

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigating if the effect of religious care education on spiritual health and life expectancy in adolescents with thalassemia major

Protocol summary

Study aim

Determining the effect of religious care education on spiritual health and life expectancy of patients with thalassemia major

Design

A clinical trial with a control group, without blinding, randomized, on 34 patients, the lottery method was used for randomization.

Settings and conduct

This study will be performed on 34 patients with thalassemia major in the thalassemia ward of Ali Asghar Hospital. Religious care in these patients will be done in 6 sessions and spiritual health and life expectancy questionnaires will be filled in before and after the intervention.

Participants/Inclusion and exclusion criteria

Patients with thalassemia major referred to the thalassemia ward of Hazrat Ali Asghar Hospital Inclusion criteria: - Conscious consent to participate in the study - Have a minimum literacy -Having a record in the thalassemia ward -age between 15-20 years Conditions for not entering the study: Having severe and chronic diseases such as cancer that make it impossible to participate in the study Drug addiction (false impact on research units) Reluctance to participate in the study Severe mental illness and severe frustration

Intervention groups

For the intervention group, spiritual care training will be done in 6 sessions of 60-45 minutes in groups and in 3 weeks in the morning shift. The content of spiritual care education will be prepared with the focus on topics such as trust, recourse, patience, prayer, supplication and prayer, self-knowledge, communication with God always, reconciliation with people and communication with others. . No intervention will be performed for the control group

Main outcome variables

Life expectancy; mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200606047670N2**

Registration date: **2021-01-08, 1399/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-08, 1399/10/19**

Update count: **0**

Registration date

2021-01-08, 1399/10/19

Registrant information

Name

sadegh dehghanmehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2481

Email address

sa.dehghanmehr@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-20, 1399/09/30

Expected recruitment end date

2021-02-17, 1399/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating if the effect of religious care education on spiritual health and life expectancy in adolescents with thalassemia major

Public title

Investigating the effect of religious education in thalassemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 15-20 Willingness to participate in the study Have undergone blood transfusion at least once every 6 months and at least once a week Having a thalassemia medical record Have a minimum literacy

Exclusion criteria:

Severe and chronic diseases such as cancer that can not be studied Drug addiction (false impact on research units) Severe mental illness and severe frustration

Age

From **15 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method will be done randomly and using a lottery among patients who will be eligible to enter the study. In this way, the number will be written in the number of sample units and placed in a bag, and patients who choose odd numbers will be in the intervention group and patients who choose an even number will be in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Health Street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Approval date

2020-09-19, 1399/06/29

Ethics committee reference number

IR.ZAUMS.REC.1399.321

Health conditions studied

1

Description of health condition studied

Beta Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Life expectancy score in Schneider life expectancy questionnaire

Timepoint

Measuring life expectancy at the beginning of the study (before the intervention) and 35 days later (3 weeks of the intervention and 2 weeks after)

Method of measurement

Schneider life expectancy questionnaire questionnaire

2

Description

Spiritual health score in Pultezin spiritual health questionnaire

Timepoint

Measuring spiritual health at the beginning of the study (before the intervention) and 35 days later (3 weeks of the intervention and 2 weeks after)

Method of measurement

Poltzin Spiritual Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, spiritual care training will be done in 6 sessions of 60-45 minutes in groups and in 3 weeks in the morning shift. The content of spiritual care education will be prepared with the focus on topics such as trust, recourse, patience, prayer, supplication and prayer, self-knowledge,

communication with God always, reconciliation with people and communication with others.

Category

Behavior

2

Description

Control group: There will be no intervention for the control group and they will receive their routine care as before.(Counseling by the center itself, which is usually done once a month and has no effect on the study.)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Thalassemia ward of Hazrat Ali Asghar Hospital

Full name of responsible person

Sadegh Dehghanmehr

Street address

Health Street

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Phone

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Email

sadeghdehghan3407@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Ali Navidian

Street address

Health Street

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Province

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Email

alinavidian@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Sadegh Dehghanmehr

Position

Instructor, Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The article and the plan that will be done will be available except for the patients' information

When the data will become available and for how long

After doing the work and printing the article

To whom data/document is available

All interested people

Under which criteria data/document could be used

In order to be used for further research and supportive treatment of patients

From where data/document is obtainable

Sadegh Dehghan Mehr, Postal Code: 9816913396, Email: sadeghdehghan3407@gmail.com

What processes are involved for a request to access data/document

with sending email

Comments