

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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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asmasalari@sport.uk.ac.ir

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
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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