Centre for Applied Autism Research (CAAR) | University of Bath | Bristol Trials Centre | NHS Leicestershire Partnership NHS Trust

ADEPT-2
Autism Depression Trial

Participant Information Leaflet

We invite you to take part in a research study

- Before you express an interest to take part, it is important that you understand what the study is about, why it is being done and what will be involved.
- Please take time to read the information in this leaflet as it will help inform your decision.
- Please ask questions using the contact details in the next column if there are any parts of this leaflet you do not understand, or you would like further information.
- You may find it helpful to talk about the study with family members or others. Feel free to do so and to share this leaflet with them.

Summary of things you need to know

You can find out more about the study in this leaflet:

- We are inviting adults who have received a diagnosis of Autism or Autism Spectrum Disorder (ASD) who experience low mood/depression, to take part in a research study called the **Autism Depression Trial-2 (ADEPT-2).**
- People who take part will receive either guided self-help or NHS support for depression (usual care), decided through a process called randomisation.
- The study aims to find out whether guided self-help supports autistic adults who experience low mood/depression.
- Participants will be sent **questionnaires** to complete **before the treatment starts, and then at 16, 32 and 52 weeks** after you join the study. The questionnaires will ask about your low mood, other symptoms, and healthcare usage.
- To thank you for your time, we will offer you a £10 gift voucher upon receipt of each completed questionnaire pack

Contact

For general enquires about the study, please contact the central ADEPT-2 study team.

General emails:
adept-rct@bristol.ac.uk

To take part in the study, please contact your local research team:

Local Email:
Nargas.begum3@nhs.net
or
Sarah.baillon@nhs.net

Tel:
Nargas Begum - 07920102781
Sarah Baillon - 07341789207

Post:
ADEPT- 2 Study Team
Swithland House
352 London Road
Leicester
LE2 2PL

For more information you can visit our website here
www.bristol.ac.uk/adept
or scan the QR code below

Join us on social media
Twitter// @adept_2

Instagram//@adept_rct
Facebook// @adept.rct

Contents

1. Why are we doing this study?

Depression is a common mental health problem that affects many people, including autistic people.

Guided Self-Help (GSH) for low mood/depression is a psychological therapy or 'talking therapy' based on the principles of Cognitive Behaviour Therapy (CBT). Guided Self-Help means that someone is provided with written materials and sessions with a therapist to 'guide' their use of those materials. We have developed written materials especially for autistic people and their therapist guide.

Results from our previous study showed that autistic people and therapist guides found the materials acceptable. We would now like to find out how effective these materials are and how useful people find them compared to the support that is usually available. We would also like to find out whether GSH represents good value for money for clinical services.

We would also like to invite carers of autistic adults who wish to take part to join the study. This is so we can understand the impact on carers.

2. Why have I been asked to take part?

You have been invited to take part in this study because you have a diagnosis of autism.

You may also be looking for help for your low mood/depression.

You may have received this leaflet because one of your healthcare providers thought that you might be interested in taking part. Alternatively, you might have contacted our research team, volunteered to hear about research opportunities, or visited our website and requested more information.

The next part of the Information leaflet tells you about what will happen if you would like to take part in the research.

For an overview of what to expect we have included a diagram called ***'Flow diagram about the ADEPT-2 Study'*** on the next page (page 4).

3. Flow diagram about the ADEPT-2 study

Invitation to take part

Read the participant information leaflet and discuss with friends/family.

Expression of interest and eligibility screening

If you are interested in taking part in the ADEPT-2 study:

- Complete the online Expression of Interest form (or return the paper version if you prefer).
- Then a member of the study team will let you know if:
  - The study is not suitable for you to take part at this time; or
  - It is suitable for you to take part and to arrange your initial ADEPT-2 appointment.
    **can be conducted via video-call or in person if you are close to one of our recruiting centres; you choose how and when.*

Initial ADEPT-2 appointment

During this appointment with **the support of a researcher** you will:

- Discuss the study and ask any questions.
- Provide further information so that the study team can complete eligibility checks (i.e. a medical letter confirming your Autism diagnosis – if you are not currently under the direct care of Autism services). The researcher will then reconfirm it is still suitable for you to take part in the study.
- Complete the consent form.
- Complete the study questionnaires (e.g. about your low mood, medications and other symptoms). We will offer you a £10 voucher upon completion of this appointment.
- Be randomly allocated to receive either Guided Self-Help (GSH) or NHS support for depression (usual care).

Group

Receive up to 9 sessions of Guided Self-Help

or

Receive information about NHS support for depression (usual care)

Questionnaires & Follow up

- **At 16, 32 and 52 weeks** after you agree to take part you will complete a questionnaire*.
- £10 gift voucher offered upon each completed timepoint.
- The 52-week questionnaire is the final study questionnaire and contact point.

**online, postal copy, video-call with a researcher, or via telephone; you choose method of completion.*

Optional:

Study Interview

4. Do I have to take part?

No. It is your choice whether you take part in this study, or not.

- **If you are interested in taking part**, please complete the **online Expression of Interest form** https://redcap.link/adept (or, if you prefer, complete and return the paper version of the form in the prepaid envelope provided).
- **If you decide to take part,** you are also free to leave the study at any time without giving a reason.
- **If you decide *not* to take part,** your usual care will not be affected in any way.
- **If you have any queries,** or you do not understand any part of this information leaflet, please contact us using the details on the front page.

5. If I decide to take part, what happens next?

Expression of interest & eligibility

The first step is to complete the expression of interest form.

If your responses to the Expression of Interest form show that the study is not suitable for you at this time:

We will let you know as soon as possible and thank you for your interest. We will then remove all identifiable information that we have about you.

If your responses to the Expression of Interest form meet the requirements to take part:

A member of the study team will contact you using your preferred method to let you know that you are potentially eligible to take part in the study. The researcher will then arrange a time to go through the eligibility assessment in more detail and answer any questions you may have.

This is called the **ADEPT-2 initial appointment.** This appointment can be conducted via video call or in person, if you are close to one of our recruiting centres, with a member of the study team*; you can choose how and when.

**In light of COVID-19, we realise that in person appointments may not be feasible. ADEPT-2 therefore offers various contact methods. If in person appointments are requested, research staff will check they are safe and follow the local NHS guidance at the time regarding face-to-face contact, including, for example, use of personal protective equipment and cleaning procedures. The safety of participants and staff are the priority, and you will not be asked to do anything that you feel uncomfortable with.*

If you are potentially eligible but no longer want to take part:

With your consent, we may ask whether you would be willing to be contacted by a researcher (using your preferred method) to discuss what you thought about the study information provided, and the reasons why you decided not to take part. This is optional. If you are not interested, then you will not be asked to do anything else and thanked for your time.

Initial ADEPT-2 study appointment

This appointment may take up to 2 hours. At the appointment, a researcher will explain what taking part in the study involves, ask questions to check you are still eligible, and answer any questions you may have.

You may be asked to provide a letter or document confirming a clinical diagnosis of

autism from your GP or Autism service, if we do not have access to this information.

A second clinically trained member of the research team will check with the researcher to ensure that it is safe and suitable for you to take part. If you are happy to proceed and the researcher and clinician confirm that the study is still suitable, you will:

1. Be asked to complete a consent form confirming that you understand the study and agree to take part.
2. Be asked to complete the first set of ADEPT-2 Study Questionnaires (using your preferred method) and other relevant questions about your diagnosis of autism, low mood/depression, other symptoms and healthcare usage.
3. Be allocated to receive either Guided Self-Help (GSH) or treatment as usual (TAU).

At this point you are **enrolled in the study**. To thank you for attending the initial ADEPT-2 appointment, we will send you £10 in gift vouchers.

6. I would like to know more about the two treatment groups and how they are allocated?

As we do not know if GSH is an effective treatment for low mood/depression in autistic adults, we are comparing it to the NHS support for depression that is usually available (Usual Care). The group that you will be allocated to will be decided through a process called **randomisation.** This means you will have an equal chance of receiving either GSH or Usual Care (UC). This is done using a secure computer software called *Sealed Envelope* which tells the researcher which group you have been assigned to at random. You will not be asked to do anything. The research team will complete this process after the initial ADEPT-2 appointment. You will then be sent a letter (through the post or via email as per your preference) explaining the outcome and what the next steps are. With your consent, this letter will also be sent to your GP along with information about your mood.

The reason randomisation is used is it creates groups of participants that are similar except for the group to which they are allocated. This will enable us to compare the two groups fairly so that we can reliably assess whether GSH is an effective treatment or not at the end of the study.

If participants in the study were allowed to choose which group they were allocated to, then the groups of people being compared may not be sufficiently similar.

Group: Guided Self Help

If you have been **allocated to GSH** you will be assigned to a therapist 'coach'. Your therapist coach will contact you to arrange your first GSH session within approximately 2 weeks of the initial ADEPT-2 study appointment, together with other supporting information. You will receive written materials and be invited to attend up to 9 individual GSH sessions. The first session will last 90 minutes and the remaining 8 sessions will last 45 minutes each. The GSH sessions will take place over a period of 16 weeks. During these sessions you will discuss the written materials and be guided by your therapist on how to use these. You can attend the GSH sessions remotely using video-call.

Audio-recording GSH sessions

With your consent, some of the GSH sessions may be audio-recorded. It is important you know this is completely **optional**. The purpose of the recordings will help us to understand how well the GSH is being delivered and if there are aspects that we can improve. Before any audio-recording can take place, a researcher will need to gain your consent in principle at the beginning of the study. If they wish to audio record a particular GSH session the researcher will check with you at the time that you are still happy to go ahead.

The GSH session will then be recorded on secure, encrypted audio recorders and transferred onto University of Bath secure servers. The audio file will be deleted from the recorder. All electronic data will be held on the University of Bath secure computer server.

Group: Usual Care

If you have been **allocated to Usual Care (UC)** we will provide you with information about NHS support that is available to you. This will include information about how to contact your local talking therapy service. We will also inform your GP with your consent.

As part of this study, local talking therapy services are being offered training resources about working with autistic people. You can also discuss the other treatment and support options that are available to you in your area with your GP.

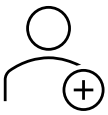
7. Questionnaires and Follow-up

In addition to the questionnaires you complete during the initial ADEPT-2 appointment, you will be asked to complete follow-up **questionnaires at 16, 32 and 52 weeks** after your initial ADEPT-2 appointment. These can be completed online but can also be done via post (a pre-paid envelope will be provided); or with a researcher via video call or telephone. On each occasion you will receive a £10 gift voucher to thank you for your time spent completing the questionnaires at each timepoint.

If you need help to complete the questionnaires, the research team will make all reasonable adjustments to assist with this. Similarly, a carer/family member or friend can provide support, but they will be advised not to answer any questions on your behalf.

If you experience any problems or have any concerns during your time in the ADEPT-2 study, please let the research team know using the contact details at the front of this leaflet.

8. Carer Study



If you tell us that you have a carer, with your consent, we would like to invite them to take part in a separate study. This will explore how the treatment of low mood/depression for autistic adults affects them as a carer. It is up to you to define who your carer is, but where possible, it would be someone who knows you well and is likely to be providing you with support throughout your involvement with this study. This might be a family member, partner, or professional support worker. If you are happy for us to approach your carer, then we will provide you with a study information pack and ask you to provide it to them at the earliest opportunity.

You are still able to take part in ADEPT-2 if your carer does not wish to take part, or if you do not have a carer.

Similarly, if your carer does agree to take part, they can remain in the study if you decide to withdraw.

9. Will I be asked to do anything else?

Study Interview

With your consent, a researcher will contact you using your preferred contact method to invite you to take part in an interview about your experience of the study overall. This is **optional** to the main ADEPT-2 study.

You will have a chance to discuss any questions you may have about this with a researcher at the start of the study.

If you **do not wish to take part in the study interview,** this will not affect your ability to take part in the main study.

Similarly, you can decide to only take part in the study interview to discuss the reasons why you chose not to participate, and you do not have to take part in the main ADEPT-2 study.

If you do decide to take part in the study interview, a researcher will contact you to arrange the best time to complete this at your convenience. This may be via video call, over the telephone, or by another preferred method. You will be sent a consent form to read over before the interview takes place.

At the start of the interview the researcher will answer any questions you may have. If you are still happy to take part, the researcher will record your verbal consent before they can continue with the interview.

If you consent to a study interview, It will be recorded on secure, encrypted audio recorders and transferred onto University of Bristol & University of Bath secure servers to help with analysis. The audio file will then be deleted from the recorder.

All electronic data will be transcribed in part or fully by the University of Bristol and University of Bath employees, or their authorised representatives. The data will then be stored on a secure computer server at the University of Bath or the University of Bristol.

No one will be able to tell you took part in the ADEPT-2 study interviews as all identifiable information will be removed from the transcripts. Any information that you may provide during the interviews will be treated as strictly confidential.

The University of Bath or University of Bristol will securely retain audio-recorded data and may use anonymised quotations and parts of voice modified audio-recordings for training, teaching, research and publication purposes for this and future studies. But we will ensure that you cannot be identified.

With your permission, anonymised transcripts of the interviews may be made available by controlled access to other researchers outside of the ADEPT 2 study who secure the necessary approvals. Again, we will ensure you cannot be identified.

Data from the anonymised transcripts may be used for purposes not related to this study, but it will not be possible to identify you from them.

In addition to the main ADEPT-2 study the study team may also use some of the data collected to help improve autism awareness training offered to existing talking therapy services.

10. How long does the research study last?

The overall study is expected to run through to **December 2024.** However, you will only remain in the study for **52 weeks**.

11. What are the possible benefits of taking part?

Your low mood/depression symptoms may improve, but there is no guarantee. You may also benefit from the extra contact that comes with being part of the study.

Even if you do not receive a direct benefit from taking part in this study, your involvement will help to improve future treatment recommendations for autistic adults who experience low mood/depression.

If you agree to have your GSH sessions and/or study interview audio-recorded you will be helping to contribute to evidence on the best way of delivering psychological treatment and improving the way we conduct research for potential participants.

Please remember that taking part in this study should not replace other services you may be receiving for any physical or mental health problem. You should continue to seek support from your GP and other services as you would usually do.

12. What are the possible disadvantages of taking part?

The first study appointment may last up to 2 hours. You may find it tiring to complete the questionnaires. We will try to ensure you are comfortable and you can take one or more breaks as needed.

We estimate that it may take up to 1 hour to complete each of the follow up study questionnaires, however this time will vary for each person; some people will take less time, and others may take longer. You will be able to complete these at a time, and by a method, convenient to you.

There are no physical risks to having your GSH sessions audio-recorded or being interviewed to understand your views on taking part in this study.

As part of the treatment being delivered, we may ask about your low mood/depression and how it impacts your life. For some people this may cause distress or anxiety. We will try to ensure that you are comfortable. You can pause or stop the treatment, optional study interview and recordings at any time; you do not have to continue.

13. Can I take part in ADEPT-2 if I am already taking part in another research study?

For your safety, we are unable to enroll you in ADEPT-2 if you are already taking part in another interventional study for mental health. This includes the research study 'STRATA' - a multicentre double-blind placebo-controlled randomised trial of Sertraline for Anxiety in adults with a diagnosis of Autism. NIHR ref 127337; ISRCTN 15984604

Please talk to the research team about any other research that you may be involved in, or considering, as they will be able to advise you on your suitability for ADEPT-2 and possible options for the future, if it is not suitable at this time.

14. What if new information becomes available during the study?

Sometimes we get new information about the treatment being studied. If this happens, the study team will tell you and discuss

whether it is in your best interest to continue in the study. If you decide not to continue, you will be withdrawn from the study. If you do continue in the study, you will be asked to sign an updated consent form.

15. Will I receive anything for taking part?

We will offer £10 in gift vouchers for completing each set of questionnaires at the start and then at 16, 32 and 52 weeks (£40 in total for the study). We will also pay for any travel expenses.

16. Will the information I provide be kept confidential?

The information you provide to the research team will be treated as confidential and will only be used for the purpose of the study, unless you tell the research team or therapist that you or someone else is at risk of harm, or that you have or intend to, commit a crime. If this happens, the research team will have to inform your GP and the relevant authority. We will make every effort to ensure this is discussed with you first.

Data about you will be given a code that makes it impossible to identify you, except by our research team.

Data with personal details included will be used by the study team to contact you during the study or to check records to make sure the research is being done properly.

Personal data will only be kept for up to 12 months after the study has ended. After 12 months these details will be destroyed. The purpose for keeping them for 12 months after the study has finished is to notify you about the results of the study.

Coded data, with all personal details removed, will be stored on password-protected computers for 5 years, in accordance with University of Bristol and University of Bath guidelines.

Your personal information will not be written on any reports about the study or to anyone outside of the study team, and no one will be able to identify you.

With your consent, data collected in this trial may be used in future ethically approved research studies on the understanding that all information may be shared anonymously with other researchers i.e., it will not contain any information about your name, date of birth or contact details so no one will be able to identify you. It will continue to be kept securely and remain confidential.

For further information on how we use your data please visit: https://adept.blogs.bristol.ac.uk/how-we-use-data/. A paper copy (called Privacy Notice) of this information will also be given to you with this information leaflet. You can also view information from the Health Research Authority on the use of patient data in research by accessing: www.hra.nhs.uk/information-about-patients/.

17. Can I stop taking part after the study has started?

Taking part is voluntary. If you decide you no longer wish to take part, you are free to leave the study at any time during the 52 weeks.

You do not have to give a reason and your medical care and legal rights will not be affected. If you do withdraw from the study we would confidentially keep the information we had already collected about you, for the purposes of the study only. We may ask if you would be willing to discuss your

reasons for leaving the study with a researcher.

18. What happens when the study is finished?

Once you have returned your final study questionnaire at 52 weeks your part in the study will be complete. You will return to the usual care of your GP.

The overall results of the study will be published in medical journals and shared with other healthcare professionals interested in this area of research at conferences.

People who take part will also be sent results of the study via a newsletter (anticipated December 2024).

19. Who funded this study and who is the lead organisation for the study?

This study is funded by the National Institute of Health Research (*ref: NIHR HTA 132343*), which is the research arm of the NHS.

The full title for this research study is:

A multicentre randomised controlled trial of guided self-help versus treatment as usual for depression for autistic adults.

The study is led by a team of experienced clinical psychologists and researchers, supported by members of an autistic advisory group

The study is sponsored by the University of Bath. Avon and Wiltshire Mental Health NHS Partnership Trust (AWP) is hosting the study. These organisations are responsible for ensuring the research meets its contractual, legal and financial obligations.

The Bristol Trials Centre at the University of Bristol is responsible for the day-to-day management of the study.

The study partners include: University of Bristol, Warwick University, Avon & Wiltshire Mental Health Partnership NHS Trust and Cumbria, Northumberland, Tyne & Wear NHS Trust.

20. Who has reviewed the study?

This study has been reviewed by the Health Research Authority and NHS Research Ethics Committee who have provided approval for this study to be conducted in the NHS. REC Reference number: 22/EE/0091

21. What if there's a problem?

If you have a concern regarding your care as a patient, please discuss this with your GP or contact 111. If you experience a life-threatening emergency, or feel you cannot keep yourself safe, you should attend your nearest A&E or phone 999. You will also be offered a leaflet with the contact details of local and national mental health support networks and autism support services.

If you become unable or unwilling to continue in ADEPT-2, we would withdraw you from the study.

In the unlikely event that something should go wrong, the University of Bath has Public Liability insurance in place if needed.

22. How do I make a complaint?

If you have a concern about any aspect of the study, please contact the ADEPT-2 study team who will do their best to answer your questions (phone 0117 455 5697 / 0117 455 8234, email adept-rct@bristol.ac.uk).

If you remain unhappy with any aspect of the study, please email the sponsor at pro-vc-research@bath.ac.uk

If you remain unhappy with the care you receive at your GP practice whilst participating in this study and wish to complain formally, you can contact NHS England either by phone, email or post.

By post to:

NHS England
PO Box 16738
Redditch
B97 9PT

By email to: **england.contactus@nhs.net**
If you are making a complaint, please state: 'For the attention of the complaints team' in the subject line.

By telephone: **0300 311 22 33**

Please visit their website for further information:

NHS England » Complaining to NHS England – www.england.nhs.uk/contact-us/complaint/complaining-to-nhse/

You can also contact the **Patient Advisory Liaison Service (PALS)** for confidential advice, support and information on health-related matters and complaints. PALS provide a point of contact for patients, families and their carers.

How do I contact my nearest PALS?

You can find your nearest PALS office on the NHS website

You can also ask your GP surgery, hospital or phone 111 for details of your nearest PALs.

23. What are the next steps?

1. Complete the expression of interest form online or return this to us using the pre-paid envelope provided.

2. Please pass the 'carer pack' onto your carer so they can decide if they wish to be involved in this research.

3. If you are eligible to take part, the study team will be in touch to record your consent and arrange your first study appointment.

Thank you for taking the time to read this information. Please keep a copy for your records.

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