

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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

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Mazandaran

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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

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Mazandaran

Postal code

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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

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

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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