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Communication-centred parent-mediated treatment for autism spectrum disorder in South Asia

Submission date
08/06/2018

Recruitment status
No longer recruiting

Registration date
22/06/2018

Overall study status
Completed

Last Edited
24/03/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims

Eighty percent of the world's children with Autism Spectrum Disorders (ASD) live in low resource settings. Recent evidence from high-income countries supports the effectiveness of targeted parent-mediated interventions for the early treatment of children with ASD. Interventions that are delivered through parents have the additional advantages of improving parental knowledge and morale, potentially promoting the social empowerment of mothers, generalising into improvements in the family environment for the child and thus potentially conferring long-term impacts on the social context, the child's environment and functional outcomes. The Pre-school Autism Communication Therapy (PACT) trial conducted in the UK is the largest yet trial of this kind. It is targeted at getting parents to recognize their child's social communication difficulties and to create an environment which gives the child a space and time to communicate at their own pace. This intervention uses video feedback techniques to work with parents to enhance their understanding and responsiveness to the atypical communications of young children with autism. The trial showed that children with ASD who received this treatment benefited from the enriched communication environment that their parents were able to create; this in turn had a positive impact on the social interactions the children initiated. More importantly these changes in parent-child interaction and independent communication from the child were sustained in a follow-up study after six years which demonstrated a decrease in autism symptoms in children who received the intervention. The intervention has now been successfully adapted for use in South Asia, including relevant cultural adaptation to enhance parental acceptability, developing a supervision and training cascade to allow the intervention to be delivered by community-based non-specialist workers, and delivery of the intervention at home. The resulting Parent mediated intervention for Autism Spectrum Disorders in South Asia (PASS) was subsequently evaluated in a pilot trial which demonstrated its acceptability, feasibility and efficacy. Subsequently, the team in India have developed and piloted a complementary comorbidity package creating a comprehensive intervention for children with ASD in the 2-9 year age group (PASS Plus). Evaluation methods have also been adapted and tested in both of these pilot studies. Most children with ASD in India and other low resource settings do not receive evidence-based care which the proposal investigators have shown can reduce the symptoms of ASD and is feasible and acceptable for delivery in the proposed study setting. The proposed trial will build on this

pilot work already carried out in India, and will carry out the largest, definitive, trial of the intervention, involving 240 participants recruited through two tertiary government hospitals in the capital city of New Delhi, which cater to an urban poor population. The intervention will be delivered through existing health system frontline workers. The trial will evaluate the effectiveness and cost effectiveness of the intervention on symptoms of ASD and parent-child interaction as well as more general impacts on child functioning, parental well-being and social empowerment. COMPASS will be the largest trial of its kind for ASD in any low resource setting and the evidence generated will have an impact not only health policy and practice in India, home to over 5 million children with ASD, but also other low resource settings in the region.

Who can participate?
Children aged 2 years to 9 years 11 months with Autism Spectrum Disorder

What does the study involve?
Participants are randomly allocated to receive the PASS-Plus intervention with Treatment-as-Usual (TAU) or TAU only. PASS-Plus is a manualised and piloted adaptation of the UK Pre-school Autism Communication Therapy (PACT) that uses video feedback with parents to help them enhance social communication in their autistic child. It is delivered by existing health system frontline workers in 12 home-based sessions. TAU in the two recruitment centres is delivered through autism clinics. Autism symptom severity is measured after 9 months.

What are the possible benefits and risks of participating?
This trial is a fair and rigorous test of whether the PASS-Plus therapy, when delivered by health workers in India, is effective in helping children with autism and their parents. If it is shown to be effective this will have implications for autism provision across India and in other Low and Middle Income Countries. Participation in COMPASS is an opportunity to be part of this wider aim. It is not anticipated that this study will result in any disadvantages or risks to families and no unwanted effects from this therapy have been found in previous studies. For all families there is of course a time commitment required for the assessment visits. For families allocated to usual services plus the PASS+ therapy, additional time is needed for therapy sessions and home practice. This may have effects on family life. In previous studies, families found the assessment process and intervention generally acceptable.

Where is the study run from?
1. All India Institute of Medical Sciences (India)
2. Lok Nayak Jai Prakesh Narayan Hospital (India)

When is the study starting and how long is it expected to run for?
April 2018 to March 2024

Who is funding the study?
Joint Global Health Trials Programme; Medical Research Council, Department for International Development, National Institute for Health Research, and the Wellcome Trust (UK)

Who is the main contact?
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Contact information

Type(s)

Public

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Communication-centred parent-mediated treatment for autism spectrum disorder in South Asia

Acronym
COMPASS

Study objectives
1. To evaluate the effectiveness at scale of a parent-mediated intervention for Autism Spectrum Disorders in South Asia, delivered by non-specialists in community health settings
2. To investigate the cost-effectiveness of the intervention
3. To generate tools and evidence for policy makers to guide the scale up the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 22/07/2019:
1. Approved 28/03/2019, Sangath Institutional Review Board, India, ref: VP_2017_31
2. Approved 28/12/2018, Indian Council of Medical Research, ref: 2017-4745
3. Approved 12/07/2018, All India Institute of Medical Sciences, ref: IEC-282/01.06.2018, RP-6 /2018
4. Approved 25/06/2018, Maulana Azad Medical College Lok Nayak Hospital, New Delhi, India, ref: F1/IEC/MAMC/162/02/2018 No 296
5. Approved 21/05/2019, University of Manchester UK Research Ethics Committee, ref: 2019-5223-10622

Previous ethics approval:
1. The Sangath Institutional Review Board, India, 18/11/2017
2. The Indian Council of Medical Research - approval pending
3. All India Institute of Medical Sciences - approval pending
4. Lok Nayak Hospital India - approval pending
5. The University of Manchester UK Research Ethics Committee - approval pending

Study design
Two-centre two-arm single (rater) blinded random allocation parallel-group study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism spectrum disorder

Interventions
PASS-Plus + Treatment-as-Usual (TAU) vs TAU.

PASS-Plus is a manualised and piloted adaptation of the UK Pre-school Autism Communication Therapy (PACT) that uses video-feedback with parents to help them enhance social communication in their autistic child. It will be delivered by existing health system frontline workers, in 12 home-based sessions.

TAU in the two recruitment centres is delivered through autism clinics and will be specified during the start-up phase.

Primary endpoint at 9 months, with follow-up at 15 months.

Intervention Type
Behavioural

Primary outcome(s)
Autism symptom severity measured by the blind-rated Brief Observation of Social Communication Change at 9 months post-baseline

Key secondary outcome(s))
Parent-child communication, child adaptation, child quality of life, and parental wellbeing measured at 9 and 15 months post-baseline

Completion date
23/03/2024

Eligibility

Key inclusion criteria

1. Child aged 2 years 0 months to 9 years 11 months
2. Child has a clinical diagnosis of Autism Spectrum Disorder (ASD) and fulfils ASD criteria on the INCLEN Diagnostic Tool for Autism Spectrum Disorder (INDT-ASD), a DSM-based clinical diagnostic algorithm developed in India and validated against specialist assessment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 years

Upper age limit
9 years

Sex
All

Key exclusion criteria
1. Significant hearing or visual impairment in child or parent
2. Child developmental age of <12 month equivalent (as assessed by research team)
3. Child with epilepsy with a seizure in the previous 6 months
4. Residence outside of pre-specified recruitment area within the National Capital Region Territory (Delhi, India)

Date of first enrolment
01/08/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
India

Study participating centre
All India Institute of Medical Sciences
New Delhi
India
110029

Study participating centre
Lok Nayak Jai Prakesh Narayan Hospital
New Delhi
India
110002

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research organisation

Funder Name
Joint Global Health Trials Programme; Medical Research Council, Department for International Development, National Institute for Health Research, and the Wellcome Trust

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/10/2023	16/10/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes