

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The impact of spiritual self- care on the efficiency and life quality in adolescents with Thalassemia

Protocol summary

Study aim

The effect of spiritual self- care on self-efficacy and quality of life on adolescents with thalassemia

Design

In this study, adolescents with thalassemia who are send to the thalassemic department of the hospital are selected. The participants in the study are selected as single-group or non-randomized. Before and after the intervention, the questionnaire is completed by adolescents.

Settings and conduct

In thalassemia ward, spiritual self- care education is given to adolescents with thalassemia.

Participants/Inclusion and exclusion criteria

inclusion criteria: 12-18 year-old thalassemic adolescents and non-chronic diseases such as asthma, cancer, tuberculosis, to have a thalassemia medical files- minimum reading and writing literacy exclusion criteria: Unwilling to participate in research

Intervention groups

Interventions are non-random and single-group. For adolescents who have the conditions for intervention, six sessions of spiritual self-education will be provided based on the Richard Z and Bergen pattern based on Islamic teachings, including reading the Qur'an, pilgrimage, praying, using nature and sports, and communicating with friends.

Main outcome variables

Self-efficacy and quality of life in thalassemic adolescents .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180107038258N1**

Registration date: **2018-09-19, 1397/06/28**

Registration timing: **retrospective**

Last update: **2018-09-19, 1397/06/28**

Update count: **0**

Registration date

2018-09-19, 1397/06/28

Registrant information

Name

Zoleikha Iri

Name of organization / entity

Islamic Azad University of Ali Abad Katoul Unit

Country

Iran (Islamic Republic of)

Phone

+98 17 3338 5277

Email address

z.iri@aliabadiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-04-20, 1397/01/31

Trial completion date

2018-04-20, 1397/01/31

Scientific title

The impact of spiritual self- care on the efficiency and life quality in adolescents with Thalassemia

Public title

The impact of spiritual self- care on the efficiency and life quality in adolescents with Thalassemia

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The thalassemic adolescents come for bloodtransfusion
 Not having another chronic disease, such as cancer
 Inclination to participate in research Age between 12 and 18 years

Exclusion criteria:

Unwilling to participate in research

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Actual sample size reached: **32**

Randomization (investigator's opinion)

N/A

Randomization description**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**

Ethics committee of Islamic Azad University of Shahrood

Street address

University blvd

City

Shahrood

Province

Semnan

Postal code

3619941167

Approval date

2018-04-24, 1397/02/04

Ethics committee reference number

لطفا در کادر جستجوی مصوبه اخلاق کمیته ملی اخلاق در پژوهش های زیست پزشکی در قسمت نام مجری /استاد راهنما/دانشجو نام اینجانب زلیخا ایری وارد شود تا جستجو انجام گردد (نام استاد راهنما دکتر گل (بهار آخوند زاده می باشد)
 مصوبه اخلاق IR.IAU.SHAHROOD.REC.1397.005

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

The impact of spiritual self- care on the efficiency and quality of life in adolescent withThalassmia in Taleghani Children s Hospital- Gonbad Kavoods 2017-18

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Efficiency

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

General Self-Efficacy Scale (GSE)

Secondary outcomes**1****Description**

Quality of life

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

quality of life questionnaire SF-36

Intervention groups**1****Description**

12-18 year/ old thalassemic adolescents who come for blood transfusion are marked. They are then divided into four groups of 8, and the group of intellectual-religious-based care groups are performed twice a week for 6 sessions per week for 45-60 minutes each group. This educational package is based on the spiritual and religious mentality based on the pattern of Richards and Bergen, with a focus on the religion of Islam. Like encouraging patients to read the Qur'an, praying, prayer, mentioning-discussing the psychological effects of praying prayers, encouraging the use of religious spaces - Recreational and sightseeing and doing sports activities according to the physician's opinion - encouraging adolescents to establish a friendly relationship with Others, encouraging teens to participate in spiritual programs-Religious-expressing the history of religious patterns.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Children's Hospital

Full name of responsible person

Zoleikha Iri

Street address

South Fajr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Zoleikha Iri

Position

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