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Guided self-help versus treatment as usual for depression for autistic adults

Submission date
01/06/2022

Recruitment status
No longer recruiting

Registration date
09/08/2022

Overall study status
Completed

Last Edited
11/04/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Individuals with autism spectrum disorder are 3-4 times more likely to be affected by depression than the general population. For individuals with mild-moderate depression in the general population, low-intensity talking therapies drawing on behavioural activation principles are recommended. There is currently no evidence supporting the use of treatments in autistic people with depression. Researchers plan to establish the clinical and cost effectiveness of an adapted low-intensity psychological intervention for depression in autistic adults. They will compare guided self-help (GSH) with treatment as usual (TAU). The GSH intervention developed for this study includes materials for nine 45-minute individual sessions, based on behavioural activation principles, facilitated by a therapist trained to support autistic adults in their use of the materials. Low-intensity therapists have foundation knowledge and training in cognitive behaviour therapy (CBT) protocols.

Who can participate?
Adults (aged 18 years and over) with a clinical autism diagnosis and current depression

What does the study involve?
Participants will be randomly allocated to either GSH or TAU. Outcomes are measured at the start of the study and 4, 8 and 12 months later, assessing depression symptoms, anxiety, quality of life and an economic evaluation. The qualitative study will examine participant and therapist views and experiences of the intervention and the trial to identify things that may impact the intervention's acceptability, effectiveness and implementation.

What are the possible benefits and risks of participating?
Participants' low mood/depression symptoms may improve, but there is no guarantee. They may also benefit from the extra contact that comes with being part of the study. Even if they do not receive a direct benefit from taking part in this study, their involvement will help to improve future treatment recommendations for autistic adults who experience low mood/depression. The first study appointment may last up to 2 hours. Participants may find it tiring to complete the questionnaires. The researchers will try to ensure the participants are comfortable and they can take breaks as needed. It may take up to 1 hour to complete each of the follow-up study questionnaires, but this time will vary for each person; some people will take less time, and

others may take longer. Participants will be able to complete these at a time and by a method convenient to them. There are no physical risks to having GSH sessions audio-recorded or being interviewed. As part of the treatment being delivered, the researchers may ask about participants' low mood/depression and how it impacts their life. For some people this may cause distress or anxiety. The researchers will try to ensure that the participants are comfortable. They can pause or stop the treatment, optional study interview and recordings at any time and they do not have to continue.

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

When is the study starting and how long is it expected to run for?
September 2021 to June 2025

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

Who is the main contact?
Dr Ailsa Russell
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Study website
https://adept.blogs.bristol.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310263

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52734, IRAS 310263

Study information

Scientific Title
A multicentre randomised controlled trial of guided self-help versus treatment as usual for depression for autistic adults: the Autism Depression Trial – 2 (ADEPT-2)

Acronym
ADEPT-2

Study objectives
To establish the clinical and cost-effectiveness of an adapted low-intensity psychological intervention (Guided Self-Help) for depression in autistic adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/06/2022, East of England - Essex Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8106, +44 (0)2071048227; Essex.REC@hra.nhs.uk), ref: 22/EE/0091

Study design
Both; Design type: Treatment, Psychological & Behavioural, Health Economic; Randomized

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Interventions

Participants will be adults (aged ≥18 years) with a diagnosis of Autism Spectrum Disorder (ASD) and current depression measured by the PHQ-9. Potentially eligible participants will be recruited from NHS adult autism services, NHS community mental health services and social care /voluntary sector services which autistic adults are engaged with. Recruitment pathways will be further specified by regional centre. The researchers will endeavour to specify a broad range of recruitment pathways for each regional centre to ensure that the adult autism population is fully represented in the study.

Potential participants will be assessed for eligibility for the study by confirming the presence of depression and a PHQ-9 score ≥10.

Randomisation

Eligible, consenting participants (n = 248) will be randomly allocated to (i) adapted Guided Self-Help (GSH) or (ii) Treatment as Usual (TAU). Randomisation will take place using a remote service once the participant is logged into the study ensuring allocations are concealed from the randomising researcher. Randomisation will be stratified by regional centre, depression severity and anti-depressant medication use. Participants cannot be kept blind to their intervention allocation. Researchers completing outcome measurements will be blind to treatment allocation to reduce any risk of observer bias at follow-up.

Intervention - Guided Self-Help

The intervention is Guided Self-Help (GSH), based on the principles of Behavioural Activation (BA) and adapted for the needs of autistic adults. The intervention comprises materials for 9 individual sessions of 45 minutes duration (except for the first session which can last up to 90 minutes) and a short manual for the therapist guide.

Comparator - TAU (treatment as usual)

There will be no constraints on TAU which will be carefully recorded at follow-up. TAU may include self or GP referral to local psychological therapy services.

The researchers will provide information about self/GP referral to TAU psychological therapy services using short leaflets and a step-by-step ‘how to’ video which will be available on the project website.

Outcomes will be measured 4, 8 and 12 months post-randomisation. These are self-report questionnaire packs sent directly to the participant (either online or paper-based). Where requested a researcher can assist the participant with completion.

The primary outcome measure will be the Beck Depression Inventory-II (BDI-II) measured at 4 months.

Secondary outcome measures (at 4 and 12 months) will also include depressive symptoms on the PHQ-9, a self-report global rating of change, anxiety (GAD-7), positive and negative affect, work and social function (WSAS), quality of life (EQ-5D), impact on carer (DASS and WEMWBS) and economic evaluation measures in the form of questionnaire items about health care use and other resources. The researchers will develop methods to measure treatment adherence across both groups.

Outcome measurement at 8 months will be limited to the primary outcome measure (BDI-II), the self-report global rating of change, and healthcare resource use.

Study interview
Participants and therapists can also take part in a study interview during the follow-up phase to discuss their experience of the treatment, or providing the treatment if they are a therapist, and being in the study.

Carers
Carers will be recruited in parallel to explore carer impact of treatment with guided self-help versus treatment as usual for depression for autistic adults in a nested sub-study. Carers who consent to take part will complete a questionnaire pack at baseline, week 16 and 52.

SWAT (study within a trial)
The researchers also plan to complete a study within a trial (SWAT). The aim of this study within a trial (SWAT) is to increase participants' perception of equipoise in the ADEPT-2 RCT. This aim will be met by providing participants with information about enhancements to usual care prior to randomisation. The enhancements will comprise the provision of training resources for usual care psychological therapists. These training resources will provide information about how to adapt standard CBT practice to meet the needs of autistic adults.The training resources will not include training in the GSH intervention or in working with depression specifically. They will comprise training materials about generic adaptations to CBT practice and closely match the foundation training resources available to the GSH therapists.

Information about the enhancements to usual care will be included in the Patient Information Leaflet (PIL) for the ADEPT-2 study. This will be carefully worded, as it is not certain that all therapists in usual care services will access the training resources.

Autism training resources will be made available to TAU psychological therapy services in the participating NHS sites for the ADEPT-2 study.

This SWAT will use primarily qualitative methods to answer the research questions.

(a) To investigate the impact of providing information about enhancement to TAU on participant randomisation preference and retention to the TAU arm of ADEPT-2, the researchers will draw on the data as part of the overall study protocol for ADEPT-2. Qualitative interviews carried out with participants consenting and not consenting to take part in ADEPT-2 as part of the overall study protocol, will include questions about their views about the enhancements to TAU as part of these interviews.

(b) The researchers will seek TAU therapists' views about the training resources which constitute the enhancement to TAU. They will ask therapists to complete a short online survey prior to accessing the training resources asking them about their experience of working with autistic people, confidence in adapting practice and perceived usefulness of CBT. The researchers will ask them to complete a short online survey immediately following their access to the training resources. This survey will ask them about the perceived usefulness of the resources. The researchers will ask participating therapists to complete a further survey 5 months following their access to the training resources to understand further any impact the training had on their practice, changes in confidence in working with autistic people, and any new areas that would be helpful to receive training in. The researchers will invite participating therapists to join a focus group with other therapists to further understand their experiences.

Intervention Type
Other

Primary outcome measure
Depression assessed using the Beck Depression Inventory-II (BDI-II) at 16 weeks

Secondary outcome measures
Current secondary outcome measures as of 19/09/2024:
1. Depressive symptoms measured using:
1.1. BDI-II depression score at 32 and 52 weeks post-randomisation
1.2. Patient Health Questionnaire-9 (PHQ-9) at 16 and 52 weeks
1.3. Patient rating of global change at 16, 32 and 52 weeks
2. Quality of life measured using the EQ-5D 5L and EQ-VAS at 16, 32 and 52 weeks
3. Anxiety measured using the General Anxiety Disorder-7 (GAD-7) at 16 and 52 weeks
4. Positive and negative affect measured using the Positive And Negative Affect Schedule (PANAS), measured at 16- and 52-weeks
5. Work and social function measured using the Work and Social Adjustment Scale (WSAS) measured at 16 and 52 weeks
6. Carer impact measured using Depression Anxiety Stress Scales (DASS), and Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at 16 and 52 weeks
7. Resource use measured via a participant-reported resource-use questionnaire, including ModRUM, the Work Productivity and Activity Impairment: General Health (WPAI-GH) and bespoke questions at 16, 32 and 52 weeks
8. Cost-effectiveness measured via quality-adjusted life years (QALYs), generated from the EQ-5D-5L, and resource use questionnaire at 16, 32 and 52 weeks

Amended from the secondary outcome measure phrasing below (no change to outcome measures themselves):

Measured at 16 and 52 weeks: -
1. Depressive symptoms measured using the BDI-II depression score and Patient Health Questionnaire-9 (PHQ-9) and Global Rating of Change
2. Quality of life measured using EQ-5D-5L and a study-specific questionnaire
3. Anxiety measured using GAD-7
4. Positive and negative affect measured using Positive And Negative Affect Schedule (PANAS)
5. Work and social function measured using the Work and Social Adjustment Scale (WSAS)
6. Impact on carer measured using the Depression Anxiety Stress Scales (DASS) and Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)
7. Resource use/cost-effectiveness measured using EQ-5D-5L (to calculate QALYs) and study-specific patient resource use questionnaire and Work Productivity and Activity Impairment (WPAI) Questionnaire

To maximise the quality of outcomes interim measurements are made at 32 weeks:
8. Depressive symptoms measured using the BDI-II depression score and Patient Health Questionnaire-9 (PHQ-9) and Global Rating of Change
9. Quality of life measured using EQ-5D-5L and a study-specific questionnaire
10. Resource use measured using EQ-5D-5L (to calculate QALYs) and study-specific patient resource use questionnaire

11. Participants' and therapists' acceptability, experiences of, and adherence to, study processes and treatment understand contextual factors for implementing the intervention, particularly in

respect to the retention of treatment principles, assessed using qualitative interviews with participants and therapists. Qualitative interviews with participants receiving GSH will occur at 4 months after they start the intervention. For those in the TAU group qualitative interviews will be scheduled for 3 months after the GSH intervention interviews. Staff intervention interviews will start from the end of the main phase recruitment period.
12. The effectiveness and use of the intervention materials and training resources, assessed using qualitative interviews with therapists and WAI-SR and goal attainment scaling (GAS) between 1-4 weeks into receiving GSH sessions and repeated at 4-8 weeks into GSH sessions

Overall study start date
01/09/2021

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years
2. A clinical diagnosis of autism spectrum disorder (ASD)
3. Current depression measured by the PHQ-9 with a score of ≥10 at screening
4. Can be on medication but dose should be stable for 6 weeks prior to randomisation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 248; UK Sample Size: 248

Total final enrolment
266

Key exclusion criteria
1. Risk of suicide - participants who endorse a score of 3 on Item 9 of the PHQ-9 will be followed up by the lead clinical researcher on each site to assess suicidal risk. Where clinic assessment or research follow-up is indicative that there is a current risk of suicidality such that a low-intensity intervention would not be clinically appropriate, this will be communicated to the relevant health care professional (e.g. referring ASD clinic and/or GP) and the participant will be excluded from the study.
2. Participants who report that they have attended >6 sessions of individual psychological treatment within a CBT framework over the past 6 months will be excluded from the study

3. A history of psychosis
4. Current alcohol/substance dependence
5. Untreated epilepsy
6. English literacy levels such that the treatment materials are inaccessible without reasonable adjustments and a supporting person is not available. This will be established by reviewing the case notes for record of cognitive/educational assessment indicating significant literacy difficulties, on information provided by the referring clinician and/or during the eligibility assessment when it is difficult to gain consent to participate in the research because of difficulties reading and thus comprehending the study information sheet. The researchers will strive to include all adults in the study if supporters are available to help an individual access the treatment where written/spoken English presents a barrier.
7. Taking part in an interventional study for mental health

Date of first enrolment
27/07/2022

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Roseberry Park Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3AF

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House

Newbridge Hill
Bath
United Kingdom
BA1 3QE

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
Leicestershire Partnership NHS Trust
Riverside House
Bridge Park Plaza
Bridge Park Road
Leicester
United Kingdom
LE4 8PQ

Study participating centre
Coventry and Warwickshire Partnership NHS Trust
Wayside House, Wilsons Ln
Coventry
United Kingdom
CV6 6NY

Sponsor information

Organisation
University of Bath

Sponsor details
c/o Prof. Julie Barnett
Sponsorship and research governance
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United Kingdom
BA2 7AY
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Sponsor type
University/education

Website
http://www.bath.ac.uk/

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR132343

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository held on a secure server at the University of Bristol and the University of Bath. Participants provide their consent for the purposes of data collection, data sharing, analysis and storage at the beginning of the study.

Added 19/09/2024:
To enable prospective meta-analyses, we anticipate that anonymised trial data may be shared with other researchers, including those outside of the UK, EU and EEA. The final trial dataset will be stored anonymously on research data storage facility (RDSF). Data will be made available to approved bona fide researchers only, after their host institution has signed a data access agreement.

Any use of study data will be subject to prior approval from the dissemination group. Requests for access to data must be via a written confidentiality and data sharing agreement (DSA)

available from the RDSF website which will be confirmed by the dissemination group. Such requests must be in writing and clearly describe the purpose(s) for which the data is required, and how it is to be used. The DSA should cover limitations of use, transfer to third parties, data storage and acknowledgements. The person applying for the use of the data will be scrutinised for appropriate eligibility by the dissemination group. A decision will be made as soon as possible following the request. All output from such work must acknowledge the source of the data, and its use must be consistent with ethical and governance approval, (either existing or sought subsequently).

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	12/08/2024	10/09/2024	No	No
Protocol article		19/11/2024	02/12/2024	Yes	No
Other files	Health Economics and Analysis Plan version 1.0	17/03/2025	11/04/2025	No	No
Statistical Analysis Plan	version 1.0	11/03/2025	11/04/2025	No	No