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# Study Protocol for a Single-center Randomized Clinical Trial: Evaluating the Effectiveness of Combined Therapy versus Conventional Therapy Approaches to Improve Physical & Behavioral Status among Children with Autism Spectrum Disorder

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## Abstract:

**Objective:** Currently, traditional Autism Spectrum Disorder (ASD) treatments include occupational therapy and speech and language therapy (SLT), however, physiotherapy has little evidence of efficacy. Hence, this study aims to compare physiotherapy, occupational therapy as well as speech and language therapy as need-based interventions for ASD patients with physical and behavioral deficits.

**Material and Methods:** An assessor and participant blinded randomized clinical trial (RCT) was designed for 70 cases diagnosed with ASD, according to Diagnostic and Statistical Manual of Mental Disorders (DSM) V, from July 2024 to April 2025, with each being randomly assigned to either Group A or Group B. Participants of Group A will receive physiotherapy plus occupational therapy with SLT and group B will receive only occupational therapy plus speech and language therapy for 4 weeks. The outcome of this study will be physical status determined by modified SF-36 scores and behavioral status via GARS-3 scores. The study site will be Proyash (an Institute of Special Education), Jashore Area, Bangladesh. Study analysis will be conducted according to the nature of the data, and will include intention-to- treat analysis.

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**Results:** The results of this study are expected to determine that comprehensive multidisciplinary practices of ASD can advocate the benefits for children and adolescents with ASD, the parents, other stakeholders and special schools throughout Bangladesh.

**Conclusion:** This study will address the research gap on the impact of the outcome of physiotherapy interventions, along with occupational therapy with SLT, on behavioral and physical status for the participants of ASD.

**Keywords:** Autism Spectrum Disorder (ASD), behavioral status, physical and emotional health, rehabilitation

## Introduction

Autism Spectrum Disorder (ASD) is one of the fastest-evolving cognitive disorders in Bangladesh that affects social interaction and basic behavior[1]. Although it can be diagnosed at any age, symptoms of autism usually appear in the initial two years of life[2]. Diagnostic Criteria of Autism in Bangladesh is according to the Directorate General of Health Services guidelines; however, symptoms of autism vary from child to child. Generally, these can be divided into three categories: social barriers, difficulties/ barriers in establishing communication, and repetitive and stereotyped. Both social and communication skills of children with autism do not develop normally. Normally, parents are the first to notice abnormal behavior in a child[3]. According to the Neuro-Developmental Disabilities Protection Trust law diagnosis criteria, among which the presence of the symptoms above are mentioned, includes the following clauses: (a), (b) and (c) is certain, and clauses (d), (e), (f), (g), (h), (i), (j) and (k), if one or more of the symptoms are observed, they will then be considered as a disabled person having features of ASD; namely:- (a) limitations in verbal or non-verbal communication, (b) limitation of social and interpersonal behavior, communication and imaginative activities, (c) repetition of similar or limited acts or conduct, (d) greater or lesser sensitivity than others in hearing, sight, smell, taste, touch, pain, balance and movement, (e) intellectual disability or any other handicap or disability, (f) extraordinary ability in one or more specific subjects and inequality of development in the same person, (g) not making or keeping less direct eye contact with others, (h) excessive excitability, excitement or incoherent crying, (i) unusual physical gestures, (j) excessive tendency to follow the same routine, and (k) any other feature prescribed by the Government, from time to time; by Gazette Notification[4]. Children with ASD often exhibit repetitive or restricted behaviors in interaction, language, and communication as well as a variety of other social problems[5]. People with ASD come from diverse socioeconomic backgrounds, races, and nations[6]. Presently, the incidence of ASD in Bangladesh is progressively increasing[7]. Nonetheless, adequate epidemiological data concerning the total prevalence of autism cases in Bangladesh is lacking. According to the Bangabandhu Sheikh Mujib Medical University Center for Child Neurodevelopment and Autism in Bangladesh, 7.5 out of every 10,000 children are diagnosed with autism[8]. The Institute for Pediatric Neurodisorders and Autism (IPNA) is a tertiary care institution, where the majority of children with ASD in the metropolitan area come for treatment[9]. A 2013 national study of 7,200 people in Bangladesh found that 1.5 out of every 1,000 children had ASD[3].

The rate was highest in Dhaka Metropolis (30 per 10,000 children), while the rate was lower in rural areas (7 per 10,000 children)[10]. In 2016, the National Center for Health Statistics estimated that one in 36 children had been diagnosed with Autism. A significant disparity in the ratio of males to girls has also been observed: notably 4:1[3]. The

severity of ASD is categorized into three levels; wherein, Level 1, indicates moderate autism that necessitates assistance; Level 2, which demands substantial support; and Level 3, representing the most severe type of autism that requires extensive aid[11]. Nonetheless, a child's growth, development, and contextual variations might affect the intensity of social skills and behaviors[12]. Moreover, children with ASD face an elevated risk of comorbidities compared to their typically developing peers[10]. Individuals with ASD exhibit lower levels of activity compared to their normally developing counterparts. Research indicates that social and emotional deficiencies, along with related comorbidities, particularly in children with ASD, may be intensified by insufficient physical activity and delayed motor skills and fitness[13]. Physical, behavioral, and emotional challenges associated with ASD may be intensified, significantly adversely affecting an individual's well-being. Presently, there is no recognized therapy for ASD. Considered the gold standard for treating core symptoms, behavioral therapy works best when started early in life[14]. However, very few people benefit from this initial, intensive behavioral therapy, as most people with ASD require lifelong supportive care[15]. The current conventional therapy approach for autism in Bangladesh consists of only speech and language therapy and occupational therapy, wherein physiotherapy is not a treatment of choice. Research has shown that physical activity helps to improve social interaction, reduce aggressive behavior, and reduce stereotypical behavior in children with ASD[16]. ASD children enhance social skills and restricted and repetitive behavior patterns through integrated physical training[17]. Additionally, exercise improves various comorbidities and symptoms including alleviating physical motor deficits[18].

At present, no study has compared conventional ASD therapies (occupational therapy with speech and language therapy) with combined therapies (physiotherapy, occupational therapy with speech and language therapy) to improve children's behavioral, physical, and emotional well-being. Hence, combination therapy must be evaluated to improve Bangladeshi autistic children's physical and behavioral parameters. This study will compare integrated treatments, using physiotherapy, occupational therapy, and speech and language therapy, versus need-based treatment, such as occupational therapy and speech and language therapy, for children with ASD.

## Material and Methods

### Study design

This study will be an assessor and participant-blinded Randomized Clinical Trial. The Standard Protocol Items: Interventional Trials (SPIRIT) – 2013 criteria will be followed to ensure transparency of experimental studies (Table 1).

### Sample size calculation

The sample size was determined utilizing ClinCalc software, concentrating on the primary outcome assessed by the Gilliam Autism Rating Scale: Second Edition (GARS – 2)[19]. The sample size was established according to the expected minimum clinically significant differences (MCID) of GARS-2: calculated at 4.7±1.7 (on a 0–10 Hiva scale derived from a 0–126 GARS-2 score). The full sample size is 66, as calculated based on a 25% minimum clinical improvement, a 1:1 enrollment ratio, 80% power, and an alpha value of 0.05[20]. To ensure safety, we will recruit 70 children with ASD, which will then be divided into two groups: 35 in each group.

### Recruitment and randomization

The study's population will consist of children with ASD at Proyash, an institute of special education at Jashore Cantonment, from July 2024 to April 2025. Participant

**Table 1** Standard procedure of the study protocols, according to SPIRIT guidelines

| Time point | Enrolment | Allocation | Post-allocation | |
|---|---|---|---|---|
| | $-T_1$ | $T_0$ | $T_1$ | $T_2$ |
| Enrolment | | | | |
| Eligibility screen | X | | | |
| Informed consent | | X | | |
| Demographic assessment | | | X | |
| Group allocation | | X | | |
| Intervention | | | | |
| PT | | | | X |
| OT | | | | X |
| SLT | | | | X |
| Assessment | | | | |
| GARS-3 | | | | |
| SF-36 | | | | |

PT=physiotherapy, OT=occupational therapy, SLT=speech and language therapy, GARS-3=Gilliam Autism Rating Scale, $T_0$=group allocation, $T_1$=baseline before the intervention, $T_2$=measurement taken in 3-months after $T_1$

selection and eligibility screening will be voluntary. At the entrance, patients will be diagnosed with ASD using the Directorate General of Health Services and Neuro-Developmental Disabilities Protection Trust guidelines. They will be randomly assigned to groups after screening. Next, participants will be divided into two groups using sequentially numbered envelopes at 1:1 ratio. The "Rand" function of Microsoft Excel 2021 will perform secret allocation.

### Study procedure

After the study registration, researchers will recruit willing participants. Parents will be invited to complete a demographic survey to screen "ASD" cases. Computer-generated random selection will choose 70 autistic children for investigation. An assessor, blinded to the group assignment, will pre-test and screen on the first day. One postgraduate physiotherapists, an occupational therapists, and a speech-language pathologists will treat the patient together. Accessories vary by treatment setup. This study will follow CONSORT guidelines.

### Study setting

The study will be conducted at Proyash (Institute of Special Education), Jashore Area, Bangladesh. Study participants will be recruited randomly from the Outpatient Service Unit of Proyash (Institute of Special Education), Jashore Area, Bangladesh.

### Eligibility criteria

Participants will be included in this study if they: (1) are between the ages of 3 and 22[19], (2) were diagnosed as children with ASD, and, based on DSM-V criteria[21], (3) are willing to participate. Participants will not be included if: (1) the respondent consents but drops out within the first week of enrollment; (2) have other neurodevelopmental disorders; such as cerebral palsy, Down syndrome and are children with intellectual disabilities; (3) have any recent (within the past six months) self-reported or parent-reported muscle or joint injury or disease[22].

### Outcome measurements

#### Socio-demographic and clinical information

Sociodemographic information, such as age, gender, mother's education, living area, monthly family income, and clinical information, like BMI, birth complication, type of delivery, first child or not, and so forth, will be gathered by a structured questionnaire[23].

#### Diagnosis of ASD

Screening of children with autism will be performed according to the DSM-5 committee diagnostic criteria[22]. The three main defining characteristics of ASD are: limited and repetitive activity patterns, deficits in verbal and nonverbal communication, and disruption of social relationships. These basic characteristics can be present irrespective of socio-economic background, caste, nationality, or culture. However, because individuals with ASD are often unique, one trait may be more common than another[24,25]. Consequently, the current clinical diagnosis of ASD is based on behavioral assessment according to the DSM-5 criteria, published by the American Psychological Association[26]. The first diagnostic category of the DSM-5 includes deficits in social communication and interpersonal interaction.

According to the third type, symptoms should be visible from childhood; however, they may fully manifest when societal expectations exceed an individual's potential. Symptoms must disrupt regular activity. The diagnosing psychologist offers a severity level of 1 to 3, based on social interactions, restricted interests, and repetitive behavioral patterns. Severity level 3 signifies that this domain is creating significant hindrances for the user[27]. This instrument has approximately 98.5% sensitivity and 92% specificity in the diagnosis of ASD[22].

#### Behavioral assessment

ASD children's behavior will be assessed using the Gilliam Autism Rating Scale (GARS-3); third edition. The 58-item scale measures Restricted/Repetitive Behaviors (13), Social Interaction (14), Social Communication (9), and Emotional Responses (8). Cognitive Style (seven measures) and Maladaptive Speech (seven items) are used for talkative youngsters. The child's current actions are evaluated with a four-point Likert scale: "not at all like the individual" (0), "not much like the individual" (1), "somewhat like the individual" (2), and "very much like the individual" (3). If an object's evaluation is ambiguous, the youngster should be monitored for an extended period, or prior observational data should be utilized. The average Cronbach's alphas for the Autism Index 4 and 6 are 0.94 and 0.93 for the four and six subscales, respectively[19].

The test-retest reliabilities of 122 people examined twice in two weeks ranged from 0.76 to 0.87 throughout the subscales, with the Autism Index 4 and 6 scoring 0.90. An exploratory factor study verified DSM-5 diagnostic indicators. The scale's predictive validity showed that the autism index scores could distinguish children with ASD from typically developing children, with a sensitivity of 0.96 (4 subscales) and 0.95 (6 subscales) in addition to a specificity of 0.95 and 0.97. However, when comparing ASD children to other developmental illnesses, the index has lower specificity (0.78 for 4 subscales, 0.84 for 6 subscales)[20].

#### Physical functioning and emotional health

A self-administered questionnaire consisting of 36 items, wherein the SF-36 yields eight scores. Four of these relate to physical health: general health, role limitations due to physical problems, physical discomfort, and physical functioning. The remaining characteristics are: vitality, mental health, role limitations due to affective illness, and social functioning. Each scale is rated on a range from 0 to 100. If a person gets a score of 100 on physical functioning, role limitation due to physical or mental problems, physical discomfort, or social functioning, it means no limitation or disability[28]. A modified SF-36 questionnaire will be employed

to evaluate the physical functioning and emotional well-being of children with ASD, focusing on activity limitations, physical health issues, and mental health concerns[29]. We will utilize three domains of the SF-36: activity limits, physical health issues, and mental health concerns, via the study's aims.

**Intervention**

**Group A (Physiotherapy and occupational therapy with speech-language therapy)**

***Physiotherapy interventions:***

Group A will receive physiotherapy, such as balance training on land and in water, coordination training, hippotherapy or therapeutic horseback riding, proprioception training, enhance motor function and lower limb strength, training with aerobic exercise to enhance sleep, motor skills, mental state, and muscle strengthening to enhance higher executive performance[30,31]. Physiotherapy interventions will be conducted daily for 30 minutes in 1.5-hour daily sessions.

***Occupational therapy interventions:***

Sensory integration will be customized to each child's unique needs, using the ten basic treatment methods outlined in the Credibility Tool. Some of these methods are: (a) arranging space to improve communication; (b) being physically safe; (c) providing alternatives to sensory input; (d) attaining and preserving suitable levels of stimulation; (e) providing qualitative challenges by changing activities; (f) ensuring the success of activities; (g) providing advice on behavior self-regulation; (h) establishing an enjoyable atmosphere; (i) selecting activities together; and (j) promoting a therapeutic partnership. These ten topics will be divided into three main groups: (1) creating sensory opportunities for the child by changing the environment during treatment; (2) providing common challenges and promoting adaptive responses; and (3) building a rapport between the therapist and the child[32]. Play therapy, balancing training, skill development drills, ball games, pegboard games, and sensory integration exercises are some other interventions that incorporate gross motor function through exercise[33]. Also, cognitive behavioral therapy and community mobility or travel training have been included[34]. Occupational therapy interventions will be conducted daily for 30 minutes in 1.5-hour daily sessions.

***Speech and language therapy interventions:***

Group A will undergo Speech and Language Therapy (SLT); incorporating methods such as: meanings Applied Behavior Analysis (ABA)[35], Applied Behavior Consequences (ABC), Relationship Development Intervention (RDI), Cognitive Behavior Intervention (CBI), meanings Picture Exchange Communication System (PECS); Augmentative and Alternative Communication (AAC) as well as Social communication strategies; such as Social Stories, and visual schedules[36,37]. Each session included 30 minutes of SLT within a 1.5-hour daily therapy schedule.

**Group B (Speech-language therapy and occupational therapy)**

Group B will receive occupational therapy with speech and language therapy, as per the above protocol, for 1.5 hours per session: each therapy intervention will continue for 45 minutes; however, they will not receive any physiotherapy.

Participants in both groups will be provided 1 hour and 30 minutes of each session, per day for 3 days a week, for up to 4 weeks. After 4 weeks, the assessor will obtain the post-test data.

**Minimization of bias and the blinding process**

The study will use a double-blind procedure to guarantee that neither participants, nor assessors are aware of the group allocations. Randomization will be performed by an independent party not associated with

the project. Participants would be kept unaware of other group therapies. Distinct responsibilities will be assigned to the examiner, therapy provider, monitoring group, and trial supervisor to enable effective working combinations. The research group will not participate in the study's execution.

### Data monitoring

Two people, not directly participating in the trial, will constitute the monitoring team. Their duties shall include: overseeing the intervention procedure, side effects, and participant group registration. Furthermore, they will examine the data and perform an interim analysis. If the Institutional Review Board (IRB) implements any modifications to the research protocols or interventions, the lead investigator shall notify them.

### Safety measures and managing adverse effects

While the treatment is predicted to have a small number of side effects, the monitoring group will document any unforeseen incidents occurring during or after the treatment and quickly inform the appropriate specialists. The therapist will capture these occurrences in their notes and communicate them to the lead investigator.

### Data audit and management:

Patient codes will be used to fill out a printed, anonymous questionnaire. A volunteer team from the Master of Physiotherapy program at Jashore University of Science & Technology's Department of Physiotherapy & Rehabilitation will enter, audit, and analyze trial data under the supervision of a faculty member not involved in trial operations. The corresponding author of Jashore University of Science & Technology's Department of Physiotherapy and Rehabilitation will keep the paper questionnaire and digital dataset secret.

### Data analysis

Statistics will be performed with IBM SPSS 26. Data distribution will be examined using Kolmogorov–Smirnov and Shapiro–Wilk normality tests. For continuous and discrete data, descriptive statistics will provide the mean, median, standard deviation, or interquartile range (IQR); whereas, categorical data will use frequencies and percentages. We will examine baseline compatibility and group differences following the test using the independent t–test or Mann–Whitney U test, depending on data distribution. Within–group comparisons will use Wilcoxon signed–rank or paired sample t–tests for paired variables. Intention–to–treat analysis accounts for one–month treatment dropouts, and statistical significance is defined as a p–value<0.05.

### Ethical issues and informed consent

The Institutional Review Board (IRB) of the Physiotherapy and Rehabilitation Department from Jashore University of Science & Technology approved the trial on May 20, 2024 (PTR–JUST/IRB/2024/05/222403). The Clinical Trial Registry India (CTRI) prospectively registered the experiment on July 8, 2024 (CTRI/2024/07/070209). The administrative authorities of Proyash Institute of Special Education, Jashore will provide authorization for the study. The researcher will follow the Helsinki Declaration ethics. Participants will give written informed permission before enrolling and can withdraw at any time without affecting therapy. Only the lead investigator, data auditors, and authors will have access to the anonymised trial dataset. Contractually, investigators that independently examine and document patient data cannot receive or share the final dataset. In case of failure, post–trial therapy will be given.

## Results

We anticipate that the complete multidisciplinary practice of ASD may be advocated throughout this

study. Additionally, this will be beneficial to children and adolescents ASD as well as to the parents and special schools in Bangladesh. The results of this study will further define certain stakeholders.

## Discussion

This study aims to evaluate the efficacy of combination therapy in enhancing the physical and behavioral status of children with ASD, addressing a worldwide concern among this population. Multiple studies have discussed various therapeutic modalities, including physiotherapy, occupational therapy, and speech and language therapy, to address the physical and behavioral conditions of children with autism. Nevertheless, no research has directly contrasted the effectiveness of physiotherapy with occupational and speech and language treatment approaches. Due to insufficient supporting evidence, a rigorously planned, randomized clinical trial is essential to assist therapeutic doctors in clinical decision-making in this aspect.

This focus on reflecting actual clinical practice increases the study's significance and applicability. Ultimately, the findings will enhance the comprehension of effective interventions for children with ASD, addressing a problem that profoundly affects neurodevelopmental diseases, such as autism spectrum disorder, worldwide. This research addresses a significant gap in existing knowledge by comparing physiotherapy therapies with occupational and speech-language therapy, offering vital guidance to doctors making treatment options for ASD. The study's findings will aid in establishing an effective, comprehensive strategy for addressing the severity of autism, regulating stereotyped behaviors, and reducing potential health risks associated with malnutrition in children with ASD.

## Conclusion

This study can aid in the formulation of comprehensive treatment guidelines for ASD in Bangladesh. The study's strength lies in its representative sampling derived from a population-based cross-sectional home survey, ensuring methodological rigor. Consequently, the study findings are restricted to individuals with ASD living in Jashore City, Bangladesh. Future multicenter trials throughout all eight divisions of Bangladesh may yield results with enhanced external validity.

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## Conflict of interest

The authors declared that they have no known competing financial interests or personal relationships that could have appeared to influence the work that will be reported in this paper.

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