

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jul 2026

### Comparison of the Effectiveness of Cognitive-Behavioral Therapy on Social Adjustment and Self-esteem in Thalassemic Patients

#### Protocol summary

##### Study aim

.The Effect of Cognitive-Behavioral Therapy on Social Adjustment and Self-esteem of Thalassemic Patients in Pasteur Hospital in Bam

##### Design

The study included two groups of control and intervention which were selected from among patients referring to the pastoral hospital of the age group of 15 years old.

##### Settings and conduct

Interventional study - Pasteur Bam Hospital

##### Participants/Inclusion and exclusion criteria

Patients with an age group over 15 years of age have a minimum level of reading and writing literacy, or if the psychological disorder is confirmed and does not fill the questionnaire for any reason or is incompletely completed.

##### Intervention groups

92 persons were selected by census method and then randomly assigned randomly to the intervention group of the control group randomly (46 people per group). the researcher divided the intervention group into two groups of 23, and the intervention group held 8 sessions of 90 minutes training. After the completion of group training sessions, one month later, posttest was performed for both intervention and control groups (14). And then, based on the data obtained, the results were examined. There was no intervention for the control group

##### Main outcome variables

social adjustment and self-esteem

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180704040333N1**

Registration date: **2018-09-29, 1397/07/07**

Registration timing: **retrospective**

Last update: **2018-09-29, 1397/07/07**

Update count: **0**

##### Registration date

2018-09-29, 1397/07/07

##### Registrant information

###### Name

Mahnaz Hasani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 4434 4609

###### Email address

m.hasani@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-04, 1396/01/15

##### Expected recruitment end date

2018-07-15, 1397/04/24

##### Actual recruitment start date

2017-04-04, 1396/01/15

##### Actual recruitment end date

2018-07-15, 1397/04/24

##### Trial completion date

2018-08-10, 1397/05/19

##### Scientific title

Comparison of the Effectiveness of Cognitive-Behavioral Therapy on Social Adjustment and Self-esteem in Thalassemic Patients

##### Public title

The Effect of Cognitive-Behavioral Therapy on Social Adjustment and Self-esteem in Thalassemic Patients

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Group over 15 years old Have at least reading and writing skills

### Exclusion criteria:

Having mental disorder confirmed Failure to complete the questionnaire for any reason or defect in completing the questionnaire Having more than two absences

## Age

From **15 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **106**

Actual sample size reached: **92**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The intervention group is randomly selected from among 106 participants, and the control group remains unaware of the study of what study and where it is done.

## Placebo

Not used

## Assignment

Parallel

## Other design features

Since the number of patients in the age group over 15 years old who referred to thalassemia clinic was 106, all patients were enrolled by census method and then divided into two intervention and control groups using simple random sampling. The samples were divided into two groups according to the gender variable ( $\pm 2$ ). In other words, the first sample was randomly assigned to one of the two intervention groups or control group using the lottery and the subsequent samples were assigned to each group according to the matching variables and the random conditions. .

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

##### Street address

Four Way Somayeh (Tahmasebabad), Beginning of Jihad Boulevard, Beginning of Ibn Sina St.

#### City

Kerman

#### Province

Kerman

#### Postal code

7619813160

#### Approval date

2018-03-30, 1397/01/10

#### Ethics committee reference number

IR.KMU.REC.1397.057

## Health conditions studied

### 1

#### Description of health condition studied

Thalassemia

#### ICD-10 code

D56.1

#### ICD-10 code description

Beta thalassemia

## Primary outcomes

### 1

#### Description

1- Social Adjustment:It means a person's compromise with the social environment that this adaptation can be created by adapting itself to the environment or changing the environment to meet the needs and achieve desirable

#### Timepoint

Before the intervention and 30 days later

#### Method of measurement

Bell Social Reconciliation Questionnaire and Rosenberg Self-Esteem Questionnaire

## Secondary outcomes

### 1

#### Description

-

#### Timepoint

-

#### Method of measurement

-

## Intervention groups

### 1

#### Description

Intervention group: The cognitive-behavioral group therapy group was evaluated in addition to receiving routine care with Bell's social adjustment questionnaire and Rosenberg self-esteem questionnaire. Then, 8 sessions of 90 minutes and one week of cognitive-

behavioral therapy were performed for them. One Month after the completion of group training sessions are evaluated using the mentioned questionnaires.

**Category**

Behavior

**2****Description**

Control group: Control group: The group only received routine care. Before the intervention group begins cognitive-behavioral therapy, a social and self-esteem Rosenberg questionnaire is used to evaluate and, during the course of this intervention, no intervention for this non- There is no routine care and after a month, the questionnaires are evaluated by this group.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Pasteur Hospital

**Full name of responsible person**

Mahnaz Hasani

**Street address**

Pasteur Hospital, Shahid Rajaee Blvd. Town Bam

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

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Abbas Pardakhti

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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**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Mahnaz Hasani

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

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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

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Potential data can be shared after unidentifiable individuals

### When the data will become available and for how long

Potential data can be shared after unidentifiable individuals

### To whom data/document is available

Start the month access period after printing the results

### Under which criteria data/document could be used

Researchers working in academia and academia

### From where data/document is obtainable

The data is sent through an official request and by e-mail

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

The data is sent through an official request and by e-mail

### Comments

The data is sent through an official request and by e-mail