

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### **Email address**

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

#### Street address

pasdaran blvrd

#### City

sari

#### Province

Mazandaran

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4815838465

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mahakcharity@gmail.com

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The University of Shahid beheshti

##### Full name of responsible person

Amir hossein Barati

##### Street address

Evin

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Tehran

##### Province

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1983969411

##### Phone

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ahbarati20@gmail.com

##### Web page address

<https://www.sbu.ac.ir/>

#### 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

## 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 scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
The University of Shahid beheshti

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Negar azizi

**Position**  
Master student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Sport injury

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**Email**  
negarazizi183@yahoo.com

## 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.