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Autism identification and moving towards treatments (Swamagnata Aakalan and Upacharachi Disha [SAAD])

Submission date
08/01/2016

Recruitment status
No longer recruiting

Registration date
27/01/2016

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Children with autism have difficulty communicating with others, whether this is to satisfy their own needs (for example asking for food when hungry), sharing an interest (for example, why they like the toy they are playing with) or expressing their feelings (for example, coming to you and showing you where they are hurt). Children with autism may also have other difficulties which may prove to be challenging, such as being very restless throughout the day or having difficulties with their sleep routines. For such behaviours there are specific strategies that can often help the child to develop better routines. We have developed an intervention called 'PASS' (Parent-mediated Intervention for Autism Spectrum Disorders in South Asia) that helps to improve communication abilities in children with autism. PASS is based on working with parents in a natural setting (usually the home) and using videos of the parent and child at play to help parents pin-point how they can increase opportunities to share and communicate with their child. In addition to the communication intervention, advice will be given to help with any other problems which may be present. We would like to recommend this intervention to all children with autism; however, we need to know whether this intervention is effective. Through our office in Kolhapur, we plan to see whether this combined PASS+ intervention makes a difference to children with autism and their families in the areas of communication and co-existing problems.

Who can participate?
40 families with a child with autism between the ages of 2 and 9 years.

What does the study involve?
Participants are randomly allocated into two groups. One group continues with the current treatment they receive while the other group continues with the current treatment and in addition receives the PASS+ intervention. Families allocated to the the PASS+ intervention receive 12 sessions with a PASS+ facilitators over 8 months. All the intervention sessions are free of cost. All children in both groups receive a detailed assessment at the start and the end of an 8-month period. During these assessments, the researcher assesses the child's social and communication abilities, their level of language, and their general level of learning ability.

Through questionnaires and interviews, we gather detailed information about the child's development and current functioning at home, the parents' experiences, their understanding of their child's problem, and the impact that these have had on their lives. We will look at the way that the parents and children communicate and interact together, including observations of their typical communication styles. Finally we gather information about any help or services that participants may have received over the previous 6 months and additional expenses that they may have incurred as a consequence of their child's difficulties. Some of the assessments in the clinic are videotaped to allow us to study them afterwards for our research information gathering. These videotapes are kept safe and secure in our research unit along with all other documentation and are destroyed after an agreed period at the end of the study. After 8 months we repeat some of the assessments that we did at the beginning of the study on all the children. Participants' expenses in relation to these research assessments are reimbursed. All the study participants receive a comprehensive report after the second closing assessment at 8 months.

What are the possible benefits and risks of participating?
All families in this study will have detailed assessments from skilled professionals at the beginning and the end of the study with which will be given to the family as a detailed report. The PASS+ research team will be in touch with all of you regularly through the study to find out how you are progressing and to hear your experiences and reactions. You will have an opportunity to make evaluations of the treatments that you receive and to talk about any difficulties you faced. Most families find this useful. The treatments that you have during the study including the PASS+ intervention may be helpful to you and your family. Most excitingly, the results of this study will help in the development of autism treatments throughout India. We do not anticipate that this study will result in any disadvantages or risks to families. We have not found any unwanted effects from this intervention. Clearly it takes additional time in relation to the session and the homework practice. In our previous study conducted in Goa, families found the intervention very acceptable and no adverse consequences were encountered.

Where is the study run from?
The Sangath Institute central office in Goa and implementation office in Kolhapur, India.

When is the study starting and how long is it expected to run for?
January to December 2016

Who is funding the study?
Grand Challenges Canada

Who is the main contact?
Dr Leena Gaikwad, +91 (0)77200 74076
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Study website
http://sangath.com/inside_page.php?nav_id=483

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1.1

Study information

Scientific Title
Parent-mediated intervention for Autism Spectrum Disorders in South Asia Plus (PASS+)

Acronym
PASS+

Study objectives
H0 - The PASS+ (Parent-mediated intervention for Autism Spectrum Disorders in South Asia Plus) intervention is not as effective as routine care for children with Autism Spectrum Disorders (ASD).

H1 - The PASS+ (Parent-mediated intervention for Autism Spectrum Disorders in South Asia Plus) intervention is more effective than routine care for children with Autism Spectrum Disorders (ASD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sangath Institutional Review Board (IRB) and Health Ministry Scientific Committee (HMSC) /Indian Council of Medical Research (ICMR), 09/10/2015, ref: GD_2014_13

Study design
Single-site, two-parallel group, single (assessor) blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Autism Spectrum Disorder (ASD)

Interventions
A single-site, two-parallel group, single (assessor) blinded randomized controlled trial of the PASS+ intervention compared to routine care for children with Autism Spectrum Disorders (ASD).

Treatment arm
The PASS+ intervention will be delivered to the participants of the intervention arm which at its core targets the social communication impairments in autism. The aim of the core intervention is to increase parental sensitivity and responsiveness to their child’s communication and reduce over-directive parental responses which are delivered through video-feedback by addressing the

parent-child interaction during a play session. The incremental development of the child's communication is helped by the promotion of a range of strategies such as action routines, familiar repetitive language, and pauses within a culturally adapted, manualised and staged intervention which represents the developmental progression of early language skills (see web appendix: http://sangath.com/images/file/PASS_Manual_web-2015.pdf). The pace of work is individualised to the parent and child's specific needs and progress and interim goals are reached before moving to the next stage. The PASS intervention has been evaluated through a two-arm pilot randomised control trial (ISRCTN79675498) and the publication is in press. The Plus component is an additional manualised intervention to address the common comorbidities found in children and families of children with autism. This includes a general psychoeducation package, and modules to address sensory integration, feeding, toileting, sleeping and behavioural problems along with a module for supporting maternal mental health. Each module comprises of a treatment decision algorithm to help identify a specific problem which then leads to stepwise advice for the care-giver. This Plus component will be introduced in the second month of the intervention period and the facilitator will be guided to the appropriate module based on the needs of the individual child and family. As in the main PASS intervention goals will be set for the parent in addition to the PASS communication goals which will be reviewed at the subsequent sessions. Clear guidelines for referral to the supervisor are included in the manual.

Control arm
This arm will receive routine care which includes a mixed service comprised of an eclectic approach of behavioural modification, physiotherapy, speech and language therapy and special education depending on the access families have to local services.

Analysis of the primary treatment effect will be undertaken 8 months after enrolment.
Analysis of treatment effects will be on an intention-to-treat basis.

Intervention Type
Behavioural

Primary outcome measure
1. ASD symptoms: Brief Observation of Social Communication Change (BOSCC), Janina, K., et al (2014)
2. Synchronous parent acts: Dyadic Communication Measure for Autism (DCMA), Green. J., et al (2010)

At baseline - from January 2016 to March 2016
At endpoint - from July 2016 to November 2016

Secondary outcome measures
1. Adaptive scores : Vineland Adaptive Behaviour Scale, Sparrow, S. S., et. al. (2006).
2. Maternal mental health: Patient Health Questionnaire – 9, Patel, V., et al. (2008).
3. Impact of comorbid problems: Developmental Behaviour Checklist (DBC), Witwer. A N. and Lecavalier. L. (2007)
4. Parental acceptance of the condition in their child: Research in Autism for Families in India (RAFIN), Rachel, B., et al (2013)
5. Parent competence in managing difficulties experienced by their child as a result of ASD: Research in Autism for Families in India (RAFIN), Rachel, B., et al (2013)
6. Empowerment experienced by the family: Research in Autism for Families in India (RAFIN), Rachel, B., et al (2013)

At baseline - from January 2016 to March 2016
At endpoint - from July 2016 to November 2016

Overall study start date
13/01/2016

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Children aged 2-9 years
2. Developmental age of > 1 year
3. Fulfilling the criterion of Autism Spectrum Disorder as defined in INCLEN Diagnostic Tool for ASD (INDT-ASD)
4. Developmental age 1 year or above
5. Residence within study area of the trial

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Children with epilepsy with uncontrolled seizures
2. Significant hearing or visual impairment in the child or parent
3. Severe psychiatric illness in parents
4. Residence outside study area of the trial

Date of first enrolment
15/01/2016

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
India

Study participating centre
Sangath
D3
Atharva Vishwa apartment
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Sponsor type
Research organisation

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ROR
https://ror.org/00y3z1g83

Funder(s)

Funder type

Not defined

Funder Name
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Results of the trial will be communicated to the participants, community stakeholders , health professionals, the PASS+ Technical Advisory Group members through dissemination workshops.

We intend to produce at least 2 publications after the completion of the study which will be disseminated through peer-reviewed journals and will be open access.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	24/01/2019	Yes	No