

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The Effect of Educational Training on Mentally Retarded Children to Reduce the Burden of Caring for Their Parents

#### Protocol summary

##### Study aim

Investigating the effect of educational training for educable mentally retarded children on reducing the burden of caring for their parents

##### Design

The clinical trial has a control group, randomized on 30 patients. Lottery was used for randomization.

##### Settings and conduct

This research is conducted in the educational and rehabilitation center for mentally retarded children in Pakdasht city and on 30 people, and no blinding will be done in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Boys and girls under the age of 14 years old with mental retardation; Filling the informed consent form to participate in research therapy sessions; Having the cooperation in completing the questionnaires. Non-inclusion criteria: Children whose intellectual performance level is not trainable, for example trainable, supportable, borderline, etc; Parents who have more than one mentally retarded child

##### Intervention groups

Intervention group: They will be trained for 3 hours a day for 6 months. Control group: in the control group, there will be no intervention and they will be on the waiting list.

##### Main outcome variables

Parental care burden pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220708055417N1**

Registration date: **2022-09-11, 1401/06/20**

Registration timing: **retrospective**

Last update: **2022-09-11, 1401/06/20**

Update count: **0**

##### Registration date

2022-09-11, 1401/06/20

##### Registrant information

###### Name

elahe dolat abadi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3603 4379

###### Email address

mohamadmahdi9566@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-01, 1401/05/10

##### Expected recruitment end date

2022-08-01, 1401/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Educational Training on Mentally Retarded Children to Reduce the Burden of Caring for Their Parents

##### Public title

Investigating the Effect of Educational Training of Intellectually Disabled Children on Their Parents

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Filling the informed consent form to participate in research therapy sessions Having the cooperation of people in completing the questionnaires Boys and girls under the age of 14 years old with mental retardation Not having vision and hearing problems Not having autism and hyperactivity disorder Parents participating in the research therapy sessions not being treated by a psychiatrist or a clinical psychologist

**Exclusion criteria:**

Children whose intellectual performance level is not trainable, for example trainable, supportable, borderline, etc Parents who have more than one mentally retarded child

**Age**

From **6 years** old to **14 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, it is a semi-experimental type of research, and the sampling method in this research is selected in the available way and assigned in a simple random way. In such a way that all the members of the statistical community will have an equal chance to be selected, this selection is done using the lottery method. In this way, the numbers of each of these beneficiaries are put in a bag and then they are taken out one by one until the desired number of the sample is obtained. The sample size in this research will include 30 people who will be randomly divided into two groups of 15 people. and will be used randomly in such a way that one group will be selected as the experimental group and one group will be selected as the control group

**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 Islamic Azad University, Semnan branch

**Street address**

Islamic Azad University Semnan branch, Shahrak Daneshgahi, Semnan

**City**

Semnan

**Province**

Semnan

**Postal code**

3513137111

**Approval date**

2022-06-22, 1401/04/01

**Ethics committee reference number**

IR.IAU.SEMNAN.REC.1401.018

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

The Effectiveness of Academic training educable mentally retarded children in reducing the burden of caring for their parents

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Percentage of care burden pressure of parents with mentally retarded children

**Timepoint**

Measurement of parental care burden after 1 month and 2 months

**Method of measurement**

Questionnaire of Zarit et al

**Secondary outcomes****1****Description**

The score of reduction of care burden pressures of parents with mentally retarded children

**Timepoint**

Measuring the care burden of parents with mentally retarded children after 1 month and 2 months

**Method of measurement**

Questionnaire of Zarit et al

**Intervention groups****1****Description**

Intervention group: intervention will takes place in an educational and rehabilitation center in Pakdasht city according to an educational protocol including basic and preliminary education including: familiarization with the surrounding environment, instructor and classmates for

two to five days, individual skills training for one to six months, skills training Social manners one to three months, training to increase accuracy and attention and concentration and eye and hand coordination six months to one year, color training two months to one year, calligraphy and painting training six months to one year, memory strengthening training six months to One year, math training takes six months to one year and physical and mental training for one year.

**Category**

Treatment - Other

**2****Description**

Control group: no intervention is done for the control group. Before the intervention a Pre-test was taken from the control group and they were put on the waiting list. At the end of the intervention, they will be given a post-test and the result will be analyzed.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Padideh educational and rehabilitation center

**Full name of responsible person**

Ameneh Haji Mazdarani

**Street address**

No. 33; Shahid Ali Qomi Alley; Moradi Street; Motehari street

**City**

Pakdasht

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Tehran

**Postal code**

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**Phone**

+98 21 3604 2276

**Email**

Padidehr344@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Hengame Bidogkti

**Street address**

Islamic Azad University, Semnan Branch, Daneshgahi Town, Semnan

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**Fax**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Elahe Dolatabadi

**Position**

University student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

3rd floor, No. 5, Fadak 3 alley, 20 Meteri Meqdad

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Elahe Dolatabadi

**Position**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Elahe Dolat abadi

**Position**

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**Latest degree**

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**Email**

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**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable