

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

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| Submission date 25/01/2012 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 25/01/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 18/11/2016 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> 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?
Andrea Cherrington
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Study website
<http://www.coincidehealth.co.uk>

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Randomised interventional treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

SCL90 depression scale measured at 6 months

Secondary outcome measures

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

Overall study start date

01/01/2012

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

UK Sample Size: 450

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

England

United Kingdom

Study participating centre

The University of Manchester

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

c/o Lynne Macrae

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Sponsor type

University/education

Website

<http://www.manchester.ac.uk/>

ROR

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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? |
|----------------------------------|-----------------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 20/08/2012 | | Yes | No |
| Protocol article | protocol update | 11/05/2013 | | Yes | No |
| Results article | results | 16/02/2015 | | Yes | No |
| Results article | results | 07/10/2016 | | Yes | No |