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Balancing ACT: evaluating the effectiveness of psychoeducation and acceptance and commitment therapy (ACT) groups for people with bipolar disorder

Submission date
24/03/2017

Recruitment status
No longer recruiting

Registration date
27/03/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background & study aims
Bipolar disorder and psychosis are serious mental illnesses. People with bipolar disorder experience extreme changes in their mood. People with psychosis experience changes in their perceptions (like hearing or seeing things that other people cannot see or hear), and in their thoughts, feelings and behaviour. People often have bipolar disorder or symptoms and psychosis together. Managing these conditions can be very difficult for sufferers, and for their families and friends. People often have to give up work or study, and may need care from mental health services in the community or in a psychiatric hospital. Psychological therapy or 'talking therapy' is helpful for bipolar and psychosis, but is not widely available. Therapies also tend to focus mainly on bipolar or mainly on psychosis, rather than on both conditions. Better psychological therapies are needed for people with bipolar and psychosis together, that can be made available to more people in mental health services. A new group therapy has been developed especially for people with bipolar and psychosis. This is a small study to find out whether the new therapy could help people more than their usual treatment. This study will not provide a final answer, but will show whether the therapy should be developed and tested more, and how this could be done. The new therapy is a combination of two approaches: Acceptance and Commitment Therapy (ACT) and psychoeducation. ACT helps people find new, more helpful ways of reacting to upsetting experiences and symptoms. Psychoeducation helps people to understand their condition, recognise relapse signs and seek treatment early.

Who can participate?
People with an established psychotic illness, bipolar disorder or bipolar symptoms, in the boroughs of Lambeth and Southwark, in the South London and Maudsley NHS Foundation Trust

What does the study involve?
Participants complete questionnaires about how they are feeling, what they are doing, and recent treatment they have received. They are randomly allocated to be offered either the new group therapy alongside their usual treatment or just their usual treatment. The new group

therapy involves ten two-hour sessions, held weekly, with a ‘booster’ session a month later (at 14 weeks). Sessions include talking about common experiences of bipolar and psychosis and ways to handle these. ‘Usual treatment’ is normally meetings with mental health professionals for a range of interventions, including medication, emotional and practical support, and help with housing, benefits, and day-to-day living, work and leisure activities. Participants complete the questionnaires again after 10 and 14 weeks. After 14 weeks, people who were only offered their usual treatment are able to complete the new group therapy if they like. Participants' quality of life is assessed, along with changes in how they are feeling, how they are reacting to upsetting experiences, how they are recovering, and much they use crisis services or are admitted to hospital.

What are the possible benefits and risks of participating?
It is hoped that the new group therapy will be helpful. The study may help improve future psychological treatments. No particular risks are expected, but talking therapies can involve uncomfortable or distressing conversations, and both the groups and questionnaires may bring upsetting experiences to mind. The staff involved in the study are all psychologists, and have training in how to respond if people do feel upset during the study.

Where is the study run from?
The study is running in Promoting Recovery services in the boroughs of Lambeth and Southwark in the Psychosis Clinical Academic Group of the South London and Maudsley NHS Foundation Trust, King’s Health Partners (UK)

When is the study starting and how long is it expected to run for?
May 2017 to August 2018

Who is funding the study?
Guy’s and St. Thomas’ Charity (UK)

Who is the main contact?
Dr Emma O’Donoghue

Contact information

Type(s)
Public

Contact name
Dr Emma O'Donoghue

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Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Balancing ACT: evaluating the effectiveness of psychoeducation and acceptance and commitment therapy (ACT) groups for people with bipolar disorder: a randomised controlled trial

Acronym
Balancing ACT

Study objectives
Research questions:
1. Are primary and secondary clinical outcomes for people with psychosis and bipolar disorder /symptoms improved by the addition of ACT and psychoeducation groups? If so, to what extent?
2. Do the groups have an impact on mood, distress, recovery and psychological processes of change?
3. Is the intervention potentially cost-effective?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London-Surrey Borders Research Ethics Committee, 23/03/2017, ref: 17/LO/0445

Study design
Single-centre Phase II two-arm interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Psychosis with bipolar disorder/symptoms

Interventions
After agreeing to take part, participants will complete questionnaires about how they are feeling, what they are doing, and recent treatment they have received. Participants will be randomised through an independent web-based service provided by the UKCRC registered King' s Clinical Trials Unit (Reg No. 53). The randomisation procedure will employ random permuted blocks of random size, which will maintain pre-randomisation allocation concealment. The trialists will stratify by site (Lambeth or Southwark) for logistical reasons, so that treatment cases are equitably allocated across therapy groups. Participants will be randomised to be offered either the new group therapy alongside their usual treatment or just their usual treatment (waitlist control). The new group therapy involves ten two-hour sessions, held weekly, with a 'booster' session a month later (at 14 weeks). Sessions include talking about common experiences of bipolar and psychosis and ways to handle these. 'Usual treatment' is normally meetings with mental health professionals for a range of interventions, including medication, emotional and practical support, and help with housing, benefits, and day-to-day living, work and leisure activities. Participants will complete the questionnaires again after 10 weeks and 14 weeks. After 14 weeks, people who were only offered their usual treatment will be able to complete the new group therapy if they would like. The following outcomes are measured: changes in quality of life, how people are feeling, how they are reacting to upsetting experiences, how they are recovering, and much they use crisis services or are admitted to hospital.

Intervention Type
Other

Primary outcome(s)
Psychological wellbeing, assessed using the Brief Quality of Life in Bipolar Disorder (Brief QoL. BD) at 10 weeks

Key secondary outcome(s))
1. Mental health relapses, measured by service use as an average per month for the 12 months preceding baseline and the 3 months post-baseline (during the trial)
2. Psychological wellbeing, assessed by the Brief QoL BD at 14 weeks
3. Mood, assessed using a bespoke Mood Monitoring Measure (MMM) and the Internal States Scale (ISS)
4. Distress, assessed using the Clinical Outcomes in Routine Evaluation Measure (CORE-10)
5. Recovery, assessed using the Bipolar Recovery Questionnaire (BRQ)
6. Psychological processes of change, assessed using the Valuing Questionnaire (VQ8); the Acceptance and Action Questionnaire-II (AAQ-II); and the Southampton Mindfulness Questionnaire (SMQ)
Assessed at baseline, 10 and 14 weeks

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Treated under Lambeth or Southwark Promoting Recovery Services
2. Diagnosis/symptoms of Bipolar Disorder
3. Available for the study duration
4. Sufficient English language ability to be able to complete assessment measures and therapy, without interpreter support (as this is not feasible in a group intervention).
5. Aged 18 years and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Inability to remain in a group setting, attend, understand and interact for up to 2 hours
2. Participants who are unable to consent for themselves (i.e. who lack capacity)

Date of first enrolment
01/05/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South London and Maudsley NHS Foundation Trust
Psychosis Clinical Academic Group
Promoting Recovery Pathway

Lambeth and Southwark borough services
United Kingdom
SW9 6AA

Sponsor information

Organisation
South London & Maudsley NHS Foundation Trust

ROR
https://ror.org/015803449

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity (ref: EFT 151106)

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Suzanne Jolley (suzanne.jolley@kcl.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/08/2018	26/11/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes