Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Rezvan Bakhshi

Name of organization / entity

Bushehr University of Medical Scienses

Country

Iran (Islamic Republic of)

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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
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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