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Trial of the clinical and cost-effectiveness of a specialist expert mood disorder team for treating depression

Submission date
25/11/2015

Recruitment status
No longer recruiting

Registration date
25/11/2015

Overall study status
Completed

Last Edited
23/10/2023

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
Unipolar depressive disorder (UDD), commonly referred to as depression, is one of the most common mental health conditions worldwide. The symptoms of UDD can vary greatly from person to person, but they generally include low mood, problems with sleeping and/or eating, and a general loss of interest in life. Treatment often relies on antidepressant medications, which work by increasing the activity and levels of a group of chemicals in the brain (neurotransmitters), and psychological (talking) therapies, such as cognitive behavioural therapy (CBT). In most cases, the treatment of a patient suffering from UDD is managed by specialists in the field of mental health (secondary care). It has been found however, that around 40% of patients with UDD treated in secondary care do not recover after receiving the generally treatments that are offered primarily. It may be a more effective option to tailor the type of treatment a patient receives to their individual needs. The aim of this study is to find out whether individual care from a team of specialists in mood disorders is a more effective treatment for depression than usual treatment options available.

Who can participate?
Adults who are suffering from depression, who have been under the care of a specialist mental health team for the last six months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are treated by a specialist mood disorders team, including a psychiatrist (a doctor who specialises in mental health) and a psychologist (a non-medical expert in psychology). The team assesses each individual participant to come up with a treatment plan involving medication and talking therapy, which is tailored to their specific needs. Those in the second group continue to have their usual treatment for the duration of the study. At the start of the study, and then again every 6 months until the end of the 36 month study period, participants in both groups complete questionnaires designed to measure how depressed they are and how well they are coping with daily life.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
September 2009 to July 2013

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Catherine Kaylor-Hughes

Contact information

Type(s)
Scientific

Contact name
Dr Catherine Kaylor-Hughes

Contact details
Institute of Mental Health Sir Colin Campbell Building
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01047124

Secondary identifying numbers
11111

Study information

Scientific Title
Randomised controlled trial of the clinical and cost effectiveness of a specialist mood disorders team for refractory unipolar depressive disorder

Study objectives

The aim of this study is determine whether a specialised mood disorder service, which offers tailored psychological and pharmacological treatment, is effective and cost-effective in the treatment of chronic unipolar depressive disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
09/H0405/42

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Topic: Mental Health; Subtopic: Depression; Disease: Depression

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants will be assessed and treated by a specialist mood disorders team for a period of 36 months. The specialist mood disorders team will include a psychiatrist and psychologist, who will assess participants and then provide a co-ordinated and supervised combination of pharmacological and psychological treatment according to guidelines developed by NICE and the British Association of Psychopharmacology. Each participant will receive a treatment plan that is tailored to his/her specific needs.

Control group: Participants receive treatment as usual for the duration of the study.

Intervention Type
Mixed

Primary outcome measure
Depression assessed using the Hamilton Depression Rating Scale at baseline, 6, 12, 18, 24 and 36 months

Secondary outcome measures
Functional ability assessed using the Global Assessment of Functioning scale at baseline, 6, 12, 18, 24 and 36 months

Overall study start date
01/09/2009

Completion date
11/07/2013

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Able and willing to give oral and written informed consent to participate in the study
3. Suffering from primary unipolar depression which is not a consequence of having another axis 1 or 2 psychiatric disorder
4. From the date of first assessment by a health professional working within the index mental health trust, primary care trust or third sector, they must have been offered or received direct and continuous care from one or more health professionals in the preceding 6 months. They must currently be under the care of a secondary care mental health team.
5. Meets NICE criteria for moderate depression (five out of nine symptoms of depression (NICE, 2004)); has a Hamilton Depression Rating Scale of at least 16; and score 60 or less on the Global Assessment of Functioning Scale (American Psychiatric Association, 1994).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 222; UK Sample Size: 222; Description: 174 patients plus 40 – 48 staff

Key exclusion criteria
1. Is receiving emergency care for suicide risk, risk of severe neglect or homicide risk. However, patients will not be excluded because of such risk provided the risk is adequately contained within their current care setting and the primary medical responsibility for care remains with the referring team.
2. Does not speak fluent English
3. Pregnancy (female participants)

Date of first enrolment
01/09/2009

Date of final enrolment
11/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Institute of Mental Health Sir Colin Campbell Building
University Of Nottingham Innovation Park
Triumph Road
Nottingham
United Kingdom
NG7 2TU

Sponsor information

Organisation
University of Nottingham

Sponsor details
University Park
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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	29/11/2010		Yes	No
Results article	results	01/09/2016		Yes	No
Results article	qualitative study results	15/06/2018		Yes	No
Results article	Follow up results	18/10/2023	23/10/2023	Yes	No