

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Evaluation of the effect of implementing continuous care model on self-care behaviors of thalassemia major patients

#### Protocol summary

##### Study aim

Determining and comparing the average score of self-care behaviors of thalassemia major patients between the intervention group and the control group before the implementation of the intervention, six weeks after the start of the intervention and immediately after the end of the intervention.

##### Design

The study is a clinical trial that has two control and intervention groups and is determined by randomization by random allocation software and is performed on 56 patients

##### Settings and conduct

This study will be conducted in the Colitis Department of Ostad Motahari Hospital in Jahrom, and the follow-up care program, which includes four stages of familiarization, sensitization, control, and evaluation, will be implemented by the researcher in a group for the people of the intervention group in the educational hall located in Motahari Hospital.

##### Participants/Inclusion and exclusion criteria

People over 18 years of age who referred to the thalassemia department of the relevant hospital, who were suffering from thalassemia major and had minimal literacy and were willing to participate in the study, were considered as inclusion criteria, and those who did not meet the stated criteria were considered as exclusion criteria in the study. is considered

##### Intervention groups

If the patient is in the intervention group, the continuous care model will be implemented. The follow-up care model has its own continuity and coherence and includes familiarization, sensitizing, control and evaluation stages respectively. which will be implemented by the researcher in a group for patients.

##### Main outcome variables

The score of the patients' general self-care behaviors is measured by the initial self-care behaviors questionnaire, the total score of the questionnaire is in the range of 0 to

84.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230115057132N1**

Registration date: **2023-02-21, 1401/12/02**

Registration timing: **prospective**

Last update: **2023-02-21, 1401/12/02**

Update count: **0**

##### Registration date

2023-02-21, 1401/12/02

##### Registrant information

##### Name

Mohammad sadegh Mohit

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5456 2202

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-25, 1401/12/06

##### Expected recruitment end date

2023-03-11, 1401/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of the effect of implementing continuous care model on self-care behaviors of thalassemia major patients

### Public title

effect of implementing continuous care model on self-care behaviors of thalassemia major patients

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Thalassemia major patients who are over 18 years old Be literate Willingness and consent of the patient to participate in the study

#### Exclusion criteria:

Age less than 18 years Lack of literacy The patient's unwillingness to cooperate The occurrence of severe physical complications caused by the disease

### Age

From **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **56**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Sampling will be done first by census and then the patients who meet the inclusion criteria will be randomly selected in accordance with the required sample size of 56 people and randomly assigned to two control groups (code 1) and random allocation software. The intervention group (code 2) will be divided.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

### Other design features

In this study, in order to make the research conditions uniform for both groups, random allocation method will be used. If the patient is placed in the intervention group, the follow-up care model will be implemented, but no intervention will be done for the control group.

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

#### Street address

Jahrom University of Medical Sciences

#### City

Jahrom

#### Province

Fars

#### Postal code

74157-13945

### Approval date

2023-02-19, 1401/11/30

### Ethics committee reference number

IR.JUMS.REC.1401.136

## Health conditions studied

## 1

### Description of health condition studied

The effect of follow-up care on self-care behaviors of thalassemia major patients

### ICD-10 code

D56.1

### ICD-10 code description

Beta thalassemia

## Primary outcomes

## 1

### Description

The total score of the self-care behaviors of the patients, which is measured by the initial self-care behaviors questionnaire, which scores the self-care behaviors of thalassemia major patients with a 5-part scale, is given a score of 4 for always, 3 for most of the time, 2 for sometimes, 1 for rarely, and 0 for never. The total score of the questionnaire is in the range of 0 to 84

### Timepoint

before the start of the intervention and six weeks and twelve weeks after the end of the study

### Method of measurement

The initial self-care behavior questionnaire, which scores the self-care behaviors of thalassemia major patients with a 5-part scale, is measured in such a way that 4 points are always given, most of the time 3 points, sometimes 2 points, rarely 1 point, and never 0 points. The total score of the questionnaire ranges from 0 to 84

## Secondary outcomes

empty

## Intervention groups

## 1

### **Description**

Intervention group: The intervention for patients in the intervention group will be carried out for 3 months as follows: 1- The first stage of the continuous care model, i.e. the familiarization stage by the student researcher who conducts the study daily during the first 2 weeks of the research, will be carried out in the surroundings of Motahari Hospital in Jahrom, during which the patients will get to know the researcher better. Clarifying the expectations from each other, explaining the steps of the model, determining the agreement for face-to-face and telephone meetings will be implemented, and the contact number of the researcher will be provided to the patients of the intervention group for further follow-up. Community Verified icon 2- The second stage of follow-up care is the sensitization stage in order to involve the patient regarding the implementation of a continuous approach in the follow-up care model and its purpose is to introduce the nature of thalassemia disease to patients, thalassemia complications and thalassemia disease treatments, the role of exercise and nutrition in disease management. Psychosocial issues and sensitizing the patient to self-care behaviors in the disease will be in coordination with the patients and the head of the Colitis Department in the educational hall of Motahari Hospital, four sessions of one and a half hours in a month based on the chapter of educational content extracted from scientific texts and articles and reviews. The educational needs expressed by the participants will be through the needs assessment forms that will be provided to them. And after the approval of the educational content by the supervisor and the consultant, a master's degree student who is a member of the research team will give lectures and show educational videos and conduct questions and answers with the training participants as a group in the conference hall of Motahari Hospital to the patients of the intervention group. became. The sequence of sessions of the sensitization phase is as follows: the subject of the training in the first session, which will be implemented during the first week, is the nature of thalassemia major and blood transfusion and treatment and its side effects. The relationship between exercise and smoking for thalassemia patients and in the fourth session, education will be related to nutrition in thalassemia. In coordination with the patients, after the sensitization phase of the second phase test, which will be 6 weeks after the start of the intervention, during the seventh week, with the aim of measuring self-care behaviors in both the intervention and control groups individually, using the questionnaire of self-care behaviors of early-onset thalassemia patients. It will be done in person at the Motahari hospital. At this stage, if it is not possible to attend the hospital for some patients in two groups due to reasons such as the distance of the route, etc., the patients will be asked to fill out the questionnaire of self-care behaviors individually. Read the questionnaire that is sent to their mobile phone by the researcher virtually through the website and complete it with an emphasis on the confidentiality of the information and send it to the researcher with one of

the Iranian messengers, or if this is not possible for the patients, the researcher will contact the patients and complete the questionnaire of self-care behaviors by calling and asking the questions for them. 3- In the third stage of follow-up care, which is the control stage, and the goal is to institutionalize and continue health behaviors in order to improve health, in which the researcher conducting the study will contact the patients of the intervention group twice a week on Saturdays and Tuesdays for 6 weeks. On Saturday, he will make a phone call and use the phone call to remind the patients of the training that was given to the patients in the previous face-to-face classes with emphasis on self-care behaviors, and their questions will be answered. And the patients of the intervention group are reminded that again, if they have any questions or problems related to the training given, they can call the researcher to receive the necessary guidance over the phone again. Although in the continuous care model, evaluation as The final stage of the model has been proposed, but due to the nature of the follow-up care model, process evaluation will be considered and current in all stages of the model implementation, and the outcome or final evaluation, such as the evaluation of the seventh week, which was the second time. Again, using the questionnaire of self-care behaviors of patients with thalassemia major for the third time, thirteen weeks after the start of the study, in the fourteenth week in both the intervention and control groups, in person and individually at Motahari Hospital, and if the patient was not present at the hospital that week it will be measured virtually or by making a phone call.

### **Category**

Rehabilitation

## 2

### **Description**

Control group: Control group: In Opteda, the questionnaire of self-care behaviors of patients with thalassemia major will be provided to them, and after completing the questionnaire, no intervention other than the treatment measures that are usually performed for these patients will be carried out, after six months have passed. One week and after the end of the intervention, after completing the questionnaire that was presented to the patients in the first session, the questionnaire will be given to the control group two more times, so that the self-care behaviors of the patients will be measured again. It will be available to patients to use its content.

### **Category**

Rehabilitation

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Jahrom University of Medical Sciences, Ostad  
Motahari Hospital

#### **Full name of responsible person**

Rasool Eslami akbar

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

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**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**

Jahrom 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**

Jahrom University of Medical Sciences

**Full name of responsible person**

Rasool Eslami Akbar

**Position**

University faculty member, assistant professor

**Latest degree**

Ph.D.

**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