

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of Roy adaptation model on the social adaptation and resilience of mothers of thalassemic children 7-19 years old in Gonbad city

Protocol summary

Study aim

Determining the Effect of Zinc System Model on Social Adjustment and Resilience of Mothers of Thalassemic Children

Design

The sample size was 25 people and were randomly selected and divided into two experimental and control groups

Settings and conduct

The place of study was Taleghani Hospital of Gonbad Department of Thalassemia which was done in eight training sessions for the experimental group. Before and after the study, both groups completed the questionnaires.

Participants/Inclusion and exclusion criteria

Entry requirements: have a thalassemia child and consent to participate in the study. Conditions of non-entry: Dissatisfaction for participation in the study.

Intervention groups

Training class and use of CD and player from computer

Main outcome variables

Resiliency; Social adjustment; Thalassemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043285N1**
Registration date: **2019-05-08, 1398/02/18**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-08, 1398/02/18**

Update count: **0**

Registration date

2019-05-08, 1398/02/18

Registrant information

Name

zeinab rashki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3422 2300

Email address

z_rashki@aliabadiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-04, 1397/02/14

Expected recruitment end date

2018-06-04, 1397/03/14

Actual recruitment start date

2019-05-04, 1398/02/14

Actual recruitment end date

2019-06-17, 1398/03/27

Trial completion date

2019-06-17, 1398/03/27

Scientific title

The effect of Roy adaptation model on the social adaptation and resilience of mothers of thalassemic children 7-19 years old in Gonbad city

Public title

Social adaptation and resilience of mothers of thalassemic

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Have at least one thalassemia child The desire to participate in research Not having physical and

psychological problems

Exclusion criteria:

Not attending two sessions of 8 sessions Non-cooperation Stir the meetings

Age

From **7 years** old to **19 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method was available from among those who were admitted to the study and randomly divided into two groups of test and control.

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 of Islamic Azad University, Shahroud Branch

Street address

Shahroud Azad University

City

shahrood

Province

Semnan

Postal code

43189-36199

Approval date

2019-03-13, 1397/12/22

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1397.039

Health conditions studied

1

Description of health condition studied

Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism(D50-D89)

Primary outcomes

1

Description

The compatibility score obtained from the Bell Compliance Inventory

Timepoint

Before and after intervention

Method of measurement

Bell compatibility questionnaire

2

Description

A resonance score derived from the Conor Davidson questionnaire

Timepoint

Before and after intervention

Method of measurement

Conor David Sohn Resilience Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Eight training sessions and presentation of pamphlets and educational CDs. The first session involves getting acquainted with the researcher and the mothers together and completing the questionnaires. The second meeting was an explanation of the incidence of thalassemia, its prevalence in Iran, the importance of family role in protecting patients, the impact of thalassemia on the family and ways to prevent it. The third session was given to mothers in relation to physiological needs such as nutrition, sleep, evolutionary needs, and the absorption and disposal of information. The fourth session was dedicated to the aspect of self-concept, which was discussed at the meeting about the importance of the mother's mental imagery, the reality of life, and the concept of self-concept and happy life. The fifth session of the role play and help to improve the roles: motherhood, fraternity, husbandry and social roles, and in the sixth session, in relation to the dimension of attachment, understanding and control of negative feelings and emotions, and reducing the positive feelings toward the problem Your child was held in a group. The seventh session was also conducted individually and individually. After the end of the sessions (eighth session), the posttest was provided to both groups and

completed with the help of the researcher.

Category

Behavior

2

Description

Control group: There is no special training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Behzad Pachenari

Street address

Taleghani street

City

Gonbad

Province

Golestan

Postal code

4979155993

Phone

+98 17 3328 6920

Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hojati Hamid

Street address

Ayat street

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Aliabad

Province

Golestan

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4941793451

Phone

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Fax

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Email

h_hojjati1362@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Zeinab Rashki

Position

master

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hamid Hojati

Position

Nursing Ph.D.

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Nursing Ph.D.

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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