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A recovery focused cognitive-behavioural therapy for older adults with bipolar disorder

Submission date
05/11/2015

Recruitment status
No longer recruiting

Registration date
12/11/2015

Overall study status
Completed

Last Edited
21/12/2023

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
Bipolar disorder, previously known as “manic depression”, is a serious mental illness that is characterised by severe episodes of depression (extreme lows) and mania (extreme highs) or hypomania (a milder form of mania). There are a number of different types of bipolar disorder, as the symptoms vary greatly between different people. Two of the most common types are known as bipolar I and II. Bipolar I is characterised by severe manic episodes, and bipolar II is characterised by severe depression alternating with episodes of hypomania. Bipolar disorder is typically diagnosed in adolescents, but it can affect people of any age. Bipolar disorder continues into older adulthood and the number of people over the age of 60 with this condition is set to rise as the population is aging. It has also been noted that the disorder can be more severe in older adults, with a higher suicide rate than in other mental illnesses in the same age group. Cognitive behavioural therapy (CBT) is a talking therapy which teaches people ways to deal with their problems by changing the way they think and behave. Many studies have shown that CBT can be an extremely effective therapy for bipolar disorder in younger patients and further research is needed to find out if it is an effective treatment in older adults. A new recovery focused CBT technique (which is geared towards improving personal recovery) has been developed for use in older adults (RfCBT-OA). The aim of this study is to find out whether this is an effective treatment for older adults who experience bipolar disorder.

Who can participate?
Adults aged 60 or over with bipolar disorder I or II.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive treatment as usual (TAU) for the length of the study. Those in the second group attend up to 14 sessions of recovery-focussed CBT for older adults (rfCBT-OA) over 6 months, alongside their TAU. At the start of the study and then every 3 months for a total of 12 months, participants complete a number of questionnaires to find out if there has been any change in their condition. The amount of participants who are recruited and any who drop out of the study are also recorded in order to find out whether a larger study testing the effects of rfCBT-OA would work.

What are the possible benefits and risks of participating?
Participants in the CBT group benefit from therapy sessions that they would be unlikely to get access to otherwise. There are no notable risks of taking part in this study.

Where is the study run from?
Spectrum Centre for Mental Health Research (UK)

When is the study starting and how long is it expected to run for?
March 2015 to January 2019

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

Who is the main contact?
Dr Elizabeth Tyler
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A feasibility randomised controlled trial of recovery focused cognitive-behavioural therapy for older adults with bipolar disorder

Acronym
Rf-CBT-OA

Study objectives
Recovery focused CBT will be feasible and acceptable for older adults with bipolar disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UK NHS Ethics Committee, 22/05/2015, ref: 15/NW/0330

Study design
Two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bipolar disorder

Interventions
A parallel two-arm randomised controlled trial (RCT) a recovery focused CBT intervention alongside treatment as usual (TAU) versus TAU alone. Participant's will be randomly allocated to either RfCBT-OA or TAU using an independent web-based computer generated randomised procedure to aid allocation concealment. The randomisation process will be set up by Lancashire Clinical Trials Unit (CTU).

RfCBT-OA arm: Participants in the recovery focused CBT arm will receive up to 14 sessions of therapy over a 6 months time period, alongside their TAU.

TAU arm: Participants in the TAU arm will continue their usual treatment plan which typically involves seeing a healthcare professional such as a GP, Psychiatrist or Community Mental Health Nurse.

Participants in both arms of the study will be followed up and complete assessments which will include a range of important clinical outcomes (e.g. recovery, time to relapse, quality of life) at baseline and then three monthly over the 12 month follow-up period.

Intervention Type
Other

Primary outcome(s)
A number of outcomes in relation to measuring the feasibility and acceptability of delivering recovery focused CBT to older adults with bipolar disorder:
1. The recruitment rate is assessed by measuring the number of eligible participants recruited by self-referral and from each of the NHS sites on a monthly basis. The total will be recorded at the

end of the 15 month recruitment window.
2. Consent rate and reasons for non-recruitment is documented on a continuous basis. The total will be recorded at the end of the 15 month recruitment window.
3. The number of participants lost to follow-up and the reasons for loss to follow-up during the 12 month follow-up period will be recorded, plus reasons for loss (if given) on a continuous basis
4. The number of therapy sessions attended will be documented out of 14 at the end of the study period
5. The number of participants who drop out of therapy is documented on a continuous basis throughout the study period

Key secondary outcome(s))
The secondary outcome of the study is to gain an estimate of the likely effect size of recovery focused CBT on a range of clinical outcomes:
1. Time to relapse will be measured by the Structured Clinical Interview for Diagnosis: Research Version (SCID-LIFE) at 3 months, 6 months, 9 months and 12 months
2. Functioning will be measured by the Personal & Social Performance Scale (PSP) at baseline, 3 months, 6 months, 9 months and 12 months
3. Personal recovery will be measured by the Bipolar Recovery Questionnaire (BRQ) at baseline, 6 months and 12 months
4. Bipolar symptomatology will be measured by the Internal State Scale (ISS) at baseline, 6 months and 12 months
5. Depression symptoms will be measured by the Centre for Epidemiologic Studies Depression Scale (CES-D) at baseline, 6 months and 12 months
6. Functioning will be measured by the Work & Social Adjustment Scale (WSAS) at baseline, 6 months and 12 months
7. Quality of life with be measured by the World Health Organisation Quality of Life scale (WHOQOL-Bref) at baseline, 6 months, 12 months
8. Quality of life will be measured by the Quality Of Life in Bipolar Disorder scale (QoL.BD) at baseline, 6 months and 12 months

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. Aged 60 years or above
2. A diagnosis of BD (I or II) according to the Diagnostic and Statistical Manual of Mental Disorders (DSM; First et al, 2004) IV research criteria
3. Not in a current episode of mania, hypomania, depression or mixed episode in the last month
4. Sufficient English language skills to comprehend the assessments and intervention content

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
60 years

Sex
All

Total final enrolment
39

Key exclusion criteria
1. Receiving concurrent psychological therapy
2. A score of less than 22 on the Montreal Cognitive Assessment (MoCA: Nasreddine et al, 2005)

Date of first enrolment
01/01/2017

Date of final enrolment
01/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Spectrum Centre for Mental Health Research
Lancaster University
Bailrigg
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Sponsor information

Organisation
Lancaster University

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Research organisation

Funder Name
National Institute for Mental Health Research

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/10/2022	21/12/2023	Yes	No
Protocol article	protocol	03/03/2016		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Developing a recovery-focused therapy for older people with bipolar disorder: a qualitative focus group study	04/08/2021	28/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes