

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Investigating effectiveness of the therapist-managed self-care training smartphone application based on video-modeling for children with autism spectrum disorder and their parents

#### Protocol summary

##### Study aim

Investigating the effectiveness of the therapist-managed smartphone application for teaching self-care activities in improving the self-care performance of children with autism spectrum disorder, their parents' participation in rehabilitation, and parent's psychosocial state

##### Design

Single-blind (examiner) two-arm parallel randomized controlled trial (RCT), with a four-block randomization method. The sample size was considered as 30 children with ASD and their primary caregiver.

##### Settings and conduct

This study will be a randomized and one-sided blind (examiner) clinical trial. The study population will include children with ASD referred to rehabilitation centers, autism centers or exceptional schools for autism in Tehran city.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having an ASD diagnosis by a child psychiatrist; The severity of autism according to the GARS test is level 1 or 2; Being a child in the age range of 5 to 12 years; According to COPM, difficulty in performing at least three self-care activities is among the main complaints of the family about the child; Being a child under occupational therapy so that self-care goals are pursued by the occupational therapist through common interventions; Ability to pay attention to images or videos on the screen for at least five minutes based on parent report; Obtaining a score above 16 in MIS in order to have the minimum ability to imitate in the use of VM; not having behavioral issues in the child based on the CSI-4

##### Intervention groups

In this study, the control group will receive live modeling by the main caregiver at home. The intervention group will receive the self-care activity training application to be used and practiced at home under the supervision of

the therapist and researcher.

##### Main outcome variables

Application; self-care performance; family functioning in rehabilitation, parent's psychosocial status

#### General information

##### Reason for update

After implementing a pilot study of the using application, some changes seemed to be required to have a more concise results.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231124060165N1**

Registration date: **2023-12-09, 1402/09/18**

Registration timing: **prospective**

Last update: **2025-04-15, 1404/01/26**

Update count: **1**

##### Registration date

2023-12-09, 1402/09/18

##### Registrant information

###### Name

Samane Zohrabi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3382 2915

###### Email address

samane\_zohrabi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-20, 1403/02/01

**Expected recruitment end date**

2024-07-22, 1403/05/01

**Actual recruitment start date**

2024-04-20, 1403/02/01

**Actual recruitment end date**

2024-08-20, 1403/05/30

**Trial completion date**

2025-11-21, 1404/08/30

**Scientific title**

Investigating effectiveness of the therapist-managed self-care training smartphone application based on video-modeling for children with autism spectrum disorder and their parents

**Public title**

Investigating effectiveness of the smartphone application of training self-care activities on self-care performance of children with autism spectrum disorder, their parents' participation in rehabilitation and psychological state

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having an ASD diagnosis by a child psychiatrist The severity of autism according to the GARS-3 test is level 1 or 2 Being a child in the age range of 5 to 12 years According to COPM, difficulty in performing at least three self-care activities is among the main complaints of the family about the child Participating in occupational therapy sessions so that self-care goals are pursued by the occupational therapist through common interventions. Ability to pay attention to images or videos on the screen for at least five minutes based on parent report Obtaining a score above 16 in MIS in order to have the minimum imitation ability necessary to use VM Not having behavioral issues in the child based on the child symptom inventory version 4 (CSI-4) with the subscales of attention deficit hyperactivity disorder, oppositional defiant disorder, and conduct disorder (ADHD, ODD, CD) The ability to read and write in parents of children Having an android-based smartphone

**Exclusion criteria:**

Existence of seizures and severe medical problems in the child based on the medical record or as reported by the parents Implementation of self-care intervention through VM in the child's current treatment plan Having a physical problem in the main caregiver

**Age**

From **5 years** old to **12 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **30**

Actual sample size reached: **31**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling will be done by randomization in blocks of four. Samples will be taken from the four possible blocks and until the samples are completed, they will be allocated between two control and intervention groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study will be a randomized and one-sided blind (examiner) clinical trial.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

An application with the aim of managing the training of self-care activities in children with neurodevelopmental disorders in the form of VM intervention in the android platform of the mobile phone was designed by the present researchers in the form of a technological plan that is going through the stages of construction and pilot study.

**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2023-11-21, 1402/08/30

**Ethics committee reference number**

IR.IUMS.REC.1402.734

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

Autism spectrum disorder

**ICD-10 code**

F84. 0

**ICD-10 code description**

A type of neurodevelopmental disorder with problems in social interactions and limited and repetitive behaviors and interests

## Primary outcomes

### 1

#### Description

self-care performance

#### Timepoint

before intervention, immediately after the intervention, and one month after the end of intervention

#### Method of measurement

Activities of Daily Living Inventory for Children with Disabilities (ADLIC-D); Canadian Occupational Performance Measure (COPM); Goal Attainment Scale (GAS)

## Secondary outcomes

### 1

#### Description

Family functioning in rehabilitation

#### Timepoint

Before the intervention, immediately after the intervention, one month after the end of intervention

#### Method of measurement

(FFQR) Family Functioning Questionnaire in Rehabilitation

### 2

#### Description

Depression, anxiety, and stress of parents of children

#### Timepoint

Before the intervention, immediately after the intervention, one month after the end of intervention

#### Method of measurement

Depression, anxiety, stress scale-42 items (DASS-42)

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, the first step is to install the app on the caregiver's smart phone and teach how to use it. In this training, the caregiver is asked to perform at least two activities that can be performed in the center under the supervision of the researcher, so that possible problems can be fixed and the necessary points are given feedback. In order to ensure the correctness and integrity of the training process by parents, in addition to the instruction section inside the application, a video record of app instruction will also be provided to parents. Also, in the app itself there is a guide section consistin the following sentences: The main caregiver can only use minimal physical guidance to the extent of helping the child to understand more about the correct implementation of the correct movement pattern of the desired activity.o The primary caregiver can use a cue or symbol that is familiar and meaningful to their child as an associator of the intended target activity (such as "beh beh" or "hum

hum" to evoke the activity of eating) to prepare the child.o As much as possible, the training time should be in the time period close to the actual performance of that activity and based on the daily routine of that activity in a way that does not cause the child's anxiety and panic. o If according to the child's routine, the desired activity or assignment is such that it may not occur at least once during the day, create a simulator or artificial situation and practice at least once a day.o If the child does not pay attention to a part of the video or is distracted, the primary caregiver can use the repeat option to show the stage or stages of the target activity again until the child watches the videos with proper attention. Otherwise, do not use the repeat option.o It is preferable to avoid using the application when the child's attention and concentration are not suitable.o Do not use the application after taking sleeping pills. o After fully viewing all the videos related to the steps of a particular activity, the child will look at the steps step by step and after completing each step, the mother will choose the correct qualitative option and then after receiving appropriate visual feedback depending on the quality of doing it Step enters the next step.o All the steps related to a particular activity should be done in one go without a break of more than 5 seconds between the steps of the activity.o In case of three consecutive records of independently performing all steps of an activity, the caregiver can no longer use the application to perform that activity.o Avoid showing videos and applications on TV, tablets or other platforms with larger frames. Then the researcher will make the activities determined in the COPM accessible in the carer application. Caregivers will practice at home based on the training provided by the researcher and follow the guidelines and record the quality of the steps in the application. After entering the section dedicated to him in the application, the therapist will monitor the quality of the selected task that the parents mark with three options: "independent", "with help", and "dependent". The communication between the caregiver and the researcher will be done through the messaging section of the application or by calling. In case of three consecutive records of independently performing all steps of an activity, the caregiver can no longer use the application to perform that activity. The intervention process will be implemented for one to months on the intervention group. The researcher will send 3 reminder messages to the caregivers via WhatsApp. From the management panel website, the caregivers' adherence and fidelity to interventions will be implemetend.

#### Category

Rehabilitation

### 2

#### Description

Control group: In this study, the control group will receive live modeling by the main caregiver at home. Therapists of these samples will be asked not to use VM during the study; because after the follow-up phase, the application will also be presented to the control group. Three reminder messages a week in WhatsApp will be delivered to families. Based on logbook, the caregivers

adherence to treatment will be monitored.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

rehabilitation clinics of Rehabilitation faculty of IUMS

##### Full name of responsible person

Laleh Lajevardi

##### Street address

Rehabilitation faculty of Iran University of Medical Sciences, Madadkaran, Shahnazari, Mother square, Mirdamad

##### City

Tehran

##### Province

Tehran

##### Postal code

1545913487

##### Phone

+98 21 2222 7124

##### Email

laleh23275@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Parsian

##### Full name of responsible person

Dr. Mehdi Alizadeh

##### Street address

Parsian rehabilitation center, Behnam st., opposite to Tarbiyat park, Ayattollah Kashani, Sadeghiyeh

##### City

Tehran

##### Province

Tehran

##### Postal code

1968633893

##### Phone

+98 912 307 0065

##### Email

mehdii.alizadeh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Majid Safa

##### Street address

Iran University of Medical Sciences, next to Milad tower, Hemmat highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 86701

##### Email

Keyvanlab@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran University of Medical 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

Iran University of Medical Sciences

##### Full name of responsible person

Samane Zohrabi

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Occupational Therapy

##### Street address

Rehabilitation faculty of Iran University of Medical Sciences, Madadkaran, Shahnazari, Mother square, Mirdamad st.

##### City

Tehran

##### Province

Tehran

##### Postal code

1545913487

##### Phone

+98 21 2222 7124

##### Email

samane\_zohrabi@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

**Full name of responsible person**

Samane Zohrabi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Rehabilitation faculty of Iran University of Medical Sciences, Madadkaran, Shahnazari, Mother square, Mirdamad st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Phone**

+98 21 2222 2059

**Email**

samane\_zohrabi@yahoo.vom

Rehabilitation faculty of Iran University of Medical Sciences, Madadkaran, Shahnazari, Mother square, Mirdamad st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Phone**

+98 41 3382 2915

**Fax****Email**

samane\_zohrabi@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

Undecided - It is not yet known if there will be 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**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Samane Zohrabi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

**Street address**