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Study Identification

Unique Protocol ID: AHNU-MIXPE-LBC-01
Brief Title: Mixed PE Program Using Sports Games and Ball Sports in Left-Behind Children (MIXPE-LBC)
Official Title: A 12-Week School-Based Mixed Physical Education Intervention Combining Cooperative Sports Games and Ball Sports to Improve Mental Health and Physical Fitness in Rural Left-Behind Children
Secondary IDs:

Study Status

Record Verification: March 2026
Overall Status: Completed
Study Start: September 1, 2025 [Actual]
Primary Completion: January 9, 2026 [Actual]
Study Completion: January 9, 2026 [Actual]

Sponsor/Collaborators

Sponsor: Anhui Normal University
Responsible Party: Principal Investigator
Investigator: Tao Fang [TaoFang]
Official Title: Principal Investigator
Affiliation: Anhui Normal University
Collaborators:

Oversight

U.S. FDA-regulated Drug: No
U.S. FDA-regulated Device: No
U.S. FDA IND/IDE: No
Human Subjects Review: Board Status: Approved
Approval Number: AHNU-EJ2025069
Board Name: Ethics Committee of Anhui Normal University
Board Affiliation: Anhui Normal University
Phone: +86-18755521117
Email: 18755521117@163.com
Address:

Data Monitoring: No

Study Description

Brief Summary: This randomized controlled trial evaluates whether a 12-week school-based physical education program that combines cooperative sports games and ball sports can improve mental health and physical fitness in rural left-behind children. Left-behind children are those who remain in rural areas while one or both parents migrate for work. These children may experience social and emotional challenges in addition to physical health concerns.

Forty sixth-grade boarding students who met the criteria for left-behind children were randomly assigned to either a mixed training group or a usual physical education control group. The intervention was delivered during regular school physical education classes three times per week, 90 minutes per session, for 12 weeks. Each session included cooperative physical games designed to promote peer interaction, followed by structured soccer or basketball training activities.

Mental health was assessed using the Mental Health Test (MHT), and physical fitness was evaluated using standardized school-based tests including lung function, running performance, flexibility, and coordination. Outcomes were measured before and after the intervention.

The study aims to determine whether optimizing the structure of routine school physical education can provide a feasible and scalable strategy to support both psychological well-being and physical development in vulnerable child populations.

Detailed Description: This study is a single-center, parallel-group randomized controlled trial conducted in a rural primary boarding school in China. The objective was to evaluate the effects of a structured 12-week mixed physical education intervention integrating cooperative sports games and ball sports on mental health and physical fitness in left-behind children.

Eligible participants were sixth-grade students who had been separated from one or both parents for more than six months and met the study's screening criteria for left-behind children. After baseline assessment, participants were randomly allocated in a 1:1 ratio to either the mixed training group (MTG) or the control group (CONG) using block randomization (block size = 4) with allocation concealment via sequentially numbered opaque sealed envelopes. Outcome assessors were blinded to group assignment.

The intervention was delivered within the routine physical education curriculum (three sessions per week, 90 minutes per session, for 12 weeks). Each session included: (1) a 20–25 minute cooperative game segment emphasizing social interaction and group participation; (2) a 55–60 minute structured soccer or basketball training segment with progressive skill development and small-sided games; and (3) a brief cool-down period. Exercise intensity was staged using target heart rate zones corresponding to approximately 60–85% of age-predicted maximal heart rate.

The primary outcome measure was the total score of the Mental Health Test (MHT). Secondary outcomes included MHT subscales and standardized physical fitness indicators (vital capacity, 50-m dash, 8×50-m shuttle run, rope skipping, sit-ups, sit-and-reach, and body mass index). All outcomes were assessed at baseline and immediately post-intervention.

Data were analyzed using two-way repeated-measures analysis of variance to assess group, time, and interaction effects. The study was conducted in accordance with the Declaration of Helsinki and was approved by the institutional ethics committee.

Conditions

Conditions: Mental Health
Physical Fitness
Left-Behind Children

Keywords: left-behind children
school-based intervention
physical education
sports games
ball sports
randomized controlled trial
child mental health
aerobic fitness
social interaction
cooperative play

Study Design

Study Type: Interventional

Primary Purpose: Prevention

Study Phase: N/A

Interventional Study Model: Parallel Assignment
Participants were randomly assigned in a 1:1 ratio to either a mixed training group (MTG) or a usual physical education control group (CONG). Both groups received physical education during the same 12-week period. The MTG received a structured mixed intervention combining cooperative sports games and ball sports, while the CONG followed the standard school curriculum. No crossover occurred between groups.

Number of Arms: 2

Masking: Single (Outcomes Assessor)
Outcome assessors responsible for physical fitness testing were blinded to group allocation. Participants and the physical education teacher delivering the intervention were not blinded due to the nature of the study design.

Allocation: Randomized

Enrollment: 40 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Mixed Training Group (MTG) Participants in this arm received a structured 12-week school-based physical education intervention delivered three times per week (90 minutes per session). Each session included a 20–25 minute cooperative sports game segment followed by 55–60 minutes of structured soccer or basketball training with progressive intensity and small-sided games.	Behavioral: Mixed Physical Education Program Participants received a structured 12-week school-based physical education program delivered three times per week (90 minutes per session). Each session included a cooperative sports game component (20-25 minutes) designed to promote peer interaction and social engagement, followed by structured soccer or basketball training (55-60

Arms	Assigned Interventions
The intervention was implemented within the regular physical education curriculum.	minutes) with progressive skill development and small-sided games. Exercise intensity was staged to achieve approximately 60-85% of age-predicted maximal heart rate. The intervention was implemented within the regular school physical education curriculum.
<p>Active Comparator: Usual Physical Education Control Group (CONG)</p> <p>Participants in this arm followed the standard school physical education curriculum for 12 weeks. The curriculum primarily included calisthenics and general physical fitness training without structured cooperative sports games or systematic ball sports training.</p>	<p>Behavioral: Usual Physical Education</p> <p>Participants followed the standard school physical education curriculum for 12 weeks, consisting primarily of calisthenics and general physical fitness activities. The curriculum did not include structured cooperative sports games or systematic soccer or basketball training as provided in the experimental intervention.</p>

Outcome Measures

Primary Outcome Measure:

1. Mental Health Test (MHT) Total Score

The Mental Health Test (MHT) is a standardized self-report instrument used to assess psychological status in school-aged children. The total score reflects overall psychological difficulty, with higher scores indicating greater levels of psychological problems.

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

Secondary Outcome Measure:

2. Interpersonal Anxiety (MHT Subscale Score)

Interpersonal Anxiety is a subscale of the Mental Health Test (MHT) assessing social anxiety and interpersonal stress. Higher scores indicate greater levels of interpersonal anxiety.

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

3. Self-Blame Tendency (MHT Subscale Score)

Self-Blame Tendency is a subscale of the Mental Health Test (MHT) evaluating self-directed negative attribution patterns. Higher scores indicate greater self-blame.

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

4. Vital Capacity (mL)

Vital capacity measured in milliliters using standardized school-based pulmonary function testing procedures.

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

5. 50-Meter Dash Time (seconds)

Time required to complete a 50-meter sprint, recorded in seconds.

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

6. 8×50-Meter Shuttle Run Time (seconds)

Total time required to complete eight 50-meter shuttle runs, recorded in seconds.

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

7. Rope Skipping Performance (repetitions per minute)

Number of rope skipping repetitions completed within one minute.

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

8. Sit-Ups Performance (repetitions per minute)

Number of sit-ups completed within one minute.

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

9. Sit-and-Reach Distance (centimeters)

Maximum forward reach distance measured in centimeters using a standardized sit-and-reach test.

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

10. Body Mass Index (kg/m²)

Body mass index calculated from measured height and weight (kg/m²).

[Time Frame: Baseline and Week 12 (Immediately Post-Intervention)]

Eligibility

Minimum Age: 12 Years

Maximum Age: 13 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- Aged 12 to 13 years
- Enrolled in the sixth grade of the participating rural primary school
- Classified as left-behind children, defined as separation from one or both parents for more than six months due to parental migration for work
- Boarding-school students during the study period
- Provided written informed consent from legal guardians and written assent from the child

Exclusion Criteria:

- Children from single-parent families or orphans
- Presence of physical, neurological, or medical conditions that would limit participation in regular physical activity
- Participation in any structured extracurricular physical training program during the study period

Contacts/Locations

Central Contact Person: Tao Fang, Doctor
Telephone: +86-18755521117
Email: 18755521117@163.com

Central Contact Backup:

Study Officials:  **NOTE : Study Official is required by the WHO and ICMJE.**

Locations: **China, Anhui**
Rural Primary School in J County
Wuhu, Anhui, China, 241000
Contact: Tao Fang, Ph.D. +8618755521117 18755521117@163.com

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services