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Promoting physical activity through group self-management support for those with multimorbidity: a randomised controlled trial

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Abstract

Background: Targeted self-management programmes may improve health and increase physical activity in people with multimorbidity.

Aim: Investigate the impact of a structured, theoretically-driven self-management group education programme on habitual physical activity levels in people with multimorbidity.

Design: Individually randomised controlled trial with 12-month follow-up.

Setting: Nine primary care practices within Leicestershire, UK.

Methods: N=353 adults with multimorbidity (age 67.8±9 years, 161 male) were randomly assigned (1:1) to intervention (n=180) or control (n=173) groups. Intervention participants were invited to attend four group-based self-management sessions, centred primarily on increasing physical activity. They also received motivational text message support. The primary outcome measure was change from baseline in device-measured (GENEActiv wrist-worn accelerometer) overall volume of daily physical activity at 12 months.

Results: At baseline, the total sample was achieving 22mins/day of moderate-to-vigorous intensity physical activity. At 12 months a reduction in daily average physical activity was seen in the intervention group relative to control participants in the complete-case analysis (-0.80 mg; 95% CI: -1.57, -0.03; p=0.04) (primary outcome data available for 71.1% and 79.2% of intervention and control groups respectively). Similar reductions were seen in time spent in moderate-to-vigorous physical activity (-3.86 mins/day; 95% CI:-6.70, -1.03; p=0.01) and time spent at an intensity equivalent to a slow walk (-4.66 mins/day; 95% CI: -8.82, -0.51; p=0.028).

Conclusions: The self-management programme elicited a slight reduction in physical activity levels in people with multimorbidity. Future studies should identify and target subgroups of those with multimorbidity at greatest need for physical activity promotion.

Keywords: Multimorbidity, physical activity, disease self-management, chronic disease, primary care.

How this fits in

People with multimorbidity typically display increased morbidity and mortality risk, driven in part by reduced levels of habitual physical activity. Disease self-management empowers patients to take more of an active role in their own healthcare and has shown promise in individual conditions, though this is under-researched in multimorbidity. This study investigated the impact of a targeted group-based disease self-management programme on habitual physical activity levels in people with multimorbidity. However, a slight decrease in physical activity levels was observed, suggesting that the intervention was ineffective, and that future research should target those at greatest need for physical activity intervention.

Introduction

Multimorbidity, defined as the coexistence of two or more chronic conditions(1,2), is a growing global health concern highly prevalent in primary care and older populations(3,4). In the UK in 2015, 54% of those aged over 65 years had multimorbidity, which is expected to reach 68% by 2035. Multimorbidity increases mortality with an additive effect for each additional condition(5), and is associated with worsened quality of life(6), physical function(7) and depression risk(8). Multimorbid populations have high hospitalisation rates, healthcare usage and healthcare costs, which increase with each additive condition(9).

Disease self-management, whereby the individual takes responsibility for all or some aspects of their day-to-day disease management(10), promotes engagement and empowerment and is recommended by the World Health Organization(11). Previous theory-driven self-management interventions, incorporating a variety of methodologies (e.g. small group sessions, eHealth/mHealth support, printed materials) have successfully improved quality of life and self-efficacy in a variety of chronic diseases (e.g. diabetes, cardiovascular disease, arthritis)(12), and other clinical outcomes in type 2 diabetes (T2DM)(13,14). However, interventions designed specifically for multimorbidity are under-investigated and therefore a research priority(15) with significant promise for improving health outcomes.

People with multimorbidity typically display low physical activity (PA) levels(7), associated with worsened all-cause mortality, disease burden(16), health-related quality of life(17), physical function(18) and mental health(19). Consequentially, PA levels display an inverse dose-response relationship with multimorbidity burden(20) and mortality(21). In people with cardiovascular disease and prediabetes, increasing PA by 2000 steps/day is associated with an 8% reduction in risk of cardiovascular events, irrespective of changes in body mass(22). However, no studies have developed or tested an intervention designed specifically to increase PA levels in people with multimorbidity. The aim of this study was to evaluate a programme in a primary care setting that targets PA, other lifestyle factors and disease self-management in people with multimorbidity.

Methods

Study design and recruitment

A detailed study protocol (ISRCTN42791781) has been published(23). The study was a single-site, two-arm, parallel-group, open-label 12-month randomised controlled trial (RCT) testing the effectiveness of a structured self-management programme in participants with multimorbidity recruited from primary care practices within Leicestershire, UK. Ethical approval was provided by West Midlands-South Birmingham Research Ethics Committee (16/WM/0505). Participants provided written informed consent before data collection.

Inclusion and exclusion criteria

Multimorbidity was defined as the coexistence of ≥2 chronic conditions(1) listed in the Quality and Outcomes Framework clinical domains(24) (Box S1). Other inclusion criteria were: aged 40-85 years; good understanding of English; able to give informed consent; mobile phone access, and able to walk independently. Exclusion criteria were: pregnancy; current or recent (<12 weeks) participation in another interventional trial, or frailty (for safety reasons relating to the promotion of unsupervised physical activity, frailty criteria in Box S2).

Randomisation and blinding

Participants were individually randomised (1:1), stratified by gender and ethnicity (White European; other) as per a computer-generated randomisation sequence using a variable block size by an independent researcher. Research nurses were unaware of allocation during data collection visits, and accelerometer analysis was completed by a blinded researcher. Participants and the central study team could not be blinded.

Treatment

Control participants continued to receive their usual disease management as required, which was unaffected by their participation in the trial.

Intervention

The MAP programme(23) was iteratively developed, tested and refined using literature reviews and patient and public co-production, using focus groups with people with multimorbidity, their relatives, and primary care clinicians and nurses. The focus groups informed the programme content, to include both a focus on physical activity and to cover generic self-management challenges. The intervention was underpinned by social learning theory(25). A draft programme was iteratively tested and modified with patient volunteers prior to finalisation. The final programme comprised four, 1.5-hour group sessions with person-centred(26) self-monitoring and goal setting, delivered at two-week intervals in local community settings by a trained facilitator. The sessions focused primarily on increasing PA, also addressing non-disease specific self-management challenges (mastering emotions, managing treatments, communication within healthcare). Programme delivery and fidelity was assessed using a structured observation tool(27,28). To support long-term health behaviour change, regular reminder and motivational text messages were sent, the frequency and content of which were fixed for the entire intervention group and based on previous self-management programmes(29-31). Frequency was daily during delivery of the group sessions and for two weeks at the 6 month time-point, and three times a week in the remainder of the 12-month period, Figure S1). Increasing PA was further facilitated by providing resistance bands and pedometers.

Primary outcome

The primary outcome was change in volume of daily PA from baseline to 12 months measured using the GENEActiv wrist-worn tri-axial accelerometer (Activinsights Ltd., Cambridgeshire, UK), which measures average movement intensity (milligravitational units, mg), indicative of the overall volume of daily PA, using the Euclidean norm minus 1*g* method(32). Participants wore the accelerometer for eight consecutive days at baseline, six and 12 months. Data were included if participants recorded ≥1 valid days (≥16hs/day) and analysed using an open source R package (GGIR)(33). To translate findings from mg, we determined the number of minutes of brisk walking that would lead to observed changes in average daily acceleration based on a change in 0.8mg representing a change of 5 minutes of brisk walking(34).

Secondary outcomes

PA-related secondary outcomes were determined from the accelerometer data (Table S1). Other secondary outcome measures were measured at baseline and 12 months and included clinical, venous blood (lipid profile, kidney function, glycated haemoglobin (HbA1c)) and anthropometric measures.

Questionnaires (baseline and 12 months) comprised: Recent Physical Activity Questionnaire (RPAQ)(35); Adherence Starts with Knowledge 12 (ASK-12)(36); EuroQol 5-dimensional, 5-level version (EQ-5D-5L)(37); Hospital Anxiety and Depression Scale (HADS)(38); Chronic Disease Self-Efficacy Scale (CDSES)(39); Self-Efficacy for Exercise (SEE) Scale(40); and dietary behaviour (based on questionnaires developed for two previous studies(41)). Intervention participants completed a questionnaire following each session to assess the perception and potential of benefit for each session.

Sample size

To detect a minimum clinically important difference (MCID) in average volume of daily physical activity at 12 months of 2.1 mg and assuming a standard deviation of 5.3 mg(42), power of 80% and significance level of 5%, 202 participants in total were required. Allowing for 20% loss to follow-up and 20% non-compliance of accelerometer/intervention attendance, at least 338 participants were required (169 per group)(23). A value of 2.1 mg was chosen as it represents an increase in physical activity that is equivalent to walking at the threshold between light-intensity and moderate-intensity (e.g. 4 km/h) for 30 minutes per day or between 10-15 minutes of brisk walking per day(43,34).

Statistical analysis

Binary and categorical baseline variables were presented by group as numbers (with percentages) and continuous variables as means (with standard deviations) or medians (with lower/upper quartiles).

The primary outcome was analysed using a linear regression model with change in overall daily PA as dependent variable and randomisation group as explanatory variable, adjusted for stratification factors (gender and ethnicity), change in wear time between baseline and 12 months and baseline outcome value. Sensitivity analysis checked the effect of ≥3valid days of accelerometer wear-time on primary outcome using similar methodology.

The main analysis was conducted using a modified intention to treat approach, where participants with follow-up data were analysed in the group to which they were assigned. A sensitivity analyses was used to assess the impact of missing follow-up data using multiple imputation and to undertake a per-protocol analysis (inclusion of only those intervention participants who attended ≥1 education session). Multiple imputation was used to replace missing values with multiple sets of simulated values to allow standard analysis on each completed dataset(44), followed by Rubin's formula(45) to combine the parameter estimates and standard errors into a single set of results. The imputation model included the variables that were included in the linear regression analysis.

Further exploratory analysis was completed on those who attended 1-3 vs 4 sessions to assess intervention impact. Subgroup analyses were performed to examine the effects between the intervention arm and pre-specified subgroups of baseline characteristics (age (<65 & ≥65), sex, median number of comorbidities (<4 & ≥4), depression, arthritic condition, cardiovascular condition, T2DM and physical activity (low & high)). The interaction effects between the treatment and subgroups were used to assess differences in outcome by subgroup. Secondary outcomes were analysed in a similar manner to the primary outcome. Statistical significance was assessed at the 5% level with 95% confidence interval. All p-values were two sided and $p<0.05$ was considered statistically significant. Analyses were completed using STATA (v.15).

Results

Participants

6011 people from nine general practices were invited. From 678 expressions of interest (11.3%), 353 were eligible and consented to take part (52.1%) and were randomised to the intervention (n=180) and control (n=173) groups (Figure 1).

Participant baseline characteristics are presented in Table S1. The mean number of conditions was 4.32. 84% had a cardiovascular condition, 30% had a respiratory condition, 45% were obese, 56% had a 'high-dependency' condition (which includes diabetes mellitus), 35% had depression, and 23% had a musculoskeletal condition.

Intervention attendance and receipt

78.3% of participants (n=141) attended Session 1, and attendance at the other three sessions was 61.1%, 55.6% and 62.2% (Table S2). 42% (n=75/180) sent a request during the study period to stop the text messages. Following the 'Moving more' session, 90% of participants agreed that moving more would benefit them, whilst only 66% reported that this opinion had changed in response to the intervention Whilst 86% reported that they were considering a change in their physical activity habits, only 66% reported feeling able to do so.

Physical activity

Primary outcome data was available for 71.1% and 79.2% of the intervention and control groups, respectively. Whilst a reduction in overall daily PA was seen in both groups (Table 1), this was significantly greater in the intervention group compared to control at 12 months in the main analysis (-0.80mg; 95% CI: -1.57 to -0.03; p=0.04) and intention-to-treat analysis (-0.83mg; 95% CI: -1.61 to-0.04; p=0.03). However, the per-protocol analysis (exclusion of participants who did not attend at least one education session), found no between-group differences in overall daily PA at 12 months (-0.65mg; 95% CI: -1.46 to 0.15; p=0.11). There was no effect of adjusting for same-household

clustering. The relative reduction of 0.8 mg in the intervention group approximates replacing 5 min of brisk walking with sedentary time(34).

Sensitivity analyses based on minimum wear criteria of three days showed comparable results (-0.85mg; 95%CI:-1.63 to 0.08; p=0.03) (Table S3). No significant effects were observed in the subgroup analyses (Figure S2).

Analysis of PA secondary outcomes showed a relative reduction in time spent in moderate-to-vigorous PA (-3.86mins/day; 95% CI:-6.70 to -1.03; p=0.01) and time spent at an intensity equivalent to a slow walk (-4.66mins/day; 95% CI: -8.82 to -0.51; p=0.03) in the intervention group. No other statistically significant findings were observed (Table 2), and no effects were observed in the session attendance exploratory analysis (Table S4).

Anthropometric and clinical measures

No statistically significant differences between groups were observed (Table 3).

Questionnaires

Questionnaire results are presented in Table S5. The dietary questionnaire showed an increase relative to control in fresh fruit consumption at 12 months (0.30; 95% CI: 0.06 to 0.54; p=0.02) in the intervention group. There was also a significant reduction relative to control at 12 months in self-rated health (visual analogue scale) from the EQ-5D-5L (-3.85 (-7.60 to -0.09), p=0.045) in the intervention group. There were no differences observed in other measures of quality of life, depression, anxiety or disease or exercise self-efficacy.

Adverse events

100 adverse events (AE) were reported (48 control, 52 intervention) during the study, six of which involved a non-elective overnight stay in hospital (2 control, 4 intervention) and were therefore described as serious adverse events (SAE). These were reported to the sponsor as part of the safety monitoring procedure and one resulted in study discontinuation (terminal cancer). Details of the AEs are provided in Table S6A and B.

Discussion

Summary

In response to a structured, theoretically-driven self-management group education programme designed to increase habitual PA levels, a reduction was observed in overall volume of daily PA and self-reported health in both groups, but more so in the intervention group. Other than an increase in self-reported fruit intake in the intervention group, no other effects were observed.

Strengths and limitations

This is the first RCT to investigate the impact of self-management on device-measured habitual PA in people with multimorbidity. Furthermore, the broad inclusion criteria increase external validity, increasing applicability to the heterogeneous multimorbid population. However, whilst the study recruited to target and 12-month follow-up rate was high (75%), overall participation was lower than other studies in this population(46) and may have introduced some recruitment bias. Furthermore, participants were not screened for PA level prior to randomisation. Given that participation bias is common in PA research(47), this may have introduced some PA-related selection bias. Embedding a process evaluation within the intervention development, as recommended by the MRC framework for complex intervention development and evaluation(48), would be useful in future research to address these limitations.

Comparison with existing literature

Whilst an age-related decline in PA levels over a 12-month period may be expected in this age group(49), the intervention group displayed a reduction of 0.8 mg relative to control. This reduction approximately equates to replacing 5 min of brisk walking with sedentary time(50). Since the study conception, evidence suggests that an increase of only 500 steps per day, equivalent to ~5 minutes of brisk walking, is associated with a decrease in cardiovascular disease risk and mortality(51-53) , with 0.8-1 mg being considered the minimum clinically meaningful difference(34). Therefore, the reduction in physical activity levels observed in the intervention group, whilst statistically significant, was at the very lower limit of what could be considered clinically meaningful. Furthermore, when

analysing only those who attended the intervention, a smaller non-clinically significant reduction was observed relative to control. It is therefore possible that the reduced levels of physical activity in the intervention group were a chance finding that were too low in magnitude to be considered as potentially harmful.

The participants on average undertook 22 mins/day of MVPA at baseline, and were therefore meeting the recommended target of 150 mins of MVPA/week, which may have limited the capacity for benefit. However, previous research revealed lower time spent in MVPA in people with multimorbidity (13 mins/day)(54) than observed here, but similar overall daily PA. This suggests that the MAP participants may have completed more intentional PA than the general multimorbid population. As only 11.3% of invitees expressed an interest and 52% of these were randomised (Figure 1), there may have been a disproportionate recruitment of physically active participants. Future research may benefit from targeting individuals with low habitual physical activity levels via a preliminary screening. Furthermore, whilst 90% of intervention participants reported that they felt increasing their PA levels would be beneficial for them, only 66% reported feeling able to do so and there was no increase is exercise self-efficacy, highlighting the importance of addressing individual barriers to PA participation.

Intervention attendance was facilitated by holding sessions within local community venues, running concurrent sessions and enabling participants to attend different venues. However, the decreased attendance from 78% at session 1 to 62% at session 4 may partly explain the lack of intervention-induced improvement. However, this attendance rate is similar to other studies investigating multimorbidity management(46), highlighting the difficulties in sustaining engagement in a population that often displays complex and diverse barriers to self-management(55).

Nonetheless, this does not explain why a reduction in PA was observed in the intervention group relative to control. The findings of the per protocol analysis suggest that non-attendees may have influenced the findings (though not being the primary analysis, this should be interpreted with caution). Intervention non-attendance may have been caused by factors that would lower PA levels, such as worsening of disease severity or mobility problems, which would also explain the reduction in

VAS score. However the VAS score reduction (-3.85) was smaller than the MCID of 7-10 reported in other chronic conditions(56-59). The negative result is surprising and does not follow the pattern of results seen in previous similar research in single disease states, though as mentioned above it is possible that this is a chance finding. It is possible that complexities surrounding variations or combinations of morbidity clustering contributed to this unexpected finding, though this trial was not designed or powered to investigate this. As physical activity promotion in multimorbidity is a relatively novel research area, there is limited previous research to which we can compare these findings, and as such further investigated is warranted.

Implications for future research and for practice and policy

It is clear that this intervention was not successful in improving physical activity levels in this population. This highlights that broad self-management interventions may be ineffective in increasing PA in the diverse multimorbid population, who likely have diverse barriers, motivators and needs concerning PA and health. Therefore, future research should focus on identifying and targeting subgroups who are most at need for PA intervention, such as those with low baseline physical activity levels. This could be accomplished via a preliminary screening stage, where resources allow, and by involving those with low physical activity levels the design of recruitment strategies. Conversely, future complex and theory-driven interventions could be developed with a Realist Evaluation approach(60) or process evaluation, allowing for investigation into what worked for whom, as well as identifying potential causal mechanisms. Given the heterogeneity of the multimorbid population (i.e. concerning co-morbidity clustering and PA needs), this would allow for improved intervention personalisation. Healthcare practitioners could then use this information to promote regular PA and other self-management techniques in patients known to have the greatest need and capacity for benefit. In order to encourage attendance and sustained engagement in self-management programmes it is important that there is direct communication between health care practitioners and patients (61) and when healthcare practitioners have a detailed knowledge of the programme, this will encourage their patients to attend(62).

Conclusion

In summary, this structured self-management intervention did not improve device-measured PA levels or other health-related outcomes in people with multimorbidity, and actually elicited a slight reduction. Increasing PA levels in people with multimorbidity remains an important health priority (63), with the potential to induce a variety of health-related improvements(21).

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Ethical Approval and Consent to Participate

Ethical approval was provided by the West Midlands-South Birmingham Research Ethics Committee (16/WM/0505). Participants provided written informed consent before data collection.

Competing Interests

Professor Khunti is the national lead for the NIHR ARC multimorbidity theme. Professor Yates reports grants from NIHR Leicester Biomedical Research Centre, received during the conduct of the study. Professor Davies reports grants from Novo Nordisk, non-financial support from the NIHR Leicester Biomedical Research Centre, during the conduct of the study; personal fees from Novo Nordisk, personal fees from Sanofi-Aventis, personal fees from Lilly, personal fees from Merck Sharp & Dohme, personal fees from Boehringer Ingelheim, personal fees from AstraZeneca, personal fees from Janssen, personal fees from Servier, personal fees from Gilead Sciences Ltd , personal fees from NAPP, personal fees from Mitsubishi Tanabe Pharma Corporation, personal fees from Takeda Pharmaceuticals International Inc., grants from Novo Nordisk, grants from Sanofi-Aventis, grants from Lilly, grants from Boehringer Ingelheim, grants from AstraZeneca, grants from Janssen, outside the submitted work. No other competing interests are reported.

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Table 1. Changes in overall daily physical activity for at least one valid day of accelerometer wear at 12-months.

	Number of participants		Mean change from baseline		Adjusted difference at follow-up [a]	
	Control (n = 173)	Intervention (n = 180)	Control	Intervention	Coefficient (95% CI)	P-value
Modified intention to treat [b]:						
Overall daily physical activity (mg)	137	128	-0.36	-1.20	-0.80 (-1.57 to -0.03)	0.04
Adjusted for same-household clustering					*-0.80 (-1.59 to -0.02)*	*0.05**
Intention to treat [c]:						
Overall daily physical activity (mg)	173	180	-0.35	-1.13	-0.83 (-1.61 to -0.04)	0.03
Adjusted for same-household clustering					*-0.83 (-1.61 to -0.04)*	*0.04*
***Per protocol*[d]**						
Overall daily physical activity (mg)	137	111	-0.36	-1.06	-0.65 (-1.46 to 0.15)	0.11
Adjusted for same-household clustering					*-0.65 (-1.46 to 0.16)*	*0.11*

CI=confidence interval

[a] Adjusted for stratification factors: sex and ethnicity; change from baseline in accelerometer wear time and baseline value of outcome

[b] Participants with missing outcome data or missing variables required for the model adjustment were excluded

[c] Missing data imputed using multiple imputation

[d] Participants who did not engage with at least one group session of the programme have been excluded from the intervention arm.

* = 0.045

Table 2. Changes in secondary outcomes of physical activity for at least one valid day of accelerometer wear at follow up.

	Number of participants		Mean change from baseline		Adjusted difference at follow-up [a]	
	Control (n =173)	Intervention (n = 180)	Control	Intervention	Coefficient (95% CI)	P-value
Overall daily physical activity (m*g*)						
6 months	140	128	-0.38	-0.36	0.12 (-0.80 to 1.04)	0.793
Average acceleration for most active continuous 30 mins (m*g*)						
6 months	140	128	-1.17	-1.68	1.07 (-3.07 to 5.21)	0.611
12 months	137	128	1.11	-4.17	-3.71 (-7.97 to 0.54)	0.087
MVPA (1 min bouts) (mins/day)						
6 months	140	128	-1.76	0.01	1.88 (-1.53 to 5.28)	0.279
12 months	137	128	0.54	-3.72	-3.86 (-6.70 to -1.03)	0.008
Time spent in slow walk (>100m*g*) (mins/day)						
6 months	140	128	-2.29	-1.04	1.70 (-3.46 to 6.86)	0.518
12 months	137	128	-1.09	-6.23	-4.66 (-8.82 to -0.51)	0.028
Time spent in brisk walk (>200m*g*) (mins/day)						
6 months	140	128	0.06	0.001	0.23 (-1.44 to 1.90)	0.789
12 months	137	128	0.10	-1.40	-1.23 (-2.81 to 0.35)	0.127
Sedentary/inactive time per day (mins)						
6 months	135	121	1.13	2.71	-1.78 (-19.33 to 15.77)	0.842
12 months	136	124	-10.15	5.22	9.91 (-11.78 to 31.60)	0.369
Sleep duration per night (mins)						
6 months	135	121	-2.20	-2.80	0.69 (-10.49 to 11.86)	0.904
12 months	136	124	5.63	2.43	-1.33(-16.98 to 14.32)	0.867

CI=confidence interval. MVPA=moderate to vigorous physical activity;

[a] Adjusted for stratification factors: sex and ethnicity; change from baseline in accelerometer wear time and baseline value. Participants with missing outcome data or missing variables required for the model adjustment were excluded

Table 3. Changes in clinical measures at 12 months.

	Number of participants		Mean change from baseline		Adjusted difference at follow-up [a]	
	Control (n = 173)	Intervention (n = 180)	Control	Intervention	Coefficient (95% CI)	P-value
BMI (kg/m^2)	130	123	-0.19	0.002	0.18 (-0.10 to 0.47)	0.205
Body weight (kg)	130	123	-0.85	-0.33	0.51 (-0.26 to 1.28)	0.192
Waist circumference (cm)	130	123	0.61	0.34	-0.33 (-1.84 to 1.19)	0.671
Hip circumference (cm)	130	123	-0.12	0.19	0.08 (-1.29 to 1.44)	0.914
Waist to hip ratio	130	123	0.01	0.001	0.005 (-0.01 to 0.02)	0.629
Left hand grip (kg)	130	123	-2.97	-1.57	1.06 (-0.51 to 2.64)	0.186
Right hand grip (kg)	129	123	-2.60	-1.59	0.78 (-0.87 to 2.43)	0.352
Systolic BP (mm HG)	130	123	-2.71	-1.21	1.61 (-2.03 to 5.25)	0.385
Diastolic BP (mm HG)	130	123	-3.61	-3.81	-0.05 (-2.03 to 1.94)	0.962
Resting heart rate (bpm)	130	123	0.12	-0.59	-0.65 (-2.57 to 1.26)	0.503
Total cholesterol (mmol/l)	124	125	-0.18	-0.24	-0.04 (-0.19 to 0.11)	0.585
HDL cholesterol (mmol/l)	124	125	-0.02	-0.01	-0.02 (-0.10 to 0.05)	0.540
LDL cholesterol (mmol/l)	123	122	-0.13	-0.23	-0.07 (-0.20 to 0.05)	0.226
Triglycerides (mmol/l)	124	125	-0.15	0.003	0.16 (-0.01 to 0.32)	0.058
TC:HDL ratio	124	125	-0.13	-0.19	-0.01 (-0.11 to 0.10)	0.925
HbA1c (%)	129	129	-0.09	-0.08	-0.001 (-0.11 to 0.11)	0.985
HbA1c (mmol/mol)	129	129	-0.96	-1.24	-0.36 (-1.66 to 0.95)	0.591

CI=confidence interval.

[a] Adjusted for stratification factors: sex and ethnicity; and baseline value. Participants with missing outcome data or missing variables required for the model adjustment were excluded.

Figure 1: Study flowchart, summarising recruitment, allocation and completion numbers.