Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of Adaptive Physical Exercise on Balance, Executive Function, and Quality of Life in Children with Intellectual Disabilities

Protocol summary

Study aim

This study aims to evaluate the effects of a 12-week, structured play-based physical activity program on fundamental motor skills and health-related quality of life in children aged 6–12 years with mild-to-moderate intellectual disabilities. Utilizing a single-blind, randomized controlled trial design within a special education school, this study investigates whether engaging in motor-skill-focused play activities yields statistically significant improvements in gross motor coordination, balance, adaptive behavior, and overall well-being compared to a standard care/waitlist control group. The primary goal is to establish an evidence-based, scalable, and engaging physical activity intervention strategy tailored to enhance functional independence and life quality for children with intellectual disabilities.

Design

A single-center, two-arm parallel group, assessor-blinded randomized controlled trial of 36 children, featuring computer-generated stratified permuted block randomization.

Settings and conduct

The trial will be conducted at a single special education school in China. All intervention sessions and assessments will take place in the school's designated indoor gymnasium and sensory-motor training room, providing a safe, controlled, and familiar environment for the participants.

Participants/Inclusion and exclusion criteria

Aged 6–15 years; diagnosed with mild-to-moderate intellectual disability (IQ 35–69 via DSM-5/ICD-11). Enrolled in special school; walks independently; follows basic 2-step instructions. Written parental consent and child assent.

Intervention groups

Structured Play-Based Physical Activity Program

Main outcome variables

Gross Motor Development / Motor Skills, Postural Balance & Coordination

General information

Reason for update

Acronym

Play-based Physical Activity in Children with Intellectual Disabilities

IRCT registration information

IRCT registration number: **IRCT20261005071299N1**
Registration date: **2026-10-16, 1405/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-16, 1405/07/24**
Update count: **0**

Registration date

2026-10-16, 1405/07/24

Registrant information

Name

Wei-Hsun Tai

Name of organization / entity

Fujian Agriculture and Forestry University

Country

China

Phone

+86 591 8370 6551

Email address

dlove520@hotmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-10, 1405/07/18

Expected recruitment end date

2026-12-10, 1405/09/19

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Adaptive Physical Exercise on Balance, Executive Function, and Quality of Life in Children with Intellectual Disabilities

Public title
Game-Based / Fun Exercise Focus
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 6 to 15 years Confirmed diagnosis of Intellectual Disability based on DSM-5 or ICD-11 criteria. Ability to walk independently without assistive devices and participate in light-to-moderate physical play activities. Capable of understanding simple two-step instructions and following basic game rules Written informed consent provided by parents/legal guardians, and verbal or non-verbal assent from the child
Exclusion criteria:
Severe motor, orthopedic, or neurological impairments (e.g., severe Cerebral Palsy, uncontrolled epilepsy) that restrict safe participation in exercise. Uncorrected severe visual or hearing impairments that significantly hinder instruction understanding or interaction during play. Severe self-injurious, aggressive, or disruptive behaviors that pose a safety risk to themselves or others during group activities. Participation in any other structured exercise or physical therapy program within the last 3 months Uncontrolled cardiovascular, respiratory, or metabolic conditions deemed unsafe for exercise by a physician
Age
From **6 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomized at the individual level in a 1:1 ratio to either the play-based physical activity group (intervention) or the control group. Because participants will be recruited from a single special education school, randomization will be stratified by age group (e.g., 6–8 years vs. 9–12 years) and baseline intellectual disability severity (mild vs. moderate) to ensure a balanced distribution of these key prognostic factors across both arms. Within each stratum, a pseudorandomization method using permuted block randomization with randomly varying block sizes of 2 and 4 will be employed. The allocation sequence will be generated prior to enrollment using a computer-generated table of pseudorandom numbers built with R software (version 4.2.0; Mersenne Twister generator with a fixed seed recorded for reproducibility) by an independent statistician who is not involved in participant recruitment or assessment. Allocation concealment will be strictly maintained using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). Once a child meets all inclusion criteria and written informed consent is obtained from their parent/legal guardian, the study coordinator will open the next sequentially numbered envelope to reveal the child's group allocation.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the play-based physical activity intervention, blinding of the participants, parents/caregivers, and exercise trainers is not feasible. However, to minimize detection and measurement bias, a single-blind (outcome assessor-blinded) design will be implemented. The outcome assessors responsible for taking baseline and post-intervention measurements (e.g., motor skill testing, quality-of-life questionnaires) will be kept completely unaware of the participants' group allocations. Assessors will be independent researchers not involved in designing or delivering the exercise program. Participants and parents will be explicitly instructed prior to each assessment session not to disclose their group assignment to the evaluators. Additionally, the data analyst will perform all statistical analyses using coded datasets (e.g., Group A vs. Group B) and will remain blinded to group identity until the primary analyses are completed.
Placebo
Used
Assignment
Parallel
Other design features
Randomization Method: Stratified permuted block randomization (stratified by age group and intellectual disability severity) using a computer-generated pseudorandom sequence.Blinding: Single-blind design where outcome assessors and the data analyst are kept completely blinded to group allocations to prevent measurement and detection bias.Study Setting: Single-center study conducted within a special education school environment.Control Group Strategy: Waitlist active/usual care control design to ensure ethical adherence, offering the play-based exercise intervention to control group participants after trial completion.Session Supervision: All play-based physical activity sessions are delivered in small groups (4–6 children) led by certified trainers with a standardized session structure and safety protocol.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Quanzhou Normal University Research Ethics Committee

Street address
No. 398, Donghai Street, Fengze District

City
Quanzhou

Postal code
362000

Approval date
2026-06-21, 1405/03/31

Ethics committee reference number
QZSYLL202621

Health conditions studied

1

Description of health condition studied
Intellectual Developmental Disorder

ICD-10 code
F70

ICD-10 code description
Mild intellectual disabilities

Primary outcomes

1

Description
Fundamental Gross Motor Skills and postural Balance and Stability

Timepoint
12 weeks after intervention

Method of measurement
Evaluator Protocol & Blinding:Assessments will be administered individually to each child by independent, trained pediatric physical therapists/assessors who are completely blinded to group allocations (Single-blind design). Assessors will strictly follow standardized testing manuals for each instrument. Special education teachers familiar with the children will be present to assist with communication without influencing test performance.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mini-basketball training program. Participants in this group receive a structured mini-basketball exercise intervention designed for children with intellectual disabilities. The training session includes a 10-minute warm-up (stretching and mobility exercises), 40 minutes of core basketball skill training (dribbling, passing, shooting, and interactive mini-games using age-appropriate mini-basketballs), and a 10-minute cool-down section. The program is conducted by certified physical education instructors. Frequency: 3 times per week. Duration per session: 60 minutes (including warm-up and cool-down). Total intervention period: 12 weeks. Location/Setting: School gymnasium.

Category
Other

2

Description
Intervention group: Rhythmic gymnastics program. Participants in this group participate in a structured rhythmic exercise program set to music tailored for children with intellectual disabilities. Each session consists of a 10-minute warm-up, 40 minutes of rhythmic movements and basic dance routines focused on coordination, rhythm, and body balance, and a 10-minute cool-down section. The exercises are led by qualified fitness instructors. Frequency: 3 times per week. Duration per session: 60 minutes (including warm-up and cool-down). Total intervention period: 12 weeks. Location/Setting: School dance studio.

Category
Other

3

Description
Control group: Usual daily activity / Standard physical education class. Participants in this group maintain their routine daily activities and normal school physical education curriculum without receiving any additional mini-basketball intervention during the study period. Total period: 12 weeks.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shishi Ren'ai Special Education School

Full name of responsible person
Xu Yingying

Street address
No. 69, Area 1, Shandou, Xiangzhi Town

City
Shishi

Postal code
362713

Phone
+86 595 6887 2050

Email
dlove520@hotmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Social Science Foundation of Fujian Province
Full name of responsible person
Xiao Menggang
Street address
Social Science Planning Office of Fujian Province, No. 83 Liuxing Road
City
Fuzhou
Postal code
350025
Phone
+86 591 8502 5030
Email
fjsskghb@163.com
Grant name
Social Science Foundation of Fujian Province
Grant code / Reference number
FJ2024C067
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Social Science Foundation of Fujian Province
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Fujian Agriculture and Forestry University
Full name of responsible person
Wei-Hsun Tai
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
No. 15, Shangxiadian Road, Cangshan District
City
Fuzhou
Province
Fujain
Postal code
350002
Phone
+86 591 8370 6551
Fax
Email
dlove520@hotmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Fujian Agriculture and Forestry University
Full name of responsible person
Wei-Hsun Tai
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
No. 15, Shangxiadian Road, Cangshan District
City
Fuzhou
Province
Fujain
Postal code
350002
Phone
+86 591 8370 6551
Fax
Email
dlove520@hotmail.com

Person responsible for updating data

Contact
Name of organization / entity
Fujian Agriculture and Forestry University
Full name of responsible person
Wei-Hsun Tai
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
No. 15, Shangxiadian Road, Cangshan District
City
Fuzhou
Province
Fujain
Postal code
350002
Phone
+86 591 8370 6551
Fax
Email
dlove520@hotmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
all collected deidentified IPD, IPD collected for the primary outcome measure only

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
only available for people working in academic institutions

Under which criteria data/document could be used
Shared de-identified individual participant data (IPD) and supporting documents (study protocol, statistical analysis plan, and informed consent form) will be restricted to methodologically sound academic research, including: Systematic reviews and meta-analyses. Secondary exploratory analyses evaluating motor skill interventions or physical activity patterns in pediatric populations with intellectual disabilities. Validation or replication of trial statistical methodologies.

From where data/document is obtainable
De-identified individual participant data (IPD) and supporting trial documents are stored in a secure, institutional encrypted repository at School of Physical Education, QuanZhou Normal University. Data files are not publicly accessible via direct web download to protect minor participants' privacy, but will be shared upon formal request approval. Preferred Method of Communication: Email communication is the preferred and primary method for all initial data access inquiries and formal applications. Primary Contact Person & Detailed Contact Information: Contact Person / Investigator: Xu Min Position / Title: Principal Investigator Affiliation: Quanzhou normal University Email Address: joxm@foxmail.com

What processes are involved for a request to access data/document
The applicant submits a formal request via email directly to the Principal Investigator at joxm@foxmail.com.

Comments