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Testing a physiotherapy programme to improve motor skills and quality of life in children with autism

Submission date
23/07/2025

Recruitment status
No longer recruiting

Registration date
24/09/2025

Overall study status
Ongoing

Last Edited
24/09/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is a neurodevelopmental condition that affects communication, social interaction, motor coordination, and behavior. This condition results in reduced physical activity and poor quality of life (QoL). Children with ASD frequently experience motor impairments that hinder daily functioning, participation in play, and social engagement. Although structured physiotherapy interventions have gained attention for improving motor and psychosocial outcomes, most existing programs remain unstructured, lack theoretical grounding and are not tailored to the unique sensory and behavioral needs of children with ASD. Moreover, many interventions are developed in high-resource Western contexts, raising questions about their relevance and applicability in Malaysian community-based rehabilitation settings. Addressing this gap requires a structured and contextually grounded physiotherapy intervention that is both scalable and evidence-based. This study aims to evaluate the effectiveness of a 12-week structured physiotherapy program in improving motor skills, physical activity, behavior, and quality of life in children with mild to moderate ASD.

Who can participate?
Children aged 6 to 10 years who have been diagnosed with mild to moderate Autism Spectrum Disorder (ASD) based on the Gilliam Autism Rating Scale – Third Edition (GARS-3) and who demonstrate motor difficulties as assessed by the Bruininks-Oseretsky Test of Motor Proficiency – Second Edition (BOT-2) are eligible to participate.

What does the study involve?
Participants will be randomly assigned to one of two groups: an intervention or control group. The intervention group will receive the 12-week structured physiotherapy program in addition to usual care. The control group will continue with usual care alone. The structured intervention will include warm-up activities, three structured motor skill circuits, which cover strength, endurance, coordination, balance, and flexibility and a cool-down phase. The structured physiotherapy program will be conducted over 12 weeks with sessions held twice per week. Each session will last for one hour and will be delivered in a paired format where two children participate together under guided supervision. Assessments will take place before and after the

intervention using validated tools to measure motor skills, autism symptom severity, physical activity, behavior, and quality of life.

What are the possible benefits and risks of participating?
Participants in the intervention group may experience improvements in motor skills, physical activity, behavior and overall well-being. There is minimal risk associated with participation. Some children may feel fatigued or frustrated during exercises but all sessions will be supervised by trained physiotherapists and activities will be adapted to suit individual needs. Participation is voluntary, and parents may withdraw their child at any time without any consequences.

Where is the study run from?
The study is coordinated by the Faculty of Health Sciences, Universiti Kebangsaan Malaysia (UKM). Data collection will take place at PDK centres in Terengganu and Klang Valley, Children's Specialist Hospital UKM and selected community centres.

When is the study starting and how long is it expected to run for?
The overall study start date was September 2024. The study's first enrollment started in May 2025 and will run for approximately 8 months, including recruitment, intervention and data analysis phases. The completion date is projected to be January 2026.

Who is funding the study?
This study is funded through a university research grant by Universiti Kebangsaan Malaysia (UKM).

Who is the main contact?
Mrs Nazurah Alwi, nazurah@moh.gov.my

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UKM PPI/111/8

Study information

Scientific Title
Effectiveness of a structured physiotherapy intervention on psychomotor and quality of life in children with mild to moderate autism spectrum disorder

Acronym
STEP-ASD

Study objectives
To evaluate the effectiveness of a structured physiotherapy intervention on the psychomotor (motor skills, physical activity, behavior problems) and QoL among children with ASD.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/01/2025, Research Ethics Secretariat of the National University of Malaysia (Tingkat 1, Blok Klinikal, Hospital Canselor Tuanku Muhriz Jalan Yaacob Latif, Bandar Tun Razak, Kuala Lumpur, 56000, Malaysia; +603-9145 5046 / 9145 5048; sepukm@ukm.edu.my), ref: JEP-2024-1127

Study design
Single-blind two-arm parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Childcare/pre-school, Community, School

Study type(s)
Quality of life, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Motor skills problem among children with Autism Spectrum Disorder (ASD).

Interventions
Randomization of participants will be conducted using randomization.com, with stratification by age (6–10 years), ASD severity (GARS-3) and gender. Group allocation will be handled by an independent research team member not involved in assessments. Outcome assessors will be blinded to group allocation to ensure single-blinded evaluation. The intervention group will receive a structured physiotherapy intervention in addition to usual care. This intervention will be delivered by the main researcher, following the FITT principle (Frequency, Intensity, Time,

Type) over 12 weeks, with two sessions per week and each session lasting for 1 hour. The program is designed to improve motor skills, physical activity, behavior, and quality of life in children with mild to moderate Autism Spectrum Disorder (ASD). Each session will consist of a warm-up, three structured motor skill circuits targeting strength, endurance, coordination, balance and flexibility and a cool-down phase. Exercise intensity will be set at 10 repetitions for motor skills and strength exercises, with aerobic activity guided by a Borg scale rating of 13 in accordance with ACSM (2003) guidelines. Sessions will be conducted in pairs, incorporating child preferences and rewarding effort with cognitive play activities. Progress will be monitored through attendance tracking and performance logs.

The control group will continue receiving usual care only, which may include consultations with pediatricians, therapists and educational services. The type and frequency of usual care will be documented and monitored throughout the study to ensure consistency in comparison.

Intervention Type
Other

Primary outcome measure
Motor skills measured using the Bruininks-Oseretsky Test of Motor Proficiency – Second Edition (BOT-2) at baseline at Week 0 and again post-intervention at approximately Week 12 with a permissible window of up to one week after the intervention ends

Secondary outcome measures
The following secondary outcome measures will be assessed at baseline (Week 0) and after the 12-week intervention period (Week 12) with a permissible window of up to one week after the intervention ends:
1. Autism symptom severity will be measured using the Gilliam Autism Rating Scale – Third Edition (GARS-3)
2. Physical activity level will be assessed using the parent-reported Godin-Shephard Leisure Time Exercise Questionnaire (GLTEQ)
3. Behavioural problems will be measured using the parent-reported Child Behavior Checklist (CBCL)
4. Health-related quality of life will be evaluated using the parent-reported Pediatric Quality of Life Inventory (PedsQL)

Overall study start date
17/09/2024

Completion date
03/01/2026

Eligibility

Key inclusion criteria
1. Children aged 6 to 10 years
2. Diagnosed with Autism Spectrum Disorder (ASD) of mild to moderate severity, based on the Gilliam Autism Rating Scale – Third Edition (GARS-3)
3. Exhibiting motor difficulties, as assessed by the Bruininks-Oseretsky Test of Motor Proficiency – Second Edition (BOT-2)
4. Parent or legal guardian able to provide written informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
64

Key exclusion criteria
1. Presence of other neurological or developmental conditions such as epilepsy, Attention-Deficit /Hyperactivity Disorder (ADHD) or cerebral palsy
2. Physical disabilities resulting from head injuries or other acquired conditions that interfere with participation in motor-based interventions
3. Currently involved in another clinical trial or intensive motor-based programme
4. Unstable medical condition or recent changes in medical treatment that may affect participation

Date of first enrolment
16/05/2025

Date of final enrolment
16/08/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
Hospital Pakar Kanak-Kanak UKM
Jalan Yaacob Latif, Bandar Tun Razak, Cheras
Kuala Lumpur
Malaysia
56000

Study participating centre

Pemulihan Dalam Komuniti Pekan Bukit Payung
Bangunan Majlis Daerah, Marang
Terengganu
Malaysia
21400

Study participating centre
Pusat Autisme Sejahtera Terengganu
1526-G, OFF, Jalan Ibrahim, Taman Kelana Setia, Kuala Terengganu
Terengganu
Malaysia
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Study participating centre
Physiotherapy Clinic UKM
Aras Bawah Blok F, Fakulti Sains Kesihatan UKM, Jalan Raja Muda Abdul Aziz
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Sponsor information

Organisation
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Sponsor type
University/education

Website
https://www.ukm.my/portalukm/

ROR
https://ror.org/00bw8d226

Funder(s)

Funder type
University/education

Funder Name
Universiti Kebangsaan Malaysia

Alternative Name(s)
Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
03/01/2027

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study will be available upon request from nazurah@gmail.com.

• Type of data to be shared: identified individual participant data (IPD) underlying the main outcomes (e.g., GARS-3, BOT-2, GLTEQ, CBCL, PedsQL), along with a data dictionary, annotated case report forms, protocol, and statistical analysis plan (SAP).
• Timing of availability: Upon publication of the primary outcomes, with availability within 6 months of publication and for at least 5 years thereafter.
• Access criteria & process: Available upon reasonable request for non-commercial research purposes. Requests will be reviewed by the study PI and sponsor; approved requestors will sign a data access agreement outlining scope of use, security, and no re-identification.
• Participant consent: Informed consent includes permission to share identified data for ethically approved research.
• Anonymization: Removal of direct identifiers; generalisation/offsetting of dates; suppression

where needed to prevent re-identification.
• Ethical/legal restrictions: Sharing will comply with local regulations (Malaysia PDPA 2010) and institutional policies; no attempts at re-identification; no onward sharing without permission.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			13/08/2025	No	No
Participant information sheet			13/08/2025	No	Yes
Protocol file			13/08/2025	No	No
Statistical Analysis Plan			13/08/2025	No	No