



University
of Exeter



Study title: Augmented Depression Therapy (ADepT) for autistic adults (including those without a formal diagnosis)

Participant Information Sheet

Invitation and brief summary:

- This study aims to test a new talking therapy for depression called **Augmented Depression Therapy (ADepT)**
- We are looking for 15 participants to take part
- Participants will receive up to 20 individual treatment sessions over a year, delivered face-to-face, telephone or video conferencing.
- You will be offered treatment at the AccEPT clinic at the Mood Disorders Centre
- You will be asked to complete questionnaire packs on symptoms, thoughts and behaviours, as well as a short interview at the end of treatment
- Your family doctor (General Practitioner; GP) will be informed of your participation in the study



Study Research Team



Hope Trimmer,
Doctorate in
Clinical Psychology
student



Serena Ng,
Doctorate in
Clinical Psychology
student



Professor Barney
Dunn, Chief
Investigator of the
project



Dr Asha Ladwa,
Postdoctoral
Research Fellow

We would like to invite you to take part in our research trial. However, before you decide whether or not to take part, we would like you to understand why the research is being done and what it would involve for you. Please read this information sheet carefully. If you are interested in participating or have any questions, please contact us via email (adeptautismresearch@exeter.ac.uk). Before you give your consent to take part (if you decide to do so) one of our team will go through this information sheet with you and answer any questions you might have. Please do talk to others about the study if you wish.

What is the purpose of the study?

A range of psychological treatments for depression exist and have been shown to be effective at reducing depression symptoms. For example, standard care in the NHS is often Cognitive Behavioural Therapy (CBT), which is recommended by the National Institute for Health and Care Excellence (NICE). However, individuals with depression often report that it can be hard to experience a sense of wellbeing. This is the ability to experience a positive mood, to have meaning and purpose in life, and to feel socially connected with the world around them. Existing treatments like CBT are less effective at repairing wellbeing than they are at reducing symptoms of depression. We have developed a new psychological therapy – Augmented Depression Therapy (ADepT) – that aims to both build wellbeing and alleviate depression symptoms. We have shown in previous work that ADepT is effective in treating adult depression in Improving Access to Psychological Therapy (IAPT) settings. We know depression is significantly prevalent in the autism community so now wish to see if ADepT can also be helpful for autistic people (whether diagnosed or self-identifying) with depression. In this study we will be inviting up to 15 people to take part in the ADepT programme. We will assess how effective the treatment is at reducing depression symptoms and building wellbeing. We will also explore Participants' views about the acceptability and feasibility of ADepT. The findings will contribute to the Doctorate in Clinical Psychology for Hope.

Why have I been invited?

You have been approached about this because it was identified you may be autistic and experiencing depression in Devon and have a Devon GP. We are inviting autistic adults (whether diagnosed or self-identifying) with depression to explore how effective Augmented Depression Therapy is for those on the autism spectrum, as it is crucial to understand and improve mental health support tailored to autistic needs.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You will be free to withdraw from the study at any time and do not have to give a reason for doing so. A decision to withdraw at any time, or a decision not to take part, will not affect whether you receive other forms of support or care from other services.

What will I have to do in the study?

STAGE 1: Getting in Contact

Once we have received permission to contact you, a member of the research team will be in contact to discuss the study in more detail with you. They will answer any initial questions you may have and will invite you to complete a short Patient Health Questionnaire (PHQ-9) - a measure of depression symptoms and the Autism Spectrum Quotient (AQ-10) – a quick screening tool for autism, to confirm your suitability for the study. If you would like to go ahead after discussing the study in more detail and you are suitable after completing the initial questionnaires, we will invite you to a face-to-face, telephone or video conference (Zoom) initial assessment meeting.

STAGE 2: Initial Assessment Meeting

We will arrange a convenient time for you to attend a meeting with a member of the research team. Before this meeting, you will be sent some questionnaires to complete either at home or with the staff member in the meeting: these questionnaires will take around 30 minutes to complete. At the meeting (which typically lasts up to an hour) the researcher will go through the questionnaires and talk through this information sheet with you in detail and give you an opportunity to ask any further questions you may have about the study.

You will then have an assessment with a therapist working on the project, which involves talking about what matters to you, how you are at the moment, whether you are feeling depressed or have done so in the past, and what you feel may make you happier. The therapist will also explain more about the therapy on offer. This gives you a chance to meet your therapist, have a relaxed conversation, share anything you would like them to know and decide if the therapy is right for you. If it is not, they will talk to you about alternative options for support. If the study and treatment is appropriate for you and you wish to go ahead you will be asked to complete a consent form. You will then be invited to fill in some questionnaires rating your mood and you will then be invited into the therapy programme.

STAGE 3: The Therapy and Follow-Up Phase

Once you have completed the questionnaires and been invited into the treatment programme, a member of the clinical team will be in touch to notify you of the name of your therapist and to arrange the date of your first treatment session. This will be randomly selected to be between 3 and 8 weeks after your initial assessment. For the weeks before your treatment starts we will ask you to fill in brief weekly measures asking you how you are feeling (taking about 5-10 minutes to complete). A couple of days before treatment starts you will be asked to complete a longer set of questionnaires and interview questions (taking about 30 minutes to complete).

Your treatment will involve up to 20 sessions of individual therapy held once a week and lasting about 60 minutes each (up to 15 weekly core treatment sessions followed by up to 3 flexibly scheduled booster sessions offered within the first 12 weeks after completing core therapy. These sessions will be face-to-face or via telephone or video conferencing, depending on your preference. Before each therapy session, you will be asked to fill in brief weekly measures asking how you are feeling (again taking about 5-10 minutes to complete). At the end of your core-treatment sessions and two months after finishing the core sessions we will ask you to complete a slightly longer set of questionnaires (taking about 30 minutes). After finishing treatment, we will also invite you to take part in an informal interview lasting about 45 minutes to seek your views about how you experienced the ADepT treatment. At the six-month follow-up we will also ask you to complete a written booklet asking your views about the booster sessions. All questionnaires can be completed in pen and paper form or electronic form and all interviews can take place face-to-face or via telephone or video conferencing (Zoom), depending on your preference.

We will ask all participants in this study for their consent to have their therapy sessions and interview recorded. If you attend face to face or via the telephone, recording will be in audio form only (via encrypted Dictaphone). If you attend via video conferencing, the recording will initially be in both audio and video form (via encrypted recording methods on video conferencing platforms). We will delete the video recording and only keep the audio recording. These recordings help with the supervision of therapists and also helps us to establish how ADepT is being delivered. The audio recordings of the interviews conducted at the end of treatment will be transcribed and analysed as part of associated research. To take part in the study you need to be willing for the recording of sessions to take place. You can opt to receive recordings of your individual sessions if this would be helpful for you. We also routinely give all individuals in our service the option to consent to their recordings being used for training purposes.

STAGE 4: The End of the Therapy Programme and Follow-Up

At the end the booster treatment you will be discharged from the clinical service. At this point, we would advise that you talk with your family doctor (GP) if you would like to pursue further psychological therapy.

Expenses and Payments

You will not receive any payments or travel expenses for taking part in the therapy. We will give you a thank you payment of a £5 electronic Amazon voucher (and if appropriate cover your travel expenses up to £10), for each research assessment you complete (when first entering the study, at the beginning of treatment, and the end of treatment, when completing the interview). You will receive an additional £5 voucher for completing the interview at the end of treatment.

What are the alternatives for treatment?

If the ADepT project is not suitable for you or you wish not to take part, we will discuss alternative treatment options with you and signpost you to them. These may include other treatment options in the Mood Disorders Centre or other services in your local area.

What are the possible benefits of taking part?

We hope that the intervention you receive will have a positive impact on your mood. Based on the results from a previous study, our own clinical experience suggests that ADepT may be a helpful approach for building wellbeing and reducing depression in these cases. We do not anticipate that this treatment will place you at any more risk than you would face if you attended other treatment programmes. In addition, taking part in the study will involve regular monitoring of your mood. The information we get from this study may help us to treat future patients with depression better, by making therapy more effective and more widely available. While ADepT has been shown to be effective in adult depression, it has not yet been formally evaluated with autistic adults so we are unsure if will continue to show the same results. You are welcome to receive a summary of the information you provide over the study period if you wish.

What are the possible disadvantages of taking part?

Some of the questionnaires you will complete as part of the research study ask about personal and sensitive areas (such as your current and past mood, and your typical patterns of thinking and acting). People have different experiences of completing these sorts of questionnaires, including finding them distressing, interesting, frustrating or helpful. You are free to decide not to answer any question at any time, and you may also contact the researchers if there are parts of the questionnaires, or your reaction to them, that you would like to discuss.

What will happen if I don't want to carry on with the study?

You are free to leave the study at any point without it affecting the support you receive from other NHS providers. If you do decide that you no longer wish to take part, we will use the information you have provided up until that point in evaluating the study, unless you tell us otherwise. You may opt to decline the research assessments but remain in the treatment, however some of the assessments (the weekly questionnaires) are an important part of the treatment and we would encourage you to continue to complete these. If you remain in the therapy programme, we will continue to use the information you provide in these measures in our research evaluation of the therapy, unless you tell us otherwise.

How will we use information about you?

We will need to use information from you for this research project. This information will include your NHS number, name, 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. Your data will have a code number instead. The University of Exeter is the sponsor of this research. The University of Exeter is responsible for looking after your information. We will keep all information about you safe and secure. Your anonymised data (with all personally identifiable data removed and only including a code number) will be shared with the research team at the University of Exeter to allow us to evaluate how well the treatment has worked. Information about your participation in the study will be shared with your General Practitioner (GP). 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.

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.

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/
- by requesting our leaflet
- by asking one of the research team
- by sending an email to hst203@exeter.ac.uk
- by sending an email to adeptautismresearch@exeter.ac.uk
- by ringing us on 01392 723493.

What will happen to my data once the study has ended?

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. The data will be stored for 20 years after completion of the study (following standard practice in the Mood Disorders Centre) before being securely destroyed.

What will happen to the results of the study?

The researchers aim submit the work in partial fulfilment of the Doctorate in Clinical Psychology Programme. They also aim to publish the work in an academic journal and to report the findings at an academic conference. We will also provide you with a summary of the results of the research if you request one. Your identity will not be revealed in any report or publication. Generally, our research is reported on the University of Exeter Mood Disorders Centre website at: <http://www.centres.ex.ac.uk/mood>

Who is sponsoring the research?

The research sponsor is the University of Exeter.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Leicester South ethics committee (361068).

What if there is a problem or I have a complaint?

We do not expect you to be caused any harm from being in this study. However, if you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact details can be found on the last page of this information sheet). If you remain unhappy and wish to complain formally, please raise the matter with your practitioner, or in writing to:

*AccePT Clinic Complaints Manager
Sir Henry Wellcome Building for Mood Disorders Research
University of Exeter,
Queens Drive
Exeter
EX4 4QG*

The following organisations are also available for you to discuss complaint procedures with:

Patient Advice and Liaison Service (PALS) - Devon
pals.devon@nhs.net

Healthwatch - Devon
<http://www.healthwatchdevon.co.uk/>

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Exeter, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

[Independent advice about participating](#)

If you would like any independent advice about participating in research you can contact PALS (the local Patient Advice and Liaison Service), or INVOLVE at <https://www.involve.org.uk>

[Who should I speak to for more information?](#)

You can contact the lead researcher by emailing hst203@exeter.ac.uk or write to us at:

ADepT Research Project
Mood Disorders Centre
University of Exeter
Washington Singer Laboratories
Perry Road
EX4 4QG

Sponsor Representative contact details:

Suzy Wignall

University of Exeter, Research Services,

Research Ethics, Governance and Compliance,

The Innovation Centre, Rennes Drive,

Exeter,

EX4 4RN

Email: res-sponsor@exeter.ac.uk

Telephone: 01392 726621

