

# 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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## Scientific summary

### **MOVE IT three-arm RCT**

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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.

### 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  $\geq 20\%$ , 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  $\geq 50 \text{ kg/m}^2$ ); 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  $\geq 20\%$ .

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 ( $\geq 20.0\%$ ) 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

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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