

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Group education on adaptive behaviors and caregiver burden in mothers of children with thalassemia major

Protocol summary

Study aim

The effect of Group education on adaptive behaviors and caregiver burden in mothers of children with thalassemia major

Design

Clinical trial with intervention and control group, Not blind, randomized,

Settings and conduct

The researcher will refer to the Zahedan Clinic of Ali Asghar (AS) by presenting a letter from the Vice-Chancellor for Research. The research will explain the research objectives for the samples that will meet the criteria for entering the study. Those willing to participate in the study would be divided into two groups of control and Intervention which will be determined randomly. Adaptive behavior and caregiver burden before and after intervention are measured and analyzed by questionnaires. According to the results of the pretest, ineffective adaptive behaviors will be identified and the educational program will be prepared and compiled. One month after the implementation; the rehabilitation questionnaire will be completed by two control and intervention groups. Results will be analyzed in spss software version 21 .

Participants/Inclusion and exclusion criteria

1-Six months past after diagnosis of thalassemia major in children 2. Having reading and writing literacy 3. No responsibility of caring for another patient in the family 4. Living with spouse 5. No known psychiatric disorders and no use of psychiatric drugs 6. Residency in Zahedan 7. Lack of participation in similar studies 8.No hospitalization history in recent months

Intervention groups

Group training will be held in the intervention group in four sessions of two hours (weekly one session). In the control group, after the end of the intervention, a training session will be held. After training, a booklet will be delivered to them.

Main outcome variables

Adaptive behaviors, caregiver burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170926036426N5**

Registration date: **2019-04-22, 1398/02/02**

Registration timing: **retrospective**

Last update: **2019-04-22, 1398/02/02**

Update count: **0**

Registration date

2019-04-22, 1398/02/02

Registrant information

Name

fatihe kermansaravi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 1415

Email address

kermansaravi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Group education on adaptive behaviors and caregiver burden in mothers of children with thalassemia major

Public title

The effect of Group education on adaptive behaviors and caregiver burden

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Six months past after diagnosis of thalassemia major in children Having reading and writing literacy Living with spouse Residency in Zahedan

Exclusion criteria:

Having responsibility to care another patient in the family Having known psychiatric disorders taking psychiatric drugs Participation in similar researches Hospitalization of the patient in recent two months

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

They assigned in two groups (intervention and control) according lottery using numbered card.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

Street address

Campus Office Complex, Zahedan University of Medical Sciences and Health Services,Khalig Phars

Blvd,Doctor Hesabi square,Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.ZAUMS.REC.1397.195

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

thalassemia major

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

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

adaptive behaviors

Timepoint

Before the intervention - one month after the intervention

Method of measurement

Coping Health Inventory for Parent

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

caregiver burden

Timepoint

Before the intervention - one month after the intervention

Method of measurement

Caregiver Burden Scale

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

Group Education will perform in four-2hour sessions (a session weekly). The contents of Educational sessions consists of full explanation of thalassemia disease , group discussion about mothers' experiences of thalassemia disease care through problem solving , stress management, and the method for confronting disease.

Category

Behavior

2

Description

Control group: After the end of the intervention, a training session will be held, and the educational pamphlets will be available to them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Hospital

Full name of responsible person

Abdolvahed Shahnnavazi

Street address

Azadi Street., Zahedan, Iran

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Fax

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Http://www.zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

Street address

Campus Administration Complex, Zahedan University of Medical Sciences and Health Services,.-Persian Gulf Blvd-Dr. Hassabi Square

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bakhshani@zaums.ac.ir

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 Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Abdolhagh Biabani

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

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Fatihe Kermansaravi

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Assistant professor

Latest degree

Master

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Health Promotion

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about people other than your first and last name

When the data will become available and for how long

Start the access period 3 months after printing the results

To whom data/document is available

For researchers working in academic and scientific institutions and People in the industry are also busy

Under which criteria data/document could be used

For use in scientific papers

From where data/document is obtainable

Use email

What processes are involved for a request to access data/document

Send email for permission

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Abdolhagh Biabani

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