

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Developing a protocol of “swallowing therapy with action observation treatment” and investigating its effectiveness on swallowing and feeding in 3 to 12 years old children with spastic cerebral palsy

Protocol summary

Study aim

Developing a protocol of “swallowing therapy with action observation treatment” and investigating its effectiveness on swallowing and feeding in 3 to 12 years old children with spastic cerebral palsy

Design

This is a concealed randomized preliminary clinical trial phase 2 with two parallel group design of 20 children. Participants and Researchers will be blinded to the allocation.

Settings and conduct

This study will be conducted in Semnan city. If children are eligible through an online assessment, their care giver will sign a consent form and enter the study. Participants will be randomly assigned to the intervention and placebo groups by an independent researcher. In the first meeting, an assessor will evaluates each child and then a therapist will hold a therapy session for each child based on their assignment and will teach the program to their caregivers and give a training brochure to them do the therapy at home twice a day, 5 days a week for 10 weeks. Children will be assessed at the beginning of the study, 10 weeks later and 1 and 3 months after the intervention.

Participants/Inclusion and exclusion criteria

Participants are 3 to 12 years old children with spastic cerebral palsy who have oral phase problems of swallowing, with no severe hearing or visual problems and intellectual disability and uncontrolled seizure and progressive neurological disease. Children should not be tube fed and their caregivers should be literate and having access to internet and a smart phone or computer.

Intervention groups

The experimental group will receive action observation therapy (AOT) which is watching each target movements before doing that, and then will imitate that movement

during functional oral sensory-motor therapy (F-OST). The placebo group will receive the same protocol but instead of AOT will watch movies not related to target oral movements.

Main outcome variables

Swallowing function

General information

Reason for update

Postponing sampling time

Acronym

IRCT registration information

IRCT registration number: **IRCT20210629051738N1**

Registration date: **2021-09-10, 1400/06/19**

Registration timing: **prospective**

Last update: **2021-11-10, 1400/08/19**

Update count: **1**

Registration date

2021-09-10, 1400/06/19

Registrant information

Name

Maryam Mokhlesin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

m_mokhlessin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-10, 1400/08/19

Expected recruitment end date

2021-12-10, 1400/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Developing a protocol of “swallowing therapy with action observation treatment” and investigating its effectiveness on swallowing and feeding in 3 to 12 years old children with spastic cerebral palsy

Public title

The effect of “swallowing therapy with action observation treatment” protocol

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Spastic cerebral palsy 3-12 years old Having problem in oral phase of dysphagia Literate caregiver Having access to internet and smart phone or computer

Exclusion criteria:

progressive neurological disease severe visual problems severe hearing problems intellectual disorder orofacial syndromes uncontrol seizure Tube feeding

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to one of the two experimental and control groups using blocked randomization method with randomly selected block sizes of 4 and 6. Randomization will be done by an independent researcher from a different research center using an internet softwares so the participants and the assessor will be concealed for assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will not know if they are in the experimental or control groups. As this a parental based program so participants do not need to come to clinic a lot and they are connected to therapists during the mostly through internet during the intervention and kept separated from each other. The evaluator is also different from the therapist and will not be given information about interventions and the individuals` assignment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Ave., Daneshjo Blvd.,Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2021-08-25, 1400/06/03

Ethics committee reference number

IR.USWR.REC.1400.122

Health conditions studied**1****Description of health condition studied**

cerebral palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

2**Description of health condition studied**

dysphagia

ICD-10 code

R13.1

ICD-10 code description

Dysphagia

Primary outcomes**1****Description**

Swallowing function

Timepoint

Pre and post intervention, 1 and 3 months after the intervention as follow up assessment

Method of measurement

Oral Motor Assessment Scale (OMAS), Schedule Oral

Motor Assessment (SOMA), Dysphagia Disorder Survey (DDS)

Secondary outcomes

1

Description

feeding performance

Timepoint

Before and after therapy, 1 and 3 months after the intervention as follow up assessment

Method of measurement

Pedi-Eat scale

2

Description

Caregivers` quality of life

Timepoint

Before and after therapy, 1 and 3 months after the intervention as follow up assessment

Method of measurement

Feeding swallowing impact survey

Intervention groups

1

Description

Intervention group: Intervention includes action observation treatment (AOT) and functional oral sensorimotor therapy (F-OST). First each target movements performing by a healthy child in a video will be observed by the participant as (AOT) and then will be practiced as F-OST. Intervention will last for 10 weeks, 5 days a week, 2 times a day and 20 minutes each time.

Category

Rehabilitation

2

Description

Control group: Like the intervention group, the intervention includes functional oral sensorineural therapy (F-OST), but instead of AOT, a placebo will be used, i.e. the person will spend the same time watching the video, but the videos are not related to the target movements. The treatment will last for 10 weeks, 5 days a week, 2 times a day for 20 minutes each time.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Behafarin rehabilitation clinic

Full name of responsible person

Maryam Mokhlesin

Street address

Behafarin rehabilitation clinic, Haftetir Ave.

City

Semnan

Province

Semnan

Postal code

3513886873

Phone

+98 23 3332 4611

Email

m_mokhlessin@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Arezoo mashayekhi

Street address

Koodakyar street, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 2218 0043

Email

phdcandidate.uswr@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

100

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

Semnan University of Medical Sciences

Full name of responsible person

Maryam Mokhlesin

Position

lecturer
Latest degree
Master
Other areas of specialty/work
Speech therapy
Street address
Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3344 1022
Email
m_mokhlessin@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Maryam Mokhlesin
Position
lecturer
Latest degree
Master
Other areas of specialty/work
Speech therapy
Street address
Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3344 1022
Email
m_mokhlessin@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Maryam Mokhlesin
Position
lecturer
Latest degree

Master
Other areas of specialty/work
Speech therapy
Street address
Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3365 4180
Email
m_mokhlessin@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data collected for the primary outcome measures are to be shared.

When the data will become available and for how long

6 months after publication

To whom data/document is available

It's only available for people working in academic institutions.

Under which criteria data/document could be used

Requests for sharing data should be sent to the person responsible for general inquiries.

From where data/document is obtainable

Requests for sharing data should be sent to the person responsible for scientific inquiries. Maryam Mokhlesin
m_mokhlessin@yahoo.com

What processes are involved for a request to access data/document

Data will be shared after receiving requests by email in less than 1 month.

Comments