ISRCTN84864870 https://doi.org/10.1186/ISRCTN84864870

Comparing the effectiveness of enhanced motivational interviewing with usual care for reducing cardiovascular risk

Submission date
11/05/2012

Recruitment status
No longer recruiting

Registration date
15/05/2012

Overall study status
Completed

Last Edited
23/12/2019

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The number of adults who do not perform the recommended levels of physical activity (a minimum of 30 minutes of walking a day) and who have unhealthy diets is increasing. These lifestyles increase the risk of heart disease, stroke and diabetes. Motivational interviewing is a type of communication style and talking therapy to help people become more confident, willing and committed to making changes to their lifestyles. The effects can be short-lived so people can find themselves returning to their old habits such as stopping and starting smoking. We want to find out if adding other strategies to motivational interviewing, such as counting the number of step we walk (pedometers), recognising our own unhelpful thinking patterns, and making the most of the support from family and friends, could help people who are at high risk of developing heart disease to make healthier lifestyle changes, and then stick to these for the next 2 years. The aim would be to reduce weight and increase normal activities such as walking and taking the stairs. We will measure changes in weight, diet and physical activity as well as emotional factors. We are looking for medium to small changes in weight and activity because we want to encourage participants to make small changes that they believe they can stick to and also because small changes for the individual can add up to big changes for the whole population.

Who can participate?
Participants will be adults age 40-74 years who screen positive for high cardiovascular disease risk on the NHS Health Checks, defined as having a 20% or higher chance of having a fatal or non fatal cardiovascular event over the next ten years and not known to have cardiovascular disease or to be on the diabetes, kidney, atrial fibrillation or stroke register. Participants can only enter the study if they are fluent in conversational English; permanent residents and planning to stay in the UK at least ¾ of year. We will not accept participants who already have cardiovascular disease; severe mental illness such as psychosis, learning disability, dementia and cognitive impairment; are registered blind; housebound or resident in nursing home; unable to move about independently; more than three falls in past year; pregnant, advanced cancer; morbid obesity or are currently participation in a weight loss programme. When in doubt we will seek the general practitioner (GP) opinion and approval.

What does the study involve?
After they consent to take part, participants will be randomised (meaning they have equal chance of being assigned to any of the three groups) to one of three groups: usual care, usual care and individual motivational interviewing, usual care and group motivational interviewing. We will compare each of the three groups in terms of changes in weight, diet and physical activity of the participants, as well as emotional factors. Participants will receive different treatment depending on what group they are randomised to. Patients in usual care will receive the usual care from their GP. Participants in usual care and group enhanced motivational interviewing will attend 10 sessions lasting 90 minutes each over 12 months delivered by health trainers trained in behaviour change techniques. The intensive phase will be 6 weekly sessions. The maintenance phase will be 4 sessions delivered at 3, 6, 9 and 12 months. The contents will focus on early setting of goals and of maintenance techniques using the group environment to facilitate change. Participants in usual care and individual enhanced motivational interviewing will experience the same treatment as participants in the usual care and group enhanced motivational interviewing but the intervention will be delivered individually. Sessions will last 30 minutes.

What are the possible benefits and risks of participating?
There are potential health benefits for all participants taking part in the study such as weight reduction, increased exercise, lowering cardiovascular disease (CVD) risk, as it is known that participation in research is associated with better outcomes. All participants are contributing to research in which results can help in the development of interventions to improve outcomes for people at risk of CVD.
Within the group intervention participants have the potential benefit of learning and social support from others. In general regular physical activity is associated with better health outcomes. Although sudden increases in physical activity in people who are generally inactive is associated with a higher risk of heart attack and/or injuries, one of the intervention techniques in this study is to deliver the message that physical activity should be increased in a gradual manner rather than suddenly. We will be discouraging sudden changes to lifestyles. We consider this risk to be small and it will be minimized by excluding participants who have existing cardiovascular disease. There is a small risk that some participants may experience rapid weight loss, but importantly our intervention is based on healthier diets, and gradual and sustainable weight loss as opposed to commercial weight loss programmes.

Where is the study run from?
The study will take place within The South London Health Innovation and Education Cluster (HIEC), which includes 11 primary care trusts (PCT) across South London, constitutes a population of approximately 3 million residents and is representative of the UK's highly diverse social, economic and ethnic communities. The primary care trusts are: Bromley, Greenwich, Southwark, Sutton & Merton, Richmond & Twickenham, Lewisham, Bexley, Kingston, Wandsworth, Croydon and Lambeth.

When is the study starting and how long is it expected to run for?
The anticipated start date for the study is currently 1st September 2012. We are scheduled to recruit participants for 1 year.

Who is funding the study?
The study is funded by the National Institute for Health and Research Health Technology Assessment Programme.

Who is the main contact?
Professor Khalida Ismail
Khalida.2.ismail@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Khalida Ismail

Contact details
Institute of Psychiatry, King's College London
Weston Education Centre
10 Cutcombe Road
London
United Kingdom
SE59RJ

Additional identifiers

Protocol serial number
HTA 10/62/03

Study information

Scientific Title
A multi-centre randomised controlled trial comparing the effectiveness of enhanced motivational interviewing with usual care for reducing cardiovascular risk

Acronym
MOVE-IT

Study objectives
Cardiovascular disease (CVD) is the most common cause of death (and premature death), morbidity and disability in middle-aged and older people in the UK and in other developed countries. CVD is highly preventable. Many of the major determinants of CVD are modifiable, including cigarette smoking, a diet high in saturated fat, obesity, physical inactivity, hypertension and diabetes. In England and Wales, compared with the general population, mortality from coronary heart disease is 50% higher in South Asians whereas mortality from cerebrovascular disease is highest in Africans and Caribbeans and higher in South Asians when compared with Europeans.

That group enhanced motivational interviewing delievered by health trainers is more effective than usual general practitioner (GP) care in reducing weight and increasing physical activity 24 months later in people at high risk of cardiovascular disease.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/106203
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/81675/PRO-10-62-03.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Three parallel arm multi-centre randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Cardiovascular disease (CVD)

Interventions
The intervention will be based on the Theory of Planned Behaviour (TPB) for initiation of behaviour change. The TPB states that in order to change behaviour, people need to form an intention. 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)
3. Self efficacy (people believe they are capable of making the change).

Our intervention will tap into all three constructs using principles and techniques from motivational interviewing (MI), cognitive behavioural therapy (CBT) and social cognitive theory (SCT). MI will be used to support participants in forming healthy intentions. MI is a directive focused non-judgemental person-centred counselling style that aims to work with resistance around behaviour change. It aims to support the commitment to change and the belief or self efficacy that change can happen. MI is characterized by three key theoretical constructs about communication: collaboration (as opposed to confrontation); evocation (as opposed to didactic reasoning) and patient autonomy (as opposed to authoritative style)

The key skills in MI are the ability to express empathy (which includes understanding the patient's ambivalence towards changing behaviour), support self efficacy, roll with resistance and develop discrepancies between the patient's values and current behaviours.

Social cognitive theory emphasizes the importance of significant others in shaping peoples behaviours. The TPB also highlights this aspect through the subjective norm construct. In our intervention, social networks from the participants own life and/or group members (in the group arm) will be actively utilized to provide practical and emotional support and opportunities for modelling health behaviours during all phases of the intervention.

Participants in this study will be randomized to one of three groups:
Group 1:Usual care
Group 2: Usual care and group enhanced motivational interviewing
Group 3: Usual care and individual enhanced motivational interviewing

Participants in Group 1 will receive usual care from their GPs participating in the study; GP's will be expected to follow their local Health Check pathway for those who have a CVD risk score >20%.

Participants in Group 2 will receive usual care and group enhanced motivational interviewing. The programme will consist of 10 sessions lasting 90 minutes each over 12 months delivered by health trainers trained in behaviour change techniques. The intensive phase will be 6 weekly sessions. The maintenance phase will be 4 sessions delivered at 3, 6, 9 and 12 months. The contents will focus on early setting of goals and of maintenance techniques using the group environment to facilitate change. We will include visual aids, patient testimonials, behavioural surveys and e-technology tools to enhance self monitoring and feedback of healthier behaviours (mobile texts, social networking sites), pedometers.

Participants in Group 3 will receive Usual care and individual enhanced motivational interviewing. This will have the same components as group 2 but delivered individually. Sessions will last 30 minutes.

Intervention Type
Behavioural

Primary outcome(s)
Differences in weight (kilograms) and in physical activity (number of timed steps) between arms at 24 months (interim outcome at 12 months). Weight using the Tanita SC240 digital weighing scale and physical activity using the Actigraph GT3X accelerometer at all time points.

Key secondary outcome(s)
1. Differences in: lipids, blood pressure, HbA1c, and CVD risk and in smoking status at 24 months
2. The EQ-5D will be used to generate quality-adjusted life years
3. Intervention costs will include training and delivering interventions, overheads and other service use will be measured using an adapted Client Service Receipt Inventory. Costs will be calculated by combining service use data with unit costs.

Completion date
31/07/2016

Eligibility

Key inclusion criteria
1. Being fluent in conversational English
2. Permanent residents and planning to stay in the UK at least ¾ of year. In our local experience of conducting
epidemiology and clinical trial studies, 5% of the African, Caribbean and South Asian population are itinerant which increases the risk of attrition, non-completion of the intervention and difficulty of measuring post-randomization factors.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1742

Key exclusion criteria
1. Established cardiovascular (CVD) disease
2. Severe mental illness such as psychosis, learning disability, dementia and cognitive impairment
3. Registered blind
4. Housebound or resident in nursing home
5. Unable to move about independently
6. > 3 falls in past year
7. Pregnancy
8. Advanced cancer
9. Morbid obesity body mass index (BMI) >50 kg/m2
10. Current participation in a weight loss programme. When in doubt we will seek the GP opinion and approval

Date of first enrolment
01/08/2012

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Psychiatry, King's College London
London
United Kingdom
SE5 9RJ

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/09/2018		Yes	No
Results article	results	01/12/2019	23/12/2019	Yes	No
Protocol article	protocol	25/03/2015		Yes	No