Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of a program based on spiritual care on self-esteem and spiritual health of patients with thalassemia major referred to Seyed Al-Shohada Hospital in Isfahan, 2022

Protocol summary

Study aim
Determining the effect of a program based on spiritual care on self-esteem and spiritual health of patients with beta thalassemia major referred to Seyed Al-Shohada Hospital in Isfahan province in 2022

Design
A clinical trial with the control group, no blinding, randomized, on 64 patients. Excel random function was used for randomization.

Settings and conduct
Patients with beta-thalassemia major in Seyed Al-Shohada Hospital of Isfahan province who are willing to participate in the study and inclusion criteria are identified and randomly entered into the study. In the first stage, their self-esteem and spiritual health are assessed and recorded using a questionnaire, then a program based on spiritual care is presented to the intervention group, then in the last session or up to two weeks later. From the last session of the program based on spiritual care, self-esteem and spiritual health of patients are reviewed and recorded using a questionnaire.

Participants/Inclusion and exclusion criteria
Age range 18 years and older. Be physically and mentally ready to participate. Have the ability to read and write in Persian. Be able to speak Persian. Absence from another similar study.

Intervention groups
The intervention includes the implementation of a spiritual care program and its impact on the self-esteem and spiritual health of the intervention group. The implementation of this program is in the form of face-to-face classes and in this study in the control group only the level of self-esteem and spiritual health is examined and no intervention is done for the control group.

Main outcome variables
Self-esteem; level of the spiritual health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211121053121N3**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-26, 1400/12/07**
Update count: **0**

Registration date
2022-02-26, 1400/12/07

Registrant information

Name
Seyed Abbas Hoseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3792 7504

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a_hoseini@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-03-19, 1400/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of a program based on spiritual care on self-esteem and spiritual health of patients with thalassemia major referred to Seyed Al-Shohada Hospital in Isfahan, 2022

Public title
The effect of a program based on spiritual care on self-esteem and spiritual health of patients with thalassemia major

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with thalassemia major Ability to read and write in Persian Ability to speak Persian

Exclusion criteria:
Reluctance to cooperate in further study. Participate in a similar study. Absence from more than one session in training sessions.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample consisted of 64 patients with beta-thalassemia major. First, a list of all patients with beta-thalassemia major will be provided. By easy sampling method, 64 of these patients were selected and then the samples were randomly divided into two groups of intervention (spiritual care) and control (32 people in each group).

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
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezarjerib Ave.,Isfahan Town

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2021-12-25, 1400/10/04

Ethics committee reference number
IR.MUI.NUREMA.REC.1400.197

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
Patient self-esteem score in the spiritual self-esteem questionnaire

Timepoint
Before the intervention and 0 to 14 days after the last training session

Method of measurement
Spiritual Self-Esteem Questionnaire of Farhoush

2

Description
Patient's spiritual health score on the Pulotzin and Ellison Spiritual Health Questionnaire

Timepoint
Before the intervention and 0 to 14 days after the last training session

Method of measurement
Pulotzin and Ellison Spiritual Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group. The mentioned care program during 6 sessions, each session of 60 minutes in groups of 5-6 people in the educational classes located in Seyed Al-Shohada Hospital in the morning and evening shifts by the researcher in the form of lectures, discussions and exchanges, video clips (using networks Valid authorized

download according to the educational content) and the presentation of a spiritual package for the intervention group will be held. All sessions of this spiritual care program are conducted by the researcher and under spiritual consultation with the spiritual care specialists of Ala Center. Intervention in the group is explained by a spiritual cognitive approach. In this approach, much emphasis is placed on expressing concepts operationally. Much of the treatment is based on the here and now approach. The main goal of treatment is to help the patient to change his attitude and reduce negative thoughts about himself, the world and the future. The group intervention program is content-oriented and tries to change and correct patients 'attitudes in four areas of relationship with God, self, others and nature in order to increase patients' hope. Since prayer is sometimes used as a confrontation It is used religiously, if looking at prayer is instrumental and problem-oriented, one uses prayer only when there is a problem; But in a comprehensive, innovative and functionalist view, prayer is a cognitive model that attention to its content and concept, can change the attitude of the individual to himself, God, creation and existence. With such a view of prayer, this intervention helps to raise hope in patients.

Category

Rehabilitation

2

Description

Control group. The control group will not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed Al-Shohada Hospital

Full name of responsible person

Mehran Sharifi

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Motahari Ave.,Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

Hezar Jerib Ave., Isfahan., Iran

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Seyed Abbas Hosseini

Position

Instructor of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Coordinating with the researcher and observing ethical principles in research

From where data/document is obtainable
Seyed Abbas Hosseini a_hoseini@nm.mui.ac.ir 03137927504

What processes are involved for a request to access data/document
Correspondence from the center of origin and determine the goals and how to use the data

Comments