Principal Investigator: Dr Alexandra Hendry
Email: start@psy.ox.ac.uk
Phone: 073108 76421

START Supporting Toddlers with a family connection to autism or ADHD to develop strong Attention, Regulation and Thinking skills

Participant Information Sheet: START Feasibility Trial

Ethics approval reference: R67115/RE003

About this study

Previous research has indicated that children with a family connection to autism or ADHD may benefit from additional support in developing attention, regulation and thinking skills (sometimes called executive functions). The START team, led by Dr Alexandra Hendry, have developed a programme which aims to provide that support, starting in toddlerhood. This Feasibility Trial is the first stage in investigating whether the programme is useful or not. We will be collecting information from 60 families, in Oxford and Southampton. The information we collect will help us to improve the programme and decide whether to progress to a larger trial.

Taking part in this study involves:

- completing questionnaires about you and your child. You can choose to complete these online, on paper versions that we post to you, or over the phone. To thank you for your time we will send you a £10 online shopping voucher after each set is completed (£30 in total).
- two face-to-face visits, in which researchers will play with your child to collect information about their strengths and difficulties. You can choose for these visits to take place in your home, or at the Oxford BabyLab. We will provide your child with a small gift to thank them for their time. If you need to travel we will reimburse the cost.
- possibly taking part in a 12-week programme with your child which aims to help toddlers to develop strong attention, regulation and thinking skills. Half of the families taking part in the study will be offered the programme, the other half will not (but can continue to access other services as usual). The programme will be assigned at random. The programme involves 12 hour-long parent-and-toddler sessions, one each week. The sessions are held in a local venue and we will cover the cost of your travel expenses.
- taking part in one or two (depending on whether are selected to receive the programme or not) online interviews to gather your feedback about taking part in the study.

Who can take part?

To be eligible for this study you must:

- Have a child who is aged under 20 months who has a close biologically-related family member (e.g. their mum, dad, brother or sister) who is autistic or who has ADHD (either diagnosed or suspected).
- Be willing and able to attend weekly 1-hour parent-toddler sessions located in a family-friendly setting in Oxford or Southampton, over a 3-month period.
- Be able to understand spoken English (so that you can take part in the parent-toddler sessions).
- Be 18 years or older.

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What will happen in the study?
If you take part in the study, this is what you would be asked to do:

1. Answer a screening questionnaire, either online or by phone to check eligibility for the study. This will generally take about 10 minutes, but may involve a follow-up questionnaire about the relative(s) with suspected autism/ADHD if they don't have a confirmed diagnosis.

2. If you are eligible for the study, when your child is around **20 months old**, we will send you a consent form to complete, and a questionnaire about your child's health, personality, strengths and difficulties, and about your family background and mental health. This will take around 40 minutes to complete, but can be completed in stages, at a time to suit you. We will send you the consent form and questionnaire either by email (so you can complete an online form) or by post, whichever you prefer. You will also have the option to complete the questionnaire by phone. We will also arrange an assessment visit where a researcher will play with your child to collect information about their strengths and difficulties.

The Assessment Visits

You can choose for these assessments to take place in your home or at the Oxford BabyLab. The Babylab has a welcome area with a range of toys, and baby changing facilities. At the start of the visit the researcher will share some toys with your child whilst they talk you through the plan for the assessment and answer any questions you might have.

There will then be a range of games and activities for your child to play, some involving toys and objects, and some games on an iPad. Some of the games are specially-designed to measure toddlers' attention, thinking and regulation skills. Others are standardised assessments of developmental ability and autism traits. The session is designed to be enjoyable for toddlers, and we can take breaks whenever they need.

You will be in the room with your child the whole time, but will sometimes be filling in another questionnaire whilst they play. The games and assessments are expected to take no more than 2 hours in total, but visits will be scheduled for 2.5-3 hours to allow plenty of time for breaks. The session is videoed so that after the session we can look closely at the different behaviours that toddlers show.

3. After the first assessment visit you will be assigned at random to either the START programme group or Usual Practice group of the study. There is a 50% (equal) chance of being assigned to either group.

If you are assigned to the START programme you will be invited to take part in a 12-week programme of parent-child sessions, starting when your child is between **21 and 24 months.** You can find out more about the programme in the About the START programme Information Sheet. You will be contacted by the facilitator running the sessions in your area. They will arrange a phone call with you to find out which times and days would most suit you, and discuss your aims and expectations for the programme. They will also find out whether there are specific adjustments we could make to make the programme sessions accessible for you and your child. This could involve providing help arranging or covering costs for transport or childcare for other children, making sure the venue has ramps, or adjusting the set-up of the room to suit sensory needs. As this is a group programme, it may take a few months for enough other families to be recruited to run the sessions. The facilitator will contact you when the sessions are ready to start, and make sure you have the information you need.

During the 12-week period that your START sessions are running, you will be asked to complete a short weekly questionnaire, or contribute verbal feedback to about the programme. You will also be asked to take part in an online interview at the end of the 12-week period to share your reflections about the programme.

If you are assigned to the Usual Practice group you do not need to do anything for 10 months. You can continue to access any services, supports or parenting groups you would have otherwise accessed.

4. When your child is around **31 months old**, you will be asked to fill in a questionnaire, either online, by post or by phone about your child's health, personality, strengths and difficulties, and your day-to-day life and experiences as a parent. This will take around 40 minutes to complete, but can be completed in stages, at a time to suit you.

5. When your child is around **36 months old**, you will be asked to fill in a similar questionnaire. This will take around 30 minutes to complete, but can be completed in stages, at a time to suit you. We will also arrange an assessment visit when your child is around 36 months old where a researcher will play with your child to collect information about their strengths and difficulties. This will be similar to the assessment visit at 20 months.

We know that it can be difficult to keep track of things when you are a busy parent so we will send you reminders for each data collection point (up to 4 reminders will be sent via email, 4 via text message, 3 via phone call/message and 2 via letter).

Do I have to take part?

No. It is up to you to decide whether or not to take part. You can withdraw yourself and your child from the study without negative consequences, by emailing or calling to tell us. You do not need to give a reason for withdrawing but we will ask if you would complete a leaver questionnaire to help us to understand if there is anything we should do differently in the future.

If you are unable to take part in the second assessment visit but are still happy for us to use the data we have already collected we will ask you to just complete a questionnaire.

What are the possible disadvantages and risks in taking part?

There are no major risks associated with taking part in the study. All the procedures in the assessment visits are non-invasive (we only measure your child's behaviour) and the tasks are designed to be enjoyable.

Some toddlers find new situations and people unsettling. To minimise discomfort and confusion to your child, only one or two researchers will be directly involved in collecting data during each assessment visit, and we can conduct the visits in your own home if preferred. You will be with your child at all times, and breaks can be taken whenever needed.

If you are assigned to the START programme they may find a group setting unsettling, especially at first. The facilitator running the sessions will do their best to help you and your child feel safe and relaxed. They will explain where you can go with your child if you need to step out of the session for a while, and you will always be welcome to return after a break.

Are there any benefits in taking part?
You may enjoy gaining a new perspective on your child's development, and ideas for games to play at home from the assessment visits. We will not be making clinical diagnoses, but if you would like to receive a copy of your child's scores to discuss with another health care or education specialist we can provide this for you after the visit.

If you are allocated to the START programme, you may benefit from the friendship and support of other parents in the group who will have similar aged children, and you may find the discussions and activities useful in supporting your child's development.

Your child may enjoy the stimulating and fun games of the assessment visits. If they are allocated to the START programme, they may enjoy the experience of a different play setting, and may benefit from the games and techniques introduced in the sessions. After some of the sessions, they will be given some toys to take home.

Your child will receive a BabyLab "Junior Scientist" t-shirt or other BabyLab branded gift at the end of each assessment visit.

Expenses and payments
If you are allocated to the START programme, you will be able to claim up to £5 without a receipt, or £15 with a receipt, to cover travel or childcare costs associated with attending each START programme session.

All participants will receive a £10 online shopping voucher after each assessment visit and questionnaire pack has been completed (£30 in total for all 3 assessments), as a token of appreciation for your participation in the study.

What information will be collected, and how will it be stored?

Name and contact information
We will collect your and your child's name and contact information (telephone number, email address, postal address) so that we can contact you about the study. This information will be stored in a secure research database on a University server. Only team members who need to contact you (the core research team, and the facilitators) will have access to this information.

In the interests of researcher safety for home visits, all members of the assessment team as well as a senior member of the Experimental Psychology department will have access to a team calendar on which the location of upcoming assessment visits, and relevant participant contact details will be stored. After the visit has been completed and all members of the testing team have returned home or to the office the lead researcher for that visit will delete the visit record.

We will ask if you consent for your contact information and the Participant ID that links your contact details with the research data (see next point) to be kept for up to 30 years to allow for the possibility of contacting you to collect follow-up data in the future. If you do not consent to this, your contact information will be kept only for the duration of the study.

We will also ask if you are happy for us to use your personal information for data linkage with other datasets, such as the National Pupil Database. This would allow us to test in the future whether the START programme has a positive impact on school outcomes.

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The paper consent form that you sign at the assessment visits will be stored in a secure filing cabinet, separate from any other data that we collect about you or your child, for a minimum of three years after publication of the primary feasibility trial study.

If you express an interest in the study but are ineligible, or do not choose to proceed to the full study, or would like your contact details to be withdrawn from our records, your details will be deleted from our records within 2 weeks of the decision being communicated.

Research data, including sensitive information

To help us be able to understand for whom the START programme does and doesn't work, we will collect some sensitive information including health information about you and your child, clinical assessment data about your child, you and your child's date of birth, sex, and ethnicity, and your family background. This, and other research data such as game scores collected at the assessment visits will be stored digitally in a secure research database on a University server. These data will be backed up at regular intervals and stored, separately from your name and contact information, on a secure, password-protected cloud storage service approved by the University.

Only members of the research team involved directly in this study, or responsible for quality assurance, will have access to the research data during the project. De-identified research data (i.e. labelled only with a Participant ID and not your name) will be kept for 30 years to allow for possible follow-up studies by the lead researcher in the future. At the end of the project, de-identified research data will be deposited on the Oxford University Research Archive (or its equivalent) for safe-keeping but will be not be made available to other researchers. De-identified research data for participants who have agreed to data sharing beyond the core research team (by ticking the optional box on the consent form) will be uploaded to an Open Science data sharing platform.

Any information provided by you on paper copies of the questionnaires, and any clinical assessment data recorded on paper forms, will be stored in secure filing cabinets separate from your and your child's name and contact details until it can be entered into the research database. Paper copies of forms will be stored for the duration of the project and shredded at the end of the project.

Audio recordings

START programme sessions will be audio recorded so that we can check that the sessions are delivered in the way intended. Interviews will also be audio recorded. The recordings will be made on an encrypted audio-recorder stored on a password-protected computer. They will be uploaded to a secure, password-protected cloud storage service approved by the University as soon as possible after the session. The recordings will not be linked to any other research data and will be labelled only with the session date and group number. Recordings will be stored until the checks are complete and the main feasibility trial study has been published, at which point they will be deleted.

Video recordings

Assessment visits will be video recorded so that we can accurately assess your child's behaviour and performance on the various games and activities in the visit. The recordings will be temporarily stored on encrypted devices and uploaded to a secure, password-protected cloud storage service approved by the University and an additional encrypted hard drive (stored in a locked office) as soon as possible after the visit. The local copy on the device will then be deleted. In the unlikely event of a device being lost or stolen before the video has been deleted from the device, the device will be auto-wiped.

Only members of the research team involved directly in this study will have access to video data, unless you give specific permission for videos to be shared for publicity or training via a separate consent form. Videos will be labelled only by the Participant ID not with your child's name. Videos will be stored until all necessary coding and checks are complete, and the associated studies have been published, after which they will be deleted.

If you want to your withdraw any information you have contributed to the research, you just need to let us know by the end of January 2025, before the data is prepared for publication.

Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will be submitted for publication and presented at academic conferences and other relevant events, and a report submitted to the project funder and other relevant agencies. It will not be possible to identify any individuals from the findings.

Who is involved in this project?

The project is led by researchers at the University of Oxford, in collaboration with researchers from University of Aberdeen and a team from the charity Peeple. The charity Autistica are also involved, for the purposes of helping with project governance, and sharing information about the project. The project has been funded by the National Institute for Health Research.

Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University of Oxford, University of Aberdeen and Peeple will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available at https://compliance.admin.ox.ac.uk/individual-rights.

Who has reviewed this study?

This study has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: R67115/RE002). The protocol has been reviewed by a Steering Committee of academics and clinicians and an independent representative from the autism community.

The initial project proposal for this study was developed in response to priorities identified in community consultations facilitated by James Lind Alliance Priority Setting Partnerships for Autism (Priorities 1, 5, 13); Childhood Disability (Priority 1); Neurodevelopmental Disorders (Canada) (Priorities 4, 5, 13); and Learning Difficulties (Scotland) (Priorities 4-7, 19). A panel of autistic adults and autism-advocates (co-ordinated by the charity Autistica) reviewed a draft of the proposal, and endorsed the project aims. The proposal was refined in collaboration with 2 independent autistic parents who have children with autism/ADHD. For the ongoing project, a Project Advisory Group (PAG) comprising 2 autistic adults (one who was involved in the original proposal development) has been established to offer recommendations for participant- or public- facing materials including outcome measures, information and consent forms, dissemination materials and ad hoc advice for the project. A panel comprising 10 parents who are themselves neurodivergent and/or have a child with autism and/or ADHD reviewed the draft START programme materials and the revisions made in light of their recommendations. The panel also advised on aspects of the broader study design.

Who do I contact if I have a question or concern about the research, or I wish to complain?
If you would like to discuss the research with someone beforehand, or if you have questions afterwards, please contact the team on start@psy.ox.ac.uk or 073108 76421.

If you have a concern about any aspect of this study, please contact Dr Alexandra Hendry on alexandra.hendry@psy.ox.ac.uk or 01865 271444 and she will do her best to answer your query. She will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

The Chair, Medical Sciences Interdivisional Research Ethics Committee;
Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB

Thank you for taking the time to read this information

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