Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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, Shiraz
City
Shiraz
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Postal code
71456-37696
Phone
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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 Street,Shiraz
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Postal code
71348-14336
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+98 71 3235 7278
Email
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

Contact

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Shiraz University of Medical Sciences

Full name of responsible person
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Position
University student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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