

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effecte of a group supportive-educative program on caregiver burden and parenting stress among Mothers of children with Thalassemia Major

#### Protocol summary

##### Summary

The aim of this study was to determine the effect of a group supportive-educative program on caregiver burden and parenting stress in Mothers of children with thalassemia major referred to Thalassemia clinic of Ali Asghar Hospital in Zahedan. The type of this research is parallel clinical trial. The studied population consists of all mothers who have 6 - 12 year old children with thalassemia referred to thalassemia unit. The sample size is 80 mothers who have children with thalassemia. Inclusion criteria in this study include: the ability to read and write; being residence of Zahedan; living with their spouse at the time of the study; and just having the responsibility of taking care of the child with thalassemia. Exclusion criteria in this study include: non-cooperative mother; mother's pregnancy; death of a family member in the last 6 months. Mothers were non-randomly divided into two intervention and control groups with 40 members in each group. After selecting the samples and obtaining consent, the questionnaires were completed by participants of both groups. The intervention group received Four sessions (90 minutes) of educational support (including illness review, definitions, causes, symptoms, maternal experiences, emotional drain, ways of controlling stress, the religious spiritual support based on Islamic teachings which derived from the Quran verses, training and practice relaxation (deep breathing diaphragm) and individual massage, answering questions, and the color manual during four weeks. The control group received usual care. Primary outcome variables: Caregiver Burden, Parental Stress in mothers.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016122731612N1**

Registration date: **2017-03-21, 1396/01/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-03-21, 1396/01/01

##### Registrant information

###### Name

Fatemeh Abbasi

###### Name of organization / entity

School of Nursing & Midwifery, Zahedan Univercity Of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 33442482

###### Email address

abbasif3@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research & Technology, Zahedan University of Medical Sciences

##### Expected recruitment start date

2016-07-20, 1395/04/30

##### Expected recruitment end date

2016-12-20, 1395/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effecte of a group supportive-educative program on caregiver burden and parenting stress among Mothers of children with Thalassemia Major

**Public title**

The effects of a group supportive-educative program on caregiver burden and parenting stress

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: the ability to read and write; being residence of Zahedan; living with their spouse at the time of the study; and just having the responsibility of taking care of the child with thalassemia. Exclusion criteria: non-cooperative mother; mother's pregnancy; death of a family member in the last 6 months.

**Age**

No age limit

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 80

**Randomization (investigator's opinion)**

Not 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**

Ethics Committee Vice Chancellor For Research and Technological, Zahedan University of Medical Sciences

**Street address**

Zahedan University Of Medical Sciences , Dr Hesabi square , Zahedan , Iran

**City**

Zahedan

**Postal code**

9816743463

**Approval date**

2016-07-18, 1395/04/28

**Ethics committee reference number**

IR.ZAUMS.REC.1395.127

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

Major Thalassemia

**ICD-10 code**

D56.1

**ICD-10 code description**

Major Thalassemia

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

Caregiver Burden

**Timepoint**

Before intervention and 1 month after intervention.

**Method of measurement**

Novak and Guest caregiver burden inventory

**2****Description**

Parental Stress

**Timepoint**

Before intervention and 1 month after intervention.

**Method of measurement**

Parental Stress Index - (PSI) Short Form (SF)

**Secondary outcomes**

empty

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

The Intervention group: received Four sessions (90 minutes) of educational support (including illness review, definitions, causes, symptoms, maternal experiences, emotional drain, ways of controlling stress, the religious spiritual support based on Islamic teachings which derived from the Quran verses, training and practice relaxation (deep breathing diaphragm) and individual massage, answering questions, and the color manual during four weeks.

**Category**

Treatment - Other

**2****Description**

The control group received usual care.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**  
Ali Asghar Hospital  
**Full name of responsible person**  
Fatemeh Abbasi  
**Street address**  
Ali Asghar Hospital, Azadi Street  
**City**  
Zahedan

+98 54 3344 2482  
**Fax**  
+98 54 3344 2481  
**Email**  
abbasif3@mums.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research and technology, Zahedan University of Medical Sciences  
**Full name of responsible person**  
Hoshang Rafighdost  
**Street address**  
Zahedan University Of Medical Science, Doctor Hesabi Square  
**City**  
Zahedan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research and technology, Zahedan 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**  
School of Nursing & Midwifery, Zahedan University Of Medical Science  
**Full name of responsible person**  
Fatemeh Abbasi  
**Position**  
Msc student in Psychiatric nursing  
**Other areas of specialty/work**  
**Street address**  
School of Nursing & Midwifery, Mashaheer Square  
**City**  
Zahedan  
**Postal code**  
9816913396  
**Phone**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
School of Nursing & Midwifery, Zahedan University of Medical Science  
**Full name of responsible person**  
Nasrin Rezaee  
**Position**  
Assistant Professor  
**Other areas of specialty/work**  
**Street address**  
School of Nursing & Midwifery, Mashaheer square  
**City**  
Zahedan  
**Postal code**  
9816913396  
**Phone**  
+98 54 3344 2482  
**Fax**  
+98 54 3344 2481  
**Email**  
nasrin\_rezaee2005@yahoo.com  
**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
School of Nursing & Midwifery, Zahedan University of Medical Science  
**Full name of responsible person**  
Fatemeh Abbasi  
**Position**  
Msc student in Psychiatric nursing  
**Other areas of specialty/work**  
**Street address**  
School of Nursing & Midwifery, Mashaheer square  
**City**  
Zahedan  
**Postal code**  
9816913396  
**Phone**  
+98 54 3344 2482  
**Fax**  
**Email**  
abbasif3@mums.ac.ir  
**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*