

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigation the effects of core stability training and child-centered play therapy on improving static and dynamic balance in female deaf children

#### Protocol summary

##### Study aim

The aim of this study was to compare the effects of core stability exercises and child-centered play therapy on improving static and dynamic balance in deaf female children.

##### Design

The exercise groups will perform the exercise protocol 3 times a week for 8 weeks. During an introductory session, participants will be introduced to the research process and the implementation of the exercise protocols. Both the CST and CCPT exercise protocols will be performed under the full supervision of a physiotherapist. Each CST and CCPT session will include a warm-up (5 minutes of walking and stretching exercises), the main intervention (i.e., 30 minutes in the first 3 weeks, increasing to 3 sessions per week and up to 45 minutes in the final 5 weeks), and a cool-down (5 minutes). The CST protocol will involve performing 11 different exercises derived from previous studies (20). The CCPT sessions will include a variety of physical challenges and skill-building activities.

##### Settings and conduct

Before and about 48 hours after the final training session, static and dynamic balance tests will be assessed. The ESS test will be employed to assess static balance and the TUG test will be used to assess dynamic balance

##### Participants/Inclusion and exclusion criteria

A documented history of absolute or severe deafness, the ability to walk independently, and no physical disabilities

##### Intervention groups

(i) Core Stability Training (CST), (ii) Child-Centered Play Therapy (CCPT), and (iii) Control group

##### Main outcome variables

Number of errors in static balance, total time spent performing the dynamic balance test, and overall score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240513061779N3**

Registration date: **2025-12-30, 1404/10/09**

Registration timing: **prospective**

Last update: **2025-12-30, 1404/10/09**

Update count: **0**

##### Registration date

2025-12-30, 1404/10/09

##### Registrant information

##### Name

Nader Hamedchaman

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3332 2230

##### Email address

nader.hamedchaman@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2026-01-05, 1404/10/15

##### Expected recruitment end date

2026-01-20, 1404/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation the effects of core stability training and child-centered play therapy on improving static and dynamic balance in female deaf children

#### Public title

Comparing the effects of two different balance training protocols on improving balance in deaf female students

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Documented history of absolute or severe deafness  
Ability to walk independently No physical disabilities

##### Exclusion criteria:

Outfit the prerequisite age range of 10 to 15 years old  
Presence or emergence of other physical disabilities  
Adding drug treatments that interfere with the hormonal profile or performance of volunteers

#### Age

From **10 years** old to **15 years** old

#### Gender

Female

#### Phase

4

#### Groups that have been masked

- Care provider
- Data analyser

#### Sample size

Target sample size: **36**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Block randomization with block size = 3 will be divided between the groups; the randomization list will be generated using the "Random allocation" software. So that first, the subjects will be grouped in consecutive blocks of fixed size of 3 in the order of their entry into the study. For each block, a random sequence of group assignments will be generated by specialized "Random allocation" software. This software ensures that the order of the groups within each block is completely random. Then, each new volunteer is assigned to one of the study groups based on their position in the current block and according to a pre-generated list. This method ensures that allocations remain balanced throughout the study and that the probability of allocation bias in short-term time intervals tends to zero.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In order to prevent the Hawthorne and Avis effect, in the present study, the examiner (clinical caregiver) and the data analyst were unaware of the content and titles of the groupings

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Sport Sciences Research Institute

##### Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street

##### City

Tehran

##### Province

Tehran

##### Postal code

1587958711

#### Approval date

2025-12-02, 1404/09/11

#### Ethics committee reference number

SSRI.REC-2510-3062

## Health conditions studied

### 1

#### Description of health condition studied

Congenital bilateral deafness

#### ICD-10 code

H90.0

#### ICD-10 code description

Conductive hearing loss, bilateral

## Primary outcomes

### 1

#### Description

Error count in the functional test of standing with one foot on a hard surface

#### Timepoint

Before and 48 hours subsequent to the 8 weeks of balance training

#### Method of measurement

Field test of balance on a hard surface

### 2

#### Description

Error count in the functional test of standing with one foot on a soft surface

#### Timepoint

Before and 48 hours subsequent to the 8 weeks of balance training

#### Method of measurement

Field test of balance on a soft surface

### 3

#### **Description**

Error count in the functional test of tandem standing on a hard surface

#### **Timepoint**

Before and 48 hours subsequent to the 8 weeks of balance training

#### **Method of measurement**

Field test of balance on a hard surface

### 4

#### **Description**

Error count in the functional test of tandem standing on a soft surface

#### **Timepoint**

Before and 48 hours subsequent to the 8 weeks of balance training

#### **Method of measurement**

Field test of balance on a soft surface

### 5

#### **Description**

Functional test of Dynamic balance

#### **Timepoint**

Before and 48 hours after 8 weeks of balance training

#### **Method of measurement**

Field test 3 meters back and forth on a balance beam

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: 8 weeks of performing full-body core stability training based on body weight with a frequency of 3 sessions per week (30 minutes in the first 3 weeks to 45 minutes in the last 5 weeks)

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group: 8 weeks of game-based exercises (including jogging, chasing, jumping) with a frequency of 3 sessions per week (30 minutes in the first 3 weeks to 45 minutes in the last 5 weeks)

#### **Category**

Rehabilitation

### 3

#### **Description**

Control group: daily routine without any special physical activity

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shomal University Gymnastics Hall

##### **Full name of responsible person**

Ensiyeh Dashti-Ahangar

##### **Street address**

Haraz st

##### **City**

Amol

##### **Province**

Mazandaran

##### **Postal code**

۴۶۱۶۱۸۴۵۹۶

##### **Phone**

+98 11 4420 3711

##### **Email**

info@shomal.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shomal university

##### **Full name of responsible person**

Hossein Ranjbar

##### **Street address**

Haraz street

##### **City**

Amol

##### **Province**

Mazandaran

##### **Postal code**

۴۶۱۶۱۸۴۵۹۶

##### **Phone**

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##### **Email**

info@shomal.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Shomal university

#### **Proportion provided by this source**

10

#### **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**

Shomal university

**Full name of responsible person**

Nader Hamedchaman

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise physiology

**Street address**

Haraz street

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shomal University

**Full name of responsible person**

Nader Hamedchaman

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There are no plans to release it

**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**

Not applicable

**Title and more details about the data/document**

Some of the volunteers' general characteristics, including their age, medical history, and body composition, will be shared.

**When the data will become available and for how long**

The access period will begin after the results are printed.

**To whom data/document is available**

Trainers, clubs and health centers

**Under which criteria data/document could be used**

Research centers can use non-personally identifiable data to conduct screenings or conduct meta-analysis studies with the aim of examining various aspects of individual health and performance

**From where data/document is obtainable**

Corresponding author's email address: Dr. Nader Hamedchaman Nader.Hamedchaman@gmail.com

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

Send an email to the corresponding author - Check the organizational affiliation and purpose of the requester

**Comments**