

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Designing and Evaluation of Theory based Intervention on Quality of life among parents of Autistic patients

#### Protocol summary

##### Study aim

Determination of the effect of educational intervention based on Social cognitive theory on Quality of life among parents of Autistic patients in Tehran Autism Centers

##### Design

Randomized control trial with control group, with parallel group, not blinded and randomized, sample size 74, pretest post test and follow up, 1 and 6 month follow up

##### Settings and conduct

This study was performed among the parents of autistic students of autism schools in Tehran. Thus, in the intervention group, self-care education was designed based on cognitive-social theory and implemented through telegram for three months. The control group did not receive any training. Data from both groups before, one month and 6 months after the intervention were collected using SF36 questionnaire and CarerQol questionnaire and analyzed by SPSS20 software.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Parents of autistic students under 13 years old in autism schools of Tehran Exceptional Education Organization. Having a smart phone and access to the Telegram application and the ability to use it and Willingness to participate in the study.

##### Intervention groups

The intervention group included the parents of autistic students of autism schools in Tehran, who received an educational intervention designed based on social cognitive theory via telegram. The control group included the parents of autistic students of autism schools in Tehran who did not receive educational intervention.

##### Main outcome variables

Quality of life among parents of Autistic patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200922048797N1**

Registration date: **2020-12-11, 1399/09/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-11, 1399/09/21**

Update count: **0**

##### Registration date

2020-12-11, 1399/09/21

##### Registrant information

###### Name

Samaneh Abolkheirian

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3318 0272

###### Email address

sabolkherian@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-14, 1398/09/23

##### Expected recruitment end date

2020-12-13, 1399/09/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Designing and Evaluation of Theory based Intervention on Quality of life among parents of Autistic patients

##### Public title

The effect of educational intervention based on Social

Cognitive Theory on Quality of Life among parents of Autistic patients

#### **Purpose**

Education/Guidance

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Parents of autistic students under 13 years old in autism schools of Tehran Exceptional Education Organization  
Having a smart phone and access to the Telegram application and the ability to use it  
Willingness to participate in the study

##### **Exclusion criteria:**

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: **74**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

In this study, after preparing the list of autism centers of exceptional education in Tehran, first the names of all centers were written on balls and put in a bag. Then 6 centers were randomly selected. Among the above centers, three centers were randomly placed in the intervention group and three centers as the control group using the random draw method. In fact, the randomization unit in this study was clusters..

#### **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**

Ethics committee of Tehran University OF Medical Science

###### **Street address**

School of health, Tehran University of Medical science, Pour Sina Ave, Keshavarz Blvd,

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1417613151

#### **Approval date**

2017-12-02, 1396/09/11

#### **Ethics committee reference number**

IR.TUMS.SPH.REC.1396.4130

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Autism spectrum disorder

##### **ICD-10 code**

F84.0

##### **ICD-10 code description**

Childhood autism

### **Primary outcomes**

#### **1**

##### **Description**

Quality of life Score in the Questionnaire

##### **Timepoint**

In this study, the quality of life of parents was measured before intervention and one month and six months after the intervention.

##### **Method of measurement**

SF36 questionnaire and CarerQol questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

the intervention group: In the intervention group, self-care training based on social cognitive theory was conducted using the Telegram group for three months. These tutorials included text messages, pictures, and short instructional videos, as well as podcasts that were sent to parents via the Telegram software.

##### **Category**

Behavior

#### **2**

##### **Description**

Control group: Control group: No action was taken in the control group.

##### **Category**

N/A

### **Recruitment centers**

#### **1**

##### **Recruitment center**

**Name of recruitment center**

Autism Schools in Tehran  
**Full name of responsible person**  
Samaneh Abolkheirian  
**Street address**  
school of health, Pour Sina Ave, Keshavarz Blvd  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417613151  
**Phone**  
+98 21 4293 3210  
**Email**  
samanehabolkherian@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mohammad Ali Sahraian  
**Street address**  
Research and Technology Dept, 6th floor, Central  
Organization of the University, Ghods St, Keshavarz  
Blvd  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417613151  
**Phone**  
+98 21 8163 3698  
**Email**  
msahrai@sina.tums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Tehran 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**

Tehran University of Medical Sciences  
**Full name of responsible person**  
Samaneh Abolkheirian  
**Position**  
PhD student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Health Promotion  
**Street address**  
school of health, Pour Sina Ave, Keshavarz Blvd  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417613151  
**Phone**  
+98 21 4293 3210  
**Email**  
samanehabolkherian@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Samaneh Abolkheirian  
**Position**  
PhD student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Health Promotion  
**Street address**  
school of health, Pour Sina Ave, Keshavarz Blvd  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417613151  
**Phone**  
+98 21 4293 3210  
**Email**  
samanehabolkherian@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Samaneh Abolkheirian  
**Position**  
PhD student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Health Promotion

**Street address**

school of health, Pour Sina Ave, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417613151

**Phone**

+98 21 4293 3210

**Email**

samanehabolkherian@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**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The total potential data can be shared after unidentifiable people.

**When the data will become available and for how long**

Start the access period, 6 months after publishing the results

**To whom data/document is available**

Data will only be available to researchers in academia.

**Under which criteria data/document could be used**

It is permitted to use data for all scientific works within the framework of ethics in research.

**From where data/document is obtainable**

To receive the data, the official request of the applicant (via organizational email) should be sent to Samaneh Abolkheirian email and only through the address: samanehabolkherian@yahoo.com.

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

The applicant application (via organizational email) should be sent to samanehabolkherian@yahoo.com and after confirmation, the data will be provided to the applicant within 14 days.

**Comments**