Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial the effect of positive thinking educational program on the sleep quality and hopefulness of major thalassemia patients

Protocol summary

Summary

The aim of this clinical trial is to determine the effects of the educational program of positive thinking on sleep quality and hopefulness of Major thalassemia patients. The sample consists of 76 patients of the special diseases ward of Fasa Shariati hospital who enter the study through census and are placed equally in experimental and control groups on the basis of random blocks. Entrance factors includes the age of 18 and over and the ability to read and write, where the exit ones cover the psychological grounds such as great depression, encountering crisis, and being admitted during the last three weeks. The intervention for the experimental group consists of eight sessions of positive thinking education such as lectures, group discussion, clip shows , and sound clips. The control group does not receive any intervention. The data would be collected with Petersburg sleep quality and Schneider hopefulness questionnaires before and one month after the experiment. The expected outcomes include improvements in sleep quality and hopefulness in the patients of the experimental group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010431774N1**
Registration date: **2017-07-03, 1396/04/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-03, 1396/04/12

Registrant information

Name

Somayeh Makaremnia

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 5333 3148

Email address

makaremnia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-04-30, 1396/02/10

Expected recruitment end date

2017-12-31, 1396/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial the effect of positive thinking educational program on the sleep quality and hopefulness of major thalassemia patients

Public title

The effect of educational program concerning the positive thinking on the sleep quality and hopefulness of patients inflicted by major thalassemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:People who are suffering from major thalassemia; are not member of virtual and real groups of positive thinking during the intervention; at least 18 years old. Exclusion criteria: failure to complete the

questionnaire in full; mental illness including chronic depression treated with medication; lack of participation in the program is fully; lack the ability to read and write; to deal with major crises such as the death of a relative during the study and over the last 3 months; hospitalization for 48 hours or more

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Central Building Shiraz University of Medical Sciences;Zand Ave ;Shiraz.

City
Shiraz

Postal code

Approval date
2017-04-18, 1396/01/29

Ethics committee reference number
ir.sums.irec.1396.5

Health conditions studied

1

Description of health condition studied
Major Thalassemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassaemia

Primary outcomes

1

Description
Sleep quality

Timepoint
before and one month after the intervention

Method of measurement
Pittsburgh Sleep Quality Index

2

Description
hopefulness

Timepoint
before and one month after the intervention

Method of measurement
Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description
Positive thinking

Timepoint
Before and one month after the intervention

Method of measurement
Positive thinking questionnaire

Intervention groups

1

Description
Intervention group: The program includes training on positive thinking positive thinking skills for 8 sessions of two hours for groups of 8-12 people will be done. If any of the members can not participate in scheduled meetings will make it possible to compensate in other groups. The number of participants will be at the discretion of the investigator. Overall content, including familiarity with positive thoughts and beliefs about themselves, others, life and future through clips and audio files with the same focus.

Category
Other

2

Description
Control group: Receives no intervention.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

TheSpecific Disease Ward Of Fasa Shariati Hospital

Full name of responsible person

Somayeh Makaremnia

Street address

Shariati Hospital, Fasa, Fars, Iran

City

Fasa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Chaman Reza

Street address

Shiraz UniversityOf Medical Sciences، Zand Ave، Shiraz;Iran

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Maksremnia Somayeh

Position

Nursing Graduate Student

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences، zand ave، Shiraz، Iran

City

Shiraz

Postal code

00987136474254

Phone

+98 71 3647 4254

Fax

Email

makaremnia@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Nursing, School of Nursing and Midwifery, Shiraz University of Medical Sciences

Full name of responsible person

Dr Zahra Khademian

Position

Assistant Professor

Other areas of specialty/work

Street address

Fatemeh (PBUH) School of Nursing and Midwifery, Namazi Square, Shiraz, Iran

City

Shiraz

Postal code

Phone

+98 71 3647 4254

Fax

Email

zahrakhademian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Makaremnia Somayeh

Position

Nursing Graduate Student

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences;zand ave; Shiraz;Iran

City

Shiraz

Postal code

Phone

+98 917 616 1710

Fax

Email

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