

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison the effect of simultaneous sensory stimulations and current occupational therapy approaches (neurodevelopmental treatment and rotary vestibular stimulations) on motor development of Down syndrome children with 6 to 18 months of age

Protocol summary

Summary

The purpose is to compare the efficacy of simultaneous sensory stimulations and two other current occupational therapy approaches on motor development of 6 to 18 month children with Down syndrome. This is a double blind clinical trial using random allocation. All healthy 6 to 18 months children with trisomy 21 and without any orthopedic or neurologic problems will be enrolled in this study. After meeting the inclusion criteria, the infants will be examined by the pediatrician and will then be introduced to occupational therapy ward. Forty four infants with Down syndrome will be randomly assigned into two experimental and control groups. In the occupational therapy ward, they will be evaluated using Gross Motor Function Measure 88 (GMFM 88) by an occupational therapy expert who is blind to the whole study procedure. They will then be treated according to the protocol assigned for each group. Intervention protocol of both groups includes the current occupational therapy approaches (facilitatory techniques of neurodevelopmental therapy and rotary vestibular stimulation). Moreover, the experimental group will also receive simultaneous exteroceptive and proprioceptive stimulations by using herbal sticky pasty on the infants' joints. The therapy sessions will be held 3 times a week for 6 months and each session will last for 45 minutes. Both groups will be evaluated 4 times (every 1.5 months) using the GMFM 88 by the same primary therapist and the results will be recorded for each patient. Finally, the data will be analyzed and compared using SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203119259N1**

Registration date: **2013-01-23, 1391/11/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-23, 1391/11/04

Registrant information

Name

Sepideh Nazi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 22227124

Email address

s-nazi@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2006-12-01, 1385/09/10

Expected recruitment end date

2013-02-15, 1391/11/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of simultaneous sensory stimulations and current occupational therapy approaches (neurodevelopmental treatment and rotary vestibular stimulations) on motor development of Down syndrome children with 6 to 18 months of age

Public title

sensory stimulations on motor development of Down syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 1 - having trisomy 21 by genetic karyotype 2 - 6 to 18 months of age 3 - having informed consent 4 - having no severe orthopedic problems or malformations, seizure, uncontrolled thyroid disturbances, severe congenital heart problems (in need for surgery), perilabour asphyxia (Apgar of minutes 1 and 5 equal to or less than 7), severe visual or auditory problems, weight less than the 3rd percentile of Down syndrome, and history of the neonatal infections (meningitis, encephalitis) 5 - having gestational age of more than 37 weeks Exclusion criteria : 1 - use of rehabilitation services, occupational therapy or physiotherapy in other centers, 2 - not attending 3 or more consecutive treatment sessions , 3 - no participation in treatment sessions for at least 8 sessions in the total intervention course, 4 - any acute or chronic disease which needs hospitalization or surgery during the intervention

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The examiner who evaluates the infants and the child's family are blind to the procedure of the therapy and group's allocation . (double blind)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address

Koodakyar Street, Daneshjoo Boulevard

City

Tehran

Postal code

Approval date

2012-03-12, 1390/12/22

Ethics committee reference number

2/21337/801/Ā

Health conditions studied

1

Description of health condition studied

Motor delay in Down syndrome infants

ICD-10 code

Q90, Q90.0

ICD-10 code description

Trisomy 21, meiotic nondisjunction, Trisomy 21, mosaicism (mitotic nondisjunction), Trisomy 21, translocation

Primary outcomes

1

Description

Gross motor development score of GMFM (Gross Motor Function Measure)

Timepoint

4 times evaluations (before, during, after intervention) every 1.5 month

Method of measurement

GMFM (gross motor function measure)

Secondary outcomes

empty

Intervention groups

1

Description

The Intervention protocol of the experimental group includes current occupational therapy approaches (facilitatory techniques of neurodevelopmental therapy and rotary vestibular stimulations) along with simultaneous exteroceptive and proprioceptive stimulations by using herbal sticky pasty on shoulder girdles, elbows, hip girdles and knees. This sticky pasty is applied 30 minutes before the session on the joints and is desiccated before the start of the intervention. The therapist then uses bondage on elbows and knees. After bondage, the child will be put in different positions using

the current occupational therapy approaches and is encouraged for active movements.

Category

Rehabilitation

2

Description

The intervention protocol of the control group includes current occupational therapy approaches (facilitatory techniques of neurodevelopmental therapy (NDT) and rotary vestibular stimulation).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Hospital, Zafar Rehabilitation Center

Full name of responsible person

Sepideh Nazi

Street address

Modares highway, Dastjerdi street, Ali Asghar hospital, Occupational therapy ward

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center of University of Social Welfare and Rehabilitation sciences

Full name of responsible person

Dr Hossain Karimi

Street address

Koodakyar Street, Daneshjoo Boulevard, Evin Street

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research center of University of Social Welfare and Rehabilitation sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Sepideh Nazi

Position

M.Sc. of Occupational therapy, head of Occupational therapy ward of Ali Asghar hospital

Other areas of specialty/work

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Position

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Web page address**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