Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 performe 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 prerequisitive 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
+98 11 4420 3711
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

City
Amol

Province
Mazandaran

Postal code
۴۶۱۶۱۸۴۵۹۶

Phone
+98 11 4420 3638

Email
nader.hamedchaman@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shomal University

Full name of responsible person
Nader Hamedchaman

Position
Assistant Professor

Latest degree
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Phone
+98 11 4420 3638

Email
nader.hamedchaman@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shomal university

Full name of responsible person
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Assistant Professor

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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