

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of six weeks of the functional training on gait kinematics of Down syndrome

Protocol summary

Summary

The purpose of this study was to evaluate the effect of functional training on gait kinematics of adult with Down syndrome. 13 men with Down syndrome who were aged 18 years or more and also their disease is caused by trisomy 21 participated in this study from Down Syndrome Association of Iran. The kinematics variable, The isokinetic peak torque of lower extremities and static balance were assessed by motion analysis, Isokinetic Dynamometer, and Stork Balance Stand Test respectively before and after application of the training program. Because knee extensor strength is the most influential variable in predicting timed task performance (chair rise, gait speed, and stair ascent and descent), all subjects randomly allocated to exercise (n=7) and control (n=6) groups based on knee extensor's isokinetic strength results. The experimental group received functional training which consisted of walking on treadmill and step-up and down performed thrice a week for 6 weeks. There were 4 fitness bands colours (violet, red, yellow, and blue) of increasing resistance for treadmill training and 4 medicine balls (2, 3 and 4 kg) for step-up and down. The control group continued with their usual activities. Research outcome were improvement in step length, step width variability, step length variability, walking speed, ankle range of motion, knee range of motion, isokinetic peak torque of lower extremities, and static balance

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102815202N1**

Registration date: **2014-06-07, 1393/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-07, 1393/03/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University

Expected recruitment start date

2013-04-30, 1392/02/10

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of six weeks of the functional training on gait kinematics of Down syndrome

Public title

The effect of functional training on walking

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: they were aged 18 years or more; their

disease is caused by trisomy 21; able to follow simple instructions; physical health; and their guardians will agree to participate in the study. Exclusion criteria: cardiovascular conditions; blindness; and deafness

Age

From **21 years** old to **38 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **13**

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

Motor Behavior Group of Shahid Beheshti University

Street address

Shahid Beheshti University, Velenjak, Tehran

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Postal code

1983963113

Approval date

2013-02-11, 1391/11/23

Ethics committee reference number

15667

Health conditions studied

1

Description of health condition studied

down syndrome

ICD-10 code

Q90

ICD-10 code description

Down syndrome

Primary outcomes

1

Description

kinematics of walking

Timepoint

Before intervention and 6 weeks after end of intervention

Method of measurement

Motion Analysis System

Secondary outcomes

1

Description

The isokinetic peak torque

Timepoint

before intervention six weeks after intervention

Method of measurement

by isokinetic dynamometer

2

Description

static balance

Timepoint

before intervention six weeks after intervention

Method of measurement

by Standing Stork Test

3

Description

muscle activity

Timepoint

before intervention six weeks after intervention

Method of measurement

by electromyography

Intervention groups

1

Description

The experimental group: Three to five minutes of active stretching exercise undertaken prior to each session. Trainings continued with walking on treadmill and step-up and down. The treadmill training protocol included two 10-minute periods (with 0% incline). There were 4 fitness bands colours (violet, red, yellow, and blue) of increasing resistance which was installed on participant's shoes. The step-up and down training was carried out with medicine balls which were 2, 3, 4 kilogram. Participants should do plantar flexion when placed on the ground. In order to enhance motivation of participant, we installed a hoop proportionate with their height in front of them and were asked to drop medicine ball into the hoop with plantar flexion. The protocol included 2 sets until they reached fatigue with 2-kilogram-weight medicine ball. The rest period was twice as long as training.

Category

Other

2**Description**

The control group: continued with their usual activities

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Down Syndrome Association

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University

Proportion provided by this source**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***2****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University

Proportion provided by this source**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**

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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