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Pro-active Care and its Evaluation for Enduring Depression

Submission date	Recruitment status
24/10/2007	No longer recruiting
Registration date	**Overall study status**
05/12/2007	Completed
Last Edited	**Condition category**
29/12/2016	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Sponsor's Project ID number: BRD/06/119

Study information

Scientific Title
Evaluation of a system of structured, pro-active care for chronic depression in primary care

Acronym
ProCEED

Study objectives
Depression is very common, affecting between 5% and 10% of UK individuals. The majority of people with depression in the UK are treated within general practice, and it is the third most common reason for consultations. Despite evidence that over half of all patients with an acute depressive episode will have a recurrence, and that the risk of further recurrences increases greatly with further episodes, there appears to be little consistency in the longer-term management of the disorder, and significant psychological, physical and social morbidity in this group. In addition, a significant minority of patients (around 18 - 25%) will have chronic depressive disorders. Chronicity is associated with greater likelihood of psychological, physical and social morbidity and an earlier death from all causes, and the health and social costs are considerable.

We wish to evaluate whether a system of pro-active care with regular reviews and the facilitation of evidence-based treatments where indicated, is reflected in better psychological, physical and social outcomes for these patients, as well as fewer days spent feeling depressed. We are including a cost-effectiveness component to establish whether perceived benefits from taking part in this study are associated with a reduction in health care or social costs.

Specific objectives are:
1. To establish whether structured, pro-active care of patients with chronic depression in primary care leads to a cost-effective improvement in medical and social outcomes when compared with usual General Practitioner (GP) care
2. To assess whether training general practice nurses leads to improved assessment and follow-up of patients with chronic depression and provides on-going skills in this area
3. To increase the understanding of inequalities in health care for people with chronic depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Royal Free Hospital and Medical School Research Ethics Committee on the 27th February 2007 (ref: 07/Q0501/15).

Study design
This is a multi-centre randomised controlled trial.

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No web format of patient information leaflet is currently available. Please contact the study team using the below contact email address if you would like a copy.

Health condition(s) or problem(s) studied
Chronic or recurrent depression in primary care

Interventions
Comparison is between 'GP usual care' (control), versus a 'structured care' approach involving regular practice nurse follow up (intervention).

1. Intervention group:
The intervention being studied is structured, pro-active care for chronic depression. This intervention will combine management strategies already familiar to primary care staff, but in a concerted and consistent manner. It will involve the practice nurse and relevant GP, in a similar model to that widely used in the care of patients with asthma or diabetes. The components of the review process will include:

1.1. Recall system:
A crucial component is the establishment of an effective recall system to ensure that patients are followed up if they fail to attend review appointments. This will be based on the practice computer and managed by the practice nurse, who will be responsible for contacting relevant patients and following up those who fail to attend.

1.2. Clinical review:
A practice nurse will undertake the baseline appointment and assessment and ask participants about current mood, social circumstances, current treatment (medication and/or psychological therapy), and any side-effects or queries. Patients will be given educational materials about depression and its treatment, and the reason for regular follow-ups explained. Queries about current or past treatments offered will be discussed and the nurses will check participants' concordance with the treatment they are currently receiving and, if this is poor, possible reasons for this. If they have current significant symptoms of depression, alternative or additional treatments will be discussed. These may be pharmacological, psychological or social and the rationale and evidence for different treatments will be made clear, both in the background literature given to patients and in their discussion with practice nurses. Social factors, which may be contributing to the chronicity of patients' depression, will be explored (e.g. social isolation, low physical activity, unemployment, finance, housing) and appropriate advice given or referrals to other agencies made.

The importance of participant choice and active participation in this process and in the intervention selected will be emphasised. The nurse and patient will then decide what is appropriate and formulate a joint management plan. This will be reviewed during subsequent appointments, together with a review of how the patient is currently feeling and any progress

made with previous goals set. One of the aims will be for participants to learn to monitor their own mental state and gain a sense of possible predictors of relapse.

1.3. Frequency of review:
Reviews for the intervention patients will take place at least 3 monthly for 24 months as part of the trial, but can be more frequent if there are any clinical concerns, or at times when patients are more depressed. The arrangements will be left to the discretion of the nurse. If patients are keeping well, it may be appropriate to conduct this review over the telephone, and evidence from other studies has shown this to be feasible. If nurses are concerned about a patient they are seeing, they are asked to discuss him or her with the relevant GP, who may also see the patient if indicated.

2. Control group:
Control group participants will have care as usual with their GP over the 24 month trial period.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure is the Beck Depression Inventory II (BDI II). The BDI II is a much used, reliable and well-validated measure for both the identification of depression severity and monitoring its clinical outcome, which has been used in many primary care studies. This will be measured at baseline and 3-monthly throughout the study period.

Secondary outcome measures
1. Depression-free days: to be calculated using BDI assessment scores following the method of Lave et al. This will be compared with patients' records of the number of days that they were sufficiently depressed for it to have affected their functioning or not, mood diary to be completed daily by participants
2. Social functioning: measured using the Work and Social Adjustment Scale (WSAS), measured at baseline and final assessment
3. Frequency of depressive episodes: will be collected via the CIDI questionnaire, measured at baseline and final assessment
4. Personality variables: to be measured using the SAPAS (Standardised Assessment Personality Abbreviated Scale), measured at baseline only
5. Quality of life: will be measured by the Euroquol EQ-5D, measured at baseline and at final assessment
6. Resource use and costs: data on services used and productivity losses will be collected using a modified version of the Client Service Receipt Inventory (CSRI), measured at baseline and final assessment
7. Practice service data

Overall study start date
01/10/2007

Completion date
31/03/2010

Eligibility

Key inclusion criteria
1. Men and women aged 18 years or above
2. GP diagnosis of depression with at least two documented episodes of depression in the previous 3 years, or chronic depression/dysthymia over a 2-year period
3. Evidence of recurrent and/or chronic depression via Composite International Diagnostic Interview (CIDI) (lifetime) questionnaire
4. Baseline Beck Depression Inventory II (BDI II) score of 14 or above (indicating at least mild depression)
5. Sufficient English to be able to complete a self-report questionnaire

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
We aim to recruit a total of 630 participants, 14 people in each of 45 general practices.

Key exclusion criteria
1. Current psychotic symptoms
2. Severe cognitive impairment (patient unable to complete questionnaires)
3. Incapacitating alcohol or drug dependence
4. Under 18 years of age
5. Patient needs an interpreter to translate information sheets and questionnaires

Date of first enrolment
01/10/2007

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

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Sponsor information

Organisation
University College London (UCL) (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
The funder of this study is The Big Lottery (UK) (ref: RG/1/010166750).

Funder Name
Grant holder is Mind, the National Association for Mental Health. Service support costs for this study have been approved by the Department of Health.

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?
Results article	results	04/08/2010		Yes	No
Results article	results	01/04/2016		Yes	No