Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 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 to12 years old children with spastic cerebral palsy who have oral phase problems of swallowing, with no sever 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)
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+98 23 3365 4180
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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 softwires 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 asessment
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.
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Semnan
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3513886873
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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
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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

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Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd

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Person responsible for updating data

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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