FULL STUDY PROTOCOL,
STATISTICAL ANALYSIS PLAN (SAP)
& INFORMED CONSENT FORMS (ICF)

Effectiveness of the B.A.S.I.C.S. Framework as a Multimodal Play-Based Intervention for Children With Autism Spectrum Disorder: A Retrospective Cohort Study

Ethical Approval: 001/12/2025/ISRB/FR/SCPT

Document Date: 20th January 2026

Sponsor: Saveetha University

Board Affiliation: Saveetha College of Physiotherapy,

Saveetha Institute of Medical and Technical Sciences

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1. Personnel

Principal Investigator: Dr. Pavithra Saravanakumar

Investigators: Dr. Jeevarathinam Thirumalai

2. Introduction

2.1 Background & Aims

Autism Spectrum Disorder (ASD) is a neurodevelopmental condition characterised by persistent challenges in social communication and interaction, together with restricted, repetitive patterns of behaviour, interests, or activities. Children with ASD frequently present with co-occurring difficulties in balance, postural control, functional independence, and social skill development, which can limit participation in everyday activities and peer engagement.

The B.A.S.I.C.S. framework (Balance, Autonomy, Social Interaction, Cognition, and Self-reliance) is a structured, multimodal play-based intervention developed to address these interconnected functional domains within a single therapeutic programme. Rather than isolating motor, cognitive, communication, or social goals into separate treatment streams, the framework integrates them through purposeful play - using cognitive-motor obstacle courses, perceptual-motor tasks, peer-based balance activities, synchronized rhythmic movement, Picture Exchange Communication System (PECS)-based communication activities, and sensory-motor fine-motor tasks with embedded cognitive demands.

The aim of this study was to evaluate the effectiveness of the B.A.S.I.C.S. framework, delivered as 45-minute multimodal play therapy sessions three times per week for six weeks, in improving functional independence and balance among children with ASD aged 6–12 years, in comparison with conventional physiotherapy. Effectiveness was assessed by comparing pre- and post-intervention scores on the Paediatric Balance Scale (PBS) and the WeeFIM (Functional Independence Measure for Children), with social functioning evaluated as a secondary outcome using the Social Skills Improvement System (SSIS) Rating Scales.

2.2 Background Literature Review

Play-based behavioural interventions have been previously shown to support developmental outcomes among children with ASD in community and semi-rural settings. A prior culturally adapted play-based behavioural intervention among children with ASD in semi-rural Tamil Nadu, evaluated through a randomized controlled trial by members of this research group, provides the foundation on which the

B.A.S.I.C.S. framework builds, extending a single-domain play-based approach into a multimodal framework spanning balance, autonomy, social interaction, cognition, and self-reliance (see Reference 1).

3. Study Protocol

3.1 Research Design Outline

This is a retrospective cohort study evaluating the effectiveness of the B.A.S.I.C.S. framework as a multimodal play-based intervention among children with Autism Spectrum Disorder (ASD), conducted at Saveetha Medical College and Hospital, Chennai, Tamil Nadu. The study used a non-randomized, parallel-assignment design with two arms: an Experimental arm receiving the B.A.S.I.C.S. framework and an Active Comparator arm receiving Conventional Physiotherapy. Outcome assessment was triple-masked (participant, investigator, and outcomes assessor).

A total of 120 participants were enrolled (actual enrollment). The primary purpose of the study was treatment-focused, and the study did not involve any FDA-regulated drug, biologic, or device product, nor was it conducted under an IND/IDE.

Study Start Date: January 03, 2026 (Actual)

Primary Completion Date: July 30, 2026 (Actual)

Study Completion Date: July 30, 2026 (Actual)

Overall Recruitment Status: Completed

3.2 Participants

Children with Autism Spectrum Disorder aged 6–12 years attending Saveetha Medical College and Hospital, Chennai, Tamil Nadu, who met the predefined eligibility criteria, were included in this study. The study accepted both male and female participants, and eligibility was not restricted by gender identity relative to biological sex.

3.3 Recruitment

Children with a diagnosis of Autism Spectrum Disorder (ASD) according to DSM-5 criteria, attending Saveetha Medical College and Hospital, were screened against the inclusion and exclusion criteria detailed in Section 3.5 below. Participation information and consent sheets detailing the inclusion and exclusion criteria were distributed to parents/guardians. Parents who agreed to their child's participation were invited to undergo baseline assessments using the Paediatric Balance Scale (PBS) and the WeeFIM (Functional Independence Measure for Children), with the Social Skills Improvement System (SSIS) Rating Scales

used to assess social functioning. All parents were required to return a signed consent form to the site principal investigator prior to enrollment.

3.4 Administration

Participants in the Experimental arm received the B.A.S.I.C.S. multimodal play-based intervention: a structured therapeutic programme integrating Balance, Autonomy, Social Interaction, Cognition, and Self-reliance. The intervention incorporated cognitive-motor integration tasks, goal-oriented perceptual-motor activities, peer-based balance activities, synchronized auditory-movement activities, Picture Exchange Communication System (PECS)-based activities, and sensory-motor fine-motor activities with cognitive tasks. Activities were individualized and progressively graded according to each child's tolerance and performance. Participants received 45-minute sessions, three times per week, for six weeks.

Participants in the Active Comparator arm received Conventional Physiotherapy, consisting of therapeutic exercises and activities primarily targeting gross and fine motor skills, balance, coordination, and postural control, focused on improving motor performance and physical functional abilities through routine physiotherapy techniques.

Component activities within the B.A.S.I.C.S. framework

- Cognitive-Motor Integration: Gross motor activities (stepping, crawling, jumping, balance-beam, rocker-board) combined with simple cognitive tasks such as colour identification and object sorting.
- Goal-Oriented Perceptual-Motor Activities: Motor sequencing, stepping, jumping, and turning tasks.
- Peer-Based Balance Activities: Cooperative balance tasks to encourage postural control and social engagement.
- Synchronized Rhythmic Movement Activities: Rhythmic movement and music-based activities to facilitate joint attention, turn-taking, recall, and social reciprocity.
- PECS-Based Communication Activities: Visual picture cards used to facilitate functional communication and choice-making.
- Sensory-Motor Fine-Motor Activities: Manipulation of play clay and moulding tools alongside cognitive tasks such as colour, shape, and counting activities.

3.5 Assessment & Outcome Measures

3.5.1 Primary Outcomes

Paediatric Balance Scale (PBS)

The Paediatric Balance Scale (PBS) is a 14-item functional balance assessment used to evaluate static and dynamic balance in children. Each item is scored on a 5-point ordinal scale from 0 to 4, with higher scores indicating better balance performance and greater independence. The total score ranges from 0 to 56. The PBS assesses functional balance abilities including standing, reaching, turning, and stepping.

[Time Frame: Baseline, 6 weeks, 12 weeks, post follow-up (24th week)]

Functional Independence Measure for Children (WeeFIM)

The WeeFIM is an 18-item assessment used to evaluate functional independence in children across self-care, mobility, and cognition. Each item is scored on a 7-point ordinal scale from 1 (total assistance) to 7 (complete independence), with a total score ranging from 18 to 126. Higher scores indicate greater functional independence.

[Time Frame: Baseline, 6 weeks, 12 weeks, 24th week]

3.5.2 Secondary Outcomes

Social Skills Improvement System (SSIS) Rating Scales

A standardized assessment of social skills and social functioning in children, including cooperation, communication, assertion, responsibility, empathy, and self-control.

[Time Frame: Baseline, 6 weeks, 12 weeks, 24th week]

4. Statistical Analysis Plan (SAP)

Descriptive and inferential statistics will be used. Normally distributed data will be presented as mean and standard deviation (SD); non-normally distributed data will be presented as median and interquartile range. Categorical data will be presented using percentages.

4.1 Primary Outcomes

The primary analyses will assess the effect of the B.A.S.I.C.S. framework and Conventional Physiotherapy on: (i) the Paediatric Balance Scale (PBS), and (ii) the WeeFIM, presented as mean and standard deviation for each group. P-values < 0.05 will be considered statistically significant.

4.2 Secondary Outcomes

The secondary analysis will assess the effect of the B.A.S.I.C.S. framework and Conventional Physiotherapy on the Social Skills Improvement System (SSIS) Rating Scales, presented as mean and standard deviation for each group. P-values < 0.05 will be considered statistically significant.

5. Informed Consent Forms (ICF)

Written consent will be obtained from the parents/guardians of children with Autism Spectrum Disorder using the consent forms attached to the application.

5.1 Rights and Risks to Participants

Rights

The parents/guardians may decide to stop being a part of this research study at any time without explanation. The parents/guardians have the right to omit or refuse to answer or respond to any question that is asked about their children. In addition, they have the right to ask any questions about the procedures practiced with their children (unless answering these questions would interfere with the study outcome). If they have any questions regarding this information sheet, testing, or training, they may ask the investigator or research in-charge person before the study begins or during the course of assessment and intervention. Participation in this study is voluntary and does not carry any remuneration or reimbursement.

6. References

1. Thirumalai J, Sekar M, Ramalingam V, Bhuvaneshwar S, Gajendran K, Jeslin GN. Culturally adapted play-based behavioral intervention among children with autism spectrum disorder in semi-rural Tamil Nadu: A randomized controlled trial. Journal of Mental Health and Human Behaviour. 2025 Jul 1;30(2):90-7.

Annex A: Protocol Registration Summary

The following summary reflects the record entered into the ClinicalTrials.gov Protocol Registration and Results System (PRS) for this study, for cross-reference with the sections above.

Study Identification

Organization's Unique Protocol ID: 001/12/2025/ISRB/FR/SCPT

Brief Title: Play Based Approach Among Autism

Study Type: Interventional

Official Title: Effectiveness of the B.A.S.I.C.S. Framework as a Multimodal Play-Based Intervention for Children With Autism Spectrum Disorder: A Retrospective Cohort Study

Sponsors and Collaborators

Responsible Party: Principal Investigator - Jeevarathinam Thirumalai [jthirumalai]

Investigator Official Title: Principal Investigator

Investigator Affiliation: Saveetha University

Sponsor: Saveetha University

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Protection Review - Board Status: Approved

Approval Number: 001/12/2025/ISRB/FR/SCPT

Board Name: Institutional Scientific Review Board

Board Affiliation: Saveetha College of Physiotherapy, Saveetha Institute of Medical and Technical Sciences

Board Contact: +91 87605 63032 | research.scpt@saveetha.com

Board Address: Department of Paediatric and Neonatal Sciences, Saveetha College of Physiotherapy, Saveetha Institute of Medical and Technical Sciences, Saveetha University, Chennai, Tamil Nadu – 602105, India

Data Monitoring Committee: Yes

Conditions and Keywords

Condition: Autism Spectrum Disorder

Keywords: Autism Spectrum Disorder; Children with Autism; Play-Based Intervention; B.A.S.I.C.S. Framework; Paediatric Balance; Rehabilitation

Study Design

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Triple (Participant, Investigator, Outcomes Assessor)

Allocation: Non-Randomized

Enrollment: 120 (Actual)

Arms and Interventions

Arm	Assigned Intervention
Experimental: B.A.S.I.C.S FRAMEWORK	Behavioral: B.A.S.I.C.S FRAMEWORK - structured multimodal play-based intervention integrating Balance, Autonomy, Social Interaction, Cognition, and Self-reliance.
Active Comparator: Conventional Physiotherapy	Behavioral: Conventional Physiotherapy - routine physiotherapy techniques targeting gross/fine motor skills, balance, coordination, and postural control.

Eligibility

Accepts Healthy Volunteers: No

Sex: All

Gender Based: No

Minimum Age: 6 Years

Maximum Age: 12 Years

Inclusion Criteria

- Children diagnosed with Autism Spectrum Disorder (ASD) according to DSM-5 criteria
- Age 6–12 years
- Both genders
- Able to understand simple commands
- Mini-Mental State Examination (MMSE) score > 24

Exclusion Criteria

- ASD associated with moderate-to-severe intellectual disability
- Neurological disorders
- Musculoskeletal deformities
- Severe visual impairment
- Severe hearing impairment

Contacts and Locations

Central Contact Person: Pavithra Saravana Kumar | +91 9790461600 | pavithras.scpt@saveetha.com

Location: Saveetha Medical College and Hospital, Chennai, Tamil Nadu, India 602105 (Site Status: Completed)

Facility Contact: Vinodhkumar Ramalingam, PhD | +91 87605 63032 | vinodhkumar.scpt@saveetha.com

IPD Sharing Statement

Plan to Share IPD: No