

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparing effect of receiving and not receiving an educational - Supportive intervention on quality of life in adult patients with thalassemia major

Protocol summary

Summary

The purpose of this study is to development and evaluation of an educational - Supportive intervention to improve quality of life in adult patients with thalassemia major. This research is a quasi - experimental and Single blind study. The study population is all adult patients with thalassemia major covered by thalassemia treatment centers of Tehran University of Medical Sciences and Tehran Blood Transfusion Organization. Sample size is 136; 68 in intervention group and 68 in control group. In the pretest, stratified random sampling method will be used. After pretest, subjects will be classified non-randomly to two intervention and control groups. Inclusion criteria: people over 18 years old; consent to participation in the study; no serious problems in physical and mental health. Exclusion criteria: younger than 18 years; the lack of consent to participate in the study; a serious problem in the physical and mental health. Questionnaires included demographic characteristics, quality of life and PRECEDE constructs (Predisposing, Reinforcing and Enabling Constructs) and validity and reliability of the questionnaire will be achieved during the study. In the intervention group, educational interventions to improve quality of life and lifestyle will be implemented. The control group will receive routine educational programs from respective medical institutions. Data extracted from each group, before and 6 months after intervention, will be compared. Primary outcome: improving the quality of life in patients with thalassemia major. Secondary outcome: improving the PRECEDE constructs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111812460N8**

Registration date: **2016-01-31, 1394/11/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-31, 1394/11/11

Registrant information

Name

Roya Sadedgi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 327 5692

Email address

sadeghir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Educational vice chancellor of Tehran University of Medical Sciences

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2016-12-31, 1395/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of receiving and not receiving an

educational - Supportive intervention on quality of life in adult patients with thalassemia major

Public title

Development and evaluation of an educational - Supportive intervention to improve quality of life in adult patients with thalassemia major

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: people over 18 years old diagnosed with thalassemia major; written and informed consent to participation in the study; no serious problems in physical and mental health. Exclusion criteria: younger than 18 years; the lack of consent to participate in the study; a serious problem in the physical and mental health

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Tehran University of Medical Sciences

Street address

Main building of Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2015-11-15, 1394/08/24

Ethics committee reference number

IR.TUMS.REC.1394.1153

Health conditions studied

1

Description of health condition studied

Major Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Major Thalassemia

Primary outcomes

1

Description

Quality of life in patients with thalassemia major

Timepoint

Before and six months after the intervention

Method of measurement

Quality of life questionnaire (SF-12)

Secondary outcomes

1

Description

PRECEDE Model constructs

Timepoint

Before and six months after the intervention

Method of measurement

Questionnaire according to PRECEDE Model constructs

Intervention groups

1

Description

In the intervention group, the following measures will be done: holding educational interventions in order to improve quality of life and lifestyle. Type of intervention, intervention of the target groups, educational content, teaching methods, number and timing of training classes, will be determined according to the analysis of the results of the pretest.

Category

Lifestyle

2

Description

There would be no intervention in control group, therefore, the control members will receive routine educational programs from respective medical institutions including: visits by doctor of clinic, vaccinations, blood transfusion, nursing care before, during and after blood transfusion, educating how to use Desferal pump, educating how to iron chelation.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zafar Adult Thalassemia Clinic

Full name of responsible person

Dr. Mojtaba Ebrahimi (General Practitioner)

Street address

No 1/1, Corner Shahin Alley, North Mehrdad Nasiri St,
Vahid Dastgerdi Av (Zafar), Shariati Av

City

Tehran

2

Recruitment center

Name of recruitment center

Baharloo Hospital

Full name of responsible person

Dr. Seyed Majid Mousavi Movahed (Fellowship /
Assistant Professor)

Street address

Behdari Av, Rah Ahan Sq, Tehran

City

Tehran

3

Recruitment center

Name of recruitment center

Ali Asghar Children Hospital

Full name of responsible person

Dr. Elham Talachian (Pediatrician)

Street address

Vahid Dastgerdi Av (Zafar), Shariati Av, Tehran

City

Tehran

4

Recruitment center

Name of recruitment center

Children's Medical Center Hospital

Full name of responsible person

Dr. Ali Rabbani(Fellowship / Professor)

Street address

No 62, Near Imam Khomeini Hospital Complex,
Mohammad Garib Av, Azadi Av, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Educational vice chancellor of Tehran University of
Medical Sciences

Full name of responsible person

Dr. Mohammad Jalili

Street address

Main Building of Tehran University of Medical
Sciences

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Educational vice chancellor of Tehran University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Roya Sadeghi

Position

PhD of Health Education and Promotion / Academic
staff

Other areas of specialty/work**Street address**

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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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty