

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The Effect Of Education base on Self-Management Empowering Model On The Quality Of Life In Adolescent and youth With Major Thalassemia

#### Protocol summary

##### Summary

In this study self-management empowerment model used to evaluate the impact on quality of life in adolescents and youth with major thalassemia. The main inclusion criteria (15 to 25 years old), the main exclusion criteria (sickle thalassemia). The sample size is 70 adolescents & youths with major thalassemia in Bushehr & Borazjan thalassemia clinics. Participants were randomly divided into two case & control groups. The intervention was carried out only in case group. The quality of life and empowering questionnaires was given to both groups. To intervene in the present model to achieve the target, five basic and logic steps is designed. Empowerment model with the concepts of awareness of personal changes, independence, role playing, adaptation, Perceived satisfaction, Being in control, in addition self-management & empowering adolescents with major thalassemia lead to changes in knowledge, attitude and behavior of patients and improve their quality of life. Intervention period is 1.5 months and 3 stages.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013042213092N1**

Registration date: **2014-02-03, 1392/11/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-02-03, 1392/11/14

##### Registrant information

###### Name

Maryam Ravanipour

###### Name of organization / entity

Bushehr University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 77 1455 0187

###### Email address

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###### Recruitment status

**Recruitment complete**

###### Funding source

Research Center of Bushehr University of Medical Sciences

###### Expected recruitment start date

2013-06-20, 1392/03/30

###### Expected recruitment end date

2013-09-21, 1392/06/30

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The Effect Of Education base on Self-Management Empowering Model On The Quality Of Life In Adolescent and youth With Major Thalassemia

###### Public title

The Effect Of Education base on Empowering Model On Major Thalassemia Patients

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion criterias: 15-25 years old patients; HIV-negative; No Mental illness or chronic diseases besides thalassemia. Exclusion criterias: Specific disease during the study period that stop samples; inability to participate in the intervention; Sickle thalassemia patients.

**Age**

From **15 years** old to **25 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**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**

Research Center of Bushehr University of Medical Sciences

**Street address**

Pardis Site of Bushehr University of Medical Sciences, Rishahr St, Sabzabad Blvd, Bushehr

**City**

Bushehr

**Postal code****Approval date**

2013-12-30, 1392/10/09

**Ethics committee reference number**

B-92-15-13

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

major thalassemia

**ICD-10 code**

D56

**ICD-10 code description**

Thalassaemia

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

Quality of Life Score

**Timepoint**

Before intervention & 1.5 months after intervention

**Method of measurement**

SF-36 Quality of Life questionnaire

**Secondary outcomes****1****Description**

Empowering Score

**Timepoint**

Before intervention & 1.5 months after intervention

**Method of measurement**

Self-Management Empowerment questionnaire

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

Intervention group: empowerment model, booklet, two section, between 1 week.

**Category**

Other

**2****Description**

Control group: routine care, no intervention

**Category**

N/A

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

Bushehr Thalassemia Clinic, Fatemeh Zahra Hospital

**Full name of responsible person**

Mrs Bashi & Mrs Saghafi

**Street address**

Bushehr Thalassemia Clinic, Parastar St, Moalem Sq, Bushehr

**City**

Bushehr

**2****Recruitment center****Name of recruitment center**

Borazjan Thalassemia Clinic, 17 Shahrivar Hospital,

**Full name of responsible person**

Mrs Mohammadi & Mrs Bordbar

**Street address**

17 Shahrivar Sq, Borazjan

**City**

Borazjan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research Center of Bushehr University of Medical Sciences

**Full name of responsible person**

Dr Afshin Ostovar

**Street address**

Research Center of Bushehr University of Medical Sciences, Pardis Site of Bushehr University of Medical Sciences, Rishahr Street, Sabzabad Blvd, Bushehr

**City**

Bushehr

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

Yes

**Title of funding source**

Research Center of Bushehr 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**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

The Persian Gulf Tropical Medicine Research Center, Bushehr university of medical sciences

**Full name of responsible person**

Dr Maryam Ravanipour

**Position**

MD/MPH, Associate professor

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## Person responsible for updating data

**Contact****Name of organization / entity**

Bushehr University of Medical Sciences

**Full name of responsible person**

Najmeh Razzazan

**Position**

MSc Student in Nursing, Student Research Committee

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**City**

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najme.razazan@yahoo.com

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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*