

A clinical trial to assess the effectiveness and barriers to implementation of Paediatric Autism Communication Therapy (PACT) in the Brazilian public health system

Submission date 12/12/2025	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 16/12/2025	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 16/12/2025	Condition category Mental and Behavioural Disorders	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

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Additional identifiers**Study information****Scientific Title**

A hybrid effectiveness-implementation study of Paediatric Autism Communication Therapy (PACT) in the Brazilian public health system

Acronym

Conecta

Study objectives

- 1.To test the real-world effectiveness of Paediatric Autism Communication Therapy (PACT) in improving child social-communication skills, caregiver-child interaction and family well-being as implemented at national scale in the Brazilian Public Health Service (SUS).
2. Use three implementation frameworks to systematically investigate barriers and facilitators to the implementation of PACT in SUS.

Ethics approval required

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Ethics approval(s)

Approved 14/10/2025, Research Ethics Committee of the Institute of Psychology, University of São Paulo (Av. Prof. Mello Moraes, 1.721, Bloco G, 2º Andar, sala 27, Cidade Universitária, São Paulo, 05508-030, Brazil; +55 1130914182; cep.ip@usp.br), ref: 86935425.6.0000.5561

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Uncontrolled

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Improvement of social communication development and caregiver-child interaction in autistic children and their primary caregivers attending public healthcare services in Brazil

Interventions

This is a type I hybrid effectiveness-implementation trial, designed to test the clinical effectiveness of PACT in the Brazilian public health service while collecting data on implementation barriers and facilitators. We will recruit public health services that support autistic children across the five regions of Brazil (at least two services per region). All eligible professionals of the services will be trained to manual fidelity in PACT and deliver the intervention (14 sessions over 6 months per family) to dyads of autistic children aged 2-10 years and their caregivers in their regular clinical practice for a period of 18 months. After consent, dyads will be randomised using Variance Minimisation within each service to receive PACT immediately or following a 6-month waitlist period during which they will receive care-as-usual. Primary and secondary outcomes will be assessed at baseline (pre-PACT/pre-waitlist) and at 6-month end-point (post-PACT/post-waitlist). Data on barriers and facilitators to implementation will be collected throughout the 18-month trial period.

Intervention Type

Behavioural

Primary outcome(s)

1. DCMA Synchrony measured using using the Dyadic Communication Measure for Autism (DCMA) synchrony subscale (DCMA Synchrony) during naturalistic caregiver-child interactions and quantified at baseline and 6-month end-point

Key secondary outcome(s)

1. DCMA Child Initiations measured using using the Dyadic Communication Measure for Autism (DCMA) Child Initiations subscale (DCMA Child Initiations) during naturalistic caregiver-child interactions and quantified at baseline and 6-month end-point

2. Child adaptive functioning measured using caregiver and teacher reports using the Vineland Adaptive Behavior Scales 3rd Edition Standard Scores for the domains of Communication, Socialization and Daily Living and the Adaptive Behavior Composite at baseline and 6-month end-point

3. Child well-being measured using caregiver and teacher report using the Brazilian Portuguese version of the Strengths and Difficulties Questionnaire Parent/Teacher 2-4 version for children aged 2-3 years and Parent / Teacher 4-17 Version for children aged 4-10 years. Total scores for the Emotion, Conduct, Hyperactivity/Attention, Peer Relationship and Prosocial scales will be used at baseline and 6-month end-point

4. Family well-being measured using caregiver report using the Autism Family Experience Questionnaire (AFEQ) at baseline and 6-month end-point

5. Caregiver capacity to reflect on and understand their own and their child's internal mental experiences and how they relate to their child's behaviour measured using caregiver report using the Portuguese version of the Parental Reflective Functioning Questionnaire at baseline and 6-month end-point

Completion date

28/02/2028

Eligibility

Key inclusion criteria

Participants of this study will be healthcare professionals and managers of Brazilian public health services that offer support to young autistic children, as well as autistic children and their primary caregivers who are attended at these services.

Eligible services will be those that:

1. Offer clinical support to autistic children delivered by clinical psychologists, speech therapists and/or occupational therapists;
2. Those that represent sociodemographic and cultural diversity across the five regions of Brazil.

Healthcare professionals will be considered eligible if they:

1. Have permanent contracts with the services;
2. Already work using any clinical intervention with autistic children.

Autistic children attended at the public health services will be considered eligible for inclusion in the trial if they:

1. Hold a diagnosis of autism or present signs of autism or social communication difficulties (as established by the service's standard assessments);
2. Are aged 2 years 0 months to 10 years 11 months at the point of recruitment (the age-range for PACT);
3. Their primary caregiver agrees to participate in the trial.

Healthy volunteers allowed

No

Age group

Child

Lower age limit

24 Months

Upper age limit

131 Months

Sex

All

Total final enrolment

0

Key exclusion criteria

Public healthcare services will be excluded if they:

1. Do not offer supports for autistic children;
2. Are temporary services;
3. Depend on research funding for provision of autism interventions.

Healthcare professionals will be excluded if:

1. They have no experience of working with autistic children;
2. They do not wish to receive training in and deliver PACT in the healthcare service.

Caregiver-child dyads will be excluded from the study if:

1. They do not wish to receive PACT.

Date of first enrolment

02/02/2026

Date of final enrolment

30/08/2027

Locations

Countries of recruitment

Brazil

Sponsor information

Organisation

University of Sao Paulo

Funder(s)

Funder type

Funder Name

Fundação de Amparo à Pesquisa do Estado de São Paulo

Alternative Name(s)

A Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP), 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

Trusts, charities, foundations (both public and private)

Location

Brazil

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available