ISRCTN75828354 https://doi.org/10.1186/ISRCTN75828354

ADepT for treatment of complex depression

Submission date	Recruitment status	[ ] Prospectively registered
04/11/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/02/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/10/2025	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 wellbeing and to function fully in everyday life. Current talking treatments do not work for everyone and there is a need to develop and evaluate new approaches, particularly for individuals suffering from more complex depression linked to difficult experiences in early life (complex trauma). People living with depression experience more frequent and intense negative emotions and less frequent and intense positive emotions, both of which need to change 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) has been co-designed with people with lived experience of depression with equal focus on building positive emotions and reducing negative emotions. Previous work has found that ADepT successfully reduces negative emotions and builds positive emotions in adults with depression, leading to marked reductions in the symptoms of depression as well as large increases in wellbeing. This research will preliminarily evaluate if ADepT can also help those with more complex depression (characterised by depression with difficulties in regulating emotions and relationships, linked to exposure to difficult early life experiences and often associated with personality difficulties). Adults suffering from complex depression will be offered ADepT in two services, one running in Devon and one running in Essex. The researchers will evaluate if it is effective and will track changes in depression and anxiety symptoms and wellbeing in the weeks before, during and after treatment. They will also invite people who received ADepT and the therapists who delivered ADepT to take part in an interview to discuss their experiences of the treatment.

Who can participate?
Individuals aged over 18 years currently suffering from complex depression

What does the study involve?
Participants receive ADepT therapy and complete a series of outcome assessments and interviews before during and after the treatment.

What are the possible benefits and risks of participating?
Participants will receive a novel therapy which the researchers anticipate will be helpful for their

mood. Participants will be asked to complete a series of research assessments and interviews around their experiences of mental health, which may temporarily lower mood when they are being completed.

Where is the study run from?
The University of Exeter (UK)

When is the study starting and how long is it expected to run for?
January 2021 to January 2026

Who is funding the study?
1. National Institute for Health and Care Research (NIHR) (UK)
2. Saudi government PhD scholarship (Saudi Arabia)

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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
318010

Central Portfolio Management System (CPMS)
54155

Study information

Scientific Title
A case series evaluation of Augmented Depression Therapy (ADepT) for the treatment of complex depression

Study objectives

As an exploratory case series, the study doesn't have specific hypotheses, but these are the study objectives:

Evaluate if ADepT for complex 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
Old ethics approval format

Ethics approval(s)
Approved 21/10/2022, East Midlands – Derby Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8154; derby.rec@hra.nhs.uk), ref: 22/EM/0216

Primary study design
Interventional

Study design
Non-randomized; Both; Design type: Treatment, Psychological & Behavioural, Complex Intervention, Qualitative

Study type(s)
Treatment

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

Interventions
PROJECT DESIGN AND SETTING
This project will follow a randomised multiple baseline case series design across two different service settings to evaluate if ADepT is feasible, acceptable, and effective in treating complex depression. Up to 30 participants will be randomised to different baseline assessment length before treatment starts (between 3 and 8 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 be for a further 8 weeks.
Participants will complete measures of depression, wellbeing, and anxiety, each week in the baseline, acute and follow-up treatment phases. In addition, participants will also complete a longer battery of measures at randomisation, pre-treatment, post-treatment, 2 months after completing acute treatment, and one year after completing acute treatment (when all booster sessions will have been completed). They will also take part in a qualitative at some point after finishing acute treatment.
Participants will be treated with the modified ADepT protocol across two sites. This approach mirrors the design in the previous ADepT case series for adult depression (Dunn et al., 2019)
The first case series site will be the Accessing Evidence-Based Psychological Therapies (AccEPT) clinic, University of Exeter (see: https://www.exeter.ac.uk/mooddisorders/acceptclinic/). This is

an NHS-commissioned specialist mood disorders clinic that sits in the gap between IAPT and secondary care services.
The second site will be based in the Inclusion Thurrock: Psychological Therapy Service (see: https://inclusionthurrock.org/). This is an NHS-commissioned service situated in the gap between primary care IAPT and secondary care psychology services.

PARTICIPANTS
Up to 30 participants will be recruited (15 at each site) and will undergo modified ADepT for complex depression. Participants will be involved in the study for no more than 2 years. Sample size estimations for intensive time series analysis (the primary analysis method) do not follow a formal power analysis approach. However, guidelines recommend a minimum of three replications of the intervention effect. To increase confidence in the generalisability of the findings, at each site we will ask three different therapists to deliver the treatment, aiming for each to treat at least three cases. For the secondary group level analyses (used to generate effect sizes for benchmarking purposes), the researchers aim to be powered to detect a large effect size in the key pre-post analysis (based on the continuation rule that ADepT needed to demonstrate a large effect size on the primary outcome variables). They therefore need to recruit at least 15 participants. The target sample size of up to 30, even allowing for up to 20% dropout and 15% attrition due to not having a stable baseline, is therefore sufficiently powered. Participants will be adults, who are currently clinically depressed according to a diagnostic interview and a self-report depression measure, and who have experienced complex trauma in childhood that leads to some secondary difficulties in interpersonal and emotional regulation. Participants will be clinically assessed to make sure that they would be likely to benefit from (and can be safely held) in an out-patient therapy setting (and that their needs would not be better managed by IAPT or secondary care. Participants will be recruited into two sites (AccEPT clinic for Devon clients; Inclusion Thurrock for Essex clients), via either self-referral or clinician-referral means.

CLINICAL INTERVENTION
The standard ADepT protocol consists of up to 15 core therapy (approximately weekly) 60-minute sessions followed by up to five optional 60-minute booster sessions offered flexibly in the year after core sessions finish. The primary goal of ADepT is to build wellbeing, viewing depression, anxiety and other sequelae of complex trauma exposure as a barrier that gets in the way of wellbeing. 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 small group format by experienced ADepT supervisors/trainers (clinical psychologists Barney Dunn or Jo Mackenzie or IAPT therapist Megan Colletta). The protocol refinement phase will make a series of adjustments to this protocol to meet the needs of clients with complex depression. Sessions can be delivered face-to-face, via telephone, or via video conferencing, depending on client preference (and if applicable the return of any COVID-related social distancing requirements).

OUTCOME ASSESSMENT
Participants will complete weekly self-report assessments of depression and anxiety symptom severity and wellbeing during the baseline phase (randomly selected to be between 3 and 8 weeks). They will also complete an extended battery of self-report and interview assessments at intake assessment, immediately prior to treatment starting, when acute treatment finishes, 2 months after acute treatment finishes and 1 year after acute treatment finishes. Participants

will also be invited to take part in a qualitative interview at some point after acute treatment has finished to gain their views on ADepT and their experiences of receiving it. The choice of measures and the overall measure burden have been discussed with experts by lived experience and felt to be appropriate.

Demographic and clinical screening assessment (to assess suitability):
1. Bespoke Demographic screening questionnaire (age, gender, ethnicity, use of medication for mental health, employment status, relationship status, highest level of education, experience of previous therapy)
2. Patient Health Questionnaire (PHQ-9) – a 9-item self-report measure of depression symptom severity over the past week, to assess for the presence of current depression)
3. PDS-ICD-11 – an 11-item self-report scale that assesses for difficulties in emotional, relationship, identity and behavioural regulation consistent with the presence of a personality disorder, to assess for the presence of difficulties in emotional and interpersonal regulation
4. Standardized Assessment of Personality (SAPAS) – an 8-item screen of personality disorder, to screen for the presence of personality difficulties
5. Modified Center for Disease Control and Prevention short Adverse Childhood Experience (ACE) tool – 11-item self-report measure of exposure to complex trauma in childhood, to assess for the presence of complex trauma exposure. The researchers have added an additional 5 items to screen for a broader array of complex trauma exposure
6. Benevolent childhood experiences questionnaire (BCE) – a 10-item screening questionnaire, to assess for (absence of) positive experiences during development
7. The International trauma questionnaire (ITQ) – 18-item self-report scale assessing for the presence of current PTSD or complex PTSD, to assess for current PTSD and to determine if the client may be better suited by a current PTSD treatment)
8. The Structured Clinical Interview for DSM-V (SCID-I) will be used to assess whether participants currently meet the criteria for a Current Major Depressive Episode.
Extended assessment battery (intake, pre, post, 2 months and 1 year)
9. PHQ-9, PDS-ICD-11, SCID-I, plus:
10. Warwick-Edinburgh Mental Wellbeing Scale short form (WEMWBS-SF) – a 7-item self-report measure of positive wellbeing experiences over the past week, validated for use in adolescents and adults
11. Generalized Anxiety Disorder scale (GAD-7) – a 7-item self-report measure of anxiety symptom severity (given depression is frequently comorbid with anxiety)
12. Snaith Hamilton Pleasure Scale (SHAPS) – a 14-item self-report measure of anhedonia severity (a loss of interest and pleasure)
13. DIALOG scale – an 11-item self-report measure of satisfaction in key life domains
14. Recovering Quality of Life tool (ReQoL-10) - a 10-item self-report measure of recovery of quality of life for people with mental health difficulties
15. Work and Social Adjustment Scale (WSAS) – a 5-item self-report measure of psychosocial impairment as a result of poor mental health
16. ADepT Outcome Tool – a bespoke 11-item measure designed to index the logic model underpinning the ADepT intervention
17. At 1-year follow-up only, participants will undergo a retrospective diagnostic interview to assess if they had met the criteria for a major depressive episode in the period of time since completing acute treatment using The Longitudinal Interval Follow-up Evaluation (LIFE) interview
Weekly outcome assessment (baseline, acute treatment and 2-month follow-up phase)
18. PHQ-9, WEMWBS-SF, GAD-7

Qualitative interview (after acute treatment)
Therapists and clients will undergo a brief (approx. 45-minute) face-to-face, telephone, or video

conferencing interview with one of the researchers exploring their experiences of the therapy at the end of treatment. Interviews will focus on how clients and therapists found the wellbeing /positivity focus of the treatment, which aspects of treatment they found most helpful or unhelpful, how it has changed their/their clients' identity/relationship to depression, and whether they/their clients have changed how they manage their difficulties as a result of treatment. They will also be asked their views about the length and delivery format of the treatment and the feasibility/acceptability of both the intervention and the outcome measurement. The interviews will follow a topic guide, but with the flexibility to adapt this based on the answers given. This enables the researchers to explore the meaning of participants' responses and to elicit more detail on themes which arise during the interview. the end of this interview, participants will also quantitatively rate the acceptability of the intervention (from 1=not at all acceptable to 5=extremely acceptable); how satisfied they were with the intervention (from 1=not at all satisfied to 5=extremely satisfied); and whether they would recommend this treatment to friends or family suffering from depression (from 1=not at all likely to 5=very likely).

Qualitative feedback booklet (at 1-year follow-up)
At one year follow-up only, participants will complete a written qualitative feedback booklet, exploring their views on the long-term outcomes linked to ADepT and how they experienced the booster sessions. The qualitative questions at 1-year follow-up are appended. Measures and interviews will be completed through a mixture of face-to-face sessions, via video conferencing, or via online surveys (based on participant preference).

CASE SERIES CONTINUATION CRITERIA
The primary analysis of this case series will focus on the feasibility, acceptability and efficacy of the intervention.
Continuation rules to proceed to the pilot trial without intervention modification are:
1. At least ten participants can be recruited at each site over a six-month window
2. > 50% of clients complete treatment with a planned discharge
3. Clients on average attend > 50% of scheduled sessions
4. > 60% of clients and therapists rate treatment as acceptable, and satisfactory and that they would recommend treatment to others
5. No serious incidents (SIRIs) occurred that could be clearly attributed to case series participation or the intervention)
6. > 60% of clients show clinical improvement on the PHQ-9, GAD-7 and/or WEMWBS (either a positive change in slope/level in time series analysis or meeting reliable improvement criteria from pre to post treatment)
7. < 30% of clients show clinical deterioration on the PHQ-9, GAD-7 or WEMWBS (either a negative change in slope/level in time series analysis or meeting reliable deterioration criteria from pre to post treatment)

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate, recorded as the number of clients recruited at each site over a 6-month window
2. Treatment engagement, recorded as the number of clients who completed treatment with a planned discharge and as the number of clients attending at least 10 sessions (50% of acute treatment dose), measured at the end of the acute treatment phase
3. Satisfaction with treatment, recorded as the number of clients and therapists rating

treatment as acceptable, satisfactory and that they would recommend it to others, measured at the end of the acute treatment phase
4. Patient safety, recorded as the number of serious incidents that could be clearly attributed to the intervention or research participation, measured over the duration of the trial
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. Depression symptoms measured using the Patient Health Questionnaire (PHQ-9)
2. Anxiety symptoms measured using the Generalized Anxiety Disorder Scale (GAD-7)
3. Wellbeing measured using the Warwick Edinburgh Mental Wellbeing Scale Short Form (WEMWBS-SF)

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 as described above
2. Wellbeing measured using the Warwick Edinburgh Mental Wellbeing Scale full scale (WEMWBS-FS)
3. Personality disorder symptoms/features measured using the PDS-ICD-11
4. Anxiety symptoms measured using the Generalized Anxiety Disorder Scale (GAD-7)
5. Anhedonia symptoms measured using the Snaith Hamilton Pleasure Scale (SHAPS)
6. Life satisfaction measured using the DIALOG Scale
7. Quality of life measured using the Recovering Quality of Life Scale 10-item version (ReQoL-10)
8. Functioning measured using the Work and Social Adjustment Scale (WSAS)
9. The hypothesized mechanism of change in ADepT assessed using the ADepT Outcome Tool
10. At 1-year follow-up only a retrospective diagnostic interview will be used to assess if individuals met the criteria for a depressive episode over the past month

All participants and therapists will be invited to take part in a qualitative interview after treatment is completed to explore their experiences of therapy

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Score in the clinical range on the PHQ-9 depression scale (scores ≥10)
3. Meet diagnostic criteria for a current major depressive episode using the Structured Clinical Interview for Diagnosis
4. Describe depression as the primary presenting problem they wish to work on
5. Report some difficulties in emotional, interpersonal, identity or impulsivity regulation, consistent with personality difficulties and/or mild personality disorder linked to exposure to complex trauma during childhood
6. Willing and able to give informed consent for participation in the trial
7. Have working knowledge of written and spoken English, sufficient to be able to make use of

therapy and to be able complete research assessments without the need for a translator
8. Willing to allow their General Practitioner to be notified of participation in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
31

Key exclusion criteria
1. Currently receiving other psychosocial therapies
2. Presenting with another area of difficulty that the therapist and/or client believe should be the primary focus of the current intervention (for example, PTSD, complex PTSD, eating disorder)
3. reporting a current/past history of schizophrenia or bipolar disorder
4. Presenting with current moderate to severe personality disorder that requires secondary or tertiary care management
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 antisocial 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 trial, may influence the result of the trial, or inhibit the participant’s ability to participate in the trial

Date of first enrolment
25/10/2022

Date of final enrolment
25/10/2023

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Inclusion Psychological Therapies Service
Thurrock Health Centre
55-57 High Street
Grays
United Kingdom
RM17 6NB

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
NIHR School for Primary Care Research; Grant Codes: MH040 / NIHR203020

Funder Name

Saudi government PhD scholarship

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request in anonymised form from Barney Dunn (b.d.dunn@exeter.ac.uk) after the primary outcomes are published for clearly defined analyses with ethical approvals in place.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No