Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of changes in Balance and balance recovery mechanism During manipulation of Vestibular and Somatosensory system and after a period of aquatic exercise and detraining and determine their relation to strength, proprioception and reaction time in blind, deaf and healthy persons

Protocol summary

Summary

Objective: The purpose of this study is to assess of changes in balance and balance recovery mechanism during manipulation of vestibular and somatosensory system and after a period of aquatic exercise and determine their relation to strength, proprioception and reaction time in blind, deaf and healthy persons. Design: In this clinical trial, 30 healthy persons, 30 blind persons and 30 deaf persons will be divided randomly in two groups of aquatic exercise and control (15 persons of each populations in one group). Setting and conduct: Aquatic exercise groups will participate in training sessions for 8 weeks while the control groups will not receive the intervention. Major inclusion and exclusion criteria: Inclusion criteria include: Age between 27 and 36; no specific sport activity during study. Exclusion criteria from the study include: Congenital disorders; previous surgery or injury especially in lower extremities; use of sedative and analgesic drugs that disrupt proprioception and balance (especially 24 hours before the test); non-normal body mass index; specific diseases; neuromuscular disease; Inability to do pre and post intervention tests; doing effective exercises in order to improving balance and no completion of training sessions. Interventions: Aquatic exercise and manipulation of sensory system. Main outcome variables: Before and after intervention, all subjects will be assessed for postural control, balance recovery strategy, reaction time, strength and proprioception.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022132705N1**
Registration date: **2017-07-15, 1396/04/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-15, 1396/04/24

Registrant information

Name

Asma Salari

Name of organization / entity

Shahid Bahonar University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shahid Bahonar University of Kerman

Expected recruitment start date

2017-01-24, 1395/11/05

Expected recruitment end date

2017-02-23, 1395/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment of changes in Balance and balance recovery mechanism During manipulation of Vestibular and Somatosensory system and after a period of aquatic exercise and detraining and determine their relation to strength, proprioception and reaction time in blind, deaf and healthy persons

Public title
Assessment of changes in Balance and balance recovery mechanism after a period of aquatic exercise and detraining in blind, deaf and healthy persons
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria include: Age between 27 and 36; no specific sport activity during study. Exclusion criteria from the study include: Congenital disorders; previous surgery or injury especially in lower extremities; use of sedative and analgesic drugs that disrupt proprioception and balance (especially 24 hours before the test); non-normal body mass index; specific diseases; neuromuscular disease; Inability to do pre and post intervention tests; doing effective exercises in order to improving balance and no completion of training sessions.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
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 committee of Kerman University of Medical Science
Street address
Somayeh Crossroads, Kerman
City
Kerman
Postal code
Approval date
2017-01-23, 1395/11/04
Ethics committee reference number
IR.KMU.REC.1395.351

Health conditions studied

1

Description of health condition studied
Falling (Loss of balance)
ICD-10 code
W01,W10,W1
ICD-10 code description
Fall on same level from slipping, tripping and stumbling,Fall on and from stairs and steps, Other fall from one level to another,Other fall on same level,Unspecified fall,Tendency to fall, not elsewhere classified,Senility

2

Description of health condition studied
Visual impairment
ICD-10 code
H54.0
ICD-10 code description
Blindness, binocular

3

Description of health condition studied
Visual impairment
ICD-10 code
H54.1
ICD-10 code description
Severe visual impairment, binocular

4

Description of health condition studied
Visual impairment
ICD-10 code
H54.2
ICD-10 code description
Moderate visual impairment, binocular

Primary outcomes

1

Description
Postural control
Timepoint
Before, after and one month after intervention
Method of measurement
By Biodex system and Y balance test

2

Description
Balance recovery strategy
Timepoint
Before, after and one month after intervention
Method of measurement
By Motion Analysis System

3

Description
Strength
Timepoint
Before, after and one month after intervention
Method of measurement
By Hand Held Dynamometer

4

Description
Proprioception
Timepoint
Before, after and one month after intervention
Method of measurement
By Photography

5

Description
Reaction Time
Timepoint
Before, after and one month after intervention
Method of measurement
By Motion Analysis System

6

Description
postural sway index
Timepoint
Before, after and one month after intervention
Method of measurement
By foot scan

7

Description
EMG activity of muscles
Timepoint
Before, after and one month after intervention
Method of measurement
By EMG device

Secondary outcomes

empty

Intervention groups

1

Description
Aquatic exercise group will participate in training sessions for 8 weeks and their status will be evaluated Before, after and one month after intervention.
Category
Prevention

2

Description
The control group will not receive the intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Blind Society
Full name of responsible person
Mr Sattari
Street address
gharani Square, Kerman
City
Kerman

2

Recruitment center
Name of recruitment center
Deaf community
Full name of responsible person
Mr Mirzadeh
Street address
Firoozeh Cross Road, , Kerman
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shahid Bahonar University of Kerman
Full name of responsible person
Dr Maryam Ehtesham Zadeh
Street address
Shahid Bahonar University, Pajohesh Square, Kerman
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Shahid Bahonar University of Kerman
Proportion provided by this source
100

Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Bahonar University of Kerman
Full name of responsible person
Asma Salari
Position
Ph.D Student
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty