

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Orem's Self-Care Model on Quality Of Life of Patients with talasemia major

Protocol summary

Summary

This study will be carry out to make the study of the Effect of Orem's Self-Care Model on Quality Of Life of Patients with major thalassemia. Included criteria:suffering from major thalassemia ,going for blood transfusions regularly, ages between 15- 25 years. Excluded criteria: Participated in a training program at the same time and patient's death. Researchers after finding the initial selection of samples and their satisfaction, will provide quality of life questionnaire SF-36 for them . In this study, 80 patients who were suffering from thalassemia and were eligible ,were given the questionnaires, they randomly divided into two groups,tested and control. The test groups were divided into five groups. Then a training session in lectures, questions and answers, a PowerPoint presentation, showing pictures of the pamphlet In the hall of the hospital will be held for each of the tested groups. The confrence lasts 60 minutes. At the end ,pamphlet will be placed at their disposal. Researcher once a week contact with patients by telephone in the intervention group and the questions will be answered . After 3 months of studing , quality of life questionnaire SF-36 Completed Again by the patient test and control groups. Finally, in order to observe the ethical issues of trained items to the tested group, the control group will also be trained in this issue too and pamphlet will be given to them . The primary outcome of this study is patient's quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121219733N2**

Registration date: **2015-05-07, 1394/02/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-07, 1394/02/17

Registrant information

Name

Mohammad Maniey

Name of organization / entity

Dezful University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 4323 0999

Email address

maniey.m@dums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Dezful University of Medical Sciences

Expected recruitment start date

2015-04-30, 1394/02/10

Expected recruitment end date

2015-10-02, 1394/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Orem's Self-Care Model on Quality Of Life of Patients with talasemia major

Public title

The Effect of Orem's Self-Care Model on Quality Of Life of Patients with talasemia major

Purpose

Health service research

Inclusion/Exclusion criteria

Included criteria : suffering from thalassemia major; going for blood transfusion regularly; do not receive planned information about taking care of themselves; should not have active infectious disease or other restrictive; ages between 15- 35 years who have had case history of hospitalization at least once; do not suffering from acute or chronic diseases such as hepatitis, heart and kidney failure, cancer, asthma and chronic obstructive pulmonary disease. Excluded criteria: Participating in a training program at the same time; Unwillingness to continue cooperation; transfer to another hospital and it cause patient's death.

Age

From **15 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Dezful University of Medical Sciences

Street address

Azadgan, Police Department, Dezful

City

Dezful

Postal code

6461653476

Approval date

2015-02-09, 1393/11/20

Ethics committee reference number

DURS-121

Health conditions studied**1****Description of health condition studied**

Thalassaemia

ICD-10 code

D56.1

ICD-10 code description

Beta Thalassaemia

Primary outcomes**1****Description**

Quality Of Life

Timepoint

Before Training, After 3 month Training

Method of measurement

Quality of Life Questionnaire SF36

Secondary outcomes

empty

Intervention groups**1****Description**

Test group: The test group's patients will divided into five members groups separately. Then a training session in lecture, question and answer, a PowerPoint presentation, showing pictures of the pamphlet by Researcher In the hall of the hospital will be hold for each of the experimental groups. At the end of training session a pamphlet will be provided for patients will given for them and also, private counseling given to patients if it possible.

Category

Lifestyle

2**Description**

Control group: This group do not receive training.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Thalassemia Ward of Dezful Major Hospital

Full name of responsible person

Roya Behmanesh

Street address

Taleghani Street, Dezful

City

Dezful

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dezful University of Medical Sciences

Full name of responsible person

Fereydoun Niroozad

Street address

Azadgan, Police Department

City

Dezful

Grant name

معاونت پژوهشی

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Dezful 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**

Dezful University of Medical Sciences

Full name of responsible person

Hamide Mashalchi

Position

MSc in Nursing, faculty member of Dezful University of Medical Sciences

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Person responsible for scientific inquiries

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Position

Nursing Student

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Full name of responsible person

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yaeghoobmadmoli@yahoo.com

Web page address

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