ISRCTN22576507 https://doi.org/10.1186/ISRCTN22576507

Augmented depression therapy adapted for treating depression in adults with autism

Submission date
06/11/2025

Recruitment status
Recruiting

Registration date
19/11/2025

Overall study status
Ongoing

Last Edited
14/11/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
Depression is very common among autistic adults, but existing treatments do not always meet their needs. Many therapies mainly focus on reducing distress (low mood, worry, negative thoughts) and symptoms of depression, and neglect building wellbeing and restoring functioning in day to day life. This study will look at a new talking therapy called Augmented Depression Therapy (ADepT). ADepT is designed not only to reduce distress but also to actively build wellbeing, quality of life, and functioning. Early research in the general population shows promising results, and this project will test how acceptable and useful it is for autistic adults with depression. The main aim is to find out whether ADepT is a good fit for autistic people, whether it is safe, and whether it shows early signs of improving mood and wellbeing. If successful, this study will lay the groundwork for a larger trial.

Who can participate?
Adults (18 years and older) who have a diagnosis of autism or score above a screening threshold for autism, experience depression as their main difficulty, and meet the criteria for Major Depressive Disorder, as well as scoring in the clinical range on a standard depression questionnaire. Participants must live in the catchment area for the Devon Integrated Care Board and be registered with a GP in that catchment area.

What does the study involve?
- After initial screening and consent, participants will be randomly placed on a short waiting period (3–8 weeks) before starting therapy.
- The therapy itself will include up to 15 weekly one-hour sessions of ADepT, either in person or by video call.
- Optional “booster sessions” may be offered later to help maintain progress.
- Participants will complete questionnaires about their depression, anxiety, and wellbeing before, during, and after treatment, as well as at a two-month follow-up.
- Therapy sessions will be recorded (with permission) to ensure therapists are delivering the treatment as intended.
- After finishing therapy, participants will be invited to take part in an interview to provide feedback to help improve the treatment for others.

What are the possible benefits and risks of participating?
Benefits:
- Participants may find ADepT helpful in reducing their depression and improving their wellbeing.
- They will contribute to developing better therapies for autistic adults with depression.
- Small tokens of appreciation (like vouchers) will be given for taking part in research activities.

Risks:
- Talking about difficult emotions may cause temporary distress.
- Some people may not find the therapy helpful.
- There is a small risk of feeling worse during therapy, although this will be monitored closely.
- If any safety risks arise (e.g., thoughts of self-harm), the research team will follow NHS safety procedures, inform the participant's GP, and ensure support is in place.

Confidentiality will be protected, and all personal information will be stored securely.

Where is the study run from?
The study will be run from the AccEPT Clinic at the Mood Disorders Centre, University of Exeter. Recruitment will take place across Devon.

When is the study starting and how long is it expected to run for?
September 2025 to May 2029. Data collection will run from November 2025 and a final analysis is anticipated to be completed in 2027. Overall, the study will last about two years.

Who is funding the study?
This project is being conducted as part of a Doctorate in Clinical Psychology (DClinPsy) at the University of Exeter. Associated costs will be covered through the programme's research support, the Accept clinic. Research support will be provided by staff employed on the depression theme of the MH-TRC mental health mission (Mental Health Translational Research Collaboration (MH-TRC) Overview – NIHR Oxford Health Biomedical Research Centre).

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
361068

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
24-25-43

Study information

Scientific Title
Augmented depression therapy adapted for treating depression in adults with autism

Acronym
ADepT-A

Study objectives
Depression is common, causes significant distress, and makes it hard to have a sense of wellbeing and function fully in everyday life. Autistic adults are four times more likely to experience depression in their lifetime, and have been found to benefit less from the currently available psychological therapies for depression, compared to those without autism. There is a

need to develop and evaluate new psychological therapies for autistic adults with depression. Augmented Depression Therapy (ADepT) is a novel talking treatment for depression that focuses on building wellbeing and functioning as well as reducing symptoms of depression. ADepT has been shown to be effective in treating adult depression, but it has not yet been adapted for those with autistic features. This research will adapt the ADepT protocol for use with adults diagnosed with autism or scoring above clinical cut-offs on screening measures for autism and conduct a preliminary evaluation of the acceptability, feasibility and effectiveness of the revised protocol for this target population. Up to fifteen adults with an autism diagnosis and /or scoring above a cut-off on an autism screening measure and suffering from depression will be offered ADepT at the AccEPT psychological therapies clinic, Devon. We will evaluate ADepT using a 'case series' methodology, tracking changes in depression and anxiety symptoms and wellbeing in the weeks before, during and after treatment. We will also invite people who received ADepT to take part in an interview to discuss their experiences of treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/09/2025, Leicester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 02071048066; leicestershout.rec@hra.nhs.uk), ref: 25/EM /0192

Study design
Randomized multiple baseline case-series design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of depression in autistic adults

Interventions
PROJECT DESIGN
This project will use a randomised multiple baseline case series design to evaluate if ADepT is feasible, acceptable, and effective in treating depression in autistic adults. 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, and the five optional booster sessions can be taken within three months post-acute intervention phase. A follow-up will occur at two months post-acute treatment and six months post-treatment. Participants will complete measures of depression, wellbeing, and anxiety in 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, two months after completing acute treatment, and six months after completing acute treatment (when all booster sessions will have been completed). They will also be invited to take part in a qualitative interview at some point after finishing acute treatment.

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 within three months after acute treatment. The primary goal of ADepT is to build wellbeing, viewing depression as a barrier that gets in the way of wellbeing. Clients are supported to identify values consistent with these 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 adapted for autistic populations.
Supervision will be provided for 90 minutes per week in a small group format by experienced ADepT supervisors/trainers. The protocol refinement phase will make a series of adjustments to this protocol to meet the needs of clients with autism. Sessions can be delivered face-to-face, via telephone, or via video conferencing, depending on client preference.

As this is a case series rather than a randomised controlled trial, the primary outcomes are a series of pre-specified continuation criteria regarding feasibility, acceptability and effectiveness. The 'green' continuation criteria (sufficient to proceed to the next stage of evaluation without subsequent revision needed of either the treatment protocol or the trial methodology) are specified in the primary outcomes.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate measured using the number of clients recruited and over what time frame in the research recruitment log at the end of the study (continuation rule: ten or more participants can be recruited over six months)
2. Treatment engagement measured using data from the clinical treatment records on 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 (continuation rule: > 60% of clients complete a minimum adequate dose of treatment [>8 sessions] with a planned discharge)
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 from a bespoke three-item rating scale, with each question being rated on a five-point Likert scale ranging from strongly disagree to strongly agree at the end of the acute treatment phase (> 60% of clients rate treatment as acceptable, satisfactory and that they would recommend treatment to others)
4. Patient safety measured using any disclosed incident (disclosed by participant, clinician, administrative team, or research team) data reported on a bespoke adverse events form used in the host service, which will be assessed by the clinic lead and project lead to determine if the incident was treatment or trial-related, on the number of serious incidents that could be clearly attributed to the intervention or research participation at the end of the study (continuation rule: no serious incidents occurred that could be clearly attributed to case series participation)
5. Preliminary signal of clinical improvement during treatment, measured using the number of clients showing at least reliable improvement pre- to post- treatment and/or a change in slope /level in the direction of clinical improvement in time series analysis of depression, anxiety and /or wellbeing (continuation rule: > 60% of clients show clinical improvement on depression, anxiety and/or wellbeing measures). These indices will be computed by analysing weekly PHQ-9,

GAD-7 and WEMWBS data taken during the baseline, acute treatment and follow-up phase (see secondary outcome measures).
6. Deterioration during treatment, indexed as the number of clients showing reliable deterioration and/or change in slope/level in the direction of clinical deterioration in time series analysis of depression, anxiety and/or wellbeing outcomes (< 30% of clients show clinical deterioration on the PHQ-9, GAD-7 and/or WEMWBS) from pre- to post-treatment. These indices will be computed by analysing weekly PHQ-9, GAD-7 and WEMWBS data taken during the baseline, acute treatment and follow-up phase (see secondary outcome measures below).

Key secondary outcome(s))
The following secondary outcome measures will be collected weekly during the baseline phase, treatment phase, and two-month post-treatment phase:
1. Depression symptom severity measured using the Patient Health Questionnaire (PHQ-9)
2. Anxiety symptom severity measured using the Generalized Anxiety Disorder scale (GAD-7)
3. Positive wellbeing experiences measured using the Warwick-Edinburgh Mental Wellbeing Scale short form (WEMWBS-SF)
4. Recovery of quality of life measured using the Recovering Quality of Life tool (ReQoL-10)
5. Psychosocial impairment measured using the Work and Social Adjustment Scale (WSAS)

The following secondary 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, WEMWBS-SF, ReQOL-10, WSAS as described above.
2. Anhedonia severity (a loss of interest and pleasure) measured using the Snaith Hamilton Pleasure Scale (SHAPS)
3. Quality of life in autistic adults measured using the Autism Spectrum Quality of Life Measure (ASQoL), a 9-item self-report measure to assess
4. Satisfaction in key life domainsmeasured using the DIALOG scale
5. Index the logic model underpinning the ADepT intervention measured using the ADepT Outcome Tool

Completion date
04/05/2029

Eligibility

Key inclusion criteria
1. Aged 18+ years old
2. Identify depression as their primary presenting problem
3. Meet diagnostic criteria for a current episode of Major Depressive Disorder (MDD; using Structured Clinical Interview for Diagnosis)
4. In a clinical range (> 10) on a validated depression measure, the Patient Health Questionnaire 9 (PHQ-9)
5. Have a diagnosis of Autism Spectrum Disorder (or Asperger's if diagnosed prior to DSM-5 criteria change) and/or score above cut off on a screening measure (Autism Spectrum Quotient; AQ-10)
6. Present with a level of clinical complexity that is appropriate for the primary care NHS-TT setting
7. Sufficient working knowledge of written and spoken English to engage and make use of therapy and complete research assessments without translation or use of an interpreter

8. Consent for their General Practitioner (GP) to be informed of their participation
9. Live in the catchment area for the Devon Integrated Care Board and are registered with a Devon GP

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. A level of risk to the self or others that cannot be safely managed in the clinic setting (e.g., an active suicidal plan) or that would significantly impair engagement in therapy.
2. Significant cognitive impairment (e.g. unable to engage in therapy due to verbal comprehension, memory, and abstract thinking impairments).
3. Current or historical psychotic symptoms and schizophrenia, indications of current mania, substance misuse issues, problematic eating that could interfere with engagement in therapy.
4. Current moderate to severe personality disorder and/or antisocial personality traits that requires secondary/tertiary care management
5. Features of a learning disability that the clinician judges would interfere with engagement in therapy and capacity to complete research assessments
6. Any severe, life-threatening, or clinically significant disease or disorder that in the assessing clinician’s judgment may either put the participants at risk because of participation in the trial, may influence the result of the trial, inhibit the participant’s ability to participate in the trial, or cannot be safely managed within the clinic setting
7. Undertaking any other psychological intervention at the time of the trial
8. Currently lacking capacity to give informed consent
9. Presence of another area of difficulty that the therapist and client believe should be the primary focus on intervention (for example, Post-Traumatic Stress Disorder).

Date of first enrolment
17/11/2025

Date of final enrolment
01/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Accept Clinic (university of Exeter)
Mood Disorders Cent, School of Psyc
University of Exeter, Perry Road
Washington Singer Building
Exeter
England
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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

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	31/10/2025	14/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes