

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of spiritual care based on the "Ghalb salim" model on the depression, anxiety and stress in thalassemic adolescents.

Protocol summary

Study aim

Determining the effect of spiritual care based on the "Galb salim" model on depression, anxiety and stress in adolescents with thalassemia

Design

Clinical trial with control group, With parallel groups, randomised

Settings and conduct

The place of the study will be Shahid Dastgheib Hospital of Shiraz. Samples will be divided into two groups of intervention and control using Permutation block method and both groups will complete two demographic and DASS- 21 questionnaires. Then, during the 4 sessions, each session being one week apart, the intervention group will be educated a part of the "Galb Salim" model. After one week of the last session, the DASS- 21 questionnaire will be completed by the two groups. At the end, the training pamphlet will be given to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Beta thalassemia, Adolescents aged 15 to 20 years, Being Muslim, Having at least primary literacy, Persian speaking, Lack of physical illness other than thalassemia, Not facing a stressful event in the last 6 months, Not having known mental illness according patient's and parent's statement, Not using drugs that affect mental health. Exclusion criteria: Unwillingness of adolescent or parents to participate in the study, Participation in spiritual care training courses in the last 6 months

Intervention groups

Intervention group: Adolescents receive «Galbe Salim» spiritual care education in four sessions (first session communication with God, second session communication with others, third session communication with environment, and fourth session communication with self) individually. The duration of each session will be 30 minutes. Control group: in control group no intervention is performed.

Main outcome variables

Depression; Anxiety; Stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190908044725N1**

Registration date: **2020-01-11, 1398/10/21**

Registration timing: **prospective**

Last update: **2020-01-11, 1398/10/21**

Update count: **0**

Registration date

2020-01-11, 1398/10/21

Registrant information

Name

Samaneh naseri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3720 6041

Email address

naserism@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual care based on the "Ghalb salim" model on the depression, anxiety and stress in thalassemic adolescents.

Public title

The effect of «Galb salim» model on depression, anxiety and stress in adolescents with thalassemia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Beta thalassemia Adolescents aged 15 to 20 years Being a Muslim having at least primary literacy Persian speaking Lack of physical illness other than thalassemia Not facing a stressful event in the last 6 months not having known mental illness based on patient's and parents' statement Not using drugs that affect mental health

Exclusion criteria:

Unwillingness of adolescent or parents to participate in the study Participation in spiritual care training courses in the last 6 months

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: **64****Randomization (investigator's opinion)**

Randomized

Randomization description

To determine intervention and control groups, four- size blocks with 6 permutations are used. The permutations are numbered and selected randomly. Arrangement of selected permutation enters to table until all samples in 2 groups are selected.

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 Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2019-08-28, 1398/06/06

Ethics committee reference number

IR.SUMS.REC.1398.659

Health conditions studied**1****Description of health condition studied**

Thalasmia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes**1****Description**

Depression

Timepoint

Before and after intervention

Method of measurement

DASS-21 questionnaire

2**Description**

Anxiety

Timepoint

Before and after intervention

Method of measurement

DASS-21 questionnaire

3**Description**

Stress

Timepoint

Before and after intervention

Method of measurement

DASS-21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: adolescents with thalassemia receive spiritual care training based on "Ghalb salim" model in 4 sessions (each week, one session) individually. Education method is face to face. Also, educational pamphlet and booklet about spiritual care are given to adolescent. Duration of each session is about 30- 45 minutes. In "Ghalb salim" model, relationships with God, others, the environment and the self are trained according to Islam.

Category

Lifestyle

2

Description

Control group: In the control group, no intervention will be performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dastgheib Hospital

Full name of responsible person

Dr. Kazem Samadi

Street address

Shahid Dastgheib Hospital , Hafezieh Crossroad,
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71456-37696

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Dastgheib@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of
Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand
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vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Samaneh Naseri

Position

Master of Pediatric Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Zahra Hadian Shirazi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Name of organization / entity

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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