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ADepT+ therapy for complex depression

Submission date
22/05/2025

Recruitment status
Recruiting

Registration date
27/05/2025

Overall study status
Ongoing

Last Edited
17/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Some people struggling with depression may also have additional difficulties managing their relationships, emotions and sense of self as adults. These difficulties are sometimes referred to as personality difficulties or diagnosed as a personality disorder. Together, this combination of difficulties is known as 'complex depression', which may be linked to difficult early life experiences, or an absence of positive early experiences. Individuals with complex depression may seek help from their GP or their local NHS Talking Therapies (NHS-TT) service in primary care. Because NHS-TT therapists are not routinely trained to help people with complex depression, this can lead to people being seen as too 'complex' for these services, and those who are offered care often report not fully benefiting as it is not tailored to their specific needs. In addition, people with complex depression are often not viewed as 'severe enough' to access secondary mental health services. When this happens, the person is often discharged into the care of the GP and left with little or no support. The aim of this feasibility study is to inform the design and conduct of a future definitive trial that aims to investigate a psychological therapy designed to address these symptoms. A total of 60 people will be randomly allocated to receive usual care or usual care plus the novel intervention (ADepT+ therapy). They will complete outcome measures at intake, 8-, 14- and 20-month follow-up. Views on the acceptability of the therapy will be collected from participants in terms of numerical ratings of acceptability, written feedback and through interviews.

Who can participate?
Adults aged 18 years and over with complex depression (depression alongside difficulties managing relationships, emotions or sense of self) who are registered with a GP in Devon.

What does the study involve?
Participants will be randomly allocated to either receive the ADepT+ therapy, alongside their usual care, or continue with their Usual care alone. All participants will complete questionnaires and an interview with a researcher about their mood, symptoms, and use of health services at 4 points throughout the study: baseline, 8, 14 and 20 months. Participants allocated to receive the therapy will be offered up to 20 weekly therapy sessions followed by up to 5 booster sessions in the following 12 months, and will complete brief questionnaires linked to each therapy session and be asked to share written comments on their experiences of therapy. Some participants who receive the therapy will also be invited to an in-depth interview to discuss their experiences of ADepT+ in more detail.

What are the possible benefits and risks of participating?
Participants will be asked to fill in various questionnaires and take part in interviews, which for some people at times temporarily lower their mood. 50% of participants will receive psychological therapy, which is anticipated to improve depression, anxiety and wellbeing.

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

When is the study starting and how long is it expected to run for?
May 2025 to July 2028

Who is funding the study?
This study is funded by a National Institute for Health and Care Research (NIHR) Doctoral Fellowship. This study is supported by the AccEPT clinic, and supported by the Office for Life Sciences and the National Institute for Health and Care Research (NIHR) Mental Health Translational Research Collaboration Mission, hosted by the NIHR Oxford Health Biomedical Research Centre.

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
337878

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 60120; Grant Code: NIHR304679

Study information

Scientific Title
Development and feasibility of augmented depression therapy for complex depression (ADepT+): a randomised, controlled feasibility trial

Acronym
ADepT+

Study objectives
The primary aim of this trial is to assess the feasibility and acceptability of the intervention and trial procedures to inform the design and conduct of a future large trial capable of examining the effectiveness of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/05/2025, Leicester South REC, Meeting held by video-conference via Zoom; +44 (0) 207 104 8193, +44 (0)207 104 8079; leicestersouth.rec@hra.nhs.uk), ref: 25/EM/0080

Study design
Randomized; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention

Primary study design

Interventional

Study type(s)
Treatment

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

Interventions
ADepT+ therapy consists of up to 20 acute 60-minute individual therapy sessions over 8 months, followed by up to 5 optional 60-minute booster sessions offered flexibly in the subsequent 12 months. Therapy will be delivered face-to-face, online or by phone according to patient preference and what is practically possible. The primary goal of ADepT+ is to build wellbeing, viewing depression, anxiety, interpersonal, emotional and identity symptoms as barriers that get in the way of wellbeing. The key adaptations (+) for complex depression from standard 'ADepT' therapy include an extended assessment phase, to support the therapeutic relationship and understand how additional difficulties and possible trauma exposure link to current depression, and additional 'change' sessions to integrate additional skills to regulate emotions and manage relationships.

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 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.

Therapy will be delivered by at least three therapists with an existing training in cognitive behavioural, behavioural or dialectical behavioural therapy and experience of working with people with mood disorders. Therapists will undergo additional ADepT+ specific training as required. Ongoing supervision will be provided for 90 minutes per week in a small group format facilitated by an experienced ADepT+ supervisor/trainer.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcomes of this study relate to the primary feasibility and acceptability aims (recruitment rate, data availability, proportion of participants receiving minimum adequate dose of therapy, therapy acceptability ratings, safety of trial and intervention procedures).

However, the candidate primary outcome for a future fully powered trial is: Recovering Quality of Life tool (ReQoL-10; 25) - a 10-item self-report measure of recovery of quality of life for people with mental health difficulties, measured at baseline, 8, 14 and 20 months.

Key secondary outcome(s))
Measured at baseline, 8, 14 and 20 months:
1. 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, also measured at each therapy session for the intervention group
2. Self-report 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
3. The International trauma questionnaire (ITQ) – an 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)
4. 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, also measured at each therapy session for the intervention group
5. Generalized Anxiety Disorder scale (GAD-7) – a 7-item self-report measure of anxiety symptom severity (given depression is frequently comorbid with anxiety), also measured at each therapy session for the intervention group
6. Snaith Hamilton Pleasure Scale (SHAPS) – a 14-item self-report measure of anhedonia severity
7. Work and Social Adjustment Scale (WSAS) – a 5-item self-report measure of psychosocial impairment as a result of
poor mental health
8. DIALOG scale – an 11-item self-report measure of satisfaction in key life domains

Interview/ clinician:
1. The Structured Clinical Interview for DSM-V (SCID-I) will be used to assess whether participants currently meet
criteria for a Current Major Depressive Episode (and to rule out past episodes at intake)
2. Retrospective diagnostic interview to assess if they had met criteria for a major depressive episode in the period of time since completing acute treatment using the Longitudinal Interval Follow-up Evaluation (LIFE) (not collected at baseline)

Process measures (measured at baseline, 8, 14 and 20 months and additionally at therapy sessions 4, 8, 12 and 20 for the intervention group only):
1. ADepT Outcome tool (Dunn et al, unpublished) – a bespoke 11-item measure designed to index values-driven behaviour within the therapy logic model
2. Engaged Living Scale (ELS) – a 16-item self-report measure of valued living and life fulfilment
3. Responses to Positive Affect scale (RPA) – a 17-item self-report measure of use of dampening and amplifying appraisals of positive emotion experience
4. The Working Alliance Inventory- Short Revised Form (WAI-SR65) – a 10-item rating of therapy alliance will measure
therapeutic alliance mechanisms of change (intervention arm only)

Completion date
31/07/2028

Eligibility

Key inclusion criteria
1. Aged 18 years or older
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 prefer therapy to focus on
5. Report difficulties in emotional, interpersonal, identity or impulsivity regulation, consistent with personality difficulties or personality disorder (assessed by scoring >=9 on the PDS-ICD-11)
6. Willing and able to give informed consent for participation within the trial

7. Have sufficient written and spoken English to be able to make use of therapy and to be able to complete research assessments without the need of a translator
8. Have completed the intake measures
9. Be registered with a General Practice within the study site catchment area (Devon) who they are willing to be notified of their participation within the trial

Therapist participant inclusion:
1. Served as a therapist on the ADepT+ feasibility trial
2. Delivered at least one ADepT+ therapy session to a participant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Currently receiving psychosocial therapy
2. Current substance dependence according to ICD-11 criteria (as this may interfere with the ability to engage in and use therapy; current substance abuse is not an exclusion criterion)
3. Current/past history of schizophrenia or Bipolar-I diagnosis (Bipolar-II diagnosis not an exclusion criterion)
4. Presents with co-occurring difficulties that cannot be safely managed in a primary care outpatient setting; or that would significantly interfere with engagement in therapy; or are indicated to be the most appropriate primary focus of current treatment (for example, PTSD, complex PTSD, problematic eating, cognitive impairment, learning disability)
5. Current moderate to severe personality disorder and/or antisocial personality traits that require secondary/tertiary care management
6. Displaying marked risk to self (self-harm or suicide) or others, that cannot be safely managed in a primary care outpatient setting
7. Participant anticipates they will be unable to regularly attend therapy sessions within the site area (e.g. planning to move out of the study area, work commitments prevent regular attendance, lengthy period of travel not mitigated by access to online therapy sessions)
8. Currently receiving inpatient mental healthcare

No specific therapist participant exclusion criteria.

Date of first enrolment
13/06/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Exeter
Sir Henry Wellcome Building for Mood Disorders Research
Queens Drive
Exeter
United Kingdom
EX4 4QQ

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
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Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

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 from the CI (Laura Warbrick, L.a.warbrick@exeter.ac.uk). Consent will be sought from participants to share anonymised data with other researchers for secondary analyses. Because of the potentially sensitive nature of the data and the potential for participants to be identifiable by their data by some members of the public, the public will not be given unrestricted access to the data. In accordance with good practice and institutional policy, the research database will be registered with the University of Exeter's public access database. The dataset will be anonymous and will be registered with a metadata-only record, allowing the research team to control access to the dataset, restricting it to appropriately qualified third parties for justified and ethically approved research.

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes