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

Submission date
19/01/2023

Recruitment status
No longer recruiting

Registration date
30/01/2023

Overall study status
Ongoing

Last Edited
28/03/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Toddlers with a family connection to autism or ADHD are more likely than average to be later diagnosed with autism or ADHD. Some toddlers with a family connection of autism or ADHD will not meet the clinical cut-off levels for a diagnosis, but will still show higher autistic or ADHD traits. Autism and ADHD are both conditions that are associated with executive function difficulties in later childhood and adulthood, so supporting early executive development may help these toddlers to thrive in later life. Many toddlers with a family connection to autism or ADHD will be neurotypical – that is they will not show any signs of a developmental condition. Supporting early executive development may still be beneficial for these toddlers as strong executive functions are associated with higher levels of health, wealth and happiness in typically developing children too. In collaboration with the charity Peeple (https://www.peeple.org.uk/), researchers at the University of Oxford have developed a new programme, called START, which aims to support toddlers with a family connection to autism or ADHD to develop strong attention, regulation and thinking skills. The National Institute for Health and Social Care Research (NIHR) has funded a feasibility trial of the START programme. This is the first stage in investigating whether the programme is useful or not. The information that will be collected will help to improve the programme and decide whether to progress to a larger trial.

Who can participate?
Adults with a child aged under 20 months who is either suspected to be autistic or 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)

What does the study involve?
Taking part in the feasibility trial involves:
1. Completing questionnaires about the parent and child. Participants can choose to complete these online, on paper versions that are posted out, or over the phone, and will receive a £10 online shopping voucher as a thank you after each set is completed (£30 in total).

2. Two face-to-face visits, in which researchers will play with the child to collect information about strengths and difficulties. These visits can take place in the home, or at the Oxford BabyLab. The child will be provided with a small gift as a thank you and travel costs will be reimbursed.
3. Possibly taking part in a 12-week programme, 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, and 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 parent-and-toddler sessions, one each week. Each session lasts an hour. The sessions are held in a local venue and travel expenses will be reimbursed.

What are the possible benefits and risks of participating?
The child may enjoy the stimulating and fun games of the assessment visits. If allocated to the START programme, the child 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, toddlers will be given some toys to take home. If allocated to the START programme, the parent may benefit from the friendship and support of other parents in the group who will have similar-aged children and may find the discussions and activities useful in supporting the child's development. There are no major risks associated with taking part in the study. All the procedures in the assessment visits are non-invasive (only measurement of the child's behaviour) and the tasks are designed to be enjoyable. The parent may enjoy gaining a new perspective on the child's development, and ideas for games to play at home from the assessment visits. The researchers will not be making clinical diagnoses, but the child's scores can be made available after the visit to discuss with another health care or education specialist.

Where is the study run from?
The START programme group sessions will be held in community settings (e.g. a local play centre) in Oxford and in Havering. Participants choose whether the assessment visits take place in their home, or at the Oxford BabyLab.

When is the study starting and how long is it expected to run for?
March 2021 to February 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Alexandra Hendry, alexandra.hendry@psy.ox.ac.uk

Study website
https://startproject.info/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR300880, CPMS 51616

Study information

Scientific Title
Feasibility randomized controlled trial of the Supporting Toddlers with a family connection to autism or ADHD to develop strong Attention, Regulation and Thinking skills (START) programme: a comparison between START and Usual Practice

Acronym
START

Study objectives
The study's primary objectives are to assess the following:
1. The feasibility of recruiting eligible participants to the study and the most effective recruitment pathways to identify toddlers with a family history of autism/ADHD.
2. Recruitment rates and retention through randomization, intervention or Usual Practice, and follow-up.
3. The acceptability of study processes, including randomization and data collection and group sizes (4-8), to parent-participants through qualitative interviews.
4. The acceptability of intervention delivery, through quantitative data collection and qualitative interviews.
5. The feasibility of proposed outcome measures for a definitive RCT, in terms of sensitivity-to-change, coefficient-of-variance, floor- and ceiling-effect metrics, completion rates and loss of data due to participant refusal or invalid administration.
6. The feasibility of proposed measures of mediating factors in terms of coefficient-of-variance, floor- and ceiling-effect metrics, completion rates and loss of data due to participant refusal or invalid administration.
7. The feasibility of proposed measures of process evaluation in terms of completion rates and validity and reliability of the measures.
8. Adherence to the intervention and fidelity of implementation, through parent- and facilitator questionnaires, qualitative interviews and evaluation of session recordings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/12/2021, Medical Sciences Interdivisional Research Ethics Committee (Research Services, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, UK; +44 (0)1865 616577; ethics@medsci.ox.ac.uk) ref: R67115

Study design
Multicentre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Patient information material can be found at https://startproject.info/about-the-trial/

Health condition(s) or problem(s) studied
Development of executive functions in toddlers with a family connection to autism or ADHD

Interventions
Participants will be randomised on a 1:1 basis using an online tool to receive either the START intervention or the Usual Practice. START is a manualised programme comprising 12 weekly 1-hour group sessions, weekly ideas sheets and take-home resources, and access to resources for optional follow-up reading online. The sessions are semi-structured parent-child play sessions, comprising facilitator-led group discussion with parents (designed to outline core concepts and to elicit peer-to-peer support), parent-child activities, songs and story sharing relating to a particular attention, regulation or thinking skill – all of which are designed to support the parent-child relationship and provide enjoyable opportunities for toddlers' skill development. The project ethos is to support all children to thrive, whether they are neuro-divergent or neuro-typical, and there will be an emphasis on inclusivity (e.g. through making necessary adjustments to the setting and to the activities) and valuing neurodiversity. Facilitator session notes outline the key learning objectives and essential components, but also encourage facilitators to adapt the specific activities to suit their group with some suggestions on why and how to do this.

Intervention Type
Behavioural

Primary outcome measure
Parent report of Executive Functions measured using the Behaviour Rating Inventory of Executive Function, Preschool Version (BRIEF-P) questionnaire at baseline, endpoint (4-11 months) and follow-up (16 months)

Secondary outcome measures
1. Parent report of Executive Functions measured using the Early Executive Functions Questionnaire (EEFQ) at baseline, endpoint (4-11 months) and follow-up (16 months)
2. Secondary-carer report of Executive Functions measured using BRIEF-P questionnaire at follow-up (16 months)
3. Problem-solving ability measured using the Problem-Solving Box task at baseline, and follow-up (16 months)
4. Executive function performance measured using a battery of tasks at baseline, and follow-up (16 months)
5. Parent report of psycho-social difficulties measured using the Strengths & Difficulties Questionnaire (SDQ) at follow-up (16 months)

Overall study start date

01/03/2021

Completion date
01/02/2026

Eligibility

Key inclusion criteria
1. The child participant must have either of the following:
1.1. At least 1 first-degree relative with a community diagnosis (as reported by the parent) OR
1.2. At least 1 first-degree relative with presumed autism who scores above the clinical threshold on an autism screening measure OR
1.3. At least 1 first-degree relative with presumed ADHD who scores above the clinical threshold on an ADHD screening measure OR
1.4. Has been identified by their parent, or health or Early Years practitioner as showing high autistic traits

2. Is aged 20 months or less at the time of the eligibility screen, and older than 20 months at the time of the final scheduled intervention start date

Participant type(s)
Patient

Age group
Child

Upper age limit
20 Months

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Significant uncorrected visual or hearing problems
2. A known genetic condition associated with developmental delay (e.g. fragile X syndrome, Down's syndrome, neurofibromatosis type 1, tuberous sclerosis complex); note that an existing diagnosis of autism is not an exclusion criterion for the study
3. Currently placed in a 24-hour residential placement or a foster placement due to end before the 36-month follow-up data collection point
4. Any parent in their family has already participated in the START trial
5. They or any parent in their family has participated in a research trial involving a parenting intervention or other EF-related intervention (i.e. via an Early Childhood Education and Care setting) within 3 months of the baseline assessment, or during the course of the START trial

Date of first enrolment
13/02/2023

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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University of Oxford

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Sponsor type
University/education

Website
https://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.
The protocol for the feasibility trial will be submitted to the Pilot and Feasibility Studies journal.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyses during the current study will be stored in a non-publicly available repository, Oxford University Research Archive (https://ora.ox.ac.uk/). Where participants have explicitly consented to their de-identified data being made publicly available this will be stored in the OSF repository.

The type of data stored will comprise clinical summary scores, performance on cognitive tasks, behavioural ratings, and parent reports. To request access please email the PI (Alexandra.hendry@psy.ox.ac.uk). The data will be deposited by September 2026. Consent for data use within the research team will be collected from all participants. Consent for sharing outside the research team will be opt-in. All data will be de-identified before depositing.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol file	28/03/2024	No	No