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UPBEAT-UK: Case Management for depression and coronary heart disease

Submission date 11/02/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 22/04/2010	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 29/01/2016	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Coronary heart disease (CHD), also known as ischemic heart disease, is one of the leading causes of death worldwide. CHD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood). When arteries are blocked or narrowed, the heart does not receive enough blood to function properly, which can cause pain and tightness in the chest (angina), or a heart attack. Depression is very common in patients with CHD, and it has been found that these patients are more likely to have a heart attack or die. There are very effective treatments for CHD and depression separately, however there is not currently any good ways of treating both of these conditions simultaneously. The aim of this study is to find out whether a personalised care programme could be an effective treatment strategy for people suffering from CHD and depression.

Who can participate?
CHD patients over 16 years old with chest pain who are suffering from depression and the GP practices that care for them.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive their usual treatment from their GP and/or practice nurse. Those in the second group continue to receive usual care but also take part in the personalised care plan for 6 months, which is given by two case managers (a community psychiatric nurse and a health psychologist who is also a qualified nurse). At the start of the study, the case managers meet with the patient in order to draw-up a 6-month personalised care plan by talking about the current problems the patient is experiencing, which is passed on to the patient's GP. The patient then works to achieve the goals set in their care plan and are followed up weekly by telephone to see how they are getting on. At the start of the study and then again after 6 months and 1 year, participants in both groups complete a number of questionnaires in order to assess any changes to their CHD and their mental wellbeing.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
General Practices based in South London (UK)

When is the study starting and how long is it expected to run for?
March 2010 to March 2012

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
UPBEAT-UK: A pilot randomised controlled trial of case management for depressed primary care patients with symptomatic coronary heart disease

Acronym
UPBEAT-UK

Study objectives
The principal research objective is to pilot case management as an intervention in primary care patients with depression and coronary heart disease (CHD) in order to inform a definitive randomised controlled trial (RCT).

Ethics approval required

Old ethics approval format

Ethics approval(s)
South East London Research Ethics Committee, ref:10/H0808/51

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary heart disease/comorbid depression

Interventions
Experimental intervention (usual care plus case management):
The intervention will be case management delivered by two clinically qualified researchers (a community psychiatric nurse and a health psychologist who is also a qualified nurse).

The case managers will arrange to meet with the participant for an initial assessment. The meeting may be at the patient's surgery, home or place of work according to the participant's preference. At the assessment, the case managers will draw-up with the participants a personalised care plan (PCP). This will take a holistic approach to the participant's current problems. A copy of the PCP will be kept by the participant, a copy by the case manager and a copy sent to the participant's GP. The case manager will help the participant choose up to two more complex problems, for example a need to increase exercise or to reduce social isolation, to work on using a goal setting technique to enhance their self-efficacy. Where appropriate, the case managers will provide written information about depression or direct the patient to other resources. Written materials and other resources will be pre-published and freely available, for instance mental health charity web pages or leaflets, that have been identified by the case managers as of good quality. The initial assessment is likely to last up to an hour. The case manager will liaise with other health professionals involved in the participant's care as appropriate.

Participants will be followed up by the case manager by telephone for 6 months. Initially, contact is likely to be at least weekly, but later may be two-weekly. During the follow-up, the participant's PCP will be reviewed and new goals set in collaboration with the participant as appropriate.

Control condition:
Usual care by the participant's GP and other relevant health professionals.

The treatment will be provided for 6 months, follow up will be for 1 year.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
Since this is a pilot study, an aim is to identify appropriate primary and secondary outcome measures. The following measures will be tested:
1. Depression (HADS, 9-item Patient Health Questionnaire [PHQ-9])
2. Coronary Heart Disease (Modified Rose Angina Questionnaire, Specific Activity Schedule)
3. Quality of Life (Euroqol 5D, 12-item Medical Outcomes Survey Short Form [SF-12])
4. Adherence to medication (Adapted version of Morisky adherence questionnaire)
5. Life events (List of Threatening Events Questionnaire)
6. Social problems (Social Problems Questionnaire)
7. Health Service Utilisation (Client Service Receipt Inventory (CSRI))
8. Illness Perceptions (Brief Illness Perceptions Questionnaire)
9. Participants' problem priorities (Psychlops)

Assessments will be at 1, 6 and 12 months for all outcomes.

Key secondary outcome(s))
No secondary outcome measures

Completion date
15/03/2012

Eligibility

Key inclusion criteria
Practices:
1. Keep a register of patients with CHD for the Quality and Outcomes Framework (QOF)
2. Willing to liaise over patients in the case management arm when necessary

Participants:
1. Symptomatic CHD as scored on the modified Rose Angina Questionnaire
2. Score greater than 9 on the Hospital Anxiety and Depression Scale (HADS)
3. Aged 16 years or over, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients:
1. Temporary registrations

2. Actively suicidal or experiencing psychotic depression as evidenced by delusions and/or hallucinations
3. Under the care of secondary care mental health teams
4. Cannot speak English
5. Currently in hospital for treatment of their CHD

Date of first enrolment
15/03/2010

Date of final enrolment
15/03/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

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

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/06/2014		Yes	No
Protocol article	protocol	06/06/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes