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Acceptance commitment therapy group for treatment-resistant participants

Submission date
08/02/2013

Recruitment status
No longer recruiting

Registration date
21/02/2013

Overall study status
Completed

Last Edited
30/01/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Despite advances in therapies for mental health difficulties, numerous studies demonstrate that cognitive behavioural, interpersonal, or psychodynamic therapy fail to help 30-60% of participants with difficulties including generalised anxiety disorder, depression, anorexia nervosa or mixed symptoms. Moreover, around 20-60% of clients with depression, obsessive compulsive disorder and panic disorder fail to respond adequately to medication. Treatment resistance is associated with more chronic and personality-disordered symptoms. Although treatment resistant clients are commonly encountered in clinical practice, research often excludes these in order to maintain a diagnostic focus. There is growing evidence that treatment resistant clients may benefit from mindfulness-based interventions (treatments) such as Dialectical Behaviour Therapy (DBT), Mindfulness-Based Cognitive Therapy (MBCT), and Acceptance and Commitment Therapy (ACT). ACT aims to foster both acceptance of the individuals situation and positive behavioural change. In addition, it encourages focus on personal values to sustain motivation during challenging times. ACT is thus a unique integration of mindfulness, values, and committed action, and has proved effective across a broad range of complex clinical disorders. An initial study assessed a group-based ACT intervention for treatment resistant participants with a broad range of complex difficulties. Improvements were maintained 6 and 12 months after therapy finished, but as the trial had no control group, this could be falsely attributed to ACT. The present study therefore compared the ACT intervention with treatment as usual, based on Cognitive Behavioural Therapy, for treatment resistant participants (CBT-TAU).

Who can participate?
Eligible participants had received at least one previous episode of psychological therapy, lasting at least 8 sessions, and had been re-referred with significant mental health difficulties.

What does the study involve?
Once referred, participants were assessed for eligibility to the study. Those who were eligible for the study and willing to participate filled in several questionnaires. Once baseline data had been collected, participants were randomly assigned to either ACT (n=30) or CBT-based

treatment as usual (CBT-TAU; n = 31). Both groups received weekly 2-hour group therapy for 16 weeks. Participants completed measures again shortly after the treatment, and 6 months after the therapy finished.

What are the possible benefits and risks of participating?
All participants had treatment for their mental health difficulties, which could improve their symptomology and quality of life. As always with psychological therapies, there was a chance that not all participants would improve, however all participants were monitored closely throughout the study and had access to standard NHS crisis care if they required this.

Where is the study run from?
Intensive Psychological Therapies Service, Poole.

When is the study starting and how long is it expected to run for?
The study commenced in February 2008 and finished in January 2010.

Who is funding the study?
The study was funded by an ESRC CASE Award Postgraduate Research Scholarship awarded to Prof. Sue Clarke and Prof. Bob Remington, University of Southampton.

Who is the main contact?
Prof. Sue Clarke
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Contact information

Type(s)
Scientific

Contact name
Prof Susan Clarke

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Acceptance commitment therapy group for treatment-resistant participants: a randomised controlled trial

Study objectives
Is Acceptance and Commitment therapy an effective treatment for treatment resistant psychopathology?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dorset Research Ethics Committee, 25/01/2007, ref: 06/Q2201/170

Study design
Single-site randomised controlled trial

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
Treatment resistant mental health conditions

Interventions
The intervention group received 16 sessions of Acceptance and Commitment Therapy over 16 weeks, and were followed-up 6 months after completion of the study.

The control group received 16 session of Treatment as Usual based on Cognitive Behavioural Therapy over 16 weeks, and were also followed-up 6 months after completion of the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The Beck Depression Inventory-II (BDI-II) was used to assess depression, with higher scores indicating greater depressive severity.
2. To measure psychiatric distress we used the Symptom Check List -90 Revised (SCL-90-R), with higher scores indicating a greater severity of symptoms. Psychiatric distress was measured using the Global Severity Index (GSI), with a higher score indicating greater distress.

All measures were completed pre- and post-intervention and at follow-up.

Secondary outcome measures
1. Quality of life was assessed with the World Health Organization Quality of Life (WHOQOL) at pre- and post-intervention and at 6 month follow-up, with higher scores indicating a greater quality of life. We used the Structured Clinical Interview for DSM-IV Axis II Disorders (SCID-II) to assess symptoms of personality disorder at baseline and 6-month follow-up.
2. In addition, measures designed to assess the processes of psychological change were assessed. The Acceptance and Action Questionnaire (AAQ, 9-item) assessed psychological flexibility, with higher scores indicating greater psychological flexibility. We used the 15-item Mindful Attention Awareness Scale (MAAS) to assess the frequency of mindful states, with higher scores indicating greater mindful awareness. Finally, the Automatic Thoughts Questionnaire/Thought Believability and Frequency (ATQ/TBTF) is a 30-item measure that assessed the believability and frequency of intrusive thoughts on a 5-point scale.

Overall study start date
01/02/2008

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. Participants who had been re-referred with significant mental health difficulties
2. Participants who had completed at least one previous episode of therapy, lasting 8 sessions or more
3. Participants could be male or female, and aged 18+

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
61

Total final enrolment
61

Key exclusion criteria
1. Psychotic illness, substance dependence and intellectual disability [based on Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)]
2. Participants who engaged in self-harming behaviour in the previous 6 months before commencement of the study (based on Kreitman, 1977)
3. Participants who had a current eating disorder and a body mass index (BMI) of < 16

Date of first enrolment
01/02/2008

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Department of Mental Health
Dorset
United Kingdom
BH13 7LN

Sponsor information

Organisation
Dorset HealthCare University NHS Foundation Trust (UK)

Sponsor details
11 Shelley Road
Bournemouth
Dorset
England
United Kingdom
BH13 7LN

Sponsor type
Hospital/treatment centre

Website
http://www.dorsethealthcare.nhs.uk/

ROR
https://ror.org/04esx4891

Funder(s)

Funder type
University/education

Funder Name
University of Southampton (UK) - ESRC Grant (PTA-033-2005-00018)

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	01/07/2014	30/01/2020	Yes	No