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3R Study (ready to reduce risk)

Submission date
11/04/2016

Recruitment status
No longer recruiting

Registration date
26/04/2016

Overall study status
Completed

Last Edited
28/07/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Cardiovascular disease is a disease of the heart and circulatory system that may lead to heart attacks and strokes. It is a major cause of death in the UK and it is estimated that 80% of these deaths are unexpected and avoidable. Identifying people at high risk of cardiovascular disease and supporting them to reduce their risk is a prime concern for the health service. Researchers have developed an intervention called the 3R (Ready to Reduce Risk) Programme to provide information and advice to people at risk of cardiovascular disease. This study aims to test whether the 3R Programme is effective at reducing this risk.

Who can participate?
Adults aged 40-74 currently on statin medication to reduce the risk of cardiovascular disease.

What does the study involve?
Participants are invited attend two clinic sessions, one at the beginning of the study and one 12 months later and asked to bring with them a sample of urine for both occasions. At the first visit, staff discuss the study and answer any questions patients may have. A trained member of the research team takes a fasting blood sample from the participant for testing. They also measure each participant's blood pressure, heart rate, weight, height, waist and hip circumference. Participants are asked questions about their health, lifestyle and current medication and complete a questionnaire booklet relating to their health behaviour and general well-being. Each participant is then randomly allocated to one of two groups. Those in group 1 are sent an information leaflet from the study team about how to reduce the risk of developing cardiovascular disease in the future. They receive the usual care currently provided by their GP or practice nurse. Those in group 2 are given the same information leaflet and will also be invited to the education programme specifically designed for this study. The education programme is given to patient groups of approximately eight people by two trained educators. The programme is made up of two separate sessions, each session lasting approximately two hours. The 3R Programme has been developed to offer an interactive and engaging group experience. The group discuss what being at risk means, what can be done to manage risk and how the risk of cardiovascular disease is calculated. Participants are given the opportunity to calculate their own risk scores in a supportive environment. Also, important issues such as personal beliefs about medications and the ability to make individual lifestyle changes are discussed with participants shown ways to take more control of their health. Following on from the education sessions, ongoing support is given in the form of telephone calls and text

messages. Trained staff call participants on two occasions during the study to discuss how they are getting on and provide any support if required. The staff will also use text messages to send participants appointment reminders for any clinics and/or education sessions. At 12 months participants from both group are contacted and asked to come to a follow up appointment. At the follow up assessment the same measures are made as at the beginning of the study. At the end of the study the team collects information from GP medical records about patients' cardiovascular risk factors when the patient was first prescribed statins. The study also collects information on how many prescriptions for statins as well as blood pressure medications (if prescribed) have been issued by the GP during the study.

What are the possible benefits and risks of participating?
Due to the nature of the study, there is very little risk that patients will be physically harmed in any way. Participants may feel slight discomfort while the blood sample is being taken and some people do experience bruising after the test. Only trained, experienced staff (either research nurses or healthcare assistants) will take the blood samples. Some people may feel uncomfortable discussing issues of a personal nature during the education sessions and some may feel distress when calculating their risk score. No individual will be expected to discuss any personal information or calculate their risk score unless they are willing to do so. The people leading the sessions have been trained to facilitate discussions effectively and to offer a supportive environment to help participants overcome any discomfort or distress they may experience.

Where is the study run from?
Northamptonshire Teaching Primary Care Trust (UK)

When is the study starting and how long is it expected to run for?
March 2014 to December 2018

Who is funding the study?
1. East Midlands Academic Health Science Network, Institute of Mental Health
2. Janssen-Cilag Ltd
3. Leicester Diabetes Centre

Who is the main contact?
Dr Jo Byrne

Contact information

Type(s)
Scientific

Contact name
Dr Jo Byrne

Contact details
Leicester Diabetes Centre
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Additional identifiers

Protocol serial number
20231

Study information

Scientific Title
A randomised controlled trial to investigate the effect of structured education on people at high risk of cardiovascular disease

Study objectives
The aim of this study is to evaluate the effectiveness of a structured education programme for people who have been identified at high risk of developing cardiovascular disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Leicester, 16/12/2015, ref: 15/EM/0472

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Prevention, Psychological & Behavioural, Complex Intervention

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Cardiovascular disease, Primary sub-specialty: ; UKCRC code/ Disease:

Interventions
Randomisation process:
The study will use simple randomisation method (1:1). Participants will be stratified by age and sex. Participants will be randomised using a password protected online randomisation tool, which confirms eligibility and stratifies before randomly allocating participants to one of the two arms.
Participants will be blinded when they give informed consent, but will be informed of the outcome when they are invited (or not) to attend the education programme, i.e. participant will be unblinded after randomisation.

Intervention (treatment):
The intervention will be the bespoke patient centred Education Programme which will address CVD risk and explore patients' perceptions of the risk. The programme will use current evidence based information to provide advice on how to make positive behavioural change and assist participants to set achievable goals. Sessions will be delivered in a facilitative style that

encourages participation with the use of reflective questioning and problem-solving activities to promote engagement.
The programme will be delivered by two trained educators (at least one of them will be registered HCP) in a group session of 8-10 participants.

Regular SMS (Short Message Service) reminder and validated motivation text messages will also be sent to patients after completion of the education session. Message delivery will be automated and unidirectional. The text messages will commence within a week of the second education session and will last for a total of 44 weeks. All participants will be sent the same number of messages in a random order. There will be a choice between a smoking and a non-smoking pathway in terms of text messages. The messages will be sufficiently short and will be the brief reminders on healthy life style.

Randomisation arms:
1. Control group will receive standard, routine management in line with practice's current recommendations for people at high risk of CVD. In addition, they will be sent the CVD leaflet, i. e. British Heart Foundation leaflet 'Keep Your Heart Healthy' which contains general information about CVD risk prevention. Control group patients are invited at their final, 12 months' appointment to repeat baseline study measures
2. Intervention group will receive the same leaflet as the control group but will also attend the 3R Education Programme (as discussed above) at a mutually convenient venue (either their GP practice or a local venue). They will also receive follow-up telephone support at approximately one and six months plus regular text messages for 44 weeks post education sessions.

Total duration of the treatment/intervention:
Duration of the treatment/intervention will include attendance at two education sessions lasting approximately 2 hours follow by 44 weeks of text messages.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measures as of 14/06/2018:
The primary outcome is medication adherence to statins at 12 months and the primary measure is a urine-based biochemical measure involving a novel assay to test for statin and anti-hypertensive levels in urine samples.

In addition, the self-reported Morisky 8-item Medication Adherence Scale is completed at baseline and 12 months. This is an established and validated scale that is commonly used to measure adherence. At the end of the study, practices are asked to provide details for individual participants regarding both statin and antihypertensive (if applicable) prescriptions issued during the 12 months of the study. These data will provide useful supporting information about the pattern of patient medication adherence behaviour over the 12-month study period.

Previous primary outcome measures:
The primary outcome is a change in medication adherence to statins which will be measured at baseline and 12 months in two ways:
1. Patient self-report (Morisky 8-item Medication Adherence Scale)
2. Biochemical tests, i.e. levels of statins in urine sample

Key secondary outcome(s)

Change measured at baseline and 12 months:
1. CVD score: Variables are collected by the study and calculated by online version of QRISK
2. TC (total cholesterol), HDL (High Density Lipoprotein), TC:HDL ratio: Non-fasting blood test taken at study clinic visits
3. Blood pressure: Taken at study clinic visits
4. BMI: Calculated using height and weight taken
5. Waist-to-hip ratio: Waist and hip measurements will be used to calculate a waist-to-hip ratio
6. The following questionnaires will be used:
6.1. Self-reported history of smoking using a standard question format
6.2. Fruit and vegetable consumption using the food frequency section of the validated 5-A-Day Consumption and Evaluation Tool (FACET) which is recommended by the Department of Health will be used to determine dietary intake in conjunction with a NHS Portion Size Guide
6.3. The validated Quality of Life Questionnaire (15D)
6.4. The EQ5D as a validated measure of health status
6.5. The validated International Physical Activity Questionnaire (short form) or IPAQ to obtain internationally comparable data on health–related physical activity
6.6. The Patient Activation Measure (PAM) as a validated measure of patient readiness for health behaviour change
6.7. The Beliefs about Medicines Questionnaire (BMQ)37 and the Brief Illness Perception Questionnaire (IPQ) will be used as validated measures of health and medication beliefs
7. Medication adherence to antihypertensives measured at baseline and 12 months by the following ways:
7.1. Patient self-report (Morisky 8-item Medication Adherence Scale)
7.2. Levels of statins in urine sample; updated 14/06/2018: Levels of anti-hypertensive in urine sample

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged 40--74 years old inclusive
2. Prescribed statin medication for primary prevention of CVD that is still active, at least 12 months prior to enrolment
3. TC level ≥5.0 mmols/L at enrolment
4. Ability to speak and read English to participate effectively in the group education programme
5. Willing and able to attend the education sessions and clinic visits
6. Willing and able to give informed consent
7. Willing to allow GP to be notified of participation in the study, so access post-consent to relevant medical records can be obtained
8. Have access to a mobile phone to receive text messages

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
212

Key exclusion criteria
1. Under 40 years of age and 75 years and over
2. Unable or unwilling to give informed consent
3. Pre-existing CVD
4. Total cholesterol < 5 mmol/l
5. Inherited lipid disorder
6. Established Type 1 or Type 2 diabetes
7. Females who are pregnant (self -reported)
8.
Currently participating or participated in another clinical intervention study in the past 12 weeks

Date of first enrolment
11/05/2016

Date of final enrolment
11/04/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northamptonshire Teaching Primary Care Trust
Francis Crick House
6 Summerhouse Road
Moulton Park Industrial Estate
Northamptonshire
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NN5 6BF

Sponsor information

Organisation
University of Leicester

ROR

https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
East Midlands Academic Health Science Network, Institute of Mental Health

Funder Name
Janssen-Cilag Ltd

Funder Name
Leicester Diabetes Centre

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/11/2018		Yes	No
Results article	results	27/07/2020	28/07/2020	Yes	No
HRA research summary			28/06/2023	No	No