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PARTICIPANT INFORMATION SHEET [displayed online to participants]

AADAPT Online - Addressing young mums' and dads' low mood and their parenting

PART 1 - A BRIEF OVERVIEW:

Watch the video below for a brief overview of the study:

[Text in italics below forms the script of a video]

Why is this research being conducted?

Researchers in the Department of Psychiatry at the University of Oxford are carrying out a study to find out if a new way to support parents aged 16-24 years old who are experiencing low mood or stress is helpful. A therapy called Behavioural Activation or BA has been shown to help people deal with negative thoughts and feelings and is widely used in the NHS. The research team want to know whether an online AADAPT BA package of information and activities, **supported by Parent Buddies** is more helpful for young parents than AADAPT Self-Guided which is a control group.

AADAPT online is a short series of sessions to help you understand the TRAPs that keep you stuck feeling low. AADAPT will give you information about feeling low and practical ideas about ways to start feeling better. There will be videos to watch and spaces where you can record things you want to work on and how you are getting through the sessions. It will also give you some information on how you are building your baby's brain every day.

AADAPT has been put together by a team at the Universities of Oxford and Exeter who have lots of experience working with people with low mood. They asked young parents who felt low when they had a baby to help them make AADAPT online.

We are inviting parents to take part who:

- 1. Are aged 16 24 years
- 2. Have a baby aged 12 months old or younger

- 3. Are currently experiencing low mood or stress (which could include feeling low, down or depressed most days for two or more weeks)
- 4. Live in the UK
- 5. Are not currently having a talking therapy, for example counselling, either with a therapist or online

Do I have to take part?

No. Taking part in this study is entirely up to you. You can stop taking part in the study at any stage if you change your mind. There is no need to give a reason for leaving the study. However, data collected up until the point you withdraw may still be used. You are ultimately in control and the research team are always here to support throughout the study.

So what will happen to me if I take part?

You will first be asked some questions to see if this study is right for you. This will also involve a call with our research team who will ask you some questions about how you are feeling and any previously diagnosed mental health conditions.

If the research team think the AADAPT study is right for you, you will be asked to fill in some questionnaires at the beginning and end of the study. You will also be asked to record two 5 minute videos of you and your baby playing. This will help the research team understand more about how babies play with their parents. You can choose not to make the video recordings but still take part in the other parts of the study. The computer will then randomly put you into one of two groups; your choice about whether you decide to take a video or not, will not influence which group the computer puts you in.

What are the groups?

One group is called AADAPT Online:

- you will be given access to a website that will provide 6 sessions of information and activities to help with your negative thoughts and feelings as well as some parenting ideas and tips
- you will get weekly support from a parent (called a Parent Buddy) who also had their first baby when they were aged 16-24 years old. Parent Buddies have had training from the AADAPT team and will continue to have weekly contact with the team while they are part of the project.

The second group is called AADAPT Self-Guided:

 you will receive a written copy of the same information and activities as the AADAPT Online group. They will be sent to you in the mail or via email about 12 weeks after you enter the study. They will be yours to keep and you can work through it in your own time and at your own pace.

What else will I be asked to do?

In about 12 weeks' time you will be asked to fill out the same questionnaires again and record another couple of videos of you and your baby playing.

You will also be invited to take part in a 30-60 minute conversation at the end of the study, which will ask about your experiences of being a young parent with low mood and about taking part in the study. You can expect to be in the study for 14 weeks.

For more information about the study, please look below

[end of video]

SOME IMPORTANT POINTS

- You do not have to take part and you can leave at any point without giving a reason. However, data collected up until the point you withdraw may still be used.
- You won't be able to choose which group you will be allocated to (AADAPT Online or Self-Guided). A computer decides this.
- All information and research data will be kept secure.

Part 2: A CLOSER LOOK AT THE STUDY IN MORE DETAIL:

6. What will happen to me if I take part in the research?

The AADAPT study uses a web platform called Trial Deck which hosts a lot of the AADAPT study materials. Firstly, you will be asked to create an account on Trial Deck so you can complete some questionnaires online about how you've been feeling and about your experiences as a parent. There is one paper questionnaire that you can either complete with the research team over the telephone or you can choose to have this posted to you to fill out yourself at home. If you choose to have this questionnaire posted to you, it will come with a return envelope. The questionnaires will take approximately 10 minutes to complete.

You will also be asked to record two 5 minute videos of you with your baby playing at home using a portable HeadCam which will be mailed to you by the research team. These are worn by yourself and your baby. The HeadCam recordings look like the photos below; we will give you a postage-paid envelope and instructions about how to return the headcams by courier (at no cost to you). At the end of your involvement in the study, we will then email you some videos and/or images of you and your baby together. It can be a lot of fun to see how your baby looks at you when you are playing with them!



If you do not want to take a video of you and your baby using the HeadCam, you can still take part in all the other stages of AADAPT. If you take some video but then decide you do not want the AADAPT team to see it, you can return the HeadCam and tell the team to delete the video footage. They will do this as soon as they receive the HeadCam; then no one will watch or store the video you have recorded and it will not be part of the research.

After you have completed the questionnaires and returned the HeadCams to us (if you have chosen to make the videos), the online computer will randomly put you in either AADAPT online or AADAPT Self- Guided. As a computer decides which group you will be in, neither you nor the research team is able to choose this.

AADAPT Online

- If the computer puts you in this group, you will be given access to online information and activities designed to help parents who are feeling low or stressed. There will also be tips and ideas about being a parent.
- You will be supported by a Parent Buddy, who also had their first baby when they were aged 16-24 years. They will contact you weekly to see how you are getting on with the AADAPT sessions and support you with the AADAPT ideas. You and your Parent Buddy will decide the best time for you to chat each week (between 9am and 5pm Monday to Thursday and 9am to 12noon on Friday); you can do this using a Teams call set-up by the research team, or using the messenger function on Trial Deck.
- If you feel that your Parent Buddy is not a good fit for you then you can contact the research team to talk about changing to a different Buddy.
- After 12 weeks we will invite you to record another two 5 minute videos with the HeadCams and complete some more questionnaires so we can see how things are going.

AADAPT Self-Guided

• If the computer puts you in this group, in 12 weeks' time we will ask you to record another two 5 minute videos with the HeadCams and complete some more questionnaires so we can see how things are going. When you have done this, you will be mailed/emailed a written version of all the information and practical activities designed for young parents who feel low or stressed. This is the same material the AADAPT Online group received (the only difference is that you will not have a Parent Buddy) This will be yours to keep and you can work through it in your own time and at your own pace.

We will send a letter to your GP letting them know that you are taking part in the study and tell them which group you are in.

At the end of the 12 weeks, we will also ask if we can talk to you for about 30-60 minutes about your experiences of being a young parent with low mood and stress and give us your feedback about taking part in the study (this is called a qualitative interview). You can expect to be in the study for 14 weeks.

7. What are the advantages of taking part?

By taking part you are helping us see if AADAPT online or AADAPT Self-Guided (control group) is more helpful for young parents. Everybody taking part in AADAPT will be given access to the support materials; one group will look at them online and have the support of a Parent Buddy and the other group will be given a written copy via mail or email to work through independently.

You will be offered the option to receive selected clips of the recordings and images of you playing with your baby.

8. Will I be reimbursed for taking part?

You will receive:

- £25 for completing the first set of questionnaires and video recordings at the beginning of the study.
- A further £25 after completing the final set of questionnaires and video recordings at the end of the study.
- £25 if you take part in the conversation about your experiences of being a parent with low mood and taking part in the study (qualitative interview).

You will be reimbursed in vouchers. You can choose between Amazon or Love2Shop.

9. What are the possible disadvantages of taking part?

Some of the questionnaires and talking about your experiences of being a young parent and feeling low in mood may bring up sensitive or difficult thoughts and feelings. You can take a break at any time during conversations with your Parent Buddy without needing to give a reason and the team will offer support. The questionnaires have been used in previous research studies and we have worked with other young parents to make sure that the questions are acceptable.

You cannot take part if you are having a 'talking therapy' such as counselling or CBT with a therapist or through an online programme. If you start a talking therapy while you are taking part in AADAPT you will be able to get a copy of the AADAPT sessions so you can continue with the exercises BUT, you will not be able to complete the second set of questionnaires and videos or be reimbursed for your time for this part of the study. If you are in the AADAPT Online group you will no longer have access to your Parent Buddy or Trial Deck. If you want to continue with AADAPT and complete the second set of questionnaires and video, you will need to wait until these are done before starting a talking therapy. NOTE: You can take part in AADAPT if you are taking medication to help your mood (e.g. antidepressants) and you can continue with the study if you start medication during your time with AADAPT.

If you decide to take part in the study, this means that a partner who lives with you is not able to take part in the study themselves. They can have access to the AADAPT Self-Guided information and activities when you have completed AADAPT.

10. Will my taking part in the study be kept confidential?

Yes. Your name will not be used in the research data. Instead, you will be given a unique study number and we will use this to label the information we collect about you.

We will only use your email address, telephone number and address where this is necessary to contact you. Information that can identify you will be held securely by the AADAPT Research Team at the University of Oxford and by our Third Party provider Global Initiative who provide the Trial Deck online platform for the purposes of the study.

Confidentiality will be maintained as far as it is possible. If we notice that you or someone you know is at risk of, or currently experiencing, any harm, we will give your contact information to Dr Louise Dalton, a consultant clinical psychologist and member of the research team. They are a qualified mental health professional. They will contact you to offer further help and will talk with you about any further steps; this may include contacting your GP or other appropriate services needed to keep you and your child safe. The research team will always tell you when they believe it is necessary to share information with other agencies and who this information will be shared with.

Responsible members of the University of Oxford, and regulatory authorities and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

11. What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study. It is the data controller, and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible.

We will store any research documents with personal information, such as consent forms, securely at the University of Oxford for 3 years after the end of the study, as part of the research record.

We will keep any other identifiable information about you until the end of the study so we can send you study summary; within 3 years after the study has finished.

- Your contact details will be stored on a secure online platform Trial Deck, hosted by the third-party supplier Global Initiative, as well as secure servers at the University of Oxford. Your unique participant number will be linked with your name on Trial Deck. The data you provide will be available to Global Initiative, the third-party software provider. They process the data strictly for functionality, technical support, and security monitoring of the Trial Deck platform, without using the data for any other purposes, such as other research or marketing.
- The data that we collect from you will be stored, transferred and processed within the UK. By submitting your personal data, you agree to this transfer, storing and processing.
- Your IP address will be required by the online system to provide functionality. This will not be used for research purposes.
- You can update your personal details at any point during the time that you are involved with the study.
- Audio recordings (and video if you choose to turn your camera on) will be collected from any conversations you have with your Parent Buddy on Teams. This is for your safety and to help your Parent Buddy continue to learn and develop in their role. Audio recordings will also be made of the qualitative interviews at the end of the study to get an accurate record of the ideas shared during the discussion. These will either be recorded on Teams or a recording device, depending on how you'd prefer for this interview to take place. All of these recordings will be transferred to, and stored on, secure servers at the University of Oxford. Any recordings on a recording device will then be deleted. At this point you could be identified, as the data will contain your voices (and faces). However, these audio files will be transcribed (written out) as soon as possible (within approximately 4 weeks) by the research team, who may use the transcribe function in Microsoft 365 Word to assist transcription. The research team will remove any identifiable information such as names and places. The audio files will then be destroyed. The transcriptions will be stored as a Word file on secure servers at the University of Oxford.
- HeadCam footage will be transferred from the recording device as soon as possible after receiving the HeadCam and stored on secure servers at the University of Oxford. The video Document: Parent Participant Information Sheet 1.1, 18.12.2024. Title: AADAPT Online Addressing young mums' and dads' low mood and their parenting. Chief Investigator: Professor Louise Dalton. IRAS ID: 347818. REC Ref: 24/WA/0366

footage will then be deleted from the original recording device. If you do not want the video footage to be transferred from the Headcam to the servers at the University of Oxford you will need to inform the research team before or at the time of returning the HeadCam device to the team.

- The HeadCam footage will be used to understand more about how babies play with their parents. If you decide to do the videos, at the end of your involvement in the study, we will then email you a link to some videos and/or images of you and your baby together. Whilst the HeadCams are in transit back to the University of Oxford offices the team have reduced the risk of loss by using a University approved courier service, however if the HeadCams were to be lost then your face and that of your child would be identifiable. Once the HeadCams are back in the offices the team will watch and analyse the footage and then permanently delete it. The footage will not be used in any research outputs. The anonymised analysis data will be stored with all research data for 3 years after publication on secure servers at the University of Oxford.
 - If you are in the AADAPT Online group: Your Parent Buddy will be given your first name only. They will not have access to your unique participation number on Trial Deck, your phone number or email address, where you live or other information about you.
 - If you are in the AADAPT Online group: Any responses you enter for the AADAPT Online exercise activities will be available to your Parent Buddy as well as the research team. This is so your Parent Buddy can support you. We will also record your chats on the messenger function on Trial Deck with your Parent Buddy for your safety and to help your Parent Buddy continue to learn and develop in their role.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting: aadapt@psych.ox.ac.uk

12. What will happen to the results of this study?

The results of this study will be summarised in scientific articles that we aim to publish and present at relevant conferences. We will also share the findings on the University website and with other organisations who might find the results interesting to help other young parents. We may use some of your words from the interviews when we present the results of the study, but no names or identifying details will be used. We will send you a short newsletter detailing the main results. You will not be identifiable in any of these instances, and your details will remain strictly confidential.

13. What if I have a question or concern about the research?

If you have any questions or concerns about the research please contact one of the research team:

Chief Investigator: Louise Dalton louise.dalton@psych.ox.ac.uk, Tele: 01865 618166

Research Team: aadapt@psych.ox.ac.uk, Tele: 01865 618330

They will do their best to answer your questions.

14. What if there is a problem?

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, 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. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Louise Dalton: louise.dalton@psych.ox.ac.uk, 01865 618166) or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

15. How have patients and the public been involved in this study?

Over 15 Young Parents who identified as experiencing low mood at some point whilst being a parent helped develop the content and materials of the AADAPT Online content. They had input in, and gave feedback on, some of the AADAPT Online animations and how the online platform looks. They also told us what key features AADAPT Online should have and we have incorporated their ideas of how they would use the platform.

Young Parents were also involved in the presentation of the study including choosing our AADAPT study Logo, and also the colours and images we should use. They helped design our study adverts and reviewed other study documents and information including this Participant Information Sheet.

16. Who is organising and funding the study?

 The University of Oxford is sponsoring the study. This study has received funding from the Prudence Trust.

17. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by Wales Research Ethics Committee 3.

18. What if I need support for my mental health?

If you do feel unwell or upset while taking part in this study, please contact your GP. In addition, here are some other options for you to contact for some help:

Samaritans: Free, confidential support for people experiencing feelings of distress or despair.

Phone: 116 123 (free 24-hour helpline)

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Website: www.samaritans.org.uk

MIND: advice and support to empower anyone experiencing a mental health problem.

Phone: 0300 123 3393

Website: www.mind.org.uk

SANE: Emotional support, information and guidance for people affected by mental illness, their

families and carers.

Textcare: comfort and care via text message, sent when the person needs it

most: www.sane.org.uk/textcare

shout: Free 24/7 mental health support

Text: SHOUT to 85258 anytime day or night

Website: https://giveusashout.org

Further information and contact details:

Please contact the AADAPT research team by emailing aadapt@psych.ox.ac.uk or call us on: 01865 618330

Thank you for considering taking part