

Care for depression in people with diabetes and /or coronary heart disease

Submission date 25/01/2012	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 25/01/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/11/2016	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

This study aims to evaluate the effectiveness and cost-effectiveness of collaborative care in treating the symptoms of depression in patients who have coronary heart disease (CHD) and/or diabetes. Collaborative care is a method of care management in which the patient, medical doctors and other specialists collaborate to design and deliver a structured care programme for the patient. In the USA there is a lot of evidence suggesting that collaborative care may be beneficial to patients with depression as well as CHD and/or diabetes.

Who can participate?

The study is open to patients aged 18 and over in the North West of the UK who have a diagnosis of CHD and/or diabetes as well as depressive symptoms.

What does the study involve?

General practice surgeries that enter the study are randomly allocated to provide either collaborative care or usual care for patients who are participating in the study.

What are the possible benefits and risks of participating?

Participants will have the chance to receive collaborative care, which has been shown to reduce symptoms of depression for CHD and/or diabetes patients in the USA. We do not anticipate any side effects, risks or disadvantages for people who participate in this study.

Where is the study run from?

The study is being run by the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) at the University of Manchester (UK).

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

January 2012 to January 2013.

Who is funding the study?

National Institute of 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
11201

Study information

Scientific Title
Collaborative INterventions for CirCulation and DEpression (COINCIDE): Care for depression in people with diabetes and/or coronary heart disease

Acronym
COINCIDE

Study objectives
Depression is a prevalent issue for patients suffering from long term conditions (LTC) such as diabetes or coronary heart disease. Patients who experience depression alongside a LTC may find it more difficult to manage their illness properly and experience a poorer standard of health. Effective treatments for depression are available but are under-prescribed for patients with LTCs as depression is frequently undetected and may be viewed by both patients and health professionals as a normal consequence of ill health.

The COINCIDE trial will test the effectiveness of collaborative care in the UK for patients with depression and a long-term condition.

More details can be found at <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=11201>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Preston MRES North West, 28/10/2011 ref: 11/NW/0742

Primary study design

Interventional

Study design

Randomised interventional treatment

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depression

Interventions

The trial is being run by the University of Manchester and will recruit 450 patients from 30 general practices in the North West of the UK. Patients will be recruited who have signs of depression as well as depression and/or diabetes. General practices will be randomised to give their patients collaborative care or usual care. We will measure levels of depression at study entry and at six month follow-up to evaluate if patients receiving collaborative care have lower levels of depression, compared to those that received usual care. The trial will also evaluate the extent to which patients have utilised health care services and examine the cost-effectiveness of collaborative care.

Followed up at 6 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

SCL90 depression scale measured at 6 months

Key secondary outcome(s)

Patient Health Questionnaire (PHQ-9) measured at 6 months

Completion date

01/01/2013

Eligibility**Key inclusion criteria**

1. Patients aged 18 or over
2. Are listed on GP practice QOF registers with a diagnosis of coronary heart disease and/or Type 1 or Type 2 diabetes
3. Have persistent depressive symptoms (>10 on Patient Health Questionnaire PHQ9).
4. Patients who are already receiving antidepressant medication or psychotherapy but who still score >10 on the PHQ9.
5. We will also include non-English speaking patients of South Asian origin
6. Male and female participants

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Aged less than 18 years old
2. Refused to consent
3. GP has removed them from the diabetes/CHD database
4. Suffer from a severe and enduring mental disorder
5. At risk of suicide and require immediate care from a crisis management team
6. If their depression is linked to bereavement

Date of first enrolment

01/03/2012

Date of final enrolment

01/09/2012

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

The University of Manchester
Manchester

United Kingdom
M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) - CLAHRC (UK)

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	16/02/2015		Yes	No
Results article	results	07/10/2016		Yes	No
Protocol article	protocol	20/08/2012		Yes	No
Protocol article	protocol update	11/05/2013		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes