

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of care plan based on Roy Adaptation Model on physiological and psychological adaptation in patient with thalassemia major

Protocol summary

Summary

Background: Patients with thalassemia are faced with several physiological and psychological problems such as disruption in physical activity, social life and school performance, that causes lower adaptation levels in these patients. The purpose of this study was to determine the effect of education based on Roy adaptation model on the level of physiological and psychological adaptation in thalassemic patients in Zahedan Ali-Asghar hospital in 2016. Methods: In this semi-experimental study, two groups with pre-test and post-test design, 80 patients with major thalassemia in Ali-Asghar hospital in Zahedan will be recruited to the study in 2016. They will be randomly assigned in intervention and control group based on week. Before the intervention, Roy adaptation questionnaire and demographic data will be completed in both intervention and control groups. Then the intervention group will train based on Roy adaptation model and the control group will receive only routine care. Two months after completion of the training sessions, the questionnaire will be completed in both groups. SPSS software version 22 will be used to analyze the data using independent T-test, paired T-test and chi-square test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071234925N2**
Registration date: **2017-09-22, 1396/06/31**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-22, 1396/06/31

Registrant information

Name

Sakineh Ghaderi

Name of organization / entity

Zahedan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 56 3240 7212

Email address

fatemeh.chagi@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Science

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of care plan based on Roy Adaptation Model on physiological and psychological adaptation in patient with thalassemia major

Public title

Effect of Roy Adaptation Model on adaptation levels of Thalassemic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age up to 18; having thalassemia diagnosis; having minimum education; don't have any physiologic or mental disease; don't have drug abuse;

don't have any hearing or sight problems; to understand farsi language; having good situation
Exclusion criteria: don't participate in one class; having an acute or vital situation

Age

From **18 years** old to **50 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

Zahedan University of Medical Science

Street address

Mashahir square, Nursing faculty

City

Zahedan

Postal code

9816743463

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

ir.zaums.rec.1395.132

Health conditions studied

1

Description of health condition studied

Thalassemia

ICD-10 code

D63

ICD-10 code description

anemia in chronic disease classified in elsewhere

Primary outcomes

1

Description

Adaptation

Timepoint

Before and 2 month after intervention

Method of measurement

Researcher made Roy Adaptation questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group: Face to face education in 5 sixty minutes sessions

Category

Other

2

Description

In control group: Just routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Hospital

Full name of responsible person

Doctor Ali Navidian

Street address

Nursing Faculty, Mashahir Sqaire

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Science

Full name of responsible person

Doctor Fariba Yaghoubimia

Street address

Nursing Faculty, Mashahir Sqaire

City

Zahedan

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 Science

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**

Zahedan University of Medical Science

Full name of responsible person

Fatemeh Soghra Chaji

Position

Nursing Master Student

Other areas of specialty/work**Street address**

Nursing Faculty, Mashahir Sqaire

City

Zahedan

Postal code

9716843463

Phone

+98 54 3329 5765

Fax

+98 33295765

Email

fatemehchaji@yahoo.com

Web page address

www.zaums.ic.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Science

Full name of responsible person

Fatemeh Soghra Chaji

Position

Master Nursing Student

Other areas of specialty/work**Street address**

Nursing Faculty, Mashahir Sqaire

City

Zahedan

Postal code

9816743463

Phone

+98 54 3329 5765

Fax

+98 33295765

Email

fatemehchaji@yahoo.com

Web page address

www.zaums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Science

Full name of responsible person

Fatemeh Soghra Chaji

Position

Master Nursing Student

Other areas of specialty/work**Street address**

Nursing Faculty, Mashahir Sqaire

City

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Phone

+98 54 3329 5765

Fax

+98 33295765

Email

fatemehchaji@yahoo.com

Web page address

www.zaums.ac.ir

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