Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of Emotion Efficacy Therapy on Fear of Negative Evaluation, Experiential Avoidance, Parental Burnout and Psychological Hardiness among Mothers with Autistic Children

Protocol summary

Study aim

The effectiveness of Emotion Efficacy Therapy on fear of negative evaluation, experiential avoidance, parental burnout and psychological hardiness of mothers with Autistic children.

Design

The research is pre-test-post-test with a control group and a follow-up period with factorial groups and a blind. 30 people were selected through available sampling and randomly assigned to two groups of 15 people, control and experimental. Statistical analysis was done with SPSS version 23 and variance analysis of repeated measures.

Settings and conduct

The statistical population was made up of mothers with Autistic children of Dasthaye Mehrabani School (Darya) in Isfahan city in 1401. 30 people were selected by available sampling and randomly assigned to two groups of 15 people.The proposed intervention was based on Emotion Efficacy Therapy (McKay and West, 2016).The sessions based on the treatment protocol were offered to the experimental group in the form of 8 sessions. For blinding, participants did not know which group they were in.

Participants/Inclusion and exclusion criteria

Research entry criteria 1-The minimum level of education 2-Mothers of Autistic children 3-Willingness to participate in the research and complete the research questionnaires completely Exclusion criteria from the research 1-Absence of more than two sessions 2-Irregular attendance at sessions

Intervention groups

A pre-test was taken from both study groups. Only the experimental group received Emotion Efficacy Therapy (McKay & West, 2016). After that, in the post-test and follow-up phase, the questionnaires were administered in both groups.

Main outcome variables

fear of negative evaluation; experiential avoidance; parental burnout ; psychological hardiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230303057598N1**
Registration date: **2023-04-14, 1402/01/25**
Registration timing: **retrospective**

Last update: **2023-04-14, 1402/01/25**
Update count: **0**

Registration date

2023-04-14, 1402/01/25

Registrant information

Name

Golnaz Ahghar Bazargan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 1272

Email address

bazargangolnaz6@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-25, 1401/04/04

Expected recruitment end date

2022-08-02, 1401/05/11

Actual recruitment start date

2022-08-23, 1401/06/01

Actual recruitment end date
2022-09-21, 1401/06/30
Trial completion date
2022-10-25, 1401/08/03

Scientific title
The Effectiveness of Emotion Efficacy Therapy on Fear of Negative Evaluation, Experiential Avoidance, Parental Burnout and Psychological Hardiness among Mothers with Autistic Children

Public title
Effect of Emotion Efficacy Therapy on fear of negative evaluation, experiential avoidance, parental burnout and psychological hardiness among mothers with Autistic children
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The minimum level of education Mothers of Autistic children Willingness to participate in the research and complete the research questionnaires completely Absence of acute psychiatric disorders at the same time Not having a child with another disorder besides ASD Not taking part in other psychotherapy sessions simultaneously
Exclusion criteria:
Having two absent sessions in the intervention process Having previous experience in therapy based on Emotion Efficacy Therapy Having defects such as physical, sensory or cognitive that prevent participation in the study Being under psychological treatment
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples were identified by random block method and using random numbers table, Random Allocation Software. Blocking and allocation sequence for concealment was done by a person not involved in the research; Allocation Concealment. Blocking: This method was used to avoid significant imbalances in the number of volunteers assigned to each group. Block randomization ensures that there is no significant imbalance between groups at any time during randomization, and that at certain points the number of participants in each group is equalized. For this purpose, the size of each block must be determined first (for example, a block of four), then write the list of blocks and assign numbers to them, then choose random numbers between 1 to 6 and finally determine the allocation of treatment based on the previous random numbers, in intervention group and control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
After receiving informed consent, the participants were randomly assigned to the intervention group. The volunteers may not have been aware of the main purpose of the research, but they only knew that they were participating in a study that could improve their psychological problems. In addition, the data analyst did not know the content of the intervention sessions and was only aware of the assumptions, goals and questions of the research.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Committees of Islamic Azad University-Isfahan (Khorasgan) Branch
Street address
No. 85, Fifth Alley, South Sheikh Sadouq St
City
Esfahan
Province
Isfehan
Postal code
8168684611
Approval date
2022-05-30, 1401/03/09
Ethics committee reference number
IR.IAU.KHUISF.REC.1401.080

Health conditions studied

1

Description of health condition studied
autism
ICD-10 code
F84.0
ICD-10 code description
Autistic disorder

Primary outcomes

1

Description

Fear of negative evaluation: The structure of fear of negative evaluation includes the feeling of apprehension and concern about the evaluations of others, the anxiety caused by these negative evaluations, and the expectation that others have about a person.

Timepoint

At the beginning of the study, after the intervention and two months after the intervention

Method of measurement

Breaf Fear of Negative Evaluation Scale Larry (1983)

2

Description

Experiential avoidance: Attempts to change the form, frequency, or situational sensitivity of difficult personal events such as thoughts, feelings, and physiological sensations.

Timepoint

At the beginning of the study, after the intervention and two months after the intervention

Method of measurement

Acceptance and Action Questionnaire-II Bund et al. (2011)

3

Description

Parental burnout: Parental burnout is defined as three dimensions of fatigue from the parental role, emotional distance from children, and loss of parental efficiency and performance.

Timepoint

At the beginning of the study, after the intervention and two months after the intervention

Method of measurement

Parental Burnout Assessment Roskam et al. (2017)

4

Description

Psychological hardiness: Hardiness is a set of personality traits that protects a person against stressful life events, as one of the sources of resistance like a shield, and enables him to face internal and external challenges. Stubbornness is a combination of beliefs about oneself and the world, which consists of the three components of commitment, control, and struggle, and makes a person immune to external and internal pressures.

Timepoint

At the beginning of the study, after the intervention and two months after the intervention

Method of measurement

Psychological Hardiness Kobasa (1989)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: they were treated based on Emotion Efficacy Therapy (McKay and West, 2016) during 8 sessions of 120 minutes (two sessions per week). First session: Awareness of excitement. Session 2: Acceptance of the conscious mind, surfing on excitement. The third session: action based on values - first part. Fourth session: Action based on values - Part II. Fifth session: Mindful confrontation, calm body and self-soothing. Sixth session: conscious mind confrontation, confrontational thoughts, fundamental acceptance. Seventh session: Mindful confrontation, returning attention and rest time. Eighth session: Fixing, fixing bugs and summarizing

Category

Rehabilitation

2

Description

Control group: a group that does not undergo any intervention. They only complete the questionnaires before and after the study. If they wish, they can undergo intervention after the end of the study.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Dasthaye Mehrabani (Darya)

Full name of responsible person
Zahra Rezaee

Street address
Serah Simin, Wali Asr town, next to Milad hospital

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Esfahan

Province
Isfehan

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8168684611

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Farsad Zamani Borojeni

Street address
East J St., Arghavanieh, University Blvd

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Phone
+98 31 3535 4001

Email
info@khuisf.ac.ir

Web page address
http://new.khuisf.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Isfahan Islamic Azad University (Khorasgan)

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Golnaz Ahghar Bazargan

Position
M A. in General Psychology

Latest degree
Master

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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 data file of the participants can only be published in general without mentioning the names and addresses of the participants. The study protocol can also be published as a table. The statistical analysis map can be published in the form of tables and statistical results obtained. Informed consent can be published in its entirety. Applied research results can be published. Statistical methods and statistical analysis are publishable. The obtained data can be published in the form of tables. All items can be presented in accordance with the guidelines of the magazines and if there is no harm to the participants.

When the data will become available and for how long

The access period starts with the opinion and agreement of the relevant publications.

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

All cases of using documents will be possible with the permission of the university of study and professors related to the research and in compliance with the existing rules and regulations.

From where data/document is obtainable

Reputable journals in which articles related to research are published. The e-mail of the supervisor and the student responsible for the project and their university website will be made available to the applicants to use the results in compliance with the rules and regulations and maintaining the confidentiality of the participants.

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

If the rules related to research documents are followed, the request will be answered as soon as possible.

Comments