ISRCTN33306437 https://doi.org/10.1186/ISRCTN33306437

Acceptance and commitment therapy for depression after psychosis: a pilot trial

Submission date
01/03/2013

Recruitment status
No longer recruiting

Registration date
19/03/2013

Overall study status
Completed

Last Edited
30/11/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is a common problem amongst people who experience psychosis. Depression is linked to greater feelings of stigma and shame, lower self esteem and increased risk of suicide. There is a need to develop specific treatments to assist individuals who have experienced psychosis who also develop depression.

Who can participate?
We are asking service users who are supported by community-based services run by NHS Greater Glasgow & Clyde (NHS GG&C), who have a diagnosis of schizophrenia and who also experience depression to participate in the study.

What does the study involve?
After a participant gives their informed consent to enter the study we will interview participants to determine how they have been feeling over the last two weeks. This will include a discussion about current symptoms including experiences of depression. Participants will also complete eight questionnaires. This meeting will last approximately 2 hours. This can take place over one or more sessions depending on preferences. Following this, participants will be seen again after 5 months and 10 months in order to find out how they are feeling. Each of these subsequent sessions will take about an hour. Taking part will not affect any current treatment that participants may be receiving or are about to receive. Everyone who takes part in the study will be offered treatment for the problems that they experience. One half or 50% of participants will also (in addition to their usual treatment) be offered a psychological therapy called Acceptance and Commitment Therapy (ACT). This will allow us to compare the outcomes for those who receive ACT as well as their usual care, with those who receive usual care. The results are compared to see if one is better than the other. To try to make sure the participants who receive ACT and those who receive usual care are the same to start with, each patient is allocated to treatment by chance (randomly). The treatment that participants receive will be selected at random by a computer. Those receiving ACT, will receive up to 20 individual sessions of ACT with a therapist over 5 months. Each session will last 50 minutes. Some participants who receive ACT will be asked if their sessions can be recorded on a digital audio recorder. This is to ensure that the therapist is doing the treatment correctly. These recordings are confidential and will be stored securely and will only be listened to by professional staff involved in the study, after

which they will be destroyed. They can also be made available for participants to listen to if they wish (some people find this helpful).

Those who are not offered ACT will also continue to receive the treatment they would normally receive.

What are the possible benefits and risks of participating?
If you take part in the study, it is hoped that both the treatment and the monitoring will be of help to you. However, it is possible that talking about some of these issues may be upsetting.

Where is the study run from?
NHS Greater Glasgow and Clyde (UK)

When is the study starting and how long is it expected to run for?
The study will start on 1st April 2013 and will run for two years.

Who is funding the study?
The Chief Scientist Office, Scottish Government and NHS Greater Glasgow & Clyde (UK)

Who is the main contact?
Professor Andrew Gumley
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Research Protocol Version Number: 1 (13/07/2012)

Study information

Scientific Title
A parallel group randomised open blinded evaluation of acceptance and commitment therapy for depression after psychosis: a pilot trial (ADAPT)

Acronym
ADAPT

Study objectives
The following research questions will be addressed:
Population:
1. What are the potential numbers of participants who fulfil eligibility criteria?
2. What proportion of potential participants provide fully informed consent to participate in the trial? Based on our pilot work we expect to randomise at a rate of 5.5 participants per month.

Intervention:
1. What proportion of participants engage with ACTdp as delivered by a trained, accredited therapist?
2. What is the fidelity and competence of therapists delivering ACTdp?
3. What is the association between therapist fidelity and competence and outcome in those participants randomised to ACTdp?

Control:
1. What follow-up do participants in both groups receive from secondary mental health services?
2. What medications (antipsychotic, antidepressant, mood stabiliser and anxiolytic) are prescribed to participants in both groups?
3. What psychological therapies are offered to participants during the course of the trial?

Outcomes:
1. What rates of improvement in quality of life, depression, hopelessness and negative symptoms are observed over at 5-month (end of treatment) follow-up and 10-month follow-up?
2. What are the rates of discontinuation from therapy?
3. What is the overall rate of follow-up in the first 5-months and at 10-months?
4. Are there identifiable characteristics of those that do not comply or are lost to follow-up?
5. What are the associations with ACT specific mechanisms (mindfulness skills, experiential avoidance and rumination) and outcome in terms of depression and negative symptoms?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 5, 19/12/2012, ref: 12/WS/0311

Study design
24-month parallel-group randomised open blinded evaluation (PROBE)

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Participants will be consecutively recruited, assessed and randomised to ACTdp plus ST or ST alone.

Acceptance and Commitment Therapy for depression after psychosis (ACTdp): Individuals will receive up to 5 months of individual ACTdp. ACTdp is based on the rationale that the experience of psychosis can threaten progress in valued life domains. The ACTdp protocol will identify problematic appraisals; highlight how attempts to avoid these appraisals can paradoxically increase their frequency; develop individuals ability to let go of appraisals rather than get caught up reacting to them; facilitate understanding about how distress can inform values; explore valued life domains; and help individuals to commit to behaviours consistent with these valued life domains.

Standard Treatment (ST): We will examine treatment received by all participants in the trial in order to establish parameters of standard treatment according to relevant SIGN and NICE guidance. We will require that all participants are in receipt of antipsychotic medication, psychiatric follow-up and follow-up from a secondary specialist mental health service.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The EQ-5D is a generic, preference-based quality of life instrument that has been successfully used in schizophrenia patients, and which facilitated the calculation of Quality Adjusted Life Years for health economic analyses.
2. The Calgary Depression Scale for Schizophrenia (CDSS); The potential for phenomenological overlap between depression, negative symptoms, and extrapyramidal symptoms is addressed by including the CDSS. This clinician administered interview measure is based on items selected from the Hamilton Rating Scale for Depression (HAM-D) and the Present State Exam (PSE) and was developed in order to reliably distinguish co-morbid depression from symptoms that are diagnostic features of schizophrenia-spectrum disorders. When compared to the gold standard SCID assessment of depressive symptoms the CDSS outperforms the BDI, PANSS Depression

subscale, and HAM-D for both sensitivity (94%) and specificity (89%)
3. The Positive and Negative Syndrome Scale (PANSS); will be used to measure psychiatric symptoms including negative symptoms. We will utilise the improved 5-factor model based on 5769 participants which incorporates positive, negative, disorganisation, excitement and emotional distress symptoms.
4. The Beck Depression Scale (BDI-II) is a well established measure of depression with excellent reliability and validity.
5. The Client Service Receipt Inventory (CSRI) is an instrument developed specifically for capturing service use among psychiatric patients. In addition to the standard health service resource use (e.g. G.P., specialist, hospital visits) the CSRI also includes specific psychiatric resource use (both hospital and community based) plus contacts with the judicial system.

Secondary outcome measures

Therapy Mechanisms:
1. Kentucky Inventory of Mindfulness Skills (KIMS) is a self-report inventory for the assessment of four mindfulness skills: observing, describing, acting with awareness, and accepting without judgement. Analyses have shown that the KIMS has good internal consistency, test retest reliability and construct validity.
2. The Acceptance and Action Questionnaire (AAQ-II) is a 7-item scale that measures experiential avoidance. Results from 2,816 participants across six samples indicate the satisfactory structure, reliability, and validity of this measure.
3. The Ruminative Response Scale (RRS) includes 22 items describing responses to depressed mood that are self-focused, symptom-focused, and focused on the possible causes and consequences of dysphoric mood. Psychometric evaluations have demonstrated good 5-month testretest reliability (r=0.80) and good internal consistency (α=.89; α=.89).
4. The Autobiographical Memory Test (AMT) is a widely used recall task based on Crovitzs classic single word cueing paradigm. Low autobiographical memory (AM) recall specificity is a known predictor of poor clinical outcome for people with unipolar depression34 and it has been argued that these problems with retrieval specificity are related to attempts to avoid unwanted mental experiences35. Reducing experiential avoidance is a central aim of the ACT approach36 but previous studies have not determined whether post-ACT improvements are associated with changes in autobiographical memory functioning. Greater AM retrieval specificity following treatment would indicate a possible mechanism of therapeutic change, namely, less avoidance of unwanted memories and related thoughts. The other main advantage of including the AMT in the current research is that it extends the assessment beyond purely questionnaire methods. Data from the ADAPT trial will provide a more nuanced understanding of the way that various change processes operate in ACT for depression after psychosis. During the administration of the AMT, participants are asked to generate a specific memory detailing an event which can be located in time and place in response to positive and negative cue words. Participants are given three practice words (enjoy, friendly, and bold). Once they are able to perform the task, six positive words (happy, proud, relieved, pleased, excited, and hopeful) and six negative words (miserable, guilty, angry, insecure, lazy, and uncomfortable) are presented in a randomised order. The cue words have been successfully used in previous published studies and the subjects are allowed up to 30 seconds to produce a response. Each word is presented verbally and visually (on a 10 cm x 30 cm card) and the same sentence cue is provided for each trial: Can you tell me of something that has happened to you that you are reminded of when you see the word...?''. When it was not clear whether the initial response refers to a specific event the examiner provides a standard prompt specified in Williams' (unpublished) procedures: Can you think of a particular time?''. Responses are coded as specific'', categoric'', extended'' or uninterpretable'' based on published definitions. Latency to produce a response is timed and answers will be audiotaped

(if participants consent) to allow reliability checks of the ratings.
5. Recovery Outcomes
5.1. The Process of Recovery Questionnaire (QPR) is a 22 item self report questionnaire which was developed by service users to measure experiences of recovery after psychosis. The QPR has two subscales measuring intrapersonal tasks and interpersonal factors relevant to personal recovery. The Questionnaire has excellent reliability and validity.
5.2. The Working Alliance Inventory Short Form Revised (WAI-SR) is a 12-item self-report measure of the working alliance that describes three components of the therapeutic relationship between a patient and therapist: (a) agreement between client and therapist on the goals of therapy, (b) agreement on the tasks of therapy, and (c) the quality of the interpersonal alliance. This measure produces scores for three subscales of alliance (Goal, Task, Bond) as well as a total alliance score and has acceptable internal consistency (.83 to .94).

Overall study start date
01/04/2013

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Outpatients, aged 16 or over, receiving secondary mental health care from community based services in NHS Greater Glasgow and Clyde (NHSGG&C)
2. Meet DSM-IV-TR criteria for schizophrenia and criteria for major depression (confirmed by Structured Clinical Interview for DSM / SCID-I & Calgary Depression Scale / CDSS for Schizophrenia; score >721). Individuals with substance use problems will not be excluded.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Those with significant learning disability
2. Who are unable to speak English

Date of first enrolment
01/04/2013

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Gartnavel Royal Hospital
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Sponsor information

Organisation
NHS Greater Glasgow & Clyde (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/content/default.asp?page=home_Research%20Development

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type

Government

Funder Name
Chief Scientist Office (CZH/4/743)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local 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?
Results article	results	01/05/2017		Yes	No
HRA research summary			28/06/2023	No	No