

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2022

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

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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

The Specific Disease Ward Of Fasa Shariati Hospital
Full name of responsible person
Somayeh Makaremnia
Street address
Shariati Hospital, Fasa, Fars, Iran
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Fasa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Street address
Shiraz University Of Medical Sciences, Zand Ave,
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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
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

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Person responsible for updating data

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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