Centre for Applied Autism Research (CAAR) | University of Bath | Bristol Trials Centre

ADEPT-2
Autism Depression Trial

We invite you to take part in a research study

- Before you decide 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 following information.
- Feel free to talk to family members or others if you wish.
- 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.

Summary of important things to know about

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

- We are inviting carers of the participants who are involved in ADEPT-2, a study of adults with autism who experience low mood/depression, to take part in a carer sub-study.
- We want to explore how the support provided for low mood/depression in these autistic adults affects their carers.
- Carers will be **contacted** by trained study staff via video call, telephone, text, or email (whichever you prefer) and asked to complete **a Carer Impact Questionnaire at the start of the study** and then **at 16 weeks and 52 weeks** after you join the study.
- The questionnaires will ask about how your caring responsibilities for someone with autism and low mood/depression are affected by the treatment they receive. We will also ask about your health and wellbeing.
- To thank you for your involvement in the study, we will offer you a £10 gift voucher upon completion of the final week 52 questionnaire.
- By taking part in this study, you will be helping to inform whether autistic adults who experience low mood/depression should receive Guided Self Help as a talking therapy.

Contact us

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

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

Local Email:
awp.adept2rctsecure@nhs.net

Tel: 07855 973171

Post: ADEPT-2 Central Study Team
Bristol Trials Centre (BTC)
Bristol Medical School
1-5 Whiteladies Road
Clifton, Bristol, BS8 1NU

For more information you can visit our website 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

ADEPT-2|Carer Participant Information Leaflet|v3.0|07JUN2023|IRAS ID 310263
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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 intervention 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 how the support provided for autistic adults experiencing low mood/depression affects their carers.

2. Why have I been asked to take part?

You have been invited to take part in this study because you care for a person with a diagnosis of autism and low mood/depression who has decided to take part in the ADEPT-2 study.

The next part of the Information leaflet tells you about what will happen if you 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 Carer ADEPT-2 study

Invitation to take part

Read the participant information leaflet and discuss with friends/family

Complete the consent form and first questionnaire

If you are interested in taking part in the ADEPT-2 study, you will need to:

- Let us know that you are interested in taking part using contact details on the front page. If you prefer, you can simply state 'YES CARER' an email to the research team they will follow up with you about the study.
- We will send you the following documents in the post to complete and post back to us:
  - A paper consent form
  - The first study questionnaire
- A pre-paid envelope will be provided to return the completed consent form and

Follow up 16-week Questionnaire

- You will be sent a **week 16 questionnaire** to complete, as per your preference*.
  **online, postal copy, video-call with a researcher, or via telephone; you choose method of completion.*

Follow up 52-week Questionnaire

- You will be sent a **week 52 questionnaire** to complete, as per your preference*.
  **online, postal copy, video-call with a researcher, or via telephone; you choose method of completion*

- Upon returning the completed 52-week questionnaire, and to thank you for your involvement in the study, you will receive a £10 gift voucher.

The 52-week questionnaire is the final contact point and the end of your involvement in the study

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**, let us know using the contact details on the front page. We will send you a **consent form and study questionnaire to complete and return to us using a pre-paid envelope provided.**
- **If you decide *not* to take part,** thank you for taking the time to consider this invitation. It is important to remember that you or the person you care for 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. Further information on carers taking part is also available on our website: https://adept.blogs.bristol.ac.uk/carer-study/.

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

Once you complete the consent form and return it to us you will be enrolled in the study.

If you would prefer to complete this process in person or you would like to speak with the research team, we can arrange this for you. It might be that this is done virtually or by a method of your choice.*

**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 in person 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.

Questionnaires

You will be asked to complete questionnaires at **the start of the study and again at 16 and 52 weeks.**

The 16 and 52 week questionnaires can be completed online, via post (a pre-paid envelope will be provided) or with a researcher over video call or the phone.

If you require assistance to complete the questionnaires, the research team will try their best to make all reasonable adjustments to help with this.

Similarly, a family member or friend can provide support, but they will be advised not to answer any questions on your behalf.

6. How long does the research study last?

The study is expected to run through to **December 2024.** However, if you decide to take part, your participation in the study will last for **52 weeks.**

7. What are the possible benefits of taking part?

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

Please remember that taking part in this study does not replace other services you may be receiving for assistance. You should

continue to seek support from these services as you would usually do.

8. What are the possible disadvantages of taking part?

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 about an hour to complete each of the 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.

We may ask about how your caring responsibilities for someone with autism and low mood/depression are affected by the treatment they are receiving. For some people this may cause distress or anxiety. We will try to ensure that you are comfortable. You can pause or stop the questionnaires at any time; you do not have to continue.

9. What if new relevant information becomes available during the study?

Sometimes we receive new information that may affect the study. If this happens, the study team will tell you and discuss whether you should 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 may be asked to sign an updated consent form.

10. Will I receive anything for taking part?

You will receive a £10 gift voucher on the returned completion of the final 52-week study questionnaire.

11. How will we use information about you?

We will need to use information from you, your medical records and your GP for this research. This information will include your name, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Data about you will be given a code number instead. We will keep information about you safe and secure.

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 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.

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.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.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/. 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/

12. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

13. Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from https://adept.blogs.bristol.ac.uk/how-we-use-data/
- by asking one of the research team
- by sending an email to adept-rct@bristol.ac.uk
- by ringing us on 07855 973171

14. 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.

15. What happens when the study is finished?

Once you have returned your questionnaire at 52 weeks your part in the study will be complete.

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

People who take part in the study will also be sent results of the study via a newsletter .

16. 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 patient and public 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.

17. Who has reviewed the study?

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

18. What if there's a problem?

If you have a concern regarding your wellbeing, please discuss this with your GP or phone 111.

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.

19. 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 07855 973171, 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, or the person you care for, receives 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) - **https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/** 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 - **https://www.nhs.uk/service-search/other-services/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363**

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

20. What are the next steps?

1. If you wish to take part in this study, please contact us using the details on the front page. We will send you a consent form and initial study questionnaire to return to us using the pre-paid envelope provided.
2. Alternatively, you can contact the research team to ask any questions you may have.
3. Additional questionnaires will be sent to you using your preferred method of contact at 16 and 52 weeks.

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

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