Title Page

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

***Authors***

Khalida Ismail1, Adam Bayley1, Katherine Twist1, Kurtis Stewart1, Katie Ridge1, Emma Britneff1, Anne Greenough2, Mark Ashworth3, Jennifer Rundle1, Derek Cook4, Peter Whincup4, Janet Treasure5, Paul McCrone6, Kirsty Winkley7, Daniel Stahl8

***Affiliations***

1 Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, King’s College London, 10 Cutcombe Road, SE5 9RJ, UK & Institute of Diabetes, Obesity and Endocrinology, King’s Health Partners Academic Health Sciences Centre.

2 Department of Women and Children’s Health, School of Life Course Sciences, Faculty of Life Sciences and Medicine, King’s College London, and MRC & Asthma UK Centre for Allergic Mechanisms in Asthma, King’s College London, and NIHR Biomedical Research Centre based at Guy’s and St Thomas’ Hospital and King’s College London.

3 Department of Primary Care and Public Health Sciences, King’s College London, Addison House, Guy’s Campus, London SE1 1UL, UK.

4 Population Health Research Institute, St George’s, University of London, Cranmer Terrace, London SW17 0RE, UK.

5 Department of Health Services and Population Research, Institute of Psychiatry, King’s College London, 16 De Crespigny Park, London SE5 8AF, UK.

6 Section of Eating Disorders, Institute of Psychiatry, King’s College London, 16 De Crespigny Park, London SE5 8AF, UK.

7 Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care, King’s College London, James Clerk Maxwell Building, London SE1 8WA, UK.

8 Department of Biostatistics and Health Informatics, Institute of Psychiatry, King’s College London, 16 De Crespigny Park, London SE5 8AF, UK.

***Corresponding author***

Professor Khalida Ismail

Department of Psychological Medicine

Institute of Psychiatry, Psychology and Neurosciences

King’s College London

London, UK

SE5 9RJ

Tel: +44 (0)207 848 5131

khalida.2.ismail@kcl.ac.uk

**Abstract**

***Objective:*** The epidemic of obesity is contributing to the increasing prevalence of people at high-risk of cardiovascular disease (CVD), negating the medical advances in reducing CVD mortality. We compared the clinical and cost-effectiveness of an intensive lifestyle intervention consisting of enhanced motivational interviewing (MI) in reducing weight and increasing physical activity (PA) for patients at high-risk of CVD.

***Methods:*** A three-arm, single-blind, parallel randomised controlled trial was conducted in consenting primary care centres in south London. We recruited patients aged 40-74 years with a QRisk2 score ≥20.0%, which indicates the probability of having a CVD event in the next 10 years. The intervention was enhanced MI which included additional behaviour change techniques) (BCT) and was delivered by health trainers in ten sessions over one year, in either group (n=697) or individual (n=523) format. The third arm received usual care (UC; n=522). The primary outcomes were PA (mean steps/day) and weight (kilograms). Secondary outcomes were changes in low-density lipoprotein cholesterol and CVD risk score. We estimated the relative cost-effectiveness of each intervention.

***Results:*** At 24 months, the group and individual interventions were not more effective than UC in increasing PA (mean difference=70.05 steps, 95%CI -288.00­­–147.90, and mean difference=7.24 steps, 95%CI -224.01–238.50, respectively), reducing weight (mean difference=-0.03kg, 95%CI -0.49–0.44, and mean difference=-0.42kg, 95%CI -0.93–0.09, respectively), or improving any of the secondary outcomes. The group and individual interventions were not cost-effective at conventional thresholds.

***Conclusions:*** Enhancing MI with additional BCTs was not effective in reducing weight or increasing PA in those at high CVD risk.

***Funding:*** Funding details: This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (Project: 10/62/03).

***Study registration:*** ISRCTN84864870.

***Section head:*** Cardiac risk factors and prevention

**Keywords**: cardiovascular disease; motivational interviewing; behavior change techniques; physical activity; lifestyle intervention; weight loss; primary care

**Key questions**

***What is already known about this subject?***

Although mortality from cardiovascular disease (CVD) is falling, the epidemic of obesity and unhealthy lifestyles is increasing the risk of CVD. There is little evidence as to whether a primarily psychological approach that aims to change a person’s intentions (cognitions) can alter lifestyle behaviour.

***What does this study add?***

This study was a response to a National Institute of Health Research commissioned brief to test whether enhanced motivational interviewing (a low-intensity psychological intervention combining motivational interviewing with additional behaviour change techniques) delivered by health trainers could improve lifestyles and thus reduce CVD risk. We found that enhanced motivational interviewing did not lead to a reduction in weight or increase in physical activity compared to usual care.

***How might this impact on clinical practice?***

We conclude that enhanced motivational interviewing have little impact for reducing CVD risk in people at high CVD risk when applied to the general population. This raises the question as to whether the administration of low intensity psychological techniques in lifestyle-related interventions are of any clinical benefit.

**INTRODUCTION**

Cardiovascular disease (CVD) remains the leading cause of mortality.1 Reduction in levels of physical activity (PA) and rising levels of obesity are limiting the decline in CVD mortality.2 The most effective interventions for primary prevention of CVD in high-risk individuals remain unclear. Walking, especially with a pedometer, is promoted as a near-perfect exercise,3,4 but this has not been studied in high-risk CVD populations. Lowering fat and increasing fibre, fruit, and vegetable intake do reduce the risk for CVD in the short-term,5 but evidence of longer-term benefits is needed.

Psychological processes are important in initiating and maintaining change to healthier lifestyles. One approach is to use motivational interviewing (MI), which is a collaborative, goal‐oriented behaviour change technique (BCT) that encourages the language of change.6 The appeal of MI is that it is brief, has a validated competency framework, and can be enhanced by other BCTs (e.g., goal-setting, self-monitoring and social support).7,8 The small number of studies assessing the effectiveness of MI in reducing CVD risk have produced mixed results.9

The primary aim was to compare the effectiveness and cost-effectiveness of enhanced motivational interviewing delivered by health trainers in increasing PA, reducing weight in people at high risk of CVD over 24 months was greater in those who received it in a group format compared to individual format or to usual care (UC).

**METHODS**

Trial design

This was a three-arm, parallel-group RCT for individuals at high-risk for CVD using a partially clustered design followed-up at 12 and 24 months from baseline. The three arms were: enhanced MI in a group format, enhanced MI in an individual format, and UC. As participants of the group arm, but not the other two arms, were clustered within groups, we had a partially clustered design. The protocol is published online.10

Setting

General practices with list sizes greater than 5000 patients in 12 south London boroughs (Bexley, Bromley, Croydon, Greenwich, Kingston, Lambeth, Lewisham, Merton, Richmond, Southwark, Sutton, and Wandsworth) representing a varied urban, socioeconomic and ethnically diverse population of approximately three million.11

Participants

Potentially eligible participants were identified from patient record databases and invited for screening. The inclusion criteria were: aged ≥ 40 and ≤ 74 years; CVD 10-year risk score of ≥20.0% calculated using QRisk2 (QResearch, Nottingham, UK) which is a validated predictive tool for identifying the percentage risk of having a fatal or non-fatal cardiovascular event in the next 10 years;12 fluent in conversational English; and permanent UK residence.

The exclusion criteria were: medical diagnosis of CVD; having a pacemaker; diabetes, kidney disease, atrial fibrillation, or stroke; chronic obstructive pulmonary disease; disabling neurological disorder; severe mental illness; registered blind; housebound or resident in nursing home; unable to move about independently; more than three falls in past year; pregnancy; advanced cancer; morbid obesity (BMI>50 kg/m2); participating in a weight loss programme; or another participant, already randomised, in the same household.

Randomisation and masking

Simple randomisation of participants was conducted by an independent Clinical Trials Unit (King's College London) using computer-generated randomisation blocks. In each block, 10 subjects were randomised to group, individual, or UC arms in a 4:3:3 ratio. The unequal allocation ratio ensured that the group arm had approximately 33% more patients to compensate for the loss of power from any clustering effect.

Baseline measures

We collectedsociodemographic factors, such as age, gender, self-report ethnicity, occupational status, educational attainment, and marital status. Biomedical data included weight (measured in light clothing, without shoes on the Class 3 Tanita SC240 digital scale), height (measured to 0.1), BMI (kg/m²), waist and hip circumferences (cm), blood pressure (BP; mmHg), HbA1c, and fasting lipids. Lifestyle data collected were alcohol intake (Alcohol Use Disorders Identification Test (AUDIT)),13 smoking status, and PA (ActiGraph GT3X accelerometer, a validated tri-axial movement sensor).14 Self-reported depressive symptoms were collected with the Patient Health Questionnaire 9-item (PHQ-9).15 Participants’ postcodes were used to calculate the English Index of Multiple Deprivation (IMD) 2015 score.16

Usual care

For UC, this consisted of referrals to locally-commissioned community-based weight loss, smoking cessation, and/or exercise programmes.

Intervention

The theoretical framework for enhanced motivational interviewing was based on social cognitive theory, and the theory of planned behaviour which states that to change behaviour, people need to form an intention (cognition).17,18 Intention formation is influenced by: i) expected value or positive attitude; ii) subjective norm; and iii) self-efficacy.

The intervention was manualised and consisted of 10 sessions over 12 months delivered by health trainers. Participants received a workbook, key learning points for every session, action planning worksheets, case studies, self-monitoring diaries, and a pedometer with instructions on its use. The intensive phase consisted of six weekly sessions during the first three months focused on PA and diet. The maintenance phase consisted of four sessions delivered at three, six, nine, and 12 months.

The training consisted of eight weeks of didactic learning, role-playing, group exercises, and case discussions using standardised materials on MI and BCTs drawn from cognitive behavior therapy (CBT) Each health trainer’s competency was assessed at the end of training via a knowledge test and through observing delivery of two sessions.10 As additional quality assurance, all sessions were audiotaped and competency was monitored and supervised weekly by the clinical psychologist. Fidelity to the manual consisted of the health trainer recording targets set and achieved per session. In the group intervention, lasting 120 minutes, patients were additionally encouraged to use peer support during and between sessions. Those randomised to the individual arm received the same intervention, but without peer support, in sessions lasting 40 minutes.

Outcomes

The primary outcomes were PA (average number of steps/day) and weight (kg) and the secondary outcomes were LDL cholesterol and QRisk2 score, measured at 12- and 24-month follow-ups and adjusted for baseline values.

Economic outcomes

The EQ-5D-3L was used to generate quality-adjusted life years (QALY). Intervention costs were calculated taking into account staff time delivering the sessions and the unit costs included overheads and on-costs and accounted for the ratio of direct to indirect contact time. We assumed the unit cost/hour of an NHS Band 3 clinician at £32.40. For the group intervention, the costs were apportioned over attendees. Other service costs were measured by combining service use data from the Client Service Receipt Inventory (CSRI) with unit costs.19,20

Statistical analysis

The primary analyses were aligned with Consolidated Standards for Reporting Trials (CONSORT). A description of the sample is presented using means (SDs) or counts (percentages). Baseline characteristics of those who did and did not provide follow-up data was described.

Analyses based on an intention-to-treat principle using all available outcome data were used to estimate the differences 12 and 24 months using mixed-effects models. In the linear mixed model ‘treatment arm’, ‘time’ (a categorical variable with two levels: 12 and 24 months), the ‘interaction between treatment group and time’, ‘borough’, ‘ethnicity’, ‘age’, ‘gender’, and the ‘baseline values’ of the outcome variable were fixed factors.

The random parts of the models were ‘GP practice’ (patients are nested in practices) and ‘therapy group’. The study’s design was complex as it is partially clustered and cross-classified. In the preliminary analyses with blinded data, the model did not converge, therefore we removed the random effect for therapist from the analysis. A two-tailed alpha of 2.5% for the two main comparisons ‘group versus UC’ and ‘individual versus UC’ was used and 97.5 % confidence intervals are presented.

Our analysis model assumes that data are missing at random with conditions for variables predictive of missingness. We compared baseline characteristics of those with and without complete PA and weight follow-up data. Models were rerun with predictors related to outcome missingness included as further covariates. Fourteen sensitivity analyses adjusting for the influence of missing data, protocol violations, and potential model misspecifications were conducted for the primary outcomes.

#### Cost-effectiveness analysis

We used bootstrapping methods to estimate 95% confidence intervals around the mean cost differences. QALYs were calculated from the EQ-5D-3L. Area under the curve methods calculated the QALY gain over the follow-up period and QALY differences were analysed controlling for baseline EQ-5D-3L score. If costs were higher for one arm compared to another and QALY gains were greater, we constructed an incremental cost-effectiveness ratio (ICER) to show the cost per extra QALY gained. Uncertainty around cost and QALY estimates was explored using cost-effectiveness planes generated from 1000 bootstrapped resamples. Finally, we generated cost-effectiveness acceptability curves, using the net-benefit approach and bootstrapping, to assess which of the three approaches was the most cost-effective. The range of values used was £0 to £100,000, including the guidance based threshold of £20,000-30,000.21 Sensitivity analyses were conducted around key costs.

***Sample size***

We selected a conservative difference of 0.25 pooled standard deviations (SD) in the main outcomes, which translates to a mean clinical difference (MCD) between two groups of 675 steps/day, 1.25kg, and 0.25mmol/L total cholesterol.22 We assumed an intraclass correlation coefficient of 0.05. To detect differences in our primary outcomes at a two-tailed alpha of 0.025 and accounting for the comparisons of ‘group versus UC’ and ‘individual versus UC’, 1,420 participants were required. Assuming approximately 17% loss to follow-up, a final sample of 1704 patients was required.

Protocol violation

On 2016-10-18, a university-wide IT network outage occurred leading to loss of 95 24-month accelerometer data files and 2651 audiotaped intervention sessions. We repeated the accelerometer data for 87 (91.6%) participants and retrieved 395 (14.9%) sessions from other computer drives.

Role of the funding source

The funder of the study had no role in study design, data collection, analysis, interpretation, or manuscript preparation. The corresponding author had full access to all the data and final responsibility for submitting for publication.

RESULTS

Of the 455 general practices invited, 135 (29.7%) consented; there was no difference in the general practices which did and did not consent.11 Participants were recruited between June 2013 and February 2015. Figure 1 shows the participant flow through the study. Participants were predominantly older, male, and of white ethnicity; there was no significant imbalance in the baseline characteristics between arms (Table 1). At baseline, participants took an average of 6757.63 (2716.55) steps/day and weighed 83.60 (15.06) kg.

Intervention delivery and receipt

Overall, 1220 participants were randomised to either the group or individual intervention; 28.2% did not start the intervention, 17.3% started but did not complete the intervention, and 54.5% completed the intervention. The three most common reasons for participants not starting or completing the intervention were being too busy (27.4%), unable to contact (16.0%), or no longer interested in participating (15.5%). Participants in the individual arm attended more sessions (median=10, IQR=7-10) than those in the group arm (median=7, IQR=5-9; p<0.001). The Supplementary Material provides further details of intervention delivery.

Fidelity to the manual was high, with the majority of participants setting targets at each session (91.6%) and the majority of these targets were achieved (90.9% achieved fully or partially; Table S3). The health trainers remained generally proficient (Supplementary Material).

**Loss to follow-up**

The loss to follow-up for both primary outcomes at 24 months was 18.4%, 19.7% and 11.9% for the group, individual and UC arms respectively. The differences in loss to follow-up between the treatment arms were significant at 24 month follow-up (χ2(2)=13.39, p=0.001). Data were collected for 91.6% of participants for at least one of the 12- or 24-month follow-ups, and for 79.7% of participants at both follow-ups. Participants missing 24-month outcome data walked significantly less at baseline (6376.9 (2497.2) versus 6833.1 (2752.5) steps per day, t=-2.78, p=0.006), were more likely to be current smokers (22.0% versus 14.4%, χ2(2)=6.4, p=0.041), to have no formal qualifications (33.2% versus 23.8%, χ2(2)=12.3, p=0.002), and to be more depressed (PHQ-9 score of 2.47 (3.87) versus 1.89 (3.05), t=2.44, p=0.015). There were no other baseline differences between participants with missing data compared to those with data. Table S4 provides a breakdown of reasons for loss to follow-up.

## Primary outcomes

Figures 2 and 3 summarise PA and weight, respectively, at each time point and include the pairwise comparison output. For PA, we did not observe any differences between the group or individual arms and UC at 12 or 24 months. For weight at 12 months, the group and individual arms had slight but significant reductions compared to UC, however, there were no differences at 24 months. All group differences (including limits of the 97.5% CIs) for PA and weight were below the MCD of 675 steps or 1.25 kg, respectively. Tables S7-S8 present the fixed and random effects of the mixed-effects regression analysis on the primary outcomes. None of the sensitivity analyses altered our conclusions for either of the primary outcomes.

Secondary outcomes

We did not observe any treatment effects for the secondary outcomes at 12 or 24 months (Table 2).

Cost-effectiveness

Service costs (including zero costs for non-users) were similar for inpatient care, outpatient attendances, and community contacts were similar between arms (Table S15). The intervention cost was highest for those in the individual arm. After controlling for baseline costs, total costs did not differ between the three arms. Mean EQ-5D tariff scores were similar for each arm and did not change markedly over time (Table S16). Controlling for baseline utility, QALYs did not differ between the three arms.

The group arm was less effective than UC and more expensive; as such it was dominated. Individual was more expensive and more effective. The ICER was £55,313 per QALY (£354 divided by 0.0064 QALYs). The ICER of the individual arm compared to the group arm was £8287 per QALY (£179 divided by 0.0216 QALYs) (Figures S2-S3). At a value of £30,000, the individual, group, and UC arms had a 38.1%, 3.2%, and 58.7% likelihood of being the most cost-effective option, respectively. The results of the sensitivity analyses did not alter the above results (Supplementary Material).

## Adverse events

523 AEs were reported between baseline and 24-month follow-up. There were no differences in mean (SD) number of AEs experienced by participants in the group, individual, and UC arms (0.37 (0.61), 0.33 (0.54), and 0.35 (0.57), respectively, (*F*(2)=0.68, p=0.51)) or in the number of fatal or non-fatal cardiovascular events (Table S17).

**DISCUSSION**

Summary of the clinical effectiveness of MOVE IT

Enhanced MI was not effective or cost-effective in improving PA, weight, LDL cholesterol, or QRisk2 scores in adults at high-risk of CVD over 24 months compared to UC.

Strengths and limitations

This RCT was powered to detect small effect sizes in a real-world setting. We developed a standardised health trainer manual for replicability. We used accelerometers as the gold standard for objectively measuring PA.

The QRisk2 had a high false-positive rate (Figure 1) because the medical records required for its algorithm were not always accurate resulting in high levels of ineligibility. Our sample may not have represented all those at higher CVD -risk as the average QRisk2 score was at the lower end.23 We also found that boroughs with higher levels of socioeconomic deprivation and greater ethnic diversity had less uptake.11Logistical barriers in research administration led to supply lag of some health trainers which contributed to longer waiting time than desired and may explain some of the reduced uptake of the interventions. Attrition from psychological interventions is a common phenomenon,24 perhaps more in those allocated to groups which may induce social avoidance in some participants. Loss to follow up was unusually lower in usual care compared to the intervention arms; we have speculated that study fatigue may have contributed.

Interpretation

One explanation for the negative finding is that our sample was skewed to non-modifiable risk factors in the QRisk2 algorithm (age, gender, and ethnicity), and on average not obese with a lower than expected CVD risk score.25 Furthermore, participants had average and possibly optimum baseline step in line with healthy older adults.4,26 It may have been more appropriate to recruit by raised BMI, blood pressure, and LDL cholesterol, which are modifiable risk factors,9 or selected a higher CVD score.

A second potential explanation is that the intervention potency was sub-therapeutic. For this clinical group, namely patients with a high CVD risk but with few psychological or physical symptomatic distress, the MI approach is inappropriate. For example, the prevalence for significant depressive symptoms was very low (1.4%), lower than the general population.

Landmark studies have repeatedly shown that intensive lifestyle instruction, such as the diabetes prevention studies27 and weight reduction programmes,28 do lead to significantly improved outcomes. In these interventions, the clinically active ingredients included intensive, highly-structured, prescribed dietary and/or PA programmes following a counselling approach and greater emphasis on formal social support, information giving and monitoring of weight and exercise. Our intervention did not prescribe a dietary or PA programme but aimed to address cognitions that resisted dietary and/or PA changes and to increase an individual’s intentions to change.

Research implications and future directions

First, this intervention might have been more successful in those with modifiable CVD risk factors or much higher CVD risk scores and if we had had much shorter waiting lists. The potential of an enhanced MI approach to a younger population, those living in deprived areas, and of non-white ethnicity remains unknown. We used the same strategies for recruitment regardless of socio-economic, ethnicity and inner city status and future studies could instead over sample in these subgroups to recruit those at higher CVD risk.

Second, we may need to consider more intensive approaches to supporting lifestyle change in those most at risk of CVD. For instance, psychological constructs such as optimistic bias and habit formation are common patterns.9,29,30 Prioritising public health or community interventions that aim to overcome the stigma towards obesity and challenging unhelpful beliefs such as optimistic bias (‘its not going to happen to me’) and habit formation maybe more effective than individualized approaches.

Summary

An intensive lifestyle intervention using enhanced MI skills was not associated with reduced weight or increased PA in people at high-risk of CVD. Future interventions should focus on those at very high CVD risk and/or with modifiable risk factors.

**REFERENCES**

1 Roth GA, Johnson C, Abajobir A, *et al.* Global, Regional, and National Burden of Cardiovascular Diseases for 10 Causes, 1990 to 2015. *J Am Coll Cardiol* 2017; **70**: 1–25.

2 Forouzanfar MH, Afshin A, Alexander LT, *et al.* Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet* 2016; **388**: 1659–724.

3 Murtagh EM, Nichols L, Mohammed MA, Holder R, Nevill AM, Murphy MH. The effect of walking on risk factors for cardiovascular disease: An updated systematic review and meta-analysis of randomised control trials. *Prev Med (Baltim)* 2015; **72**: 34–43.

4 Harris T, Kerry SM, Limb ES, *et al.* Physical activity levels in adults and older adults 3-4 years after pedometer-based walking interventions: Long-term follow-up of participants from two randomised controlled trials in UK primary care. *PLoS Med* 2018; **15**: e1002526.

5 Rees K, Dyakova M, Wilson N, Ward K, Thorogood M, Brunner E. Dietary advice for reducing cardiovascular risk. In: Brunner E, ed. Cochrane Database of Systematic Reviews. Chichester, UK: John Wiley & Sons, Ltd, 2013. DOI:10.1002/14651858.CD002128.pub5.

6 Miller WR, Rollnick S. Motivational interviewing: Helping people change, 3rd edn. Guilford press, 2012.

7 Greaves C, Sheppard K, Abraham C, *et al.* Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health* 2011; **11**: 119.

8 Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Heal Psychol* 2008; **27**: 379–87.

9 Lee WW, Choi KC, Yum RW, Yu DS, Chair SY. Effectiveness of motivational interviewing on lifestyle modification and health outcomes of clients at risk or diagnosed with cardiovascular diseases: A systematic review. *Int J Nurs Stud* 2016; **53**: 331–41.

10 Bayley A, de Zoysa N, Cook D, *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.

11 Bayley A, Stahl D, Ashworth M, *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.

12 Collins GS, Altman DG. Predicting the 10 year risk of cardiovascular disease in the United Kingdom: independent and external validation of an updated version of QRISK2. *BMJ* 2012; **344**: e4181.

13 Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption-II. *Addiction* 1993; **88**: 791–804.

14 Plasqui G, Westerterp KR. Physical activity assessment with accelerometers: an evaluation against doubly labeled water. *Obes*  2007; **15**: 2371–9.

15 Spitzer RL, Kroenke K, Williams JBW. Validation and utility of a self-report version of PRIME-MD. The PHQ primary care study: primary care evaluation of mental disorders. Patient Health Questionnaire. *JAMA* 1999; **282**: 1737–44.

16 Ministry of Housing Communities & Local Government. English indices of deprivation 2015. 2015. https://www.gov.uk/government/statistics/english-indices-of-deprivation-2015 (accessed July 2, 2018).

17 Bandura A. Social foundations of thought and action: a social cognitive theory. Englewood Cliffs, NJ: Prentice Hall, 1986.

18 Ajzen I, Azjen I. The theory of planned behavior. *Organ Behav Hum Decis Process* 1991; **50**: 179–211.

19 Curtis L. Unit Costs of Health and Social Care 2012. Canterbury: Personal Social Services Research Unit, 2012 http://www.pssru.ac.uk/project-pages/unit-costs/2012/.

20 Chisholm D, Knapp MRJ, Knudsen HC, Amaddeo A, Gaite L, Van Wijngaarden B. Client socio-demographic and service receipt inventory - European version: Development of an instrument for international research. EPSILON study 5. *Br J Psychiatry* 2000; **177**. DOI:10.1192/bjp.177.39.s28.

21 National Institute for Health and Care Excellence. Guide to the methods of technology appraisal 2013. 2013.

22 Bravata DM, Smith-Spangler C, Sundaram V, *et al.* Using pedometers to increase physical activity and improve health: A systematic review. *JAMA* 2007; **298**: 2296–304.

23 British Heart Foundation. CVD STATISTICS – BHF UK FACTSHEET. 2018.

24 Barrett MS, Chua W-J, Crits-Christoph P, Gibbons MB, Casiano D, Thompson D. EARLY WITHDRAWAL FROM MENTAL HEALTH TREATMENT: IMPLICATIONS FOR PSYCHOTHERAPY PRACTICE. *Psychotherapy* 2008; **45**: 247–67.

25 van Staa T-P, Gulliford M, Ng ES-W, Goldacre B, Smeeth L. Prediction of cardiovascular risk using Framingham, ASSIGN and QRISK2: how well do they predict individual rather than population risk? *PLoS One* 2014; **9**: e106455.

26 Lee I-M, Shiroma EJ, Kamada M, Bassett DR, Matthews CE, Buring JE. Association of Step Volume and Intensity With All-Cause Mortality in Older Women. *JAMA Intern Med* 2019; published online May 29. DOI:10.1001/jamainternmed.2019.0899.

27 Knowler WC, Barrett-Connor E, Fowler SE, *et al.* Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002; **346**: 393–403.

28 Ahern AL, Wheeler GM, Aveyard P, *et al.* Extended and standard duration weight-loss programme referrals for adults in primary care (WRAP): a randomised controlled trial. *Lancet* 2017; **389**: 2214–25.

29 Thakkar J, Heeley EL, Chalmers J, Chow CK. Inaccurate risk perceptions contribute to treatment gaps in secondary prevention of cardiovascular disease. *Intern Med J* 2016; **46**: 339–46.

30 Gardner B. A review and analysis of the use of ‘habit’ in understanding, predicting and influencing health-related behaviour. *Health Psychol Rev* 2015; **9**: 277–95.

**Data Availability Statement**

Data are available from the corresponding author upon reasonable request.

**Declaration of interests**

KI has received honoraria for educational lectures from Sanofi, Novo Nordisk, Janssen, and Eli Lilly. KW received consultancy fees from Merck Sharp & Dohme. MA, DC, and PW received grants from the NIHR HTA programme during the conduct of the study. The authors have no other competing interests to declare.

**Acknowledgements**

We would like to thank: the participants who took part in this trial, including those were screened for eligibility but did not participate; the 135 NHS GP practices across south London who participated while managing intensive workloads; Trial Steering Committee (Prof Steve Iliffe (Chair), University College London; Prof Tom Marshall, University of Birmingham; Prof James Carpenter, London School of Hygiene and Tropical Medicine, MRC Clinical Trials Unit; Dr. Tim Anstiss, independent medical doctor ); the Data Monitoring and Ethics Committee (Prof Betty Kirkwood (previous Chair), London School of Hygiene and Tropical Medicine; Prof Helen Weiss (Chair), London School of Hygiene and Tropical Medicine; Prof Stephanie Taylor, Queen Mary University of London, Barts and The London School of Medicine and Dentistry, Blizard Institute; Dr. David Blane, Imperial College London); the independent raters of the audio recordings, Pam Macdonald and Amy Harrison; the expert by experience patient participants (Jennifer Bostock, Carole Haynes); the research team, Nicole de Zoysa (previous clinical psychologist) and the lifestyle facilitators.

**Contribution of Authors**

Khalida Ismail led the development of the protocol and the conduct of the study; Mark Ashworth, Derek Cook, Anne Greenough, Janet Treasure Peter Whincup & Kirsty Winkley contributed to the protocol development, senior project management, interpretation of the analysis and manuscript drafting. In addition to the above, Paul McCrone and Daniel Stahl led the cost effectiveness analysis and main statistical analysis, respectively. Adam Bayley, Katherine Twist, Katie Ridge, Emma Britneff were the trial managers. Kurtis Stewart provided administrative support, conducted the statistical analysis, and drafted the reports. Jennifer Rundle led the set-up and delivery of the psychological interventions and supervised the fidelity analysis.

**Ethical approval**

The trial has been reviewed and approved by the Dulwich Ethics Committee (reference: 12/LO/0917). Written informed consent was gained from all participants prior to undergoing screening in order to validate their eligibility to participate.

**Funding details**

This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (Project: 10/62/03). Khalida Ismail, Daniel Stahl, and Dominic Stringer were part-funded by the NIHR Mental Health Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King’s College London. Kirsty Winkley is part funded by an NIHR HEE Senior Lectureship Award. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health.

The Corresponding Author has the right to grant on behalf of all authors and does grant on behalf of all authors, an exclusive licence (or non exclusive for government employees) on a worldwide basis to the BMJ Publishing Group Ltd and its Licensees to permit this article (if accepted) to be published in HEART editions and any other BMJPGL products to exploit all subsidiary rights.

**TABLES**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 1. Baseline characteristics of participants by trial arm.** | | | | |
|  | **Trial arm** | | |  |
|  | Group (n=697) | Individual (n=523) | UC (n=522) | Total (n=1742) |
| Age, *mean (SD)* | 69.59 (4.16) | 69.76 (4.11) | 69.96 (4.05) | 69.75 (4.11) |
| Gender, 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, n (%) |  |  |  |  |
| *White* | 614 (88.1) | 471 (90.1) | 473 (90.6) | 1558 (89.4) |
| *Asian* | 75 (10.8) | 45 (8.6) | 41 (7.9) | 161 (9.2) |
| *African/Caribbean* | 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) |
| Qualification, n (%) |  |  |  |  |
| *No formal qualifications* | 186 (27.2) | 126 (24.4) | 122 (23.8) | 434 (25.3) |
| *GCSE or equivalent* | 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) |
| IMD 2015 quintile, n (%) |  |  |  |  |
| *1st (most deprived)* | 63 (9.1) | 46 (8.8) | 52 (10.0) | 161 (9.3) |
| *2nd* | 122 (17.6) | 125 (23.9) | 108 (20.7) | 355 (20.4) |
| *3rd* | 136 (19.6) | 88 (16.9) | 93 (17.8) | 317 (18.2) |
| *4th* | 166 (23.9) | 116 (22.2) | 124 (23.8) | 406 (23.3) |
| *5th (least deprived)* | 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* | 11.6 (8.4) | 11.0 (8.1) | 11.2 (9.2) | 12.7 (10.9) |
| 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) |
| *GCSE=General Certificate of Secondary Education* | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Table 2. Descriptive summary of secondary outcomes by trial arm and time and pairwise comparison output.** | | | | | | | |
|  |  | **Trial arm** | | | **Pairwise comparisons** | | |
|  | **Time** | Group | Individual | UC | Group – UC | Individual – UC | Individual – Group |
| **LDL cholesterol (mmol/mol)** | Baseline | 3.11 (0.85) | 3.14 (0.89) | 3.07 (0.88) |  |  |  |
| 12 months | 2.93 (0.85) | 2.92 (0.83) | 2.91 (0.87) | 0 (-0.07–0.07) | 0 (-0.07–0.08) | 0 (-0.07–0.08) |
| 24 months | 3.04 (0.90) | 3.02 (0.88) | 2.94 (0.90) | 0.07 (-0.01–0.15) | 0.05 (-0.04–0.14) | -0.02 (-0.10–0.07) |
| **QRisk2 score**  **(%)** | Baseline | 24.95 (4.79) | 25.26 (5.27) | 24.93 (4.81) |  |  |  |
| 12 months | 25.18 (5.60) | 25.54 (5.93) | 25.50 (6.04) | -0.28 (-0.79–0.23) | -0.14 (-0.68–0.40) | 0.14 (-0.36–0.64) |
| 24 months | 26.73 (7.12) | 27.04 (6.59) | 26.69 (6.76) | 0.01 (-0.68–0.71) | 0.05 (-0.63–0.72) | 0.03 (-0.64–0.71) |
| Cell values are mean (SD) or estimate (95% CI). | | | | | | | |