

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of counseling on the quality of life in patients with major thalassemia referred to thalassemia treatment center in Bushehr in 2016

Protocol summary

Summary

The study aimed to determine the effect of counseling on the quality of life in patients with major thalassemia with random allocation to treatment or control groups with Inclusion criteria: patients with a minimum age of 12 years suffering from thalassemia major in thalassemia treatment center in Bushehr with medical records and the ability to complete the questionnaire and also have a desire to participate in the study, Exclusion criteria: disease or other chronic ailments in addition to the psychological profile of patients with thalassemia. Lack of sample firms in more than two sessions of group therapy counseling. The total sample size of 62 individuals and group counseling intervention for intervention by a clinical psychologist within 6 weeks (2 sessions per week) (intervention group consists of three sub-group each 4 sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070328750N1**

Registration date: **2016-07-16, 1395/04/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-16, 1395/04/26

Registrant information

Name

Rezvan Bakhshi

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 3422 9797

Email address

r.bakhshi@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice President of Research, Bushehr University of Medical Sciences

Expected recruitment start date

2016-08-05, 1395/05/15

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling on the quality of life in patients with major thalassemia referred to thalassemia treatment center in Bushehr in 2016

Public title

The effect of counseling on the quality of life in patients with major thalassemia

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: patients with a minimum age of 12 years old suffering from thalassemia major in thalassemia treatment center in Bushehr, Iran with medical records and the ability to complete the questionnaire and also have a desire to participate in the study. Exclusion criteria: the psychological profile of the treated disease or other chronic disease thalassemia in addition to the obstacle of the samples used in the study. Lack of sample firms in more than two sessions of group

therapy counseling.

Age
From **12 years** old to **46 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

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
Bushehr University of Medical Sciences

Street address
Bushehr, Rishehr, next to Salman Farsi Hospital

City
Bushehr

Postal code

Approval date
2016-06-20, 1395/03/31

Ethics committee reference number
IR.BPUMS.REC.1395.51

Health conditions studied

1

Description of health condition studied
Major thalassemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Quality of life

Timepoint

Before intervention and one month after intervention

Method of measurement

SF- 36 quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Programs psychological counseling group in which the intervention group (n = 31) into three groups (two subgroups of 10, a group of 11 people) is divided and for each subgroup 4 sessions of 60-90 minutes two sessions per week, total 12 sessions for 6 weeks conducted by a clinical psychologist with a cognitive behavioral approach.

Category

Behavior

2

Description

No intervention in control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Thalassemia treatment Center in Bushehr

Full name of responsible person
Mrs. Bashi

Street address
Thalassemia treatment center in Bushehr

City
Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice President of Research, Bushehr University of Medical Sciences

Full name of responsible person
Dr. Afshin Ostovar

Street address
Bushehr University of Medical Sciences, Salman Farsi Street, Bahmani St.

City
Bushehr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice President of Research, Bushehr 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

Bushehr University of Medical Sciences

Full name of responsible person

Sherafat Akabarian

Position

Master of nursing,science Committee

Other areas of specialty/work

Street address

Nursing Faculty, Bushehr University of Medical Sciences

City

Bushehr

Postal code

Phone

+98 77 3455 0187

Fax

Email

sh.akabarian@bpums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Dr. Masoud Bahreini

Position

PhD in Nursing Education

Other areas of specialty/work

Street address

Nursing Faculty, Bushehr University of Medical Sciences

City

Bushehr

Postal code

Phone

+98 77 3345 0187

Fax

Email

msdbahreini@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Sherafat Akabarian

Position

Master of nursing,science Committee

Other areas of specialty/work

Street address

Nursing Faculty, Bushehr University of Medical Sciences

City

Bushehr

Postal code

Phone

+98 77 3455 0187

Fax

Email

sh.akabarian@bpums.ac.ir

Web page address

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