

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effectiveness of reality therapy on perceived stress and self-efficacy of mothers of children with Down syndrome in the city of Bandarabbas, 2017

Protocol summary

Study aim

Effect of reality therapy on the level of perceived stress and self-efficacy of mothers of children with Down syndrome before and after intervention in intervention and control groups

Design

With a control group, based on the community of mothers of children with Down syndrome, with parallel groups, simple random

Settings and conduct

This study is done in Jahesh rehabilitation center. Eligible mothers of children with Down syndrome are given informed consent forms. They are then randomly divided into intervention (n=20) and control (n=20) groups. Both groups will fill out a demographic questionnaire, Cohen's perceived stress scale, and Sherer's self-efficacy scale. Control group receives no intervention. The intervention group receives nine 60-minute sessions on perceived stress and self-efficacy, and the effect of reality therapy on perceived stress and self-efficacy.

Participants/Inclusion and exclusion criteria

Entry: Desire to participate in research. Failure to arrive: Having a physical and mental problem.

Intervention groups

Intervention group: The intervention group received nine 60-minute sessions on perceived stress and self-efficacy and the effect of reality-therapy on perceived stress and self-efficacy. Control group: consists of 20 people who have entered the research. These people do not receive any training.

Main outcome variables

Perceived stress and Self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180119038436N1**

Registration date: **2018-08-13, 1397/05/22**

Registration timing: **retrospective**

Last update: **2018-08-13, 1397/05/22**

Update count: **0**

Registration date

2018-08-13, 1397/05/22

Registrant information

Name

Shiva Gharibpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3375 1978

Email address

sh.gharibpour@aliabadiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-15, 1397/04/24

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of reality therapy on perceived stress and self-efficacy of mothers of children with Down syndrome

in the city of Bandarabbas, 2017

Public title

Effectiveness of reality therapy on perceived stress and self-efficacy of mothers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers of Down syndrome children who are willing to Participate in Research. Mothers of Down syndrome children who do not have physical and psychological problems. Mothers with at least one child with Down syndrome. Mothers of Down syndrome children who have the ability to read and write.

Exclusion criteria:

People who have participated in similar studies.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Random sampling, Simple randomization, Individual, Random Number Tables

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

Islamic Azad University of Shahrood Branch

Street address

Shahrood Blvd. Shahrood Islamic Azad University

City

Shahrud

Province

Semnan

Postal code

43189-36199

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1397.007

Health conditions studied

1

Description of health condition studied

Down Syndrome

ICD-10 code

Q90

ICD-10 code description

Down syndrome

Primary outcomes

1

Description

Perceived Stress

Timepoint

Measuring perceived stress before the intervention begins and after 9 training sessions lasts for 2 months.

Method of measurement

Cohen's Perceived Stress Questionnaire and Colleagues

2

Description

Self-efficacy

Timepoint

Self-efficacy measure before intervention and after 9 training sessions

Method of measurement

Sherer General Self-efficacy Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes 20 people Who have entered the research. They have 9 sessions of 60 minutes About perceived stress and self-efficacy And the effect of the therapeutic reality on perceived stress and self-efficacy learns. Control group: consists of 20 people who have entered the research. These people do not receive any training.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Welfare of Hormozgan Province

Full name of responsible person

Gholam Hossein Ranjbar

Street address

Opposite Ghadir Store., Western Side of Imam Sajjad
., Ayatollah Ghaffari Avenue

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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Ghulam Hussein Ranjbar

Street address

Shahid Chamran Blvd., University of Medical Sciences

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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

Bandare-abbas 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**

Islamic Azad University

Full name of responsible person

Shiva Gharibpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Right door. 5, Ghadir Alley. 8, Ghadir Street., Azadi
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Person responsible for updating data**Contact****Name of organization / entity**

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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

No more 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available