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Nurturing Brazilian babies' early social and communication development in families with history of autism and attention-deficit /hyperactivity disorder (ADHD)

Submission date
16/08/2022

Recruitment status
No longer recruiting

Registration date
17/08/2022

Overall study status
Ongoing

Last Edited
25/06/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Infants with a first-degree family member with a diagnosis of autism or attention-deficit /hyperactivity disorder (ADHD) are more likely to meet diagnostic criteria for these conditions later in childhood. Many research studies have followed the development of these infants from the first months after birth into the early- and mid-childhood years. Those studies found that differences in social-communication, sensory processing, attention and self-regulation are seen in some of the infants from as early as the first year of life. These early developmental differences are associated with difficulties in day-to-day functional abilities and symptoms of autism and ADHD later in childhood. The research studies also found that parents of infants with family history of autism and ADHD tend to respond to their infants with lower sensitivity and responsiveness and greater directiveness in their day-to-day interactions. These findings are important because it is known that parental sensitivity, responsiveness and non-directiveness promote healthy child development.

Based on these findings, the iBASIS-VIPP therapy was designed to support the early development of infants with family history of autism. This therapy helps parents to use strategies in their day-to-day interactions with their infants. The strategies are designed to improve the parent's sensitivity, responsiveness, directiveness, empathy and understanding of their infant. The therapy also supports parents to better understand and respond to any early differences in infant behaviour, such as social-communication or attentional difficulties or altered sensory processing. The iBASIS-VIPP therapy was found to improve the early development of social-communication and some aspects of attention in infants with family history of autism in controlled studies in the UK and Australia. However, the therapy has not yet been tested for infants with family history of autism in other countries with fewer resources and different socioeconomic and cultural norms, such as Brazil. The iBASIS-VIPP therapy has also not been tested for infants with family history of ADHD, who may also benefit from the therapy.

The aim of the current study is therefore to assess how well the iBASIS-VIPP therapy works in supporting the early development of social-communication in infants with family history of autism and ADHD living in Brazil.

Who can participate?
Infants aged 6 months 0 days to 11 months 28 days and their primary caregiver can participate in the study if they meet the following criteria:
(1) the infant has (a) an older sibling or biological parent with a diagnosis of autism, or (b) an older sibling or biological parent with a diagnosis of ADHD
(2) the infant does not have a known genetic or neurological condition
(3) the infant was born with at least 36 weeks gestation and without serious birth complications, like asphyxia
(4) the infant does not have any visual or hearing disabilities that are not corrected (with glasses or hearing aids, for example)
(5) the infant's primary caregiver agrees to participate in the study and does not have a serious intellectual or psychiatric disability that would prevent them from participating in the intervention

What does the study involve?
Participants who decide to take part in this study will first be asked to sign a consent form. Next, each infant and their primary caregiver will visit the Department of Psychiatry at the University of São Paulo to complete some assessments. The assessments involve some play-based tasks with the infant that measure different aspects of the infant's development, a measure of the infant's brain activity using a painless and non-invasive technique called "electroencephalography" (EEG), a video-recorded interaction between the caregiver and the infant, and some questionnaires and interviews with the caregiver about the infant's development and the caregiver's own wellbeing and stress. Each infant and caregiver will then be randomly allocated, using a computer programme, to receive either the iBASIS-VIPP therapy or a control programme of psychoeducation for five months.

The caregivers who are allocated to receive the iBASIS-VIPP therapy will participate in ten fortnightly individual sessions with a trained therapist. The sessions will take place online via the video-call platform Google Meet. During each session, the therapist will record a video of the caregiver interacting with the infant. The therapist and the caregiver will watch the video of the interaction together and the therapist will help the caregiver to learn and use strategies that will support their infant's development. In between each of the sessions with the therapist, the caregiver will practice the strategies at home with the infant for 10-15 minutes per day.

The caregivers who are allocated to the control psychoeducation programme will receive general information about infant development for a period of five months. Each month, the caregiver will receive a link to a pre-recorded video-lecture in which a psychologist will present information about a different topic of infant development. The caregiver will be free to watch the video as many times as they like during the month.

At the end of the five months of the iBASIS-VIPP therapy or the psychoeducation programme, each infant and primary caregiver will return to the Department of Psychiatry at the University of São Paulo to repeat the assessments that were done at the first visit. Finally, each infant and caregiver will visit the Department of Psychiatry, University of São Paulo, for some final assessments when the infant is aged 24 months. The final assessments will once again include play-based tasks with the infant that measure the infant's development, a measure of brain

activity using EEG, a video-recorded interaction between the infant and the caregiver, and some questionnaires and interviews with the caregiver about the infant's development and the caregiver's own wellbeing and stress.

What are the possible benefits and risks of participating?
The main benefit of this study is the possibility of implementing a therapy that could support the development of infants who are vulnerable to developmental difficulties in Brazil. The assessments and the iBASIS-VIPP therapy and psychoeducation programme do not pose any risks but may lead to tiredness or discomfort due to the novelty and frequency of the activities. Caregivers will be free to withdraw at any time from the study, without any adverse consequences. Participants will be reimbursed for travel and food expenses during all study visits.

Where is the study run from?
The study is run from the Department of Psychiatry at the University of São Paulo in the city of São Paulo, Brazil.

When is the study starting and how long is it expected to run for?
February 2020 to April 2026

Who is funding the study?
The study is funded by the São Paulo Research Foundation (Brazil)

Who is the main contact?
Dr Elizabeth Shephard, lizzieshephard@usp.br

Study website
https://www.projetofloreah.com.br/

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
Nil known

Study information

Scientific Title
Efficacy of the parent-mediated iBASIS-VIPP intervention versus psychoeducation for supporting early social-communication development in infants with elevated familial likelihood of autism and attention-deficit/hyperactivity disorder (ADHD) in Brazil

Acronym
Floreah

Study objectives
The iBASIS-VIPP intervention will improve infants' social-communication development more than psychoeducation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/11/2021, University of São Paulo Medical School Ethics Committee (Rua Ovídio Pires de Campos 225, 5o andar, São Paulo, 05403-903, Brazil; +55 11 2661-7585; cappesq.adm@hc.fm.usp.br), ref: CAAE: 52449321.8.0000.0068.

Study design
Single-centre two-parallel group single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Support of early social-communication development in infants aged 6-11 months with family history of autism and attention-deficit/hyperactivity disorder (ADHD)

Interventions
Participants (infants with elevated familial likelihood of autism, N=100, or with elevated familial likelihood of ADHD, N=100, and their primary caregivers) are randomised to receive the iBASIS-VIPP intervention (n=50 infants with elevated familial likelihood of autism, n=50 infants with elevated familial likelihood of ADHD) or psychoeducation (n=50 infants with elevated familial likelihood of autism, n=50 infants with elevated familial likelihood of ADHD). Randomisation is conducted by an independent researcher who is not involved in the study other than to conduct the randomisation. The randomisation procedure is realised in MATLAB software using the Variance Minimisation Procedure (Sella et al., 2021, doi:10.3758/s13423-021-01970-5). Randomisation is stratified by familial likelihood group (autism or ADHD); infant age (in month) and sex are controlled to ensure groups differ as little as possible in these characteristics.

iBASIS-VIPP intervention:
The iBASIS-VIPP intervention is a parent-mediated intervention designed to support the early social-communication development of infants aged 6-18 months. The intervention consists of ten fortnightly sessions between a trained therapist and the infant's primary caregiver delivered over five months. In each session, the therapist uses video-feedback of an interaction between the caregiver and the infant to guide the caregiver in developing skills and strategies to (1) enrich the infant's socio-communicative environment, and (2) help the caregiver recognise, understand and support any early appearing differences in social-communicative, repetitive, attentional or sensory behaviour in the infant. All therapist sessions are conducted online via a video-conferencing program. Between each therapeutic session, the caregiver practices the strategies at home with the infant every day for approximately 10-15 minutes.

Psychoeducation (control) intervention:
The psychoeducation intervention acts as a control condition against which the efficacy of the iBASIS-VIPP intervention will be compared. The psychoeducation intervention consists of five pre-recorded videos in which a psychologist delivers psychoeducational information about different aspects of early child development. Each of the five videos covers a different area of child development: 1) early brain and motor skills development, 2) cognitive and language development, 3) social-communication development, 4) early development of autism, 5) early development of ADHD. The videos are shared via a link with each primary caregiver allocated to the psychoeducation intervention individually at a frequency of one video per month for a duration of five months. The primary caregiver is asked if they watched each video at the end of each month.

Total duration of intervention (iBASIS-VIPP or psychoeducation) is five months. Assessments are conducted at baseline (Time 1: trial month 0), post-intervention (Time 2: trial month 6) and at follow-up when the infants reach age 24 months (Time 3: age 24 months).

Intervention Type
Behavioural

Primary outcome measure

Social-communication ability measured using an examiner-coded play-based interaction assessment (the Communication and Symbolic Behavior Scales) at Time 1 (trial month 0) and Time 2 (trial month 6).

Secondary outcome measures

Current secondary outcome measures as of 11/04/2023:
1. Parent-child interaction synchrony and parental sensitive responsiveness and non-directiveness measured using the examiner-coded Manchester Assessment of Caregiver-infant Interaction (MACI) from videos of natural interactions of the caregiver and infant at Time 1 (month 0) and Time 2 (month 6) and with the examiner-coded Joint Engagement Rating Inventory (JERI) at Time 3 (at age 24 months)
2. Traits of autism measured using the examiner-coded Autism Diagnostic Observation Scale – 2nd Edition (ADOS-2) and the parent-rated Social Responsiveness Scale – 2nd Edition – Preschool Version at Time 3
3. Traits of attention-deficit/hyperactivity disorder (ADHD) measured using the examiner-coded Behavioral Rating Inventory for Children (BRIC) and the ADHD Coding Project at Time 1, Time 2 and Time 3 and using the parent-rated Child Behavior Checklist (CBCL) at Time 3
4. Self-regulatory ability and executive function measured using the parent-rated Infant Behavior Questionnaire-Revised/Early Childhood Behavior Questionnaire and the examiner-coded Reverse Categorisation, Spin the Pots and Glitter Wand tasks at Time 3
5. Adaptive functioning measured using the Vineland Adaptive Behavior Scales III Parent-Interview at Time 1, Time 2 and Time 3
6. Development of cognitive, language and motor abilities assessed using the examiner-coded Bayley Scales of Infant Development III at Time 1, Time 2 and Time 3
7. Language development measured using the parent-report McArthur-Bates Communication Development Inventories at Time 1, Time 2 and Time 3
8. Parental stress measured with the parent-report Depression, Anxiety and Stress Scale – 21 (DASS-21) at Time 1, Time 2 and Time 3
9. Environmental noise in the family home measured with the Confusion, Hubbub and Order Scale (CHAOS) at Time 1, Time 2 and Time 3
10. Neurodevelopment measured using electroencephalography (EEG) at Time 1, Time 2 and Time 3

Previous secondary outcome measures:
1. Parent-child interaction synchrony and parental sensitivity, responsiveness and non-directiveness measured using the examiner-coded Manchester Assessment of Caregiver-infant Interaction (MACI) from videos of natural interactions of the caregiver and infant at Time 1 (month 0) and Time 2 (month 6) and with the examiner-coded Dyadic Communication Measure of Autism (DCMA) at Time 3 (at age 24 months)
2. Traits of autism measured using the examiner-coded Autism Diagnostic Observation Scale – 2nd Edition (ADOS-2) and the parent-rated Social Responsiveness Scale – 2nd Edition – Preschool Version at Time 3
3. Traits of attention-deficit/hyperactivity disorder (ADHD) measured using the examiner-coded Behavioral Rating Inventory for Children (BRIC) and the ADHD Coding Project at Time 1, Time 2 and Time 3 and using the parent-rated Child Behavior Checklist (CBCL) at Time 3
4. Attention measured using the examiner-coded ADHD Coding Project, electrophysiological indices of attentional processing, and parent-rated attention on the Infant Behavior Questionnaire-Revised/Early Childhood Behavior Questionnaire
5. Self-regulatory ability measured using the parent-rated Infant Behavior Questionnaire-Revised /Early Childhood Behavior Questionnaire and examiner-coded frustration at Time 1, Time 2 and Time 3

6. Executive function measuring using the examiner-coded Knock & Tap task at Time 3
7. Adaptive functioning measured using the Vineland Adaptive Behavior Scales III Parent-Interview at Time 1, Time 2 and Time 3
8. Development of cognitive, language and motor abilities assessed using the examiner-coded Bayley Scales of Infant Development III at Time 1, Time 2 and Time 3
9. Language development measured using the parent-report McArthur-Bates Communication Development Inventories at Time 1, Time 2 and Time 3
10. Neurodevelopment measured using electroencephalography (EEG) at Time 1, Time 2 and Time 3
11. Parental stress measured with the parent-report Depression, Anxiety and Stress Scale – 21 (DASS-21) at Time 1, Time 2 and Time 3
12. Environmental noise in the family home measured with the Confusion, Hubbub and Order Scale (CHAOS) at Time 1, Time 2 and Time 3 .

Overall study start date
01/02/2020

Completion date
30/04/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/04/2023:
Eligible participants are infants and their primary caregivers. Infants must:
1. be aged between 6 months 0 days and 11 months 28 days
2. have either (a) an older sibling or biological parent with autism (diagnosed or suspected) or (b) an older sibling or biological parent with ADHD (diagnosed or suspected)

Previous inclusion criteria:
Eligible participants are infants and their primary caregivers. Infants must:
1. be aged between 6 months 0 days and 11 months 28 days
2. have either (a) an older sibling with autism (diagnosed or suspected) or (b) an older sibling or biological parent with ADHD (diagnosed or suspected)

Added 16/09/2022:
Note on criterion 2: the difference in inclusion criteria for the infants with a family history of autism and infants with a family history of ADHD is to remain consistent with previously published studies with infants with a family history of autism and ADHD. That is, while the past work with infants with a family history of ADHD has included infants with an older sibling or parent diagnosed with ADHD, the past work with infants with a family history of autism has only included infants who have an older sibling diagnosed with autism and not a parent diagnosed with autism.

Participant type(s)
Other

Age group
Mixed

Sex

Both

Target number of participants
200

Key exclusion criteria
Infants and their primary caregivers will be excluded if:
1. the infant has a known genetic or neurological condition
2. the infant was born with significant prematurity, i.e., born at less than 36 weeks gestation
3. the infant had significant birth complications e.g., asphyxia
4. the infant has uncorrected visual or auditory disability
5. the primary caregiver that would participate in the trial has intellectual disability or serious psychiatric or medical condition that would interfere with the intervention

Date of first enrolment
10/04/2022

Date of final enrolment
01/07/2024

Locations

Countries of recruitment
Brazil

Study participating centre
Instituto de Psiquiatria da Faculdade de Medicina da Universidade de São Paulo
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Sponsor information

Organisation
Universidade de São Paulo

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Sponsor type
University/education

Website
https://ipqhc.org.br/

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
Government

Funder Name
Fundação de Amparo à Pesquisa do Estado de São Paulo

Alternative Name(s)
São Paulo Research Foundation, State of São Paulo Research Foundation, Foundation for Research Support of the State of São Paulo, FAPESP

Funding Body Type
Private sector organisation

Funding Body Subtype
Local government

Location
Brazil

Results and Publications

Publication and dissemination plan
The results of this study will be published in international, peer-reviewed scientific journals and presented at international conferences. The findings will also be shared in a lay-reader format with families participating in the study and via social media.

Intention to publish date
30/04/2027

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		24/06/2024	25/06/2024	No	No
Statistical Analysis Plan		24/06/2024	25/06/2024	No	No