

Participating in scientific research, what does it mean to you?

Dear Sir/Madam,

The purpose of this information letter is to ask you if you would like to take part in scientific research. You will read about what kind of research it is, what it means for you, and the advantages and disadvantages. It's a lot of information. Do you want to read it and decide if you want to take part? If you want to participate, you will find the consent questions in Appendix B.

Ask your questions!

The information you find in this information letter may help you decide whether to participate. In addition, we recommend you to:

- Ask questions to the researcher, Kim Tönis.
- Talk about this study with your partner, family or friends.
- Ask questions to the independent expert, Mirjam Galetzka.

What information will you find in this information letter?

You will find the following information in this letter:

- What is the trial about?
- What does it mean for you if you take part in the study?
- What do we expect from you if you take part?
- Are there any side effects?
- What are the advantages and disadvantages of taking part in the trial?
- When will the trial end?
- What will we do with your data?
- Are you specially insured for this research?
- Will you be paid?

You will find the following attachments to this information letter:

- A: Contact details of the researchers, independent expert and data protection officer
- B: Informed consent form

Why are we asking you to take part in this study?

Your child has ADHD and/or autism or you suspect that your child may have ADHD and/or autism. Research has shown that parents of children with ADHD and/or autism experience a lot of stress. A self-help app called Adappt has been developed to support parents. Adappt is based on positive psychology and mindfulness. We want to find out if this app can really help parents improve their mental resilience. That is why we are inviting you to take part in this study.

Aim of the study

Adappt has been developed in collaboration with parents of children with ADHD and/or autism as part of a European study (called R2D2-MH, see <https://www.r2d2-mh.eu/> for more information). The content of Adappt is based on existing effective exercises from positive psychology. The app is developed to support parents of children with autism and/or ADHD in their mental resilience. The researchers at the University of Twente want to test whether this app helps to increase mental resilience.

What will it mean to you if you take part in the trial?

How long will the study last?

The study will last 7 months, during which you will complete a questionnaire four times (at baseline, after using the app, three months after using the app and six months after using the app) and you will use the app every day as much as possible once a day for one month. Each questionnaire will take about 30 minutes to complete.

Who can take part in the study?

You can take part in the study if you meet the following criteria:

- You are the parent of a child diagnosed with or suspected of having a neurobiological developmental disorder such as ADHD or autism (under 18 years of age)
- You are over the age of 18
- Have a smartphone or tablet with a good internet connection and an email address
- You are willing and able to use the app for 10-15 minutes a day for (approximately) one month
- Are not currently receiving treatment for mental health problems

The research is aimed at parents of a child with a neurobiological developmental disorder, such as ADHD and/or autism, who need support to increase their mental resilience. You may be experiencing mild psychological distress, such as anxiety, sadness or stress, but not severe psychological distress.

The app

If you are accepted into the study, a lottery will be held to determine who can use the app immediately and who will have to wait another 4 months to use the app. If you are able to use the app, you will be asked to download the app onto your smartphone or tablet. Using the app, you will do one positive psychology or mindfulness exercise a day for one month to improve your mental well-being. To support you, the app will send you a daily reminder. The information you enter into the app will be stored on your phone. As researchers, we can see if and how often people use the app, but not what they enter into it. The exception to this is the question about how good/bad you think each exercise is; these ratings will be passed on to the researchers.

How does the study work?

Registration and declaration of consent

If you are interested in taking part in the research, you can register on the study website. The website will give you more information about the app and the research. If you want to take part, you can give your consent to take part in the study in the registration questionnaire.

Questionnaire survey and lottery

We will check whether you meet the eligibility criteria for the study and inform you of the results by email. You will then be invited to complete the first questionnaire. Once you have completed this, a lottery will be held to determine who will be able to use the app immediately and who will have to wait another 4 months to use the app. You will receive an email with the results of the lottery. People who can use the app immediately will receive an email explaining how to download the (free) app and can start using it. After one month everyone receives the second questionnaire. Three months after the second questionnaire, everyone will receive the third questionnaire. Those who had to wait will then receive an email explaining how to download the app and can start using the app. After another three months, everyone will receive the fourth and final questionnaire. You will receive the questionnaires via a link in an email and you can complete them online. It takes about 30 minutes to complete.

Voluntary participation

If you decide not to take part, you don't have to do anything. You don't have to say why you don't want to take part in the study. If you do participate, you can always change your mind and stop anyway, even if you don't want to give a reason. You can also do this during the trial.

What is expected of you?

The study will ask you to complete a questionnaire four times. It is also important that you are motivated to use the app for 1 month and that you will work on the exercises for about 10-15 minutes a day during this period.

Advantages and disadvantages of taking part in this study

By taking part in this study, you will be making an important contribution to knowledge about the effects of the app with positivity exercises on the well-being and resilience of parents of children with ADHD and/or autism. This may also help other parents in the future.

Taking part in the study may lead to improved mental well-being and resilience. There are no disadvantages of taking part in the study. However, it will cost you the time needed to use the app and complete the questionnaires. The exercises take about 15 minutes a day, 7 days a week (for 4 weeks). Completing the questionnaires will take about 30 minutes each time (4 times in total).

Privacy

Your personal information and your answers to the questionnaires will be kept confidential and stored in encrypted form. This means that your information is given a code is given that cannot be directly traced back to you. All completed questionnaires will be stored separately from your personal information. We are required to keep your research data separate from your personal data for 10 years separated from each other. You will agree to this when you take part in this study. You can contact the research at any time during the study if you want to see your data. After the study, anonymous data (data that cannot be traced back to an individual) will be stored in a repository and may be used for future research.

As part of the exercises in the app, you can answer questions. The answers to these questions are stored locally, on your phone. They will not be visible to us as researchers. We as researchers will see a summary per participant showing the number of exercises completed per participant.

When will the study stop?

The study will stop in the following situations:

- When the last questionnaire has been completed (7 months after the start of the study).
- If you decide that you no longer wish to participate in the study and/or use the app. You can do this at any time. Please inform the researcher by email. You don't need to explain why you are stopping.
- The researcher thinks it is better for you to stop.
- One of the following authorities decides that the study must be stopped:
 - o The University of Twente,
 - o The government, or
 - o The (medical) ethics committee that evaluates the research.

Research approval

The Ethics Committee of the BMS Faculty of the University of Twente has approved this study. This means that the research complies with internationally established standards and guidelines, which will be carefully followed.

Will I receive any compensation for taking part in the study?

No, you will not receive any compensation for taking part in the study. You can use the Adappt app for free.

Is there an additional insurance for participants?

No, there are no risks associated with using the app.

More information about the trial

If you would like more information about the trial, you can find it at:

- The trial website: <https://www.utwente.nl/en/bms/adappt/>
- The Trial registry: <https://clinicaltrials.gov/study/NCT06248762?intr=adappt&rank=1>

Would you like more information about the trial?

If you have any questions, you can always contact Kim Tönis, who is running the trial (see below for her contact details). Would you like independent advice about taking part in this research? Then you can contact an independent expert. She is not directly involved in the study, but has enough information to answer your questions. Her details are: Mirjam Galetzka, email: m.galetzka@utwente.nl, phone: +31534893329.

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher, please contact the Secretary of the Ethics Committee of the Faculty of Behavioural, Management and Social Sciences at the University of Twente by ethicscommittee-bms@utwente.nl.

Kim Tonis

Researcher at the University of Twente

adappt-bms@utwente.nl

Appendix A. Contact information

Researchers University of Twente

Main researcher

Kim Tonis

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Coordinating researcher

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Independent expert

Dr. Mirjam Galetzka,

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Data Protection Officer

Annika van der Putten

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Appendix B. Consent Form for Participation in Research on an App for Parents of Children with ADHD and/or Autism

By ticking each of the following conditions, you are agreeing to the terms and conditions for participation in the study:

- I confirm that I have read and **understand** the information for research participants.
- I have had enough time to think about my participation. I have had the opportunity to ask questions. These questions have been answered satisfactorily.
- I agree to participate in this study of the app for parents of children with ADHD and/or autism. This will involve using the app and completing four questionnaires.
- I understand that my participation is completely voluntary and that I can withdraw my consent at any time without giving a reason.
- I agree to the use of my research data and the reuse of my anonymous data in the manner described in the information letter, under the heading “privacy”.
- I understand that any personally identifiable information collected about me that can identify me (e.g. my name and email address) will not be shared beyond the study team