ISRCTN18062495 https://doi.org/10.1186/ISRCTN18062495

Neurodevelopment and autism in South Asia

Submission date
07/01/2026

Recruitment status
Recruiting

Registration date
15/01/2026

Overall study status
Ongoing

Last Edited
14/01/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Early identification and support for neurodevelopmental disabilities (NDDs), including autism spectrum disorder (ASD), can improve child outcomes and lessen severity of future impairments. However, despite high prevalence of NDDs in South Asia, the region lacks affordable and quality resources to meet children's complex social, medical, and educational needs. This exacerbates difficulties for families and communities. Task-shifting, i.e., a process of restructuring the workforce in a way where responsibilities are shifted from a highly specialised workforce to one with relatively fewer qualifications might pose a solution to this concern.

Leveraging the potential of task-shifting, the Neurodevelopment and Autism in South Asia: Treatment and Evidence (NAMASTE) implementation programme aims to strengthen existing public health and care systems within four sites in South Asia: Delhi and Goa in India, Colombo in Sri Lanka, and Godawari in Nepal. The programme is empowering a team of specialist and non-specialist health and care providers to screen children for NDDs, including ASD, within communities and provide them with appropriate, evidence-based support, through a trans-diagnostic detection-to-care pathway. It is a collaborative endeavour among the University of Manchester, Sangath (India), Sri Lanka College of Paediatricians, and Autism Care Nepal Society.

Who can participate?
Families with children aged 1 year 6 months to 9 years residing within the study geographies are eligible for screening. Among these, families with children aged between 1 year 6 months to 9 years detected with signs of NDDs, including ASD, are eligible to receive appropriate interventions.

What does the study involve?
NAMASTE's detection-to-care pathway is being implemented through four parallel processes:
1. Screening for NDDs: Across the four sites, a team of specialist and non-specialist health and care providers have been trained to screen children within communities for NDDs, using specific, culturally adapted tools. In India and Nepal, these include the Social Attention and Communication Surveillance (SACS) and the Rashtriya Bal Swasthya Karyakram (RBSK), while in Sri Lanka, the SACS and Child Health and Development Record (CHDR) are used.
The SACS-Revised (SACS-R) and SACS-Preschool (SACS-PR), developed at LaTrobe University, Australia, identify infants, toddlers, and preschoolers on the autism spectrum and have high diagnostic accuracy, making it ideal for community-based developmental surveillance. The RBSK

is a programme by the Indian government's Ministry of Health & Family Welfare that uses a screening tool for children and adolescents between 0-18 years of age for birth defects, diseases, deficiencies, and developmental delays. The CHDR is given as an early childhood growth and development monitoring tool to caregivers of children in Sri Lanka at birth to record the child's progress till age 18, focussing on physical well-being and psychosocial development.
2. Evaluation: Pre- and post-intervention outcome measurement will consist of administering a battery of assessments on child, caregiver, and familial outcomes. Considering the unique multi-site approach, India, Nepal, and Sri Lanka, have tailored these evaluation measures to suit their contexts. Detailed information about these measures have been provided in the primary and secondary outcome measures sections.
In NAMASTE, outcome evaluations with triaged families would be conducted at two distinct time points. The first of these would be at baseline, i.e., before intervention delivery and the latter at endline, i.e., 3 to 6 months from intervention delivery for WHO CST families and 8 to 12 months from baseline for PASS Plus families.
3. Intervention: NAMASTE interventions have been tailored to meet specific needs of triaged children. Children presenting with difficulties indicative of a broad range of NDDs, such as social communication difficulties and delayed speech, would receive the World Health Organisation's Caregiver Skills Training (WHO CST), while those showing signs of or diagnosed with ASD would be provided the Parent mediated Autism Social Communication Intervention for Non-specialists Plus (PASS Plus). PASS Plus addresses social communication challenges and difficulties in learning and performing daily living skills, along with parental well-being. The WHO CST, a group-based intervention, equips caregivers with strategies and techniques to support children with activities of daily living, communication, and reducing challenging behaviours through play-based routines, while addressing parental well-being. Both the interventions have been piloted in India and were deemed appropriate for community-based implementation.
Detailed information about PASS Plus and WHO CST has been provided in the Interventions section.
4. Community engagement & involvement: Across sites, NAMASTE has actively involved individuals with NDDs to raise awareness about and destigmatise NDDs. To facilitate this, the workstream has developed a community engagement and involvement (CEI) toolkit consisting of audio-visual and pictorial aids.
Intervention effectiveness would be assessed using a stratified pre-post quasi-experimental observational cohort design. Regression models will estimate pre-post change in child developmental and symptom outcomes accounting for covariates. Similar analysis will be undertaken for the secondary outcome variables of parent-child interaction and parent and child wellbeing.
NAMASTE would be assessing the implementation and effectiveness of this transdiagnostic detection-to-care pathway in these four diverse health systems within the consolidated framework for implementation research (CFIR).

What are the possible benefits and risks of participating?
Participation in NAMASTE will help children with NDDs and ASD receive appropriate services that may address their social, communication, and similar difficulties. The programme's outcomes may inform policy recommendations for India, Sri Lanka, and Nepal. Additionally, in appreciation of their time and commitment to participate in the evaluations, families in India will be provided with a token amount of INR 1500 (GBP 12.81) at each assessment timepoint; caregivers are not provided with any participatory token for attending intervention sessions except for travel reimbursements. In Nepal, PASS Plus families would receive NPR 2000 (GBP 10.41) following all sessions and WHO CST families will receive NPR 500 (GBP 2.60) following each session. Likewise, in Sri Lanka, families undergoing travel for the intervention sessions and

evaluations would receive LKR 1000 (GBP 2.43) as travel reimbursement. Families in Sri Lanka and Nepal do not receive any additional participatory token for participating in pre- and post intervention outcome evaluations.

The only potential disadvantage is the time commitment required for the pre- and post-intervention outcome assessments and intervention sessions.

Where is the study run from?
The NAMASTE programme is being implemented in East Delhi and North Goa in India, Colombo in Sri Lanka, and Godawari Municipality of Lalitpur district in Kathmandu, Nepal.

When is the study starting and how long is it expected to run from?
The NAMASTE programme began on 01 September 2022, with the first enrolment on 26 September 2024. It is anticipated to be completed on 30 September 2027.

Who is funding the study?
The National Institute of Health and Care Research/United Kingdom-International Development.

Who is the main contact?
1. Dr Jonathan Green, University of Manchester, co-principal investigator, jonathan.green@manchester.ac.uk
2. Dr Gauri Divan, Sangath, co-principal investigator, gauri.divan@sangath.in

Contact information

Type(s)
Public, Scientific

Contact name
Mr Reetabrata Roy

Contact details
House No. 451 (168), Bardez, Bhatkar Waddo, Aradi Socorro, Porvorim, Goa
Goa
India
403501
+91 8800563339
r.roy@sangath.in

Type(s)
Principal investigator

Contact name
Dr Gauri Divan

Contact details
House No. 451 (168), Bardez, Bhatkar Waddo, Aradi Socorro, Porvorim, Goa
Goa
India

403501
+91 98817 22551
gauri.divan@sangath.in

Type(s)
Public, Scientific

Contact name
Ms Sara Neupane

Contact details
Harisiddhi 29
Lalitpur
Nepal
44600
+977 9841203279
sara.neupane@autismnepal.org

Type(s)
Principal investigator

Contact name
Dr Rena Shrestha

Contact details
Harisiddhi 29, Lalitpur 44600, Nepal
Lalitpur
Nepal
44600
+977 1 5912549/ +977 1 5912554
rena.shrestha@autismnepal.org

Type(s)
Principal investigator

Contact name
Dr Sunita Maleku Amatya

Contact details
Harisiddhi 29, Lalitpur 44600, Nepal
Lalitpur
Nepal
44600
+977 1 5912549/ +977 1 5912554
sunita.maleku@autismnepal.org

Type(s)
Public, Scientific

Contact name
Dr Buddhika Fernando

Contact details
44/1, Gnanartha Pradeepa Mawatha, Colombo 08, Sri Lanka
Colombo
Sri Lanka
00800
+94 760222479
bfernando2009@gmail.com

Type(s)
Principal investigator

Contact name
Dr Asiri Hewamalage

Contact details
44/1, Gnanartha Pradeepa Mawatha
Colombo
Sri Lanka
00800
+94 77 751 3650
asiri11@yahoo.com

Type(s)
Principal investigator

Contact name
Dr Dilini Vipulaguna

Contact details
44/1, Gnanartha Pradeepa Mawatha
Colombo
Sri Lanka
00800
+94 77 200 7952
dilvip777@yahoo.com

Type(s)
Principal investigator

Contact name
Dr Kathy Leadbitter

Contact details
The University of Manchester, Oxford Road
Manchester
United Kingdom
M13 9PL
+447786675436
kathy.leadbitter@manchester.ac.uk

Type(s)
Public

Contact name
Dr Gopika Kapoor

Contact details
31, Street No. 2, Dayanand Block, Block D, Dayanand Colony, Shakarpur Khas
New Delhi
India
110092
9821197925
gopikakapoor@gmail.com

Type(s)
Principal investigator

Contact name
Dr Shruti Garg

Contact details
The University of Manchester, Oxford Road
Manchester
United Kingdom
M13 9PL
+447745576271
shruti.garg@manchester.ac.uk

Type(s)
Principal investigator

Contact name
Dr Jonathan Green

Contact details
The University of Manchester, Oxford Road
Manchester
United Kingdom
M13 9PL
+44 7957541206
jonathan.green@manchester.ac.uk

Additional identifiers

National Institute for Health and Care Research (NIHR)
134702

Study information

Scientific Title

Neurodevelopment and autism in South Asia: treatment and evidence

Acronym
NAMASTE

Study objectives
NAMASTE will test the implementation and effectiveness of a transdiagnostic detection-to-care pathway; identifying children with neurodevelopmental disabilities (NDDs), including autism spectrum disorder (ASD), and linking them to appropriate interventions. It will test the components of this pathway implemented in four distinct health systems, along with building their clinical and research capacity and investigating cost effectiveness of delivery.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 11/09/2022, Sangath Institutional Review Board (House no. 451 (168), Bardez, Bhatkar Waddo, Aradi Socorro, Porvorim, Goa, 403501, India; +91 7887872345; irb@sangath.in), ref: GD_2022_78

2. approved 02/08/2024, University Research Ethics Committee (Research Governance, Ethics, and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, United Kingdom; +44 (0) 161 306 6000; research.ethics@manchester.ac.uk), ref: 2024-18880-36838

3. approved 09/08/2024, Health Ministry's Screening Committee (Department of Health Research 2nd Floor, IRCS Building 1, Red Cross Road, New Delhi, 110001, India; 011-23736222, 011-23736219; hmsc-ihd@icmr.gov.in), ref: 2024-17984

4. approved 20/07/2024, Institute Ethics Committee (All India Institute of Medical Sciences (AIIMS), Room no. 102, First floor, Old O.T. Block, Ansari Nagar, New Delhi, 110029, India; 26594579; sheffaligulati@aiims.edu), ref: AIIMSA1260/07.06.2024, RP-19/2024

5. approved 18/06/2024, Clinical Trials Registry - India (V. Ramalingaswami Bhawan, P.O. Box No. 4911, Ansari Nagar, New Delhi, 10029, India; 011-26588636; ctri@gov.in), ref: CTRI/2024/06/068938

6. approved 06/09/2024, Directorate of Health Services, Government of Goa (Special Cell, Campal, Panaji, Goa, 403001, India; +9011025066; dir-heal.goa@nic.in), ref: DHS/Sp.Cell/F.No.24-166(Ethics)/2024-25/1230

7. approved 19/10/2924, Ethics Review Committee of the Sri Lanka College of Paediatricians (44/1, Gnanartha Pradeepa Mawatha, Colombo, 08, Sri Lanka; +94 11 2683178, +94 77 7508218; office@slcp.lk), ref: SLCP/ERC/2024/22

8. approved 31/03/2023, Nepal Health Research Council (Ramshah Path, Kathmandu, P.O.Box 7626, Nepal; +977-1- 4254220 (Ext no 125); approval@nhrc.gov.np), ref: 484_22

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Health services research, Supportive care, Treatment

Study type(s)
Screening, Treatment

Health condition(s) or problem(s) studied
Neurodevelopmental disabilities (NDDs), Autism Spectrum Disorder (ASD)

Interventions
NAMASTE is a multicentre non-randomised single-arm interventional study.

A team of specialist and non-specialist health and care providers are screening for children with neurodevelopmental disabilities (NDDs), including autism spectrum disorder (ASD), using the Social Attention and Communication Surveillance (SACS) and Rashtriya Bal Swasthya Karyakram (RBSK) in India and Nepal and the SACS and Child Health Development Record (CHDR) in Sri Lanka. Children screened using these tools for NDDs and ASD are triaged to receive the World Health Organization's Caregiver Skills Training (WHO CST) and Parent-mediated Autism Social Communication Intervention for Non-specialists Plus (PASS Plus) interventions, respectively. Both interventions promote child social-communication and well-being and caregiver well-being.

Blinding is not possible considering that NAMASTE is a single-arm study with all participants receiving one of the two interventions. Programme participants include children aged 1 year 6 months-9 years who have been screened for NDDs, including ASD. As pre- and post-interventions would be conducted to determine intervention efficacy, outcome assessors will also be aware of the kind of intervention each participant received.

PASS Plus' development is adapted from the UK-based Paediatric Autism Communication Therapy (PACT). A series of therapeutic modules to address comorbidities commonly associated with autism were integrated into the intervention, leading to the development of the PASS Plus. The "Plus" component addresses comorbidities, such as, sensory sensitivities, feeding, toileting behaviour, sleep and behavioural issues, etc. The intervention consists of 12 home-based sessions and a video-feedback mechanism. A 13-minute play session is arranged for the measurement of dyadic communication to occur which is video-recorded by a trained researcher. This video is then coded based on three levels of interaction. The play session requires a particular set of toys be used for the assessment and a highly controlled environment to ensure quality administration. In NAMASTE, the Dyadic Communication Measure for Autism (DCMA) will be administered only with families receiving the PASS Plus intervention.

WHO CST is a group-based intervention for families of children with developmental delays and disabilities aged between 2-9 years. The intervention does not require that a child be diagnosed with any specific NDD and therefore, caters to a wide range of developmental delays, and can be delivered by non-specialist community-based workers. Through nine group sessions and three individual home visits, the WHO CST trains caregivers on using play and home-based activities to enhance their child's social communication skills, daily living activities, caregiver well-being, and reduce the child's challenging behaviours.

In NAMASTE, the World Health Organization's Caregiver Skills and Knowledge Training (WHO CKST) would be administered only with families receiving the WHO CST and the tool's translations were modified for the Hindi and Marathi versions and it was culturally adapted into Konkani, Nepali, Sinhala, and Tamil.

Secondary measurement tools
1. The Goals and Goal-based Outcomes (GBO) tool used with families receiving PASS Plus in India has three sections – one to record goals, another to rate progress on the day of administration, and one to chart progress towards the goals following delivery of each intervention session. The tool was translated into Hindi, Konkani, and Marathi for use in NAMASTE.
2. In NAMASTE, three sections of the Vineland Adaptive Behaviour Scales - 3rd Edition (Vineland-3) form would be used to assess the child's adaptive behaviour skills with families receiving the PASS Plus intervention in Nepal and Sri Lanka. It has been culturally adapted to Nepali and translated into Sinhala and Tamil for NAMASTE.
3. Health status of the child on the day of the administration to determine Quality-Adjusted Life Years (QALYs) measured using the Child Health Utility-9DIndex (CHU-9D) from enrollment to the end of treatment at 3-6 and 8-12 months. It has two separate versions – one for children below the age of five and another for those above 5 years of age. The CHU-9D was culturally adapted for COMPASS in Hindi and for NAMASTE in Konkani, Marathi, Sinhala, Tamil, and Nepali.
3. The Child Health Utility-9D Index (CHU-9D) has two separate versions – one for children below the age of five and another for those above 5 years of age. The CHU-9D was culturally adapted for COMPASS in Hindi and for NAMASTE in Konkani, Marathi, Sinhala, Tamil, and Nepali.
4. The Warwick Edinburgh Mental Well-being Scale (WEMWBS) has 14 items, each rated on a 5-point Likert scale, ranging from 1 (None of the time) to 5 (All of the time). For NAMASTE, the tool was culturally adapted into Hindi, Konkani, Marathi, and Nepali. Sinhala and Tamil versions of the tool were already available.
5. The EuroQol 5 Dimensions 5 Levels (EQ-5D-5L) respondent has to answer each question by choosing one out of five levels – No problems, Slight problems, Moderate problems, Severe problems, and Extreme problems. At the end of the measure, the caregiver has to rate their health on a scale from 1 (Worst health you can imagine) to 100 (Best health you can imagine). The tool's translation was modified for the Hindi, Konkani, Marathi, and Nepali versions. Sinhala and Tamil versions of the tool were already available.
6. The Children and Adolescents Economic Resources Questionnaire (CAER-Q) was restructured from Sangath Cost of Illness Inventory (COII), the CAER-Q was digitised and tailored to suit an implementation programme, broadening its scope. The tool was developed in English at Sangath and was translated into Hindi, Konkani, Marathi, Sinhala, Tamil, and Nepali, with appropriate context-specific modifications.

Intervention Type
Behavioural

Primary outcome(s)

1. Caregivers' knowledge and understanding of the level of functioning demonstrated by the child and caregivers' confidence in dealing with their children measured using the World Health Organization's Caregiver Skills Training (WHO CST) at enrolment and at the end of treatment at 5 months

2. Social communication and interaction between a caregiver and a child with autism spectrum disorder (ASD) measured using the Dyadic Communication Measure for Autism (DCMA) at enrolment and at the end of treatment at 10 months

Key secondary outcome(s))
1. To record and track goals set by nominated caregivers at baseline that they aspire to meet through the intervention measured using the Goals and Goal-based Outcomes (GBO) tool (Note: only in the 2 sites of India viz., East Delhi and North Goa) at enrolment and at the end of treatment at 10 months

2. Adaptive behaviour skills – Communication, Daily living skills, and Socialization skills measured using the Vineland Adaptive Behaviour Scales - 3rd Edition (Vineland-3) (Note: only in the 2 sites viz., Godavari in Nepal and Colombo in Sri Lanka) at enrolment and at the end of treatment at 10 months

3. Health status of the child on the day of the administration to determine Quality-Adjusted Life Years (QALYs) measured using the Child Health Utility-9D Index (CHU-9D) at enrolment and at the end of treatment at 5 months WHO CST participants, and at enrolment and at the end of treatment at 10 months for PASS Plus participants

4. Caregiver mental well-being and psychological functioning measured using the Warwick Edinburgh Mental Well-being Scale (WEMWBS) at enrolment and at the end of treatment at 5 months WHO CST participants, and at enrolment and at the end of treatment at 10 months for PASS Plus participants

5. Caregiver's health status across five domains - mobility, self-care, pain/discomfort, anxiety /depression, and usual activities measured using the EuroQol 5 Dimensions 5 Levels (EQ-5D-5L) at enrolment and at the end of treatment at 5 months WHO CST participants, and at enrolment and at the end of treatment at 10 months for PASS Plus participants

6. Routine care service utilisation for children with NDDs, including ASD, and costs incurred on the same measured using the Children and Adolescents Economic Resources Questionnaire (CAER-Q) at enrolment and at the end of treatment at 5 months WHO CST participants, and at enrolment and at the end of treatment at 10 months for PASS Plus participants

7. Socio demographic parameters measured using a socio demographic tool at enrolment

8. Adverse and Serious Adverse Events measured using an adverse and serious adverse events reporting tool at the end of the treatment at 5 months for WHO CST and 10 months for PASS Plus

Completion date
30/09/2027

Eligibility

Key inclusion criteria
For India and Nepal:
1. Children between the ages of 1 year 6 months to 9 years
2. Families residing in the study geography - Lalitpur district in Nepal, East Delhi district in Delhi, and North Goa district in Goa
3. For PASS Plus intervention - More than 3 key items positive on the Social Attention and Communication Surveillance (SACS) and autism-specific items in the Rashtriya Bal Swasthya Karyakram (RBSK)
4. For WHO CST - <=2 key items positive on the SACS or RBSK Cognitive Learning Attention items positive
For Sri Lanka:
1. Children between the ages of 2 years 6 months-3 years 5 months
2. Families residing in the study geography of Colombo district
3. For PASS Plus - More than 3 key items positive on the SACS
4. For WHO CST - <=2 key items positive on the SACS or Speech and Language items positive on the Child Health Development Record (CHDR)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1.5 years

Upper age limit
9 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Children with significant hearing or visual impairment
2. Children with primary caregivers with hearing or visual impairment
3. For India and Nepal - Children less than 1 year 6 months and older than 9 years of age
4. For Sri Lanka - Children less than 2 years 6 months and older than 3 years 5 months of age
5. Families residing outside the study geographies of the four sites

Date of first enrolment
26/09/2024

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
India

Nepal

Sri Lanka

Study participating centre
Sangath
NAMASTE Site Office, 31, Street No. 2, Dayanand Block, Block D, Dayanand Colony, Shakarpur Khas
New Delhi
India
110092

Study participating centre
Sangath
House No. 451 (168), Bardez, Bhatkar Waddo, Aradi Socorro, Porvorim
Goa
India
403501

Study participating centre
Sri Lanka College of Paediatricians
44, 1 Gnanartha Pradeepa Mawatha
Colombo
Sri Lanka
00800

Study participating centre
Autism Care Nepal Society
Harishiddi – 29
Lalitpur
Nepal
44600

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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?
Participant information sheet	Caregiver Copies for India, Nepal and SL_English version 1.0	14/01/2026	14/01/2026	No	Yes