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Comparing counselling and guided cognitive behavioural therapy self-help for low mood

Submission date
31/05/2012

Recruitment status
No longer recruiting

Registration date
12/06/2012

Overall study status
Completed

Last Edited
17/08/2015

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is a major public health issue. Persistent depressive symptoms below the threshold criteria for major depression is a chronic condition with a prolonged course and high risk of relapse or progression to major depressive episodes. Hence, it is important to establish which treatments for persistent sub-threshold depressive symptoms and mild depression are cost-effective and should therefore be provided in the National Health Service (NHS) in the UK. We are carrying out an initial study comparing the results of two different psychological therapies for depression: counselling and low-intensity cognitive behavioural therapy. This study will provide a number of estimates that are necessary for the design of the main study and will help to identify any potential problems that will need to be addressed before the main study.

Who can participate?
We aim to recruit 50 patients at five general practices in Glasgow with the diagnosis of persistent sub-threshold depressive symptoms and mild depression.

What does the study involve?
Patients will be randomly allocated to either eight weekly sessions of person-centred counselling or eight weeks of self-help cognitive-behavioural resources with telephone support. Person-centred counselling (PCC) is the most common psychological intervention offered in community settings in the UK. PCC focuses on the provision of an empathic, accepting, and genuine therapeutic relationship, which aims to foster patients' inner capacities and resources, promoting positive change. Guided self-help cognitive-behavioural therapy (CBT) is a recommended intervention for mild to moderate depression. It is termed a low intensity treatment because the amount of doctor time is limited compared to traditional high intensity expert-led treatments. Guided self-help CBT will be delivered through booklets and online resources.

What are the possible benefits and risks of participating?
Participants will receive either a course of eight sessions of person-centred counselling or eight telephone support sessions for guided self-help CBT. Access to psychological therapies in primary care is limited, so access to such treatments may be seen as a benefit for those participating in the trial. These treatments are widely used within primary care in the NHS. Any

potential risks are therefore minimal. All participants will continue to be under the care of their GP for the duration of the trial and GP will be able to monitor any adverse effects.

Where is the study run from?
The study is organised by the University of Aberdeen, in collaboration with the University of Glasgow and University of Strathclyde.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in November 2012. Participants will be enrolled on the study for a period of 8 months. The overall duration of this project will be 15 months.

Who is funding the study?
The CLICD study is funded by a grant from the Chief Scientist Office, which is part of the Scottish Government Health and Social Care Directorates.

Who is the main contact?
Dr Elizabeth Freire
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Contact information

Type(s)
Scientific

Contact name
Dr Elizabeth Freire

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CZH/4/723

Study information

Scientific Title

Counselling versus Low-Intensity Cognitive Behavioural Therapy for persistent subthreshold and mild Depression (CLICD): a pilot/feasibility randomised controlled trial

Acronym
CLICD

Study objectives
This study will test the feasibility of a randomised controlled trial of the clinical and cost effectiveness of Low Intensity Cognitive Behaviour Therapy (LI-CBT) and Person-Centred Counselling (PCC) for patients with persistent subthreshold depressive symptoms and mild depression. This study will provide estimates for the recruitment, adherence, and retention rates, as well as estimates of the variability of outcome measures to inform power calculations for a definitive trial. Estimates of comparative intervention effects will be produced, but this study is not designed to have sufficient power to detect differences, nor to demonstrate non-inferiority between interventions. The pilot will test the feasibility of attaining adequate recruitment and retention, as well as identifying a range of moderator variables. Finally, this study will help to identify any potential problems that will need to be addressed before a definitive trial.

On 29/10/2012 the following changes were made to the record:
1. The public title was updated. Previously it was "Comparing Counselling and Low-Intensity Cognitive behavioural therapy for Depression"
2. The overall trial start date was updated from 01/09/2012 to 01/10/2012
3. The overall trial end date was updated from 31/11/2013 to 31/12/2013

As of 13/01/2014, the overall trial end date was changed from 30/12/2013 to 30/06/2014. Recruitment to the trial is now closed, but follow-up assessments with participants continue.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee 3, 03/09/2012, ref: 12/WS/0173

Study design
Two-arm parallel-group randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Not specified

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
Patients will be randomised to either eight weekly sessions of person-centred counselling or eight weeks of cognitive-behavioural self-help resources with telephone support.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Recruitment, adherence and retention rates at six months from baseline

Secondary outcome measures
1. Changes at 6 months on depressive symptoms (as measured by GRID-HAMD-17 and PHQ-9)
2. Recovery from, or prevention of, depression according to DSM-IV diagnosis at 6 months
3. Changes at 6 months on impairment in functioning (as measured by Work and Social Adjustment Scale - WSAS)
4. Changes at 6 months on health status (as measured by EQ5D and SF12)

Overall study start date
01/10/2012

Completion date
30/06/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/01/2014; this change was applied to patients screened from 16 /04/2013 onward:
1. Aged ≥ 16
2. Scoring 5-18 on the Patient Health Questionnaire (PHQ-9) (i.e. mild or moderate low mood)
3. Screened positive for persistent (i.e., > 6 months) subthreshold depressive symptoms or mild depression (SCID)
4. Capable of taking part in research procedures

Previous inclusion criteria:
1. Aged ≥ 16
2. Scoring 5-14 on the Patient Health Questionnaire (PHQ-9) (i.e. mild or moderate low mood)
3. Screened positive for persistent (i.e., > 6 months) subthreshold depressive symptoms or mild depression (SCID)
4. Capable of taking part in research procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Alcohol/substance dependence
2. Receiving other psychological intervention
3. Bipolar disorder
4. Bereavement as presenting issue
5. Post-traumatic Stress Disorder (PTSD)
6. Cognitive impairment
7. Unable to understand, speak, read or write in English
8. Terminal illness
9. Unable to take part in any of the interventions.

Date of first enrolment
01/11/2012

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
AB24 5UA

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
University Office
King's College
Regent Walk
Aberdeen
Scotland
United Kingdom
AB24 3FX

Sponsor type
University/education

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

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (CSO), Scotland (UK) (ref. CZH/4/723)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local 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	05/11/2014		Yes	No
Results article	results	15/08/2015		Yes	No