

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effectiveness of dialectical behavior group therapy in stress, depression symptoms and cognitive emotion regulation in mothers of mentally retarded students

#### Protocol summary

##### Study aim

The effectiveness of dialectical behavior group therapy in stress, depression symptoms and cognitive emotion regulation in mothers of mentally retarded students

##### Design

Clinical trial with control group, with parallel, uncorrected, randomized groups, on 285 patients. Excel software rand function was used for randomization.

##### Settings and conduct

Ferdowsi University of Mashhad based on pre-test and post-test results of anxiety and depression

##### Participants/Inclusion and exclusion criteria

Mothers with students with mental disabilities in exceptional centers of Mashhad Informed consent Major conditions of non-inclusion in the study Fa Participates simultaneously in other treatment programs (pharmacological and non-pharmacological) during the research. Reluctance to continue cooperation. Absence of more than one session in treatment sessions.

##### Intervention groups

Its research design is two-group pretest-posttest with unequal control group. The statistical population of this study includes all mothers with students with mental disabilities in Mashhad in the academic year 1400-1401 to 1100 people. The statistical sample of this study, based on the Kyokokran formula, will be 285 mothers with mentally retarded children in Mashhad in 1401-1400, who will be selected by available sampling method and voluntarily, and selected based on the inclusion criteria and Accidents will be replaced in experimental (n = 143) and control (n = 142) groups.

##### Main outcome variables

Hope and quality of life

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101130005280N50**

Registration date: **2022-03-26, 1401/01/06**

Registration timing: **prospective**

Last update: **2022-03-26, 1401/01/06**

Update count: **0**

##### Registration date

2022-03-26, 1401/01/06

##### Registrant information

###### Name

Raheleh Nejati

###### Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3711 2540

###### Email address

nejatir2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-18, 1401/01/29

##### Expected recruitment end date

2022-06-19, 1401/03/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effectiveness of dialectical behavior group therapy in stress, depression symptoms and cognitive emotion regulation in mothers of mentally retarded students

## Public title

The effectiveness of dialectical behavior group therapy in stress

## Purpose

Diagnostic

## Inclusion/Exclusion criteria

### Inclusion criteria:

Mothers with students with mental disabilities in exceptional centers of Mashhad Informed consent

### Exclusion criteria:

Simultaneous participation in other treatment programs (pharmaceutical and non-pharmaceutical) during the research Reluctance to continue cooperation Absence of more than one session in treatment sessions

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 285

## Randomization (investigator's opinion)

Randomized

## Randomization description

En Randomization is done in a simple way and using a table of random numbers using the site [www.randomization.com](http://www.randomization.com). The numbers will be placed in sealed envelopes and upon the entry of the participants, each envelope will be assigned to one of the two groups. The individuals of the even envelopes are the control group and the individuals of the individual envelopes are the intervention 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 Ferdowsi University of Mashhad

##### Street address

Ferdowsi University of Mashhad, Azadi Square

## City

Mashhad

## Province

Razavi Khorasan

## Postal code

9117948974

## Approval date

2022-03-13, 1400/12/22

## Ethics committee reference number

IR.UM.REC.1400.397

## Health conditions studied

### 1

#### Description of health condition studied

Mentally retarded children

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Effective life expectancy and resilience

#### Timepoint

Before behavioral therapy and after two months and after the sessions

#### Method of measurement

Beck Depression Inventory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: Its research design is pre-test - post-test in two groups. In the intervention group, behavioral therapy sessions will be performed. There will be 143 mothers of mentally retarded students in Mashhad in the academic year 1401-1400. Therapeutic sessions will be done in 12 sessions

#### Category

Diagnosis

### 2

#### Description

Control group: Control group: The research plan of 142 mothers with students with mental disabilities will be pre-test-post-test

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Exceptional centers of Mashhad

**Full name of responsible person**

Hossein Share

**Street address**

Exceptional centers of Mashhad

**City**

MASHHAD

**Province**

Razavi Khorasan

**Postal code**

9617976487

**Phone**

+98 51 4441 0104

**Email**

minayazdanian96@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Asadi Zanganeh

**Street address**

Khorasan Razavi - Sabzevar - Tohid Shahr - Hakim  
Sabzevari University Campus

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617976487

**Phone**

+98 51 4441 0104

**Email**

minayazdanian96@gmail.com

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

Yes

**Title of funding source**

Sabzevar 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mina Yazdanian

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

Khorasan Razavi - Sabzevar - Tohid Shahr - Hakim  
Sabzevari University Campus

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617976487

**Phone**

+98 51 4441 0104

**Email**

minayazdanian96@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hossein Share

**Position**

استادیار

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychology

**Street address**

Ferdowsi University of Mashhad, Azadi Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948974

**Phone**

+98 51 3879 6773

**Email**

hoshareh@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hossein Share

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychology

**Street address**

Ferdowsi University of Mashhad, Azadi Square

**City**

Mashad

**Province**

Razavi Khorasan

**Postal code**

9177948974

**Phone**

+98 51 3879 6773

**Email**

hoshareh@gmail.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