ISRCTN85278228 https://doi.org/10.1186/ISRCTN85278228

Pilot randomised controlled trial of augmented depression therapy

Submission date	Recruitment status
20/03/2017	No longer recruiting
Registration date	**Overall study status**
27/03/2017	Completed
Last Edited	**Condition category**
07/02/2025	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
Depression is one of the most common mental disorders worldwide. The symptoms of depression can vary greatly from person to person, but generally include low mood, problems with sleeping and/or eating, and loss of interest in life. There are a range of treatments available for people suffering from depression, including a range of different talking therapies and medications. Although many find the current treatments effective, they do not work for everyone and there is room to improve. Current psychological treatments are effective at reducing negativity (thinking and feeling sad) but are less successful at building positivity (thinking and feeling happy). It is known that reduced positivity predicts that individuals will stay depressed for longer and are more likely to become depressed again in the future. Augmented Depression Therapy (ADepT) is a new therapy which has been developed to treat depression, which aims to simultaneously reduce negativity and build positivity in an effort to keep people well in the long term. The aim of this study is to find out whether a large study looking at the effectiveness of ADepT would be possible.

Who can participate?
Adults suffering from depression

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive up to 20 sessions of cognitive behavioural therapy (CBT), which is a type of talking therapy that identifies and modifies negative automatic thinking and unhelpful beliefs to assist people to develop more helpful ways of thinking and behaving. Those in the second group receive up to 20 sessions of ADepT, which identifies what is important to people in their work, relationships, hobbies and self-care and helps them work towards these goals (trouble shooting as necessary if depression trips them up during this process). Participants are followed up at six, 12 and 18 months after beginning treatment with interviews and questionnaires to assess the impact of the treatment on depression and wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in their depressive symptoms. There are no notable risks involved with participating.

Where is the study run from?
1. University of Exeter (UK)
2. Devon Partnership Trust (UK)

When is the study starting and how long is it expected to run for?
July 2016 to January 2020

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

Who is the main contact?
Prof Barney Dunn
b.d.dunn@exeter.ac.uk

Contact information

Type(s)
Public

Contact name
Prof Barney Dunn

ORCID ID
https://orcid.org/0000-0002-0299-0920

Contact details
Sir Henry Wellcome Building for Mood Disorders Research
University of Exeter
Perry Road
Exeter
United Kingdom
EX4 4QQ
+44 (0)1392 726449
b.d.dunn@exeter.ac.uk

Type(s)
Scientific

Contact name
Prof Barney Dunn

ORCID ID
https://orcid.org/0000-0002-0299-0920

Contact details
Sir Henry Wellcome Building for Mood Disorders Research
University of Exeter
Perry Road
Exeter
United Kingdom

EX4 4QQ
+44 (0)1392 726449
b.d.dunn@exeter.ac.uk

Additional identifiers

Protocol serial number
33421

Study information

Scientific Title
Improving depression treatment outcomes by better repairing positivity deficits: A Feasibility pilot randomised controlled trial evaluation of an Augmented Depression Therapy targeting wellbeing (ADepT)

Acronym
ADepT

Study objectives
1. What are the estimated between-group differences (and 95% confidence intervals) in patient-related outcomes following Augmented Depression Therapy relative to CBT?
2. How acceptable is Augmented Depression Therapy to key stakeholders?
3. What proportion of patients approached to take part will agree to do so?
4. What proportion of patients who agree to take part will adhere to a pre-defined per-protocol dose of Augmented Depression Therapy or CBT?
5. What proportion of patients who agree to take part complete all outcome assessments?
6. What proportion of patients who agree to take part will remain in the trial at 18 month follow-up?
7. How do patients' views about Augmented Depression Therapy relate to the variability in the number of treatment sessions they attend?
8. What are patient and therapist views about the best choice of primary outcome in the definitive trial?
9. What is the variance in patient-related outcomes following Augmented Depression Therapy and CBT, and how do they correlate with patients' baseline scores?
10. What is the cost of providing Augmented Depression Therapy and CBT?
11. How well does the Augmented Depression Therapy Supervisory Rating Scale function?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Plymouth and Cornwall Research Ethics Committee, 17/02/2017, ref: 17/SW/0009

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Depression; UKCRC code/ Disease: Mental Health/ Mood [affective] disorders

Interventions
Participants are randomly allocated to either receiving augmented depression therapy or cognitive behaviour therapy.

Augmented Depression Therapy (ADepT) consists of up to 15 weekly core therapy sessions followed by five booster sessions (approximately bi-monthly) over the following year (each of one hour duration). Sessions are conducted face to face and follow a structured but formulation driven programme. The primary goal of ADepT is to build wellbeing, viewing depression as a barrier that gets in the way of this aim. Clients are supported to identify values consistent goals and to behaviourally activate themselves towards achieving these goals. Patterns of thinking and behaving that get in the way of dealing with challenges (being resilient) and taking opportunities (thriving) when working towards these goals are mapped out and new adaptive patterns of thinking and behaving are rehearsed. A wellbeing plan is developed at the end of the core sessions and booster sessions review progress with this wellbeing plan. Therapists delivering ADepT follow a bespoke treatment manual (developed during a prior case series evaluation of ADepT) and receive up to 90 minutes of supervision per week in a group format.

Cognitive Behaviour Therapy (CBT) consists of up to 20 weekly, face-to-face sessions of one hour duration, following a structured but formulation driven programme. Treatment begins with behavioural change techniques before moving on to identify and modify negative thoughts and beliefs. A relapse prevention plan is developed at the end of treatment, helping clients anticipate and manage possible stressors that could trigger a further depressive episode. Participants receive up to 90 minutes of supervision per week in a group format.

Participants are asked to complete measures (questionnaires, interviews, feedback booklets etc.) before therapy, at six months (approximately when therapy ends), twelve months, and eighteen months.

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
1. Severity of depression and anxiety symptoms are measured using the 9 item Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001) and the 7 item version of the Generalized Anxiety Disorder questionnaire (GAD-7; Spitzer et al., 2006) at baseline, six, 12 and 18 months
2. Wellbeing outcomes are measured using the 14 item version of the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS; Clark et al., 2003) at baseline, six, 12 and 18 months
3. Cost of therapies are measured using records from therapists (including training, preparation, supervision, session, and travel time) using standard micro-costing (bottom-up) approaches at baseline, six, 12 and 18 months
4. Participants views and experiences are assessed with feedback booklets at the end of

treatment, with a subset of respondents being invited to take part in interviews between the end of treatment and 12 month follow-up

Key secondary outcome(s))
1. Impact of ADepT versus CBT are measured using patient self-report, laboratory experimental and experience sampling data at baseline and six months
2. Health economic analyses are measured using Adult Service Use Schedule (AD-SUS), the Investigating Choice Experiments Capability Measure for Adults (ICECAP-A), the EuroQol Five Dimensions Questionnaire (EQ-5D-5L), and the Absenteeism and Presenteeism items of the World Health Organization Health and Performance Questionnaire (HPQ) at baseline, six, twelve and eighteen months

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. Aged over 18 or over
2. Suffering from a current major depressive episode (MDE) assessed by structured clinical interview for diagnosis (SCID-I)
3. Have a Patient Health Questionnaire (PHQ-9) depression score =>10
4. Present with significant anhedonic symptoms (PHQ-9 item 1 score =>2)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
82

Key exclusion criteria
1. Depression is not the primary presenting problem
2. Alcohol or drug dependent
3. Acutely suicidal or self-harming
4. Cognitively impaired
5. Have bipolar disorder or psychosis/psychotic symptoms ascertained at baseline research interviews
6. Currently receiving another psychological therapy

Date of first enrolment
29/03/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Exeter
AccEPT Clinic
Sir Henry Wellcome Building for Mood Disorders Research
Perry Road
EX4 4QG
Exeter
United Kingdom
EX4 4QG

Study participating centre
Devon Partnership Trust
Wonford House
Dryden Road
Exeter
United Kingdom
EX2 5AF

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/07/2023	17/07/2023	Yes	No
Protocol article		01/12/2019	29/03/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		05/02/2025	07/02/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes