Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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