

ORIGINAL RESEARCH

Feasibility of a community-based interdisciplinary lifestyle intervention trial on weight loss (the HealthTrack study)

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Abstract

Aim: The aim of this study was to test the feasibility and acceptability of a novel interdisciplinary intervention on weight loss.

Methods: A 3-month parallel, blinded, randomised controlled trial compared the effects of an interdisciplinary model of care (individualised interdisciplinary advice delivered through dietitians) with control (general advice on diet and physical activity delivered by primary care nurses). The primary outcome was assessing feasibility and acceptability of the protocol, with secondary outcomes including body weight, clinical, dietary, physical activity and psychological variables.

Results: Twenty-four participants were randomised and 21 included in the final analysis. The recruitment rate was 42% (24/57) and the eligibility rate 83% (24/29). The withdrawal rate was low (13% overall) compared with similar trials. Attendance at study visits was higher in the intervention arm compared with control (100 vs 83%), which may be an artefact of the greater individualised treatment provided in the integrated model.

Conclusions: This study confirmed the feasibility and acceptability of the novel interdisciplinary lifestyle intervention within the region.

Key words: behavioural research, community health, evidence-based practise, health service, physical activity, weight control.

Introduction

Non-communicable diseases such as cardiovascular disease, type 2 diabetes, cancers and chronic respiratory diseases account for the nearly two-thirds of deaths in the world today and drive up health-care and disability costs.¹ A recent

review argued that risk factors such as overweight and obesity, lack of physical activity and poor diet are among a number of risk factors that lead to this burden.² In Australia, overweight contributes to 7.5% of the national disease burden.³ The prevalence of overweight and obesity in adults aged ≥ 18 years continued to rise from 56.3% in 1995 to 63.4% in 2011–2012.⁴ In the Illawarra region of New South Wales Australia, data from 17 general practices (representing 39.7% of the regional population) demonstrated that the prevalence of chronic diseases was higher than the national average: obesity/overweight 65.9 versus 63.4%, hypertension 11.9 versus 10.4% and anxiety disorders 5.0 versus 3.8%, respectively.⁵

The benefits of interdisciplinary lifestyle interventions, including weight loss, physical activity and behavioural aspects, have been shown to improve cardiovascular disease risk and diabetes.^{6–8} Current Australian Medicare programmes support multidisciplinary services for chronic disease management, requiring the general practitioner to develop a management plan with up to five consultations

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with allied health professionals.⁹ This model is delivered using a referral process to individual practitioners. The complexities of organising and coordinating these individual consultations and ensuring cohesive care and follow-up can lead to high dropout rates and failure to achieve sustained lifestyle improvements. A model of care in which allied health professionals negotiate roles and share expertise may be more effective. The aim of this study was to test the feasibility and acceptability of a novel interdisciplinary intervention on weight loss.

Methods

Interdisciplinary design Utilising Australian guidelines and international scientific literature, representatives from five groups of health professions—medicine, nutrition and dietetics, exercise physiology, psychology and nursing—developed two models of care: one reflecting usual care in a primary care context delivered by nurses (control) and the other combining the expertise of dietitians, exercise physiologists and psychologists where the face-to-face counselling was provided by the dietitian (intervention). Best practice assessments for chronic disease risk factors, anthropometry, dietary intake, physiological parameters (blood pressure (BP), physical activity and fitness) and psychological health were negotiated and included in surveys and assessments. Standard operating procedures were also developed for screening, assessment and delivery of lifestyle counselling.

Briefly, the roles of the health practitioners in the process of protocol development and trial implementation are defined in Table 1.

Ethical approval to conduct the study was provided by the University of Wollongong Human Research Ethics Committee (HE13/189). The larger trial following this pilot, the HealthTrack study, has been registered (ANZCTR N 12614000581662). This research was conducted in

compliance with the Declaration of Helsinki (as revised in Edinburgh 2008), available at <http://www.wma.net/en/30publications/10policies/b3/>. All participants were aged 25 years or over and provided written informed consent.

Feasibility and acceptance study The design reflected a 3-month single-centre, blinded, parallel, randomised controlled trial with two arms: control (usual care) and intervention (interdisciplinary approach). It was conducted between July and November 2013. Randomisation to the two groups was 1:1. Recruitment was conducted via advertising in local University websites and flyers. Potential participants saw this on their computers, passing billboards or locations where flyers were placed.

Inclusion factors were men and women from the Illawarra Shoalhaven community of New South Wales, Australia (adults aged 25–54 year, permanent resident), at higher risk of lifestyle-related disease (defined by body mass index (BMI) range 25–40 kg/m²). Exclusion criteria were inability to communicate in English, severe medical conditions impairing ability to participate in the study, other medical conditions thought to limit survival to 1 year, immunodeficiency, reported illegal drug use or regular alcohol intake associated with alcoholism (>50 g/day); difficulties or major impediments to participating in components of the study. People with Type 1 diabetes were excluded as the more specific dietary requirements were considered impediments to the study.

A one-off health-coaching workshop for participants was attended by 6 of the 11 intervention group participants prior to their baseline counselling. At this workshop an experienced clinical psychologists advised on cognitive behavioural strategies utilising acceptance commitment theory.¹⁰ All participants attending the workshop received printed psychological support materials designed to increase motivation and behavioural commitment and received weekly motivational email reminders.

Table 1 Roles of professionals in protocol development and delivery

Practitioner	Protocol development	Intervention implementation
Medical practitioner	Development of all usual care protocols, clinical and pathology tests and surveys.	Clinical review of data, assessment of data for inclusion of participants and communication with GP.
Psychologist	Development of intervention workbooks and materials. Considerations of equivalence for the control group.	Oversight of theoretical approach to behavioural intervention and related survey material.
Exercise physiologist	Development and oversight of surveys and tests for assessment of physical activity. Development of general guidelines for activity for participants.	Review and advice on fitness tests.
Dietitians	Development and oversight of survey materials for dietary assessment.	Delivery of dietary interviews, diet and physical activity counselling in intervention group. Conduct of assessment measures.
Nurses	Development of usual care protocols.	Delivery of usual care materials (Australian dietary and physical activity guidelines). ^{10–12}

GP, general practitioner.

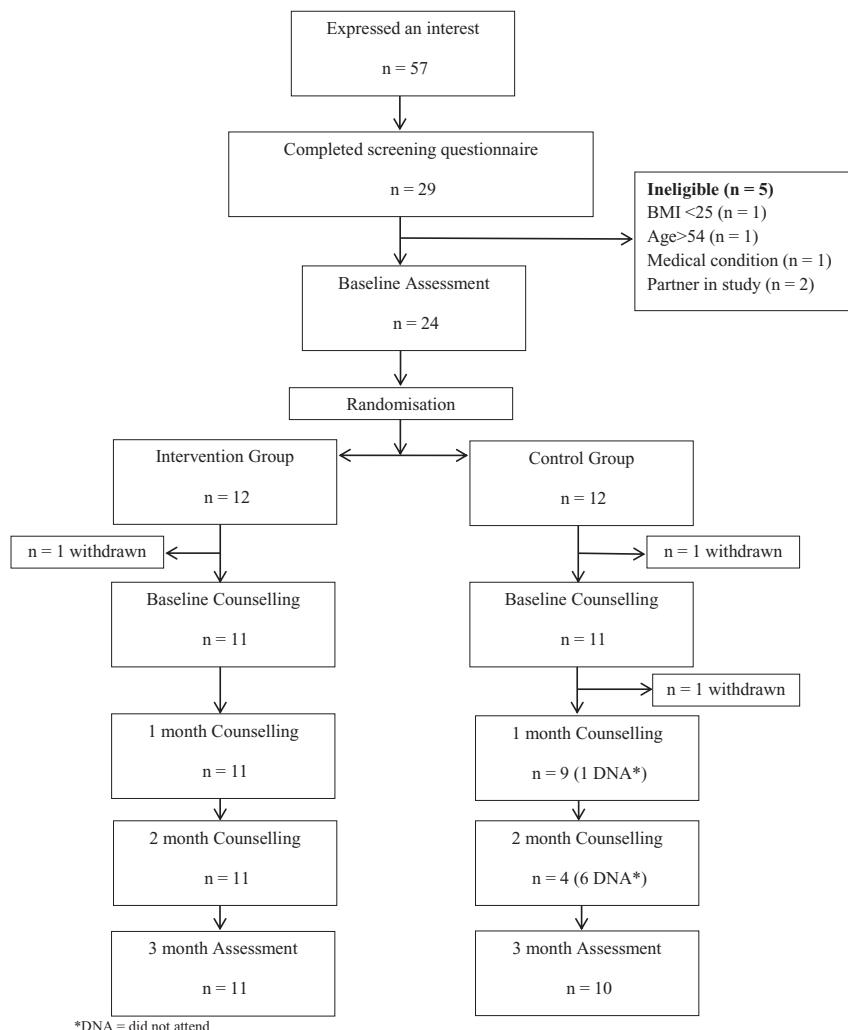


Figure 1 The flow of study (CONSORT diagram). BMI, body mass index.

Both groups attended the clinic at baseline, 1, 2 and 3 months of visits with a health practitioner (nurse/control or dietitian/intervention) (Figure 1). After screening, both groups attended an initial baseline assessment including anthropometric, diet and BP measures conducted by an accredited practising dietitian (APD). Both groups attended the clinic for ongoing support from the nurse or dietitian and had their weight and %body fat measured at the 1, 2 and 3 months of visits. All participants were encouraged to set diet and physical activity goals. All participants were asked to perform physical activity in accordance with the national physical activity guidelines.¹¹ In addition at the 3-month visit anthropometric, diet and physiological assessment measures were repeated in both groups by another APD.

The variation between the intervention and control groups was that for the control group nurse practitioners used a client-centred approach to counselling, which involved seeking the patients perspective and fitting advice around their needs. In addition, the control participants were provided with information sheets utilising general/national diet and physical activity guidelines as per the 2013

Australian Guide to Healthy Eating.¹¹⁻¹³ For the intervention group, the APD delivered a client-centred approach to advice on diet and physical activity suited to their individual needs. This included providing participants with a personalised diet prescription based on core food groups from the Australian Guide to Healthy Eating,⁵ that is, vegetables, fruit, grain foods, meat/fish/eggs/cheese, milk/yoghurt and nuts/seeds/spreads/oils, providing ~80% energy requirements for age, weight and sex (as per the Mifflin Equation¹⁴). Specific exercise goals were developed for the intervention group with reference to the National Physical Activity guidelines.¹¹

The following measures were undertaken:

BP and anthropometry: Weight was measured at baseline and 3 months in minimal clothing (without shoes) using scales with a bio-electrical impedance component to estimate body fat (Tanita TBF-662, Wedderburn Pty, Ltd, Ingleburn, NSW, Australia). Lightly clad or directly on skin, waist and hip circumferences were measured in accordance with standard protocols. Height was measured using a stadiometer. BP and heart rate was measured with the participant resting in a supine position for 5 minutes on an Omron HEM-907

(Omron Healthcare Co Ltd, Port Melbourne, Victoria, Australia) automated BP monitor. Three BP measurements were taken and the average of these measurements was calculated.

Pathology: Fasting blood lipids (total cholesterol, triglycerides, high-density lipoprotein and low-density lipoprotein cholesterol) and glucose were collected via referral to an accredited pathology centre (name removed for blind peer review) Medical Laboratory (a fully owned subsidiary of Sonic Health Care Limited, Wollongong, NSW, Australia).

Dietary assessment: Diet intake was assessed using a diet history interview at clinic visits and 4-day food records (including 1 weekend day) completed in the period prior to attending the clinic. Participants recorded all foods consumed including amounts and recipes. Dietary data were calculated and analysed using FoodWorks (version 6; Xyris Pty Ltd, Kenmore Hills, Qld., Australia) nutrient analysis software using the AUSNUT 2007 food composition survey database.¹⁵

Physical activity: Physical activity was assessed using the International Physical Activity Questionnaire (IPAQ) short form survey questions.¹⁶

Quality-of-life assessment: Quality of life (physical and mental health) was assessed using the SF-12 health survey.¹⁷ Scores were based on the contribution of each item and computed using weighted formulas in accordance with the developers' recommendations.¹⁸ Higher scores indicate higher physical and mental health.

The primary aim of the study was to test the feasibility and acceptability of a lifestyle intervention trial comparing the effects of an interdisciplinary approach and usual care (control). Feasibility was assessed by recruitment rate (number randomised/number responding to advertisement) and eligibility rates (number deemed eligible/number completing screening survey). Acceptability was assessed by withdrawal rate (number of withdrawals/number enrolled), and degree of attendance at study visits (number attending /total number of required attendances).

The secondary aims of the study compared the effects of the two approaches for over 3 months on weight, body fat %, BP, dietary intake, lipids, physical activity (assessed by IPAQ) and quality of life (assessed by SF12).

Randomisation was conducted by a researcher independent of the participant interface. Participants were block randomised, stratified by sex into control or intervention groups, using STATA (V12, College Station, TX, USA). As this was a feasibility study, a sample of 10 per group was judged suitable to implement the study protocols and determine variation in effects on the primary outcome. Significant differences in secondary outcomes were not anticipated. Baseline characteristics were summarised without formal between-group comparison. Statistical analysis was conducted using a linear-mixed model (SPSS V21, IBM Corporation, Armonk, NY, USA).

Results

Fifty-seven people expressed an interest in the trial (Figure 1). Of these about half ($n = 29$) completed the

screening questionnaire, and 24 were deemed eligible and underwent baseline assessments. This converts to a recruitment rate of 42% and an eligibility rate of 83%. The time from initial advertisement to completing recruitment was 1 month. Twenty-four participants were randomised to the control and intervention group, but there were two drop-outs (one control, one intervention) prior to the baseline counselling (not wishing to continue in the study) and one after the first session in the control group (health reasons). In the control group, one participant did not attend the 1-month counselling and six did not attend the 2-month counselling, but all attended the 3-month assessment visit (Figure 1). This converts to 100% attendance by the intervention group and 83% attendance by the control group.

Baseline characteristics of the total cohort and each group (Table 2) indicated that there were fewer males than females in the study (8 vs 13, respectively). The mean age of the sample was 43.8 (± 8.8) years, and the sample was largely obese (mean BMI $30.5 \pm 2.9 \text{ kg/m}^2$). Major baseline characteristics were similar in the two groups. Only one participant in the study was taking lipid-lowering medication and no participants were on antihypertensive medication. Baseline characteristics were not statistically compared as per the CONSORT statement guidelines.¹⁹

After 3 months the intervention group lost significantly more weight than the control group (adjusted mean difference -3.98 kg (95% confidence interval (CI) $-6.17, -1.79$) $P = 0.002$), coinciding with a reduction in BMI (adjusted mean difference -1.24 kg/m^2 (95% CI $-2.05, -0.44$) $P = 0.002$) (Table 3). The body fat component of the weight loss was significantly reduced in the intervention arm, compared with control (adjusted mean difference % body fat -3.25% (95% CI $-6.05, -0.48$) $P = 0.034$). In addition, waist circumference significantly reduced in the intervention arm compared with control (adjusted mean difference 5.14 cm (95% CI $7.74, -2.53$) $P = 0.001$), with a non-significant reduction in hip circumference (adjusted mean difference -2.45 cm (95% CI $-5.05, 0.17$) $P = 0.08$).

BP measurements decreased for both groups over the 3 months ($-5/-3 \text{ mmHg}$ systolic BP/diastolic BP in the control and $-8/-8 \text{ in}$ the intervention group, $P < 0.001$), with the intervention group showing a significantly greater reduction in diastolic BP compared with control ($P = 0.02$). There was no statistically significant change in total cholesterol, triglycerides or glucose in either group within the 3 months of follow-up.

Both groups reduced their energy intake (kJ) similarly over the 3-month follow-up (mean decrease 1589 kJ (standard deviation (SD) 1138) $P < 0.001$); however, the intervention group reported a significant decrease in percent energy from dietary fat over the 3-month follow-up (-4.5% (SD 4.0) $P = 0.004$), whereas the usual care group did not change ($+1.1\%$ (SD 3.2) $P = 0.300$) (adjusted estimate 5.4% (95% CI $2.0, 8.7$) $P = 0.003$). Both groups increased physical activity ($P = 0.031$), but there were no differences between the two groups (adjusted estimate 816 METS (95% CI $-694, 2327$) $P = 0.27$). There were no significant changes in the

Table 2 Baseline characteristics

Variable	Control	Intervention	Total
Male/female	5/5	3/8	8/13
Anthropometric			
Age (years)	43.5 (± 9.0)	44.1 (± 9.1)	43.8 (± 8.8)
Height (m)	1.70 (± 0.09)	1.66 (± 0.07)	1.68 (± 0.08)
Weight (kg)	86.6 (± 12.9)	86.3 (± 10.2)	86.4 (± 11.3)
BMI (kg/m^2)	29.7 (± 2.7)	31.2 (± 3.0)	30.5 (± 2.9)
Body fat (%)	33.3 (± 8.6)	38.9 (± 5.8)	36.3 (± 7.6)
Fat free mass (%)	66.7 (± 8.6)	61.1 (± 5.8)	63.7 (± 7.6)
Waist circumference (cm)	94.2 (± 8.2)	97.9 (± 8.7)	96.1 (± 8.5)
Hip circumference (cm)	112.7 (± 9.0)	112.6 (± 5.1)	112.6 (± 7.0)
Clinical			
Systolic blood pressure (mmHg)	131 (± 11)	126 (± 12)	128.2 (± 11.4)
Diastolic blood pressure (mmHg)	87 (± 5)	88 (± 8)	87.5 (± 6.6)
Resting heart rate (beats/min)	66 (± 9)	67 (± 8)	66.4 (± 8.2)
Total cholesterol (mmol/L)	5.2 (± 1.0)	5.1 (± 0.9)	5.2 (± 0.9)
Triglycerides (mmol/L)	1.0 (± 0.5)	1.6 (± 0.9)	1.3 (± 0.8)
Glucose (mmol/L)	5.3 (± 0.4)	5.3 (± 0.6)	5.3 (± 0.5)
Dietary			
Energy intake (kJ)	9413 (± 2474)	7985 (± 1332)	8665 (± 2044)
Energy from fat (%)	35.5 (± 4.2)	33.7 (± 6.0)	34.6 (± 5.2)
% energy from saturated fat	12.6 (± 2.6)	13.2 (± 3.3)	12.9 (± 3.0)
% energy from carbohydrate	36.8 (± 5.0)	39.5 (± 6.6)	38.2 (± 5.9)
% energy from alcohol	3.8 (± 3.4)	1.6 (± 1.9)	2.7 (± 2.9)
Dietary fibre (g)	33.3 (± 14.5)	23.8 (± 6.3)	28.4 (± 11.7)
Physical activity			
Physical activity (Met.min/week)	1924 (± 1107)	1867 (± 1498)	1892 (± 1303)
Mean steps/weekday	11 610 (± 4433)	8672 (± 1912)	9304 (± 3488)
Mean steps/weekend day	9682 (± 3986)	6971 (± 3539)	7601 (± 3805)
Quality of life (SF-12)			
Physical Component Score	51.7 (± 6.9)	50.8 (± 7.3)	50.9 (± 6.8)
Mental Component Score	51.3 (± 10.0)	48.5 (± 7.7)	48.7 (± 8.9)

Data are expressed as mean (\pm standard deviation).

BMI, body mass index.

quality-of-life assessment (SF12) over time or between the two groups.

Discussion

This feasibility study demonstrated that the proposed trial of an interdisciplinary intervention as described is feasible and appears acceptable to participants. The number of people responding to minimal advertising within a month ($n = 57$) was reasonable. The recruitment rate of 42% was also reasonable, given the inclusion and exclusion criteria, and the eligibility rate of 83% was high. The rate of withdrawal (one in the intervention, two in the control group) was low compared with other lifestyle intervention studies that have reported withdrawal rates of 20–50%.^{20–22} The higher rate of attendance at study visit by the intervention group compared with the control (100 vs 83%) may be an early reflection of the greater response to the interdisciplinary approach, but that would have to be tested in larger numbers.

As a feasibility study that confirmed the use of study protocols, the research reported here was not designed with

power to show an effect; however, it was demonstrated that the intervention group had a greater weight loss of around 4 kg. As the intensity of visits and volume of information provided to both groups was similar, the difference in effects may possibly be attributed to the individualised programmes by Accredited Practising Dietitians with support from an exercise physiologist and health counsellors. In addition, the study demonstrated significantly reduced BMI and % body fat in the intervention group compared with control, with a reported improvement in BP.

It must be acknowledged that small studies such as this are often biased demonstrating larger estimates of population effect size than would be seen in a larger sample.²³ Therefore, the statistical significance of the secondary outcome results is not the main focus of our findings. In using the between-group differences for estimates for a larger sample, various methods including using the upper 95%,²⁴ bootstrap resampling²⁵ or Bayesian methods incorporating relevant prior information²⁶ could be employed. The focus of the study reported here is the feasibility of the novel combination of the health disciplines being implemented by a

Table 3 Anthropometric, clinical, dietary and physiological/physical activity values at 0 and 3 months

Variable	Change 3 months		P values*		
	Control (n = 10)	Intervention (n = 11)	Time	Group	Interaction
Males/females	5/5	3/8			
Anthropometric					
Weight (kg)	-0.45 (±1.51)	-4.41 (±3.10)	<0.001	0.800	0.002
BMI (kg/m ²)	-0.17 (±0.53)	-1.56 (±1.11)	<0.001	0.744	0.002
Body fat (%)	-0.69 (±1.40)	-3.55 (±3.60)	0.002	0.418	0.034
Waist (cm)	-1.19 (±2.28)	-6.89 (±3.73)	<0.001	0.750	0.001
Hip (cm)	-1.30 (±1.36)	-3.62 (±3.87)	0.001	0.592	0.084
Clinical					
Mean systolic BP (mmHg)	-5 (±4)	-8 (±7)	<0.001	0.225	0.214
Mean diastolic BP (mmHg)	-3 (±5)	-8 (±5)	<0.001	0.730	0.020
Total cholesterol (mmol/L)	-0.05 (±0.74)	-0.10 (±0.65)	0.291	0.702	0.402
Triglycerides (mmol/L)	-0.05 (±0.48)	-0.39 (±0.61)	0.214	0.081	0.609
Glucose (mmol/L)	-0.11 (±0.31)	0.07 (±0.75)	0.154	0.801	0.938
Dietary					
Energy (kJ)	-1127 (±1068)	-2009 (±1075)	<0.001	0.006	0.089
% energy from protein	2.2 (±2.5)	1.3 (±2.8)	0.844	0.153	0.320
% energy from fat	1.1 (±3.2)	-4.5 (±4.0)	0.039	0.012	0.003
% energy from saturated fat	-0.4 (±2.3)	-3.2 (±2.4)	0.109	0.849	0.815
% energy from carbohydrate	-2.8 (±3.3)	1.1 (±5.5)	0.463	0.020	0.082
% energy from alcohol	-0.4 (±1.6)	0.8 (±1.5)	0.451	0.256	0.115
Dietary fibre (g)	-6.0 (±10.1)	-0.3 (±5.3)	0.084	0.065	0.117
Physiological/physical activity assessments					
Physical activity (Met.min/wk)	1260 (±2177)	515 (±1061)	0.031	0.708	0.273
Quality of life (SF-12)					
Physical Component Score	0.6 (±7.2)	1.8 (±7.7)	0.398	0.810	0.473
Mental Component Score	-0.9 (7.6)	3.8 (±8.8)	0.466	0.870	0.417

Data expressed as mean (±standard deviation).

* Linear-mixed model, significant at $P < 0.05$.

BMI, body mass index; BP, blood pressure.

single practitioner. No significant changes were seen in quality-of-life measures as expected with the sample size and duration of study, but the inclusion of psychology in this research is important as several decades of research suggests that people overeat or fail to exercise for psychological reasons.^{27–31}

The feasibility study assessed participants after 3 months, whereas long-term change will be the ultimate goal of the research. The effectiveness of an interdisciplinary approach has been previously demonstrated,⁶ as has the ability to obtain sustained changes following lifestyle interventions.^{7,8} The focus of this research was to develop a protocol that is relevant in the regional context, but applicable on a broader scale. In principle, the research introduced a lifestyle intervention model that incorporated multiple health disciplines but was implemented by a single health practitioner. This model would reduce the burden on the health system and the patients. Two previously published diabetes prevention trials focused on diet and physical activity as the major components of behaviour change and dietitians provided the substantive component of lifestyle counselling. In the Finnish National Diabetes Prevention Program (DPP), it was noted that over 12 months weight loss in the follow-up

community intervention was less than in the DPP trial itself (DPS) (1 vs 4.2 kg, respectively), suggesting greater efficacy with the clinical model. In addition, participants in the DPS appeared well motivated to maintain lifestyle changes.⁸ Similarly, the US-based trial of a similar nature to the DPS, the DPP, demonstrated reductions in energy intake up to 9 years later.⁷ A previous dietary intervention trial conducted by our research team also demonstrated weight loss over 12 months to a similar level as the DPS.³² With a view to enhancing these effects in the current study, greater behavioural strategies and physical activity guidance were implemented, and appeared to be successful.

Bearing in mind this is a feasibility study, a limitation for reporting effects could be that only four of the control subjects attended the 2-month counselling session. However, this may also likely reflect the lack of effectiveness of the control arm and may provide further support for the interdisciplinary model. As 10 of the 11 control group participants returned for the 12-week assessment and the results were analysed using a linear-mixed model, the findings from the analysis of secondary outcomes may represent the potential benefits of the interdisciplinary approach on an intention-to-treat basis.

Finally, in our study, the context of health-care delivery is important. There is some argument that commercial services may provide a preferable alternative to publically funded services. In one multicentre trial (Germany, Australia, UK), referral to commercial weight loss programmes that addressed diet, physical activity and motivation was shown to be clinically effective,³³ but weight loss maintenance was poor during the non-intervention follow-up after 2 years, and loss to follow-up was high.³⁴ In contrast, for the same period of time, an interdisciplinary program provided by nutritionists, psychologists and kinesiologists in Montreal, Canada, was shown to be more effective than usual care.⁶ In this case a, 2-year follow-up was provided by nurses and physicians. This suggests that delivery within health-care systems may be significantly better in the long term. Likewise, the health-care system may be important for recruitment and screening. This proof of concept feasibility study is being rolled out in the full HealthTrack study in 377 participants over a 12-month follow-up; recruitment is completed with final follow-up occurring in June 2016.

The initial results of the HealthTrack lifestyle intervention trial suggest that a single model of care using an interdisciplinary approach to provide lifestyle counselling is feasible within its current context and acceptable to participants. The ability of five health professions to negotiate a study design including an integrated strategy has been demonstrated. Further research will be required to address questions of how the model can be translated into primary health-care and other local health district services.

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Conflict of interest

All authors report that they have no conflicts of interest.

Authorship

The following authors were responsible for the study concept and design (LCT, ML, MB, JC, GP), study setup (LCT, ML, RT), ongoing management (LCT, ML, RT), participant visits (RT), data cleaning (RT), data analysis (MB, LCT, ML, JR, JC, GP, AM) and writing of manuscript (LCT, ML, MB, JR, JC, GP, AM). The authors would like to thank the participants of the clinical trial for their time in participating in this research study.

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