

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of an intervention based on Participatory Care Model on fatigue status patients with major thalassemia

Protocol summary

Study aim

Determining the Effect of Participatory Care Pattern Based Intervention on Fatigue Status in Patients with Thalassemia Major

Design

A total of 122 major thalassemic patients undergoing regular treatment are enrolled in a full-scale study, divided into 12 groups based on gender and age.

Settings and conduct

.Intervention on patients with thalassemia major referred to the thalassemic department of Yasouj Shahid Beheshti Hospital, which was entered into the study, is conducted and the classes and all activities are performed in the hall for teaching the Yasuj Shahid Beheshti Hospital.

Participants/Inclusion and exclusion criteria

Diagnosis of thalassemia major approved by the hematologist and treated under regular care.

Intervention groups

In this study, individuals are divided into two groups: intervention and control. To achieve the goals of the educational program, a participatory care model is implemented. This template has 4 steps: 1- Motivation 2- Preparation 3- Engagement and 4- Evaluation. By randomization, the control group is divided into groups of 10 to 11, and the training classes are held according to the participatory care model for them, and the control group does not see any training during this period. At the first intervention session (motivation), the best mechanism for motivating patients to be informed about the status quo and the possible consequences for them is to try to communicate with patients and get their medical history. In the second session (preparation), an educational timetable is provided to them, and here the requirements are also explained to the clients about the nature of the visits (training sessions and follow-up), the duration of each visit and the purpose of the visits.

Main outcome variables

fatigue status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190424043367N1**

Registration date: **2019-08-11, 1398/05/20**

Registration timing: **retrospective**

Last update: **2019-08-11, 1398/05/20**

Update count: **0**

Registration date

2019-08-11, 1398/05/20

Registrant information

Name

ahmad karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3323 5141

Email address

ahmad.karami1993@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-07-02, 1398/04/11

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-08-02, 1398/05/11

Trial completion date

2019-11-22, 1398/09/01

Scientific title

The effect of an intervention based on Participatory Care Model on fatigue status patients with major thalassemia

Public title

The effect of an intervention based on Participatory Care Model on fatigue status patients with major thalassemia

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of thalassemia major approved by the hematologist and treated under regular care.

Exclusion criteria:

Unwillingness to continue participating in the study for any reason

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **122**

Actual sample size reached: **112**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasouj University of Medical Sciences

Street address

Jahad

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

75919-94799

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.YUMS.REC.1398.023

Health conditions studied

1

Description of health condition studied

Thalassemia

ICD-10 code

D55.3

ICD-10 code description

Anaemia due to disorders of nucleotide metabolism

Primary outcomes

1

Description

Fatigue status

Timepoint

At the beginning of the study and two months after the last training session

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group is randomly divided into 10 to 11 groups, and training sessions are held according to the stages of the collaborative care model. The first intervention (motivation) session is the best mechanism to motivate patients to be aware of the status quo and the potentially dangerous consequences and consequences of trying to communicate well with patients and get their medical history. The second session (preparation) provides them with a training schedule and also explains to the clients the nature of the visits (training sessions and follow-up), the duration of each visit and the purpose of the visits. The third session (first participatory educational visit), fourth and fifth (second and third educational participatory visit), sixth (first follow-up participatory visit), and seventh (second follow-up participatory visit) are the presence of clients. They are discussed. The eighth session is an evaluation intervention that conducts step by step evaluations at the beginning and end of each visit and in the final evaluation to assess the impact of implementing a collaborative care model on controlling for symptoms and symptoms, as well as changes in the patient's fatigue status by measuring instruments in the group. Intervention is measured.

Category

Lifestyle

2

Description

Control group: The intervention in the control group consisted of two training sessions in order to meet ethical standards.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Yasuj Hospital

Full name of responsible person

Ali Karam Alamdari

Street address

Jahad

City

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Kohgilouyeh-va-Boyrahmad

Postal code

75919-94799

Phone

+98 74 1223 3707

Email

Ahmad.Karami1993@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Alikaram Alamdari

Street address

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City

Yasuj

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Postal code

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Phone

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Email

Ahmad.Karami1993@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Ahmad Karami

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ahmad Karami

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

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Phone

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Email

Ahmad.Karami1993@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

This study, after being approved at the Yasouj University of Medical Sciences and obtaining the necessary permissions to be accepted into the pop-fashion database and the ISI.

When the data will become available and for how long

Immediately after the approval of the college

To whom data/document is available

Yasouj University of Medical Sciences

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Ahmad karami

What processes are involved for a request to access data/document

Send email to the person who owns the article

Comments

There is no other explanation.