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Improving the effectiveness of psychological interventions for depression and anxiety in the cardiac rehabilitation pathway: a single-blind randomised controlled trial

Submission date
08/04/2015

Recruitment status
No longer recruiting

Registration date
08/04/2015

Overall study status
Completed

Last Edited
20/01/2025

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
Depression and anxiety are common among cardiac rehabilitation (CR) patient populations with 37% of patients experiencing significant anxiety and/or depression. Available drug and psychological treatments have only small effects on distress and quality of life, and no effects on physical health in this population. Extensive evidence shows that a particular style of thinking dominated by rumination (dwelling on the past) and worry maintains emotional distress. A psychological intervention (treatment) called Metacognitive therapy has been shown to reduce this style of thinking and alleviate depression and anxiety. Evidence also shows that a particular style of thinking dominated by rumination (dwelling on the past) and worry maintains emotional distress. Metacognitive Therapy (MCT), a psychological intervention, has been shown to reduce this style of thinking and to alleviate depression and anxiety in mental health settings. The PATHWAY study aims to integrate a group metacognitive therapy intervention (Group-MCT) into current CR services. The intervention will lead to better informed and integrated care with the potential to improve psychological and physical wellbeing as well as reduce NHS costs.

Who can participate?
Adults patients (aged at least 18) referred to CR and experiencing anxiety and/or depression.

What does the study involve?
The programme is undertaken at three NHS trusts. Initially, a pilot trial of the Group-MCT intervention is run to test whether adding the Group-MCT intervention to standard CR works better at alleviating anxiety and depression than standard CR alone. We then run a full-scale trial of the Group-MCT intervention. Participants are randomly assigned to either intervention or control conditions. Patients in the intervention condition are given six sessions of Group-MCT which are integrated into the CR pathway programme. The intervention is given by trained health professionals. Health professionals are trained in delivering Group-MCT by Professor Adrian Wells (the originator of MCT) and by Dr Peter Fisher. The control condition receive care as usual along the CR pathway. Each participants anxiety and depression levels are measured at

four and 12 month after treatment. Participants taking part in the pilot study are also interviewed before treatment starts, during the treatment and then after treatment. We also seek to interview patients who decline the intervention or drop-out, in addition to control patients. We will include the patients' principal carer in interviews if the patient wishes.

What are the possible benefits and risks of participating?
The information we gather from this study will help to inform care on the cardiac rehabilitation pathway for future patients. The group metacognitive therapy sessions are designed to help in managing distress so patients may benefit from receiving this therapy as part of their usual care. It is possible that talking about their difficulties that this may cause some distress to patients. However, the group metacognitive therapy sessions are designed to aid patients in managing their feelings better.

Where is the study run from?
Hospitals from the University Hospital of South Manchester NHS Foundation Trust, Central Manchester University Hospitals NHS Foundation Trust, East Cheshire NHS Trust.

When is the study starting and how long is it expected to run for?
June 2015 to February 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Lora Capobianco, lora.capobianco@gmmh.nhs.uk
(updated 28/09/2021, previously: Dr Jane Garnett)

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT02420431

Protocol serial number
18718

Study information

Scientific Title
Improving the effectiveness of psychological interventions for depression and anxiety in the cardiac rehabilitation pathway: a single blind randomised controlled trial with four month and twelve month follow up comparing GroupMCT plus usual CR (intervention) with usual CR (control).

Acronym
PATHWAY

Study objectives
The study aims to improve access to more effective psychological interventions for the range of heart disease patients attending cardiac rehabilitation services. The principle research question is: Does the addition of group metacognitive therapy to treatment as usual improve psychological outcomes (distress) more than treatment as usual alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee North West – Preston, ref: 15/NW/0163

Study design
Randomized; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
1. Experimental: metacognitive therapy plus CR Group psychological treatment focused on reducing worry and rumination and modifying beliefs about thinking in addition to treatment as usual (standard cardiac rehabilitation). Metacognitive therapy (MCT) helps clients to identify episodes of worry and rumination in response to negative thoughts and bring these responses under control. This process is facilitated by exercises that enhance the flexibility of attention control, challenge unhelpful beliefs about thinking and enable new relationships with thoughts
2. Active Comparator: Usual group-based cardiac rehabilitation (treatment as usual) involving stress management, exercise, education.

Intervention Type
Other

Primary outcome(s)
Change in Hospital Anxiety and Depression Scale (HADS) [Time Frame: Baseline pre treatment, four-month post baseline, 12 months follow-up]

Key secondary outcome(s))
1. Metacognitions Questionnaire
2. Cognitive Attentional Syndrome
3. Impact of Event Scale-Revised
4. Health Related Quality of Life
5. Economic Patient Questionnaire (EPQ)

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Heart disease patients referred to CR who meet DoH and/or BACPR CR eligibility criteria
2. Minimum of 18 years old
3. Competent level of English language skills (able to read, understand and complete questionnaires in English).
4. Acute coronary syndrome used for any condition brought on by sudden, reduced blood flow to the heart
5. Following revascularisation is the restoration of perfusion to a body part or organ that has suffered ischemia
6. Stable heart failure
7. Stable angina is chest pain or discomfort that most often occurs with activity or stress
8. Following implantation of cardioverter defibrillators/cardiac resynchronisation devices
9. Heart valve repair/replacement
10. Heart transplantation and ventricular assist devices
11. Adult congenital heart disease identified in adulthood
12. A score of = 8 on either the depression or anxiety subscale of the HADS.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
332

Key exclusion criteria
1. Cognitive impairment which precludes informed consent or ability to participate
2. Acute suicidality
3. Active psychotic disorders (i.e., two [or more] of the following: delusions, hallucinations, disorganized speech, grossly disorganized or catatonic behaviour, negative symptoms)
4. Current drug/alcohol abuse a maladaptive pattern of drinking, leading to clinically significant impairment or distress
5. Concurrent psychological intervention for emotional distress
6. Antidepressant or anxiolytic medications initiated in the previous 8 weeks
7. Life expectancy of less than 12 months

Date of first enrolment
01/06/2015

Date of final enrolment
28/02/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Mental Health and Social Care Trust (Host study site and non-recruiting)
Manchester
United Kingdom
M13 9WL

Study participating centre
University Hospital of South Manchester NHS Foundation Trust
Manchester
United Kingdom
M23 9LT

Study participating centre
Central Manchester University Hospitals NHS Foundation Trust
Manchester
United Kingdom
M13 9WU

Study participating centre
East Cheshire NHS Trust
Cheshire
United Kingdom
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Sponsor information

Organisation
Manchester Mental Health & Social Care Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/07/2021	28/09/2021	Yes	No
Results article		03/06/2022	21/06/2022	Yes	No
Protocol article	protocol	10/09/2020	15/09/2020	Yes	No
Protocol article	protocol	03/04/2018	11/02/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	internal pilot acceptability and feasibility study	30/06/2020	09/07/2024	Yes	No
Other publications	Economic evaluation	20/12/2024	20/01/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes