Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
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Other areas of specialty/work
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Person responsible for updating data

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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