

# 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

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7914964595

**Phone**

+98 76 3331 3031

**Email**

Sh.gharibpour@aliabadiaiu.ac.ir

**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

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7916613885

**Phone**

+98 76 3333 3280

**Email**

mail@hums.ac.ir

**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

**Street address**

Right door. 5, Ghadir Alley. 8, Ghadir Street., Azadi  
Shahr Cove

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7919768589

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

Islamic Azad University

**Full name of responsible person**

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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