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Is collaborative care more clinically and cost effective than usual care in the management of patients with moderate to severe depression in UK primary care?

Submission date
30/09/2008

Recruitment status
No longer recruiting

Registration date
28/11/2008

Overall study status
Completed

Last Edited
26/02/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression causes misery to many people and is a major health problem in the UK. Although effective treatments are available, many people do not have access to them and we are always looking for treatments that are easier and quicker for patients to receive. New ways of organising treatment have been developed in the United States but we do not know if they are better than usual care in the UK. Therefore, this study will investigate a way of organising the way we deliver treatment for depression. This is called collaborative care for depression and it is being compared with the usual care given by General Practitioners (GPs).

Who can participate?
We are asking people from a number of different GP surgeries in three UK areas if they would like to take part. All participants will have a diagnosis of depression.

What does the study involve?
If people agree to take part in the research the first thing we will want to do is to find out about them. We will need to ask about their current and past mental health as well as their life more generally. This meeting will take about 90 minutes. We then arrange to see people in 4, 12 and 36 months time. These meetings will be a little shorter as they only involve filling out some questionnaires. We expect these meetings to take about 45 minutes. We also need to collect some information from their medical records. The research study will last for five-and-a-half years, but individual participants will only be involved for 36 months.
Every participant will continue to have their treatment managed by their GP, but people from half of the GP surgeries will also receive Collaborative Care, while the other half will receive usual care (exactly the same treatment as if they chose not to take part in the study). The decision about whether a surgery will offer Collaborative Care is made totally by chance, and participants will not know which group their GP surgery is in until they decide to take part in the study. People receiving Collaborative Care are assigned a case manager, who is a health worker specially trained to help people with depression. Case managers help to organise the persons

care and will give them advice on overcoming depression. For example, the case manager may advise about medication or explain some very simple ways that a person can help themselves to start to feel better. Case managers see people face to face initially, at a time and place to suit them, and the meeting will usually take about 40 minutes. After this first meeting, they will telephone the person at regular times to support them in their treatment. These calls take about 15 minutes, and will be booked at times to suit the patient. Usually, the case manager will call once a week for the first month and then once a fortnight for the next 3 months, but how often they call is totally up to the patient. Participants have contact with the case manager for 4 months.

What are the possible benefits and risks of participating?
We hope that both the new treatment and usual care will help participants. The information we get from this study may help us to treat future patients with depression better. We are not aware of any side effects, disadvantages or risks to participants of taking part in this research.

Where is the study run from?
The University of Exeter (UK)

When is the study starting and how long is it expected to run for?
September 2008 to February 2014

Who is funding the study?
The UK Medical Research Council

Who is the main contact?
Professor David Richards
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Study website
http://www.pms.ac.uk/cadet/AboutCADET.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRC ref: G0701013

Study information

Scientific Title
Multi-centre randomised controlled trial of collaborative care for depression

Acronym
CADET (CollAborative DEpression Trial)

Study objectives
Is collaborative care more clinically and cost effective than usual care in the management of moderate to severe depression in UK primary care?

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=5670

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has received Multi-Centre Research Ethics Committee approval from the South West Research Ethics Committee. Local Research Ethics Committee and NHS Research and Development approvals have also been given for each recruitment site.

Study design
Multicentre two-arm cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised 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
Intervention group:
UK-specific collaborative care protocol developed from our Trial Platform delivered via scheduled telephone and face-to-face contacts by a supervised case manager over four months and including:
1. A multi-professional approach to patient care
2. A structured patient management plan including medication support and/or cognitive behavioural therapy (CBT) based behavioural activation
3. Scheduled patient follow-ups
4. Enhanced inter-professional communication

The control group will receive usual care from their GP.

Intervention is for 4 months, follow-ups are at the end of intervention (4 months from recruitment) and 12 months from recruitment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Self-report severity of depression at 4 and 12 months follow-up, assessed using the Patient Health Questionnaire-9 (PHQ9). The PHQ9 is a self-report measure and therefore less subject to observer bias. It is sensitive to change with good psychometric properties and we have recently validated its sensitivity and specificity for a UK population.

Secondary outcome measures
The following outcome measures except CSQ-8 will be taken at baseline, 4 and 12 months follow-up:
1. Diagnosis of depression assessed by Clinical Interview Schedule (CIS-R), a computerised interview, and the Beck Depression Inventory II (BDI-II)
2. Health related quality of life, assessed by the SF-36 Health Survey
3. Health care utilisation, measured using case records and a patient service utilisation questionnaire
4. Health state utilities, assessed by EuroQoL
5. Satisfaction with care, measured by the Client Satisfaction Questionnaire (CSQ-8) at 4 months
6. Economic analysis. The incremental cost per Quality-Adjusted Life Years (QALY) of the intervention compared to the control will be calculated from NHS and Personal Social Services (PSS) perspectives.

Process data will be collected within the trial. The extensive quantitative and qualitative work in our pilot trial has indicated that the planned intervention is effective and acceptable, and our process evaluation in the main trial will focus on:

1. The process of implementation of the intervention, and
2. Mechanisms of change and differential response in patient subgroups

Investigation of the process of implementation will involve qualitative interviews with patients, GPs, case managers and specialist professionals, augmented with routinely collected data on from case records and session audio-tapes. Key stakeholders including GPs, patients, case managers and supervisors will be purposively sampled to represent a range and diversity of views and experiences. We will conduct between 30 - 40 interviews with these stakeholders until theoretical saturation has been achieved. All interviews will be audio-taped and transcribed verbatim. The analysis will examine the implementation of collaborative care, with a focus on differences between sites and different case managers. Investigation of mechanisms of change and differential response in patient subgroups will include quantitative measurement of key patient baseline characteristics (e.g. severity, duration of depression, patient preferences, attitudes towards treatment), treatment process measures (e.g. therapeutic alliance), contextual practice variables (e.g. Quality and Outcome Framework compliance rates, anti-depressant prescription rates; availability of counselling and other mental health services) and will follow conventional procedures for analysis.

Overall study start date
01/09/2008

Completion date
28/02/2014

Eligibility

Key inclusion criteria
We will include patients (both males and females) meeting the diagnostic criteria for depression who are aged 18 years and above and who are not currently receiving treatment for depression from specialist mental health services. We will establish the diagnosis of depression by the use of the Clinical Interview Schedule (CIS-R) undertaken by a research worker. We wish our trial to reflect the real world as closely as possible by including all patients with depression; we will therefore include both patients newly identified as depressed, with or without one or more previous depressive episodes, and those with a current depressive illness which has not responded to primary care management in the previous four months. We will also include patients who are suffering from peri- or post-natal depression, with either co-morbid physical illness or co-morbid non-psychotic functional disorders, such as anxiety. In line with the pragmatic nature of this trial, we will reflect usual GP care and participants will be eligible to participate whether they are in receipt of antidepressant medication or not.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
550

Key exclusion criteria
1. Patients whose risk of suicide is sufficiently acute to demand immediate management by a crisis team. Case managers will be trained to recognise and manage less acute risk through applying the procedures taught in the STORM (Skills-based Training On Risk Management) training, we will follow the trial suicide protocol. We will ensure that the patient's GP is involved immediately so they can take appropriate action for patients with suicidal plans.
2. Psychotic patients
3. Patients where the low mood is better explained by a simple bereavement reaction
4. Patients whose primary presenting problem is alcohol or drug abuse

Date of first enrolment
01/09/2008

Date of final enrolment
18/04/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK) (ref: G0701013)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	16/10/2009		Yes	No
Results article	results	19/08/2013		Yes	No
Results article	results	01/05/2014		Yes	No
Results article	results	01/02/2016		Yes	No