Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Examining the Effect of Continuous Care Model on Quality of Life in Patients with Thalassemia Major

Protocol summary

Study aim
Determining and comparing the mean total score of quality of life of thalassemia major patients before, one and three months after the implementation of the follow-up care model in the intervention and control groups

Design
The clinical trial has two groups of intervention and control, which are randomly identified by a card and performed on 60 patients

Settings and conduct
The above project is performed in the thalassemia ward of Hazrat Ali Asghar Hospital in Zahedan and the follow-up care program includes four stages of identification, sensitization, control and evaluation; Individually to the intervention group in the training class located in the hospital; Will be implemented by the researcher

Participants/Inclusion and exclusion criteria
People over 18 years old referred to the thalassemia ward of the relevant hospital who have thalassemia major and live in Zahedan; It also has a minimum of educational literacy and tends to participate in the study is considered as an entry condition؛ and people who do not want to participate in the study and are other than the stated cases is considered as an exclusion criterion

Intervention groups
If the patient is in the intervention group, the follow-up care model will be implemented. The follow-up care program has its own continuity and coherence and includes four stages of identification, sensitization, control and evaluation, respectively. Which will be performed individually for the patient by the researcher

Main outcome variables
quality of life, physical health, mental health, social relationships, environmental health،Quality of life and general health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200926048842N1**
Registration date: **2020-09-29, 1399/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-29, 1399/07/08**
Update count: **0**

Registration date
2020-09-29, 1399/07/08

Registrant information

Name
Sajad Salehipour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-13, 1399/05/23

Expected recruitment end date
2021-08-14, 1400/05/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Examining the Effect of Continuous Care Model on Quality of Life in Patients with Thalassemia Major

Public title
The Effect of Continuous Care Model on Quality of Life in Patients Thalassemia Major

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years No problems such as mental retardation, behavioral and mental disorders, hearing, speech according to medical records Ability to access and control the patient during 3 months Complete consent of the patient and family to refer and follow up by phone and, if necessary, in person for care and to continue the training and care counseling required by the researcher Resident of Zahedan Having a cell phone in person or in the family or having a landline at home Failure to participate in similar training courses Have a minimum literacy Get a quality of life score less than 50 from the WHOQOL-BREF Quality of Life Questionnaire

Exclusion criteria:
Reluctance to continue cooperation Incidence of severe physical complications from the disease

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done by available methods. The selected patients are then randomly divided into control and intervention groups. First, an envelope containing the name of the group is prepared and randomly arranged for the total number of people studied, and by referring to and gradually selecting the individuals, one of the cards will be assigned to them, which determines the group of individuals in the intervention group or Will be in control. Due to random sampling, the samples will have an equal chance of being selected in both intervention and control groups

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
After selection, in order to standardize the research conditions for the two groups of intervention and control, a special random method will be used. If the patient is in the intervention group, the prosecution care model is implemented, but no intervention was performed for the control group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Dr. Hesabi Square - Campus of Medical Sciences

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zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2020-08-09, 1399/05/19

Ethics committee reference number
IR.ZAUMS.REC.1399.169

Health conditions studied

1

Description of health condition studied
The effect of continuous care on the quality of life of patients with thalassemia major

ICD-10 code
D56.1

ICD-10 code description
Beta thalassaemia

Primary outcomes

1

Description
Quality of life score, which is measured by the World Health Organization quality of life questionnaire and its score range is from 26-130

Timepoint
It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement
The World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales. And the difference between the two is 28; Mental Health Sub-Scale: The sum of the scores of questions 5-6-7-11-19-26 in the questionnaire The range of scores of this subscale will be between 6 and 30 and the difference between the two is 24; Social Interface Sub-Scale: The sum of the scores of questions 20-21-22 in the questionnaire The range of scores of this sub-scale will be between 3 and 15 and the difference between the two is 12; Environmental Health Sub-Scale: The sum of the scores of the questions 8-9- 12-13- 14-23-24-25 25 in the questionnaire The range of scores of this subscale

will be between 8 and 40 and the difference between the two is 32; Quality of life and general health: The sum of the scores of questions 1 and 2 in the questionnaire The range of scores of this subscale will be between 2 to 10 and the difference between the two is 8

2

Description

Physical health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 7-35

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales. Physical Health Sub-Scale: The sum of the scores of the questions 3- 4- 10- 15-16-17-18 in the questionnaire. The range of scores of this subscale will be between 7 and 35. ; And the difference between the two is 28

3

Description

Mental health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 6-30

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The World Health Organization Quality of Life Questionnaire, a 26-item questionnaire that includes four subscales of mental health subscale: Total scores of questions in the questionnaire 5- 6 -7 -11- 19- 26 subscale scores range between 6 to 30 will be the difference These two are 24

4

Description

Social relations health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 3-15

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales; Social Relations Sub-Scale: The sum of the scores of the questions 20-21-22 in the questionnaire The range of scores of this sub-scale will be between 3 and 15 and the difference between the two is 12

5

Description

Environmental health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 8-40

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales, Environmental Health Sub-Scale: Total scores of questions 8-9- 12-13-14-23-24-25 in the range of scores of this subscale between 8 Will be 40 and the difference between the two is 32

6

Description

Quality of life and general health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 2-10

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales; Quality of life and general health: The sum of the scores of questions 1 and 2 in the questionnaire The range of scores of this subscale will be between 2 and 10 and the difference between the two is 8

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At first, the quality of life questionnaire of the World Health Organization will be provided to them, and after answering it, four stages of the follow-up care model, which include familiarization, sensitization, control and evaluation; In the first stage, the researcher introduces himself to the patient and explains the purpose of the work to him, and in the second stage, which is the main stage of the intervention and includes 6 training sessions in the period of 45-60 minutes, The training class of the hospital was intended; Formation and after the completion of 6 training sessions, the third stage, which is control and follow-up, has begun, and in this stage, the patient for 3 months after the intervention, weekly and based on the arrangements made before and during the familiarization stage. , Calls the patient and asks him what he has been taught, and with the patient's answer, he enters the care checklist prepared, and the fourth stage, which is evaluation, is divided into two stages, once a month after the intervention and once Another three months after the intervention; The desired questionnaire is provided to individuals. Also the content of each session is as follows. Session 1: Anatomy and physiology of blood and

thalassemia. In this session, what are the types of blood cells, hemoglobin, thalassemia ?, What are the causes of thalassemia ?, Types of thalassemia, What are the risk factors in thalassemia? Diagnosis of thalassemia major, symptoms of the disease will be explained. Session 2: Complications of the disease, treatment of thalassemia In this session, questions and answers from the first session, abnormal increase in iron, symptoms and effects of increased iron load, other complications of the disease, types of thalassemia treatment will be explained. Session 3: Diet and exercise in thalassemia patients In this session, questions and answers from the previous session, iron, calcium, vitamin D, the main antioxidants including vitamin E and vitamin C, carotenoids, flavonoids, the effect of exercise on thalassemia will be explained. . Session 4: Basic treatment in thalassemia and treatment complications. In this question and answer session from the previous session, injectable blood transfusion. Complications of blood transfusion. Desferal iron overload and how it works, contraindications and precautions in desferrioxamine, side effects of desferrioxamine, drug interactions, drug administration, patient evaluation and drug effects will be explained. Session 5: Teaching your relaxation techniques. In this question and answer session from the previous session, what are the relaxation methods? Deep breathing, advanced relaxation, body scan meditation, mindfulness, imaging meditation, (training and practice), how the technique Incorporate relaxation into everyday life? Will be explained and implemented. Session 6: Social skills improvement training. In this session, practicing self-relaxation techniques, the previous session, 12 social skills strategies will be explained and summarized. Also, at the end of the last session, all the items that have been explained in person to the patient and his family are made available to the patient and the family in the form of a booklet so that they can use it if necessary.

Category

Rehabilitation

2

Description

Control group: Initially, the WHO Quality of Life Questionnaire will be provided to them, and after completing the questionnaire, no intervention will be made other than the usual treatment procedures that are performed for patients in the ward. One month and three months after the completion of the questionnaire that was presented in the first session of patient service, the same questionnaires will be provided to the patients of the target group again to assess their quality of life score again. At the end of three months and after completing the questionnaire, the educational booklet that was held for the members of the intervention group in person, will be provided to this group of patients to use its educational content

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences, Hazrat Ali Asghar Hospital

Full name of responsible person

Mahnaz Ghaljeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Zahedan 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
Zahedan University of Medical Sciences
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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