

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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

Registration timing: **retrospective**

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.

Last update:

Update count: **0**

Registration date

2017-03-21, 1396/01/01

Registrant information

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Fatemeh Abbasi

Name of organization / entity

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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

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122731612N1**

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

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
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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
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Zahedan University Of Medical Science, Doctor Hesabi Square
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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

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

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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