Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 phrsiological and psychologiacal 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 psychologic 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 mounth 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, paird 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 Sciense
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciense

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; dont have any physiologic or mental disease; dont have drug abuse;

dont have any hearing or sight problems; to understand farsi language; having good situation Exclusion criteria:dont 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 mounth 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 sesions

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 Squaire

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 Squaire

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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 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

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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