Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
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+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. 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
۹۱۷۷۹۴۸۹۷۴
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

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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

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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
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

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Person responsible for scientific inquiries

Contact

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استادیار

Latest degree
Specialist

Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences

Full name of responsible person
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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychology

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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