Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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

Public title
The effecte 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 Committe Vice Chancellor For Research and Technological، Zahedan University of Medical Scienc
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

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
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Person responsible for scientific 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