

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

**The effect of cognitive behavioral stress management on quality of life in patients with psychosomatic disorder refers to the Isfahan psychiatry clinic in 2013.**

### Protocol summary

#### Summary

The goal of this study is the effect of cognitive behavioral stress management on quality of life in patients with psychosomatic disorder refers to the Isfahan psychiatry clinic in 2013. This study is randomized control trail and has two groups. every groups are 35 persons. we have 8 sessions weekly for intervention group. we give an audio CD to control group after intervention.

### General information

#### Acronym

-

#### IRCT registration information

IRCT registration number: **IRCT2014071418481N1**

Registration date: **2014-11-04, 1393/08/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2014-11-04, 1393/08/13

#### Registrant information

##### Name

Esmat Rahimi

##### Name of organization / entity

Isfahan university of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3441 7223

##### Email address

rahimiesmat44@yahoo.com

#### Recruitment status

**Recruitment complete**

#### Funding source

Isfahan University of Medical Science

#### Expected recruitment start date

2014-05-08, 1393/02/18

#### Expected recruitment end date

2014-09-11, 1393/06/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of cognitive behavioral stress management on quality of life in patients with psychosomatic disorder refers to the Isfahan psychiatry clinic in 2013.

#### Public title

The effect of stress management on quality of life in patients psychosomatic disorders

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria; Age up 18; Don't have any sever mental disease like schizophrenia and MDD; Don't have substance abuse Exclusion criteria; Absent up 2 session; Don't want stay at study

#### Age

From **18 years** old to **139 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Isfahan University of Medical Sciences

##### Street address

Nursing midwifery school; Isfahan University of Medical Science; Hezar garib St; Isfahan

##### City

Isfahan

##### Postal code

8174673461

#### Approval date

2004-05-06, 1383/02/17

#### Ethics committee reference number

393158

## Health conditions studied

### 1

#### Description of health condition studied

psychsomatic disorders

#### ICD-10 code

F54

#### ICD-10 code description

Psychological and behavioural factors associated with disorders or diseases classified elsewhere

## Primary outcomes

### 1

#### Description

quality of life

#### Timepoint

pre- 2 monthes after and 1 month following end of program

#### Method of measurement

sf-36 questioner

## Secondary outcomes

### 1

#### Description

Quality of life and its 8 dimens

#### Timepoint

pre- 2 monthes fter and 1 month after following program

#### Method of measurement

SF36 score

## Intervention groups

### 1

#### Description

For intervention group 8 session weekly cognitive behavioral stress management

#### Category

Lifestyle

### 2

#### Description

For control group after filled the questioner; will give them a book about psychosomatic disorders and audio CD

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Psychological Clinic

##### Full name of responsible person

Hamid Afshar Zanjani

##### Street address

Isfahan Psychological Clinic; Shariati St; Isfahan

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Full name of responsible person

Ashraf Kazemi

##### Street address

Isfahan University of Medical Sciences; Hezar jarib ST; Isfahan

##### City

Isfahan

#### Grant name

393158

#### Grant code / Reference number

393158

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Isfahan University of Medical Science

**Full name of responsible person**

Fariba Taleghani

**Position**

nursing PHD

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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Master

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## Person responsible for updating data

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Mohsen Yazdani

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Masters of degree

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**Web page address**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*