucose, and serum HBA1c were assessed through a registered Pathology service (Southern IML Pathology) quarterly. For 24 hour urinary sodium assessments a 24 hour urine sample was provided at 0, 3 and 12mo. Dietary intake was assessed using a diet history interview[24] and physical activity using the International Physical Activity Questionnaire (IPAQ)[25] and via a pedometer (Yamax Digiwalker SW200, Pedometers Australia). worn for a four day period every quarter. A range of psychological assessments were applied, including the Physical and Mental Health SF-12 (12 questions)[26], Depression Anxiety Stress Scale (short form 21 questions)[27], and Acceptance and Action Questionnaire for Weight-related problems (11 questions) (AAQW)[28] at 0, 3 and 12mo.

Participants were randomly assigned to usual care (C, general advice), intervention (I, interdisciplinary advice) and intervention+ food supplement (IW, I+ 30g walnuts/day). Usual care involved a nurse providing general advice based on the Australian Guide to Health Eating, (AGHE)[29] and National Physical Activity Guidelines[30]. Phone contact at quarterly intervals was also made with the by the study administrator delivering semi scripted patient centred support of short duration. In the intervention counselling session an Accredited Practising Dietitian negotiated changes in specific food choices based on a diet history assessment and materials that referred to the food groups outlined in the AGHE (vegetables, fruits, grains, protein rich foods, dairy foods, oils). This consultation included advice to increase physical activity and reduce sedentary behaviour by identifying opportunities in leisure, occupation and household activities, with additional categorical guidance prepared by the Exercise Physiologist following exercise assessment. The psychologist developed a workbook for participants and trained health coaches to deliver related scripted calls of short (15 minute) duration at quarterly intervals. The psychological coaching component was based on principles from Acceptance and Commitment Therapy[31] and involved clarification of underlying values to increase motivation related to weight loss, increasing mindfulness and awareness to facilitate better health choices, and self-compassion to promote continued valued-action even in the presence of setbacks.

Randomisation was performed remotely in randomly allocated blocks of 3, 6 or 9 by an investigator unrelated to the clinic. A computer generated randomisation sequence was used (STATA V12, StataCorp LP, College Station Tx). The randomisation was stratified according to sex and BMI (low BMI:≤30 and high BMI:>30). The randomisation list was provided to the study team who added eligible participants sequentially for each of the strata. Participants were blinded to their randomised allocation and only advised they would be seen by a health practitioner.

Effectiveness outcomes

All endpoints compared baseline data with 12mo results. The primary outcome was body weight (kg). Secondary outcomes were fasting blood lipids, glucose and HbA1c, systolic blood pressure, dietary intake, measures of physical activity and psychological wellbeing.

Statistical analysis

Outcomes were analysed using mixed models. The primary outcome variable weight was analysed using a published model building procedure[32]. Initially a simple model with main effects and a group by time interaction was considered. Initial data exploration suggested quadratic and cubic terms may be needed and these were added in turn and tested with likelihood ratio tests to determine improvement in model fit. Random effects for both intercept and slope were included in the weight model. A similar procedure was followed for all other variables. Significant higher order interaction terms were followed up by ANCOVA to determine differences between groups at each time point with baseline value as a covariate. Gender was included as a covariate in the body composition models. As the dropout rate at the end of the follow up period (12mo) was substantial, several sensitivity analyses were performed. Firstly multiple imputation of 100 datasets was used to verify the significance of the difference between the groups at all time points. The imputation model included group, age and gender as well as weight at each time point. A complete case analysis, last observation carried forward and baseline observation carried forward were also performed. Model building was performed using LMER in the LME4 package of R (RStudio V0.99.489, RStudio Inc). Multiple Imputation was performed in SAS (V9.4 SAS Institute Inc, Cary NC) using PROC MI, PROC MIXED and MIANALYSE, for the ANCOVA. F tests for the 100 multiple imputation using PROC MIXED were combined using the package MICEADDS in R.

RESULTS

Participants

Recruitment began in May 2014 and the last participant completed in May 2016. Surveys were sent to 718 respondents, 439 of whom underwent baseline assessments. N=377 were randomised into the C (n=126), I (n=125) and IW groups (n=126). The intensive phase was completed by 298 participants (withdrawal rate 18%) and the 12mo follow up by n=178 participants (withdrawal rate 39%) (Figure 1). Screening and baseline data are reported elsewhere[23]. The sample comprised mostly obese (BMI 32 (29-35) kg/m^2), non-smoking (98%) well educated (85% post school qualifications) females (74%) of median age 45 (37-51) years. They also suffered from anxiety (26.8%) and depression (33.7%) and were treated for hypertension (25%). Metabolic syndrome was identified in 34% of participants[33].

Participants attended the Clinical Trials Unit of the Illawarra Health and Medical Research Institute. After randomisation 67 participants withdrew, with most (75%) citing an inability to commit time and/or personal reasons. The next major withdrawal (n=49) occurred after the 3mo intensive phase for similar reasons. Attendance gradually reduced for all groups but IW participants attended more, and were more likely to complete the phone coaching calls than the I group (at quarters 2,3,4; P<0.05). Less than a quarter of participants were on medications for glucose, lipids, and blood pressure. There were no differences between groups for medication use (P>0.05) (Table 1).

Table 1: Number (%) of participants reporting medication during the HealthTrack study

Medication type	Control	Intervention	Intervention + walnuts	p-value*
Antihypertensive (n [%])				
Baseline	14 (11)	20 (16)	17 (14)	0.521
3 months	10 (10)	16 (16)	17 (17)	0.410
6 months	7 (10)	10 (15)	12 (14)	0.654
9 months	6 (10)	8 (15)	13 (17)	0.491
12 months	6 (10)	9 (20)	13 (18)	0.267
Hypoglycaemic/insulin (n [%])				
Baseline	6 (5)	4 (3)	5 (4)	0.945
3 months	6 (6)	3 (3)	5 (5)	0.584
6 months	2 (3)	2 (3)	4 (5)	0.819
9 months	1 (2)	3 (6)	3 (4)	0.563
12 months	1 (2)	3 (7)	3 (4)	0.429
Hypolipidaemic (n [%])				
Baseline	15 (12)	10 (8)	7 (6)	0.201
3 months	14 (15)	8 (8)	7 (7)	0.147
6 months	10 (14)	6 (9)	5 (6)	0.190
9 months	9 (15)	6 (11)	5 (7)	0.287
12 months	10 (16)	5 (11)	3 (4)	0.064

*Chi square test

Primary outcomes

Weight loss

After 12mo weight reduced in all groups with a significant difference between groups (P=0.0002) (Tables 2 and 3). The primary analysis model including group, gender and time, found a quadratic time by group interaction. The effect was seen with the IW group showing initial weight loss and then a gain from 6mo, while the other groups maintained their weight loss over time (Figure 2). Post hoc analysis on complete cases indicated significantly greater weight loss in I and IW compared to C at 3mo (-1.2 kg, P=0.045 I; -1.3kg, P=0.025 IW) and at 6mo for IW (-2.1kg; P=0.010). The ANCOVA compared the groups using a mixed model on the actual data and the combined estimates for 100 imputations (Table 2 and Supplementary Materials). A sensitivity analysis confirmed the effects (Table 3). An ANCOVA on complete cases for the 12 month weight change adjusted for baseline weight, gender and age showed an effect approaching significance P=0.056 reflecting a difference between the C - IW group of -2.2kg (95%CI -4.6,0.1kg P=0.068) compared with differences between the C-I groups -1.9kg (95%CI -4.5,0.7kg P=0.228) and the I and IW groups -0.3kg(95%CI -2.8,2.2kg P=1.00).

Table 2: Effectiveness End Points for the Intention to Treat Population‡

Variable		Control		Intervention		Intervention + walnuts	Group	Time	Group x time
	n	value	*n*	value	*n*	value	p-value	p-value	p-value
Body weight, mean (SD), kg							0.644	0.004(3)	<0.001
Baseline	126	91.8 (14.7)	125	91.9 (15.2)	126	91.4 (15.6)			
3mo	96	90.0 (14.1)	99	90.3 (15.3)	103	88.3 (14.7)			
12mo	61	87.8 (14.9)	45	86.5 (17.8)	72	87.9 (14.2)			
Body fat, median (IQR), %							0.599	0.070(3)	0.022
Baseline	125	41.3 (36.2 – 45.1)	125	41.4 (35.4 – 46.1)	125	41.4 (36.2 – 46.1)			
3mo	95	41.0 (35.0 – 44.6)	99	39.2 (33.8 – 45.1)	103	39.8 (34.7 – 43.0)			
12mo	61	40.7 (32.0 – 43.3)	45	37.0 (31.8 – 41.9)	72	38.2 (33.9 – 43.5)			
Systolic blood pressure, median (IQR), mmHg*							0.441	<0.001(2)	0.551
Baseline	126	123 (113 – 132)	124	124 (114 – 134)	125	123 (114 – 134)			
3mo	93	118 (109 – 129)	96	119 (109 – 131)	102	119 (110 – 127)			
12mo	61	116 (109 – 127)	45	118 (106 – 128)	71	123 (111 – 131)			
Glucose, median (IQR), mmol/L							0.340	<0.001(2)	0.399
Baseline	126	5.2 (4.9 – 5.6)	124	5.2 (4.9 – 5.7)	126	5.2 (4.9 – 5.8)			
3mo	69	5.2 (5.0 – 5.5)	69	5.2 (4.9 – 5.7)	84	5.2 (4.9 – 5.6)			
12mo	52	5.5 (4.9 – 5.7)	37	5.3 (5.0 – 5.7)	64	5.3 (5.0 – 5.7)			
HbA1c, median (IQR), (%)							0.301	0.003(3)	0.407
Baseline	126	5.2 (5.0 – 5.5)	125	5.2 (4.9 – 5.4)	126	5.1 (4.9 – 5.4)			
3mo	69	5.3 (5.1 – 5.4)	69	5.2 (5.0 – 5.4)	84	5.2 (5.0 – 5.5)			
12mo	52	5.2 (5.0 – 5.4)	37	5.1 (4.9 – 5.4)	63	5.1 (4.9 – 5.4)			
Total cholesterol, median (IQR), (mmol/L)							0.193	<0.001(3)	0.135
Baseline	126	5.3 (4.7 – 6.0)	124	5.0 (4.4 – 5.8)	126	5.1 (4.6 – 5.7)			
3mo	70	5.2 (4.4 – 5.6)	69	5.0 (4.4 – 5.5)	83	4.8 (4.3 – 5.6)			

12mo	52	5.0 (4.2 – 5.6)	37	5.4 (4.5 – 6.0)	64	5.4 (4.6 – 5.8)			
Triglycerides, median (IQR), (mmol/L)							0.005	0.142	0.368
Baseline	125	1.3 (0.9 – 1.6)	124	1.1 (0.8 – 1.6)	126	1.1 (0.8 – 1.5)			
3mo	70	1.3 (0.9 – 1.6)	69	1.2 (0.9 – 1.8)	83	1.0 (0.8 – 1.4)			
12mo	52	1.3 (0.9 – 1.6)	37	1.2 (0.8 – 1.7)	64	1.1 (0.9 – 1.6)			
HDL, median (IQR), (mmol/L)							0.236	<0.001(3)	0.098
Baseline	126	1.3 (1.1 – 1.7)	124	1.4 (1.2 – 1.6)	126	1.4 (1.2 – 1.7)			
3mo	70	1.3 (1.0 – 1.6)	69	1.3 (1.1 – 1.6)	83	1.4 (1.2 – 1.8)			
12mo	52	1.3 (1.1 – 1.6)	37	1.5 (1.2 – 1.8)	64	1.5 (1.2 – 1.8)			
Cholesterol:HDL ratio, median (IQR)							0.036	<0.001	0.739
Baseline	125	3.9 (3.0 – 4.7)	124	3.5 (3.1 – 4.4)	126	3.6 (2.9 – 4.3)			
3mo	70	4.0 (3.3 – 4.8)	68	3.8 (3.1 – 4.5)	83	3.4 (2.7 – 4.1)			
12mo	52	3.8 (3.0 – 4.2)	37	3.3 (2.9 – 4.4)	64	3.5 (2.9 – 4.4)			
LDL, median (IQR), (mmol/L)							0.516	<0.001(3)	0.295
Baseline	123	3.2 (2.7 – 3.7)	123	3.0 (2.4 – 3.6)	126	3.1 (2.6 – 3.7)			
3mo	69	3.2 (2.4 – 3.8)	69	3.1 (2.5 – 3.4)	83	2.8 (2.3 – 3.5)			
12mo	52	3.1 (2.3 – 3.6)	37	3.1 (2.4 – 4.0)	64	3.2 (2.5 – 4.0)			
MET-mins/week (IPAQ), median (IQR)*									
Baseline	124	876 (396 – 1523)	123	918 (396 – 1551)	124	1040 (563 – 2329)	0.053	<0.001	0.341
3mo	92	1461 (793 – 2486)	94	1540 (842 – 2635)	102	2020 (1236 – 3125)			
12mo	61	1782 (807 – 3451)	46	2009 (924 – 3015)	77	1678 (827 – 3732)			
Energy, median (IQR), kJ/day*							0.095	<0.001(2)	0.444
Baseline	126	9400.2 (7840.5 – 11574.3)	125	8647.5 (7158.2 – 10993.8)	126	8932.9 (7458.3 – 10785.5)			
3mo	93	7443.8 (6479.0 – 9087.9)	97	6891.1 (6045.1 – 8700.3)	103	7264.4 (6239.3 – 8444.5)			

12mo	60	7864.7 (7014.0 – 9345.7)	44	7184.9 (5754.3 – 9078.2)	71	7805.5 (6622.9 – 9718.9)			
Fibre, median (IQR), g/day							0.989	0.059	0.005
Baseline	126	26.1 (21.7 – 33.3)	125	25.2 (21.5 – 31.1)	126	25.0 (19.8 – 32.2)			
3mo	93	24.6 (19.1 – 30.6)	97	27.0 (22.0 – 33.1)	103	26.7 (22.2 – 32.5)			
12mo	60	22.9 (19.7 – 32.5)	44	26.8 (22.2 – 30.1)	71	26.5 (20.6 – 32.1)			
P:S ratio, median (IQR)*							<0.001	<0.001(2)	<0.001 (2)
Baseline	126	0.4 (0.3 – 0.5)	125	0.4 (0.3 – 0.5)	126	0.4 (0.3 – 0.5)			
3mo	93	0.5 (0.4 – 0.7)	97	0.5 (0.4 – 0.7)	103	1.3 (0.9 – 1.8)			
12mo	60	0.5 (0.3 – 0.6)	44	0.5 (0.4 – 0.7)	71	0.8 (0.6 – 1.1)			
Quality of life (SF12), physical summary, median (IQR)									
Baseline	126	49.3 (43.1 – 54.4)	124	49.6 (45.0 – 54.1)	125	51.1 (44.8 – 55.2)	0.027	<0.001	0.660
3mo	91	51.3 (45.1 – 55.9)	96	51.0 (42.9 – 54.6)	102	53.5 (46.6 – 56.4)			
12mo	60	54.3 (48.6 – 57.4)	44	52.6 (44.2 – 57.5)	69	54.0 (51.7 – 57.4)			
Quality of life (SF12), mental summary, median (IQR)									
Baseline	126	48.7 (41.3 – 53.5)	124	48.4 (37.7 – 55.0)	125	47.5 (39.4 – 53.9)	0.772	0.002 (2)	0.788
3mo	91	51.0 (45.6 – 56.7)	96	49.9 (43.1 – 56.4)	102	51.7 (44.9 – 57.2)			
12mo	60	51.9 (41.4 – 57.1)	44	54.7 (44.5 – 56.5)	69	51.1 (42.3 – 55.2)			

Mixed model. (2) quadratic term (3) cubic term *ln transformed prior to analysis †sqrt transformed prior to analysis ‡ results for the following variables are presented in Supplementary Materials: diastolic blood pressure, steps, percent energy from protein, total fat, carbohydrate, and alcohol, urinary sodium excretion, DASS-21, AAQW

Table 3: Sensitivity analysis, comparison of differences in weight between groups at each time point

Method		3			6			9			12		P (Interaction)
	Control-Walnut	Control-intervention	Intervention-Walnut	Control-Walnut	Control-intervention	Intervention-Walnut	Control-Walnut	Control-intervention	Intervention-Walnut	Control-Walnut	Control-intervention	Intervention-Walnut	
Mixed	**-1.25* (-2.35,-0.15)**	**-1.11* (-2.23,-0.00)**	**-0.13 (-1.23,0.96)**	**-2.20 ** (-3.90,-0.49)**	**-1.53 (-3.36,0.30)**	**-0.67 (-2.42,1.08)**	**-1.98 (-3.95,0.00)**	**-1.67 (-3.80,0.46)**	**-0.31 (-2.32,1.71)**	**-1.91 (-4.06,0.25)**	**-1.72 (-4.15,0.71)**	**-0.19 (-2.54,2.17)**	**<0.001**
MI	-1.27** (-2.17,-0.37)	1.04* (-1.91,-0.16)	-0.23 (-1.12,0.65)	-1.82** (-3.14,-0.50)	-1.26 (-2.57,0.04)	-0.56 (-1.88,0.76)	-1.69* (-3.22,-0.16)	-1.46* (-2.92,-0.00)	-0.24 (-1.72,1.24)	-1.15 (-2.77,0.47)	-1.06 (-2.57,0.47)	-0.11 (-1.65,1.43)	0.002
Complete	-1.70** (-3.06,-0.33)	-1.14 (-2.66,0.38)	-0.56 (-1.99,0.88)	-2.30* (-4.28,-0.32)	-1.30 (-3.51,0.91)	-1.00 (-3.08,1.07)	-2.22* (-4.44,0.00)	-1.89 (-4.36,0.58)	-0.33 (-2.65,1.99)	-1.61 (-3.90,0.68)	-1.40 (-3.95,1.16)	-0.21 (-2.19,0.68)	<0.001
LOCF	-1.11* (-2.02,-0.19)	-0.95* (-1.87,-0.04)	-0.15 (-1.07,0.76)	-1.57** (-2.77,-0.36)	-1.05 (-2.26,0.16)	-0.52 (-1.73,0.69)	-1.44 (-2.74,-0.15)	-1.27 (-2.56,0.26)	-0.18 (-1.47,1.12)	-1.04 (-2.33,0.24)	-1.09 (-2.37,0.20)	0.04 (-1.24,1.33)	<0.001
BCF	-1.11* (-2.02,-0.19)	-0.95* (-1.87,-0.04)	-0.15 (-1.07,0.76)	-1.73** (-2.87,-0.59)	-0.78 (-1.92,0.36)	-0.96 (-2.09,0.19)	-1.40** (-2.53,-0.28)	-0.64 (-1.78,0.49)	-0.76 (-1.89,0.37)	-1.30* (-2.45,-0.15)	-0.46 (-1.61,0.70)	-0.84 (-2.00,0.31)	<0.001

**<0.01, *<0.05

MI= multiple imputation, using groups, age, gender and weight at each time point

Complete = complete analysis

LOCF = Last observation carried forward

BCF = baseline observation carried forward

Achievement of 5% weight loss target

Chi square analyses indicated significant differences in the proportion of participants achieving the clinically significant effect of 5% weight loss. At 3, 6, and 9mo the proportion achieving 5% weight loss in the C group was lower than expected (P=0.04, 0.03, 0.03, respectively), although there was no difference at 12mo (p=0.091) with 33% IW, 38% I and 20% C meeting the 5% target. At 6mo the number in the IW group was higher than expected (P=0.03), consistent with the primary analysis. Likewise there was a group difference in change in percent body fat (interaction effect P=0.022) (Table 2).

Secondary outcomes

Clinical effects

Systolic blood pressure (SBP) decreased between baseline and 3mo but then remained unchanged (Table 2). Changes in SBP also reflected patterns of sodium excretion (a marker of dietary intake) decreasing from baseline to 3mo (P<0.001) and increasing to 12mo (P=0.002). Likewise, fasting blood glucose was lower than baseline at 3mo (P=0.040) and 6mo (P<0.001), and then remained lower than 12mo (P=0.003). HbA1c at 12mo was lower than the baseline value (P=0.031).

In keeping with this pattern of effects, total cholesterol and LDL concentrations were lowest for the sample at 3mo (P<0.001; P≤0.031 respectively) and at 6mo they remained lower than baseline (P=0.020; P=0.034 respectively). The Cholesterol: HDL ratio decreased particularly after 6mo, while HDL-C values first dropped at 3mo then returned to greater than baseline at 12mo (P≤0.021). The group effect for total cholesterol showed a lower overall mean for the IW group compared with controls (P=0.001) and I (P=0.037) (Table 2).

Behavioural effects

As with the pattern of weight change, reported energy and total fat intakes (as a percent of energy) were lower than baseline at 3mo (P<0.001) and still at 12mo (P<0.001), but they increased between 3mo and 12mo (P=0.020) (Table 2). Changes in percent energy from protein were the opposite for dietary fat. The value was higher than baseline at 3 and 12mo (P<0.001), but lower at 12mo than 3mo (P=0.04). Percent energy from carbohydrate reduced from baseline to 12mo (P=0.002), and from alcohol (P=0.012) decreased from baseline to 12mo (P=0.041). The only reported difference between groups was for the Polyunsaturated:Saturated (P:S) fatty acid ratio, where the the IW group showed a higher value over time compared to the other groups (interaction effect P<0.001).

The time effects for increased physical activity were stronger in self-reported MET-Mins/week (IPAQ) (P<0.001; significantly higher than baseline at all time points, Table 2) than measurements of steps/day (P=0.046) (Supplementary Materials). The changes in diet and physical activity were accompanied by increases in scores for positive psychological parameters (Quality of Life, QoL, Table 2) and decreases for negative parameters (Depression Anxiety Stress, DASS-21; Acceptance and Action for Weight Related problems, AAQW, Supplementary Materials). The IW group scored highest for Quality of Life (QoL SF12) physical summary scores throughout the study period (group effect P=0.027). The QoL (SF12) mental summary score increased after 3mo, with differences from baseline to 12mo (time effect P=0.002). The DASS-21 and AAQW scores were lower at 12mo (P<0.001) but the significant decreases occurred at 3mo (P<0.001) (Supplementary Materials).

DISCUSSION

Main findings

Despite the same intensity of intervention and a focus on national diet and physical activity guidelines, the interdisciplinary protocol produced greater and more clinically significant effects on weight loss than usual care (Figure 2). Although there were repeated attempts to retrieve participants who failed to attend visits, attrition was higher than expected, so multiple approaches including random effects mixed model analyses were applied as this would assure quality reporting required of clinical trials[34]. The ANCOVA compared the groups using a mixed model on the actual data and the combined estimates for 100 imputations (Table 2 and Supplementary Materials). A sensitivity analysis confirmed the effects (Table 3) using multiple imputation (using groups, age, gender and weight at each time point), last observation carried forward (LOCF) and baseline observation carried forward (BOCF) techniques. As interaction terms were significant using all approaches, we were confident of the effects observed.

While it is not possible to separate out the components of the interdisciplinary approach, it appears more individualized advice including a focus on specific foods may have enhanced the effect. This was especially evident with the food supplemented group who continued to produce a greater weight loss at 6 months. The size of the effect and the time taken to achievement are also highly relevant to practice. The effects were similar to those reported in a systematic review of weight loss interventions which found that for combined diet and exercise interventions ranging from 12-18 months, mean weight losses ranged from 0.3 to 5.9kg for women and 4.2-7.3kg for men[35]. Without unusual retention strategies, we found that a 3 month commitment to an intensive treatment was feasible, and in that time the intervention protocol delivered a greater proportion with a 5% weight loss target. In Western societies, it is estimated that the adult population gains 0.45kg weight/year[36], so our effects could be interpreted as even greater. Had we continued with monthly rather than quarterly clinic visits after 3 months we may have improved retention and study power, but that would

meant greater healthcare costs. A simple sample size calculation based on the differences between groups for the completers at 12 months indicates that approximately 124 subjects per group would be required to complete the study for differences between the 3 groups to be statistically significant when adjusted for multiple comparisons.

Secondary outcomes

We confirmed the observation that a 5% weight loss can have an impact on disease risk factors[15]. Significant reductions in systolic blood pressure occurred with weight loss, as expected, but this also occurred with increased physical activity, improved mental health scores and a reduction in urinary sodium, a dietary factor known to be associated with blood pressure[37]. The latter implies that the dietary changes went beyond that of energy restriction. As the national dietary guidelines were a reference point for all groups, differences in sodium intakes were not observed in this intention to treat analysis. Per protocol analyses may be able to detect whether greater changes occurred in the groups with the dietitian (I and IW) confirming effects seen in other primary care studies[38]. Similarly the improvements in blood glucose parameters occurred with weight loss in the presence of increased physical activity and a reduced carbohydrate load for the study cohort. Further research on the types of carbohydrate-rich foods may be informative in detecting more specific differences between groups.

The changes in blood lipids were as expected with changes in weight. The lower overall mean for total cholesterol for the IW group occurred in the presence of a significantly different dietary P:S ratio. We have previously shown that integrating walnuts in an energy controlled diet can change the dietary P:S ratio with concomitant effects on lipids (31). Given that walnuts are a fat-rich food, their inclusion in the dietary modelling for the IW group

would be expected to influence the overall diet profile.

Implications for practice

Practice involves an integration of evidence on many factors, and in this research we examined a number of components. We confirmed that changes in disease risk factors occurred alongside changes in body weight, physical activity, mental health scores and dietary factors known to have an impact on disease risk such as dietary sodium, fibre, and fatty acid profile[10 12 16 39]. In this trial the dietitian provided the face-to-face counseling with participants. Being more specific about actual foods to consume may be more effective and providing a significant healthy food (walnuts) emphasized this point. While the effects of walnuts in the diet can be found in the literature[40 41], there may have been synergistic effects with psychological factors in our trial. The reduced psychological avoidance of weight related issues (AAQW scores) was particularly relevant and further analyses of our data may clarify the effects of health coaching when integrated into diet and physical activity advice. In addition, and based on our previous research[42], the greater initial weight loss achieved by the IW group may have influenced retention, and this may have also resulted in the higher QoL scores, but it is difficult to determine if the provision of the food supplement alone acted as the main incentive[43]. The greater attendance at phone coaching sessions by the IW group, which targeted skills in mindfulness and acceptance, also may have helped deal with the stress associated with achieving health goals[18]. It is difficult to tease out any singular effect as there is so much interdependence between behavioral factors, but this study has helped expose significant elements. The pattern of weight loss reflected reduced energy intake and increased physical activity (Table 2), providing evidence for applying expertise in both diet and exercise[44 45]. As sources of nutrients, the food choices drove nutritional changes underpinned by the involvement of dietitians[46 47].

Strengths and limitations

The sample comprising volunteers from the community attending a single clinic was a limitation, and, although the proportion of individuals not speaking English well in the primary recruitment area was relatively low (approximately 3%)[48], excluding these individuals may have further minimized access to a high risk group. As a case study in planning services, however, the recruitment strategy gave us an indication of who might attend for these types of treatment. The study was testing an approach applicable to primary care, so the analysis was conducted on an intention to treat basis rather than on compliance to treatment. In addition there was a high level of control of potential confounding variables. The design where all groups received the same intensity of intervention with dietary advice referring to foods in the Australian Guide to Healthy Eating (AGHE)[29] may have masked our ability to show true effects. In similar highly controlled circumstances it has been argued that for every kg increase in weight loss by controls, treatment effects may be reduced by about 0.3kg[49].

While weight loss was observed, the lack of between group differences in reported energy intakes may reflect inaccuracies in dietary reporting and limitations in databases for estimating food energy. For example, the available energy from walnuts has been measured as 20% less than conventional estimates[50], and this may relate to other whole foods[51]. The between group differences in weight loss are plausible from the literature[8 52]. Like other research in this area[8 53], this study confirms the benefit of thinking beyond energy restriction, where other dietary factors act in synergy to influence outcomes.

The trial was aligned to translation to practice, so we did not employ enhanced retention strategies, but we know that early weight loss and age > 50yrs may predict retention[42]. Whilst we observed considerable participant drop-out which was predominantly due to time constraints and personal reasons, participant drop-out is common in weight loss trials[54]. We also compared a number of missing data analysis techniques via sensitivity analyses[54]. Research indicates that psychological and behavioural factors appear more aligned with attrition than other background participant characteristics[55], something we aim to study further with this dataset. In the evaluation survey of the trial, participants indicated general approval of the approach and the three most listed positive features were individual attention, the health practitioner and the education provided (data not shown). Research indicates that, as part of chronic disease management, avoidance of weight gain may reduce health care costs in the long term[56]. Four visits within the 3mo model of care could fit within the current annual Australian Medicare arrangements[57], albeit with considerations for eligibility, and possible co-payments. These aspects all require confirmatory research. Research is also needed on whether attending for 3mo would be sufficient to achieve this initial target, acknowledging that a 'flattening' of effects after 6mo is typical and reflects metabolic and behavioural adaptions[16 17].

This study addressed a research gap providing evidence for developing effective healthcare teams in chronic disease management[20 21]. Further analyses will be able to examine motivation and commitment barriers that both participants and health care teams must face. It is acknowledged that addressing long term behaviour change is difficult in primary care[58], and that a lack of motivation and incentives may hinder trials on novel lifestyle interventions[59]. Our trial recruited from the community, but medical supervision and communications with primary care physicians was part of the safety management, and provided insights into translation.

Conclusion

The primary care context provides many opportunities for dealing seriously with weight management as a health issue. Excess body weight is linked to the pathology of major non-communicable chronic disease, and is influenced by both physiological and behavioral factors. More research with greater consolidation of interdisciplinary expertise, and establishing greater integration with medical and nursing practices will assist translation into primary care. Familiarity in standards of operation for the various professions building a full appreciation of knowledge and skills is required. Promoting opportunities to collaborate and providing guidelines[60] are a start to developing long term plans.

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Figure legends

Figure 1: Participant flow in the HealthTrack randomised controlled trial

Figure 2: Difference in change in weight, weight change, and % body fat over time

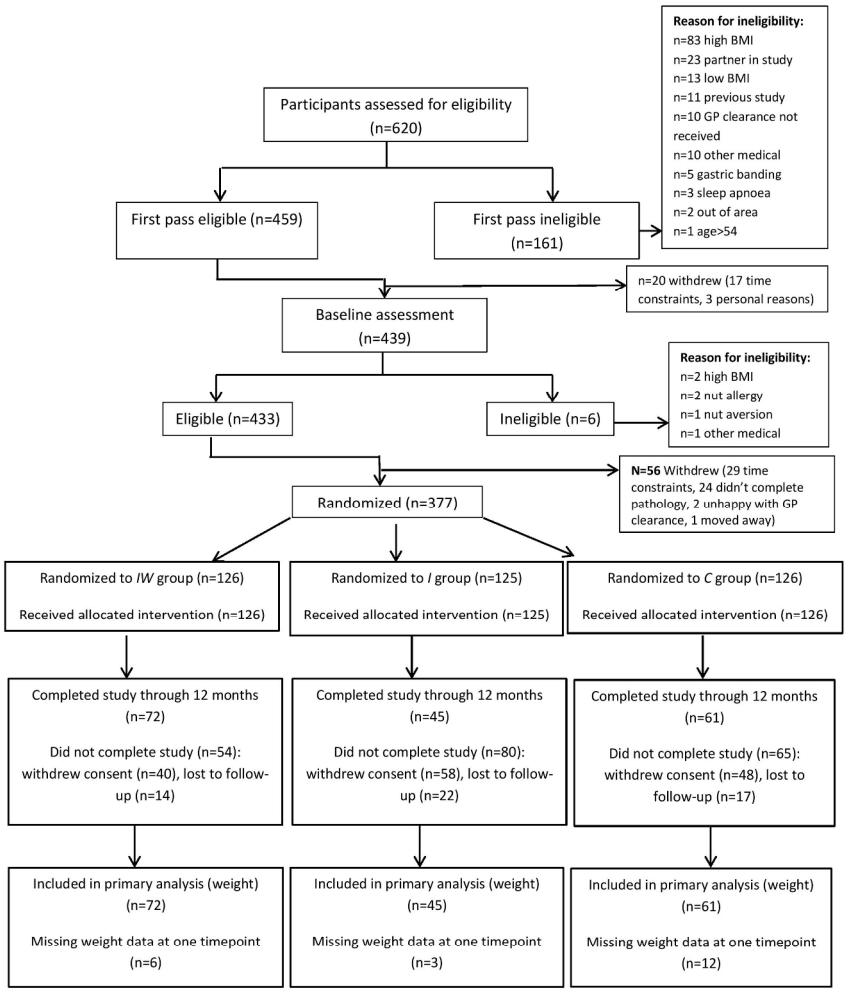

Figure 1: Participant flow in the HealthTrack randomised controlled trial

Figure 1: Participant flow in the HealthTrack randomised controlled trial

215x279mm (300 x 300 DPI)

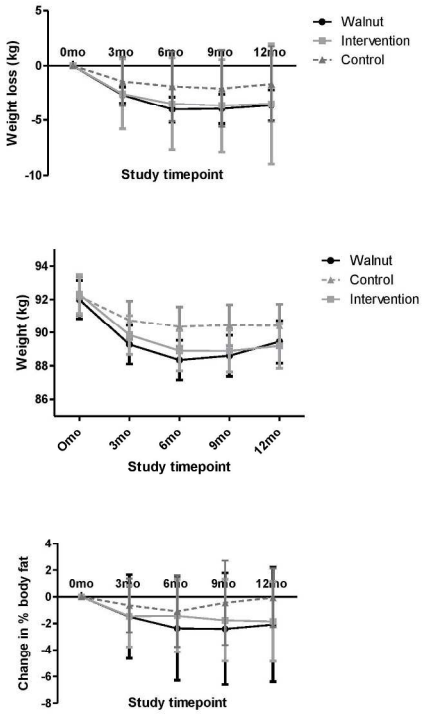

Figure 2: Difference in change in weight, weight change, and % body fat over time

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Supplementary Appendix: Effectiveness End Points for the Intention to Treat Population

Variable		Control		Intervention		Intervention + walnuts	Group	Time	Group x time
	n	value	*n*	value	*n*	value	p-value	p-value	p-value
Diastolic blood pressure, median (IQR), mmHg*							0.671	<0.001(2)	0.712
Baseline	126	73 (66 – 79)	124	73 (65 - 80)	125	74 (65 – 79)			
3mo	93	69 (63 – 77)	96	70 (60 – 76)	102	70 (63 – 76)			
12mo	61	70 (63 – 77)	45	69 (61 – 77)	71	71 (63 – 77)			
Steps per day, median (IQR)*									
Baseline	101	6856 (5398 – 9659)	96	7139 (5040 – 9095)	98	7419 (6058 – 9248)	0.380	0.046(3)	0.571
3mo	41	8383 (6879 – 11009)	51	8265 (5715 – 10380)	59	7747 (6133 – 11024)			
12mo	39	7790 (6052 – 10011)	29	6954 (5468 – 10126)	48	8531 (5800 – 10996)			
Protein, median (IQR), % energy*							0.735	<0.001(2)	0.454
Baseline	126	19.8 (17.0 – 22.6)	125	20.2 (17.8 – 22.9)	126	19.8 (17.3 – 22.9)			
3mo	93	21.2 (18.7 – 24.2)	97	22.1 (19.5 – 25.9)	103	21.7 (19.4 – 23.6)			
12mo	60	20.4 (17.9 – 23.4)	44	22.4 (20.0 – 25.3)	71	20.5 (18.5 – 22.6)			
Total fat, median (IQR), % energy*							0.937	<0.001(2)	0.397 (2)
Baseline	126	33.7 (29.9 – 38.2)	125	32.8 (28.6 – 36.3)	126	33.1 (29.6 – 36.9)			
3mo	93	31.8 (28.0 – 37.4)	97	27.3 (23.6 – 32.6)	103	33.4 (29.5 – 36.5)			
12mo	60	32.8 (28.3 - 36.7)	44	32.4 (29.1 – 35.5)	71	33.0 (27.8 – 37.3)			
Carbohydrate, median (IQR), % energy*							0.633	0.002	0.556
Baseline	126	42.0 (36.5 – 46.8)	125	41.6 (37.9 – 46.0)	126	42.1 (38.1 – 46.6)			
3mo	93	42.3 (34.3 – 47.7)	97	43.4 (38.7 – 48.8)	103	40.8 (36.6 – 43.8)			
12mo	60	41.9 (36.6 – 45.8)	44	40.5 (36.6 – 43.1)	71	40.4 (35.9 – 45.1)			
Alcohol, median (IQR), %							0.500	0.012 (2)	0.624

energy*									
Baseline	126	1.30 (0.00 – 3.43)	125	1.19 (0.01 – 4.42)	126	1.14 (0.01 – 4.18)			
3mo	93	1.06 (0.03 – 3.22)	97	0.79 (0.01 – 4.31)	103	1.33 (0.02 – 4.07)			
12mo	60	1.25 (0.05 – 3.53)	44	0.70 (0.02 – 4.54)	71	1.86 (0.24 – 5.68)			
Urinary sodium excretion, median (IQR), mmol/day									
Baseline	122	151 (101 – 193)	117	135 (101 – 172)	125	137 (101 – 192)	0.236	<0.001(2)	0.686
3mo	68	114 (81 – 157)	65	125 (89 – 183)	84	110 (83 – 140)			
12mo	44	138 (98 – 162)	35	130 (104 – 162)	61	129 (97 – 183)			
DASS-21 total, median (IQR)†									
Baseline	126	13 (6 – 19)	125	11 (7 – 19)	126	11 (7 – 18)	0.469	0.002 (2)	0.677
3mo	92	9 (6 – 16)	94	8 (5 – 16)	101	7 (4 – 14)			
12mo	51	9 (4 – 18)	37	9 (5 – 15)	64	9 (5 – 13)			
AAQW, median (IQR)									
Baseline	103	84 (22)	106	85 (20)	104	85 (24)	0.8110	<0.001(2)	0.881
3mo	92	76 (21)	94	77 (21)	102	73 (20)			
12mo	51	76 (22)	37	69 (20)	65	73 (21)			

Mixed model. (2) quadratic term (3) cubic term *ln transformed prior to analysis †sqrt transformed prior to analysis

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	3
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
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	N/A
Participants	4a	Eligibility criteria for participants	6 -7
	4b	Settings and locations where the data were collected	7,10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7,8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7,9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	Protocol paper
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
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	7,8
	11b	If relevant, description of the similarity of interventions	7,8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8,9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8,9
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	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	10
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2 and sup materials
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 2 and sup materials
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)	Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Table 3
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	24,25
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	24 , 25, 26
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21 - 26
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	29

*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.