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

ADEPT-2
Autism Depression Trial

Therapist 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 and discuss it with others 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.

Summary of things you need to know

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

- We are carrying out a clinical trial into depression treatment for adults with a diagnosis of Autism or Autism Spectrum Disorder (ASD). The study is called the **Autism Depression Trial-2 (ADEPT-2).**
- We are inviting therapists who provide NHS support to people with depression to take part in ADEPT-2 and access training materials about adapting CBT practice for autistic people.
- We will explore whether explaining to participants in ADEPT-2 that NHS therapists have been offered this training affects their perception of receiving NHS support for depression.
- We will also explore whether accessing this training impacts CBT therapists' perceptions and experience of delivering interventions to autistic people.
- Therapists will complete a **short survey at the start** of the study; **immediately after reviewing** the autism **training materials** and again at **16-20 weeks post training**
- The surveys will ask about your level of confidence working with autistic people and your level of satisfaction with the training materials
- You will also have an opportunity to join an optional focus group to give your views on the training materials.

Contact us

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

General Email:
bath_adept-2@bath.ac.uk

Tel: 0117 455 8234

Post:
ADEPT-2 Central Study Team
University of Bristol
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
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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 treatment or 'talking treatment' 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 - 'usual care'. We would also like to find out how cost effective GSH is for clinical services. We will also invite carers of autistic adults who wish to take part to join the study to better understand the impact on carers.

As part of the ADEPT-2 study, local talking therapy services are being offered training materials about adapting CBT practice for autistic people. These training resources will provide information about how to adapt standard CBT practice to meet the needs of autistic adults.

We would like to see whether providing information about the training offered impacts autistic adults' perception of usual care in the ADEPT-2 study.

The training resources will not include training in the GSH intervention or in working with depression specifically. They will comprise training materials about adaptations to CBT practice for autistic people more generally.

2. Why have I been asked to take part?

You have been invited to take part in this study because you may work in a service that provides support for depression.

You may also be looking to improve your knowledge of providing psychological therapy to autistic people.

You may have received this leaflet because the service that employs you 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 decide to take part in the research.

You do not have to take part in the research study to access the training materials. However, your participation will help us to understand the usefulness of the training materials.

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 therapist information leaflet and discuss with friends/family/research team

Consent to take part & Initial Survey

- If you would like to take part in the ADEPT-2 study you should:
  - Give your consent to take part at the beginning of the initial survey.*
  - Continue to complete the questions on the initial survey.

*Within the invitation email to join the study, you will receive a **password.** This password grants you access to the ***Information for CBT Therapists*** section of the **ADEPT-2 study website.** Here you can access the surveys and training materials.

Review Training Materials & Complete Survey

- Within the **'Information for CBT Therapists'** section of the ADEPT-2 website you can access and review the training materials.
- Immediately after viewing these materials, you will be prompted to complete a second survey.

Follow-up Survey

- **At 16-20 weeks** after you viewed the training materials you will be reminded by email to complete a final online survey.
- The 16-20 week survey is the **final study activity**, unless you have given your consent to take part in the **optional focus group.**

Optional: Focus group

A researcher will email you to invite you to a focus group to ask about your experience of being in the study and your view on the training materials.

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 provide your consent by accessing the initial survey on the 'Information for CBT Therapists' section of the ADEPT-2 study website.
- **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,** you or your employment will not be affected in any way. You will still be able to access the training materials.
- **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 about the research study is also available on our website: www.bristol.ac.uk/adept.

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

Initial Survey

Once you have received the invitation to join the study you will be provided with a password to access the *'Information for CBT Therapists'* page of the study website. This page contains a link to the online survey. By clicking on the survey link you will be prompted to provide your consent to take part in the study. Then, you will be asked to provide answers about your job role, experience of working with autistic people and your level of confidence providing psychological therapy to autistic

The survey may take up to 15 minutes to complete.

Training Materials

The training materials will be available for you to access in your own time on the '*Information for CBT Therapists'* page of the ADEPT-2 study website. We recommend you view the training materials to support you in providing usual care for autistic people with low mood/depression.

The training materials will take approximately 1 hour to review. They include the presentation of some information about adapting CBT practice and short filmed demonstrations.

Survey Follow-up

In addition to the initial survey, you will be prompted to complete a follow-up **survey immediately after you have viewed the training materials and again at 16-20 weeks after the training.**

A researcher will send you an email reminder to complete the final survey at 16-20 weeks.

All of the surveys can be completed online by clicking a link on the *'Information for CBT Therapists'* page of the ADEPT-2 study website. Each follow-up survey will take up to 15 minutes to complete.

If you would prefer to complete any of the surveys on paper, paper copies can be downloaded from the website, or sent to you by email or post. You can request this using the contact details at the start of this information leaflet.

If you need help to complete the surveys, the research team will make all reasonable adjustments to assist with this.

You can contact the research team at any point during the study if you have any concerns.

6. Will I be asked to do anything else?

Focus group

With your consent, a researcher will contact you to invite you to take part in a focus group with up to 5 other therapists. The focus group will be held after you have completed the final 16-20 week survey.

The purpose of the focus group is to understand your experience of the training materials and any impact on your CBT practice. This is **optional** to the ADEPT-2 therapist surveys.

You will have the chance to discuss any questions you may have about this with a researcher at the start of the study, using the contact details at the front of this leaflet.

If you **do not wish to take part in the focus group,** this will not affect your ability to access the training materials or complete the surveys.

If you do decide to take part in the focus group, a researcher will contact you to arrange the best time to complete this at everyone's convenience. This focus group will be conducted with a researcher over video call. You will be sent a consent form to read over before the focus group takes place along with instructions on how to join.

At the start of the focus group, 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 focus group.

The focus group will last up to 1 hour. There will be questions and discussion points for the group regarding their views and experience of accessing the training resources and implementing these in CBT practice.

If you consent to the focus group, 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 University of Bath employees, or their authorised representatives. The data will then be stored on a secure computer server at the University of Bath.

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

The University of Bath 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 focus group 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.

7. 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 up to **20 weeks**.

8. What are the possible benefits of taking part?

Your understanding of providing psychological interventions to autistic people 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. Additionally, it will help to inform the design of clinical trials with a usual care treatment group.

If you agree to the focus group being audio-recorded, you will help to contribute to evidence on improving autism awareness for psychological interventions. You may also find hearing about the experience and work of other therapists educational.

Please remember that taking part in this study should not replace any other training you may be receiving as part of your continued professional development.

9. What are the possible disadvantages of taking part?

The training materials will take **up to 1 hour to review.** You may find it tiring to complete the training & surveys. You can take one or more breaks as needed.

We estimate that it may take **up to 15 minutes to complete each of the surveys**, 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 the focus group audio-recorded or joining a focus group to understand your views on taking part in this study.

If you find any part of the optional focus group uncomfortable or tiring, you can ask to pause or stop the focus group and the recordings at any time. You do not have to continue.

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

Sometimes we get new information that may impact on the study. If this happens, the study team will tell you and you can decide whether you still wish to continue. If you do, you will be asked to complete an updated consent form.

11. Will I receive anything for taking part?

Unfortunately, we are unable to provide reimbursement for taking part in this study, However, we hope that you will find the training materials useful for your practice.

12. Will the information I provide be kept confidential?

All information you provide will be kept strictly confidential and will only be used for this study. 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 (i.e., your email address) 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 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. 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 of this information is also available.

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/.

13. 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 20 weeks.

You do not have to give a reason and your employment 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.

14. What happens when the study is finished?

Once you have completed the final survey, at 16-20 weeks, your part in the study will be complete. If you agree to take part in the optional focus group, this will take place after you complete the final survey.

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).

15. 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.

16. 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

17. What if there's a problem?

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

18. 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

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

19. What are the next steps?

If you would like to take part, please use the password provided in the invitation email to access the *Information for CBT Therapists* page on the ADEPT-2 study website.

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

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