

Participant Information Sheet for Parents Version: 5.0 Date: 12/10/2022

Title of Project: *Online Parent Training for The Initial Management of ADHD Referrals: A two-arm parallel randomised controlled trial of a digital parenting intervention implemented on a treatment waitlist.*

Short title: OPTIMA RCT

We would like to invite you to take part in the OPTIMA RCT study, which has been set up by King's College London together with the Universities of Southampton and Nottingham. King's College London and the South London and Maudsley NHS Foundation Trust are the study co-sponsors, which means they are the organisations that lead the study and that have authority and control over its conduct. The universities of Nottingham and Southampton are the study collaborators, which means they are the organisations that provide support for this study.

Before you decide to take part, it is important for you to fully understand why we are doing this research and what it will involve. Please take time to read the following information carefully and discuss it with your partner or a friend/relative. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether to take part or not.

Why is the study needed?

It is recognised that many children referred to children's services have behavioural problems, which create challenges for parents. It is also recommended that parents get help to manage these as soon as possible after the referral is made. This help should be in the form of parent training, an evidence-based intervention, which helps parents to find more effective ways to manage their children's behaviour. However, parent training is usually delivered face-to-face and only after a clinic has made a full assessment following months-long wait. To speed up access to parent training, we have developed a new digital application (app) called Structured E-Parenting Support (STEPS).

Before we can recommend using this app, we need to make sure that it works in the way we expect it to. To do this, we will test STEPS in a randomised controlled trial with parents of children, who have been recently accepted onto a waiting list by one of the children's health services participating in our study. We expect that 352 parents will take part in this study. Half the parents will get access to the app and half will remain on the wait list as usual. We will then test whether the app has a positive effect on children's behaviour and parenting compared to not using the app.

What is STEPS and do I have to use it?

STEPS is a parenting support intervention delivered as an app. It can be accessed through a smartphone at any time and any place. STEPS is inspired by the New Forest Parenting Programme, a face-to-face parent training intervention. Its content has been shaped by the latest research about parenting and child behaviour as well as many years of clinical experience. Users can move through the content, organised in modules (steps), at their own pace – it usually takes about 20 minutes to complete a module in one go. STEPS is an unguided intervention, which means there is no personal clinical support for parents using

the app. The content is delivered mainly using short videos and audio clips. To register with the app, each parent will receive a unique ID number (provided by the study team), which will be used to link app usage data with the information obtained from other sources (i.e., questionnaires, medical records, interviews).

If you are allocated to the STEPS intervention group, you will be given access to the app for 3 months. You will be asked to complete at least the two first modules of the app and you will receive a short instruction video explaining how to make the best out of STEPS. If you are in the waitlist as usual control group, you will be given access to STEPS (also for 3 months) after about 12 months, when you complete all follow-up questionnaires.

Why have I been invited and am I eligible?

We have invited you because your child has been recently accepted onto a waiting list in one of the children's health services that are participating in the OPTIMA RCT

You are eligible to take part if:

- Your child is aged 5-11 years and has been on the services waitlist for less than 9 months.
- Your clinical records show that you have rated your child as having high levels of attention problems and disruptive behaviour.
- You have access to a smartphone with operating system Android 4.1. or later or iOS 9.0 or later that can connect to the internet (mobile or wi-fi).
- You do not have difficulties in understanding written/spoken English.

You are not eligible to take part if:

- Your child is under care of the Local Authority.
- Your child has already completed a clinical assessment or started a treatment.
- You have previously enrolled in this trial.

What will taking part in the study involve?

To find out if STEPS is helpful to parents, we will put them into two equal groups: parents in the STEPS intervention group will receive the app and will be asked to use it for 3 months, parents in the control group will remain on the waitlist as usual. Each parent will be put into a group by chance (i.e., randomly) – this will be done by a researcher using software provided by a company called Sealed Envelope.

Taking part in the study will also involve:

- Completing a consent form for the trial online.
- Completing online questionnaires about yourself and your child five times during the study, at the start, and then after 3, 6, 9 and 12 months. If you prefer, you can complete the questionnaires on the phone with help from one of the OPTIMA researchers.
- Taking part in an online drawing task (Etch-a-Sketch Online; optional) with your child 3 times during the study, at the start, and then after 3 and 12 months. During the task lasting 5 minutes, parents and children will take turns drawing a simple picture on a mobile phone screen. The task will be completed on a mobile phone and will be audio recorded using Microsoft Teams.

- The online consent form and the online questionnaires will be completed using the Red Pill platform. To read their privacy notice, please click here [insert link].
- Agreeing to give the study team permission to access your child's medical and other health-related records and permitting to link this information with the answers that you provided in the questionnaires about yourself and your child.
- Agreeing to give the study team permission to contact your GP to let them know that you are taking part.
- Agreeing to long-term storage and sharing of your anonymised data with other researchers (e.g., online databases). Any personal information that could identify you will be removed or changed before files are shared or results are made public.
- Agreeing to take part in the follow-up interviews (optional).

If you are selected for the STEPS intervention group, we will also ask you to:

- Download the STEPS app immediately after you receive information about group assignment and use it for 3 months.
- Allow the app to track your usage data and give the study team permission to access your STEPS app usage data (e.g., how much time you use the app, how many modules you have completed, etc.) and for long-term anonymised storage and use of this information for future ethically-approved research only. To access STEPS privacy notice please click [here](#) and go to the Privacy notice tab.

Do I have to take part?

No, it is completely up to you. If you decide to take part, you will be asked to complete a consent form online (see a sample copy of the consent form attached to this information sheet). We will email you a copy of this document to keep for your record. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you or your child receives.

Incentives

As a thank you for taking part, you will receive up to £65 of online shopping vouchers: £10 when you complete the first set of online questionnaires; £25 after completing the 3-month follow-up questionnaires, and then £10 after you have completed each of the 6, 9 and 12-month follow-up questionnaires. Your child will also receive up to £15 in book or shopping vouchers and certificates, £5 every time they complete the online drawing task. All vouchers and certificates will be emailed to you.

What should I do if I want to take part?

If you would like to join the study, then all you need to do is email the research team at optima@kcl.ac.uk and let them know that you are interested in taking part. A researcher will get in touch with you to arrange a phone call.

What will happen during the phone call?

A researcher will ask if you have received and understood this information sheet and whether you would like to take part in the study. You can also ask any questions that you might have before deciding whether to take part.

A researcher will then confirm whether you are eligible to join the study and, if you are, you will receive a link to complete a study consent form online.

What will happen after I have joined the study?

As soon as you have joined the study, we will email you with a link to online questionnaires, which will include:

- A very short questionnaire about you, your family circumstances, and your expectation about taking part in the trial.
- Four questionnaires about your child's behaviour.
- A questionnaire about your child's health and other service use, including any prescribed medication.
- A questionnaire about your child's general health, and a questionnaire about your general health.
- Four questionnaires about parenting and your worries about your family life.
- A questionnaire about any medical or psychological events or symptoms that you or your child has experienced shortly before joining the study.
- An open-ended question about your recent parenting experience.

Completing these questionnaires will take about 60-90 minutes. You don't need to do them all in one go, but it is important that you complete these questionnaires within 7 days of receiving the link. We will not be able to allocate you to the study group until we receive your completed questionnaires. **If you prefer to do the questionnaires on the phone with one of our researchers, please let us know and we'll arrange this for you.**

Will anything else happen in the study?

After you have completed the online questionnaires, we will let you know whether you are in the STEPS intervention or in the control group. **Please do not tell the researcher which group you are in. It is very important that they don't know this.**

If you are in the STEPS intervention group, we will email you instructions on how to download the app. If you are having trouble with downloading the app or setting up STEPS, you should let us know and one of the researchers will get in touch to help you through this process. You will have access to the app for 3 months. Note that after 3 months from downloading STEPS, it will be stopped, and you will no longer be able to use it.

If you are in the control group, you will remain on the waitlist as usual. The team will get in touch with you when it is time to complete the follow-up questionnaires.

After 3 months, we will be in touch again, and we will ask you to complete online questionnaires about you and your child – this time, it should take you about 60 minutes.

The same thing will happen 6, 9 and 12 months after you joined the study, but at the 6- and 9-month follow-up, there will be fewer questionnaires to complete.

All questionnaires will be available online. While we ask you to complete them within 7 days of receiving them, you do not need to complete them all at once. If you prefer to do them on the phone, please let your researcher know.

Online drawing task

If you agree, we will ask you to complete an online drawing task (Etch-a-Sketch online) with your child 3 times during the study, at the beginning, after 3 months and again after 12 months. During the task you and your child will take turns to draw a simple shape (e.g., a house) on the mobile phone screen. A researcher will get in touch with you to arrange a convenient time for this and send a link to access the task.

The task will be completed on your own mobile phone and will take about 5 minutes (please allocate about 15 minutes for the whole session). It is easy to set this up and we can help if you need it. We will audio record it with Microsoft Teams. The recording will be saved in Microsoft Stream and a trained researcher will use it to rate your child's speech during the task, to help us answer our research questions.

Follow-up interviews

If you agree to take part in the follow-up interviews, a researcher may get in touch with you at a later date (in about 3 months' time) to arrange a convenient time for this. The interviews will last about 60 minutes and will take place online, using Microsoft Teams. The interviews will be audio and video recorded, but you may wish to turn your camera off. The recording will be saved in Microsoft Stream. The transcript that is automatically generated by Microsoft Stream will be further checked and transcribed by the member of the research team to remove any identifying information.

If you have trouble accessing Microsoft Teams, you could also speak to the researcher on the phone or give your answers via email. The telephone interview will be recorded and saved in the same way as if was the Microsoft Teams interview. Interviews provided via email responses will be downloaded onto a KCL OneDrive for Business and any identifying information will be removed. Please note that security cannot be guaranteed when communicating by email using a non-secure email address. Interviews transcripts with all the identifying information removed will be stored on KCL OneDrive for Business and KCL SharePoint. Each parent will receive £20 as a thank you for taking part in the interview.

Are there any benefits of taking part?

If you use the app, we hope that STEPS will help parents to become more confident and effective in managing their children's difficult behaviour. The app is designed to be particularly helpful for the parents of children who are temperamentally more difficult to manage, such as those with attentional and impulse control problems. STEPS has been designed to decrease conflict in the family by reducing levels of children's difficult behaviour. If you are in the control group, we do not expect you to benefit from taking part.

Are there any disadvantages or risks in taking part?

There are no known risks linked to taking part in this study. There is a small possibility that completing online questionnaires or using the STEPS app may result in you having new concerns about your child's behaviour, your relationship with your child or even how you manage as a parent. This is why we will ask you to tell us about any medical or psychological events/symptoms during the study. If you feel you are really struggling, please contact your local clinical services or your GP. Also, you will receive contact details for crisis services, should you need to contact them.

How will information about me and my child be kept confidential?

We will always protect your own and your child's privacy and we will take the following steps to ensure confidentiality:

- Your consent to take part in the study will be recorded on an electronic form that will contain identifiers including your name, email address and mobile phone number. These forms will be stored digitally and separately from the study data.
- Your app usage data and information provided on questionnaires will not include any personally identifying details. Your data will be stored using a unique code number. Researchers, who do not need to know who you are, will not be able to see your name or contact details.
- A single table linking your code number to your name will be stored in a separate password-protected file within the restricted-access folder on the King's College London (KCL) cloud server (OneDrive for Business), which may be accessed only by authorised researchers. Usually, these are people, who are responsible for contacting you regarding participation.
- The research team will retain your personal information for 7 years after the study has ended. After this time, it will be securely destroyed.
- Information that you have taken part in the study will be added to your child's clinical notes, which are confidential. We will also inform your child's GP about your participation in the trial.
- The STEPS app will be available through Apple App Store and Google Play. Your name, email address or your mobile number (whichever you usually use to download apps) will be required to create a STEPS account when you first install the app.
- Audio recording from the drawing task and the audio/video recordings from interviews or email answers will be stored digitally in a secure KCL cloud location with access restricted to authorised researchers.
- Recordings will be rated (online drawing task) or transcribed (interviews) by a member of the study team and the original recordings or emails will be deleted from the cloud location.
- The results from this study may be published on the website, presented at conferences and scientific journals and in the report to the funder. However, we will only present information about the whole group, and in a way that it will not be possible to work out who took part. Direct quotes from the interviews may appear in publications, but will be attributed generally, so that it is impossible to identify the person, who made the comment.

All information collected will be treated as strictly confidential, except where there may be a real risk of harm to you or your child for which expert help may be needed, or in the event of any adverse findings where your clinical team or your GP may be informed with your consent.

How will we use information about you?

We will need to use information from you and from your child's medical records. This information will include your name and contact details and your child's name, date of birth and health information for this research project. 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. We will keep all information about you safe and secure.

Some of your information will be shared with researchers based at the universities of Nottingham and Southampton. They must follow our rules about keeping your information safe.

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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your child's health from the health services you were referred to. If you do not want this to happen, tell us and we will stop.
- 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/
- Our leaflet available from www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research (KCL)
<https://www.slam.nhs.uk/about-us/privacy-and-gdpr> (SLaM)
- By asking one of the research team.
- By sending an email to the Data Protection Officer info-compliance@kcl.ac.uk (KCL) or dataprotectionoffice@slam.nhs.uk (SLaM)

We will use the Firebase service provided by Google to process some of your personal data, (e.g., name, email address, telephone number) on our behalf. The information about your app use will be transmitted to and stored by Google on their servers. Google does not have permission to use your data for their own purpose. They can only process the data on our instructions and need to look after your information very carefully. Information processed by Google is required to run, operate and maintain the app, notify users about updates to the app and will allow us to find out how the users engage with the STEPS app.

Firestore Terms of Service are available here: <https://firebase.google.com/terms>

Firestore Privacy and Security Information is available here: <https://firebase.google.com/support/privacy>.

To allow the STEPS app to send you text message notifications, your mobile number will be shared with Twilio, a company providing cloud-based communication solutions. Twilio privacy policy can be found here: <https://www.twilio.com/legal/privacy>

To send you text message reminders about online questionnaires, your mobile number will be shared with MessageBird. Please see <https://www.messagebird.com/legal/privacy> for more information about how they will handle your data.

Your research data will be stored at KCL for 20 years.

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

The study will be most valuable if few people withdraw from it. It is important to discuss any worries you may have with a member of the study team before you agree to participate. However, you can leave the study at any time and without giving a reason. You can leave either by ignoring the reminders to complete the follow-up questionnaires or by emailing us at optima@kcl.ac.uk. This will allow us to call you to discuss your concerns with you and decide which of the three withdrawal options is most appropriate:

- “Stop intervention”: This means that you no longer wish to use STEPS, but you are happy to be contacted by the team with requests for follow-up information. You can stop using STEPS and delete the app from your phone at any time.
- “No further contact”: This means that the study team would no longer contact you directly. But they would still have your permission to retain and use questionnaire information and app usage data collected previously and to obtain and use further information from your health records.
- “No further data collection”: This means that the study team would no longer contact you directly or no longer obtain and use further information from your child's health records. But they would still have your permission to retain and use questionnaire information and app usage data collected previously.

If, after having discussed the options and your worries about the study, you decided to leave the study then we would email you a withdrawal form to confirm your decision in writing. We will also ask you to provide short feedback of the reasons for your withdrawal – this is optional but would be very helpful for us know. Your completed consent and withdrawal form will be kept as a record of your decision.

What will happen at the end of the study?

At the end of the 12-month follow-up period you will complete your final set of questionnaires. We will contact you by email to let you know the study has ended and to thank you for your contribution. When everyone has finished taking part, we will analyse the data and the results of the study will be published in a scientific journal. The summary of the findings will also be available on the study website.

What if there is a problem?

If you have a concern about any aspect of this study, please do not hesitate to call the trial manager, Dr Kasia Kostyrka-Allchorne on 020 7848 3682, or email her at kasia.kostyrka-allchorne@kcl.ac.uk.

If you remain unhappy and wish to complain formally, you can do this through the SLAM Patient Advice and Liaison Service (PALS) on 0800 731 2864, or by email pals@slam.nhs.uk.

What if something goes wrong?

If something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). King's College London has obtained insurance which provides no-fault compensation i.e., for non-negligent harm, you may be entitled to make a claim for this.

Who is organising and funding the research?

The study has been organised by King's College London (the study co-sponsor with the South London and Maudsley NHS Trust) and the Universities of Nottingham and Southampton (study collaborators). The research is being funded by the National Institute of Health Research.

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 find out more click [here](#)), to make sure that research is fair and to protect your interests. This study has been reviewed and given favourable opinion by Research Ethics Committee North West - Liverpool Central Research Ethics Committee. [<https://optimastudy.co.uk/resources/>].

THANK YOU FOR TAKING TIME TO READ OUR STUDY INFORMATION!