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ADepT for hard-to-treat depression

Submission date	Recruitment status	[ ] Prospectively registered
02/10/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/10/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/10/2025	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Depression is common, causes significant distress, and makes it hard to have a sense of well-being and function fully in everyday life. Current talking treatments do not work for everyone; many who finish NHS Talking Therapies treatment options still suffer from symptoms of depression and are still considered as experiencing depression by services. This highlights the need to develop and evaluate new approaches, particularly for those who still have symptoms of depression after NHS Talking Therapy treatments. People with depression experience more negative emotions and thoughts, and experience fewer positive emotions and thoughts including feeling content and experiencing wellbeing. Both need to improve if people are to fully recover. Current talking treatments are useful in repairing negative emotions but are less good at rebuilding positive emotions. Augmented Depression Therapy (ADepT) was co-designed with people with lived experience of depression with an equal focus on building positivity (including building well-being) and reducing negativity (such as having negative thoughts). Previous work shows that ADepT successfully reduces negative emotions and builds positive emotions in adults with depression, leading to reductions in the symptoms of depression as well as large increases in well-being. This research will begin to evaluate if ADepT can also help those who are still depressed after attempting NHS Talking Therapies treatment options for depression (characterised as scoring at least 10 on a routinely administered measure of depression in NHS Talking Therapies called the PHQ-9, after completing 10 or more sessions). Up to fifteen adults suffering from depression will be offered ADepT at the AccEPT clinic, Devon. This study will evaluate if it is effective using a ‘case series’ methodology, tracking changes in depression and anxiety symptoms and well-being in the weeks before, during and after treatment. People who received ADepT will be invited to take part in an interview to discuss their experiences of treatment.

Who can participate?

Adults suffering from depression who are still unwell after receiving at least 10 sessions of high-intensity therapy for depression in Devon NHS Talking Therapies services in the past six months.

What does the study involve?

Participants will receive up to 15 weekly acute sessions and up to five booster sessions in the year after acute treatment has finished of ADepT. To evaluate ADepT, participants will be asked to fill out a short series of questionnaire measures weekly before, during and two months after therapy. They will also be asked to fill in a longer series of measures before, after, two months

after and one year after completing treatment and to take part in an interview exploring their views of treatment.

What are the possible benefits and risks of participating?
Participants will receive psychological therapy which is anticipated to improve depression, anxiety and wellbeing. Participants will be asked to fill in various questionnaires and take part in interviews, which for some people at times temporarily lower their mood.

Where is the study run from?
The study is run from the AccEPT clinic, Mood Disorders Centre, University of Exeter

When is the study starting and how long is it expected to run for?
May 2023 to May 2027

Who is funding the study?
The study is being run as part of routine care delivered at the AccEPT clinic, supported by research staff funded by the mood disorders theme of the UK Mental Health Mission, at NIHR Oxford Biomedical Research Centre, and two clinical psychology trainees.

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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Prof Barney Dunn

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Additional identifiers

Integrated Research Application System (IRAS)
331707

Protocol serial number
2022-23-34

Study information

Scientific Title
A case series evaluation of Augmented Depression Therapy (ADepT) for those who are still experiencing depression after completing NHS Talking Therapies high-intensity interventions

Acronym
ADepT-HTD

Study objectives
As an exploratory case series, the study does not have specific hypotheses, but these are the study objectives:

Evaluate if ADepT for hard-to-treat depression is:
1. Feasible/acceptable to service-users and therapists
2. Results in clinically meaningful improvement in depression symptoms, anxiety symptoms, and /or wellbeing levels
3. Results in no significant treatment-related adverse reactions for any participants

In addition:
1. Refine the intervention protocol on the basis of efficacy/acceptability outcomes and qualitative interview data

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/10/2023, North West - Greater Manchester (GM) South (Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 23/NW/0319

Primary study design
Interventional

Study design
Randomized multiple baseline case series design

Study type(s)
Treatment

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

Interventions
This project will follow a randomised multiple baseline case series design to evaluate if ADepT is feasible, acceptable, and effective in treating depression in those who remain depressed after completing an adequate dose of a high-intensity intervention in NHS Talking Therapies. Up to 15 participants will be randomised to different baseline assessment lengths before treatment starts (between three and eight weeks), with a random sequence generated by a computer-based package. The acute intervention phase will consist of up to fifteen weekly sessions. The follow-up phase will last for one year.

Randomisation to different baseline lengths (between three and eight weeks) will be performed using Microsoft Excel to randomly generate a number between 3 and 8 for each participant.

The ADepT protocol consists of up to 15 core therapy sessions (approximately weekly), 60-minute sessions followed by up to 5 optional booster sessions (also 60-minute) offered flexibly in the year after sessions finish. The primary goal of ADepT is to build well-being, viewing depression as a barrier that gets in the way of well-being. Clients are supported to identify values and consistent goals and to behaviourally activate themselves towards achieving these goals. Patterns of thinking and behaving that get in the way of individuals dealing with challenges (being resilient) and taking opportunities (thriving) as they work towards these goals are mapped out and then the client is encouraged to learn new adaptive patterns of thinking and behaving. All therapists delivering the treatment are experienced therapists who will undergo additional ADepT-specific training. Ongoing supervision will be provided for 90 minutes per week in a small group format by experienced ADepT supervisors/trainers.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate measured using the number of clients recruited and over what time frame at the end of the study
2. Treatment engagement measured using the number of clients who completed treatment with a planned discharge and the number of clients attending at least 8 sessions (50% of acute treatment dose), at the end of the acute treatment phase
3. Satisfaction with treatment measured using the number of clients and therapists rating treatment as acceptable, satisfactory and that they would recommend it to others at the end of the acute treatment phase
4. Patient safety measured using the number of serious incidents that could be clearly attributed to the intervention or research participation at the end of the study
5. Preliminary signal of clinical efficacy, indexed as the number of clients showing at least reliable improvement and/or a positive change in slope/level in time series analysis of depression, anxiety and/or wellbeing (see list of secondary outcome measures below for details), measured at the end of the acute treatment phase

Key secondary outcome(s)
The following clinical outcome measures will be collected weekly during the baseline, treatment, and 2-month post treatment phase:
1. Current depression symptom severity over the past week measured using the Patient Health Questionnaire (PHQ-9)
2. Positive wellbeing experiences over the past week measured using the Warwick-Edinburgh Mental Wellbeing Scale long form (WEMWBS-LF)
3. Anxiety symptom severity (given depression is frequently comorbid with anxiety) measured using the Generalized Anxiety Disorder scale (GAD-7)
4. Psychosocial impairment as a result of poor mental health measured using the Work and Social Adjustment Scale (WSAS)

The following clinical outcome measures will be collected at intake, pre-treatment, post-treatment, 2-month follow-up and 1-year follow-up extended assessment:
1. PHQ-9, GAD-7, WSAS and WEMWBS-LF as described above
2. Anhedonia severity (a loss of interest and pleasure) measures using the Snaith Hamilton Pleasure Scale (SHAPS)

3. Satisfaction in key life domains measured using the DIALOG scale
4. The recovery of quality of life for people with mental health difficulties measured using the Recovering Quality of Life tool (ReQoL-10)
5. The logic model underpinning the ADepT intervention measured using the ADepT Outcome Tool
6. Positive and negative emotions for clients from week-to-week as they engage in everyday life measured using the Positive and Negative Affect Scale (Short-form; SF-PANAS)
7. Attitudes toward savouring positive experiences measured using the self-report Savouring Beliefs Inventory (SBI)

Completion date
02/05/2027

Eligibility

Key inclusion criteria
1. Aged 18+ years old
2. Have not remitted (demonstrated by a PHQ-9 score of ≥10 to meet NHS Talking Therapies clinical threshold for depression 'caseness') to the minimal effective dose (≥10 sessions) of high-intensity treatment for depression (as their primary presenting problem) in NHS Talking Therapies within the last 6 months
3. Meet diagnostic criteria for a current episode of MDD (using Structured Clinical Interview for Diagnosis)
4. Sufficient working knowledge of written and spoken English to make use of therapy and complete research assessments without translation
5. Willing for us to notify their General Practitioner of their participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Currently receiving other psychosocial therapies
2. Individuals who are eligible for, would be seen by, or their needs would be best met by secondary care services
3. Presenting with another area of difficulty that the therapist and/or client believe should be

the primary focus of the current intervention
4. Current/past history of schizophrenia or bipolar disorder
5. Displaying marked risk to self (self-harm or suicide) or others that the clinician judges could not be managed safely using weekly therapy in an out-patient setting and that would interfere with engagement in therapy
6. Presenting with features of substance misuse, problematic eating, and/or personality difficulties that the clinician judges could not be managed safely using weekly therapy in an out-patient setting and that would interfere with engagement in therapy
7. Presenting with features of a learning disability that the clinician judges would interfere with engagement in therapy and capacity to complete research assessments
8. Currently lacking capacity to give informed consent
9. Presenting with any other significant, severe or life-threatening disease, disorder, or cognitive impairment that the clinician judges may either put the participants at risk because of participation in the study, may influence the result of the study, or inhibit the participant's ability to participate in the study

Date of first enrolment
24/10/2023

Date of final enrolment
08/02/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
AccEPT clinic
Mood Disorders Centre
University of Exeter
Exeter
United Kingdom
EX4 4QQ

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon reasonable request from Barney Dunn (b.d.dunn@exeter.ac.uk), subject to approval by the AccEPT clinic and Mood Disorders Centre overseeing the project. Some data will be removed or edited to preserve client confidentiality.

IPD sharing plan summary
Available on request