

Acceptance commitment therapy group for treatment-resistant participants

Submission date 08/02/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/02/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/01/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Susan.clarke@dhuft.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Prof Susan Clarke

Contact details

University Department of Mental Health

St Ann's Hospital

69 Haven Road

Poole

Dorset

United Kingdom

BH13 7LN

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