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Parent-mediated Intervention for Autism Spectrum disorders in South Asia

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/05/2013	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/01/2019	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The vast majority of children with Autism Spectrum Disorders (ASD) live in low and middle-income countries and have no access to effective interventions or services. Most of the researches in interventions for ASD that work have been conducted in richer countries with relatively large numbers of ASD specialist therapists. One of the best-researched interventions, in which parents are trained to help their children communicate, has been found to work very well in the UK (the PACT intervention). The aim of this study is to adapt this intervention carefully so that it can be used by parents of children living in low-income countries. Furthermore, because there are very few specialists in these settings, the study will explore the impact of the delivery of the intervention by trained and supervised non-specialists.

Who can participate?
Children aged 2-9 years with an Autism Spectrum Diagnosis.

What does the study involve?
The study will have three phases. In the first phase, we will talk to parents who have children with ASD, about their experiences. We will also talk to people who may have tried to help these parents and their children and to local experts who are involved in developing services for children. Using this information, the team from the UK will work with local experts to make necessary changes to the intervention so that it can work in these south Asian settings.
In the second phase we will test the PASS communication intervention to find out if it works, by delivering it to 30 children with ASD and comparing them to another 30 children who will not receive the intervention. The children, who will be recruited from Goa and Rawalpindi, will be randomly allocated into treatment and control groups in such a way each child has an equal chance of being in either group. We will analyse the effects after 8 months and one year by carrying out a number of tests for parent-child interaction, the childs social functioning.
In the third phase, we will analyse the results of our study and publish them through conferences and papers for journals. We feel this project is important because it aims to develop an intervention that has the potential to be used by many families in poor communities; it uses our expertise of simplifying interventions so they can be delivered by non-specialists; and because it has the potential for being taken up at a larger scale by health planners.
What are the possible benefits and risks of participating?

All families in this study (i.e. those in both the intervention and non-intervention groups) will have detailed assessments from skilled professionals and will have feedback about the results of these. The research team will be in touch with all families regularly through the study to find out how they are progressing and to hear their experiences. Half of the families involved will receive the PASS communication intervention which may be helpful to children and families. The results of this study should assist in the development of autism treatments throughout the UK.
There is a time commitment requirement on behalf of families. Otherwise we do not anticipate that this study will result in any disadvantages or risks to families.

Where is the study run from?
The project will be conducted in Goa, India and Rawalpindi, Pakistan, sites situated in a region with the highest number of children and the greatest unmet need for interventions in autism.

When is the study starting and how long is it expected to run for?
The study started in March 2013 and will run till April 2014.

Who is funding the study?
Autism Speaks Global Autism Public Health Initiative, USA

Who is the main contact?
Prof Atif Rahman
Atif.Rahman@liverpool.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Atif Rahman

Contact details
University of Liverpool
Institute of Psychology, Health & Society
Child Mental Health Unit
Alder Hey Children's NHS Foundation Trust
Mulberry House, Eaton Road
Liverpool
United Kingdom
L12 2AP

Additional identifiers

Study information

Scientific Title
Parent-mediated Intervention for Autism Spectrum Disorders in South Asia: A two-site two-arm single-blinded randomised controlled trial

Acronym

PASS

Study objectives
The aims of this exploratory RCT will be to test:
1. The feasibility and acceptability of the implementation of intervention and trial design in South Asian settings
2. The success of the task-shifting approach (use of community health workers to deliver the intervention) in delivering fidelity to the intervention model
3. The effectiveness of the adapted model in replicating treatment effects found in the UK PACT intervention allowing power estimation for further large trials

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Indian Council of Medical Research, New Delhi, India, 27/12/2012, ref: Indo-Foreign/34/M /2012-NCD-1
2. Sangath Institutional Review Board, Goa, India, 09/01/2012, ref: VP_2012_01

Primary study design
Interventional

Study design
Two-site two-arm single-blinded randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism Spectrum Disorders

Interventions
Intervention: 30 children will receive an adaptation of the parent-mediated video-aided communication-focussed PACT (Pre-school Autism Communication Therapy) approach, a theory-based, relatively low intensity, manualised intervention and evidenced in the PACT trial (Green et al 2010)

Control: 30 children will receive routine care for children with ASD

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Parent-child dyadic social communication, rated on the Dyadic Communication Measure for Autism (DCMA) at 8 months after intervention (updated on 23/07/2013: original record stated "6 months after intervention")

Key secondary outcome(s)

1. The Communication and Symbolic Behaviour Scales
2. The Vineland Adaptive Behaviour Scale, Parent/Caregiver Rating
3. Count of child word use and mean length of utterance within parent-child interaction
Measured at 8 months after intervention (updated on 23/07/2013: original record stated "6 months after intervention")

Completion date
30/04/2014

Eligibility

Key inclusion criteria
Children aged 2-9 years with an Autism Spectrum Diagnosis, fulfilling ASD criteria on the IDEA algorithm and with a developmental level above 12 months

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. Clinically severe psychiatric impairment in parent

Date of first enrolment
01/03/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
United Kingdom

England

India

Pakistan

Study participating centre
University of Liverpool
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
University of Liverpool (UK)

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Other

Funder Name
Autism Speaks Global Autism Public Health Initiative (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016	21/01/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes