Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparison of the effects of 10 weeks of balance and aerobic exercises on the balance, cancer-related fatigue, and quality of life of children with leukemia.

Protocol summary

Study aim

The overall goal of the present study is to compare the effect of 10 weeks of balance and aerobic exercises on the balance, cancer-related fatigue, and quality of life in children with leukemia.

Design

The study groups include the aerobic intervention group, the balance intervention group, and the control group. It has a control group, with factorial groups, non-blinded, randomized; the tests are conducted on-site/in the field on 27 patients.

Settings and conduct

The research is conducted at Bu-Ali Hospital in Sari, and the pre-tests include assessment of balance, fatigue (CFS-24h), and quality of life (PedsQL).

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Children with leukemia between the ages of 5 and 15 years. 2. Children in the maintenance phase of treatment with more than 20 weeks elapsed since the start of the phase. 3. Height, weight, and BMI within the normal range. 4. Children must be capable of performing physical activity. 5. Must not have symptoms related to acute illness, for example, fever (< 38 degrees Celsius), severe anemia. Exclusion Criteria: Non-leukemic individuals are excluded from entry."

Intervention groups

Sample: 27 children with leukemia undergoing chemotherapy were randomly divided into three groups (9 children in each group). Balance Exercise Group: Static and dynamic exercises including two-leg standing, tandem stance, single-leg stance, and crossover walking; for 10 weeks, 2 sessions per week, with each session including a warm-up and cool-down. Aerobic Exercise Group: Outdoor walking for 10 weeks, 2 sessions per week; exercise intensity will be controlled based on the Karvonen formula (50% to 75% HRR) and the Visual Analog Scale (RPE=11-13). Control Group: No exercise intervention, maintaining usual lifestyle and receiving current medical care.

Main outcome variables

Aerobic fitness and balance improvement.

General information

Reason for update

Acronym

BATCL

IRCT registration information

IRCT registration number: **IRCT20251023067733N1**
Registration date: **2025-11-18, 1404/08/27**
Registration timing: **prospective**

Last update: **2025-11-18, 1404/08/27**
Update count: **0**

Registration date

2025-11-18, 1404/08/27

Registrant information

Name

Negar Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3332 0789

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negarazizi183@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison of the effects of 10 weeks of balance and aerobic exercises on the balance, cancer-related fatigue, and quality of life of children with leukemia.

Public title
"Comparison of the effects of balance and aerobic exercises on children with leukemia"
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children with leukemia in the age range of 5 to 15 years Children in the maintenance phase of treatment and time elapsed since the start of the phase of more than 20 weeks Height, weight, and BMI within the normal range Children should be capable of performing physical activity Should not have acute illness-related symptoms, for example, fever (< 38 degrees Celsius), severe anemia
Exclusion criteria:
Non-leukemic individuals should not enter the study
Age
From **5 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **27**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Simple. Unit of randomization: Individual. Stratified randomization. Randomization tool based on statistical software. Method of generating the random sequence: The allocation sequence was first defined in the aforementioned software by determining block sizes, allocation ratio, and stratification variables. Then, the final list was generated by coding the groups as 'A' and 'B' and kept in an encrypted file. None of the research team members had access to this file until participants were allocated to the groups. Allocation concealment was achieved by using opaque, sealed, and tamper-evident envelopes; each envelope had a serial number synchronized with the random sequence. Upon confirming the eligibility criteria, the person responsible for enrolling study participants opened the envelope corresponding to the individual's number and assigned the participant to the intervention or control group based on the contents inside the envelope. This process prevented the prediction of allocation and eliminated selection bias.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics code of Shahid Beheshti University
Street address
Farhang Street, Farhangian Alley, Third Alley, Sayeh Apartment.
City
Sari
Province
Mazandaran
Postal code
4818815393
Approval date
2025-09-20, 1404/06/29
Ethics committee reference number
IR.SBU.REC.1404.172

Health conditions studied

1

Description of health condition studied
Leukemia
ICD-10 code
C91
ICD-10 code description
Lymphoid leukemia

Primary outcomes

1

Description
Balance score in the Modified Stork Test and Tandem Walking Test.
Timepoint
The primary outcomes are measured at two time points: before the start of the intervention and immediately after the completion of 10 weeks of balance and aerobic exercises.
Method of measurement
Balance assessment of children: using the modified Stork Test and Tandem Walking.

Secondary outcomes

1

Description
Cancer-related fatigue assessment
Timepoint
Pre-test and post-test
Method of measurement
Cancer-related fatigue assessment: using the Persian version of the Children, Parents, and Staff Fatigue Questionnaire CFS-24h

2

Description
Assessment of children’s quality of life
Timepoint
Pre-test and in post-test
Method of measurement
Assessing Quality of Life in Children: Using the Child Quality of Life Inventory Questionnaire

3

Description
Controlling Exercise Intensity
Timepoint
Pre-test and Post-test
Method of measurement
Controlling exercise intensity: using the Visual Analog Scale of Perceived Exertion and measuring heart rate.

Intervention groups

1

Description
Control group: regular daily activities.
Category
Rehabilitation

2

Description
Intervention group: balance exercises.
Category
Rehabilitation

3

Description
Intervention group: aerobic exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahak hospital
Full name of responsible person
Amir hossein barati
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https://maahakcharity.com/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Shahid beheshti
Full name of responsible person
Amir hossein Barati
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ahbarati20@gmail.com
Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University of Shahid beheshti
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
The University of Shahid beheshti

Full name of responsible person
Amir hossein Barati

Position
Associate professor

Latest degree
Medical doctor

Other areas of specialty/work
Sport Medicine

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Person responsible for updating data

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Negar azizi

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Other areas of specialty/work
Sport injury

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

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

Clinical Study Report
Not applicable

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
I will make a decision after completing the research and consulting with my supervisor.

When the data will become available and for how long
After completing the research and after the article is published.

To whom data/document is available
I will make a decision after completing the research and consulting with my supervisor.

Under which criteria data/document could be used
I will make a decision after completing the research and consulting with my supervisor.

From where data/document is obtainable

To all authors

What processes are involved for a request to access data/document

Request to the authors

Comments

I will make a decision after completing the research and consulting with my supervisor.