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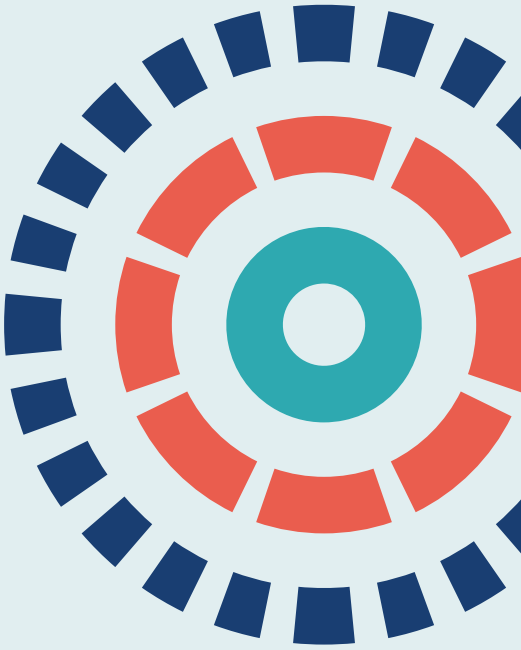

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Enhanced motivational interviewing for reducing weight and increasing physical activity in adults with high cardiovascular risk: the MOVE IT three-arm RCT

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[1]Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[2]Department of Biostatistics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[3]Department of Primary Care and Public Health Sciences, King's College London, London, UK
[4]Population Health Research Institute, St George's, University of London, London, UK
[5]Department of Health Services and Population Research, Institute of Psychiatry, King's College London, London, UK
[6]Section of Eating Disorders, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[7]Division of Asthma, Allergy and Lung Biology, King's College London, Guy's Hospital, London, UK

*Corresponding author

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Abstract

Enhanced motivational interviewing for reducing weight and increasing physical activity in adults with high cardiovascular risk: the MOVE IT three-arm RCT

Khalida Ismail,[1]* Daniel Stahl,[2] Adam Bayley,[1] Katherine Twist,[1] Kurtis Stewart,[1] Katie Ridge,[1] Emma Britneff,[1] Mark Ashworth,[3] Nicole de Zoysa,[1] Jennifer Rundle,[1] Derek Cook,[4] Peter Whincup,[4] Janet Treasure,[5] Paul McCrone,[6] Anne Greenough[7] and Kirsty Winkley[1]

[1]Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[2]Department of Biostatistics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[3]Department of Primary Care and Public Health Sciences, King's College London, London, UK
[4]Population Health Research Institute, St George's, University of London, London, UK
[5]Department of Health Services and Population Research, Institute of Psychiatry, King's College London, London, UK
[6]Section of Eating Disorders, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[7]Division of Asthma, Allergy and Lung Biology, King's College London, Guy's Hospital, London, UK

*Corresponding author khalida.2.ismail@kcl.ac.uk

Background: Motivational interviewing (MI) enhanced with behaviour change techniques (BCTs) and deployed by health trainers targeting multiple risk factors for cardiovascular disease (CVD) may be more effective than interventions targeting a single risk factor.

Objectives: The clinical effectiveness and cost-effectiveness of an enhanced lifestyle motivational interviewing intervention for patients at high risk of CVD in group settings versus individual settings and usual care (UC) in reducing weight and increasing physical activity (PA) were tested.

Design: This was a three-arm, single-blind, parallel randomised controlled trial.

Setting: A total of 135 general practices across all 12 South London Clinical Commissioning Groups were recruited.

Participants: A total of 1742 participants aged 40–74 years with a $\geq$ 20.0% risk of a CVD event in the following 10 years were randomised.

Interventions: The intervention was designed to integrate MI and cognitive–behavioural therapy (CBT), delivered by trained healthy lifestyle facilitators in 10 sessions over 1 year, in group or individual format. The control group received UC.

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Randomisation: Simple randomisation was used with computer-generated randomisation blocks. In each block, 10 participants were randomised to the group, individual or UC arm in a 4 : 3 : 3 ratio. Researchers were blind to the allocation.

Main outcome measures: The primary outcomes are change in weight (kg) from baseline and change in PA (average number of steps per day over 1 week) from baseline at the 24-month follow-up, with an interim follow-up at 12 months. An economic evaluation estimates the relative cost-effectiveness of each intervention. Secondary outcomes include changes in low-density lipoprotein cholesterol and CVD risk score.

Results: The mean age of participants was 69.75 years (standard deviation 4.11 years), 85.5% were male and 89.4% were white. At the 24-month follow-up, the group and individual intervention arms were not more effective than UC in increasing PA [mean 70.05 steps, 95% confidence interval (CI) –288 to 147.9 steps, and mean 7.24 steps, 95% CI –224.01 to 238.5 steps, respectively] or in reducing weight (mean –0.03 kg, 95% CI –0.49 to 0.44 kg, and mean –0.42 kg, 95% CI –0.93 to 0.09 kg, respectively). At the 12-month follow-up, the group and individual intervention arms were not more effective than UC in increasing PA (mean 131.1 steps, 95% CI –85.28 to 347.48 steps, and mean 210.22 steps, 95% CI –19.46 to 439.91 steps, respectively), but there were reductions in weight for the group and individual intervention arms compared with UC (mean –0.52 kg, 95% CI –0.90 to –0.13 kg, and mean –0.55 kg, 95% CI –0.95 to –0.14 kg, respectively). The group intervention arm was not more effective than the individual intervention arm in improving outcomes at either follow-up point. The group and individual interventions were not cost-effective.

Conclusions: Enhanced MI, in group or individual formats, targeted at members of the general population with high CVD risk is not effective in reducing weight or increasing PA compared with UC. Future work should focus on ensuring objective evidence of high competency in BCTs, identifying those with modifiable factors for CVD risk and improving engagement of patients and primary care.

Trial registration: Current Controlled Trials ISRCTN84864870.

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List of supplementary material

Report Supplementary Material 1 Additional data and results for *Chapter 5* (main clinical results of the trial)

Supplementary material can be found on the NIHR Journals Library report project page (www.journalslibrary.nihr.ac.uk/programmes/hta/106203/#/documentation).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

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List of abbreviations

A&E	accident and emergency
AE	adverse event
AOR	adjusted odds ratio
AUDIT	Alcohol Use Disorders Identification Test
BCT	behaviour change technique
BMI	body mass index
CACE	complier average causal effect
CBT	cognitive–behavioural therapy
CCG	Clinical Commissioning Group
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CP	clinical psychologist
CSRI	Client Service Receipt Inventory
CVD	cardiovascular disease
DHSC	Department of Health and Social Care
DMEC	Data Monitoring and Ethics Committee
EQ-5D	EuroQol-5 Dimensions
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
GP	general practitioner
HDL	high-density lipoprotein
HLF	healthy lifestyle facilitator
ICC	intraclass correlation coefficient
ICER	incremental cost-effectiveness ratio
IMD	Index of Multiple Deprivation
IQR	interquartile range
IT	information technology
ITT	intention to treat
LDL	low-density lipoprotein
MCD	minimum clinically significant difference
MI	motivational interviewing
MITI	Motivational Interviewing Treatment Integrity
MOVE IT	enhanced MOtiVational intErviewing InTervention
MVPA	moderate to vigorous physical activity
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PA	physical activity
PHQ-9	Patient Health Questionnaire-9 items
PI	principal investigator
PPI	patient and public involvement
QALY	quality-adjusted life-year
RCT	randomised controlled trial
REC	Research Ethics Committee
SD	standard deviation
SLHIEC	South London Health Innovation and Education Cluster
SMS	short message service
TSC	Trial Steering Committee
UC	usual care

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Plain English summary

People who have a high risk of heart disease can reduce this risk by changing their lifestyles, such as by improving their diets and increasing their physical activity levels. However, there is no good evidence on how best to support people to change and then maintain healthier lifestyles. It is thought that support from others might be helpful. An intervention based on two talking therapies, called motivational interviewing and cognitive–behavioural therapy, to help people make a commitment to living healthier lives was developed. People from the local community with a health-related background were recruited and trained in these skills. Then general practitioners invited patients on their register who were at high risk of heart disease to participate. Those patients who replied and met the study criteria were randomly allocated to one of three arms. Participants received either group- or individual-based intensive lifestyle sessions or usual care. Those who were randomised to the lifestyle course were offered 10 sessions of therapy over 12 months by lifestyle trainers. Two years later, it was found that there were no differences in weight or physical activity levels between the three arms. The lifestyle interventions were not cost-effective compared with usual care. When the possible explanations were studied, it was found that those who could have benefited the most from the therapy (such as those who were most overweight, those from poorer backgrounds and those who were of African Caribbean ethnicity) were less likely to participate. Whether or not the skills of the therapists made a difference could not be properly assessed. Sometimes, patients and their doctors were not sure why they were invited. Future research should focus on people who have lifestyles that can be changed (e.g. more overweight individuals with unhealthy diets), on finding ways of improving the quality of the intervention and on ensuring that patients have more information.

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Scientific summary

Background

Interventions targeting multiple risk factors for cardiovascular disease (CVD) are more effective than interventions targeting a single risk factor. Most lifestyle interventions lead to early improvements but are difficult to maintain longer term. Motivational interviewing (MI) is associated with modest short-term improvements in diet and physical activity (PA) and is a brief intervention. Adding behaviour change techniques (BCTs) using cognitive–behavioural therapy (CBT) skills may support maintenance long term. Deployment of health trainers to deliver lifestyle interventions is a potentially cost-effective method to reduce health inequalities. The importance of peer learning to support lifestyle change compared with individual support to reduce CVD risk is understudied.

Objectives

The overall purpose was to design and evaluate an intensive lifestyle intervention based on psychological theory using BCTs, to reduce the risk of CVD. This would be delivered by a healthy lifestyle facilitator (HLF) employed from the local community.

Primary objectives

To assess whether or not MOVE IT (enhanced MOtiVational intErviewing InTervention), delivered in either (1) a group or (2) an individual format, is more effective than usual care (UC) in reducing weight and increasing PA 24 months later.

Secondary objectives

- To assess whether or not group MOVE IT is more effective than the individual format in reducing weight and increasing PA 24 months later.
- To assess whether or not MOVE IT, delivered in either (1) a group or (2) an individual format, is more effective than UC in reducing low-density lipoprotein (LDL) cholesterol and reducing CVD risk score 24 months later.
- To compare the number of fatal or non-fatal cardiovascular events, and other recorded adverse events (AEs), per treatment allocation.
- Cost-effectiveness: to assess whether or not MOVE IT, delivered in either (1) a group or (2) an individual format, is more cost-effective than UC, in terms of quality-adjusted life-years (QALYs) gained over the 24-month follow-up period.
- To conduct a process evaluation to understand the mechanisms of action of the intervention by assessing mediation, participation bias, competency and fidelity of the intervention, and participant and therapist experience.

Methods

Setting

The study was set in 12 South London Clinical Commissioning Groups aiming to capture socioeconomic and ethnic diversity. General practices with list sizes of > 5000 patients were invited to participate.

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Study criteria

The case definition includes adults aged 40–74 years who screen as positive for high CVD risk and who are not known to have CVD or to be on the diabetes mellitus, kidney, atrial fibrillation or stroke registers. The QRISK®2 score (QResearch, Nottingham, UK) was used to identify those with a CVD risk score of ≥ 20%, indicating the chance of having a fatal or non-fatal cardiovascular event over the next 10 years.

The inclusion criteria were being fluent in conversational English, having permanent residency and planning to stay in the UK for at least three-quarters of the year.

The exclusion criteria were having established CVD; having a pacemaker; being on a register for diabetes mellitus, kidney disease, atrial fibrillation or stroke; having chronic obstructive pulmonary disease; having a disabling neurological disorder; having a severe mental illness; being registered blind; being housebound or resident in a nursing home; not being ambulatory; having more than three falls in the previous year; pregnancy; having advanced cancer; having morbid obesity (body mass index of ≥ 50 kg/m^2); or currently participating in a weight-loss programme.

Sample size

A conservative effect size of 0.25 was selected, which translates to a difference between two arms of 675 steps per day (PA), 1.25 kg of weight and total cholesterol of 0.25 mmol/l at the 24-month follow-up. Clustering effect within the arm was taken into account. A sample size of 1420 participants was needed to detect these differences with a two-tailed alpha of 0.025. Assuming an approximate dropout rate of 20%, 1704 participants (648 in the group intervention arm and 528 each in the individual intervention and UC arms, accounting for the dropout rate) were needed.

Baseline measures

Sociodemographic data, family history of CVD, biomedical data, QRISK2 score, smoking status, alcohol intake, PA [measured objectively using the ActiGraph GT3X accelerometer (ActiGraph, Pensacola, FL, USA) and using self-report scales], diet (measured using a standardised multiple-pass 24-hour dietary recall questionnaire), depressive symptoms (measured using the nine-item Patient Health Questionnaire), illness perceptions, and self-efficacy for changing PA and dietary habits were collected.

Randomisation and allocation concealment

Participant randomisation was conducted by the data manager from an independent clinical trials unit (King's College London) using computer-generated randomisation blocks. In each block, 10 participants were randomised to the group intervention arm, individual intervention arm or UC in a 4 : 3 : 3 ratio. It was not possible to conceal the allocation to the participants or the HLFs post randomisation, but assessors were blind to the allocation for the primary and secondary outcomes.

Planned interventions

Arm 1 received UC only. General practitioners participating in the study were expected to follow their local NHS Health Check pathway for those who have a CVD risk score of ≥ 20%.

Arm 2 received UC and enhanced MI in a group format. The intervention was based on the theory of planned behaviour and delivered using principles and techniques from MI, CBT and social cognitive theory. A training manual, an intervention curriculum and a participant workbook were developed. The intervention consisted of 10 sessions, plus an introductory session, over 12 months. The intensive phase consists of six weekly sessions at the beginning of the first quarter. The maintenance phase consists of four sessions delivered at 3, 6, 9 and 12 months. Abraham and Michie's BCT taxonomy was used to classify the specific techniques.

Arm 3 received UC and enhanced MI in an individual format. This was the same as arm 2 except that the components were delivered individually (one to one).

Measurement of outcomes

The primary outcomes are change in weight (kg) and PA (average number of steps per day assessed by accelerometry) between arms. Secondary outcomes are change in LDL cholesterol and CVD risk score, dietary habits, health beliefs and depression.

The EuroQol-5 Dimensions was used to generate QALYs for use in the economic analyses. Intervention costs were calculated and service use was measured at baseline and at the 12- and 24-month follow-up assessments using an adapted Client Service Receipt Inventory.

Statistical analysis plan

Analysis and reporting was in line with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Primary analyses were on an intention-to-treat basis. The differences in treatment effect between the three arms at 12 and 24 months of this partially nested design were analysed using mixed-effects models with pre-randomisation values as a covariate. Sensitivity analysis included adjusting for potential baseline variables of age, sex, Index of Multiple Deprivation, education, marital status, smoking status and missing data. There are no formal stopping rules.

Health-care costs were compared between the three arms using bootstrapping methods to estimate 95% confidence intervals (CIs) around the mean cost differences.

Process evaluation

The main outcome measures were a quantitative assessment of participation bias (reach), quantitative assessment of the competency (and also fidelity) of the intervention and patient and therapist experiences of the process of change.

Adverse events

Participants receiving the intervention were able to report AEs at any time during the intervention period to the HLF and this information was routinely collected at 12 and 24 months.

Results

This three-arm parallel randomised controlled trial tested the effectiveness of an enhanced MI intervention, delivered by specially trained health trainers (HLFs), in a group format versus an individual format, and versus UC, for reducing weight and increasing PA in adults at high risk (≥ 20.0%) of developing CVD in the next 10 years. The mean age of participants was 69.75 years (4.11 years), 85.5% were male and 89.4% were white, with baseline characteristics being similar between the three arms.

There were only minor and non-significant differences between treatment arms in PA at 12 or 24 months. Participants in the individual intervention arm walked a mean of 210 steps (95% CI –19.5 to 439.9 steps) more at 12 months than UC participants and those in the group intervention arm walked a mean of 131 steps (95% CI –85.3 to 347.5 steps) more at 12 months than UC participants. All differences (including limits of the 95% CIs) were less than the minimum clinically significant difference (MCD) of 675 steps as defined in the study protocol. Similarly, at the 12-month follow-up and using 97.5% CIs, minor and non-significant differences in the mean number of steps between the individual and UC arms (210.22 steps, 97.5% CI –52.44 to 472.89 steps) and the group and UC arms (131.10 steps, 97.5% CI –116.35 to 378.55 steps) were observed.

For weight, there was a small but significant mean difference between the individual and UC arms of –0.55 kg (95% CI –0.95 to –0.14 kg) and between the group and UC arms of –0.52 kg (95% CI –0.90 to –0.13 kg). However, the mean differences (including the 95% CI limits) are below the MCD of 1.25 kg. There was no mean difference between the group and individual intervention arms (–0.03 kg, 95% CI –0.43 to 0.37 kg). At 24 months, no significant mean differences were observed. Similarly, at the 12-month

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follow-up and using 97.5% CIs, minor mean differences between the individual and UC arms (–0.55 kg, 97.5% CI –1.01 to –0.08 kg) and the group and UC arms (–0.52 kg, 97.5% CI –0.96 to –0.08 kg) were observed.

It was found that there was no treatment effect for any of the secondary outcomes at either follow-up point. There were no differences in the number of fatal or non-fatal cardiovascular events and other recorded AEs between the three treatment arms.

The health economic results revealed that there was little difference in terms of service use and costs between the three arms other than those resulting from the interventions themselves. Total service costs over the follow-up period were highest for the individual intervention arm, followed by the group intervention arm, and then followed by the UC arm. Differences were not statistically significant. QALYs were very similar for each arm. The group intervention was dominated by UC, which had lower costs and produced more QALYs. The individual intervention did produce more QALYs than UC but the incremental cost-effectiveness ratio indicated a cost per QALY far in excess of the threshold commonly used by NICE. For this reason, neither form of the intervention was cost-effective. There was much uncertainty around the cost and outcome differences but the conclusion of a lack of cost-effectiveness holds.

Process evaluation results

Mediators

It was found that dietary changes did not mediate any treatment effects on the primary outcomes. Further mediational analyses were not conducted, as there was no change in the primary or secondary outcomes.

Participation bias

It was found there was significant evidence of reduced reach, in that those patients with higher CVD risk, higher levels of deprivation status and of African Caribbean ethnicity were less likely to reply to invitations from their general practice to participate in this trial.

Fidelity analysis

There were significant methodological limitations of conducting a fidelity analysis because of internet outage resulting in the loss of all audio data. From data retrieved from elsewhere, consisting of a highly selected sample, there was evidence that nearly all of the HLFs had sufficient competencies in at least one MI skillset.

Patient experience

The main themes that emerged were (1) perceived benefits of the study (benefits of increased health awareness, positive lifestyle changes and the opportunity to learn from others); (2) factors enhancing behaviour change (continuity of sessions over a longer period and having continuity of the same HLF); and (3) perceived risk of CVD (this was lower than was expected). One further theme that emerged solely for the non-completers was (4) potential barriers to change, such as lack of feedback, and overcoming these barriers.

Therapist experience

The overall view was that the formal training period could have been shortened, with more exposure to training cases, and that the HLFs had not been prepared for the real-world challenges once in the clinical setting. They perceived themselves as competent in the MI approach and BCT. They observed the importance of working with patients towards their goals but there were some common challenges, such as patients not engaging and some of the intervention materials not being deemed age-appropriate. The HLFs felt that support from supervisors, and administrative support, was insufficient but that they could problem-solve by supporting each other.

Conclusions

This study suggests that an intensive lifestyle intervention using BCTs based on MI and CBT is not effective in reducing weight and increasing PA in a population-based sample of people at high risk of CVD. The reason may be that the study did not reach those with modifiable CVD risk factors as this sample consisted of predominantly older males. This suggests that the QRISK2 engine on its own is not suitable for identifying those patients most likely to benefit from intensive lifestyle interventions. Further research should focus on interventions for those subgroups most at risk who are less likely to participate in lifestyle interventions (people of African Caribbean ethnicity or in low socioeconomic settings) or who have a higher proportion of modifiable CVD risk factors (evidence of being overweight or having high lipids levels).

Trial registration

This trial is registered as ISRCTN84864870.

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Chapter 1 Introduction

Epidemiology of cardiovascular disease and its risk factors

Cardiovascular disease (CVD) is the leading cause of mortality, morbidity and disability in the UK and in other developed countries.[1] However, many of the major determinants of CVD are modifiable, including tobacco smoking, a diet high in saturated fat, high low-density lipoprotein (LDL) cholesterol, obesity, a sedentary lifestyle, hypertension and diabetes mellitus.[2–6] Lower educational attainment and lower socioeconomic status are associated with a greater risk of CVD, and this association is strongest for females.[7] The risk of CVD varies markedly between ethnic groups, with a higher rate of ischaemic heart disease in those of South Asian ethnicity and a higher rate of cerebrovascular disease in those of African ethnicity among those living in England and Wales.[8]

Although CVD remains the most common cause of death in developed nations, mortality rates have been falling. Between 1981 and 2000, CVD mortality in the UK fell by 62% in men and 45% in women.[9] Cohort studies and prediction models suggested that a fall in the prevalence of tobacco smoking, a decline in population blood pressure levels and changes in cholesterol levels were important contributors.[9,10] Population-wide changes in modifiable risk factors, such as dietary intake, can bring about substantial benefits and further changes in blood lipids, particularly reductions in levels of non-high-density lipoprotein (HDL) cholesterol.[10] However, limited changes in physical activity (PA) and rising levels of obesity have limited the decline in CVD mortality.[10] Further efforts are therefore needed to bring about positive changes, particularly in diet, obesity and PA.

Cardiovascular risk identification

The NHS in England introduced the Health Check programme in 2009 as part of the Department of Health and Social Care (DHSC)'s long-term vision for the future of public health in England.[11] In offering Health Checks to all those aged 40–74 years without a known diagnosis of CVD, the aim is to prevent heart disease, stroke, diabetes mellitus and kidney disease and to reduce health inequalities. The risk assessment includes collection of demographic data, smoking status, cholesterol level, blood pressure and diabetes mellitus status. An individualised risk management plan is given in accordance with the assessment to support lifestyle changes, such as referral to smoking cessation sessions, exercise prescriptions, lifestyle advice and signposting to local resources.

A lower-than-anticipated coverage of NHS Health Checks has been reported,[12] with regional variations in attendance ranging from 27% to 52%,[12] with greater uptake in patients of older age and in regions of lower deprivation.[13] Reductions in CVD risk have been reported for those attending Health Checks;[14] however, a systematic review of the implementation of Health Checks found no reduction in mortality or morbidity.[15] The programme has attracted criticism owing to a lack of an up-to-date evidence base and Clinical Commissioning Groups (CCGs) lacking the resources to implement them.[16]

Several risk algorithms have been developed and validated to estimate the risk of developing CVD based on known risk factors; these risk algorithms include the Framingham Risk Score,[17] the ASSIGN score,[18] QRISK®[19] and QRISK®2[20] (both QResearch, Nottingham, UK). The latter is now recommended by the National Institute for Health and Care Excellence (NICE) for the identification of people at risk of CVD up to the age of 84 years in England.[21] The QRISK2 algorithm takes into account self-report ethnicity, deprivation and other relevant clinical conditions, and is updated annually to reflect changes in clinical evidence, data recording and population demographics. Once a high CVD risk is ascertained, the primary prevention of CVD is recommended via lifestyle advice and interventions.

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The evidence for increasing physical activity

Physical inactivity increases mortality and the risk of diseases such as CVD and diabetes mellitus.[22] The DHSC advises adults to perform ≥ 30 minutes of at least moderate-intensity PA on ≥ 5 days per week, in ≥ 10-minute bouts, for optimum health benefits.[23] Walking is the most common form of PA in adults and is associated with reductions in CVD and all-cause mortality, and walking pace is a stronger predictor of improved outcomes than walking duration.[24] Walking is promoted as a near-perfect exercise as it has the lowest risk of harm and is now included in UK public health policy.[25,26]

However, the proportion of those achieving PA recommendations is low, particularly when objective measures are used to assess PA. In England, 39% of men and 29% of women self-report achieving the recommended PA levels, but objective assessment of PA using accelerometers in a subsample of the Health Survey for England found that only 5% of men and 4% of women aged 35–64 years achieved the recommended levels.[27]

Systematic reviews and meta-analyses report moderate positive short-term increases in PA following lifestyle interventions, in either a group or an individual format, but findings are limited because most studies used self-report measures.[28,29] Evidence for brief PA interventions suggests improvement in PA in the short term, but there is limited evidence for the long-term impact, cost-effectiveness and deliverability in a primary care setting.[30,31] A review of 32 trials reported that walking interventions led to improvement in a number of cardiovascular risk factors, including blood pressure and weight, but not in lipids.[32] The majority of the reviewed intervention trials recruit motivated volunteers and report low response rates, which may limit the representativeness of observed findings.

The contents of assessed interventions to promote PA differ significantly, but social support and cognitive–behavioural therapy (CBT) strategies, rather than health education alone, are recommended in older adults.[33] The use of pedometers as a method of self-monitoring can increase PA and improve health in the short term.[34] Compared with usual care (UC), the use of pedometers and a brief walking intervention in primary care led to improvements in 12-month PA in a sample of adults not achieving the recommended activity levels at baseline.[35] The intervention was as effective when delivered by post as when delivered by nurses in primary care, suggesting that PA can be improved in physically inactive patients with minimal resources. Details of the components used in trials of interventions to promote PA, including information on the behaviour change techniques (BCTs) used, are recommended to improve implementation and evidence syntheses.[29,36]

The evidence for dietary interventions

Modest beneficial changes to dietary intake, specifically changes to fat, fibre, fruit and vegetable intake, are found following healthy diet interventions in primary care, but there is variability in intervention design and delivery as well as the methodological quality of previous studies.[37] Based on the limited evidence available, estimates of the cost-effectiveness of dietary interventions in primary care suggest that interventions need to be targeted towards the older population at greatest risk of disease to be cost-effective.[38]

A systematic review of randomised controlled trials (RCTs) assessing generic dietary advice for reducing CVD risk found modest beneficial effects on mean total and LDL cholesterol levels and small reductions in blood pressure up to 12 months later, suggesting that dietary advice may contribute to an improved CVD risk profile.[39] However, the longer-term effects of dietary interventions are unknown owing to limited follow-up periods of reviewed studies. Compared with UC, dietary interventions produce modest weight losses that diminish over time.[40] Further work is needed to understand how the modest benefits of dietary interventions may be maintained.

The evidence for motivational interviewing

Motivational interviewing (MI) is a common approach to behaviour change in health care, defined as a collaborative, goal-oriented style of communication with particular emphasis on the language of change.[41] It is designed to strengthen motivation for and commitment to a specific behavioural goal by eliciting and exploring personal reasons for change within an atmosphere of acceptance and compassion.[42] The appeal of MI is that it is brief, can be delivered by a range of health-care providers, has a competency framework and can be applied to a range of health-care settings, with evidence of benefits to health outcomes when compared with other interventions.[43]

Systematic reviews and meta-analyses have demonstrated significant, moderate effects of MI on diet and exercise behaviours,[44] as well as on health outcomes such as reduced weight, cholesterol and blood pressure, although the number of trials is small.[45,46] However, a systematic review of MI used in lifestyle interventions for people at risk or with a diagnosis of CVD found little evidence of the benefits of MI, noting the considerable variability between interventions and the outcomes measured and that few have included a long-term follow-up to assess whether or not any observed benefits are sustained.[47] A 14-month follow-up of diabetic patients who had received a MI lifestyle intervention found no benefits in lifestyle, biomedical or psychological outcomes compared with UC.[48] A RCT with a 12-month postintervention follow-up period found that the benefits of up to five MI sessions delivered over a period of 6 months on walking and cholesterol levels were maintained in a sample of overweight or obese patients, but other CVD risk factor outcomes were not maintained.[49] Effects were stronger for those found to be at higher risk at baseline, suggesting that interventions should target high-risk patients to achieve the best results.

A taxonomy of behaviour change techniques

The limitations of current models of lifestyle interventions, particularly their short-term effects, have led to a search for more sophisticated and targeted behavioural interventions.[50] A Cochrane Database Systematic Review of multiple risk factor interventions for the primary prevention of coronary heart disease observed that techniques based on instruction and information were associated with small improvements in lipid levels and blood pressure, especially when embedded in a theoretical framework related to behaviour change.[51] A systematic review of behavioural interventions found that the techniques most effective in improving diet and PA were based on self-regulatory behaviours, such as goal-setting, self-monitoring, giving feedback, utilising social support and MI.[52] Interventions based on a psychological theory, such as the theory of planned behaviour,[53] were more effective, as were those for high-risk populations. There is less evidence to support the case for any minimum threshold of intensity, mode of delivery, intervention provider and setting;[50–52] therefore, further study is required to understand how the benefits of behavioural interventions on lifestyle and health outcomes can be maintained. Evaluating interventions in the context of a taxonomy of BCTs and an intervention map offers a framework that is easier to teach, test, replicate and translate.[52–54]

In a pilot RCT, a group intervention developed in line with evidence of the most effective BCTs[52] led to reductions in weight, when co-interventions and comorbidities were controlled for, but did not increase PA at the 12-month follow-up in people at high risk of CVD, compared with UC.[55] As this was a pilot RCT, the authors note that the intervention was acceptable to participants and that outcomes could be improved by adapting the intervention accordingly. The effects of the group-based setting were not compared with a one-to-one setting, and there is little evidence in the literature on the differences between group and individual approaches. It has been found that the benefits of group sessions outweigh individual sessions even when it is not preferred by participants,[56] and that group sessions are highly valued by participants.[57] However, it is also reported that at least one individual session is critical to the success of interventions and in ameliorating disengagement in some participants.[57,58] The variability in patient samples involved in these studies, the intervention delivered and the methodology of each study limit the generalisability of the findings.

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By enhancing a MI approach with effective BCTs, the modest effect sizes of each may lead to improvement in outcomes. In people with type 1 diabetes mellitus, four sessions of MI alone was not associated with improved glycaemic control, but four sessions of MI followed by eight sessions of CBT was associated with improved glycaemic control, compared with UC.[59] However, the effects were not maintained after 12 months,[60] and participants stated that MI helped them to become more ready to change their behaviour but that further support was needed to implement the change.[61] The evidence for enhancing MI with CBT is not consistent, as the landmark COMBINE (Combined Pharmacotherapies and Behavioural Interventions for Alcohol Dependence) study did not demonstrate increased abstinence from alcohol in those receiving the psychological intervention.[62]

The role of health trainers

The DHSC recommended the deployment of health trainers into the most deprived areas of the UK in a White Paper published in 2004.[63] A health trainer is employed by the NHS from the local community in which they serve to provide lifestyle advice to those at risk of disease, with the overall aim of the programme being to address health inequalities, an important issue within multi-ethnic and variably deprived settings.[64] The role involves identifying clients from hard-to-reach and disadvantaged groups, providing one-to-one support in identifying potential problems in lifestyles, setting goals, supporting behaviour change and reviewing client progress.[65] The health trainer programme has been found to increase uptake of NHS Health Checks, particularly in men, younger age groups and those from less affluent areas.[66]

A comprehensive review of interventions delivered by lifestyle advisors found little evidence of the benefits of interventions promoting healthy diet and/or increased PA in North American trials; there was no effect on weight and little evidence of improvement in PA levels, but the intervention contents, delivery and goals varied considerably.[67] A review of the available evidence on the NHS health trainer programme thus far indicates positive outcomes and acceptability, but critics argue that the models of service provision are varied, evaluations have included no comparator group and there is a lack of evidence for the maintenance of behaviour change.[68] A health trainer programme for CVD risk reduction in patients with at least one CVD risk factor found significant reductions in CVD risk after 12 months for only those who were identified as being at high risk of CVD (a Framingham Risk Score for CVD of $\geq$ 20.0%) at baseline.[69] The service also led to high levels of behavioural goal achievement and small, but significant, increases in quality of life. However, as this was a service evaluation there was no comparator group and achievement of behavioural goals was self-reported and unrelated to changes in CVD risk. Further work is needed to assess the potential for health trainers to deliver complex behavioural interventions, including the employment of objective outcome measures, the assessment of maintenance of behavioural change and clinical benefits, and comparison of outcomes with a control group.

The case for an enhanced motivational interviewing intervention

At the population level, the potential benefits of reducing weight and increasing PA in those who are at risk of CVD are considerable. Modest, short-term beneficial effects of various behaviour change interventions for the primary prevention of CVD emphasise the need for more complex, targeted interventions and RCTs that assess long-term benefits. MI provides broad appeal for its collaborative patient-centred style, evidence base and deliverability, and by enhancing a MI approach with the specific BCTs that have the strongest evidence, and incorporating techniques designed to enhance maintenance, observed outcomes may be improved. The relative effectiveness of a group intervention versus an individual intervention remains uncertain, but the former offers social support and may be more cost-effective, if it is acceptable to participants. Health trainers may improve the acceptability of interventions to harder-to-reach populations and positive outcomes have been reported in health trainer programmes thus far. The investigation of the

potential for a health trainer to deliver more sophisticated interventions, and for the effects to be compared with UC in a RCT setting, is yet to be undertaken.

The overall aim was to compare the effectiveness of MOVE IT (enhanced MOtiVational intErviewing InTervention), which integrates MI with CBT BCTs, in reducing weight and increasing PA in those at high risk of CVD over 24 months across three arms: (1) enhanced MI in a group format versus (2) in an individual format versus (3) UC. The primary interest was whether or not MOVE IT in a group format was more effective and cost-effective than the individual format or UC because of its potential for social support.

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Chapter 2 Research objectives

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The purpose of this study was to design and evaluate MOVE IT for people at high risk of CVD, to be delivered by a healthy lifestyle facilitator (HLF) employed from the local community and trained in the intervention. We opted for the job title of HLF, rather than health trainer or lifestyle advisor, as this was thought to better reflect the principles of collaborative work underpinning MI.

Primary objective

To assess whether or not MOVE IT delivered in either a (1) group or (2) individual format is more effective than UC in reducing weight (kg) and increasing PA (average number of steps per day assessed via accelerometry) 24 months later.

Secondary objectives

- To assess whether or not group MOVE IT is more effective than the individual format in reducing weight and increasing PA 24 months later.
- To assess whether or not MOVE IT, delivered in either (1) a group format or (2) an individual format, is more effective than UC in reducing LDL cholesterol and in reducing CVD risk score 24 months later.
- To compare the number of fatal or non-fatal cardiovascular events, and other recorded adverse events (AEs), per treatment allocation.
- Cost-effectiveness: to assess whether or not MOVE IT delivered in either (1) a group format or (2) an individual format is more cost-effective than UC, in terms of quality-adjusted life-years (QALYs) gained over the 24-month follow-up period.
- Process evaluation: using mixed methods, we conducted the following –
    - Mediational analysis: to examine whether or not changes in behavioural and psychological factors, such as dietary intake, health beliefs, depressive symptoms and self-efficacy, mediate the association between the intervention and outcomes.
    - Participation bias: to assess whether or not the RCT recruited those it intended, we assessed the participation bias by comparing the sociodemographic characteristics and QRISK2 scores of those who responded to the invitation to participate and those who did not.
    - Fidelity analysis: to assess whether or not MOVE IT was delivered in accordance with the manual and to compare whether or not the levels of competencies among the HLFs were associated with variations in outcomes using thematic contents analysis of sessions.
    - Participant and therapist experience: using qualitative methods, we describe the perceived expectations, benefits, strengths and limitations of the intervention from the patient and intervention provider perspective.

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Chapter 3 Methods

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Trial design

This was a three-arm parallel RCT for individuals at high risk of CVD. The three arms were (1) UC and enhanced MI in a group format, (2) UC and enhanced MI in an individual format and (3) UC. As participants in the group intervention arm, but not in the other two arms, were clustered within groups, this trial has a partially clustered (or nested) design. Interventions were delivered in 10 sessions across a period of 12 months. Participants were followed up at 12 and 24 months from baseline.

Ethics approval and research governance

The Dulwich Research Ethics Committee (REC) (reference number 12/LO/0917) granted ethics approval. The trial was registered with an International Standard Randomised Controlled Trial Number (ISRCTN84864870).

Setting

The study was set in 12 South London CCGs (Bexley, Bromley, Croydon, Greenwich, Kingston, Lambeth, Lewisham, Merton, Richmond, Southwark, Sutton and Wandsworth) that are linked to each other by the South London Health Innovation and Education Cluster (SLHIEC) and inherent in this infrastructure is an efficient method for recruitment. South London has additional advantages: the population is approximately 3 million;[71] nearly one-quarter of the population is African, Caribbean or South Asian; it spans the range of population densities, urbanisation and socioeconomic profiling; the development of a Health Innovation Network in South London can allow for rapid dissemination of research findings; and research resources can be shared across adjacent CCGs during periods of varying workload. General practices with list sizes of > 5000 patients were invited to take part, representing approximately 60% of all practices within the SLHIEC.

Eligibility criteria

The following eligibility criteria were used by general practitioners (GPs) during the initial search for eligible patients. In addition, exclusions were made following patient response to the invitation when the research assistant found that the patient did not meet the following criteria. When in any doubt, the opinion and approval of the patient's GP was sought.

The inclusion criteria were:

- being aged ≥ 40 years and ≤ 74 years
- having a CVD risk score of ≥ 20.0%, calculated using QRISK2, a validated predictive tool for identifying the percentage risk of having a fatal or non-fatal cardiovascular event in the next 10 years[72]
- being fluent in conversational English
- being permanently resident and planning to stay in the UK at least three-quarters of a year.

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The exclusion criteria were:

- having established CVD (including congenital heart disease, angina, myocardial infarction, coronary revascularisation procedures, peripheral artery disease, coronary artery bypass graft or angioplasty)
- having a pacemaker
- being on a register for diabetes mellitus, kidney disease, atrial fibrillation or stroke (either ischaemic or haemorrhagic, including transient ischaemic attacks)
- having chronic obstructive pulmonary disease
- having a disabling neurological disorder
- having a severe mental illness such as psychosis, a learning disability, dementia or cognitive impairment
- being registered blind
- being housebound or resident in a nursing home
- being unable to move about independently or not being ambulatory
- having more than three falls in the previous year
- being pregnant
- having advanced cancer
- being morbidly obese [body mass index (BMI) of > 50 kg/m^2]
- currently participating in a weight-loss programme
- living in the same household as another participant who was already randomised.

Sample size

The power calculation of our main outcome variables is based on the findings of previous research.[34,73] We selected a very conservative effect size of 0.25, expressed as the difference in units of pooled standard deviations (SDs), which translates to an ability to detect differences between two arms of 675 steps per day, 1.25 kg of weight and total cholesterol of 0.25 mmol/l. Our study was powered to detect changes that may be modest at the individual level but that would have an important impact if occurring at the population level.[74]

We took into account clustering effect within the group intervention [intraclass correlation coefficient (ICC) of 0.05] by calculating the optimal sample size in presence of differential clustering effects.[75] A sample size of 1420 participants in total was needed to detect these differences in our primary hypotheses, and a two-tailed alpha of 0.025 was used to take account of multiple comparisons for 'individual versus UC', 'group versus UC' and 'group versus individual'. Assuming an approximate 17% loss to follow-up, a total sample size of 1704 was calculated.

Recruitment

Invitation procedure

Participating general practices screened primary care databases for eligible patients using either EMIS (EMIS Health, Leeds, UK) or Vision (In Practice Systems, London, UK) medical records systems, two of the clinical software programmes most commonly used in UK primary care. Patients who met the eligibility criteria were invited to participate via a standardised letter from their general practice, which was posted along with a participant information sheet. A prepaid return envelope was included for the return of a reply slip, for the patient to express interest to take part, to the main study centre. After the patient had given permission to be contacted, a research assistant made telephone contact with the patient to confirm that they met all eligibility criteria and to schedule a first appointment.

Consenting participants

As participants attended a first appointment with the research assistant, they were asked to read and complete a consent form. Participants were given the opportunity to ask any questions regarding the study or the consent statements.

Calculation of cardiovascular disease risk score

Once consented, data collection began with CVD risk screening; a summary is given in *Table 1*. High CVD risk was calculated using QRISK2, a validated predictive tool for identifying those at a ≥ 20.0% chance of

TABLE 1 Data collection schedule summary

Data collection	Time point						
	CVD risk screening	Baseline	Post baseline and pre randomisation	12 months	Post 12 months[a]	24 months	Post 24 months[a]
Eligibility form	✓						
Consent form	✓						
Sociodemographic characteristics	✓	✓					
Changes to sociodemographic characteristics				✓		✓	
7-day accelerometer data returned			✓		✓		✓
Biomedical data	✓			✓		✓	
Blood results analysed	✓				✓		✓
Record of past interventions		✓		✓		✓	
AUDIT		✓		✓		✓	
Smoking status	✓			✓		✓	
PHQ-9		✓		✓		✓	
GPPAQ		✓	✓	✓	✓	✓	✓
IPAQ		✓	✓	✓	✓	✓	✓
BIPQ		✓		✓		✓	
Self-efficacy scale		✓		✓		✓	
EQ-5D		✓		✓		✓	
24-hour dietary recall		✓	✓	✓	✓	✓	✓
CSRI		✓		✓		✓	
Medication data		✓		✓		✓	
AE questionnaire						✓	
Participant feedback questionnaire						✓	

AUDIT, Alcohol Use Disorders Identification Test; BIPQ, Brief Illness Perception Questionnaire; CSRI, Client Service Receipt Inventory; EQ-5D, EuroQol-5 Dimensions; GPPAQ, General Practice Physical Activity Questionnaire; IPAQ, International Physical Activity Questionnaire; PHQ-9, Patient Health Questionnaire – 9 items.
a Post 12 months and post 24 months refer to accelerometer wear conducted after the respective follow-up appointment.

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having a fatal or non-fatal cardiovascular event over the next 10 years.[72] The measures required for the calculation of QRISK2 score are:

- Age (years).
- Sex.
- Self-report ethnicity.
- Postcode.
- Smoking status – current (if current, how many cigarettes or equivalent per day), ex-smoker or non-smoker. We also collected the number of years smoking for current and ex-smokers.
- Diabetes mellitus status (none, type 1 or type 2).
- Rheumatoid arthritis status.
- Chronic kidney disease status.
- Atrial fibrillation status.
- Hypertensive treatment status.
- Family history of CVD (a first-degree relative diagnosed with angina or heart attack when < 60 years of age).
- Height (cm) and weight (kg) were taken for a calculation of BMI (kg/m^2).
- Systolic blood pressure (mmHg) – the third of three measurements taken.
- The ratio of HDL cholesterol (mmol/l) to total cholesterol (mmol/l).

Postcode data were collected for the calculation of Index of Multiple Deprivation (IMD) 2010 scores[76] (based on lower-layer super output area).[77] The IMD incorporates seven domains: income deprivation, employment deprivation, health deprivation and disability, education deprivation, crime, barriers to housing and services and living environment.

Levels of LDL cholesterol (mmol/l), triglycerides (mmol/l), plasma glucose (mmol/l) and glycated haemoglobin (HbA_{1c}) (mmol/mol) were also taken at this time point, and patients with a HbA_{1c} level of > 47 mmol/mol were subsequently excluded.

Baseline measures

If QRISK2 score was calculated as ≥ 20.0%, participants were subsequently invited to a second appointment for the collection of the following data prior to randomisation.

Sociodemographic data

These were age, sex, self-report ethnicity and family history of CVD collected for the QRISK2 calculation, occupational status, educational attainment, marital status, literacy [using the Rapid Estimate of Adult Literacy in Medicine (REALM)[78]] and place of residence.

Biomedical data

These were weight, height, BMI, blood pressure, plasma glucose level, lipids and HbA_{1c} level, which were collected for the QRISK2 calculation. Data collection included a full-body composition analysis and measurement of waist, hip and arm circumferences.

Weight and body composition were measured in light clothing without shoes on the Class 3 Tanita® SC-240 digital scale (Tanita, Amsterdam, the Netherlands) to 0.1 units for weight (kg), fat range (%), fat mass (kg), fat-free mass (kg), body water (kg), muscle mass (kg), bone mass (kg) and to the nearest 1 unit for visceral fat (level) and impedance (ohm) and basal metabolic rate (kcal). Height was measured to 0.1 cm using stadiometers with the supported stretch stature method and weight and height measurements were used to calculate BMI (kg/m^2).

Waist circumference (cm) was measured horizontally halfway between the lowest rib and the upper prominence of the pelvis using a non-extensible steel tape against the bare abdomen. Hip circumference (cm) was measured at the widest part of the hip. Arm circumference (cm) was taken from the mid-upper

arm, at the midpoint between the top of the shoulder and the point of the elbow. Two measurements were taken for each circumference, with a third taken if the first two measurements differed by > 0.5 cm.

Blood pressure (mmHg/mmHg) and resting heart rate (beats per minute) were measured with digital Omron blood pressure monitors [Omron Healthcare (UK) Ltd, Milton Keynes, UK) using standardised procedures of three readings taken 1 minute apart while seated.

Lifestyle data

These were smoking status collected for QRISK2 calculation, PA, alcohol intake and dietary intake.

Physical activity was measured objectively using the ActiGraph GT3X accelerometer (ActiGraph, Pensacola, FL, USA), a validated tri-axial movement sensor that also records step count.[79] The research assistant explained to the participant how to wear the accelerometer: on a belt over the hip for 7 days, from waking in the morning until going to bed at night and removing only for bathing. Participants were asked to keep a log of activities, including sedentary activity, to assist with the qualitative interpretation of the data. The output from the accelerometer includes number of steps taken and time spent doing PA using standard cut-off points for sedentary activity and light, moderate, vigorous and very vigorous PA. The research assistant ensured that, on the participant returning the accelerometer, it had been worn for ≥ 540 minutes on each of ≥ 5 days, and, if not, the participant was asked to wear the accelerometer for another 7 days. Step count per day and a measurement of PA at an at least moderate level [moderate to vigorous PA (MVPA)] in > 10-minute bouts were extracted from the collected data. Standardised vertical axis cut-off points for PA were used to classify sedentary (0–99 counts per minute), light (100–1951 counts per minute), moderate (1952–5724 counts per minute), vigorous (5725–9498 counts per minute) and very vigorous (≥ 9499 counts per minute) activity, with MVPA equating to ≥ 1952 counts per minute.[80] Self-report PA was also measured using the General Practice Physical Activity Questionnaire and the International Physical Activity Questionnaire[81] at both the baseline appointment and after 1 week of accelerometer wear.

Alcohol intake was measured using the Alcohol Use Disorders Identification Test (AUDIT),[82] which has a range of scores values from 0 to 40. Participants were categorised as abstainers (score 0), low-risk drinkers (score 1–7) or possibly harmful drinkers (score ≥ 8).

Dietary intake was assessed using a standardised multiple-pass 24-hour dietary recall, which provides a more objective and reliable measure of change in intervention studies, at both the baseline appointment with the research assistant and independently after 1 week of accelerometer wear. Research assistants were trained to follow a standardised protocol and ask neutral probing questions to encourage recall of food items, and were taught about different methods of food preparations and brands in different cultures. Portion size was assessed using food photographs to estimate daily calorie intake.[83,84] Dietplan7 software (Forestfield Software Ltd, Horsham, UK) was used for coding the 24-hour recall diaries and deriving nutrient intake. For food not listed in the software's database, we created new food codes and inputted the available nutritional information. If nutritional information was unavailable for an unlisted type of food, we selected the most similar type of food already in the database.

Psychological data

These included depressive symptoms, health beliefs and health state. Depressive symptoms were collected using the Patient Health Questionnaire-9 items (PHQ-9),[85] as depression is associated with worse outcomes in CVD.[86] Each of the nine items are scored from 0 to 3 depending on frequency of occurrence of symptoms, for a score in the range of 0–27. One or two missing items can be substituted with the average score of non-missing items. When there are more than two missing values, the questionnaire is not scored. The questionnaire is followed by a functioning question, and the questionnaire results are provided to the patient's GP.

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The Brief Illness Perception Questionnaire was adapted to be used for 'high risk of CVD' rather than for an illness.[87] The questionnaire asks the participant to rate their beliefs of the causes of their high risk of CVD and how being at high risk affects them. A total score is calculated by summing together all items, with items 3, 4 and 7 reverse-scored, a higher score reflecting a more serious view of the high risk of CVD.

We also used a validated self-efficacy questionnaire for exercise,[88] and adapted this to assess self-efficacy in keeping to a healthy diet as well as psychological processes we were seeking to change through the intervention. Average scores for both exercise and diet self-efficacy were calculated by summing together the score of each answered item and dividing by the number of items answered.

The EuroQol-5 Dimensions (EQ-5D) was used to measure the health state of the participant on the dimensions of mobility, self-care, usual activities, pain or discomfort and anxiety or depression using three levels: no problems, some problems or extreme problems.[89] Participants are asked to rate their current health state within the 0–100 range.

Health-care usage data

Health-care usage was assessed using the Client Service Receipt Inventory (CSRI),[90] which included usage of hospital services, community-based services and support received from friends or relatives for any health reasons for the 12-month period leading up to the appointment. Data on current prescription medication were also collected from medical records.

Randomisation and allocation concealment

Simple randomisation was used, with general practice included as a random factor in the model and emphasis being on more practices and fewer patients per practice. Randomisation of participants was conducted by the data manager from an independent clinical trials unit (King's College London) using computer-generated randomisation blocks with block sizes of 10. In each block, 10 participants were randomised to the group intervention arm, the individual intervention arm or the UC arm in a 4 : 3 : 3 ratio. The unequal allocation ratio ensured that the group intervention arm had approximately 33% more participants, allowing the group sessions to run with enough participants.

As this is a complex psychological intervention, it was not possible to conceal the allocation to the participants or the HLFs post randomisation. Research assistants, statisticians and technicians were blind to the allocation. Participants were reminded in advance of and during the follow-up appointments not to reveal their allocation.

Outcome measures

At the 12- and 24-month follow-up assessments, participants were asked if there had been any change to their sociodemographic status, such as accommodation, relationship status and educational attainment. AE and participant feedback questionnaires were administered. All other baseline measures were repeated at the 12- and 24-month follow-ups (see *Table 1*).

Trial arms and intervention details

Arm 1: usual care and enhanced motivational interviewing in a group format

Theoretical framework

The intervention is based on the theory of planned behaviour for initiation of behaviour change: to change behaviour, people need to form an intention.[53] Intention formation is influenced by three constructs: (1) expected value or positive attitude (people see the value in making the change), (2) subjective norm

(significant others and peers also value the change) and (3) self-efficacy (people believe that they are capable of making the change).

Our intervention taps into all three constructs using principles and techniques from MI,[41] CBT[91] and social cognitive theory[92] (*Figure 1*). MI is used to support participants in forming healthy intentions. MI is a collaborative conversation style for strengthening a person's own motivation for, belief in and commitment to change. Hobbis and Sutton[91] highlight the gap between translating intention into action and illustrate how CBT can be applied to bridge this gap. For this intervention, techniques from CBT are used to support the transition from intention to action, and action to maintenance.[93] Identifying and challenging unhelpful thoughts or thinking styles can promote more positive emotions and behaviours, for example 'When I get breathless after some exercise (bodily sensation), this means that I am going to damage my heart (incorrect cognition)' or 'I have eaten one doughnut (behaviour), I might as well eat the whole bag (all or nothing cognition)'.

Social cognitive theory emphasises the importance of significant others in shaping people's behaviours. The theory of planned behaviour also highlights this aspect through the 'subjective norm' construct. In our intervention, social networks from the participants' own lives and/or group members (in the group intervention arm) were actively utilised to provide practical and emotional support and opportunities for modelling health behaviours during all phases of the intervention.

Intervention development

We conducted a scoping study to identify manuals published in English in the previous 5 years to improve diet and/or PA in the peer-reviewed and grey literature. The aim was to map the quality, contents and cultural diversity of these manuals to inform the content of our intervention. The clinical psychologist (CP) devised the intervention based on this synthesis and on our expertise in developing lifestyle interventions.

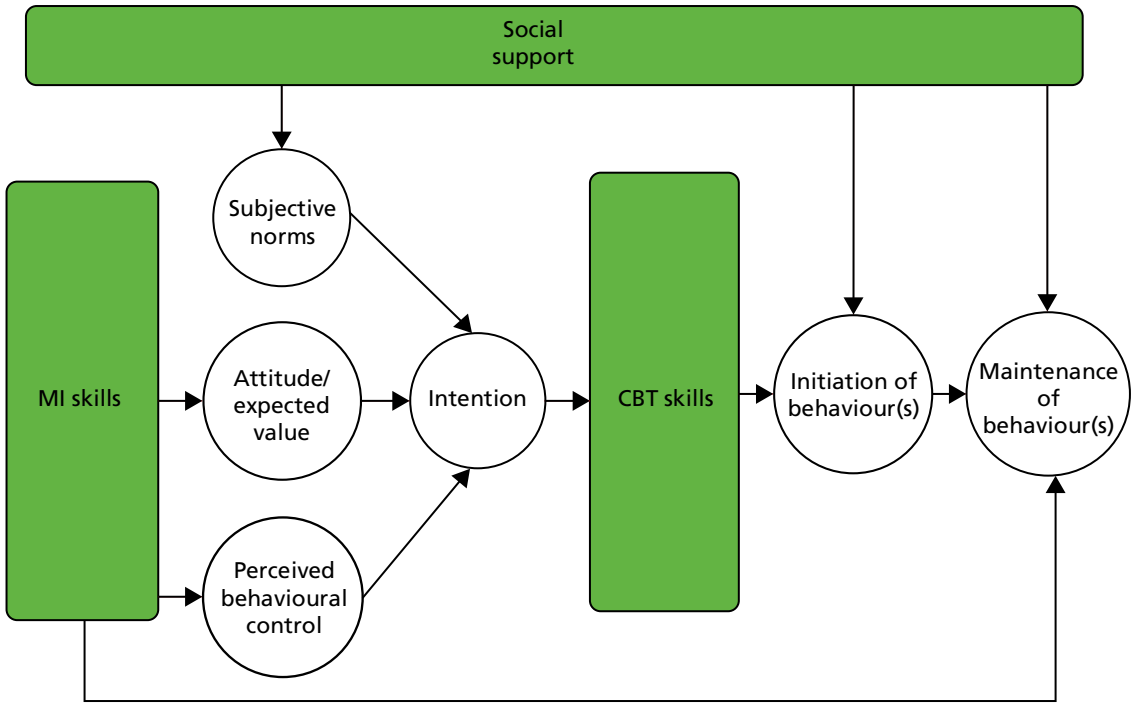

FIGURE 1 Theoretical framework and intervention map. White background indicates psychological process; green background indicates behaviour change technique.

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We used an iterative process to draft the manual and refine it over 2–3 cycles. There are two manualised outputs from the trial:

1. An intervention curriculum. This provides an outline of each intervention session, including key learning points, interactive activities and action planning.
2. A participant workbook. This includes key learning points from each session, action planning worksheets, case studies and a self-monitoring diary for each participant.

The participants also received a pedometer, with guidance on how to use it effectively, and access to online, DVD (digital versatile disc) and paper resources on CVD risk.

The programme consisted of 10 sessions, plus an introductory telephone session, spread over 12 months. The outline of each session is given in *Table 2*. Each participant allocated to a treatment arm had a 'session 0' telephone call as an introduction to the intervention, to receive their intervention packs and to become familiar with the HLF. The intensive phase consisted of six weekly sessions at the beginning of the first quarter. The first three sessions focused on PA and the second three sessions focused on diet. The maintenance phase consisted of four sessions delivered at 3, 6, 9 and 12 months after intervention commencement.

Those randomised to the group intervention arm were encouraged to use peer learning and the peer support environment to facilitate change during both the intensive phase and the maintenance phase. Each group had a maximum of 11 participants and sessions lasted for 120 minutes. The intervention was delivered in local venues, such as community halls and health centres. Between sessions and during follow-up, participants were encouraged to communicate with each other and the HLF. Novel methods and teaching aids were used to supplement the delivery of BCTs, such as visual aids (food labels)/cue cards, exercise demonstrations, video/audio material of patient testimonials, activity-based learning around meal planning, and text/e-mail reminders. HLFs were expected to offer sessions between 08.00 and 21.00, enabling flexibility for participants in full-time work or with carer roles. Cultural and religious awareness was built in to the intervention.

For ease of translation, the key components of the programme have been defined in accordance with Abraham and Michie's BCT taxonomy:[54]

i. provide information on consequences
ii. prompt intention formation
iii. prompt barrier identification
iv. prompt specific goal-setting
v. prompt review of behavioural goals
vi. prompt self-monitoring of behaviour
vii. teach to use prompts or cues
viii. agree on behavioural contract
ix. use follow-up prompts
x. plan social support or social change
xi. relapse prevention
xii. MI.

Training the healthy lifestyle facilitators

The HLFs were employed at NHS band 3 level by King's College Hospital and seconded as appropriate to the CCG. The training programme lasted for 8 weeks and involved a standardised package of training materials. The teaching was a combination of didactic learning, role playing and feedback, group exercises, reading and case study discussion. The HLFs used rating scales for self-monitoring of skill progression during role playing.

TABLE 2 Intervention session contents

Session (time from intervention commencement)	Content
Intensive phase	
Session 0	Focus: introduce the intervention Examples of delivery: structure of the programme, ice breaker, rapport building with HLF, give out pedometers and baseline measures
Session 1: PA (week 1)	Focus: increasing routine activity Examples of delivery: elicit views regarding walking more and sitting less and instruction on use of pedometer. Support individual goal-setting
Session 2: PA (week 2)	Focus: increasing non-routine activity Examples of delivery: elicit views on recommended activity levels and reflect on previously enjoyed exercise and its benefits. Provide information/demonstration/ leaflets regarding local exercise options. Support individual goal-setting
Session 3: PA (week 3)	Focus: to maintain PA changes Examples of delivery: elicit views regarding lapse vs. relapse using case studies. Discuss lapse triggers and strategies to manage them. Support individual relapse-prevention plans (including implementation intentions)
Session 4: diet (week 4)	Focus: increasing health food choices Examples of delivery: elicit views on healthy eating principles. Interactive games regarding healthy snacks. Support individual goal-setting
Session 5: diet (week 5)	Focus: decreasing unhealthy food choices Examples of delivery: elicit views on foods to avoid in excess. Interactive games regarding food labelling and high-fat and high-salt foods. Support individual goal-setting
Session 6: diet (week 6)	Focus: to maintain dietary changes Examples of delivery: elicit views regarding lapse vs. relapse using case studies. Discuss lapse triggers and strategies to manage them. Support individual relapse-prevention plans (including implementation intentions)
Maintenance phase	
Session 7 (3 months)	Focus: review progress and problem-solve setbacks Examples of delivery: highlight positive changes in review session, discuss setbacks and potential ways forward. Support individual relapse-prevention plans
Session 8 (6 months)	Focus: review progress and problem-solve setbacks Examples of delivery: highlight positive changes in review session, discuss setbacks and potential ways forward. Support individual relapse-prevention plans
Session 9 (9 months)	Focus: review progress and problem-solve setbacks Examples of delivery: highlight positive changes in review session, discuss setbacks and potential ways forward. Support individual relapse-prevention plans
Session 10 (12 months)	Focus: review progress and problem-solve setbacks Examples of delivery: highlight positive changes in review session, discuss setbacks and potential ways forward. Support individual relapse-prevention plans

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Each HLF's competency was assessed at the end of training via a knowledge test and through observing delivery of two sessions (one intensive, one maintenance). Four domains were assessed: MI, BCTs, group skills and time management, utilising relevant coding frameworks (see *Appendix 1*). The competency thresholds were adapted for the study,[94–96] requiring each HLF to demonstrate 'moderate proficiency' in each of the domains before delivering the intervention, meaning that they delivered 70% of BCTs, were 90% MI-adherent and scored in the moderate range in at least two of the other Motivational Interviewing Treatment Integrity (MITI)[97] categories, in at least three of the group skills categories and in time management. HLFs that were not competent on initial assessment received further training and reassessment to reach the required competency level.

Healthy lifestyle facilitator competency was monitored throughout the intervention by the CP, who facilitated fortnightly group supervision and weekly e-mail supervision (based on the HLFs completing reflective practice logs). The CP also conducted quality assurance of the intervention administration by regularly reviewing audiotaped sessions (one individual session per month and two group sessions every 8 months) and providing feedback, as needed.

Arm 2: usual care and enhanced motivational interviewing in an individual format

This had the same components as the group intervention arm but was delivered individually (i.e. one to one). There was no opportunity/expectation/guidance for participants to form groups with each other between sessions. The number, content and spread of sessions was the same and sessions lasted for 40 minutes; we reduced the duration of each session to approximately control for attention in the two treatment arms.

Arm 3: usual care only

General practitioners participating in the study were expected to follow their local Health Check pathway for those patients who had a CVD risk score of $\geq 20.0\%$.

Clinical effectiveness

Primary outcomes

The primary outcomes were change in weight (kg) and PA (average number of steps per day) between arms.

Secondary outcomes

Changes in LDL cholesterol and CVD risk score were assessed. The QRISK2 measurement of CVD risk is sensitive to changes in weight, cholesterol level, blood pressure, HbA_{1c} level and smoking status. The number of fatal and non-fatal CVD events and hospital admissions were recorded using an AE questionnaire and by recording hospital services usage using the CSRI. Changes in dietary habits were measured via analysis of dietary recall data. Health beliefs and depression at 12 and 24 months were assessed as measures of mediating processes.

Cost-effectiveness

The main perspective for the economic evaluation is that of the health-care system. The EuroQol-5 Dimensions, three-level version (EQ-5D-3L) is used to generate QALYs for use in economic analyses.[98] Intervention costs were calculated taking into account staff time for delivering the sessions and the unit costs include elements for overheads and oncosts and account for the ratio of direct-to-indirect contact time. We assumed that the clinician would be grade 3 and that the unit cost per hour was £32.40. For the group intervention, the costs are apportioned over the number of attendees, which averaged 5.5. Other service use was measured at baseline, 12 months and 24 months using the CSRI. EQ-5D instruments were developed in the 1980s and have been subsequently adapted for use in around 500 studies. Service costs

were calculated by combining service use data with information on unit costs.[99,100] We had originally planned to explore the cost of lost employment. However, these data were not adequately recorded and so this was omitted.

Process evaluation

The overall aim of the qualitative analysis is to identify and describe factors and processes that affect the delivery, receipt and outcome of the study to aid interpretation and translation of the observed findings. Process data are analysed before outcome data wherever possible to reduce bias in interpretation. The main themes are described in the following sections.

Participation bias

The extent to which the intervention reached out to eligible participants is assessed by (1) the makeup of general practices that agreed and declined to participate, (2) participation biases and (3) attrition biases. We also invited participants who did not complete the intervention to attend a focus group to give feedback on the programme.

Fidelity analysis

We measured adherence and competence of the trained HLF team in delivering the manualised intervention. See *Chapter 8* for a full description.

Processes of change

The HLFs would record if targets were met (not at all, partially or fully) at the beginning of each session as a measure of participant adherence to the intervention. Supervision and interviews with the HLFs were used to assess which BCTs were popular, why and for which lifestyle behaviour. We administered a process questionnaire at the end of the study that required all randomised participants to discuss, in open-ended and standardised structured questions, which techniques they had found most useful, their appraisal of the techniques and their level of satisfaction with the interventions of their allocated arms. We included the UC arm to assess the similarity and differences with the intervention arms as there may have been some overlap. In addition to the questionnaire, we conducted focus groups with a small number of participants to elicit more detailed feedback (see *Chapter 4*).

Statistical analysis

Analysis and reporting is aligned with Consolidated Standards of Reporting Trials (CONSORT) guidelines,[101] with primary analyses being on an intention-to-treat (ITT) basis. A description of the sample will be presented using mean (SD) or count (percentage). The baseline characteristics of those who withdrew and those who did not complete the intervention are compared with those of participants who completed follow-up. Descriptive data also include maximum values, minimum values, medians and interquartile ranges (IQRs) when appropriate. Significance is reported to a two-tailed alpha level of 0.05 as appropriate for comparisons.

The differences in treatment effect between the three arms at 12 and 24 months of this partially nested design are analysed using mixed-effects models, with pre-randomisation values as a covariate.[102] In the linear mixed model, ‘treatment arm’, ‘time’ (as a categorical variable with two levels: 12 and 24 months), the ‘interaction between treatment group and time’, ‘borough’, ‘ethnicity’ and the ‘baseline values’ of the outcome variable are the fixed part of the model. The random parts of the models are ‘general practice’ (participants are nested in practices) and ‘therapy group’. The design of the study is complex because we have a partially clustered cross-classified design. In the previous version of the analysis plan, we planned to account for the partially nested design of ‘therapy group’ in an approach that matches the non-parallel data structure.[103] However, preliminary analyses with blinded data revealed that this complex model of a partially nested, cross-classified design did not converge. Thus, in agreement with the Trial Steering

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Committee (TSC) and Data Monitoring and Ethics Committee (DMEC) (on 6 July 2017), we decided to drop the random effect for therapist from the primary analyses. We are aware that we may underestimate standard errors of treatment effects; however, health intervention therapist effects in similar studies [e.g. the National Institute for Health Research (NIHR)-funded IMPACT[104] and Diabetes-6[105] RCTs] ranged between negligible and small (ICC range 0 to 0.02).

The dependency of the repeated observations of the same participants at 12 and 24 months and the covariance between the residuals within the lowest-level group 'patients' are correlated by using an unstructured covariance pattern model. For the final model, the group difference estimates and associated confidence intervals (CIs) are reported for 12 (for secondary analyses) and 24 months after randomisation.

In a sensitivity analysis, the random effect of borough was replaced by a partially nested random effect for therapist group, as described previously, and results compared.

The described analysis approach provides valid inferences under the assumption that the missing data mechanism can be ignored (missing at random). Sensitivity of results to missing data was further assessed by including covariates predictive of missingness in the analyses model.

The significance level was 2.5% (two-sided) for the two main comparisons of (1) group format versus UC and (2) individual format versus UC. The (secondary) comparison (group format vs. individual format) was assessed on a 5% significance level as our research hypotheses is a null hypothesis of no difference.

The large sample size should have ensured that all possible confounding variables are equally distributed between treatment arms. However, in the sensitivity analysis, we extended the model of the primary analysis by including baseline variables with substantial imbalance, thought to be important in determining outcome. The potential baseline variables were age, sex, IMD, education, marital status and smoking status.

The following further sensitivity analyses were conducted and, for all analyses, changes in predicted treatment outcome differences are presented in the analysis plan – available on the project webpage [see www.journalslibrary.nihr.ac.uk/programmes/hta/106203/#/ (accessed 29 April 2019)].

Sensitivity analysis adjusting for delay in intervention start

Participants allocated to the intervention arms began intervention sessions at different time points relative to randomisation. Therefore, we conducted a sensitivity analysis to include time between randomisation and session 0 of the intervention in the model.

Sensitivity analysis adjusting for unblinding of research assistants at follow-up

Every effort was made to avoid participants revealing their treatment allocation to the research assistant at follow-up. Research assistants recorded whether or not they were unblinded to treatment allocation at either the 12- or the 24-month follow-up. We conducted a sensitivity analysis to include unblinding (yes/no) at follow-up time into the model.

Sensitivity analysis adjusting for insufficient accelerometer wear at baseline

We conducted a sensitivity analysis to include the number of valid days (≥ 540 minutes) of accelerometer wear at baseline in the model.

Sensitivity analysis adjusting for insufficient accelerometer wear at follow-up

We conducted a sensitivity analysis to include the number of valid days (≥ 540 minutes) of accelerometer wear at 12 and 24 months in the model.

Sensitivity analysis adjusting for the recruitment of participants with a body mass index of < 25 kg/m²

Although BMI was not included in the eligibility criteria, an aim of the study was to assess reduction in weight, which would be inappropriate for participants who were of healthy weight or underweight at baseline. We conducted a sensitivity analysis to include a BMI of < 25 kg/m² (yes/no) at baseline in the model.

Sensitivity analysis adjusting for the recruitment of participants with a QRISK2 score of < 20.0%

We conducted a sensitivity analysis to include a QRISK2 score of ≥ 20.0% (yes/no) at baseline in the model.

Dietary intake analysis

When available, the dietary recall diary from the appointment (or, if missing, the later diary) was used. Owing to resource constraints, we a priori elected to analyse a random sample of 602 participants who had a recall diary available for each time point (baseline and 12- and 24-month follow-ups). The random selection of the 602 participants approximately followed the treatment allocation ratio used for the study (4 : 3 : 3). Thus, the arm sizes for the group, individual and UC arms were 240, 180 and 182, respectively.

Food quantities and nutrient intake were checked for outliers, indicating possible data entry errors. Eight nutrients (water, protein, fat, carbohydrates, total sugar, fibre, saturated fat and sodium) and total energy intake (kcal) were selected as variables of interest. These variables were selected based on their relevance to the intervention (i.e. its emphasis on reducing fat/sugar/salt intake and increasing water/fibre intake).

Dietary intake data are summarised at each time point using means (SDs). A linear mixed-effects model, accounting for the partially nested design, tested if there were any effects of treatment arm and time or their interaction on nutrient intake. The model controlled for participant age, sex, ethnicity, IMD 2010 baseline score[76] and if the day recalled was Saturday/Sunday (binary yes/no variable).

A series of mediation analyses were conducted to test if dietary intake measured at the 12-month follow-up mediated the effect of the intervention on the primary outcomes (weight and PA) or QRISK2 score at the 24-month follow-up. Owing to the limitations of the software used – R version 3.4.2 (The R Foundation for Statistical Computing, Vienna, Austria) and the *mediation* package [URL: https://cran.r-project.org/web/packages/mediation/mediation.pdf (accessed 29 April 2019)] – each mediation analysis was constrained to testing differences between two of the treatment arms. Thus, a total of 81 mediation analyses were run [three outcomes × nine diet variables × three treatment arm comparisons (UC vs. group, UC vs. individual, group vs. individual)]. The mediation models controlled for participant age, sex, ethnicity, IMD 2010 baseline score,[76] if the day recalled was Saturday/Sunday (binary yes/no variable), baseline diet and baseline value for the respective outcome.

Although many statistical tests were carried out for the dietary intake analysis, these tests were largely exploratory. Therefore, a two-tailed alpha level of 0.01 was used to determine statistical significance. For the linear mixed-effects models, the fixed-effect estimates for the effects of time and treatment arm and their interaction were bootstrapped with 1000 replicates and their 95% CIs calculated.

Cost-effectiveness analysis

Health-care costs are compared between the two treatment arms and UC. Given that the data are likely to be skewed, we use bootstrapping methods to estimate 95% CIs around the mean cost differences. QALYs are calculated from the EQ-5D-3L administered at baseline, 12 months and 24 months. Area under the curve methods allow us to calculate the QALY gain over the entire follow-up period and QALY differences are analysed controlling for baseline EQ-5D-3L score in a regression model. If costs were higher for one arm than for another and QALY gains are greater, we then constructed an incremental cost-effectiveness ratio (ICER) to show the cost per extra QALY gained. There will be uncertainty around cost and QALY estimates and this is explored using cost-effectiveness planes generated from 1000 bootstrapped resamples of the data for each of the comparisons. Bootstrapping was carried out using the bsample routine in Stata®

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Version 15 (StataCorp LP, College Station, TX, USA), with the strata option used so resampling was by arm. Separate regressions of costs and QALYs were performed on each bootstrapped sample and results retrieved and plotted on the plane. Finally, we generated cost-effectiveness acceptability curves, using the net-benefit approach and bootstrapping, to indicate the probability that any of the three approaches is the most cost-effective for different values placed on a QALY gain. The range of values used is £0 to £100,000. This includes the threshold that is used by the NICE: £20,000–30,000. Sensitivity analyses are carried out around key costs, particularly those for the interventions themselves. We did not impute for missing values and a complete-case analysis was instead conducted.

Ethics issues

The trial was reviewed by the Dulwich REC and has been approved (reference 12/LO/0917). The TSC provided overall trial supervision, supported by the DMEC. The main ethics consideration was to ensure that the risk of harm to participants was minimised and that they were fully informed of any risks. We considered literacy and cultural sensitivities in obtaining informed consent. Other ethics considerations were in ensuring that recruitment and informed consent were handled in such a way that potential participants were not put under pressure to take part and that confidentiality was preserved. All participant data are stored using a unique study identifier and electronic data are password protected.

In general, regular PA is associated with improved health outcomes and this outweighs the risk of sedentary lifestyles. However, sudden increases in vigorous PA for otherwise sedentary individuals is associated with a higher risk of myocardial infarction and of musculoskeletal injuries, which may be pertinent as we were intervening in a group that is at high risk of CVD. However, one of the components of BCTs is to deliver the message that PA should be increased in a graded manner rather than suddenly. The intervention discouraged excessive and/or sudden changes to lifestyles. Weight loss could worsen frailty by accelerating the usual age-related loss of muscle that leads to sarcopenia, but combining weight loss with increased PA can actually ameliorate frailty.[106] Importantly, our intervention is based on healthier diets and gradual and sustainable weight loss as opposed to commercial weight-loss programmes. We considered risks to be small and minimal owing to the exclusion of patients with existing CVD and the use of GP advice when CVD events occurred during participation.

Adverse events

An AE, which may be classed as serious, was defined as any untoward occurrence during the study that should be reported to the REC and TSC within an agreed time frame. A suspected unexpected serious AE was defined as an untoward occurrence that is related to the intervention and is unexpected. Participants had the opportunity to report AEs at 12-month and 24-month study appointments with the research assistant as an AE questionnaire was administered, and participants receiving the intervention were able to report at any time during the intervention period to the HLF. All serious AEs and laboratory values were reviewed by the principal investigator (PI) and a co-investigator, and the PI was responsible for determining causality and reporting any AE related to the study to the REC using the National Research Ethics Service guidance.

The AE questionnaire included asking specifically about physical injuries, which were coded as one of the following types of injury: (1) dislocation, (2) fracture, (3) sprain/strain, (4) other injury to a muscle/tendon or (5) other. Details were also collected of how the injury occurred (context, e.g. if the participant fell) and whether or not any treatment was administered. Cardiovascular events were similarly coded, with the following categories used: (1) angina, (2) atrial fibrillation, (3) coronary heart disease, (4) coronary bypass, (5) myocardial infarction, (6) stroke or transient ischaemic attack, or (7) other. Details were also added and verified by checking the participant's medical records, as necessary.

Obtaining informed consent

General practice staff conducted the searches using our guidance and invited potential participants to give permission for research assistants to contact them. Research assistants invited potential participants to meet them in the general practice, and they were given verbal and written information about the study and at least 1 week to think about participating. We invited patients who were eligible but declined participation to give informed consent for the collection of baseline data to assess the generalisability of our findings.

Withdrawal and stopping rules

Participants were free to withdraw from the study at any time. If the participant withdrew from the intervention, they were asked if they were happy to attend follow-up study appointments and for further data to be collected. If they withdrew from the study without consent to follow-up, no further data were collected.

There were no formal stopping rules. This is because the intervention did not ask participants to do anything more than follow usual GP advice regarding diet and PA. However, the PI evaluated the causality of any AE and advised withdrawal if necessary.

Time period for retention of trial documentation

Copies of patient consent forms were kept for 12 months after the study ended. Personal data that are identifiable by patient name or address will be destroyed 3 years after the study ended. Other trial records will be archived for 7 years after the trial ended before being destroyed.

Patient and public involvement

Before the trial began, we held a focus group with 10 patients from a general practice in Peckham, London. All patients were of African, Caribbean or South Asian ethnicity, first generation migrants and at high risk of CVD, and were distributed equally between sexes. The group understood the rationale of the MOVE IT trial. They recognised that daily stressors affect lifestyle choices and welcomed the chance to talk about this and think differently. The preference was for interventions in an individual format, but they could see the potential benefits of learning from others in a group. Flexible appointment times were stressed as being important, so that the intervention could fit around other activities. The patients felt that it was necessary to provide more information about individual health status rather than just telling patients that they are at high risk of heart disease. They also gave tips on how to recruit; they thought that by getting some patients on board, these patients could network in the local community. These comments were incorporated into the intervention.

We invited this group of patients to form a patient and public involvement (PPI) group to help with the development of study documentation, including the patient information sheet and consent form. A PPI group of five patients was formed, and two members remained involved until the end of the trial. Their role during recruitment involved advertising the trial to both general practices and potential participants, advising on the development of poster and leaflet campaigns to increase public awareness and actively recruiting general practice sites across four of the CCGs. As part of the process evaluation, we sought PPI in the development of topic guides to be used in focus groups to gain feedback from participants who attended the intervention.

Throughout the trial, the trial team updated PPI members with progress and welcomed feedback. The PPI members attended all TSC meetings throughout the trial to gain more detailed feedback and discuss points of interest with the trial manager, PI and co-investigators.

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Chapter 4 Protocol changes

It was necessary to make amendments to the original protocol for a number of unforeseen reasons and to enable improvement in our study methodology and the collected data.

Low uptake of NHS Health Checks

In parallel to setting up MOVE IT, there were increasing numbers of reports and concerns that there was a lower-than-anticipated uptake of NHS Health Checks,[12] with regional variations in attendance ranging from 27% to 52% and greater uptake among older patients and in regions of lower deprivation.[13] We also observed this when we started recruiting and that this was delaying the project.

It was necessary to amend the protocol to detail that the researcher would repeat all CVD risk algorithm measures at screening. General practice searches for eligible participants could therefore not rely on recent Health Check data but instead on estimates of CVD risk using outdated data or inaccurate substitutions for missing data.

This change to the protocol led to the exclusion of a large number of patients whose medical record data suggested that they were at a $\geq 20.0\%$ QRISK2 score but on screening were found to have a score of $< 20.0\%$ (see *Chapter 5*). Consequently, more resources were required to complete recruitment to target (substantial amendment; approved in July 2013).

Change to recruitment and study time frame

As research assistants were screening a larger proportion of ineligible patients who could not be randomised, the recruitment period had to be extended from 12 months to 21 months to allow the target sample size to be reached. This required an increase in funding to support a greater number of research assistants and for a longer period of time to support the recruitment procedures at a greater number of research sites. As a result, the end-of-study follow-ups were also extended by a further 9 months (minor amendment; approved on 16 March 2015).

Research sites

We initially invited general practice sites with list sizes of > 8000 patients. We extended invitations to smaller practices with > 5000 patients, as we required an increase in the number of sites owing to the high number of responses from ineligible patients (substantial amendment; approved in July 2013).

Randomisation

Randomisation was not stratified by general practice and ethnicity as planned, as the numbers of patients in many practices are not large enough to stratify by both factors. Simple randomisation was agreed to be the best method, with surgery included as a random factor in the model, and emphasis being on more practices and fewer patients per practice (substantial amendment; approved in July 2013).

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Research measures

Three blood pressure measures were taken. The third, rather than the mean, systolic blood pressure is used in the QRISK2 algorithm and will be reported in this final report (substantial amendment; approved on 9 June 2015).

Intervention details

The proposed health trainer job title was changed to HLF to better incorporate the MI aspect of the intervention whereby the participant was 'facilitated' rather than 'trained' to make healthy lifestyle changes.

We revised the definition and description of MI to that used in the third edition of the MI textbook.[42] The intervention was updated to include a session 0, which was an introductory session via telephone. The length of group intervention sessions was increased to 120 minutes, rather than 90 minutes, to better match for attention with the individual intervention sessions (substantial amendment; approved in July 2013).

Further to the above changes, we changed the protocol to state that participants would be seen for intervention sessions within 6 months from randomisation, as this time period was not initially stated and the start of intervention sessions was presumed to be immediate. The time period varied greatly owing to (1) large numbers of participants randomised and waiting to be seen, as a result of the accelerated recruitment rate to meet the target, and (2) HLF staff turnover and the subsequent recruitment and training of new staff members, which created delays. When this time period was exceeded, we made every effort to still engage participants in the intervention and continued to follow-up for the ITT analysis (substantial amendment; approved on 9 June 2015).

Additional consent procedures

Participants were given the opportunity to consent to the following additional items post randomisation:

- Once participants had completed all research measures, they were asked if we could link their data to other collaborating research studies in which they also participated (substantial amendment; approved on 21 September 2015).
- We requested access to Hospital Episodes Statistics data,[107] information on all hospital appointments for up to a 6-year period beginning 12 months before participating in the study. However, as this was requested after participants completed the study, we did not gain consent from all participants for this and thus did not seek the Hospital Episodes Statistics data and used only CSRI information on hospital services usage (substantial amendment; approved on 21 September 2015). We requested that participants provided consent to these points remotely, via a letter to and a telephone call with the participant, to avoid unnecessary appointment scheduling (minor amendment; approved on 13 January 2016).
- A small number of participants who received the intervention (group or individual) were randomly selected to be invited to a focus group to provide feedback. They were asked to provide written informed consent to take part in an audiotaped focus group (substantial amendment; approved on 7 March 2016).
- A small number of participants were asked to consent to a video recording or photograph of an intervention session to be used to promote the study for educational and training purposes only (substantial amendment; approved on 7 March 2016).

Elaboration of process evaluation: participation bias

We gained ethics approval to collect anonymised demographic data on all patients who were identified as potentially eligible and invited to participate when screening the GP medical records. These data enabled an estimation of participation bias through examining differences in age, sex, ethnicity, deprivation and QRISK2 score between responders and non-responders to the study invitation (substantial amendment; approved on 8 January 2016).

King's College London network outage and impact on the fidelity analysis

On 18 October 2016, a university-wide information technology (IT) network outage occurred as a result of an infrastructure fault, restricting us from accessing the shared network drives in which various trial data were stored (as per university protocol) and resulting in some data being lost. Although King's College London IT services made an extensive effort to forensically retrieve data from backup sources, all audiotaped intervention session data were lost from the university-managed shared network drive. We estimated this to be almost 2000 hours of intervention delivery. In addition, we lost data from approximately 200 dietary recall diaries (which could be re-inputted from their paper copies) and 95 accelerometry data files from the 24-month follow-up. For the accelerometry data, we asked the 95 participants to rewear the accelerometer; of those, eight declined and consequently had missing data for the PA outcome. We conducted a sensitivity analysis adjusting for participant rewear of the accelerometer.

The loss of the intervention session data was reported to the TSC. At the subsequent TSC meeting (on 6 July 2017), its members recommended that we attempt to recover the session recordings from other sources and conduct the fidelity analysis in accordance with the original plan as closely as possible. Of the data lost, we were able to recover approximately 400 hours from local backups and physical audiotapes, with the co-operation of university IT services and previous HLF staff. This precluded us from conducting the a priori fidelity analysis and randomly selecting coding data from a larger sample of tapes in the database. Instead, we adapted our analysis plan to code and analyse all of the limited, non-random data that were available. Furthermore, we had planned to use the data from the fidelity assessment to determine whether or not the levels of competencies between the HLFs were associated with variations in patient outcomes or mediated the treatment effect. However, the quality of the data recovered precluded us from conducting this analysis as well. See *Chapter 8* for further details on our adapted fidelity analysis.

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Chapter 5 Main clinical results of the trial

Practice recruitment

Of the 310 general practices with a list size of > 5000 in the 12 South London CCGs that were invited, 126 (40.6%) agreed to participate. A further nine (out of 145) general practice sites with a list size of < 5000 were recruited. Therefore, a total of 135 (29.7%) of the 455 general practices within the 12 South London CCGs participated.[108] The list of participating general practices is provided in *Appendix 2*. The distribution of practices participating in each CCG and the differences in IMD 2010 scores of participating and non-participating practices are given in *Table 3*. There were no differences in general practices' participation by IMD 2010 score.

There was greater initial interest from practices in outer-London CCGs, such as Bromley, Bexley and Merton, and feedback from inner-London CCGs, such as Lambeth and Wandsworth, was that practices are overexposed to research studies and may not have the resources to participate. No formal process of collecting reasons for non-participation of general practices was conducted.

TABLE 3 General practice participation in the MOVE IT trial and practice deprivation by each South London CCG

	General practices			
	Participating in MOVE IT		Not participating in MOVE IT	
CCG	*n* (% of all CCG practices)	IMD 2010[76] score, mean (SD)	*n* (% of all CCG practices)	IMD 2010[76] score, mean (SD)
Bromley	22 (48.9)	16.65 (8.93)	23 (51.1)	15.95 (8.42)
Merton	10 (40.0)	16.40 (5.16)	15 (60.0)	15.62 (7.09)
Lewisham	16 (39.0)	30.32 (4.26)	25 (61.0)	31.28 (3.62)
Southwark	16 (36.4)	31.36 (6.45)	28 (63.6)	30.72 (5.71)
Greenwich	14 (33.3)	30.40 (6.89)	28 (66.7)	30.80 (6.59)
Bexley	9 (33.3)	18.19 (9.98)	18 (66.7)	16.94 (4.68)
Sutton	8 (29.6)	13.00 (4.52)	19 (70.4)	17.44 (6.34)
Croydon	14 (24.1)	22.02 (6.52)	44 (75.9)	25.02 (7.97)
Kingston	6 (23.1)	10.42 (1.09)	20 (76.9)	11.39 (1.35)
Lambeth	9 (18.8)	32.19 (4.58)	39 (81.3)	30.84 (3.72)
Richmond	5 (17.2)	9.69 (1.21)	24 (82.8)	11.28 (3.12)
Wandsworth	6 (14.0)	20.67 (6.24)	37 (86.0)	22.60 (5.38)
Total	135 (29.7)	22.42 (9.85)	320 (70.3)	23.14 (9.20)

Data source: Public Health England [https://fingertips.phe.org.uk/profile/general-practice/data (accessed 1 November 2017)].
Note
t-test comparisons of practice deprivation between participating and non-participating practices in each CCG and, overall, were non-significant ($p > 0.05$).

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Participant recruitment and flow through the trial

An electronic search for eligible patients was conducted by each general practice using inclusion and exclusion criteria as Read codes[109] and including a calculated estimate of QRISK2 value based on values for risk factors already recorded. Participants were recruited between June 2013 and February 2015; recruitment per CCG is given in *Table 4*. *Figure 2* is the CONSORT flow diagram showing participant progression through the trial. Screening eligible participants at general practices led to invitations being sent to 17,775 patients. An expression of interest to take part was received from 3515 patients (a response rate of 19.8%). Participation biases (the differences between those who responded to the invitation and those who did not) are explored in *Chapter 7* as part of the process evaluation. Following a brief telephone screening questionnaire, 3183 patients attended for a first appointment with a researcher and provided consent.

In the first appointment, eligibility was assessed using all measures required for QRISK2 score calculation. This led to the exclusion of 1332 participants as they did not meet the eligibility criteria. The main reason for this (1105 participants; 83.0% of all exclusions) was that the QRISK2 score was < 20.0% on recalculation at face-to-face screening. For 71 participants, blood test results indicated a raised HbA_{1c} level (> 47 mmol/mol) and they were directed to their GP for further advice and informed that they were not eligible to participate. Eighty-eight participants did not complete all screening measures and, therefore, QRISK2 could not be calculated (see *Figure 2* for further details of exclusions).

Of the 1851 participants eligible to be randomised, 1742 were randomised and the remaining 109 declined to participate further. Of the randomised sample, 697 were allocated to the group intervention arm, 523 to the individual intervention arm and 522 to the UC arm.

TABLE 4 Participant recruitment by CCG

		Participants, *n* (%)	
CCG	Date first participant recruited to trial	Consented (*N* = 3183)	Randomised (*N* = 1742)
Sutton	7 June 2013	265 (8.3)	151 (8.7)
Merton	10 June 2013	149 (4.7)	79 (4.5)
Kingston	20 June 2013	107 (3.4)	59 (3.4)
Croydon	21 June 2013	472 (14.8)	259 (14.9)
Bexley	3 July 2013	177 (5.6)	103 (5.9)
Richmond	5 July 2013	98 (3.1)	54 (3.1)
Bromley	9 July 2013	885 (27.8)	510 (29.3)
Lewisham	11 September 2013	350 (11.0)	182 (10.4)
Southwark	10 October 2013	134 (4.2)	82 (4.7)
Wandsworth	22 October 2013	139 (4.4)	61 (3.5)
Lambeth	11 November 2013	219 (6.9)	97 (5.6)
Greenwich	6 March 2014	188 (5.9)	105 (6.0)

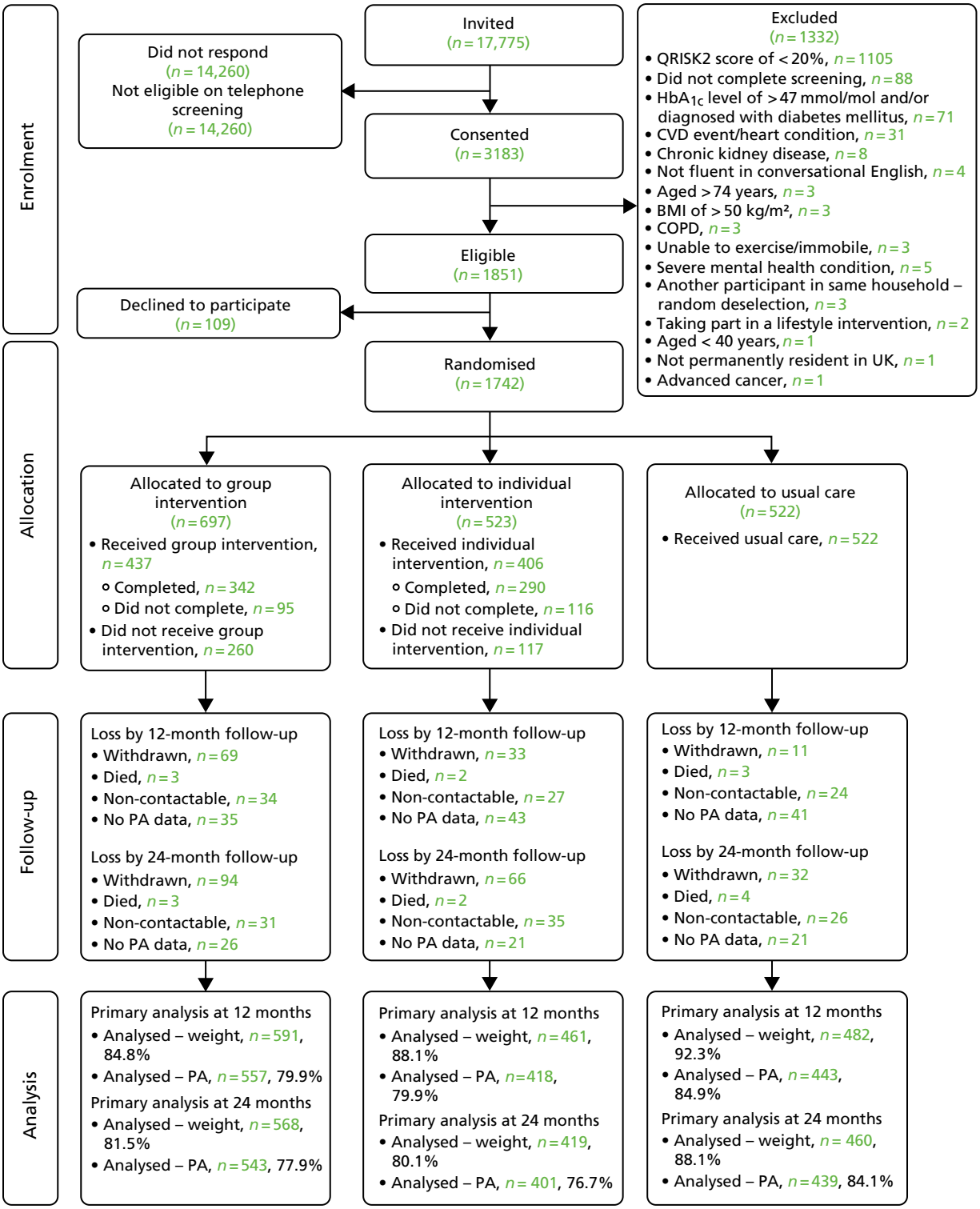

FIGURE 2 The CONSORT flow diagram. COPD, chronic obstructive pulmonary disease. Reproduced from Ismail *et al.*[110] © Author(s) (or their employer(s)) 2019. Re-use permitted under CC BY. Published by BMJ. This is an open access article distributed in accordance with the Creative Commons Attribution 4.0 Unported (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited, a link to the licence is given, and indication of whether changes were made. See: https://creativecommons.org/licenses/by/4.0/.

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Intervention delivery

Sessions received

A summary of the intervention received by participants randomised to either of the intervention arms is presented in *Table 5*. Overall, 665 participants (54.5%) completed the intervention, whereas 344 participants (28.2%) did not start the intervention sessions and 211 participants (17.3%) started but did not complete the intervention sessions. Differences in intervention receipt were significantly different between the intervention arms [$\chi^2(2) = 38.30$; $p < 0.001$].

For all participants who started the intervention ($n = 843$), a mean of 8.2 (SD 3.2) sessions (median 9 sessions, IQR 7–11 sessions), including the introductory session 0, were received. The differences in attendance between treatment arms is given in *Table 6*, with the individual intervention arm attending significantly more sessions ($U = 55{,}388$; $p < 0.001$).

TABLE 5 Summary of intervention receipt

	Participants randomised to intervention arms, *n* (%)		
Intervention received	Group (*N* = 697)	Individual (*N* = 523)	Total (*N* = 1220)
Did not start intervention	260 (37.3)	117 (22.4)	377 (30.9)
Completed intervention	342 (49.1)	290 (55.4)	632 (51.8)
Did not complete intervention			
Attended 1/11 sessions	34 (4.9)	33 (6.3)	67 (5.5)
Attended 2/11 sessions	11 (1.6)	14 (2.7)	25 (2.0)
Attended 3/11 sessions	9 (1.3)	13 (2.5)	22 (1.8)
Attended 4/11 sessions	5 (0.7)	5 (1.0)	10 (0.8)
Attended 5/11 sessions	6 (0.9)	4 (0.8)	10 (0.8)
Attended 6/11 sessions	10 (1.4)	12 (2.3)	22 (1.8)
Attended 7/11 sessions	11 (1.6)	15 (2.9)	26 (2.1)
Attended 8/11 sessions	5 (0.7)	11 (2.1)	16 (1.3)
Attended 9/11 sessions	3 (0.4)	7 (1.3)	10 (0.8)
Attended 10/11 sessions	1 (0.1)	2 (0.4)	3 (0.2)

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TABLE 6 Number of sessions attended, by participants in the intervention arms who started the intervention and by session type

	Intervention arm			
	Group (*n* = 437)		Individual (*n* = 406)	
Sessions	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
All session types				
Including session 0	7.62 (2.96)	8 (6–10)	8.82 (3.38)	11 (8–11)
Excluding session 0	6.72 (2.93)	7 (5–9)	7.83 (3.39)	10 (7–10)
Intensive sessions (*n* = 6)	4.58 (1.80)	5 (4–6)	5.07 (1.93)	6 (6–6)
Maintenance sessions (*n* = 4)	2.14 (1.56)	3 (0–4)	2.76 (1.70)	4 (1–4)

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Participants attended a mean of 4.8 sessions (SD 1.9, median 6, IQR 4–6 sessions) out of the six intensive sessions and a mean of 2.4 sessions (SD 1.7, median 3, IQR 0.5–4 sessions) out of the four maintenance sessions. Participants in the individual intervention arm attended significantly more intensive sessions ($U = 62{,}806$; $p < 0.001$) and maintenance sessions ($U = 65{,}424$; $p < 0.001$) than participants in the group intervention arm. A comparison of attendance between the arms and session types is presented in *Table 6*.

Delays to intervention commencement

There were unexpected delays to intervention commencement, due to factors mentioned in *Chapter 4*. The date of intervention commencement was missing for 35 participants (2.9%). We endeavoured to start the intervention within 6 months of randomisation, and this was possible for 986 out of 1185 participants (83.2%): 561 out of 682 (82.3%) in the group intervention arm and 425 out of 503 (84.5%) in the individual intervention arm. The time between randomisation and the start of the intervention for participants randomised to each intervention arm is illustrated in *Figure 3*.

Participants who were randomised to receive the intervention (in either the group intervention arm or the individual intervention arm) waited a mean of 3.12 ± 2.70 months (minimum 0.16, maximum 15.21, median 2.07, IQR 0.92–4.99 months) from randomisation to their scheduled session 0. The wait time did not differ between the group (3.17 ± 2.78 months; $n = 682$) and individual (3.04 ± 2.59 months; $n = 503$) arms [$t(1120.5) = 0.83$; $p = 0.41$].

Intervention duration

For those participants attending at least one of sessions 1–10 ($n = 782$), we calculated the time between session 0 and the final session attended. Across the intervention arms, the mean time between session 0 and the final session was 330.6 ± 173.8 days [minimum 6, maximum 808, median 366, IQR 231–440 days; dates were unavailable for one participant (0.1%)]. The time between session 0 and the final session was significantly longer in the individual intervention arm (355.6 ± 173.1 days; $n = 373$) than in the group intervention arm (307.8 ± 171.4 days; $n = 408$) [$t(771.4) = 3.87$; $p < 0.001$].

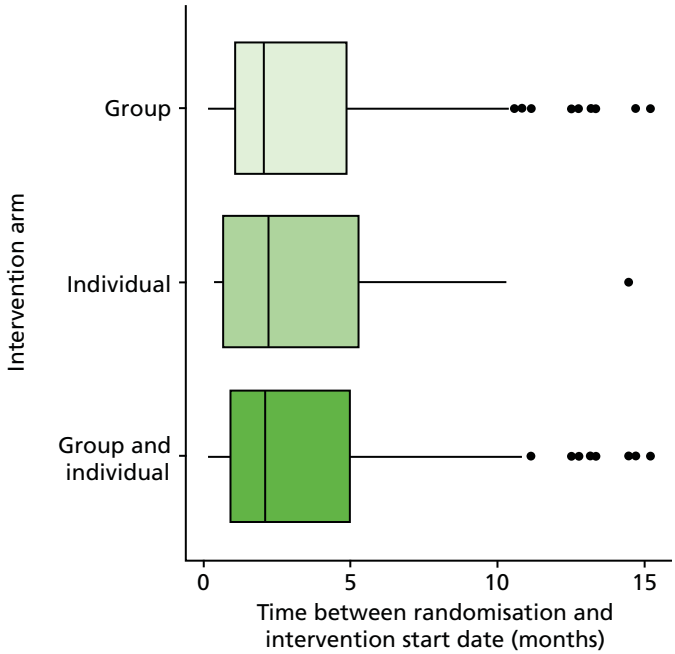

FIGURE 3 Time between randomisation and intervention start date (session 0), by intervention arm. Reproduced from Ismail *et al.*[110] © Author(s) (or their employer(s)) 2019. Re-use permitted under CC BY. Published by BMJ. This is an open access article distributed in accordance with the Creative Commons Attribution 4.0 Unported (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited, a link to the licence is given, and indication of whether changes were made. See: https://creativecommons.org/licenses/by/4.0/.

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Reasons for not starting or not completing the intervention

When participants decided not to start the intervention that they had been randomly allocated to, they were invited to provide a reason for this. When participants decided to stop attending intervention sessions before the course finished, they were also asked for a reason. *Table 7* presents the reasons given for not starting or not completing the intervention by participants in each intervention arm.

We qualitatively explore the reasons for non-completers withdrawing from treatment, as part of the process evaluation, in *Chapter 9*.

Participant adherence to the intervention

After the completion of each intervention session, the HLF was responsible for recording (1) if the participant set a target for that session (yes/no) and (2) if that target was achieved (coded as no/partially/fully). Session 0 was not included as participants were not asked to set goals for that session.

Of the 1220 participants randomised to the intervention arms, 774 (63.44%) had available adherence data. Of those, 407 (58.39% of those randomised) were in the group intervention arm and 367 (70.17% of those randomised) were in the individual intervention arm.

The 774 participants attended a total of 5932 sessions. *Table 8* shows the rate of targets set overall and by intervention arm and *Figure 4* shows the number of targets set at each session. The overall rate of targets set differed significantly between arms [$\chi^2(1) = 6.12$; $p = 0.01$] but the distribution of targets set at each session did not differ significantly between arms [$\chi^2(9) = 16.18$; $p = 0.06$].

For each target set, the HLF also recorded if the participant achieved it; achievement was rated as 'not at all', 'partially' or 'fully'. *Table 9* shows the number of targets achieved by intervention arm and in total; the distribution of targets achieved (excluding missing data) differed significantly between arms [$\chi^2(2) = 7.25$; $p = 0.03$]. *Figure 5* shows the distribution of target achievement at each session number.

TABLE 7 Reason given for not starting or not completing the intervention, by participants in each intervention arm

Reason	Intervention arm, *n* (%)			
	Group		Individual	
	Did not start intervention (*N* = 103)	Did not complete intervention (*N* = 116)	Did not start intervention (*N* = 241)	Did not complete intervention (*N* = 95)
Delay to start of intervention	3 (1.2)	1 (1.1)	2 (1.7)	4 (3.4)
Ill health	12 (4.6)	7 (7.4)	6 (5.1)	10 (8.6)
Location of sessions	24 (9.2)	3 (3.2)	2 (1.7)	1 (0.9)
Multiple reasons	9 (3.5)	3 (3.2)	3 (2.6)	2 (1.7)
No benefit	6 (2.3)	11 (11.6)	5 (4.3)	4 (3.4)
No longer interested	41 (15.8)	13 (13.7)	14 (12.0)	18 (15.5)
Other	7 (2.7)	6 (6.3)	2 (1.7)	6 (5.2)
Too busy	68 (26.2)	20 (21.1)	26 (22.2)	38 (32.8)
Unable to contact	31 (11.9)	13 (13.7)	25 (21.4)	20 (17.2)
Unhappy with intervention design	7 (2.7)	9 (9.5)	6 (5.1)	10 (8.6)
Unknown	52 (20.0)	9 (9.5)	26 (22.2)	3 (2.6)

TABLE 8 Summary of intervention adherence: target set by intervention arm

	Participants randomised to intervention arms with available data, *n* (%)		
Target set?	Group (*N* = 407)	Individual (*N* = 367)	Total (*N* = 774)
Target set at session	2582 (90.66)	2852 (92.48)	5434 (91.60)
No target set	266 (9.34)	232 (7.52)	498 (8.40)
Total	2848	3084	5932

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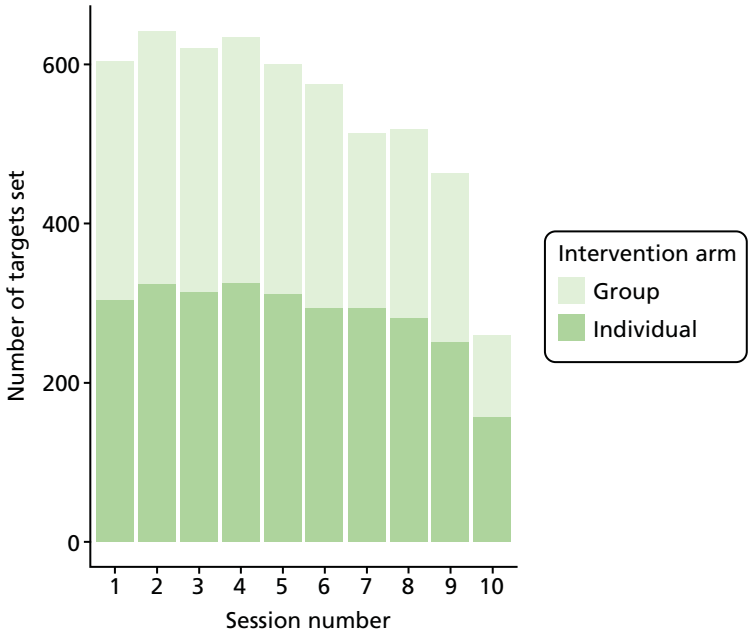

FIGURE 4 Number of targets set, by each session and intervention arm.

TABLE 9 Summary of targets achieved for intervention adherence

	Targets set by trial arm, *n* (%)		
Target achieved?	Group intervention	Individual intervention	Total
Not at all	143 (5.54)	158 (5.54)	301 (5.54)
Partially	664 (25.72)	679 (23.81)	1343 (24.71)
Fully	1376 (53.29)	1676 (58.77)	3052 (56.16)
Missing rating	399 (15.45)	339 (11.89)	738 (13.58)
Total	2582	2852	5434

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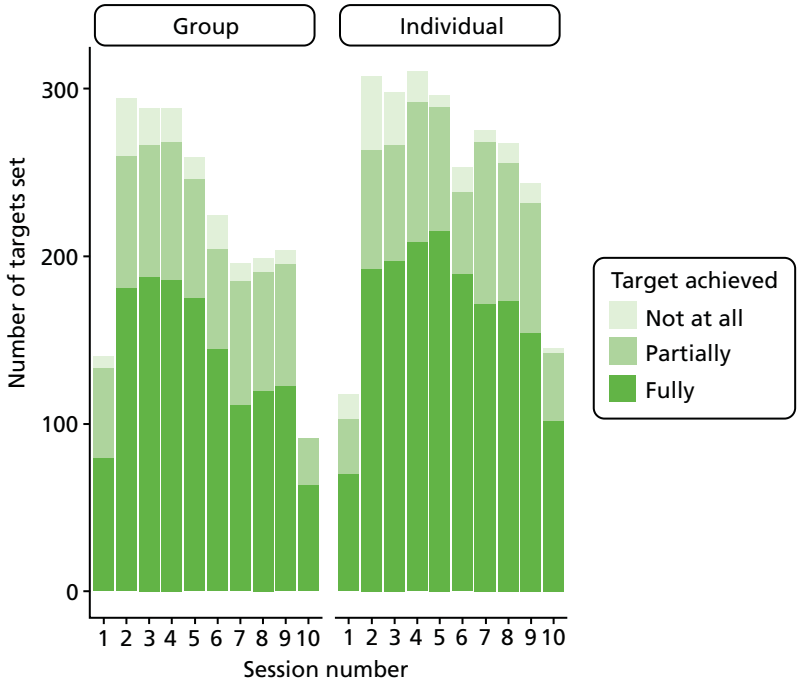

FIGURE 5 Distribution of target achievement, by intervention arm and session number.

The rate of target achievement differed by session number [$\chi^2(18) = 116.99$; $p < 0.0001$]. When looking within each session number, the rate of target achievement differed significantly between the intervention arms at sessions 1 [$\chi^2(2) = 6.40$; $p = 0.04$] and 6 [$\chi^2(2) = 6.75$; $p = 0.03$] only.

Loss to follow-up

Participants were not seen at follow-up for one of three reasons: (1) they had withdrawn from the study, (2) they had died or (3) they were non-contactable at the follow-up due date (attempts were made to contact the participant up to 6 months after the due date). Participants who were randomised to either of the intervention arms but who did not take part in the intervention did not necessarily withdraw from the study, and their data are included at follow-up to carry out the ITT analysis. *Table 10* shows loss to follow-up at both the 12-month follow-up and the 24-month follow-up, with the reasons for withdrawal given. Those who were permanently lost to follow-up at 12 months (withdrawn/died) were not contacted again at 24 months, whereas those who were non-contactable at 12 months were contacted again at 24 months.

We exceeded the target follow-up of 83% of participants required by the original sample size calculation. The total loss to follow-up across all arms of the study at 12 months was 11.8%; it was 15.2% in the group intervention arm, 11.9% in the individual intervention arm and 7.3% in the UC arm. The total loss to follow-up across all arms of the study at 24 months was 16.8%; it was 18.4% in the group intervention arm, 19.7% in the individual intervention arm and 11.9% in the UC arm. Data were collected for 91.6% of all participants for at least one of the 12- and 24-month follow-ups, and for 79.7% of participants at both 12 and 24 months. The differences in loss to follow-up between the treatment arms were significant at the 12-month follow-up [$\chi^2(2) = 17.99$; $p < 0.001$] and the 24-month follow-up [$\chi^2(2) = 13.39$; $p = 0.001$]. Withdrawal rates differed significantly between treatment arms at both the 12-month follow-up [$\chi^2(2) = 27.08$; $p < 0.001$] and the 24-month follow-up [$\chi^2(2) = 15.98$; $p < 0.001$].

TABLE 10 Reasons for loss to follow-up, by arm at 12 and 24 months

Reason	Trial arm, *n* (%)		
	Group intervention	Individual intervention	UC
By 12-month follow-up			
Death	3 (2.8)	2 (3.2)	3 (7.9)
Withdrawal			
Ill health	11 (10.4)	5 (8.1)	3 (7.9)
Too busy	9 (8.5)	10 (16.1)	1 (2.6)
Unhappy with study	6 (5.7)	5 (8.1)	1 (2.6)
No perceived benefit	6 (5.7)	6 (9.7)	1 (2.6)
No longer interested	11 (10.5)	2 (3.2)	3 (7.9)
Relocated	8 (7.5)	2 (3.2)	2 (5.3)
Unknown	18 (17.0)	3 (4.8)	0 (0.0)
Non-contactable	34 (32.1)	27 (43.5)	24 (63.2)
Total	106 (100.0)	62 (100.0)	38 (100.0)
By 24-month follow-up			
Death	3 (2.3)	2 (1.9)	4 (6.5)
Withdrawal			
Ill health	22 (17.2)	13 (12.6)	15 (24.2)
Too busy	12 (9.4)	15 (14.6)	2 (3.2)
Unhappy with study	8 (6.3)	9 (8.7)	5 (8.1)
No perceived benefit	8 (6.3)	8 (7.8)	1 (1.6)
No longer interested	14 (10.9)	10 (9.7)	6 (9.7)
Relocated	12 (9.4)	3 (2.9)	3 (4.8)
Unknown	18 (14.1)	8 (7.8)	0 (0.0)
Non-contactable	31 (24.2)	35 (34.0)	26 (41.9)
Total	128 (100.0)	103 (100.0)	62 (100.0)

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Accelerometer data completeness

The remaining participants did attend follow-up appointments but did not necessarily complete accelerometer wear for the collection of PA outcomes. *Table 11* provides details of the number of accelerometer data collected by trial arm at each time point. The required PA data at baseline was ≥ 5 days of ≥ 540 minutes of accelerometer wear. A number of participants did not wear the accelerometer for the sufficient amount of time at baseline and, therefore, were randomised in error. In the original analysis plan, we stated that we included those with ≥ 4 days of data in the primary analysis to limit exclusions; however, after discussions with the statistician of the TSC (James Carpenter) we included all participants to minimise loss of power and to avoid inducing a potential bias. In agreement with the TSC, for all time points we used the wearable data points if participants wore the accelerometer for at least 1 full day (≥ 540 minutes). Otherwise, the data were considered missing.

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TABLE 11 Summary of accelerometer data collection at each time point and by trial arm

	Time point (*n*)								
	Baseline			12-month follow-up			24-month follow-up[a]		
	Trial arm								
Accelerometer data collection	Group intervention	Individual intervention	UC	Group intervention	Individual intervention	UC	Group intervention	Individual intervention	UC
No accelerometer issued									
Withdrawn	–	–	–	69	33	11	94	66	32
Died	–	–	–	3	2	3	3	2	4
Non-contactable	–	–	–	34	27	24	31	35	26
Number of valid days (≥ 540 minutes) that the accelerometer was worn									
0	9	7	5	35	43	41	26	21	21
1	4	3	4	2	4	3	2	3	5
2	6	7	8	8	5	7	10	8	8
3	12	3	8	12	4	9	11	8	9
4	21	16	25	20	13	17	20	10	18
5	63	46	28	47	31	40	44	40	43
6	122	87	94	115	65	84	98	70	77
7	460	354	350	353	296	283	358	262	279

a Owing to the IT outage, 95 accelerometer data files were lost: 33 in the group intervention arm, 34 in the individual intervention arm and 28 in the UC arm. A total of 87 participants rewore the accelerometer: 29 in the group intervention arm, 31 in the individual intervention arm and 27 in the UC arm.

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The total percentage of missing activity data across all arms of the study at baseline was 0.5% ($n = 8$ participants) and at 12 months it was 18.6%: 20.1% in the group intervention arm, 20.1% in the individual intervention arm and 15.1% in the UC arm [$\chi^2(2) = 5.9$; $p = 0.052$]. The total percentage of missing activity data across all arms of the study at 24 months was 20.6%: 22.1% in the group intervention arm, 23.3% in the individual intervention arm and 15.9% in the UC arm [$\chi^2(2) = 10.4$; $p = 0.006$]. At least one activity follow-up measurement was available for 88.1% of the study participants: 86.4% in the group intervention arm, 86.6% in the individual intervention arm and 91.8% in the UC arm [$\chi^2(2) = 9.7$; $p = 0.008$].

Baseline characteristics

Tables 12 and *13* present the baseline characteristics and secondary outcome measures, respectively, of participants by treatment arm for baseline comparability. [For baseline values of the primary outcomes, see *Tables 16* (PA) and *18* (weight).] A comparison of baseline characteristics between arms did not reveal any major imbalance, including all prespecified variables that may affect primary outcome (age, sex, ethnicity, IMD 2015 score, education status, marital status and smoking status).

TABLE 12 Baseline characteristics of participants, by trial arm

Characteristic	Trial arm			
	Group intervention (*N* = 697)	Individual intervention (*N* = 523)	UC (*N* = 522)	Total (*N* = 1742)
Age (years)				
Mean (SD)	69.59 (4.16)	69.76 (4.11)	69.96 (4.05)	69.75 (4.11)
Median (minimum, maximum)	70.34 (48.94, 75.83)	70.77 (48.27, 75.83)	70.61 (54.02, 75.51)	70.56 (48.27, 75.83)
IQR (lower quartile–upper quartile)	5.24 (67.44–72.68)	5.20 (67.66–72.86)	5.54 (67.6–73.14)	5.33 (67.55–72.88)
Sex, *n* (%)				
Male	593 (85.1)	457 (87.4)	440 (84.3)	1490 (85.5)
Female	104 (14.9)	66 (12.6)	82 (15.7)	252 (14.5)
Ethnicity,[a] *n* (%)				
White	614 (88.1)	471 (90.1)	473 (90.6)	1558 (89.4)
Asian or Asian mixed	75 (10.8)	45 (8.6)	41 (7.9)	161 (9.2)
Black or black mixed	8 (1.1)	7 (1.3)	8 (1.5)	23 (1.3)
Current employment?, *n* (%)				
Yes	166 (23.8)	114 (21.8)	99 (19.0)	379 (21.8)
No	531 (76.2)	409 (78.2)	423 (81.0)	1363 (78.2)
Qualifications, *n* (%)				
No formal qualifications	186 (27.2)	126 (24.4)	122 (23.8)	434 (25.3)
O level/GCSE/CSE/NVQ	188 (27.4)	141 (27.3)	143 (27.9)	472 (27.6)
A level or higher	311 (45.4)	249 (48.3)	247 (48.2)	807 (47.1)
Relationship status, *n* (%)				
Married/cohabiting	521 (74.7)	412 (78.8)	371 (71.1)	1304 (74.9)
Divorced/separated/widowed	100 (14.3)	62 (11.9)	82 (15.7)	244 (14.0)
Single	76 (10.9)	49 (9.4)	69 (13.2)	194 (11.1)

continued

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TABLE 12 Baseline characteristics of participants, by trial arm (*continued*)

Characteristic	Trial arm			
	Group intervention (*N* = 697)	Individual intervention (*N* = 523)	UC (*N* = 522)	Total (*N* = 1742)
IMD 2015 score[111]				
n	695	522	522	1739
Mean (SD)	15.52 (10.75)	16.26 (10.82)	16.43 (11.17)	16.02 (10.90)
IMD 2015 quintile, *n* (%)				
First (least affluent)	63 (9.1)	46 (8.8)	52 (10.0)	161 (9.3)
Second	122 (17.6)	125 (23.9)	108 (20.7)	355 (20.4)
Third	136 (19.6)	88 (16.9)	93 (17.8)	317 (18.2)
Fourth	166 (23.9)	116 (22.2)	124 (23.8)	406 (23.3)
Fifth (most affluent)	208 (29.9)	147 (28.2)	145 (27.8)	500 (28.8)
Smoking status, *n* (%)				
Current smoker	112 (16.1)	75 (14.3)	81 (15.5)	268 (15.4)
Ex-smoker	380 (54.5)	315 (60.2)	290 (55.6)	985 (56.5)
Non-smoker	205 (29.4)	133 (25.4)	151 (28.9)	489 (28.1)
Number of cigarettes per day if current smoker				
Mean (SD)	11.60 (8.36)	11.04 (8.12)	11.15 (9.15)	12.70 (10.88)
Median (minimum, maximum)	10 (0, 50)	10 (1, 45)	9 (1, 40)	10 (0, 100)
IQR (lower quartile–upper quartile)	13 (5–18)	10 (5–15)	14 (4–18)	13 (5–8)
Alcohol intake (AUDIT score), *n* (%)				
Abstainer (0)	73 (10.5)	54 (10.3)	55 (10.5)	182 (10.4)
Low risk (1–7)	506 (72.6)	397 (75.9)	383 (73.4)	1286 (73.8)
Possibly harmful (≥ 8)	118 (16.9)	72 (13.8)	84 (16.1)	274 (15.7)
Depressive symptoms (PHQ-9 score)				
Mean (SD)	2.07 (3.38)	1.98 (3.05)	1.88 (3.13)	1.99 (3.21)
Median (minimum, maximum)	0 (0, 26)	0 (0, 18)	0 (0, 21)	0 (0, 26)
IQR (lower quartile–upper quartile)	3 (0–3)	3 (0–3)	3 (0–3)	3 (0–3)
Severity of depressive symptoms (PHQ-9 score), *n* (%)				
None (0–4)	583 (83.6)	436 (83.4)	448 (85.8)	1467 (84.2)
Mild (5–9)	82 (11.8)	72 (13.8)	51 (9.8)	205 (11.8)
Moderate (10–14)	23 (3.3)	10 (1.9)	18 (3.4)	51 (2.9)
Moderately severe (15–19)	7 (1.0)	5 (1.0)	4 (0.8)	16 (0.9)
Severe (20–27)	2 (0.3)	0 (0.0)	1 (0.2)	3 (0.2)
Rheumatoid arthritis?, *n* (%)				
Yes	17 (2.9)	18 (3.9)	17 (3.5)	52 (3.4)
No	574 (97.1)	443 (96.1)	465 (96.5)	1482 (96.6)
Prescribed blood pressure medication?, *n* (%)				
Yes	385 (55.2)	280 (53.5)	276 (53.0)	941 (54.0)
No	312 (44.8)	243 (46.5)	245 (47.0)	800 (46.0)

TABLE 12 Baseline characteristics of participants, by trial arm (*continued*)

Characteristic	Trial arm: Group intervention (*N* = 697)	Trial arm: Individual intervention (*N* = 523)	Trial arm: UC (*N* = 522)	Total (*N* = 1742)
Family history of angina or myocardial infarction?, *n* (%)				
Yes	192 (27.5)	140 (26.8)	148 (28.4)	480 (27.6)
No	505 (72.5)	383 (73.2)	374 (71.6)	1262 (72.4)

A level, Advanced level; CSE, Certificate of Secondary Education; GCSE, General Certificate of Secondary Education; NVQ, National Vocational Qualification; O level, Ordinary level.
a The number of categories of ethnicity data was reduced from 17 to 3. One participant born in Chile was initially coded as 'other ethnicity' and recoded to 'white ethnicity'.

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TABLE 13 Secondary outcome measures at baseline, by trial arm

Measure	Trial arm: Group intervention	Trial arm: Individual intervention	Trial arm: UC	Total
QRISK2 score (%)				
n	697	523	522	1742
Mean (SD)	24.95 (4.79)	25.26 (5.27)	24.93 (4.81)	25.04 (4.94)
BMI (kg/m^2)				
n	697	523	522	1742
Mean (SD)	28.17 (4.11)	28.31 (4.28)	28.37 (4.59)	28.27 (4.31)
Total cholesterol (mmol/l)				
n	697	522	522	1741
Mean (SD)	5.09 (1)	5.10 (1.01)	5.05 (1.00)	5.08 (1.00)
LDL cholesterol (mmol/l)				
n	694	515	517	1726
Mean (SD)	3.11 (0.85)	3.14 (0.89)	3.07 (0.88)	3.11 (0.87)
Total cholesterol/HDL ratio				
n	697	523	522	1742
Mean (SD)	4.17 (1.13)	4.20 (1.16)	4.11 (1.13)	4.16 (1.14)
HbA_{1c} level (mmol/mol)				
n	684	515	515	1714
Mean (SD)	37.58 (3.39)	37.55 (3.48)	37.56 (3.45)	37.56 (3.43)
Waist circumference (cm)				
n	692	520	520	1732
Mean (SD)	102.37 (11.64)	103.24 (11.83)	102.54 (12.29)	102.68 (11.89)

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Missing data

Patterns of missing follow-up data for the primary outcome were investigated by comparing the baseline data of those with missing primary outcome data at follow-up with the data of those who provided follow-up data. Participants missing 12-month follow-up assessment data walked significantly less at baseline (6509.0 vs. 6802.6 steps per day; $t = 1.99$; $p = 0.048$) and were significantly more likely to be current smokers [23.1% vs. 14.3%; $\chi^2(2) = 13.6$; $p = 0.001$]. Participants with missing 24-month follow-up assessment data walked significantly less at baseline (6376.9 vs. 6833.1 steps per day; $t = -2.78$; $p = 0.006$), were significantly more likely to be current smokers [22.0% vs. 14.4%; $\chi^2(2) = 6.4$; $p = 0.041$], were significantly more likely to have no formal qualifications [23.8% vs. 33.2%; $\chi^2(2) = 12.3$; $p = 0.002$] and were significantly more likely to be more depressed (PHQ-9 score of 1.89 vs. 2.47; $t = 244$; $p = 0.015$). There were no differences between numbers of participants missing at either follow-up point compared with participants who were present in age, sex, weight, BMI, QRISK2 score, relationship status, ethnicity, IMD 2015 score[111] or alcohol consumption (AUDIT score).

Predictors of missing outcome data at 12 and 24 months

In addition to participants missing the follow-up assessment, activity data were also missing because accelerometers were not worn for sufficiently long enough. Two participants did not provide weight data at 24 months. An analysis of missing outcome data was therefore carried out in addition to an analysis of missing attendance data. A stepwise logistic regression with baseline variables, treatment arm, borough at baseline and potential predictors of missing outcome data at 12 and 24 months for weight and PA separately revealed that education, smoking status, PHQ-9 depression score and treatment arm were the most important predictors. However, only little variation was explained by the models (< 2.5% pseudo-R^2). Education, smoking status and PHQ-9 depression score were included as predictors of missingness in a sensitivity analysis to assess potential bias due to missing outcome data.

Table 14 presents a summary of baseline comparisons between participants with missing data at the 12-month follow-up and those who attended the 12-month follow-up. *Table 15* presents a summary of the baseline comparison between participants with missing data at the 24-month follow-up and those who attended the 24-month follow-up.

TABLE 14 Summary of baseline characteristics of participants with present vs. missing primary outcome data at the 12-month follow-up

Missing/present data	Characteristic					
	Weight (kg)	BMI (kg/m^2)	PA (number of steps)	Age (years)	QRISK2 score (%)	PHQ-9 total score
Missing						
Mean	84.07	28.89	6509.043	68.94	24.82	2.63
SD	18.45	5.47	2024.38	4.10	5.67	3.79
n	208	208	202	208	208	208
Present						
Mean	83.61	28.32	6802.64	70.04	24.94	1.82
SD	14.91	4.51	2755.58	4.04	4.74	3.07
n	1534	1534	1532	1534	1534	1534

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TABLE 15 Summary of baseline characteristics of participants with present vs. missing primary outcome data at the 24-month follow-up

Missing/present data	Characteristic					
	Weight (kg)	BMI (kg/m^2)	PA (number of steps)	Age (years)	QRISK2 score (%)	PHQ-9 total score
Missing						
Mean	84.43	28.63	6376.94	69.71	25.32	2.47
SD	15.35	4.44	2497.19	4.32	5.12	3.87
n	293	293	287	293	293	293
Present						
Mean	83.43	28.20	6833.13	69.76	24.98	1.89
SD	15.00	4.28	2752.55	4.07	4.91	3.05
n	1449	1449	1447	1449	1449	1449

Primary outcomes

Physical activity

Table 16 presents a descriptive summary of the PA (number of steps) outcome by trial arm and time point. These are the imputed data (methods are described in *Chapter 3*) and are used for the analyses. *Report Supplementary Material 1* presents a descriptive summary of the original (non-imputed) data, which are simply the means of all wearable data points per participant. We observed a near-perfect correlation (r's > 0.98) between the imputed and original data at each time point. *Figure 6* shows the mean PA level with 95% CIs for each arm over time.

TABLE 16 Summary of PA (number of steps) outcome, by trial arm

Time point	Trial arm			
	Group intervention (*N* = 697)	Individual intervention (*N* = 523)	UC (*N* = 522)	Total (*N* = 1742)
Baseline				
n (%)	695 (99.71)	519 (99.24)	520 (99.62)	1734 (99.54)
Mean (SD)	6692.78 (2702.08)	6820.87 (2747.26)	6781.18 (2708.37)	6757.63 (2716.55)
12-month follow-up				
n (%)	557 (79.91)	418 (79.92)	443 (84.87)	1418 (81.40)
Mean (SD)	6847.70 (2921.44)	6918.56 (2867.54)	6738.29 (2872.85)	6834.41 (2889.32)
24-month follow-up				
n (%)	543 (77.91)	401 (76.67)	439 (84.10)	1383 (79.39)
Mean (SD)	6412.51 (2716.39)	6584.61 (2729.06)	6520.21 (2861.38)	6496.60 (2765.79)

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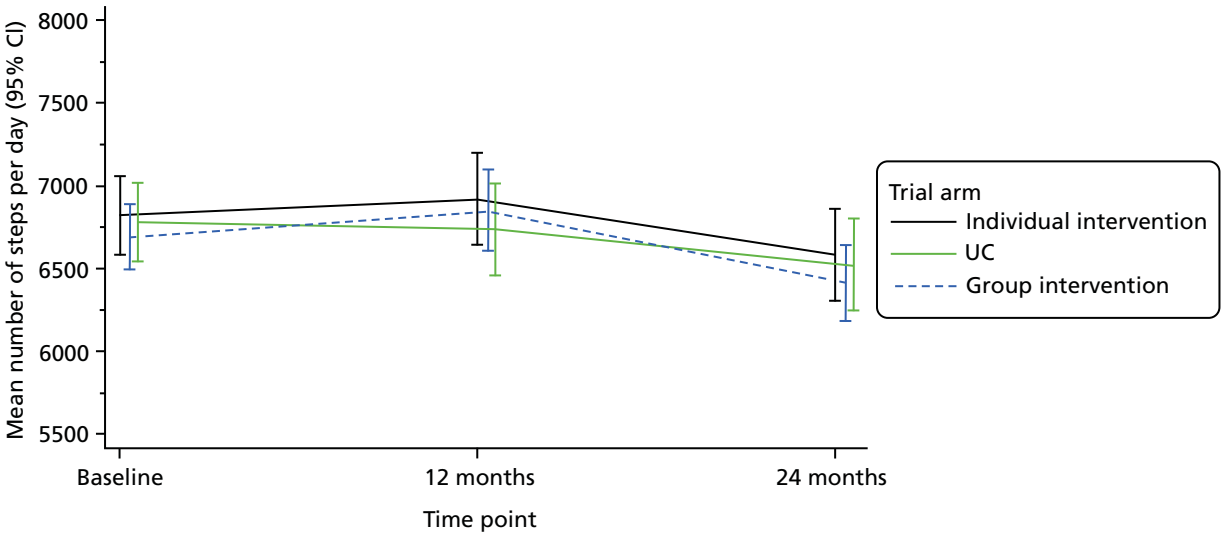

FIGURE 6 Mean PA (number of steps) with 95% CIs for each arm over time. Reproduced from Ismail *et al.*[110]
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Assessment of assumptions

Distribution of data

Box plots, Q–Q plots and histograms reveal unimodal distribution with some positive skew for PA (see *Report Supplementary Material 1*); however, the skew is similar in all groups at all time measurements. Furthermore, there are no serious outliers. This suggests that the distribution of the outcome measures does not seriously violate the assumption of being normally distributed and that there is no need for transformations.

Assessment of standard deviations between arms and over time

Assessments of SDs reveal only small differences in variances between groups or over time for PA (see *Table 16*), which further justifies the use of a mixed-effects model with continuous outcome data assuming a multivariate normal distribution for the analysis of PA.

The primary analysis (mixed-effects regression) of the treatment effect on PA was conducted on 2801 observations. There were 133 unique general practices, with a mean of 21.1 observations for each (range 1–99 observations). There were 1534 unique participant identifiers, with a mean of 1.8 observations for each (range 1–2 observations). *Table 17* presents the pairwise comparisons. The fixed and random-effects outputs can be found in *Report Supplementary Material 1*.

There were only minor and non-significant differences between treatment arms in PA levels at 12 or 24 months. At 12 months, compared with participants in the UC arm, participants in the individual intervention arm walked, on average, 210 steps (95% CI –19.5 to 439.9 steps) more and those in the group intervention arm walked, on average, 131 steps (95% CI –85.3 to 347.5 steps) more. All differences (including limits of the 95% CIs) were less than the minimum clinically significant difference (MCD) of 675 steps as defined in the study protocol. Similarly, at the 12-month follow-up and using 97.5% CIs, we observed minor and non-significant differences between the individual and UC arms (mean difference 210.22 steps, 97.5% CI –52.44 to 472.89 steps) and the group and UC arms (mean difference 131.10 steps, 97.5% CI –116.35 to 378.55 steps).

TABLE 17 Pairwise comparisons of trial arms of treatment effect on the primary outcomes

	Outcome			
	PA (number of steps)		Weight (kg)	
Comparisons	Mean difference (95% CI)	*p*-value	Mean difference (95% CI)	*p*-value
12-month follow-up				
Individual and UC	210.22 (–19.46 to 439.91)	0.073	–0.55 (–0.95 to –0.14)	0.008
Group and UC	131.1 (–85.28 to 347.48)	0.24	–0.52 (–0.90 to –0.13)	0.009
Individual and group	79.12 (–157.73 to 315.98)	0.51	–0.03 (–0.43 to 0.37)	0.89
24-month follow-up				
Individual and UC	7.24 (–224.01 to 238.5)	0.95	–0.42 (–0.93 to 0.09)	0.104
Group and UC	70.05 (–288 to 147.9)	0.53	–0.03 (–0.49 to 0.44)	0.91
Individual and group	77.29 (–153.37 to 307.95)	0.51	–0.40 (–0.86 to 0.07)	0.096

Weight

Table 18 presents a descriptive summary of weight by trial arm and at each time point. *Figure 7* shows the mean weight with 95% CIs for each arm over time.

Assessment of assumptions

Distribution of data

Box plots, Q–Q plots and histograms reveal unimodal distribution with only minor positive skew for weight (see *Report Supplementary Material 1*). The skew is similar in all groups at all time points. Furthermore, there are no serious outliers. This suggests that the distribution of the outcome measures could be treated as normally distributed without the need for transformations.

TABLE 18 Summary of weight (kg) outcome by trial arm

	Trial arm			
Time point	Group intervention (*N* = 697)	Individual intervention (*N* = 523)	UC (*N* = 522)	Total (*N* = 1742)
Baseline				
n (%)	697 (100)	523 (100)	522 (100)	1742 (100)
Weight (kg), mean (SD)	83.15 (14.75)	84.15 (15.35)	83.65 (15.19)	83.60 (15.06)
12-month follow-up				
n (%)	591 (84.79)	461 (88.15)	482 (92.34)	1534 (88.06)
Weight (kg), mean (SD)	82.59 (15.19)	83.31 (15.13)	83.43 (15.07)	83.07 (15.13)
24-month follow-up				
n (%)	568 (81.49)	419 (80.11)	460 (88.12)	1447 (83.07)
Weight (kg), mean (SD)	82.72 (15.29)	82.98 (15.40)	83.10 (15.13)	82.92 (15.26)

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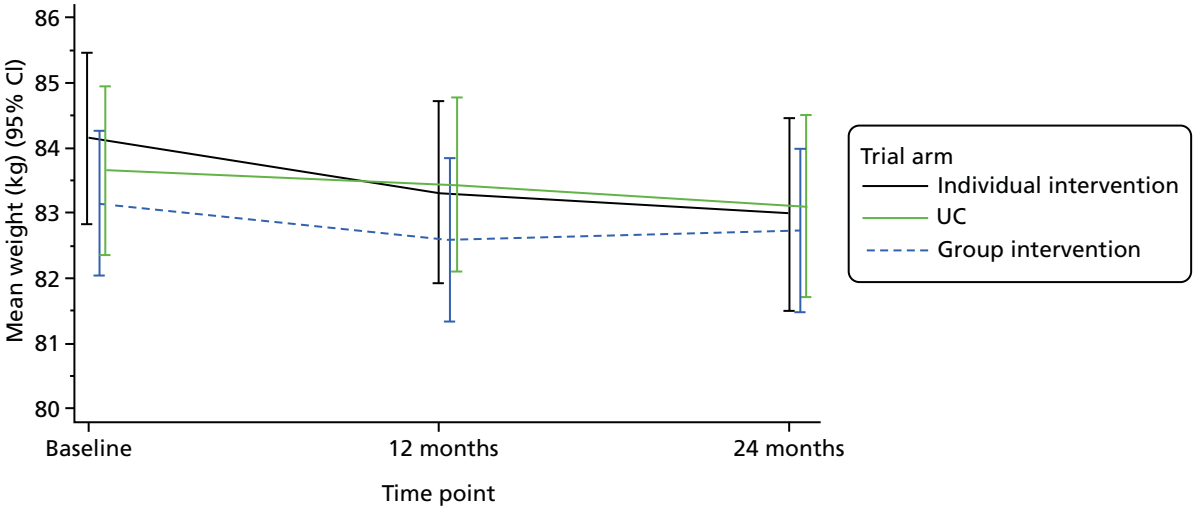

FIGURE 7 Mean weight with 95% CIs for each arm over time. Reproduced from Ismail *et al.*[110] © Author(s) (or their employer(s)) 2019. Re-use permitted under CC BY. Published by BMJ. This is an open access article distributed in accordance with the Creative Commons Attribution 4.0 Unported (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited, a link to the licence is given, and indication of whether changes were made. See: https://creativecommons.org/licenses/by/4.0/.

Assessment of standard deviations between arms and over time

Assessments of SDs reveal little differences in variances between groups or over time for each scale (see *Table 18*), which further justifies the use of a mixed-effects model with continuous outcome data, assuming a multivariate normal distribution for the analysis of weight.

The primary analysis (mixed-effects regression) of the treatment effect on weight was conducted on 2981 observations. There were 133 unique general practices, with a mean of 22.4 observations for each (range 2–104 observations). There were 1595 unique participant identifiers, with a mean of 1.9 observations for each (range 1–2 observations). *Table 17* presents the pairwise comparisons. The fixed and random-effects outputs can be found in *Report Supplementary Material 1*.

There was a small but significant mean difference between the individual and UC arms of –0.55 kg (95% CI –0.95 to –0.14 kg) and between the group and UC arms of –0.52 kg (95% CI –0.90 to –0.13 kg). However, the differences (including the 95% CI limits) are below the MCD of 1.25 kg. There was no difference between the group and individual intervention arms (mean –0.03 kg, 95% CI –0.43 to 0.37 kg). At 24 months, no significant differences were observed. Similarly, at the 12-month follow-up and using 97.5% CIs, we observed minor differences between the individual and UC arms (mean difference –0.55 kg, 97.5% CI –1.01 to –0.08 kg) and the group and UC arms (mean difference –0.52 kg, 97.5% CI –0.96 to –0.08 kg).

Sensitivity analyses

Sensitivity analysis adjusting for imbalances in baseline characteristics

No imbalances were observed in any of the prespecified baseline characteristics; therefore, a sensitivity analysis adjusting for these confounders was not carried out for either of the primary outcomes.

A total of 15 sensitivity analyses were conducted for each (except for two instances; the weight outcome was not completed) of the primary outcomes:

1. adjusting for partially nested random effect for therapist
2. adding therapist and general practice as random factors and exchangeable residual covariance matrix
3. removing potential outliers (removed 12 for weight and 6 for PA)
4. only including patients with a BMI of > 25 kg/m^2 (analysed 2298 for weight and 2159 for PA)
5. adjusting for treatment compliance, including participants in the group or individual intervention arms who attended at least one intervention session (analysed 2427 for weight and 2305 for PA)
6. adjusting for the delay in intervention start (continuous variable)
7. adjusting for the unblinding of the research assistant at each follow-up appointment (binary variable)
8. adjusting for the number of days of accelerometer wear at baseline (> 3 days, binary variable)
9. adjusting for the number of days of accelerometer wear at baseline (> 5 days, binary variable)
10. adjusting for the number of valid days of accelerometer wear at baseline (≥ 540 minutes, continuous variable); not completed for weight
11. adjusting for the number of days of accelerometer wear at each follow-up appointment (continuous variable); not completed for weight
12. adjusting for a BMI score of < 25 kg/m^2 at baseline (binary variable)
13. adjusting for a QRISK2 score ≥ 20.0% at baseline (binary variable)
14. adjusting for predictors (PHQ-9, smoking status and education) of missing outcome data
15. adjusting for accelerometer rewear at the 24-month follow-up (binary variable); not completed for weight.

Report Supplementary Material 1 presents the output of the sensitivity analyses for each of the primary outcomes, following the numbering above. None of the above sensitivity analyses altered our conclusions for either of the primary outcomes.

Complier-average causal effect analysis

Because there is no evidence of any clinically important treatment effect using a per-protocol analysis (analysing only compliers in the treatment arms), we did not conduct a complier-average causal effect (CACE) analysis. A lack of a clear binary adherence variable for all participants also prevented us from undertaking a reliable CACE analysis.

Secondary outcomes

Table 19 presents the pairwise comparison output for each of the secondary outcomes. We did not observe any treatment effects for any of the secondary outcomes at 12 or 24 months.

Dietary intake analysis

Table 20 shows nutrient intake at each time point and by treatment arm. The linear mixed-effects models showed four significant effects for three of the nutrients:

1. fat: a time effect ($b = -3.19$, 95% CI –6.10 to –0.13)
2. fibre: a treatment-arm-by-time interaction effect for the group intervention arm versus the UC arm ($b = 1.20$, 95% CI 0.15 to 2.29)
3. saturated fat: a treatment arm effect for the group intervention arm versus the UC arm ($b = -3.32$, 95% CI –6.37 to –0.11)
4. saturated fat: a time effect ($b = -1.53$, 95% CI –2.89 to –0.20).

The mediation analyses revealed that none of the nutrients of interest at the 12-month follow-up mediated the effect of the intervention on the 24-month outcomes ($p > 0.24$ for all analyses).

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TABLE 19 Pairwise comparisons between trial arms of treatment effect on secondary outcomes

	Secondary outcome									
	QRISK2 score (%)		HbA_{1c} level (%)		LDL cholesterol level (mmol/l)		Diastolic blood pressure (mmHg)		Systolic blood pressure (mmHg)	
Comparison	Mean difference (95% CI)	*p*-value	Mean difference (95% CI)	*p*-value	Mean difference (95% CI)	*p*-value	Mean difference (95% CI)	*p*-value	Mean difference (95% CI)	*p*-value
12-month follow-up										
Individual and UC	–0.14 (–0.68 to 0.40)	0.62	0 (–0.37 to 0.38)	0.99	0 (–0.07 to 0.08)	0.94	–1.12 (–2.25 to 0.01)	0.051	–1.83 (–3.96 to 0.29)	0.09
Group and UC	–0.28 (–0.79 to 0.23)	0.29	0.08 (–0.27 to 0.42)	0.66	0 (–0.07 to 0.07)	0.96	–0.25 (–1.29 to 0.80)	0.64	–0.61 (–2.58 to 1.37)	0.55
Individual and group	0.14 (–0.36 to 0.64)	0.59	–0.08 (–0.41 to 0.25)	0.65	0 (–0.07 to 0.08)	0.90	–0.88 (–1.94 to 0.19)	0.107	–1.23 (–3.23 to 0.77)	0.23
24-month follow-up										
Individual and UC	0.05 (–0.63 to 0.72)	0.89	0.02 (–0.39 to 0.43)	0.91	0.05 (–0.04 to 0.14)	0.26	–1.04 (–2.20 to 0.11)	0.077	–0.29 (–2.37 to 1.79)	0.79
Group and UC	0.01 (–0.68 to 0.71)	0.97	0.19 (–0.20 to 0.59)	0.33	0.07 (–0.01 to 0.15)	0.108	–0.07 (–1.21 to 1.07)	0.90	1.74 (–0.21 to 3.68)	0.08
Individual and group	0.03 (–0.64 to 0.71)	0.92	–0.17 (–0.50 to 0.16)	0.31	–0.02 (–0.10 to 0.07)	0.69	–0.97 (–2.09 to 0.14)	0.088	–2.03 (–4.01 to –0.04)	0.045

TABLE 20 Summary of nutrient intake at each time point, by treatment arm

Nutrient	Trial arm, mean (SD)			
	Group ($n = 240$)	Individual ($n = 180$)	UC ($n = 182$)	Total ($N = 602$)
Baseline				
Water (g)	1685.90 (954.28)	1704.70 (1052.29)	1557.10 (745.33)	1652.58 (929.12)
Protein (g)	73.41 (32.03)	75.00 (31.06)	73.07 (34.89)	73.78 (32.60)
Fat (g)	66.79 (34.40)	70.51 (38.66)	70.01 (35.34)	68.87 (35.98)
Carbohydrates (g)	205.78 (80.57)	211.91 (86.02)	207.46 (79.44)	208.12 (81.81)
Energy (kcal)	1769.25 (619.96)	1828.19 (719.03)	1817.39 (647.54)	1801.43 (658.65)
Total sugar (g)	91.63 (49.53)	94.89 (56.35)	93.04 (50.68)	93.03 (51.93)
Fibre (g)	19.54 (8.54)	19.98 (9.33)	19.90 (8.77)	19.78 (8.84)
Saturated fat (g)	23.84 (14.51)	26.21 (16.99)	25.90 (14.93)	25.17 (15.43)
Sodium (mg)	2116.47 (1273.13)	2386.72 (1393.46)	2195.32 (1347.91)	2221.11 (1335.23)
12-month follow-up				
Water (g)	1583.16 (808.22)	1570.28 (823.08)	1564.05 (756.09)	1573.53 (796.10)
Protein (g)	66.04 (28.50)	68.45 (28.44)	70.27 (26.28)	68.04 (27.84)
Fat (g)	58.55 (29.98)	61.82 (33.61)	66.90 (32.30)	62.05 (31.94)
Carbohydrates (g)	194.66 (76.52)	200.70 (75.91)	211.24 (77.02)	201.48 (76.67)
Energy (kcal)	1607.90 (588.22)	1673.23 (616.31)	1771.27 (567.89)	1676.83 (593.68)
Total sugar (g)	80.70 (46.11)	83.33 (41.69)	88.90 (42.59)	83.96 (43.83)
Fibre (g)	19.95 (9.42)	19.42 (8.83)	20.20 (8.30)	19.87 (8.91)
Saturated fat (g)	20.69 (13.12)	22.81 (15.20)	24.72 (14.23)	22.54 (14.18)
Sodium (mg)	1902.25 (1194.57)	1971.90 (1258.57)	2022.70 (1098.10)	1959.49 (1185.31)
24-month follow-up				
Water (g)	1674.34 (814.50)	1628.88 (867.23)	1640.77 (802.37)	1650.60 (825.89)
Protein (g)	72.35 (31.53)	70.52 (28.10)	71.58 (27.00)	71.57 (29.16)
Fat (g)	66.47 (35.00)	61.53 (29.60)	63.60 (26.40)	64.13 (31.02)
Carbohydrates (g)	206.11 (74.14)	208.88 (80.67)	206.72 (73.29)	207.12 (75.78)
Energy (kcal)	1752.88 (637.69)	1706.12 (562.62)	1726.69 (528.81)	1730.98 (583.60)
Total sugar (g)	84.60 (42.88)	88.93 (47.73)	86.92 (41.14)	86.60 (43.85)
Fibre (g)	21.31 (10.11)	19.59 (9.73)	19.50 (7.73)	20.25 (9.36)
Saturated fat (g)	22.89 (14.54)	23.24 (13.61)	22.84 (11.42)	22.98 (13.36)
Sodium (mg)	1988.68 (1283.79)	2099.04 (1316.58)	2087.66 (1150.50)	2051.61 (1254.18)

Adverse events

A total of 523 AEs were reported between baseline and the 24-month follow-up. Seventy-four participants reported experiencing multiple AEs: nine reported experiencing three AEs and 65 reported experiencing two AEs (*Table 21*). The mean number of AEs experienced by each participant was 0.35 ± 0.58 and the means did not differ across trial arms [$F(2) = 0.68$; $p = 0.51$]. The proportions of AEs by subcategories were largely similar across the trial arms (*Table 22*).

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TABLE 21 Summary of AEs per participant, by trial arm

AE reporting	Trial arm			Chi-squared test output[a]
	Group intervention ($N = 697$)	Individual intervention ($N = 523$)	UC ($N = 522$)	
Any AE reported, *n* (%)	212 (30.4)	151 (28.9)	160 (30.7)	0.48
Multiple AEs, *n* (%)	34 (4.9)	17 (3.3)	23 (4.4)	4.20
2	27 (3.9)	16 (3.1)	22 (4.2)	
3	7 (1.0)	1 (0.2)	1 (0.2)	
Number of AEs per participant, mean (SD)	0.37 (0.61)	0.33 (0.54)	0.35 (0.57)	

a Chi-squared tests, two degrees of freedom, $p > 0.05$.

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TABLE 22 Summary of AEs, by subcategory and trial arm

AE type	Trial arm, *n* (%)			Chi-squared test output[a]
	Group intervention ($N = 697$)	Individual intervention ($N = 523$)	UC ($N = 522$)	
Death	3 (0.4)	2 (0.4)	4 (0.8)	0.92
Any physical injury	109 (15.6)	65 (12.4)	85 (16.3)	3.61
Dislocation	5 (0.7)	1 (0.2)	2 (0.4)	1.96
Fracture	16 (2.3)	8 (1.5)	7 (1.3)	1.82
Sprain/strain	10 (1.4)	17 (3.3)	12 (2.3)	3.90
Muscle/tendon	28 (4.0)	16 (3.1)	25 (4.8)	2.33
Other	48 (6.9)	22 (4.2)	39 (7.5)	5.72
Fall	37 (5.3)	17 (3.3)	23 (4.4)	3.00
Any cardiovascular event	42 (6.0)	22 (4.2)	22 (4.2)	2.94[b]
Angina	2 (0.3)	2 (0.4)	1 (0.2)	0.33
Atrial fibrillation	7 (1.0)	2 (0.4)	4 (0.8)	1.56
CHD	0 (0.0)	0 (0.0)	1 (0.2)	2.34
Coronary bypass	4 (0.6)	0 (0.0)	0 (0.0)	6.01[c]
Myocardial infarction	6 (0.9)	3 (0.6)	3 (0.6)	0.50
Stroke/TIA	9 (1.3)	3 (0.6)	6 (1.1)	1.60
Other	14 (2.0)	15 (2.9)	7 (1.3)	3.03

a Chi-squared test, two degrees of freedom, $p > 0.05$ except where indicated.
b Degrees of freedom = 8.
c $p = 0.0495$.

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The PI and a clinical co-investigator evaluated whether or not any reported AE could have been related to trial participation. It was determined that no AE was the direct consequence of participating in the study or receiving the intervention. There were nine deaths reported during the trial: three participants in the group intervention arm, two participants in the individual intervention arm and four participants in the UC arm. The causes of death, when provided, were not deemed to be related to the intervention.

We asked specifically about CVD events at follow-up, as a number of these would be expected in a sample of participants at high risk of CVD. However, there were no significant differences in numbers of CVD events reported between trial arms [$\chi^2(2) = 2.94$; $p > 0.05$]. We also asked specifically about physical injuries, as this was the only AE with the potential to be linked to an increase in PA as a result of participating. There were also no significant differences in numbers of physical injuries reported between trial arms [$\chi^2(2) = 3.61$; $p > 0.05$].

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Chapter 6 Cost-effectiveness

The number and percentage of participants using specific services or groups of services are shown in *Table 23*. In the 12-month period prior to baseline assessment, the use of all services was very similar between the three treatment arms. There were relatively few people attending accident and emergency (A&E) or day hospitals or being admitted as inpatients. About half of the participants in each arm had outpatient contacts and nearly every participant had community contacts. This was largely due to GP visits.

In the 12 months prior to the 12-month follow-up, around two-thirds of the group intervention arm and three-quarters of the individual intervention arm received the relevant intervention. Numbers of visits to A&E and outpatient attendances had increased slightly from baseline but there were no clear differences between treatment arms. These patterns were again observed in the 12-month period prior to the second follow-up, although there was again a slight increase in the proportions having outpatient attendances.

For those with specific service contacts, the average number of contacts is shown in *Table 24*. At baseline, community services were used more intensely than other services. The inpatient contacts refer to the number of days in hospital. It can be seen that there are no major differences between arms. The data for the 1-year follow-up show that the individual intervention arm had slightly more intervention contacts than the group intervention arm. Those admitted to hospital from the individual intervention arm had more days in hospital than the other two arms. There were no clear differences between arms in the period up to the 24-month follow-up.

Service costs (including zero costs for non-users) were similar for inpatient care, outpatient attendances and community contacts (*Table 25*). Costs of services did not differ markedly between arms, although inpatient costs were somewhat higher for the individual intervention arm at the 12-month follow-up and lower at the 24-month follow-up. The intervention cost was highest for those in the individual intervention arm.

Compared with the UC arm, the total costs at baseline were, on average, £151 more for the group intervention arm (95% CI –£27 to £328) and £55 more for the individual intervention arm (95% CI –£96 to £203). The group intervention arm costs were, on average, £95 (95% CI –£93 to £299) more than those for the individual intervention arm. After controlling for baseline in a regression model, the total costs in the 12-month period prior to the first follow-up were, on average, £89 (95% CI –£274 to £390) more for the group intervention arm than for the UC arm and £409 (95% CI –£171 to £1133) more for the individual intervention arm than the UC arm. The individual intervention arm costs were, on average, £320 (95% CI –£170 to £1133) more than those for the UC arm. By the second follow-up, and again controlling for baseline, the mean costs for the group intervention arm were £82 (95% CI –£93 to £263) more than those for UC and £39 (95% CI –£108 to £188) more for UC than for the individual intervention arm. Costs were £121 (95% CI –£37 to £309) more for the group intervention arm than for the individual intervention arm.

Mean total costs over the whole 24-month follow-up period with year 2 costs discounted by 3.5% were £2071 (SD £3363) for the group intervention arm, £2230 (SD £7645) for the individual intervention arm and £1852 (SD £3726) for the UC arm. Compared with UC and controlling for baseline, the group intervention arm had costs that were, on average, £172 higher (95% CI –£237 to £599) and the individual intervention arm had costs that were £352 higher (95% CI –£309 to £1271). For cases in which both cost and QALY data were available, the group intervention arm had incremental costs of £173 compared with the UC arm and the individual intervention arm had incremental costs of £356 compared with the UC arm. These are the incremental costs subsequently used in the ICERs.

Mean EQ-5D tariff scores were similar for each arm and did not change markedly over time (*Table 26*). Controlling for baseline utility and compared with the UC arm, the group intervention arm had 0.0150 fewer QALYs (95% CI –0.0388 to 0.0088 QALYs) and the individual intervention arm had 0.0039 more

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TABLE 23 Number of participants using services in the 12 months prior to baseline and at each follow-up

	Time point, *n* (%)								
	Baseline			12-month follow-up			24-month follow-up		
	Trial arm			Trial arm			Trial arm		
Service	Group intervention (*N* = 697)	Individual intervention (*N* = 523)	UC (*N* = 522)	Group intervention (*N* = 597)	Individual intervention (*N* = 466)	UC (*N* = 493)	Group intervention (*N* = 570)	Individual intervention (*N* = 422)	UC (*N* = 459)
Intervention	0 (0)	0 (0)	0 (0)	437 (63)	406 (78)	0 (0)	0 (0)	0 (0)	0 (0)
A&E	59 (8)	43 (8)	40 (8)	82 (14)	54 (12)	58 (12)	80 (14)	67 (16)	64 (14)
Day hospital	55 (8)	42 (8)	42 (8)	40 (7)	36 (8)	30 (6)	26 (5)	18 (4)	12 (3)
Inpatient	43 (6)	31 (6)	20 (4)	47 (8)	27 (6)	31 (6)	37 (6)	24 (6)	29 (6)
Outpatient	355 (51)	268 (51)	266 (51)	346 (58)	280 (60)	301 (61)	383 (67)	272 (65)	302 (66)
Community	667 (96)	502 (96)	503 (96)	588 (98)	461 (99)	489 (99)	564 (99)	412 (98)	449 (98)

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TABLE 24 Mean number of contacts, by those using services in the 12 months prior to baseline and at each follow-up

	Time point, mean (SD)								
	Baseline			12-month follow-up			24-month follow-up		
	Trial arm			Trial arm			Trial arm		
Service	Group intervention ($n = 697$)	Individual intervention ($n = 523$)	UC ($n = 522$)	Group intervention ($n = 597$)	Individual intervention ($n = 466$)	UC ($n = 493$)	Group intervention ($n = 570$)	Individual intervention ($n = 422$)	UC ($n = 459$)
Intervention	–	–	–	7.6 (3.0)	8.8 (3.4)	–	–	–	–
A&E	1.5 (1.6)	1.3 (0.6)	1.3 (0.7)	1.5 (1.4)	1.3 (1.1)	1.5 (1.0)	1.8 (3.3)	1.3 (0.8)	1.6 (1.7)
Day hospital	3.4 (4.1)	1.8 (2.3)	2.4 (2.0)	1.8 (1.4)	1.7 (1.9)	1.6 (1.2)	1.5 (1.0)	1.7 (1.5)	1.0 (0.0)
Inpatient	4.7 (10.1)	4.7 (5.0)	3.8 (5.9)	7.4 (12.4)	14.7 (47.9)	6.9 (21.1)	5.8 (9.3)	3.0 (3.1)	4.0 (3.3)
Outpatient	3.2 (4.2)	3.0 (4.1)	3.2 (4.5)	3.6 (4.2)	4.1 (4.5)	4.0 (5.4)	3.9 (4.2)	4.2 (4.6)	4.1 (4.0)
Community	7.1 (5.4)	7.5 (8.0)	7.0 (6.9)	8.8 (6.5)	9.2 (7.1)	9.1 (6.5)	9.4 (8.1)	8.9 (7.3)	9.2 (6.8)

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TABLE 25 Mean service costs (2015/16 £) in the 12 months prior to baseline and at each follow-up

	Time point, mean (SD)								
	Baseline			12-month follow-up			24-month follow-up		
	Trial arm			Trial arm			Trial arm		
Service	Group intervention ($n = 697$)	Individual intervention ($n = 523$)	UC ($n = 522$)	Group intervention ($n = 697$)	Individual intervention ($n = 523$)	UC ($n = 522$)	Group intervention ($n = 697$)	Individual intervention ($n = 523$)	UC ($n = 522$)
Intervention	0 (0)	0 (0)	0 (0)	55 (50)	136 (98)	0 (0)	0 (0)	0 (0)	0 (0)
A&E	19 (94)	16 (58)	15 (59)	30 (107)	23 (83)	27 (90)	36 (204)	32 (88)	33 (123)
Day hospital	193 (1049)	105 (573)	137 (618)	85 (405)	95 (497)	68 (341)	49 (271)	53 (328)	19 (114)
Inpatient	172 (1605)	164 (955)	85 (788)	340 (2333)	499 (6940)	256 (3207)	219 (1609)	99 (590)	149 (745)
Outpatient	222 (460)	210 (442)	221 (485)	284 (492)	327 (542)	329 (630)	355 (524)	366 (568)	361 (505)
Community	225 (260)	241 (331)	222 (187)	306 (253)	317 (233)	306 (220)	324 (253)	306 (232)	321 (279)
Total	831 (2127)	736 (1299)	680 (1132)	1107 (2520)	1407 (7067)	985 (3312)	984 (1915)	855 (1079)	884 (1114)

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TABLE 26 Mean EQ-5D tariff scores and QALYs, by arm and time point

	Trial arm, mean (SD)		
Time point	Group intervention	Individual intervention	UC
EQ-5D tariff scores			
Baseline	0.8738 (0.1973)	0.8831 (0.1870)	0.8828 (0.1630)
12-month follow-up	0.8869 (0.1958)	0.9085 (0.1632)	0.8947 (0.1688)
24-month follow-up	0.8994 (0.1639)	0.9064 (0.1475)	0.9144 (0.1459)
QALYs	1.7717 (0.3073)	1.8123 (0.2306)	1.8014 (0.2462)

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QALYs (95% CI –0.0217 to 0.0294 QALYs). For cases in which both cost and QALYs were available, the group intervention arm produced 0.0149 fewer QALYs than the UC arm and the individual intervention arm produced 0.0064 more QALYs than the UC arm. These figures are used as the denominators in the ICERs.

The group intervention arm was less effective and more expensive than the UC arm. For this reason, it was dominated. The individual intervention was more expensive and more effective than UC. The ICER was £55,625 per QALY (£356 divided by 0.0064 QALYs). Uncertainty around the estimates are shown in the cost-effectiveness planes (*Figures 8* and *9*). In *Figure 8*, comparing the group intervention arm with the

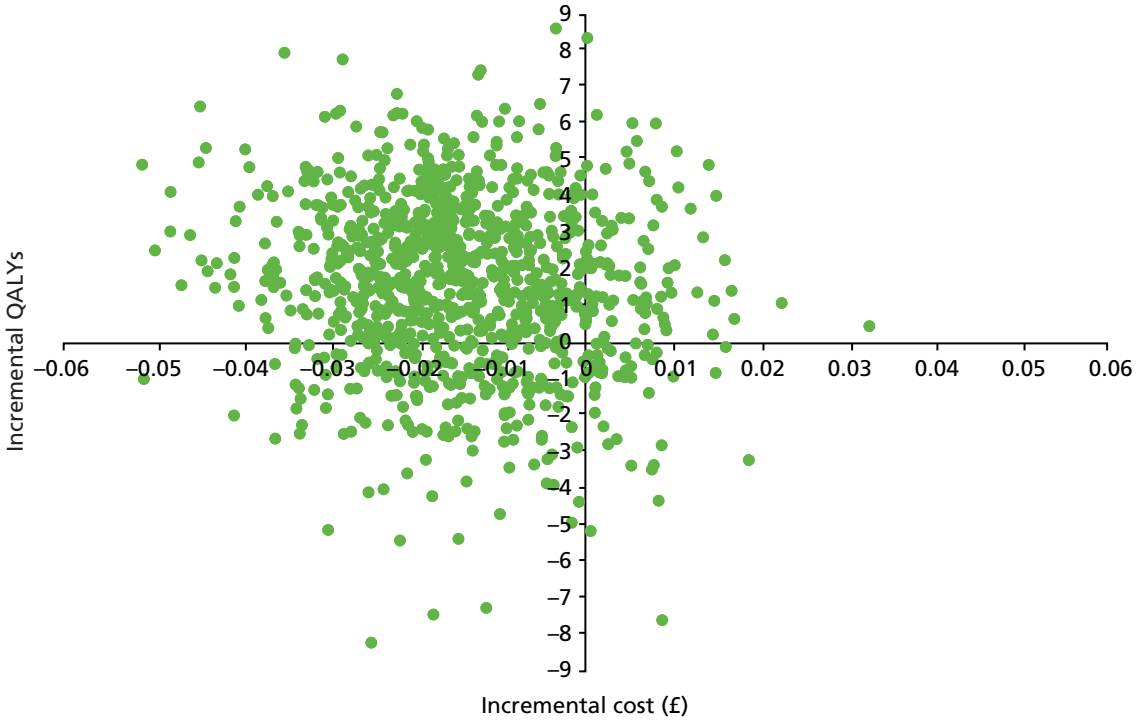

FIGURE 8 Cost-effectiveness plane comparing the group intervention arm and UC. Reproduced from Ismail *et al.*[110] © Author(s) (or their employer(s)) 2019. Re-use permitted under CC BY. Published by BMJ. This is an open access article distributed in accordance with the Creative Commons Attribution 4.0 Unported (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited, a link to the licence is given, and indication of whether changes were made. See: https://creativecommons.org/licenses/by/4.0/.

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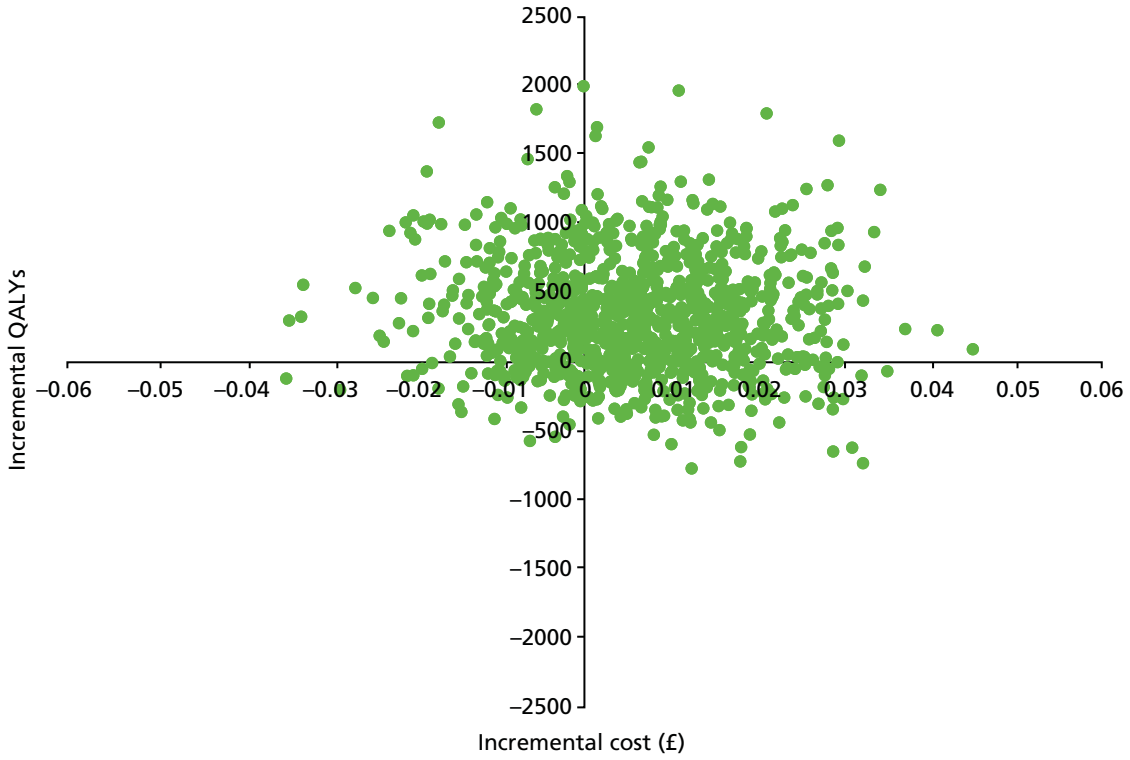

FIGURE 9 Cost-effectiveness plane comparing the individual intervention arm and UC. Reproduced from Ismail *et al.*[110] © Author(s) (or their employer(s)) 2019. Re-use permitted under CC BY. Published by BMJ. This is an open access article distributed in accordance with the Creative Commons Attribution 4.0 Unported (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited, a link to the licence is given, and indication of whether changes were made. See: https://creativecommons.org/licenses/by/4.0/.

UC arm, it can be clearly seen that the majority (69%) of bootstrapped replications fall in the north-west quadrant, in which the group intervention arm has higher costs and produces fewer QALYs. In the north-east quadrant, in which costs are still higher but more QALYs are produced, 8.5% of replications fall. In the south-east quadrant, in which costs are lower and more QALYs are produced, 4% of replications fall. Finally, 18.5% of replications fall in the south-west quadrant, in which the group intervention arm is less expensive but produces fewer QALYs.

In *Figure 9*, comparing the individual intervention arm with the UC arm, 52.3% of replications are in the north-east quadrant, in which the individual intervention arm has higher costs and produces more QALYs; 15.7% are in the south-east quadrant, in which costs are lower and there are more QALYs produced; 5.8% are in the south-west quadrant, in which costs are lower and there are fewer QALYs produced; and, finally, 26.2% of replications are in the north-west quadrant, in which the individual intervention arm has higher costs and produces fewer QALYs.

Figure 10 shows the cost-effectiveness acceptability curves in which all three arms are compared for different values placed on a QALY gain. When a zero value is placed on a QALY, UC has by far the highest probability of being the most cost-effective option (in this situation, only costs are relevant and UC is less expensive). As the value placed on a QALY is increased, the probability that the individual intervention arm is the most cost-effective option increases steadily and the other two arms see a fall in the probability that they are the most cost-effective. This is to be expected as the individual intervention arm is more expensive and more effective than the other options, and as the effect (i.e. increased QALYs) is valued more, it increasingly offsets the cost. However, at a value of £30,000 (above which NICE is likely to decide an intervention is not cost-effective) the individual intervention arm has a 37.4% likelihood of being the most cost-effective option, compared with 58.1% for UC. At this value, the group intervention arm has a likelihood of 4.5% of being the most cost-effective option.

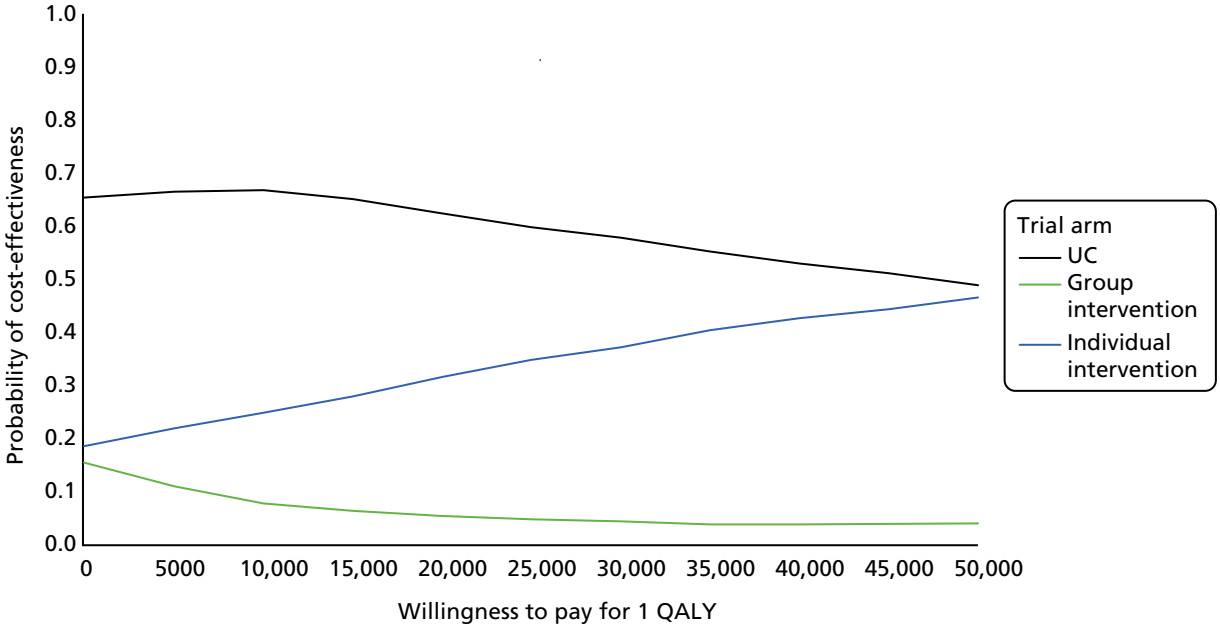

FIGURE 10 Cost-effectiveness acceptability curves. Reproduced from Ismail *et al.*[110] © Author(s) (or their employer(s)) 2019. Re-use permitted under CC BY. Published by BMJ. This is an open access article distributed in accordance with the Creative Commons Attribution 4.0 Unported (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited, a link to the licence is given, and indication of whether changes were made. See: https://creativecommons.org/licenses/by/4.0/.

In sensitivity analyses, the intervention costs were increased and decreased by 25% and 50%, respectively, to reflect different grades of staff delivering the interventions. When intervention costs were reduced by 25%, the group intervention arm had costs that were, on average, £188 more than for the UC arm, whereas costs for the individual intervention arm were £395 more than for the UC arm; the differences when intervention costs were increased by 50% were £204 and £434, respectively. Not surprisingly, these increased differences mean that the interventions are even less likely to be cost-effective compared with UC.

When intervention costs are reduced by 25%, the group intervention arm has costs that are, on average, £157 more than for UC. With fewer QALYs, UC is still dominant. The individual intervention now costs £317 more than the cost of UC, resulting in a cost per QALY of £49,531. With a reduction of 50%, the group intervention arm still has higher costs than UC (by £141) and so continues to be dominated, whereas the individual intervention arm has costs that are £278 higher, resulting in a cost per QALY of £43,438.

Summary

The health economic analyses show that the group intervention is not a cost-effective alternative to UC as it produces fewer QALYs and results in higher health-care costs. The individual intervention is more effective than UC in terms of QALYs produced but the higher costs result in an ICER that is in excess of the £20,000- to £30,000-per-QALY threshold usually used in England to determine cost-effectiveness and so is also not cost-effective. The ICER for the individual intervention arm compared with the group intervention arm is below this threshold, but UC is still the preferred option. Sensitivity analyses did not alter the results in a substantial way.

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Chapter 7 Participation biases

Background

Lifestyle intervention trials have previously reported low response rates and do not always recruit those most at risk, which will limit the generalisability of observed associations.[112,113] Failure to recruit those with the highest risk of CVD to the MOVE IT trial could have led to limited representativeness and underestimated effect sizes, and could have contributed to increasing rather than reducing health inequalities. It is important, therefore, that RCTs such as MOVE IT report on participation bias.

The factors found to increase likelihood of participation in walking and lifestyle intervention trials are mid-life, female sex, living in more affluent areas, white ethnicity and university education.[112,114] Ethnic minorities are at higher risk of CVD and related disorders, such as type 2 diabetes mellitus.[115] Regarding the health of participants versus non-participants, some trials report that participants are more likely to be of poorest health,[112,116–118] whereas other studies report that participants are healthier or more active.[113,117,119,120]

We compared the anonymised sociodemographic data and CVD risk of responders and non-responders to the MOVE IT invitation to participate. We aim to test the hypothesis that people who are older, female, living in more affluent areas, at lower risk of CVD and of white ethnicity are more likely to respond.

Methods

Using a cross-sectional design, we compared anonymous data from medical records of patients who responded to the invitation to participate in MOVE IT and those of patients who did not. We gained REC approval to extract anonymised data for all patients invited to participate unless an informed dissent code was present on medical records.

The measures collected anonymously for all patients invited to participate included age (at time of screening), sex, postcode data to calculate IMD 2010 score,[76] QRISK2 score and ethnicity.

QRISK2 score was estimated on medical records via a batch calculator, using age- and sex-based national averages for missing data values.

Ethnicity data from medical records were grouped into white, black African or Caribbean, South Asian, other Asian, other/mixed or missing for this analysis. South Asian and other Asian ethnicities are coded separately because South Asian ethnicity is associated with a higher CVD risk.[72] The category of other/mixed incorporates any ethnicity that is reported and does not fit into the previous categories, as well as including mixed ethnic backgrounds.

Data are summarised as mean (SD) or percentages. The adjusted odds ratios (AORs) for response to invitation by the sociodemographic and CVD risk data collected were calculated using logistic regression in Stata version 14. General practice was included as a random effect in the model to allow for clustering by practice. AORs for age are presented per 5-year increase, for IMD 2010 scores per 10-point increase and for QRISK2 scores per 5-percentage-point increase to provide a better comparison of the strength of the relationships.

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Results

Lists of patients invited to participate were not saved by general practices and we returned to practices later to extract anonymous data. Sixty practices provided the original anonymised data. Sociodemographic data and QRISK2 scores were extracted for 8902 patients, representing 50.5% of the 17,618 patients originally invited to participate. *Table 27* shows the CCGs from which anonymised data were collected and the deprivation and ethnicity census data of each local authority.[71] General practice deprivation scores (IMD 2010)[76] of practices from which anonymised data were extracted did not differ significantly from that of all other practices in South London [$t(440) = 0.57$; $p = 0.57$).[108]

The sociodemographic and QRISK2 data of responders ($n = 1489$) and non-responders ($n = 7413$) are presented in *Table 28*. The mean age of all patients at the time of invitation was 67.3 ± 5.7 years, and 20.7% were female. The mean IMD 2010[76] score of patients invited was 21.7, a score that falls within the second-most-deprived quintile, and the mean QRISK2 score of invitees was 25.2%. Of all patients invited, 69.9% had a white ethnic background, 13.9% had ethnic minority backgrounds and 16.2% had no ethnicity data recorded in their medical records.

The logistic regression analyses that were conducted to estimate the odds of response are also presented in *Table 28*. Response rates were higher with increasing age (AOR 1.19, 95% CI 1.12 to 1.26); the odds of response increased by 19% for each 5-year increase in age. The response rate was greater in male patients (AOR 1.24, 95% CI 1.07 to 1.44) and decreased with greater levels of deprivation (AOR 0.84, 95% CI 0.79 to 0.90); for every 10-point increase in IMD 2010 score, the odds of responding decreased by 16%. Increased CVD risk also lowered the response rate (AOR 0.83, 95% CI 0.77 to 0.88); for every 5-point increase in QRISK2 score, the odds of responding decreased by 17%. The response rate was lower for patients of black African or Caribbean ethnicity (AOR 0.66, 95% CI 0.45 to 0.96) and those with missing ethnicity data (AOR 0.55, 95% CI 0.46 to 0.66) than for patients of white ethnicity. The response rates of Asian and other ethnic backgrounds were not significantly different from those of patients of white ethnicity.

Pairwise comparisons were conducted to explore differences in response between different ethnic minority groups, but there were no significant differences. Response rates of patients with missing ethnicity data were significantly lower than those of patients of South Asian ethnicity ($p = 0.002$). Owing to small numbers of invitees from non-white ethnic backgrounds, a sensitivity analysis was undertaken to investigate predictors of response to invitation with ethnicity removed from the model. Older age ($p < 0.001$), male sex ($p = 0.017$), being more affluent ($p < 0.001$) and having a lower CVD risk ($p < 0.001$) remained significant predictors of response.

Summary

In *Chapter 5*, we demonstrated that the trial successfully recruited general practices that did not differ significantly from all other practices in South London in practice deprivation, and this was also true for the smaller group of practices involved in this analysis. Therefore, the MOVE IT trial successfully recruited from socioeconomically varied areas. For this analysis, we found evidence of participation bias towards patients who were older, male, residing in more affluent areas and at a lower CVD risk and we found that patients of black African or Caribbean ethnicity were less likely to respond than patients of white ethnicity. South Asian patients were as likely to respond as patients of white ethnicity but the QRISK2 score identified a smaller sample size of people of African Caribbean and Asian ethnicities. This could be partly because those CCGs with the highest IMD 2010 scores and greater ethnic diversity were less likely to participate in MOVE IT. It is noteworthy that these CCGs were the slowest to respond to participate although all CCGs were invited at the same time. We also observed high rates of missing ethnicity data on medical records and this group of patients with missing ethnicity data was less likely to respond than patients of white or South Asian ethnicity. These findings suggest that there may have been a participation bias towards those with lower CVD risk compared with those most at risk.

TABLE 27 South London CCG deprivation, ethnicity and anonymous data collected

	CCG											
Characteristics	Bexley	Bromley	Croydon	Greenwich	Kingston	Lambeth	Lewisham	Merton	Richmond	Southwark	Sutton	Wandsworth
Borough deprivation (IMD 2010 rank[76])[a] (*n*)	180	217	99	19	252	14	16	208	286	25	193	102
Borough ethnicity (%)[b]												
White	81.9	84.3	55.2	62.5	74.5	57.1	53.6	64.9	85.9	54.3	78.6	71.4
Black African or Caribbean	8.5	6.0	20.2	19.1	2.4	25.9	27.2	10.4	1.5	26.8	4.8	10.6
South Asian	3.6	2.7	10.5	4.7	6.5	3.3	2.8	8.9	3.9	4.0	5.4	6.5
Other Asian	2.9	2.5	5.9	7.0	9.9	3.5	6.5	9.2	3.4	5.5	6.2	4.4
Other/mixed	3.0	4.5	8.4	6.7	6.6	10.1	10.0	6.5	5.2	9.4	5.0	7.1
Anonymous data collected (*n*)												
General practices	1	11	11	1	1	6	11	2	0	9	3	4
Patients	328	2463	1663	255	27	845	1281	41	0	666	786	646

a Ranked from 1 (most deprived) to 326 (least deprived) from 326 local authorities.
b Based on census 2011 data.[20,71]

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TABLE 28 Comparison of responders and non-responders to the trial invitation

Characteristics	Patients			Response rate (%)	OR for response to mailout (95% CI)		Test for trend (*p*-value)
	All invited (*N* = 8902)[a]	Responded to invitation (*N* = 1489)	Did not respond to invitation (*N* = 7413)		Unadjusted	Adjusted	
Age at invitation (years), mean (SD)	67.3 (5.7)	68.1 (5.1)	67.2 (5.8)		1.14 (1.08 to 1.21)[b]	1.19 (1.12 to 1.26)[b]	< 0.001
Age group at invitation (years), *n* (%)							
40–59	976 (11.0)	124 (8.4)	852 (11.6)	12.7			
60–64	1462 (16.4)	200 (13.5)	1262 (17.0)	13.7			
65–69	2989 (33.6)	536 (36.0)	2453 (33.1)	17.9			
70–75	3475 (39.0)	629 (42.2)	2846 (38.4)	18.1			
Sex, *n* (%)							
Female	1847 (20.7)	291 (19.5)	1556 (21.0)	15.8	1.00	1.00	
Male	7055 (79.3)	1198 (80.5)	5857 (79.0)	17.0	1.07 (0.93 to 1.23)	1.24 (1.07 to 1.44)	0.004
Ethnicity, *n* (%)							< 0.001[c]
White	6223 (69.9)	1128 (75.8)	5095 (68.7)	18.1	1.00	1.00	
Black African or Caribbean	272 (3.1)	34 (2.3)	238 (3.2)	12.5	0.74 (0.50 to 1.07)	0.66 (0.45 to 0.96)	0.032
South Asian	578 (6.5)	98 (6.6)	480 (6.5)	17.0	0.90 (0.70 to 1.14)	1.07 (0.84 to 1.37)	0.593
Other Asian	240 (2.7)	31 (2.1)	209 (2.8)	12.9	0.69 (0.47 to 1.03)	0.71 (0.48 to 1.05)	0.086
Other/Mixed	147 (1.7)	16 (1.1)	131 (1.8)	10.9	0.62 (0.36 to 1.05)	0.61 (0.36 to 1.05)	0.072
Missing	1442 (16.2)	182 (12.2)	1260 (17.0)	12.6	0.58 (0.48 to 0.69)	0.55 (0.46 to 0.66)	< 0.001
IMD 2010 score,[d] mean (SD)	21.7 (12.0)	19.4 (11.3)	22.2 (12.1)		0.82 (0.76 to 0.87)[e]	0.84 (0.79 to 0.90)[e]	< 0.001

Characteristics	Patients			Response rate (%)	OR for response to mailout (95% CI)		Test for trend (*p*-value)
	All invited (*N* = 8902)[a]	Responded to invitation (*N* = 1489)	Did not respond to invitation (*N* = 7413)		Unadjusted	Adjusted	
IMD 2010 quintile, *n* (%)							
1 (least deprived)	1407 (15.8)	293 (19.7)	1114 (15.0)	20.8			
2	1531 (17.2)	285 (19.1)	1246 (16.8)	18.6			
3	1616 (18.2)	315 (21.2)	1301 (17.6)	19.5			
4	2725 (30.6)	420 (28.2)	2305 (31.1)	15.4			
5 (most deprived)	1604 (18.0)	171 (11.5)	1433 (19.3)	10.7			
Unknown	19 (0.2)	5 (0.3)	14 (0.2)	26.3			
QRISK2 score, mean (SD)	25.2 (5.0)	24.6 (4.5)	25.3 (5.1)		0.86 (0.81 to 0.92)[f]	0.83 (0.77 to 0.88)[f]	< 0.001
QRISK2 score category, *n* (%)							
20–24.9%	5357 (60.2)	968 (65.0)	4389 (59.2)	18.1			
25–29.9%	2245 (25.2)	347 (23.3)	1898 (25.6)	15.5			
≥ 30%	1300 (14.6)	174 (11.7)	1126 (15.2)	13.4			

OR, odds ratio.
a All patients invited to participate in the trial from general practice sites at which it was possible to extract anonymised data.
b OR per 5-year increase in age.
c Chi-squared test for independence of ethnicity groups.
d IMD 2010 score;[76] higher score is more deprived.
e OR per 10-point increase in IMD score.[76]
f OR per 5% increase in QRISK2 score.

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Chapter 8 Fidelity analysis

Introduction

As part of the process evaluation of the study, we assessed fidelity, here defined as delivery of the enhanced MI intervention by the HLFs in accordance with the manual. Furthermore, we were interested in determining if the level of HLF competency in delivering the intervention differed between the individual and group intervention arms.

As described in *Chapter 3*, HLFs received extensive training and supervision before and during the intervention to ensure that they were competent in delivering MOVE IT. HLFs were asked to audiotape each intervention session, and these data were stored on King's College London's shared network drives, as per the university protocol. *Chapter 4* describes how a university-wide network outage caused the recorded session data to be completely lost, with only a limited sample being subsequently recovered from other sources. In this chapter, we will describe our original aims and methods and how these were adapted following the network outage.

Aims

For the analysis, we were originally interested in answering five questions:

1. What was the degree of adherence by the HLFs to the MI and BCT elements in the group and individual intervention arms?
2. What was the level of HLF competency in delivering the MI aspects?
3. What was the level of HLF competency in delivering the BCTs?
4. Were there any differences in competency in delivering the MI and BCT elements between the group and individual treatment arms?
5. Were the HLF competency levels in delivering the intervention associated with patient outcomes or mediators of any treatment effects?

Owing to the network outage and the number and quality of data that were subsequently recovered, we were unable to address question 5. In addition, although the HLFs were trained to a certain level of competency in two other domains (group skills and time management; see *Chapter 3*), we were not interested in assessing their competency in these domains for this fidelity analysis.

Original methods

Identifying sessions to rate

Ideally, if every patient randomised to the individual or group intervention attended each of the 10 sessions, we would have obtained 6200 hours of recordings (*Table 29*). In addition, by assuming a 20% dropout rate halfway through the intervention, we would have obtained 5201 hours of recordings. We originally had 2756 tapes of the intervention sessions, comprising 1989 hours of content.

We planned to randomly select and rate 25% of the available recordings, stratified by intervention arm (group vs. individual), ensuring that every participant in the individual intervention arm and every group in the group intervention arm had at least one recording assessed for fidelity. Sessions lasting ≥ 20 minutes would be selected. We planned that a 20-minute segment (randomly selected from the beginning, middle or end) of each tape would be rated for individual sessions, and we selected a 50-minute segment of the

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TABLE 29 Potential and actual hours of session recordings

Scenario	Number of participants/groups	Average length (hours)	Total number of hours
Ideal			
Individual	523 (10 sessions)	0.70	3671
Group	139 (10 sessions)	1.81	2529
Total			6200
Anticipated			
Individual	418 (105) (10 sessions, 5 dropouts)	0.70	3304
Group	125 (14) (10 sessions, 5 dropouts)	1.81	1897
Total			5201
Original (pre outage)[a]			
Individual	2251	0.57	1289
Group	400	1.55	619
Total			1908[b]
Recovered (post outage)[b]			
Individuals	324	0.70	227
Groups	71	1.81	129
Total			356

a Owing to the nature of how the audiotaped session data were recorded and stored, we could not determine the number of sessions completed by each participant/group.
b 81 hours have been removed from this total, as the associated session tapes had not been coded for intervention arm.

group sessions, as this would allow a fairer opportunity for MI skills to be demonstrated in a group context. During our preparation for the fidelity coding, we found that a 20-minute segment was not suitable for group sessions, as the structure and format of group sessions meant that significant amounts of time were devoted to group exercises that could not be coded.

Measures of competency

We assessed the MI and BCT aspects of the intervention. To assess HLF fidelity to the MI aspects of the intervention, we used the MITI manual (version 3.1.1),[97] which counts the number of MI techniques used. The MITI tool has been validated and is viewed as the gold standard of MI fidelity, has been translated into multiple languages[121] and is used widely as a coding system, including in other large-scale studies.[122,123]

The MITI rating tool comprises several variables. 'Global' ratings are given for each of 'spirit' and 'empathy', scored on a scale from 1 to 5 (with the coder assuming a beginning score of 3 and moving up or down based on the HLF's observed skill). Behaviour count scores are provided for 'giving information', 'MI adherent' behaviours, 'MI non-adherent' behaviours, 'closed questions', 'open questions', 'simple reflections' and 'complex reflections'. The MITI guidance provides minimum scores that a practitioner must achieve to reach proficiency and competency (*Table 30*).

TABLE 30 Minimum values to achieve for MITI proficiency and competency

Measure	Beginning proficiency	Competency
Global spirit rating, mean score	3.5	4
Reflection-to-question ratio	1	2
Percentage with open questions	50	70
Percentage with complex reflections	40	50
Percentage who were MI adherent	90	100

To assess HLF adherence to administering the 11 BCTs, each was coded as present (at least once) or absent during a session. The 11 BCTs were:

- provide information on consequences
- prompt intention formation
- prompt barrier identification
- prompt specific goal-setting
- prompt review of behavioural goals
- prompt self-monitoring of behaviour
- teach to use prompts or cues
- agree on behavioural contract
- plan social support or social change
- self-talk
- relapse prevention.

Raters were provided with a BCT coding framework, which listed each BCT label alongside a description and an example quotation (see *Appendix 3*). MI, which is considered the 12th BCT in the taxonomy,[54] was removed and considered separately, as the CPs developing the intervention deemed this to be the communication process by which the BCTs were used with participants, rather than as a BCT itself. The BCT coding framework was developed by the authors and raters specifically for this trial, as our review of the extant literature did not reveal an existing coding framework that would be appropriate. The coding framework was developed through an iterative process and piloted internally; however, it was not validated before being utilised in the study.

Interrater reliability

Two independent psychologists who had completed formal training in using the MITI tool and were experienced in this method (having worked together on previous studies) coded the recordings. To determine interrater reliability, the two raters initially coded the same selection of tapes. First, 40 tapes (20 individual and 20 group sessions) were randomly selected. Then, for each tape, a segment that was 20–50 minutes in length was randomly selected, reflecting the variability in quality and length of the tapes.

The raters worked together extensively in adapting the MITI tool to suit the group format. They met on several occasions to discuss discrepancies between the coding of individual and group transcripts. Individual issues were also discussed as they arose until agreement was reached on coding principles.

To ensure that rater drifting did not happen, the raters initially met weekly. As the coding proceeded and any raised issues were resolved, the raters and one of the CPs met regularly. The raters also engaged in peer supervision, in which they would discuss with each other any coding issues that were raised for a tape and how to resolve them. The raters closely followed the principles detailed in the MITI tool and

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referred to this document on a regular basis. For example, it was necessary to identify the nature of facilitative and structural statements compared with the utterances that constituted MITI behaviour counts, such as complex and simple reflections or giving information.

Intraclass correlation coefficients using a two-way consistency model were calculated for global spirit and empathy scores and absolute agreement percentages for each BCT. For the individual sessions, the two raters achieved ICCs of 0.89 (95% CI 0.75 to 0.96) and 0.84 (95% CI 0.65 to 0.94) for the global ratings of empathy and spirit, respectively; both ICCs are considered good to excellent.[124] The mean absolute agreement was 94.09% (range 85–100%) for the 11 BCTs.

For the group sessions, the two raters achieved ICCs of 0.69 (95% CI 0.37 to 0.87) and 0.71 (95% CI 0.41 to 0.88) for the global ratings of empathy and spirit, respectively; both ICCs are considered good. The mean absolute agreement was 86.82% (range 70–100%) for the 11 BCTs.

Revised methods

Identifying sessions to rate

The network outage at King's College London resulted in all tapes being lost, with 84.22% of them irretrievably lost. We were able to recover 435 tapes that could be coded. *Table 31* summarises the characteristics of the recovered tapes, excluding the 40 used for determining interrater reliability (described in the previous section). When comparing the characteristics of the original and recovered tapes, we found that there were significant differences with regards to the distribution of session number and which HLF administered the session, but no difference in session type (see *Table 31*). Furthermore one HLF was missing from the recovered tapes (HLF13).

TABLE 31 Comparison of session characteristics of original and recovered recordings

	Recordings, *n* (%)		
Characteristics	Original (*N* = 2651)[a]	Recovered (*N* = 395)	Statistical test output
Session number			
0	40 (1.87)	17 (4.30)	$\chi^2(10) = 86.31$; $p < 0.0001$
1	255 (11.93)	49 (12.41)	
2	237 (11.09)	54 (13.67)	
3	233 (10.90)	46 (11.65)	
4	232 (10.86)	57 (14.43)	
5	197 (9.22)	61 (15.44)	
6	190 (8.89)	50 (12.66)	
7	199 (9.31)	33 (8.35)	
8	180 (8.42)	9 (2.28)	
9	189 (8.84)	4 (1.01)	
10	185 (8.66)	15 (3.80)	
Session type			
Individual	2251 (84.91)	324 (82.03)	$\chi^2(1) = 1.98$; $p = 0.16$
Group	400 (15.09)	71 (17.97)	

TABLE 31 Comparison of session characteristics of original and recovered recordings (*continued*)

Characteristics	Recordings, *n* (%)		Statistical test output
	Original (*N* = 2651)[a]	Recovered (*N* = 395)	
HLF			
1	571 (20.72)	200 (50.63)	$\chi^2(12) = 398.05$; $p < 0.0001$
2	472 (17.13)	64 (16.20)	
3	140 (5.08)	55 (13.92)	
4	30 (1.09)	30 (7.59)	
5	97 (3.52)	15 (3.80)	
6	109 (3.96)	7 (1.77)	
7	194 (7.04)	5 (1.27)	
8	86 (3.12)	5 (1.27)	
9	455 (16.51)	4 (1.01)	
10	155 (5.62)	4 (1.01)	
11	66 (2.39)	3 (0.76)	
12	341 (12.37)	3 (0.76)	
13	40 (1.45)	0 (0.00)	

a 105 sessions were excluded, as they had not been assessed for their characteristics prior to the outage.

We also adapted the protocol and decided that the entirety of each recovered tape, as opposed to a 20- or 50-minute segment, would be coded and its data used in the fidelity analysis. This protocol change was discussed with and approved by the TSC. The initial 5 minutes of each tape were not coded, as we found this time to be devoted to content other than delivering the intervention (e.g. introductions and housekeeping from previous sessions). Approximately 50% of available tapes were randomly allocated to each rater using minimisation to ensure balance with respect to session type, session number and HLF.

Association between healthy lifestyle facilitator competencies and patient outcomes

We were unable to conduct this analysis (question 5) because the competency data had unacceptable levels of measurement error. Namely, the quality of the recovered data prevented us from matching session-level HLF competencies to patient-level outcomes.

Results

Fidelity to the intervention

A total of 395 sessions were coded for fidelity (324 individual sessions, 82.03%). We observed treatment arm differences in several of the MITI domains, generally favouring the group sessions (*Table 32*). None of the HLFs achieved proficiency across the five necessary MITI domains, based on the MITI guidance (*Table 33*). Two HLFs were at least proficient in four domains and two were at least proficient in three domains. Using our adapted competency framework, three HLFs met the competency criteria. *Table 34* shows the MITI scores for each HLF by session type.

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TABLE 32 Summary of MITI domain scores

MITI domains	Intervention arm, mean (SD)		Total ($n = 395$), mean (SD)	Statistical test output
	Group ($n = 71$)	Individual ($n = 324$)		
Global ratings				
Empathy	3.07 (0.82)	3.03 (0.92)	3.04 (0.90)	$t(112.67) = 0.39$; $p = 0.70$
Spirit[a]	3.44 (0.63)	3.52 (0.74)	3.51 (0.72)	$t(115.48) = -1.00$; $p = 0.32$
Behaviour counts				
Giving information	25.54 (18.45)	12.54 (10.04)	14.88 (12.97)	$t(79.32) = 5.75$; $p < 0.0001$
MI adherent	6.83 (4.49)	6.35 (4.27)	6.44 (4.31)	$t(99.72) = 0.83$; $p = 0.41$
MI non-adherent	1.30 (2.19)	1.15 (1.88)	1.17 (1.94)	$t(94.01) = 0.54$; $p = 0.59$
Percentage who were MI adherent[a]	83.74 (27.30)	84.68 (21.61)	84.51 (22.71)	$t(88.91) = -0.27$; $p = 0.79$
Closed questions	22.48 (13.29)	14.44 (8.76)	15.89 (10.19)	$t(83.8) = 4.87$; $p < 0.0001$
Open questions	21.21 (10.65)	10.81 (6.63)	12.68 (8.50)	$t(82.27) = 7.90$; $p < 0.0001$
Total questions	43.69 (20.80)	25.26 (13.63)	28.57 (16.72)	$t(83.63) = 7.14$; $p < 0.0001$
Percentage with open questions[a]	49.35 (14.01)	43.32 (14.74)	44.40 (14.78)	$t(106.74) = 3.26$; $p < 0.0001$
Simple reflections	30.73 (18.86)	18.35 (12.20)	20.57 (14.42)	$t(83.28) = 5.30$; $p < 0.0001$
Complex reflections	15.31 (6.88)	10.31 (6.01)	11.21 (6.46)	$t(94.84) = 5.66$; $p < 0.0001$
Total reflections	46.04 (22.07)	28.71 (15.12)	31.83 (17.85)	$t(85) = 6.30$; $p < 0.0001$
Percentage with complex reflections[a]	36.28 (14.17)	37.26 (16.98)	37.08 (16.50)	$t(118.63) = -0.51$; $p = 0.61$
Reflection-to-question ratio[a]	1.17 (0.57)	1.37 (0.95)	1.33 (0.90)	$t(168.66) = -2.28$; $p = 0.024$

a Domains used by the MITI tool to determine proficiency/competency.

The 11 BCTs were generally coded as present in most of the group (median 45/71, range 20–58) and individual (median 179/324, range 69–267) sessions (*Table 35*). The distributions of each BCT being coded present were similar between session types, except for BCT 1 ('provide information on consequences').

Table 36 shows mean BCT adherence by HLF and session type, aggregated over the 11 BCTs, with ≥ 70% indicating competency.

TABLE 33 The MITI scores, by HLF, combining session types

HLF	Number of tapes coded	MITI domains, mean (SD)				
		Global spirit	Percentage with complex reflections	Percentage with open questions	Reflection-to-question ratio	Percentage who were MI adherent
1	200	**3.71 (0.61)**	39.80 (16.42)	43.28 (13.15)	**1.58 (0.80)**	**90.34 (18.74)**
2	64	3.25 (0.66)	37.55 (15.68)	41.74 (16.10)	**1.15 (0.73)**	83.33 (23.58)
3	55	3.20 (0.77)	30.27 (15.78)	**54.51 (15.32)**	0.82 (0.75)	68.13 (25.57)
4	30	3.36 (1.11)	32.39 (18.10)	41.48 (11.67)	0.68 (0.30)	81.05 (23.59)
5	15	3.33 (0.50)	30.70 (12.45)	47.66 (15.27)	**2.39 (2.05)**	83.60 (20.09)
6	7	**4.00 (0.00)**	**48.12 (13.11)**	**51.31 (15.63)**	**1.10 (0.32)**	87.43 (18.66)
7	5	**3.93 (0.49)**	**40.02 (6.91)**	45.85 (6.24)	0.82 (0.12)	**94.18 (8.85)**
8	5	3.33 (0.47)	**48.81 (18.31)**	24.43 (19.31)	0.99 (0.77)	80.00 (44.72)
9	4	3.42 (0.42)	34.38 (8.90)	39.59 (16.27)	**1.33 (0.41)**	78.98 (21.91)
10	4	2.92 (0.68)	22.65 (22.06)	23.28 (5.69)	**1.00 (0.29)**	71.39 (23.10)
11	3	**3.67 (0.58)**	23.46 (13.10)	**50.46 (10.48)**	**1.12 (0.77)**	**94.44 (9.62)**
12	3	2.77 (0.84)	33.58 (3.49)	46.76 (7.58)	**1.51 (0.19)**	54.26 (26.85)

Note
Bold values indicate proficiency for that domain.

TABLE 34 The MITI scores, by HLF and session type

HLF	Number of tapes coded	MITI domains, mean (SD)				
		Global spirit	Percentage with complex reflections	Percentage with open questions	Reflection-to-question ratio	Percentage who were MI adherent
Individual sessions						
1	152	3.76 (0.61)	41.00 (17.36)	42.11 (13.41)	1.64 (0.87)	91.88 (13.97)
2	50	3.25 (0.67)	37.32 (15.58)	39.14 (16.08)	1.28 (0.76)	82.76 (24.58)
3	47	3.22 (0.80)	29.69 (14.94)	53.47 (13.54)	0.85 (0.80)	67.98 (25.41)
4	30	3.36 (1.11)	32.39 (18.10)	41.48 (11.67)	0.68 (0.30)	81.05 (23.59)
5	15	3.33 (0.50)	30.70 (12.45)	47.66 (15.27)	2.39 (2.05)	83.60 (20.09)
6	7	4.00 (0.00)	48.12 (13.11)	51.31 (15.63)	1.10 (0.32)	87.43 (18.66)
7	4	4.00 (0.54)	39.31 (7.77)	45.08 (6.92)	0.83 (0.14)	92.73 (9.51)
8	5	3.33 (0.47)	48.81 (18.31)	24.43 (19.31)	0.99 (0.77)	80.00 (44.72)
9	4	2.92 (0.68)	22.65 (22.06)	23.28 (5.69)	1.00 (0.29)	71.39 (23.10)
10	4	3.42 (0.42)	34.38 (8.90)	39.59 (16.27)	1.33 (0.41)	78.98 (21.91)
11	3	2.77 (0.84)	33.58 (3.49)	46.76 (7.58)	**1.51 (0.19)**	54.26 (26.85)
12	3	**3.67 (0.58)**	23.46 (13.10)	**50.46 (10.48)**	**1.12 (0.77)**	**94.44 (9.62)**
Group sessions						
1	48	3.55 (0.62)	35.97 (12.42)	46.98 (11.67)	**1.41 (0.52)**	85.44 (28.85)
2	14	3.26 (0.63)	38.38 (16.59)	**51.05 (12.76)**	0.68 (0.28)	85.34 (20.39)
3	8	3.04 (0.60)	33.59 (20.89)	**60.65 (23.58)**	0.66 (0.31)	68.93 (28.20)
7	1	**3.66 (–)**	**42.86 (–)**	48.94 (–)	0.74 (–)	**100 (–)**

Note
SDs could not be calculated for HLFs with only one session available; only four HLFs have group sessions available.
Bold values indicate proficiency for that domain.

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TABLE 35 Summary of BCT adherence

	Intervention arm, *n* (%)			
BCT	Group (*N* = 71)	Individual (*N* = 324)	Total (*N* = 395), *n* (%)	Statistical test output
1	48 (67.61)	169 (52.16)	217 (54.94)	**$\chi^2(1) = 5.01$; $p = 0.025$**
2	**57 (80.28)**	**267 (82.41)**	**324 (82.03)**	$\chi^2(1) = 0.09$; $p = 0.76$
3	45 (63.38)	224 (69.14)	269 (68.10)	$\chi^2(1) = 0.70$; $p = 0.40$
4	**53 (74.65)**	**239 (73.77)**	**292 (73.92)**	$\chi^2(1) = 0.00$; $p = 1.00$
5	**54 (76.06)**	216 (66.67)	270 (68.35)	$\chi^2(1) = 1.87$; $p = 0.17$
6	40 (56.34)	147 (45.37)	187 (47.34)	$\chi^2(1) = 2.32$; $p = 0.13$
7	35 (49.30)	179 (55.25)	214 (54.18)	$\chi^2(1) = 0.65$; $p = 0.42$
8	**58 (81.69)**	**241 (74.38)**	**299 (75.70)**	$\chi^2(1) = 1.23$; $p = 0.27$
9	33 (46.48)	160 (49.38)	193 (48.86)	$\chi^2(1) = 0.11$; $p = 0.74$
10	20 (28.17)	69 (21.30)	89 (22.53)	$\chi^2(1) = 1.18$; $p = 0.28$
11	21 (29.58)	99 (30.56)	120 (30.38)	$\chi^2(1) = 0.00$; $p = 0.97$
Overall	464 (59.41)	2010 (56.40)	2474 (56.94)	$\chi^2(1) = 2.02$; $p = 0.16$

Note
n (%) indicates the number and percentage of sessions in which the BCT was coded present.
Bold indicates competency.

TABLE 36 Behaviour change technique adherence, by HLF and session type

	Session type, % (*n*)	
HLF	Group	Individual
1	62.12 (48)	66.75 (152)
2	62.99 (14)	37.64 (50)
3	35.23 (8)	47.97 (47)
4	–	50.61 (30)
5	–	32.73 (15)
6	–	66.23 (7)
7	**72.73 (1)**	**81.82 (4)**
8	–	56.36 (5)
9	–	68.18 (4)
10	–	54.55 (4)
11	–	66.67 (3)
12	–	**72.73 (3)**

Note
Cell values indicate mean percentage of BCTs delivered (number of sessions).
Only four HLFs have at least one taped group session.
Bold indicates competency.

Discussion

We coded 395 recorded intervention sessions for fidelity. We observed that nearly all (11/13) of the HLFs achieved high levels of competency on at least one dimension of MI but fewer did so with the BCT, in which only 2 out of 13 HLFs achieved competency. The HLFs received extensive training in delivering the MI and BCT elements of MOVE IT and were supervised throughout the trial; our analysis of a non-random and probably underpowered sample of tapes indicates that the intervention was administered with acceptable levels of competencies in MI but the competency of HLFs in delivering the BCTs is not known.

When combining MITI scores across HLFs, we found that the MI aspects of the intervention were not delivered at the desired competency level. At the HLF level, none of the HLFs reached the minimum MITI-based proficiency level and only three met the competency criteria adapted for the study. By further stratifying by session type, however, we found that two HLFs delivered the MI elements in individual sessions at a level deemed competent for our study.

We observed treatment arm differences in several of the MITI domains. Most of these differences were in domains with count scores, hence these were expected given the longer length of the group session format (i.e. HLFs had more opportunity to use the technique repeatedly). Of particular interest, HLFs in group sessions demonstrated a greater percentage of open questions, whereas in individual sessions they made more reflections relative to questions. This may be because in group sessions a large proportion of time was spent facilitating group discussion, which lends to repeated use of open questions. In addition, in group sessions there may have been less opportunity for HLFs to ask closed questions, which naturally follow open questions in individual sessions (e.g. to clarify what the individual has just said or encourage further conversation). In terms of the reflection-to-question ratio, this could be explained by the fact that reflections require a deeper level of listening and understanding, which the group session format does not lend itself to as easily as individual sessions do.

Most HLFs were 'partially proficient' in delivering BCTs. Only three BCTs ('prompt intention formation', 'prompt specific goal-setting' and 'agree on behavioural contract') were administered in $> 70\%$ of sessions. Furthermore, two BCTs ('self-talk' and 'relapse prevention') were delivered in approximately $< 30\%$ of sessions. Across the BCTs defined for the trial, we observed treatment arm differences in only one ('provide information on consequences'); however, this is possibly a false positive owing to the number of tests conducted. Finally, only two HLFs delivered, on average, $\geq 70\%$ of the BCTs across the sessions assessed (however, this was only five sessions for one HLF and three individual sessions for the other). These results should be interpreted cautiously as we used an unvalidated BCT coding framework developed for this study; thus, we may have underestimated HLFs' competency in delivering the BCTs.

Limitations

Owing to the network outage and loss of recorded sessions, the characteristics of the recovered tapes are based on a non-random subsample of the original tapes. Thus, it is highly likely that our findings are biased and probably an underestimation of the HLFs' competency. We are uncertain when these sessions were recorded. For instance, if the sessions were recorded earlier in the study, the HLFs may have had less competency than later in the study. We do not know why these specific tapes were saved. As part of supervision, the HLFs were required to identify sessions in which they had had difficulties and, therefore, these may be tapes representing lower competencies.

As the data loss occurred while we were preparing our database of recorded sessions, some session details were left incomplete. When comparing the characteristics of the sessions in our original (pre-IT outage) and recovered databases, we found that distributions of session numbers and HLFs were different. In particular, the recovered sessions contained fewer maintenance sessions. The majority were retained by one HLF and another HLF had no sessions recovered at all. Thus, it is likely that this fidelity analysis of the recovered sessions is biased towards an underestimation.

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We did not observe any pattern concerning the number of sessions delivered by each HLF and their MI skills. The HLF who also supervised and trained other HLFs had the largest number of sessions recovered.

Furthermore, the fidelity analysis that we conducted was possibly unsuited to the content of the intervention. For instance, although the MITI tool was the optimum coding system for assessing fidelity in the individual sessions, it has not been previously validated for MI delivered in a group format. Thus, the raters faced challenges in using this to code the group sessions. For example, as the structure of the group sessions contained more group exercises and more didactic interactions, it was difficult to detect sufficient utterances that demonstrated empathy. Instead, it may have been better to use a different coding system for MI in the group sessions.

Similarly, the nature of MOVE IT may have prevented the BCTs from being consistently captured by the fidelity raters. For example, six of the BCTs (ii–iv and vii–ix) were intended to be delivered by the HLFs during one-to-one portions of the group sessions when participants completed their action plans, which were probably not captured by the recordings. Furthermore, three of the BCTs (ix–xi) were intended to be delivered in the maintenance sessions only; hence, it is not surprising that these were among the least captured in the fidelity analysis. And this issue is compounded by the fact that fewer maintenance sessions were recovered after the network outage. Thus, we felt that the data loss from the outage barred us from conducting a more robust and detailed analysis of BCT delivery by the HLFs.

Chapter 9 Qualitative findings: the views of participants

Background

Randomised controlled trials provide a reliable and rigorous method of assessing the effectiveness of an intervention.[125] However, owing to their complex nature there are a number of additional challenges that may arise when reproducing the intervention. Therefore, it is important to evaluate the delivery and processes of the intervention from the patient's perspective.[126]

Focus groups give participants the opportunity to provide in-depth reflections of their experiences and views of the intervention.[127,128] Understanding the experiences of participants is vital to provide an insight into potential barriers and improvements that often occur in lifestyle interventions.[129] Therefore, the use of focus groups can enable researchers to review the different behavioural or social processes that may not be evident from the use of quantitative analysis only, leading to the successful implementation of an intervention in the future.[126]

A recent systematic review and meta-analysis revealed the effectiveness of structured lifestyle interventions that target both diet and PA as being successful in reducing CVD risk factors.[130] Studies have found that the delivery of MI for health-related behaviour change in lifestyle interventions to be beneficial, particularly in the short term.[49,131,132] However, few have investigated the maintenance of behaviour change in the long term with the use of qualitative methodology.

The aim of this qualitative analysis was to explore the views of participants of MOVE IT in terms of reasons for engagement, factors enabling behaviour change and the potential barriers to engagement.

Methods

Two groups of participants were approached for process evaluation: (1) those who attended the intensive phase of the intervention, that is, six or more sessions (completers), and (2) those who withdrew before the intensive phase was completed or did not attend at all (non-completers). Participants were invited, based on a purposive sampling method to form heterogeneous groups. Only those who had completed all three follow-up appointments were approached.

Participants were separated into six focus groups: four groups of completers (labelled as 1A–1D) and two groups of non-completers (2A and 2B). Each group had two facilitators, who were research assistants from the MOVE IT programme and had not met the patients before, to avoid response bias. For each group, we aimed to include at least one female participant, an individual with an ethnic minority background and a mix of those who attended individual and group sessions.

Focus groups using a semistructured interview schedule were carried out with the use of a topic guide (see *Appendix 4*). The topic guide was informed by preliminary analysis from the HLF contribution, input from the research team and investigators, and feedback from PPI members. It consisted of open-ended questions relating to (1) the invitation to take part in the study, (2) lifestyle changes made since joining the MOVE IT programme, (3) most and least helpful aspects of the sessions, (4) participant diversity and (5) potential online interventions.

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Informed consent was obtained and each group was audiotaped. Data were anonymised and transcribed verbatim. The transcripts were analysed using thematic analysis.[133] The analysis was descriptive and interpretative and facilitated by the use of NVivo version 10 (QSR International, Melbourne, VIC, Australia) to code emerging themes and subthemes.

Results

A total of 74 participants were invited to attend a focus group, with 26 ultimately participating. There were four groups of completers and two groups of non-completers. The characteristics of those who took part are outlined in *Appendix 5*.

A thematic analysis of all six focus groups resulted in three generic themes. A fourth theme was generated from only the non-completers' responses, as shown in *Table 37*.

Theme 1: perceived benefits of the study

Personal behaviour changes

Participants described positive lifestyle changes they had made with regards to their diet and PA during the study:

> *I found it beneficial. I took on the pedometer stuff, I took on the five a day, I took on the number of glasses of water a day, the oily fish, all of those, you know, don't just live a sedentary lifestyle of a night, get up and move around, all of those things, were lessons that I took on board . . . they have been beneficial to me.*
>
> *Participant 9*

> *I am in a habit of doing daily exercises in the morning. Although I do it at home at least half an hour stretching and dancing. So that makes up for the lack of walking. All in all it has made quite a positive impact.*
>
> *Participant 5*

TABLE 37 Summary of themes and subthemes

Themes	Subthemes
1. Perceived benefits of the study	• Personal behaviour changes • Increased health awareness
2. Factors enhancing behaviour change	• Social support and learning from others • Ease of programme structure and content • Continuity and strength of therapeutic alliance
3. Perceived risk of CVD	• Perceptions of their own CVD risk • Perceptions of the CVD risk to others
4. Potential barriers to change and overcoming these barriers	• Lack of feedback • Lack of engagement • The role of authority

Lifestyle changes were sustained following the completion of the sessions:

> *They're in there. They're programmed in. So on an evening, I try not to sit there plonked in front of the television, I get up and do stuff. Make the tea, go and get some fruit. You know, just keep getting up and doing stuff rather than just have a sedentary evening every evening.*
>
> *Participant 9*

> *I found I am counting the number of different fruits and veg that I'm having each day . . . and then I was like 'Ohh . . . five today,' 'Uh fine gosh, seven yesterday oh well'. You know, I am still doing it every single day . . . what am I going to eat . . . when am I having it. Oh yeah . . . every day.*
>
> *Participant 4*

Increased health awareness

The main benefits described by the participants are the increased knowledge and health awareness from taking part in the intervention. Primarily, individuals reported that the sessions highlighted the importance of keeping active and making healthy lifestyle choices regarding their food intake:

> *I think I've got much more of an awareness of how . . . Oh perhaps I can leave the car behind for a short journey. Do I need it? It's that permanent awareness. Do I need to? Are we having enough fruit and veg? Oh gosh. We haven't had fish for quite a . . . quite a long time. You know . . . Just. It's there all the time.*
>
> *Participant 2*

> *But what MOVE IT did for me certainly did highlight that I wasn't doing it. So it's made me more aware, and that's why I ate oily fish before I came out today, not particularly because I was coming to this focus group, but it's ingrained in my subconscious now that I ought to eat a certain amount. I . . . so just to reinforce . . . what this has done is benefited me in that it's now in my consciousness. I don't adhere to it religiously but overall I feel it's been beneficial.*
>
> *Participant 9*

More specifically, there was an increase of awareness and understanding of the use of the labels on packaging (i.e. the traffic light system):

> *It wasn't until I noted how much sugar and how much saturated fat was in food that we eat. So when we buy things we're more aware of what we're buying and now and then we've got food that's got a bit of red in it [laughs] on the traffic lights . . . But as long as . . . it's not really frequently we don't get too upset about it.*
>
> *Participant 16*

Theme 2: factors enhancing behaviour change

Social support and learning from others

Participants who had attended group sessions rather than individual sessions felt that being part of a group had a positive impact on their ability to engage with the study. The opportunity to discuss their achievements or setbacks and be in a positive social environment was something they appreciated and enjoyed:

> *It was nice to, have other people there were going through the same experiences if you like. And you would talk about it and bring back the same sort of problems or any success. So it's nice to have experience with it.*
>
> *Participant 16*

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I think it's quite good really, because you know, you. People in our group you know got on quite well, quite nice to talk to other people. Yeah . . . how you been doing, how many steps they done that week. No . . . I think it's quite a good social atmosphere.

Participant 13

In addition, those who had individual sessions felt that they would have benefited from having support from others:

Whether it's an individual session or a group session, maybe a group session more, you have to develop a kind of . . . a group dynamic, that compels people to want to come back, because they're a part of that group. I think the first three groups, the first three meetings or so, if you can really get people hooked in, they'll come back because they're a part of that group, or something like that. More will come back, because they're kind of part of that group.

Participant 21

Social support had a beneficial effect for people close to the participants. Participants had the opportunity to share their experiences with family members and see positive effects on them too:

Yeah. I suppose so. For me the family as well. I did tell my wife about it . . . and it did have an effect on her. You know, what she ate and stuff.

Participant 13

What was helpful – because of all the things about the diet etcetera, my son went to for blood test and was told he was potentially diabetic, put me in the panic. So I cooked everything for him . . . I did all the cooking and sent it round. And he lost about 3 stone in very short time and then they said he wasn't gonna be a diabetic at all . . . So it did for him as well as for me . . . because of what I've learnt. Yeah. So that was a bonus.

Participant 15

Ease of programme structure and content

An important factor reported to enhance behaviour change was the simplicity of the techniques that participants developed throughout the intervention. For example, setting small goals, awareness-raising and the preparation of setbacks enabled them to achieve sustainable lifestyle changes:

And they told me the procedure was very simple once I started. I found that if I avoid snacking, then my weight goes down. So I lost quite a bit of weight.

Participant 9

I thought personally, the pedometer was a very very good thing and it was so simple.

Participant 3

That training was excellent. You know, everybody has got a sometime or the other or you can have a setback. So, they told us how to keep going, not to stop. So that was a very good training. There will be step backs but those techniques help keep going.

Participant 7

You are now conditioned to be a bit more aware, and that is very important. It doesn't mean that I do 10,000 (steps) a day, but it is that awareness, that keeps my mind going.

Participant 7

Continuity and strength of therapeutic alliance

To sustain healthy behaviour changes, some participants felt that it was important that there was continuity of sessions. It was reported that participants felt less motivated to continue during the later stages of the programme because the sessions were less frequent:

> *I found the first six sessions really easy, because it was close together and it was just like we knew that every Thursday you would go. It's, when they were spread out then I felt like oh! You know, for the last one I really did not want to go. But you know, I said it to the nice lady.*
>
> *Participant 2*

Participants highlighted the importance of the therapeutic relationship built with the HLFs and how this encouraged them to return to the later sessions. During the process, there were changes to the HLFs, which some participants found to be quite disruptive:

> *I found when they spread out was, so in the first six it was one and the same person and you got almost on the one-to-one thing. So you got this rapport with someone then you hear . . . 'Hello, she's left I am taking over'.*
>
> *Participant 4*

> *'Well, she's left, I've taken over.' Well it was complete stranger, there was no rapport, and well they thought, 'How are you doing?' And well . . . I don't know . . . you don't know . . . And it was a complete stranger and you have no idea.*
>
> *Participant 4*

Maintaining continuity of staff to sustain engagement with participants was highlighted by participant 2:

> *I was definitely one of the lucky ones 'cause I had the same lady all the way through . . . so I mean we had usually an hour and a half. You know, 'cause you know, when you to get to know somebody you talk a lot. I mean, that was very useful.*
>
> *Participant 2*

Theme 3: perceived risk of cardiovascular disease

Participants' perceptions of their own cardiovascular disease risk

Participants dismissed themselves from being at risk of CVD owing to a lack of family history or an absence of current health problems. Some associated their risk of CVD solely with their age and discredited the contribution of other risk factors (e.g. poor diet and lack of PA):

> *When I got a letter . . . from the King's College. I was a bit . . . I was a bit surprised. I don't have a problem with the heart, so why they did . . . wrote letter like that, join. So I thought it might have some benefit . . . so I joined.*
>
> *Participant 14*

> *You know . . . go to the doctor and the doctor had never said . . . oh . . . you know . . . you're a particularly high risk of heart disease. So it comes in the post . . . and it says, you're in this high-risk group. So . . . you know . . . you do a bit of a double take. I don't know whether. But anyway . . . you've got nothing to lose and do the . . . come on and do the study and find out. But I think, as [participant 12] said, on the things they use to work out the risk factor, as soon as you put in your age and put in you're 70, you're immediately in the 70% category.*
>
> *Participant 13*

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Perceptions of the cardiovascular disease risk to others

The participants distanced themselves from having a risk of developing CVD and projected this onto others. Some felt that those who were selected were not appropriate for the study as they were not at risk or had no history of being at risk of CVD:

> *I said the thing is, I'm old anyway, surely it's people who are in their 30s and 40s to preclude them from maybe getting a risk of or having an inherent risk of heart trouble or whatever. Surely, it's the people who drive a hundred yards, or a hundred metres to the fish and chip shop, load themselves up – mind you I love fish and chips – every day of the week, and they are the people, surely at risk.*
>
> *Participant 8*

> *Well, I think all the people in our group. You know . . . they seemed to be reasonably fit and you know. You know . . . you harp on about diet really. You know . . . these things . . . are kind of self-selective aren't they?*
>
> *Participant 13*

Participant 13 suggests that those who agreed to take part may not actually be the individuals who need help:

> *So you wonder . . . the people that really . . . I'm not saying we didn't benefit from it, but you know, there weren't really obese people there. And I think I . . . so you wonder whether the people . . . the people who would really benefit from it. You know . . . the people who are possibly volunteering, are the ones that need it the least.*
>
> *Participant 13*

Theme 4: potential barriers to change and overcoming these barriers

Lack of feedback

A recurrent subtheme for participants in both the individual intervention arm and the group intervention arm was the lack of feedback received during the study. Particularly, participants felt that feedback seemed to be predominantly negative throughout, without the encouragement of positive results to engage them further with the study.

One suggestion was to provide positive feedback regarding weight loss and participants' progress as a means of potentially increasing motivation:

> *The person doing the testing didn't want us to give feedback about the group. I understand. But we didn't seem to get any feedback, like 'Oh, your weight's gone up' or you know . . . because that's a motivation in itself. You know . . . there was never that kind of discussion. Like 'this has changed, your cholesterol's . . . whatever . . . or'. 'Cause the things they test, there didn't seem to be any feedback. Now, I thought it would have been important to say to people 'well, this is OK . . . but this is not good' you know . . . and whatever. 'Cause that's a motivation in itself.*
>
> *Participant 21*

> *So you'd get the negative, we would get it if it was a negative result but if you wanna keep people more motivated they need to know about, the positive stuff as well, because that's why they're going. They want to know, they're getting better. If you're not gonna tell me you're getting better . . . well why?*
>
> *Participant 23*

Lack of engagement

A further barrier that was described was the lack of engagement or a relationship being developed on a personal level during the study:

> *There you well 'mm . . . you've been doing this for a year, it's been bought to your mind. What are the consequences? What's changed in your life at all . . . that's not enabled you to do it' whatever . . . you know it's just. I think that relates to my earlier point. I think there is a lack of engagement on a personal level. If you want to motivate people, you need to get people hooked in partly, as an individual as well as the group . . . I think I became this name and this number without any particular relationship being developed.*
>
> *Participant 21*

The role of authority

There were varying suggestions surrounding possible reasons why some individuals might not have decided to take part and changes that may improve this in the future. A recurrent theme was the importance of the role of authority from a health-care professional, such as a GP.

One participant suggested that their involvement may therefore be helpful to encourage those who are more reluctant to take part:

> *Now . . . people tend to listen to their doctor . . . or respond to the doctor, better than the MOVE IT study from, King's Univ- well, who the hell are they? You know, you got to . . . there's no engagement there. Whereas, if the doctor sends the letter, or a covering letter . . . then . . . as a as an intro, that's a more powerful intro than just a letter from you know because clearly . . . well . . . if a doctor said, we are collaborating or co-operating whatever word you choose, with this study from ah, and from your records it would appear that you are at risk of . . . whatever. Perhaps you would be, you'd, perhaps it would be ah, they could suggest that the study might be beneficial to you. Now, now that would be, that would be a fairly powerful introduction I think.*
>
> *Participant 21*

This was also highlighted by the completers, who mentioned that their GPs were unaware of their risk:

> *. . . and I thought . . . oh . . . all right . . . I'll go along with it. Then when I next saw my doctor, I said, like you know, what's this about high risk of heart attack and he looked at me vacantly and he says 'I dunno'. He said probably your age. He said, that's all I can think of.*
>
> *Participant 12*

Summary

This qualitative analysis explored the views of participants allocated to the intervention arms of MOVE IT. The main themes that emerged were (1) perceived benefits of the study, (2) factors enhancing behaviour change and (3) perceived risk of CVD. One further theme that emerged solely for the non-completers was (4) potential barriers to change and overcoming these barriers.

We found that participants described having positive experiences during the intervention sessions, citing the benefits of increased health awareness, positive lifestyle changes and the opportunity to learn from others. We identified several factors that might have affected the maintenance of participant behaviour change. Primarily, participants noted that the continuity of sessions and having the staff involved throughout were very important. The changes to the HLFs who carried out the sessions were disruptive for some and led to reduced engagement with the intervention. The continuity and frequency of sessions also had an impact on participants' motivation to take part and make healthy lifestyle changes. Owing to the pragmatic design, duration of the intervention and short-term contracts of the HLFs, there was a natural

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staff turnover that could not be prevented, except with a vast increase in funding to potentially hire more HLFs or offer longer contracts.

Non-completers had expressed that there was a lack of feedback and engagement throughout the intervention. To improve this, it would be beneficial to provide more positive feedback from HLFs or to have an alternative method of self-reflection during the sessions. This would increase motivation for patients to continue participation and for behaviour change to be sustained. Participants' perceptions of their own CVD risk may be viewed as a barrier to engagement.

Most participants did not believe CVD risk to be an issue and often attributed the risk to their age rather than their own lifestyle choices. In addition, some GPs were not aware of their patients' risks or the study itself, which may have altered individuals' perceptions of CVD risks. Therefore, for future interventions, it is important to work more closely with GPs to emphasise the benefits for patients' health and potential to ameliorate CVD risk. There may be other reasons why the non-completers felt a lack of engagement, as they may have higher levels of psychological distress or social problems that were not articulated during the focus group.

MOVE IT emphasised the importance of the use of qualitative methodology in providing detailed experiences of participants for assessing the effectiveness of a RCT. As previously reported, studies have supported the benefits of lifestyle interventions in the short term but few have supported them in the long term.[49,131,132]

The detailed reflections from participants involved in a long-term intervention support the use of qualitative methods for gaining greater understanding of the factors facilitating engagement and barriers to engagement. The responses from participants highlight the benefits of lifestyle interventions and the maintenance of behaviour changes for diet and PA levels. Finally, this study reveals areas of improvement for the future delivery and implementation of the study, including continuity of care and duration of the intervention. Although attendance at group sessions was lower than attendance at individual sessions, those who attended group sessions appeared to value the peer support aspect.

Chapter 10 Qualitative findings: the views of healthy lifestyle facilitators and clinical psychologists

Background

The HLF team were trained by a CP to deliver MOVE IT. Training in MI involves achieving a number of core competencies,[134] and HLFs were also trained to incorporate BCTs into intervention delivery.[52] There is no fixed length for the training of MI; however, a review of 28 studies found that most training schedules required 9–16 hours of training.[135] The training methods for MI involve didactic supervision and learning activities, such as role play, group exercises, discussions and feedback.[42]

The application of MI is considered helpful in working with patients towards lifestyle changes in primary care by nurses who incorporate it into their practice.[136,137] Previous studies of the application of MI in practice have suggested that it can be demanding but rewarding and that the spirit of MI and simple competencies are frequently achieved, but that the application of MI skills reduces over time and further support is required for more complicated competencies.[136,138] The ability to reflect on practice, continuing to develop skills and ongoing supervision are thought to be crucial to enhancing the long-term benefits of a MI approach.[139] There is evidence that enhancing MI with CBT techniques is achievable for nurses supporting diabetes mellitus control[140] or alcohol cessation,[62] and that intervention providers perceive both positive and negative impacts of the intervention on patient care depending on the patient's ability to engage.[141] Evaluating any novel intervention, from the perspective of stakeholders such as the intervention providers, is important for translation to policy.[142]

The views and experiences of intervention providers are vital to assessing the feasibility of widespread implementation into practice, by exploring the challenges in training and delivery. The HLF role was newly developed for the MOVE IT trial, drawing on the promising preliminary findings of the NHS health trainer programme, and adapted to be in line with MI, which underpins the intervention. Therefore, as the intervention and job role are both novel, we sought to gain detailed feedback on HLF training and intervention delivery from both the CPs who were responsible for training and supervision and the HLF team.

Methods

A qualitative approach was adopted to study HLFs' and CPs' views and experiences of developing and delivering the interventions. All 13 HLFs and two CPs were invited to interviews. Semistructured interviews were carried out, consisting of open-ended questions relating to the training, supervision, intervention, participants and values in psychological therapies. The topic guides used for HLFs and CPs are provided in *Appendix 6*. Interviewees were invited to give their feedback and the discussion was audiotaped. To gather meaning from the data, inductive thematic analysis explored any underlying concepts that were mentioned regularly.

The interviews were conducted by an independent research assistant to avoid response bias, which could exist if the interviewer was part of the MOVE IT team. Audiotapes were transcribed verbatim and the data collected were anonymised. NVivo software was used to analyse the data. Emerging themes from the interview transcripts were coded and categorised into themes and subthemes.

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Results

A total of nine female health-care professionals (seven HLFs and the two CPs) were interviewed. All HLFs except one were working on the MOVE IT trial at the time of their interviews. The HLFs who no longer worked on the trial were unavailable to participate. The characteristics of those interviewed are given in *Table 38*.

A thematic analysis resulted in three generic themes:

1. challenges and suggested improvement for the training
2. supervision issues and peer support
3. challenges with delivering the intervention.

Theme 1: challenges and suggested improvement for the training

The healthy lifestyle facilitator perspective

All HLFs were required to attend training during a 6-week period, with most agreeing that all subjects were adequately covered in this time. The HLFs appreciated the MI and CBT skills and the knowledge of how to apply these skills gained in the sessions. Although the information was thorough and prepared the HLFs for various situations that could occur during their sessions, the HLFs identified the 6-week training period as intensive and time consuming:

> *I think towards the end people felt like 'OK I am ready to go now' so it could have been maybe a little bit shorter.*
>
> *HLF4*

> *We, I say we because we have actually discussed this already, would have preferred it if it would have actually been pushed out quicker so that we experience it rather than just continuing to do scenarios which we kept doing every day.*
>
> *HLF6*

TABLE 38 Characteristics of intervention providers

Identifier	Number of months in position at time of interview	In post at time of interview?
HLF1	23	Yes
HLF2	9	No
HLF3	18	Yes
HLF4	8	Yes
HLF5	8	Yes
HLF6	8	Yes
HLF7	23	Yes
CP1	10	No
CP2	12	Yes

Note
Anonymous identifiers for the HLFs do not match those in *Chapter 8*.

At the beginning was kind of a lot of practising, it was a bit too much and it became mechanic because we did it with each other so much.

HLF7

There was particular reference to the role-playing exercises during the training, as reflected by comments such as:

. . . since we were role playing between ourselves we were taking it easy on each other.

HLF6

So we had training for 2 months, September and October. It was intense and it got quite repetitive and in my opinion it got quite tedious to the point where we started overthinking everything we did.

HLF7

The HLFs reported that sessions varied considerably in terms of the participant and their motivations to participate in the MOVE IT trial. This differed from the preparation they had undertaken in the training period:

The patients that we had were totally opposite of what we were trained to do and that's what threw everyone off. Everyone was trained to talk a certain way, got to their patients but then everyone was the total opposite.

HLF2

The clinical psychologist perspective

Both CPs were interviewed regarding their views on the training that had been developed by CP1. CP1 trained and handed over responsibilities to CP2 over an 8-week period. Within the first year, five out of the eight HLFs that CP2 had trained had left the study, leaving three HLFs to split the workload. When CP2 was employed, three new HLFs joined the study, bringing the total number of HLFs to six. The curriculum was adapted as the training was designed for larger groups. Despite this, CP2 felt that the HLFs managed the situation very well despite the intensity of the curriculum and amount of material covered:

I think it was kind of split into sort of face-to-face interactive sessions . . . They were given resources to go and self-study and some ideas of what to practice and how to practice the sessions . . . None of them really had previous experience of actually delivering psychology-based interventions . . . I suppose the tricky thing with something like MI, which I suppose is the key approach that is underpinning everything in MOVE IT, is that actually there is only so much you can teach directly because a lot of it is actually through practice and getting things wrong and reflecting on it . . . I guess that was also another challenge, just to know which were the crucial elements to kind of teach and how to get those across in a simplified and manageable way . . . It is quite a challenge because the concept of MI is still quite undefined in some ways as an intervention.

CP2

They came more from a health promotion background so their thing is being much more directive, telling people what to do, getting information, giving education, so they love all that . . . what's difficult is to try to pick them up into it and to try not to destroy their confidence too much so that they do not want to come back to training . . . what we can teach people and what we can actually take on board in my experience is quite different, so you can probably cut it [the curriculum] down by half and they might get some of that. Maybe the content, maybe it's more about doing less, better.

CP1

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Along with MI and CBT skills and the process of being assessed, requiring knowledge of CVD and its risk factors contributed to the length of the training, as CP1 explains:

> *. . . we had been working on another trial which was training diabetes nurses also in MI and some CBT techniques, so we were looking for a length of time which would allow them enough time to understand the theory, enough time to get to know each other and role play with each other, and understand a whole new curriculum and how to deliver it, plus everyone needed to be assessed which is a really lengthy process . . . I think the additional thing is that it is also the third strand is having to provide education about CVD.*
>
> *CP1*

Theme 2: supervision issues and peer support

Issues with supervision

A recurrent theme regarded the supervision received and lack of support provided, as seen in the following excerpts:

> *If we had a problem it was hard to know who we should go to and sort it out quickly because they tended to palm it off on each other quite a lot, not to be disrespectful or anything.*
>
> *HLF1*

> *But in terms of managerial supervision, we had that, but it was kind of formalities as opposed to kind of a necessity, I don't think they wanted to be there and we didn't really want to be there either and I think towards the end there was some tension between the HLFs and the supervisor.*
>
> *HLF2*

> *The project manager didn't really come to our supervision that much, I thought they were going to be there more to like help out with any other problems. I suppose the project manager could have been a bit more hands on, in supervision I mean.*
>
> *HLF3*

In addition, the HLFs felt that there were positive and negative consequences of some of them being at different stages of their sessions. On the one hand, a HLF further along in the training provided useful information to listen to and learn from. However, for those HLFs who were ahead, they felt that this was time consuming and that the time could be used to complete other tasks:

> *After the training, which was an intense period, you go out so it was good to constantly have that reminder of techniques and things, and then also that other girls are at different stages in their delivery so you can kind of hear about what's upcoming if someone is a session or two ahead of you . . . I think timing was probably a thing with supervision because they do seem to drag and it seemed like talking about the same thing a lot.*
>
> *HLF4*

Peer support

In relation to the lack of support experienced from management, the HLFs recognised the importance of supporting each other through difficult situations:

> *We, I say we because we have actually spoken about it. It's very useful in the sense that you get to hear what other HLFs are experiencing as well, so you might pick up on something someone else brings up and because we are talking about it in the supervision you get to help each other. Therefore, if that kind of situation presents itself again you know what to do.*
>
> *HLF6*

If there are similar problems and successes then it's nice to hear it but we talk about them anyway. And it's not nice to brag about it if someone else has an issue so I tend not to say too much, I didn't really participate too much.

HLF2

Once you are away from that sort of life it can be hard to come back to it, but they all encouraged me and the clinical psychologist is really very supportive . . . They are so supportive. At the beginning I was really slow with the IT and that sort of thing. Each other they helped with something, all of them. So they helped me a lot.

HLF5

We were a tight family; there were eight of us and all around similar ages and personalities. We got on so well that we were like one big team and family, we supported each other more than anyone else did in the study.

HLF2

Healthy lifestyle facilitators 4 and 5 also expressed a lack of guidance for the administrative work that was required. However, the situation improved after the MOVE IT administrator assisted in liaising with booking rooms for sessions, scheduling sessions with participants and contacting potential volunteer group facilitators:

. . . I know probably everyone is saying it, but I feel like I wasted a lot of time trying to sort that out [administrative work] when I could have actually been doing what I am supposed to be doing.

HLF4

The administrator is helping us quite a lot and that way is fine. Even the last group invitations the administrator helped send it and is looking for volunteers, there is help for us from there and we are lucky in that aspect.

HLF5

One HLF was promoted to a senior position and organised meetings to discuss practicalities and problem-solve non-clinical issues that arose. The senior HLF (HLF1) could then mediate between the group and the CPs:

I think that's really helped [promoting HLF] because it means that supervision with me is a bit more protective for perhaps other more therapeutic issues or issues with the curriculum itself.

CP2

Reflective logs

It was noted that the communication and structure of fortnightly supervision meetings improved after a senior HLF was appointed. Both CP1 and CP2 highlighted the benefits of the weekly reflective log that each HLF completed:

Sometimes when we would start, maybe because it's a little anxiety-provoking as well, they don't necessarily have issues that they would come out with then the way around that is that they have these reflective practice logs . . . They fill in these weekly practice logs and then supervision is every fortnight so often I would make a few notes of things that they brought up in their practice logs and then we would talk about it in more depth.

CP2

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> *The supervision was in two parts, one was a face-to-face [meeting] every fortnight and the other was weekly e-mail exchange where they would fill in a reflective practice log about what had gone well and less well and what we needed to focus on for the following week. I would read everyone's entry and reply by e-mail, so they would get that support as well which worked pretty well because everyone could read everyone else's logs so they were all learning from each other continuously. Everyone had to log at the end of the week.*
>
> *CP1*

The CPs felt that adequate support was provided, consisting of face-to-face supervision and reflective practice logs. CP1 provided an example of the importance of a weekly log when a HLF was unable to attend face-to-face supervision:

> *. . . there was one person who had a string of supervision that clashed with her running groups, that was kind of bad because I felt like she really needed to come to supervision but again you have this comfort with getting numbers through for the trial so we couldn't have her abandon the group, but thankfully she was active with the logs.*
>
> *CP1*

Theme 3: challenges with delivering the intervention

Challenges with patients

All HLFs mentioned enjoying interactions with patients and building a bond with them; they saw the patients benefiting from the interventions and received positive feedback:

> *What I love is when they come back with the results, when they say they used to be size 20 and now they are size 18, that's really nice. I had someone who came off one of their medications, so they were on medication before to control their blood pressure and cholesterol but now they are not anymore because they have managed their diet and changed their lifestyle.*
>
> *HLF6*

However, challenges with delivering the intervention emerged as a common theme. Resistant patients disputing any advice proved challenging for the HLFs, as did those who did not engage:

> *. . . one person walked out of the session as soon as we started with introductions the person just said 'I'm out I'm out!' and that scared me.*
>
> *HLF7*

Two of the HLFs mentioned the age of the participants as a barrier to delivering the intervention:

> *The participants are of an age range that aren't used to 'collaborative' care and often just want to be told/prescribed advice. This can make session delivery difficult as participants get frustrated at not being given a straight answer.*
>
> *HLF4*

> *The patients that we had were totally opposite of what we were trained to do and that's what threw everyone off. Everyone was trained to talk a certain way, got to their patients but then everyone was the total opposite.*
>
> *HLF2*

Another challenge that the majority of the HLFs encountered was that participants often thought that the HLFs were medical health experts; CP1 also noted this as a potential issue when delivering the intervention:

> *There are other issues that they has like their health problems, we are only trained to do the intervention but if they come to you with other problems you are not skilled in it you don't really know what to do . . . I had to keep telling them that I am not in the medical profession.*
>
> *HLF2*

> *If you say that five a day is good for you then he would immediately disagree and ask where I researched that from and how do I know if the fruit is actually good for you and not full of chemicals.*
>
> *HLF6*

> *I think other things that HLFs found challenging, especially with an older population with realistic medical problems was when participants would say that they couldn't exercise due to back pains, angina or other various reasons. Then the HLFs are a bit stumped because they weren't sure how to respond to that because they think that it could be dangerous for them to make the participants do X, Y.*
>
> *CP1*

The HLFs also mentioned that the initial information sheet sent out to the participating patients was not sufficient to prepare them for what the intervention would involve. HLF7 felt that a lot of patients would be less reluctant to participate in the trial if they knew what each session would include:

> *I feel like people aren't aware of what they are signing up to at the researcher stage, so many people are not sure what we are talking about and I just wonder what they are told in the beginning. I wonder if it's been made clear that once they've done this then they are going to be given something, some people are really hot on it and some have no clue what you're talking about . . . That's one big thing that I feel that people aren't aware of what they are signing up to.*
>
> *HLF4*

> *From my perspective people do not want to join the group because some expected to be weighed, or do some physical activity because of our name like healthy lifestyle facilitators – facilitate what, is it exercise? The name is good for using and the letter didn't explain anything. I would expect less dropout if you explain yourself better in the letter, because people become less nervous.*
>
> *HLF7*

Issues with the activity booklet

The lengths of the sessions (group and individual) were praised by the HLFs as there was adequate time to cover the material and manage digressive conversations. A common issue referred to the provided activity booklet being inappropriate for the age group. Participants had found the activity booklet childish or patronising:

> *It's probably the actual booklet; some people like it and some people think it's referred to a sort of working class. Some of the examples and case studies in there don't particularly relate to them . . . I guess they've had to write it for it to cater to different sort of educations, so some people are obviously very well educated and it's pretty much very basic. Some people find that a little offensive almost so that builds up some resistance and then you are battling against that almost, so myself and loads of the other girls have found that kind of tricky in terms of sort of putting the workbook a bit to the side and chatting with them about things . . . There are bits in the actual goal-setting that people don't particularly like, which makes us feel like you almost don't want to mention the question and just want to put your hand over it and pretend it isn't there.*
>
> *HLF1*

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> *Aspects of the actions plan such as rewards and reminders can be difficult to have this 'older' generation understand. Often they will say 'why do I need a reward/reminder, if I'm going to do it . . . I'll do it'.*
>
> *HLF4*

> *People often say that this is not us but then I refer them and couple of individuals have mentioned that this is quite patronising, the curriculum examples could be better and more age-fitting because the patients do not relate.*
>
> *HLF5*

CP1 observed the struggles that the HLFs had with the activity booklet:

> *I think the HLFs found that difficult because they were trying to do a manualised structured worksheet that they must fill in and the participants were just not on board, and they struggled with that.*
>
> *CP1*

Despite the issues with the activity booklet, CP2 highlighted the competence of the HLFs in guiding the participants towards the booklet during an observation of a session:

> *They are also very good at, I suppose this is where their comfort zone is, giving the information in a very clear way and making use of the resources in the workbook and pointing and steering people towards those.*
>
> *CP2*

Summary

This qualitative analysis explored the views of HLFs and CPs regarding the process of implementing MOVE IT. Of all 13 HLFs invited to interviews, we gained feedback from seven; we also gained feedback from both of the CPs who trained and supervised the HLF team. The main themes that emerged were (1) challenges faced during training and suggested improvements, (2) issues with supervision and peer support and (3) difficulties in delivering the intervention.

The HLFs enjoyed learning how to implement MOVE IT in addition to working with the patients. The training was described as time consuming and arduous, and HLFs felt that it could have been completed in a shorter time allowing more time for hands-on learning. Although there was a lot of information to cover, none of the HLFs mentioned a lack of confidence in the delivery of the intervention. With regards to the relationship with their supervisors, many of the HLFs felt that the fortnightly sessions were not utilised efficiently or that they could become repetitive.

The HLFs developed a strong support network between one another, and the relationship with their superiors improved once a HLF was promoted and could mediate between them, making better use of their time. It was noted that the activity booklets were age-inappropriate for the participants involved, which became a barrier during some sessions. In addition, some participants assumed that the HLFs were medical professionals who were able to discuss other health complaints and HLFs would have to reiterate that they were not medically trained while ensuring that the participants did not lose confidence in the help that they could provide. Both CPs noted the proficiency of the HLFs in working around these difficulties.

Enhanced MI was reported as an enriching and effective approach. The training undertaken by the HLFs in this study could have been adapted to allow the HLFs to learn via experience as opposed to continual rehearsal. This analysis also demonstrated the importance of effective and useful communication and support between HLFs and those managing them. It is therefore important to consider a practical and ongoing support structure. Furthermore, it may be useful to adapt the tools used in such an intervention to the age of the target group to remove potential barriers to engagement.

Chapter 11 Discussion

Summary of the clinical effectiveness of MOVE IT

This three-arm parallel RCT study tested the effectiveness of an enhanced MI intervention, delivered by specially trained health trainers (HLFs), in a group versus individual format, versus UC for reducing weight and increasing PA in adults at high risk (≥ 20.0%) of developing CVD in the next 10 years.

For the primary objective, the main findings were that there were no significant changes in weight or PA 24 months later between group enhanced MI or individual enhanced MI compared with UC.

For the secondary objectives, we found that MOVE IT delivered in a group format was not more effective than when delivered in the individual format in reducing weight and increasing PA or in reducing LDL cholesterol or CVD risk score 24 months later. There were no differences in the number of fatal or non-fatal cardiovascular events and other recorded AEs between the three treatment arms.

The health economic results revealed that there was little difference in terms of service use and costs between the three arms other than that resulting from the interventions themselves. Total service costs over the follow-up period were highest for the individual intervention arm, followed by the group intervention arm, followed by the UC arm. Differences were not statistically significant. QALYs were very similar for each arm. The group intervention was dominated by UC in that the latter had lower costs and produced more QALYs. The individual intervention did produce more QALYs than UC but the ICER indicated a cost per QALY far in excess of the threshold commonly used by NICE. For this reason, neither form of the intervention was cost-effective. There was much uncertainty around the cost and outcome differences but the conclusions of a lack of cost-effectiveness hold.

The findings of the process evaluation were as follows.

- Mediators: we found that dietary changes did not mediate any treatment effects on the primary outcomes. We did not conduct any further mediational analyses, as there was no change in the primary or secondary outcomes.
- Participation bias: we found that there was significant evidence of reduced reach in that those with a higher CVD risk, higher level of deprivation status and of African-Caribbean ethnicity were less likely to reply to invitations to participate from their general practice.
- Fidelity analysis: there were significant methodological limitations of conducting a fidelity analysis but, based on the much-reduced highly selected sample, there was evidence that nearly all of the HLFs had sufficient competencies in at least one MI skillset.
- Patient experience: the main themes that emerged were (1) perceived benefits of the study (benefits of increased health awareness, positive lifestyle changes and the opportunity to learn from others), (2) factors enhancing behaviour change (continuity of sessions over a longer period and having continuity of the same HLF) and (3) perceived risk of CVD (this was lower than was expected). One further theme that emerged for the non-completers only was (4) potential barriers to change and overcoming these barriers, such as lack of feedback and lack of engagement by their GPs.
- Therapist experience: the overall view was that the formal training period could have been shortened, more exposure to training cases could have been provided and the HLFs had not been prepared for the real-world challenges once in the clinical setting. They perceived themselves as competent in the MI approach and BCTs. They observed the importance of working with patients towards their goals but there were some common challenges, such as patients not engaging and some of the intervention materials not being deemed age-appropriate. The HLFs felt that support from supervisors, and administrative support, was insufficient but that they could problem-solve by supporting each other.

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Strengths and limitations

This RCT was powered to detect small effect sizes and, therefore, we can be confident that our (negative) findings are statistically valid. We used accelerometers as the gold standard for measuring PA. However, there may still have been a Hawthorne effect because the participants were aware of equipment and were not blind to allocation as this was a talking therapy. If there was a Hawthorne effect of wearing the accelerometer then it was negligible as the overall effect of the intervention was minimal on PA and weight loss. We had greater attrition for complete PA follow-up data. Previous research has set a standard for the amount of accelerometer wear time required per wear-day owing to variability between days of the week.[143] We found that those not providing sufficient data at follow-up were less active and more likely to smoke, had no formal educational qualifications and had more depressive symptoms. However, in the Health Survey for England, participants who provided sufficient accelerometer wear time did not differ from those who did not wear their accelerometer for the requested time.[144] As participants in our recruited sample were older than the target population, the use of fewer days of accelerometer wear data may be acceptable, as previous work has detailed that 3 consecutive wear-days accurately predicts PA levels in older adults.[145] Analysis of sedentary behaviour can require more wear-days, but this was not a main outcome of our study.

We recruited from all 12 CCGs covering the South London region, which has > 3 million residents representing a diverse socioeconomic and ethnically diverse community, including some inner-city London boroughs with high rates of CVD mortality. This was a positive aspect of the study. On the other hand, we did not include residents from the rest of the UK where there are high rates of CVD mortality, such as the north of England, south Wales and central Scotland, and therefore this sample may not have been representative of all people at high CVD risk.[146] Another limitation is that the South London sample may not be representative of the rest of the UK (i.e. owing to the health inequalities between the north and south of the UK). In addition, those London CCGs with more deprivation were slower to respond to the invitation and therefore when we were already halfway through recruitment and by the time we had completed recruitment, less time had been spent recruiting from these CCGs. This may also have led to under-recruitment of those most at risk, namely from deprived areas and non-white ethnic groups.

A pragmatic feature and strength of this study included using the GP QRISK2 tool, which is routinely available on the electronic records software for calculating CVD risk. Although this was a strength because it is an objective measure of risk, which could potentially be easily used by GPs, the limitation was that it had a high false-positive rate, generating a very high denominator number of patients, all of whom were invited for consent for screening for eligibility. The accuracy, completeness and age of data required for the QRISK2 algorithm based on the data stored in medical records were variable. This resulted in inviting and consenting many patients who turned out to have lower and therefore ineligible QRISK2 scores when screened. We had to assess an additional 1332 patients who turned out to be ineligible to participate, which was costly and time consuming. However, there were few other options. The NHS Health Check programme was not appropriate as it achieved a lower-than-expected uptake across England.[12]

A limitation of the study was that there were delays in recruitment that had repercussions in that the intervention delivery was delayed for some participants. The unexpected inefficiency in using the NHS Health Check led to delaying recruitment. Switching recruitment strategy to using the QRISK2 tool introduced another delay, which had repercussions for the delivery of the intervention. This is because the switch from Health Checks to QRISK2 required a protocol change, ethics approval and application of a cost extension from NIHR. The delays in recruitment and uncertainty of funding extension approval resulted in most of the HLFs seeking jobs elsewhere as their contracts started coming to an end. At around the same time, the co-applicant's clinical health psychologist also resigned. We had to employ and complete the induction of a second clinical health psychologist and train a new cohort of HLFs. This meant that when recruitment returned once additional funding and ethics approval had been secured there was a waiting list for delivery of the intervention. This may have contributed to some of the dropout from the intervention.

A strength was that our intervention was embedded and delivered in the heart of the community to match the real-world setting and we were able to be flexible with timing of the sessions (including late afternoons and early evenings). Our intervention focused on supporting maintenance once changes had been made in the initial phases. However, a limitation was that we could not offer sessions immediately and there was a waiting list for patients while HLFs were trained to competency. Approximately 50% of participants randomised to the individual and group interventions dropped out of the intervention after the introductory session. As most of our participants were retired, providing flexibility in the timing of sessions around work schedules was less important. We observed that participants in both the group and individual intervention arms generally adhered well to the intervention, based on the HLFs asking participants to set targets at each session and record if these were achieved or not.

We developed a standardised health trainer manual that could be readily replicated and used for training and supervision. A limitation was that the HLFs preferred practical training rather than didactic learning and classroom-based role play. We would have preferred to have the HLFs undertake more practical training with patients and this might have improved competencies, but this was impossible in terms of resources and the inherent nature of delivering a complex intervention as a research study. The HLFs were employed as NHS staff on short-term contracts; thus, we would have had to set up a CVD risk clinic very quickly, screen patients and then offer the intervention. As this was a 12-month intervention, this was not feasible.

We conducted a comprehensive process evaluation to understand the underlying mechanisms of action. We ensured a long follow-up to capture both short-term and long-term, or maintenance, outcomes. As a result of the process evaluation, we found that we did not reach those at the highest risk of CVD, participants who did not complete the intervention expressed lack of feedback and engagement as a reason, and participants attributed their high CVD risk to their age rather than their own lifestyle choices. Although we did observe several participation biases (see *Chapter 7*), it is unclear if more specific targeting of the intervention would have had a clinical effect, given that the absolute differences observed were small and a large sample was recruited. In addition, participants noted a lack of engagement from their GP concerning their high CVD risk, which may have negatively influenced any treatment effects. However, given the large number of GPs recruited to the study, it would not have been feasible to incorporate a larger amount of GP engagement in the study design.

Our PPI group was interactive and involved throughout. There are a number of areas in which the methodology of the trial may be improved. For instance, the importance of the invitation process and materials were highlighted by both PPI members and the intervention providers, and appropriate targeting of those who may benefit most from participation in the trial may improve the reach of the study.

There were limitations in the cost-effectiveness analyses. We relied on self-report of service use information and this may have led to recall inaccuracy. This was largely unavoidable given the range of services we wished to include in the measure of cost. Other studies have found this approach to be reasonable and there is no reason to suppose that any inaccuracy biased the findings.[147,148] A further limitation was that the EQ-5D-3L may not have been sensitive to change in this patient group. It is the recommended measure for such analyses but further work on assessing its appropriateness is warranted. The lack of differences in QALYs does support the main clinical findings of the study. Finally, we had hoped to include lost employment costs in a societal perspective; however, data on this were not available.

Interpretation

There are several possible explanations for the results of this trial: (1) although the clinical population was at high risk of CVD, the risk factors were not modifiable by lifestyle interventions, or (2) the psychological theories were not the most appropriate and/or psychotherapeutic approaches are not sufficiently potent alone.

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One explanation for the negative findings is that we may not have recruited those with high CVD risk who had modifiable risk factors. The use of a QRISK2 score of ≥ 20.0% ensured that our study recruited those at the highest risk of CVD in accordance with an objective risk algorithm that takes into account numerous modifiable risk factors. However, the risk factors with the greatest weighting in the algorithm are the non-modifiable risk factors: age, sex and ethnicity.[20] It has previously been shown that risk calculators, including the QRISK2, may not have the specificity to identify CVD risk at the individual, as opposed to the population, level.[149] Those patients of older age, male sex and South Asian ethnicity are at the highest risk, but these individuals may be otherwise healthy in terms of their modifiable risk factors that are inputted into the algorithm, and therefore the aims and contents of the intervention may not be applicable to them. The use of a QRISK2 score of ≥ 20.0% may have meant that the recruitment strategy led to a sample skewed against those with high BMIs, blood pressure and LDL cholesterol levels (exactly those participants who were most likely to benefit as these risk factors are modifiable).

Indeed, we found that older people with a normal or underweight BMI were recruited, raising challenges for the intervention team considering the primary aim of a reduction in weight. Previous research has demonstrated that participants at the highest risk benefit most from preventative interventions. In Gidlow *et al.*,[69] an observational study based in primary care in Stoke-on-Trent, followed three groups of patients: those with at least one modifiable CVD risk factor using the Framingham risk engine score, those with diabetes mellitus or coronary heart disease (secondary prevention) and those who were obese and had a CVD risk of > 15%. They received a patient-tailored, health-trainer-delivered, lifestyle intervention over 6–12 months with face-to-face and telephone/SMS (short message service) support. They observed modest improvements in risk factors and health-related quality of life, but not in CVD risk score, except in the subsample of patients who were at highest risk (> 20%) at baseline. In the study by Hardcastle *et al.*,[49] the investigators focused on CVD risk factors, such as excess weight (BMI of ≥ 28 kg/m^2, based on a value used in the recruiting general practice), hypertension (systolic/diastolic blood pressure of ≥ 150/90 mmHg) or hypercholesterolemia (≥ 5.2 mmol/l), rather than CVD risk score. They observed that the MI intervention was particularly effective for patients with elevated numbers of CVD risk factors at baseline.

The participants in this trial had average step counts at baseline that were in line with that previously reported for healthy older adults who were participating in exercise classes.[150] Therefore, on average, the participants recruited to MOVE IT may at baseline have been at their ceiling in terms of PA achieved, leaving little room for improvement. Previous studies of PA interventions for older adults, using accelerometer measurement as an outcome measure, tend to report significant increases up to a 12-month follow-up but there have been few psychological interventions to help maintain the increased PA.[151] Another explanation for the negative findings is that patients in our sample were not obese. The association between increasing PA and decreasing HbA_{1c} level following behavioural intervention is stronger in those who are obese (BMI of ≥ 30 kg/m^2),[152] and it may be that our sample was not at a high enough risk (the mean BMI was 28.3 kg/m^2) to see significance in outcomes.

The objective accelerometer measurement of PA provides a more reliable measure than self-report as it is less prone to bias. However, the days for which the PA measure is collected may not represent normal PA levels of participants; they may, for example, be elevated above the usual level owing to social desirability.[153] A review of the impact of interventions combining BCTs that target diet and PA found no differences in PA outcomes with UC when self-report PA outcome measures were used.[154] These studies did find a significant impact on BMI, suggesting that beneficial effects of the intervention had taken place and that perhaps a change in PA levels could not be successfully captured by the self-report measure or at the long-term follow-up. It may be that participants in our study made some initial increases in PA levels that were not captured at the 12- and 24-month follow-ups through accelerometry or at baseline; in addition, outcome PA measures of all participants may have been artificially raised. To further investigate the impact of interventions on PA, studies would need to undertake continuous objective measurement throughout participation, as opposed to the norm of 4–7 consecutive days' wear.[143] Low-cost and unobtrusive means to monitor PA throughout participation in a RCT, such as wearable and smartphone technology, provide this opportunity, although the reliability and validity of these methods are yet to be assessed.[155,156]

A second possible explanation for the negative findings is that the intervention potency or overall dose was suboptimal. The psychological skills were based on sound well-established psychological theories: (1) the theory of planned behaviour for initiation of behaviour change, which states that in order to change behaviour, people need to form an intention,[53] (2) principles underpinning MI that emphasise that the patient's motivation to change can be used as a therapeutic tool,[41] (3) CBT[91] and (4) social cognitive theory,[92] which emphasises the importance of peer support in shaping behaviour, which was applied to the group intervention arm of MOVE IT.

We used well-established and evidence-based psychotherapeutic techniques to apply the theoretical framework for MOVE IT. MI was used to support participants in forming healthy intentions. MI is a collaborative conversation style for strengthening a person's own motivation, belief and commitment to change. We used principles from CBT to support the transition from intention to action and from action to maintenance[93] by identifying and challenging unhelpful thoughts or thinking styles and promoting more positive emotions and behaviours. Using an iterative process, we devised the intervention curriculum and a participant workbook to support training, supervision, collaboration and replication. We had an intensive phase and the maintenance phase consisted of four sessions delivered at 3, 6, 9 and 12 months from intervention commencement. Those randomised to the group intervention arm were encouraged to use peer learning and the peer-support environment to facilitate change during both the intensive and maintenance phases. Novel methods and teaching aids were used to supplement the delivery of BCTs, such as visual aids (food labels)/cue cards, exercise demonstrations, video/audio material of patient testimonials, activity-based learning around meal planning and SMS/e-mail reminders. Cultural and religious awareness is built in to the intervention.

We employed and trained health trainers with an intensive package of didactic learning, role playing and feedback, group exercises, reading and case study discussion over 3 months. Competency in administering the intervention was assessed through a knowledge quiz and delivering several sessions to volunteers.[94–96] For HLFs that were not competent, they underwent further training until competent. HLF competency was monitored throughout the intervention by the CP regular supervision and quality assurance by reviewing audiotaped sessions.

This process is a standard approach to developing and evaluating a set of psychotherapeutic skills. It may be that for this clinical setting this approach is, or components of this approach are, insufficient. The theoretical frameworks were originally developed for mental health conditions that can remit, such as alcohol dependence, anxiety and depressive disorders. It would seem that a clinical state such as risk of CVD as a construct that could remit if one could develop and change one's thinking patterns about lifestyles has face validity for applying similar psychotherapeutic techniques. However, perhaps a psychological model is not appropriate and intensive instruction is more apt.

Landmark studies have repeatedly shown that intensive lifestyle instruction that focuses primarily on behaviour change, such as the diabetes prevention studies,[157–159] weight reduction programmes[160] and, recently, studies on reversal of type 2 diabetes mellitus,[161] does lead to significantly improved outcomes. Even the simple behavioural act of prescribing a pedometer leads to improved PA.[34] In these interventions, the clinically active ingredients were access to intensive, highly-structured and prescribed dietary and/or PA instruction following a counselling approach with minimal psychotherapeutic techniques. Our approach was to use talking therapies to instigate behaviour change rather than instruction, with the philosophy that intentions need to change before behaviours do and that changing people's way of thinking (as opposed to instructing them) would also be cheaper in the long term and more likely to be maintained. It could be that with lifestyles interventions the active ingredients are intensive instruction and advice. This suggests that the theoretical models of theory of planned behaviour and the theory that everyone has a degree of motivation and intent may not be appropriate for lifestyle change.

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A related, but perhaps separate, explanation is that the techniques we used to apply these theories were too weak. Secondary to factors totally outside our control, we could not assess competencies fully, but the extremely limited evidence we had was that the competencies, although acceptable, were not highly proficient. Assuming that this was indeed the case, then despite the intensive MI training of the HLFs this in itself was insufficient and one needs to establish very high levels of competencies in these skills. The health trainers did refer to this in the process evaluation; they thought that there was too much didactic and classroom-based teaching when they would have preferred more clinical cases and more supervision during the intervention. There have been very few studies that measure the competencies of low-intensity psychotherapy in lifestyle-based interventions. In the field of supporting self-management in type 2 diabetes mellitus, there have been only three studies that have formally tested competencies in MI.[105,162,163] The original landmark studies of MI were delivered by those who had developed the models, were leaders in the field and specialised wholly in MI.[41] As champions of MI and developers of the competency materials, it is likely that the earlier studies of MI would have shown high competencies and that this led to improved outcomes. It is unfortunate that although these data were collected we are not able to measure the competencies that would allow us to examine the level of skill. It may be reasonable to assume that the competencies delivered were probably adequate even if not excellent, in keeping with what would be expected for a large-scale delivery of MI by NHS band 3 equivalent health trainers. The reasons are that the health trainers were self-selected, most already had experience in this field and were given excellent references, they received high-intensity training and supervision, and their own feedback suggested that they were very motivated to improve their skills and seek more practical support and had insight into their clinical needs.

Although we observed that the HLFs generally had lower than expected competency in delivering the BCTs, it is important to note that the employed BCT coding framework was developed by us and was not validated, potentially leading us to underestimate HLFs' competencies in this domain. If we had the full data set of recorded intervention sessions, we believe that we would have observed much higher levels of competency. Anecdotes from the HLFs suggested that they were highly motivated, professional, committed, ambitious and knew that they were being observed; these are all the key generic therapist elements often needed to be competent in delivering talking therapies.

Finally, it is worth considering that participants in the UC arm may have received a high level of standard care over the course of the study, which could have positively affected their PA and weight, thus obscuring any treatment effects from MOVE IT. However, given that the UC arm did not have a significant increase in PA or reduction in weight, this alternative is unlikely.

Clinical implications

There are a number of clinical implications to consider. These findings suggest that low-intensity psychological intervention in the form of MI to the general population at high risk of CVD risk is not effective. The acquisition of a workforce of health trainers who have received extensive training in MI to a level of low-to-moderate skills in MI is probably also not indicated. If this kind of training was to be offered, perhaps the focus should use the manual we have developed as a basis but to focus on practical learning through case work (i.e. practical experience and case studies). There is also some consideration to be given as to whether these findings apply to other clinical settings that require lifestyle change, such as obesity, prediabetes, diabetes mellitus and people with CVD. Some older, male patients have a perception that they are not at risk of CVD or that this risk is to be expected at this stage in their lives. This view may need to be studied further to understand if it is associated with worse health outcomes.

The implication of the cost-effectiveness analyses is that introducing a generic enhanced MI-based health trainer programme for people at high risk of CVD is not a cost-effective use of resources.

Research implications and future directions

There are number of potential directions for the future. The first is to test whether or not this intervention would be more successful with people at much higher risk of CVD who have modifiable risk factors. This would involve selecting patients from primary care or community settings, and perhaps younger patients, with higher levels of obesity, lipids and other CVD risk factors that are potentially modifiable (unlike risk factors such as age, ethnicity and sex, which are not modifiable). One potential next step could be to model the intervention in different populations, as we are not aware of intensive MI interventions to support lifestyle change in which there was improved targeting.

An alternative approach would have been to increase the actual CVD risk for eligibility and to restrict the study to a younger population, those living in deprived areas and those of non-white ethnicity. Another improvement could be to change the format of the intervention or its delivery (i.e. being led by a practice nurse).[164] Setting BMI thresholds for recruitment would be another improvement to our methodology, which may mean that we recruit patients at higher risk and who may have benefited more from the intervention. However, our sensitivity analyses adjusting for different BMI thresholds did not indicate that this factor influenced the effect of intervention.

Second, there may need to be a paradigm shift in the psychological constructs underpinning lifestyle change in chronic disease self-management. Brief interventions for medical conditions that are chronic are increasingly showing to be not effective and outdated. New concepts are needed that take into account the burden, or the long haul, of living with a chronic condition. Our intervention was for 12 months but perhaps interventions that consist of bursts of support over years need to be evaluated; the dilemma is that these are expensive to fund and the results take a long time to be reported, and there may be a cohort effect as medical science might move forward in that time. MOVE IT emphasised the importance of the use of qualitative methodology in providing detailed experiences of participants for assessing the effectiveness of a RCT. As previously reported, studies have supported the benefits of lifestyle interventions in the short term but few have supported their benefits in the long term.[49,131,132] In MOVE IT, continuity of care and duration of the intervention was of value to those who attended. Although attendance to group sessions was less than attendance to individual sessions, those who attended group sessions appear to value the peer support. Future research should include more qualitative work on why those at the highest risk of CVD or those with modifiable risk factors do not attend lifestyle interventions. It was impossible to do this in MOVE IT as we could not gain ethics approval to contact patients who had not replied to our invitation sent via their GPs.

Summary

An intensive lifestyle intervention using enhanced MI skills was not associated with reduced weight or increased PA in a sample of people at risk of CVD. The reasons for this are probably attributable to the sample having predominantly non-modifiable risk factors. Future interventions should focus on those at high CVD risk and with modifiable risk factors and should be delivered at high levels of measured competency.

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Contributions of authors

Khalida Ismail (Professor of Psychiatry and Medicine and Consultant Liaison Psychiatrist) led the grant application and conduct of all aspects of the trial as PI.

Daniel Stahl (Reader in Biostatistics and Head of the Statistics Learning Group) contributed to the grant application, protocol writing and ongoing study monitoring, developed the statistical analysis plan, advised on the collection of outcome measures and data management and conducted the primary and secondary analyses.

Adam Bayley (Clinical Trial Manager) provided oversight of the research team, contributed to the day-to-day conduct of the trial and was involved in writing and collating contributions to the report.

Katherine Twist (Clinical Trial Manager) provided oversight of the research team and contributed to recruitment of research sites and the day-to-day conduct of the trial.

Kurtis Stewart (Trial Administrator) provided administrative support to the trial and contributed to sections of the report, including intervention details and fidelity analysis.

Katie Ridge (Assistant Trial Manager) contributed to the recruitment of research sites, data collection schedule development and ongoing day-to-day running of the trial.

Emma Britneff (Assistant Trial Manager) provided oversight of the research team and contributed to the day-to-day conduct of the trial.

Mark Ashworth (Senior Lecturer in General Practice) contributed to the grant application, protocol writing and ongoing study monitoring. He networked with, advised and facilitated the study for the new CCGs in South London and advised on primary-care-related issues.

Nicole de Zoysa (Senior Clinical Psychologist) contributed to the grant application, protocol writing and intervention development. She developed the manual, curriculum and competency framework and trained and supervised the HLF team.

Jennifer Rundle (Clinical Psychologist) provided ongoing training and supervision of the HLF team and contributed to the development of the process evaluation, including preliminary fidelity analyses.

Derek Cook (Professor of Epidemiology) contributed to the grant application, protocol writing and ongoing study monitoring. He supervised setup and collection of PA data and the interpretation of outcome measures.

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Peter Whincup (Professor of Cardiovascular Epidemiology) contributed to the grant application, protocol writing and ongoing study monitoring. He was responsible for senior supervision of all aspects of CVD epidemiology, Health Checks and health service aspects of the trial.

Janet Treasure (Professor of Psychiatry) contributed to the grant application, intervention development (MI approach, training and manual development) and ongoing study monitoring.

Paul McCrone (Professor of Health Economics) contributed to the grant application, protocol writing and ongoing study monitoring. He conducted the cost-effectiveness analysis.

Anne Greenough (Professor of Neonatology and Clinical Respiratory Physiology) contributed to the grant application, protocol writing and ongoing study monitoring.

Kirsty Winkley (Postdoctoral Fellow and Lecturer in Diabetes and Psychology) contributed to the grant application, protocol writing and ongoing study monitoring. As the senior project manager, she provided oversight of both the research team and the HLF team during recruitment and intervention delivery. She supervised the recruitment of staff members, the quality assurance of data collection and the process evaluation.

The MOVE IT trial team

We set up a multidisciplinary team to ensure that all scientific and practical considerations were addressed for the successful conduct of this study. This represented international reputations and expertise in health psychology, clinical psychology, nursing, clinical epidemiology of long-term conditions (obesity, depression, CVD and diabetes mellitus), clinical trials, health economics of complex interventions, statistics in behavioural sciences, academic and commissioning primary care and project management. Collectively, we have a wealth of expertise in running large cohort clinical trials of complex interventions and in the dissemination and translation into local services and training programmes, especially in the local multicultural setting. Our strength also lies in the collaboration between two teaching hospitals via the health innovation and education cluster.

Members

- Principal investigator: Khalida Ismail.
- Co-investigators: Mark Ashworth, Derek Cook, Anne Greenough, Paul McCrone, Daniel Stahl, Janet Treasure, Peter Whincup and Kirsty Winkley.
- Trial managers: Adam Bayley, Emma Britneff, Katie Ridge and Katherine Twist.
- Trial administrators: Kurtis Stewart and Clare Tucker.
- Research assistants: Hina Akram, Jasmine Anilmis, Jennifer Bales, Naomi Croft, Stephanie Fincham-Campbell, Lucinda Gledhill, Ana Jovovic, Alexandra Keyes, Paulina Kuczynska, Lisa Kuriakose, Leona McGarrigle, Louise Mercer, Anna Rokakis, Arann Rowe, Katherine Sparrow and Emily Staite.
- Clinical psychologists: Nicole de Zoysa and Jennifer Rundle.
- HLFs: Mwaita Bonga, Anna-Marie Bowtle, Nurcan Cahill, Emily Costelloe, Elizabeth Cruz, Salwa Dafalla, Charlotte Irving, Jessica Mark, Kashmir Mangat, Arbaktun Mohammed, Ekta Patel and Raquel Ramos-Fraga.
- PPI: Jennifer Bostock and Carole Haynes.
- Volunteers and students: Gita Ahluwalia, Emily Bralee, Christina Deller, Aurelia Harjanto, Vera Ludwig, Tracy Tang, Patrick Timpel, Alexander Warrilow-Wilson, Farah Yakub and Natalie Zaremba.

Trial Steering Committee

We would like to thank the TSC members: Professor Steve Iliffe (Chairperson), University College London; Professor Tom Marshall (member of the Health Technology Assessment and Efficacy and Mechanism Evaluation boards, 2009–11), University of Birmingham; Professor James Carpenter, London School of Hygiene and Tropical Medicine, Medical Research Council Clinical Trials Unit; and Dr Tim Anstiss, independent medical doctor and consultant. We would also like to thank the PPI members for attending all TSC meetings throughout the trial.

Data Monitoring and Ethics Committee

We would like to thank the DMEC members: Professor Betty Kirkwood (previous Chairperson), London School of Hygiene and Tropical Medicine; Professor Helen Weiss (Chairperson), London School of Hygiene and Tropical Medicine; Professor Stephanie Taylor, Queen Mary University of London, Barts and The London School of Medicine and Dentistry, Blizard Institute; and Dr David Blane, Imperial College London.

Publications

Bayley A, de Zoysa N, Cook DG, Whincup PH, Stahl D, Twist K, *et al.* Comparing the effectiveness of an enhanced MOtiVational intErviewing InTervention (MOVE IT) with usual care for reducing cardiovascular risk in high risk subjects: study protocol for a randomised controlled trial. *Trials* 2015;**16**:112.

Bayley A , Stahl D, Ashworth M, Cook D, Whincup P, Treasure J, *et al.* Response bias to a randomised controlled trial of a lifestyle intervention in people at high risk of cardiovascular disease: a cross-sectional analysis. *BMC Public Health* 2018;**18**:1092.

Ismail K, Bayley A, Twist K, Stewart K, Ridge K, Britneff E, *et al.* Reducing weight and increasing physical activity in people at high risk of cardiovascular disease: a randomised controlled trial comparing the effectiveness of enhanced motivational interviewing intervention with usual care [published online ahead of print December 12 2019]. *Heart* 2019.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 Proficiency levels adapted for healthy lifestyle facilitator training

Technique/skill	Proficiency level[a] None	Partial	Moderate	Full	Notes
BCTs (× 11) (% of participants)	0	50	70	100	
MI (with MITI)					
Global (*n*)	< 3	3	3.5	4	
Reflection-to-question ratio (*n*)	0	0.5	1	2	
Percentage with open questions (% of participants)	10	30	50	70	
Percentage with complex reflections (% of participants)	10	30	40	50	
Percentage who were MI adherent (% of participants)	50	70	90	100	
Group skills (adapted from AMIGOS)[165] (*n*)					
Activities	0	1	2	3	0 = none, 1 = a little, 2 = somewhat, 3 = extensively
Dynamics	0	1	2	3	
Rapport	0	1	2	3	
Boundaries	0	1	2	3	
Time management (*n*)	0	1	2	3	0 = none, 1 = a little, 2 = somewhat, 3 = extensively

AMIGOS, Assessment of Motivational Interviewing Groups Observer Scale.

a Trial proficiency: BCTs = 70%; MITI = 90% MI adherent and two categories in moderate score range; group skills = three categories in moderate score range; time management = moderate score range.

Note

Green shading denotes minimum target proficiency level.

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Appendix 2 List of participating general practices

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TABLE 39 List of participating general practices

CCG and general practice name	General practice code	Date when the first participant was recruited	List size on 1 April 2013	Number of patients aged 40–74 years	General practice IMD 2010 score[76]	Anonymised search saved[a]	Number of potentially eligible patients invited	Number of patients		
								Who responded[b]	Who consented	Randomised
Bexley										
Good Health	G83630	4 December 2013	5807	1836	30.20	No	63	12	11	4
Ingleton Avenue Surgery	G83024	20 September 2013	5038	2110	11.00	No	87	23	21	18
Lakeside Medical Practice	G83018	8 July 2013	15,320	5253	33.50	Yes	335	38	34	15
Lyndhurst Road Medical Centre	G83049	3 April 2014	7943	3600	14.30	No	70	–	13	5
Plas Meddyg Surgery	G83029	7 October 2013	7220	3188	7.77	No	111	36	34	28
Slade Green Medical Centre	G83062	2 August 2013	6521	2315	29.70	No	107	14	4	2
The Westwood Surgery	G83002	5 August 2013	7770	3191	10.90	No	157	40	22	10
Welling Medical Practice	G83025	5 August 2013	13,368	5984	15.00	No	85	35	17	7
Woodlands Surgery	G83057	14 August 2013	10,424	4749	11.30	No	158	47	21	14
Bromley										
Ballater Surgery	G84040	21 August 2014	6685	2890	11.50	Yes	138	–	31	21
Bromley Common Practice	G84024	2 December 2013	7814	3031	14.50	No	29	5	4	2
Broomwood Road Surgery	G84019	27 August 2013	9978	3923	32.90	No	107	–	42	17
Charterhouse Surgery	G84021	9 July 2013	9127	4374	8.37	Yes	150	–	49	30
Chelsfield Surgery	G84020	18 July 2013	7552	3591	8.91	No	211	51	61	27
Cornerways Surgery	G84018	24 June 2014	8531	3810	9.61	No	179	46	42	30
Derry Downs Surgery	G84005	21 January 2014	5630	2440	26.50	No	110	35	27	15

CCG and general practice name	General practice code	Date when the first participant was recruited	List size on 1 April 2013	Number of patients aged 40–74 years	General practice IMD 2010 score[76]	Anonymised search saved[a]	Number of potentially eligible patients invited	Number of patients		
								Who responded[b]	Who consented	Randomised
Eden Park Surgery	G84011	9 October 2013	8180	3609	11.80	No	171	31	45	24
Forge Close Surgery	G84030	2 April 2014	6563	3002	6.87	Yes	113	27	32	19
Links Medical Practice	G84003	27 August 2013	10,638	3974	30.60	Yes	221	23	33	14
London Lane Clinic	G84016	7 August 2013	15,558	6699	15.00	No	304	20	72	47
Park Group Practice	G84025	1 August 2013	8147	2983	30.10	No	126	16	15	8
Pickhurst Surgery	G84033	12 December 2013	6786	3106	6.82	Yes	180	44	56	28
Poverest Medical Centre	G84007	25 September 2013	9141	3791	23.40	Yes	199	34	53	32
Robin Hood Surgery	G84029	27 February 2014	5725	2541	27.20	Yes	93	14	14	6
South View Partnership	G84001	20 March 2014	6114	2647	11.70	No	195	51	69	45
Station Road Surgery	G84015	23 July 2013	12,572	5873	7.80	Yes	100	–	79	47
Stock Hill Surgery	G84004	31 July 2013	11,241	5386	10.40	Yes	323	–	92	55
Sundridge Medical Centre	G84629	16 December 2013	5066	1844	16.80	Yes	112	18	15	10
Trinity Medical Centre	G84022	28 July 2014	6006	2346	27.80	No	120	–	13	6
Tudor Way Surgery	G84035	20 August 2014	7108	3076	7.76	No	63	–	10	8
Woodlands Practice	Y00542	31 July 2014	9161	3812	19.80	Yes	202	–	31	19

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TABLE 39 List of participating general practices (*continued*)

CCG and general practice name	General practice code	Date when the first participant was recruited	List size on 1 April 2013	Number of patients aged 40–74 years	General practice IMD 2010 score[76]	Anonymised search saved[a]	Number of potentially eligible patients invited	Number of patients		
								Who responded[b]	Who consented	Randomised
Croydon										
Brigstock Family Practice	H83608	21 June 2013	4211	1474	25.00	Yes	172	–	30	13
East Croydon Medical Centre	H83044	18 November 2013	12,308	4189	17.90	Yes	287	–	63	30
Greenside Medical Practice	H83631	16 August 2013	7833	2347	33.60	No	36	–	2	1
Keston Medical Practice	H83016	30 January 2014	9406	3968	15.80	Yes	216	–	58	34
Leander Road Surgery	H83042	25 June 2014	7035	2620	21.20	Yes	127	–	25	14
London Road Medical Practice (Cavendish House)	H83021	30 September 2014	5866	2240	28.10	Yes	114	–	12	6
Morland Road Surgery	H83023	10 July 2013	6942	2638	23.00	Yes	193	–	24	15
Old Coulsdon Medical Practice	H83013	27 January 2014	12,527	5526	13.20	Yes	237	–	58	32
Parchmore Medical Centre	H83053	16 June 2014	13,878	5173	27.70	Yes	186	–	29	17
Parkside Group Practice	H83015	2 April 2014	12,505	5020	15.40	Yes	206	–	43	31
Portland Medical Centre	H83001	3 July 2013	12,829	4987	28.40	No	164	–	15	7
Selsdon Park Medical Practice	H83018	22 July 2013	10,679	4759	13.10	Yes	258	–	42	23
Stovell House Surgery	H83039	25 September 2013	7116	2973	18.50	Yes	250	–	61	31
Upper Norwood Group Practice	H83005	12 September 2013	11,077	3981	27.40	No	35	–	10	5

CCG and general practice name	General practice code	Date when the first participant was recruited	List size on 1 April 2013	Number of patients aged 40–74 years	General practice IMD 2010 score[76]	Anonymised search saved[a]	Number of potentially eligible patients invited	Number of patients		
								Who responded[b]	Who consented	Randomised
Greenwich										
All Saints Medical Centre	G83030	27 May 2014	5006	1945	36.70	No	93	22	18	11
Burney Street	G83065	6 January 2015	13,146	3594	28.50	No	55	8	10	5
Coldharbour Hill	G83003	14 November 2014	4098	1706	25.10	No	141	31	23	13
New Eltham	G83628	27 June 2014	5788	2188	13.40	No	125	20	15	9
Glyndon	G83060	13 November 2014	7014	2466	40.80	No	66	8	4	2
Manor Brook	G83001	18 June 2014	12,590	4831	27.20	Yes	276	54	47	27
Mostafa	G83647	17 June 2014	5701	2050	32.50	No	96	20	12	6
Plumstead Health Centre	G83019	18 December 2014	5445	2400	30.50	No	89	10	7	4
Royal Arsenal Medical Centre	G83016	3 June 2014	5823	2207	36.20	No	60	9	6	2
Sherard Road Medical Centre	G83027	19 December 2014	9790	3828	31.30	No	171	6	5	3
St Mark's	G83039	26 June 2014	7325	2662	39.00	No	55	11	8	6
Tewson Road Practice	G83007	25 June 2014	4972	2073	30.60	No	102	11	10	3
Vanbrugh Group Practice	G83021	6 March 2014	9520	3349	26.20	No	174	24	16	10
Waverley	G83635	6 November 2014	5253	2103	27.60	No	77	11	7	4

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TABLE 39 List of participating general practices (*continued*)

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								Who responded[b]	Who consented	Randomised
Kingston										
Brunswick Surgery	H84015	22 April 2014	6397	2594	10.40	No	73	14	13	5
Central Surgery	H84030	5 August 2013	12,203	5130	10.10	No	163	51	47	26
Claremont Medical Centre	H84619	20 June 2013	9823	3245	10.70	No	52	12	12	6
Hook Surgery	H84025	16 April 2014	5957	2259	12.30	Yes	137	24	21	15
The Groves Medical Centre	H84016	11 November 2013	11,513	4884	8.99	No	45	12	9	2
Kingston Health Centre	H84061	17 December 2014	6569	2457	10.00	No	62	–	5	5
Lambeth										
Brockwell Park Surgery	G85137	27 November 2013	5841	1895	26.60	Yes	91	–	27	11
Crown Dale Medical Centre	G85022	29 July 2014	10,813	4245	29.50	Yes	160	23	30	22
Hetherington Group Practice	G85045	19 November 2013	10,094	3344	29.80	No	136	–	23	11
The Hurley Clinic	G85053	27 November 2013	14,255	5235	31.90	Yes	206	–	41	19
Lambeth Walk Group Practice	G85054	10 February 2014	7543	2988	34.10	Yes	177	–	26	12
Minet Green Health Practice (Iveagh House)	G85135	14 January 2014	7711	2666	41.10	No	136	18	11	1
Stockwell Group Practice	G85028	13 November 2013	13,802	5201	35.90	Yes	155	24	20	7
Streatham Common Group Practice	G85014	11 November 2013	7496	2796	27.20	Yes	230	–	38	14
Streatham Place Surgery	G85118	10 December 2013	4656	1710	33.60	No	54	–	4	1

CCG and general practice name	General practice code	Date when the first participant was recruited	List size on 1 April 2013	Number of patients aged 40–74 years	General practice IMD 2010 score[76]	Anonymised search saved[a]	Number of potentially eligible patients invited	Number of patients		
								Who responded[b]	Who consented	Randomised
Lewisham										
Bellingham Green Surgery	G85124	9 June 2014	7113	2431	38.90	No	97	–	12	6
Brockley Road Surgery	G85048	30 October 2013	4561	1634	23.20	No	90	–	12	6
Grove Medical Centre	G85085	26 September 2013	8101	2321	35.10	Yes	90	11	9	5
Hilly Fields Medical Centre	G85055	17 October 2013	12,856	4696	24.90	Yes	225	–	60	32
Honour Oak Group Practice	G85089	1 November 2013	9290	3093	30.00	No	143	10	7	2
Jenner Practice	G85004	5 June 2014	15,045	5901	28.70	No	135	–	23	7
Morden Hill Surgery	G85035	8 May 2014	8654	3079	32.10	Yes	112	20	19	11
Nightingale Surgery	G85727	18 August 2014	5099	1628	26.60	Yes	90	–	16	11
Queens Road Partnership	G85015	23 June 2014	11,163	4264	34.00	Yes	156	–	22	14
Rushey Green GP	G85633	29 October 2013	11,332	3699	33.90	Yes	208	32	31	16
South Lewisham Group Practice	G85005	9 October 2013	14,094	5592	33.30	Yes	250	–	44	23
St John's Medical Centre	G85038	29 September 2014	12,553	4621	29.30	Yes	178	–	27	16
Torridon Road Medical Practice	G85032	11 September 2013	10,021	3982	24.30	Yes	113	–	30	11
Triangle Group Practice	G85120	25 February 2014	7159	2665	31.80	Yes	86	–	12	8
Woodlands Health Centre	G85722	11 July 2014	7091	2099	29.40	No	45	–	6	2
Woolstone Medical Centre	G85061	11 June 2014	7133	2992	29.60	Yes	112	20	20	12

continued

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TABLE 39 List of participating general practices (*continued*)

CCG and general practice name	General practice code	Date when the first participant was recruited	List size on 1 April 2013	Number of patients aged 40–74 years	General practice IMD 2010 score[76]	Anonymised search saved[a]	Number of potentially eligible patients invited	Number of patients		
								Who responded[b]	Who consented	Randomised
Merton										
Alexandra Surgery	H85656	3 July 2014	5566	1928	12.10	No	106	8	13	5
Central Medical Centre	H85070	6 September 2013	8271	2935	20.90	No	174	–	5	2
Grand Drive Surgery	H85101	1 October 2013	9065	3204	8.39	No	170	–	33	16
Lambton Road Medical Practice	H85051	17 September 2013	6113	2058	9.11	No	117	–	18	8
Merton Medical Practice	H85634	5 August 2013	6740	1687	16.60	Yes	30	–	9	6
Mitcham Family Practice (Graham Road)	H85078	27 May 2014	3074	1202	21.50	No	79	10	5	2
Morden Hall Medical Centre	H85037	10 June 2013	13,788	5123	17.10	No	138	–	34	19
Riverhouse Medical Practice	H85092	15 May 2014	5621	1820	15.00	No	55	11	10	10
Rowans Surgery	H85035	14 June 2013	9147	3468	21.70	No	43	–	10	4
Wide Way Medical Centre	H85029	5 November 2013	7208	2541	21.60	Yes	64	–	12	7
Richmond										
Brockbank (Park Road)	H84002	5 July 2013	12,339	5553	8.02	No	94	26	20	11
Flood (Essex House)	H84023	5 November 2013	8919	3682	11.10	No	118	28	24	12
Jackson (Acorn)	H84007	3 July 2014	7950	3488	8.94	No	83	–	21	12
O'Flynn (Hampton Wick)	H84032	25 July 2013	8835	3885	10.30	No	103	21	17	11
Pennycook (Hampton Hill)	H84623	22 August 2013	8819	3570	10.10	No	117	20	16	8

CCG and general practice name	General practice code	Date when the first participant was recruited	List size on 1 April 2013	Number of patients aged 40–74 years	General practice IMD 2010 score[76]	Anonymised search saved[a]	Number of potentially eligible patients invited	Number of patients		
								Who responded[b]	Who consented	Randomised
Southwark										
Albion Street Group Practice	G85138	13 February 2014	11,970	3536	24.30	Yes	81	5	5	5
Bermondsey and Lansdowne Medical Mission	G85094	8 May 2014	15,673	4527	28.80	No	112	–	17	9
Concordia Parkside	G85030	7 July 2014	6634	2338	34.30	No	53	3	1	1
Lister Primary Care Centre	G85134	11 December 2013	5824	1975	35.90	No	51	4	3	0
East Street	G85721	17 March 2014	7080	2497	37.70	Yes	53	4	4	3
Acorn and Gaumont	G85006	10 October 2013	11,879	3964	38.80	Yes	196	25	10	5
Camberwell Green	G85013	28 March 2014	10,881	4042	33.10	Yes	61	–	11	6
Elm Lodge Surgery	G85051	1 May 2014	7373	3155	16.40	Yes	96	–	30	24
Hambleden Clinic	G85112	24 February 2014	3318	1093	25.00	No	34	4	3	0
Lordship Lane Surgery	G85681	28 November 2013	3924	1383	26.90	Yes	69	10	8	5
Melbourne Grove	G85132	27 June 2014	7158	2498	24.20	No	45	3	2	2
Nexus Health Group (Manor Place)	G85034	18 July 2014	12,021	4003	34.70	Yes	102	6	6	4
Nunhead Surgery	G85685	23 April 2014	7640	2777	33.30	Yes	130	–	24	13
Old Kent Road Surgery	G85052	9 January 2014	5920	1869	36.90	No	57	6	5	1
Queens Road Surgery	G85040	12 February 2014	3672	1519	38.90	No	56	3	2	1
Sir John Kirk Close Surgery	G85050	11 July 2014	3894	1343	32.60	Yes	60	2	2	2

continued

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TABLE 39 List of participating general practices (*continued*)

CCG and general practice name	General practice code	Date when the first participant was recruited	List size on 1 April 2013	Number of patients aged 40–74 years	General practice IMD 2010 score[76]	Anonymised search saved[a]	Number of potentially eligible patients invited	Number of patients		
								Who responded[b]	Who consented	Randomised
Sutton										
The Beeches Surgery	H85662	24 June 2014	5593	2671	9.89	No	46	–	19	15
The GP Centre	H85019	25 July 2013	5066	2270	8.76	No	273	–	34	16
Cheam GP Centre	H85054	9 June 2014	5065	2196	9.02	No	116	30	28	20
Dr Scott and partners	H85063	26 July 2013	5088	2236	8.61	No	73	–	17	8
The Health Centre (Robin Hood Lane)	H85095	21 June 2013	10,017	3528	15.90	Yes	180	–	26	12
Manor Practice	H85116	7 June 2013	8583	3159	20.60	No	114	–	16	8
Shotfield Medical Practice	H85115	16 July 2014	10,370	4466	15.20	Yes	209	52	50	28
Wallington Family Practice	H85653	11 September 2014	11,081	4772	16.00	Yes	264	–	75	44

CCG and general practice name	General practice code	Date when the first participant was recruited	List size on 1 April 2013	Number of patients aged 40–74 years	General practice IMD 2010 score[76]	Anonymised search saved[a]	Number of potentially eligible patients invited	Number of patients		
								Who responded[b]	Who consented	Randomised
Wandsworth										
Brocklebank Group Practice	H85048	9 January 2014	16,781	5046	19.90	Yes	248	35	29	17
Chartfield Surgery	Y01132	17 December 2013	11,662	3946	18.90	Yes	212	33	31	12
Elborough Street Surgery	H85057	5 March 2014	6008	1973	11.30	Yes	120	31	31	10
Mayfield Surgery	H85006	28 November 2013	5521	1874	29.90	No	139	20	16	4
Open Door Surgery	H85087	17 April 2014	9312	3823	24.70	No	179	10	8	6
Wandsworth Medical Centre	H85001	22 October 2013	14,145	2860	19.30	Yes	168	30	24	12
Total			1,154,963	439,100			17,775	3515	3183	1742

a Anonymised data of all patients invited to participate saved on medical records by practice. Data subsequently extracted for participation bias analyses.
b The number of patients who responded was not accurately recorded for all practices, and is missing in some cases. Total numbers of responses were reported accurately. Therefore, total numbers of responses equal the sum of available response data and missing response data.

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Appendix 3 Behaviour change technique coding framework for the fidelity analysis

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BCT code	BCT label	BCT description	Score (0 = not delivered, 1 = delivered)	Line/page numbers (transcript)	Sample quotations	Total number and frequency
1	Provide information on the consequences (elicit-provide-elicit)	Give, or make salient, information about the risk factors of CVD and how a healthier diet and/or more PA could lower risk			*There are a number of risk factors associated with CVD, some are non-modifiable which include . . . and some are modifiable which include . . .* *By following national guidelines of healthy eating and physical activity, you can reduce your risk of CVD and therefore your overall health*	
2	Prompt intention formation	Support patient to form a specific statement about what they intend to do this week (i.e. 'I will . . . for X times per day/week')			*So you have identified that you would like to . . . What would you like to focus on in the week ahead?* *What do you intend to do this week?*	
3	Prompt barrier identification	Support patient to think in advance of the barriers to achieving their goal and how they can be managed			*What barriers might occur to you achieving this goal?*	
4	Prompt specific goal-setting	Support patient to list specific behavioural actions that will support their goal. Ensures goal and action steps are realistic and meaningful. Offer 'other' option if prompts are not relevant			*How will you go about achieving this goal?* *How many times a week will you do that?* *How realistic do you think this goal is?*	
5	Prompt review of behavioural goals	Use neutral, open questions to review past progress with goals set in previous sessions			*I am interested to hear how you got on with your goals set in our last session* *Please tell me how you got on . . .*	
6	Prompt self-monitoring of behaviour	Support patient to use diary sheet and e-monitoring to record progress			*I would encourage you to use this diary to monitor how you get on with your goal by ticking each day that you achieve it* *I would encourage you to use the pedometer to keep track of your number of steps*	

BCT code	BCT label	BCT description	Score (0 = not delivered, 1 = delivered)	Line/page numbers (transcript)	Sample quotations	Total number and frequency
7	Teach to use prompts or cues	Support patient to use reminder prompts			*What might help to remind you?*	
8	Agree on behavioural contract	Support patient to complete action plan and talk through with HLF or another group member			*Let's complete this action plan together* *Would you like to complete this action plan?*	
9	Plan social support or social change	Support patient to consider who can support them at home. If no one, suggest buddying			*Who might be able to support you with this goal, e.g. someone at home or a friend or another group member?*	
10	Prompt self-talk	Explain/elicit CBT lapse–relapse model. Support patient to find their own cheerleading statements when they have a setback			*One way of helping to prevent a relapse is to think of some cheerleading statements you can say to yourself when you have a setback, what might these be for you?*	
11	Relapse prevention	Elicit common barriers to diet/exercise changes and ways to manage/minimise. Support patient to identify lapse triggers and 'if . . . then' statements			*What situations would you be most likely to relapse?* *If that occurs, let's think about what you could do now to avoid a relapse*	
Comments		Please list any necessary comments or points of clarification				

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Appendix 4 Participant focus group topic guides

Focus group 1: participants who received six or more intervention sessions

Invitation/information received

Our first set of questions are about the invitation you received from your GP informing you of the study and inviting you to take part. This letter would have informed you of your high risk of heart disease, who was running the study and the motivational interviewing that would be used. In order to participate you would have had to send back a reply slip expressing your interest.

Q1) What made you volunteer to take part?

How did the following influence your decision to take part?

- Finding out that you were at high risk of heart disease (according to the NHS screening)
- Potential health benefits of a healthy lifestyle intervention
- Potential for helping others prevent heart disease in the future
- The researcher appointment, which included clinical tests and questionnaires about your lifestyle.

Sessions

You would have received sessions with a healthy lifestyle facilitator. You may have had different experiences of this – different HLFs, different number of sessions, different types of session (one-to-one or in a group). We want to hear about all of your thoughts and experiences. The weekly sessions consisted of an introduction to the concept of heart disease and its risk factors, followed by two sessions on exercise, two on diet and two on maintaining healthy habits. After which there were follow-up meetings once every 3 months.

Q2) Did you change any aspects of your lifestyle as a result of the treatment?

- If there were changes, could you give some examples?
- If there were no changes, why do you think that was?

Q3) How did the treatment impact on your lifestyle?

- Could you tell us more about how effective you thought the following aspects of the intervention were in helping you change your lifestyle?
    - Content of sessions (information given, tools, workbook)
    - Format/structure (length, number, spacing of sessions)
    - Behaviour change techniques (action plans, reminders, talking about setbacks)
    - Conversation style (including relationship with HLF)
    - Social support (other group members, family and friends).

Q4) The study aimed to invite a diverse range of people from different cultural, social and ethnic minority backgrounds. Based on the treatment you received, what aspects of the treatment made it suitable or unsuitable for a wide range of populations to participate?

Were any of the following aspects of the treatment a help or a hindrance?

- The materials used.
- What was it about the HLF that helped/did not help?
    - Did you feel you had something in common with the HLF?
    - Or the opposite, having nothing in common (e.g. did not come from your world/culture/age group).

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- The other members of your group (if applicable).

  - Did you feel you had something in common with the other group members?
  - Or the opposite, having nothing in common (e.g. did not come from your world/culture/age group).

Q5) Is there anything I have not mentioned that you would like to add?

- Is there anything you would change about MOVE IT?

Focus group 2: participants who received fewer than two intervention sessions

Invitation/information received

Our first set of questions are about the invitation you received from your GP informing you of the study and inviting you to take part. This letter would have informed you of your high risk of heart disease, who was running the study and the motivational interviewing that would be used. In order to participate you would have had to send back a reply slip expressing your interest.

Q1) What made you volunteer to take part?

How did the following influence your decision to take part?

- Finding out that you were at high risk of heart disease (according to the NHS screening)
- Potential health benefits of a healthy lifestyle intervention
- Potential for helping others prevent heart disease in the future
- The researcher appointment, which included clinical tests and questionnaires about your lifestyle.

Sessions

You were allocated to receive either one-to-one or individual sessions with a healthy lifestyle facilitator. However, you either did not attend any sessions or attended only the first session. We think that it is important for us to find out why this may be.

Q2) What were the key reasons that made you drop out?

Examples of reasons we thought some people might drop out are:

- Lack of time to take part. If time was an issue for you, can you tell us more specifically about what resulted in time being a problem?
- The MOVE IT workbook/documents you may have received from the HLF in session 0; if this was a reason for dropping out, can you tell us what things you didn't like?
- Participants not necessarily feeling that the treatment relates to them or would not be useful. If this influenced your reason for dropping out, can you tell us what aspects of the treatment you felt did not relate to you?
- The allocation (group or individual) you were assigned to. Would you have been more likely to take part if allocated to the other condition?
- The duration of each session, the number of sessions and the intervention duration as a whole (12-month period)? If this relates to you, can you tell us more about how this affected your participation?
- Ill health or illness within your family. If this relates to you, can you tell us more about how this affected your participation?
- Not wanting to share personal information, with either the HLF or other group members. If this relates to you, can you tell us more about how this affected your participation?
- Can you tell us more about what influenced your decision to drop out?

Q3) The study aimed to invite a diverse range of people from different cultural, social and ethnic minority backgrounds. Based on the treatment you received, what aspects of the treatment made it suitable or unsuitable for a wide range of populations to participate?

Were any of the following aspects of the treatment a help or a hindrance?

- The materials used.
- What was it about the HLF that helped/did not help?
    - Did you feel you had something in common with the HLF?
- Or the opposite, having nothing in common (e.g. did not come from your world/culture/age group).
- The other members of your group (if applicable).
- Did you feel you had something in common with the other group members?
- Or the opposite, having nothing in common (e.g. did not come from your world/culture/age group).

Q4) What would have helped you to continue with the treatment?

Q5) Is there anything I have not mentioned that you would like to add?

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Appendix 5 Characteristics of focus group attendees

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TABLE 40 Characteristics of focus group attendees

Group and participant	Borough	Trial arm	Number of sessions attended[a]	Age (years)	Sex	Ethnicity	Deprivation quintile[b]	Educational attainment	Relationship status	Occupational status	QRISK2 score
1A											
P1	Bexley	Group	10	74	Male	White	3	No formal qualifications	Married	Retired	19.9
P2	Bromley	Individual	9	75	Female	White	2	A level or above	Divorced	Retired	22.7
P3	Lewisham	Individual	10	70	Male	White	2	A level or above	Married	Retired	20.0
P4	Croydon	Individual	10	72	Female	White	5	A level or above	Married	Retired	21.3
P5	Croydon	Group	6	69	Male	Asian	2	A level or above	Married	Employed	22.3
P6	Sutton	Individual	10	69	Male	Asian	4	A level or above	Married	Employed	20.4
P7	Merton	Individual	10	73	Male	White	5	A level or above	Married	Retired	20.4
1B											
P8	Bromley	Individual	7	76	Male	White	4	No formal qualifications	Married	Retired	20.5
P9	Croydon	Individual	8	71	Male	Mixed	4	O level/GCSE	Married	Retired	19.4
P10	Kingston	Group	7	68	Female	Asian	5	A level or above	Married	Retired	22.1
1C											
P11	Bromley	Group	7	73	Female	Asian	4	O level/GCSE	Married	Retired	22.9
P12	Merton	Group	8	76	Male	White	4	No formal qualifications	Widowed	Retired	21.4
P13	Lambeth	Group	8	73	Male	White	3	A level or above	Married	Retired	18.7
P14	Lambeth	Individual	10	76	Male	Asian	3	A level or above	Married	Retired	39.9

Group and participant	Borough	Trial arm	Number of sessions attended[a]	Age (years)	Sex	Ethnicity	Deprivation quintile[b]	Educational attainment	Relationship status	Occupational status	QRISK2 score
1D											
P15	Bexley	Individual	10	74	Female	White	2	A level or above	Married	Retired	28.9
P16	Bexley	Group	10	69	Male	White	4	O level/GCSE	Married	Retired	20.3
P17	Bromley	Individual	10	75	Female	White	5	O level/GCSE	Divorced	Retired	21.3
P18	Southwark	Individual	10	67	Male	White	1	No formal qualifications	Married	Retired	22.0
P19	Croydon	Individual	6	73	Female	White	2	O level/GCSE	Single	Retired	26.4
P20	Croydon	Individual	10	71	Male	White	5	A level or above	Married	Employed	25.1
2A											
P21	Richmond	Group	1	71	Male	White	5	A level or above	Married	Retired	21.6
P22	Sutton	Individual	2	71	Male	Asian	5	A level or above	Married	Retired	33.4
P23	Kingston	Group	0	66	Male	White	5	A level or above	Married	Employed	36.6
2B											
P24	Southwark	Individual	0	74	Male	White	3	A level or above	Cohabiting	Employed	21.2
P25	Merton	Group	1	71	Male	Asian	4	A level or above	Married	Retired	32.6
P26	Sutton	Group	0	63	Male	White	5	A level or above	Divorced	Employed	22.8

A level, Advanced level; GCSE, General Certificate of Secondary Education; O level, Ordinary level; P, participant.
a Excluding session 0.
b Calculated from the IMD 2015 score (1 is most deprived).[111]

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Appendix 6 Health-care professional feedback topic guides

Healthy lifestyle facilitator interview topic guides

Some content has not been reproduced here

Training

You attended the training and supervision at King's.

- What were your views on the supervision?
- Can you tell me any ways in which you think the supervision could have been improved?
- Have you had any previous supervision in facilitating psychological therapies?

Supervision

- What are your views about the supervision you received throughout the study?
- What are your views about the support you received from the research team in general?
- How did other members of staff at your practice feel about you taking part in the study?
    - Were they supportive/not supportive? How so?
- What would have made it easier for you to participate?

Intervention

Now I'd like to ask you about delivering the intervention.

- What went well, could you give me some examples?
- What went less well?
- How did you find the sessions with patients?
    - How did you find the length of the sessions?
- What are your views about the admin time involved in the study?

Self-awareness

- How confident did you feel about delivering the group intervention?
- How confident did you feel delivering the individual intervention?
- How confident did you feel about managing the caseload?

Patients

- Can you tell me about any difficulties you experienced in getting patients to attend the sessions?
    - Was there any difference in response between the individual and group sessions?
    - Which method (group or individual) do you feel is more effective?
    - Did you book the patients in yourself?
- What were the challenges that you faced in using CBT skills with these patients?
- What other challenges were there when delivering the intervention?

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Clinical psychologist interview topic guides

Training

You delivered the training and supervision to the HLFs.

- What were your views on the supervision?
    - HLF engagement?
    - Frequency?
    - Length?
- Can you tell me about any problems you experienced with the supervision?
    - What would have made it easier for you?
    - What were the challenges that you faced when teaching CBT skills to the HLFs?
- Can you tell me any ways in which you think the supervision could have been improved?
- Have you had any previous experience in facilitating psychological therapies?
- What are your views about the support you received from the trial manager and your team (NDZ) in general?
    - Were they supportive/not supportive? How so?
    - What would have made it easier for you to participate more?

Supervision (fortnightly)

What are your views about the supervision you have delivered throughout the study?

- Can you tell me about any difficulties you experienced in getting HLFs to attend the supervision?
- Do the HLFs find it useful/helpful?
- Have you had any negative feedback about the supervision from the HLFs, if so could you give me some examples?
- Have you had any positive feedback about the supervision from the HLFs, if so could you give me some examples?

Intervention

Now I'd like to ask you about your views on delivery of the intervention. You sometimes shadow the HLFs at their surgeries, from your perspective:

- What goes well, could you give me some examples?
- What goes less well, could you give me some examples?
- What are your views about the HLF admin time involved in the study?
- Which method (group or individual) do you feel is more effective?

EME
HS&DR
HTA
PGfAR
PHR

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