

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The Effect of Group Hope therapy on hope and adherence to treatment in adolescents with β -Thalassemia major

Protocol summary

Study aim

The Effect of Group Hope Therapy on Hope and Adherence to Treatment in Adolescents with Beta Thalassemia

Design

The study is a randomized, single-blind, placebo-controlled clinical trial.

Settings and conduct

Given that the number of adolescents in the present study age range in the Sarver center is 63 people, Therefore, adolescents who meet the inclusion criteria will be randomly assigned to the intervention and control groups. For the intervention group patients, the hope group therapy program will be held for 8 sessions of 60 minutes, two sessions a week with the help of a researcher. Only routine actions will be provided for the control group. Before, immediately and one month after the intervention, adherence to treatment will be assessed using Medanloo Adherence Questionnaire and Hope Snyder Hope Questionnaire in both groups. The analysis will then be performed by intergroup and intergroup comparisons and analysis of variance with repeated measures.

Participants/Inclusion and exclusion criteria

Beta thalassemia major, age 14 to 18 years, minimum primary education, no other chronic comorbidities

Intervention groups

Participants in the study will be assigned to intervention and control groups. For each group of adolescents in the intervention group, the Hope Therapy Program will be designed in 8 sessions of 60 minutes (two sessions per week) based on Snyder studies. For the control group, only routine ward activities (routine nursing care) will be performed during this time.

Main outcome variables

Adherence to treatment and hope

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190827044634N1**

Registration date: **2019-11-01, 1398/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-01, 1398/08/10**

Update count: **0**

Registration date

2019-11-01, 1398/08/10

Registrant information

Name

Saeedeh Ilkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5252 7790

Email address

ilkhanis1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-11, 1398/06/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Group Hope therapy on hope and adherence to treatment in adolescents with β -Thalassemia major

Public title

The effect of Hope therapy on thalassemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adolescents with thalassemia major aged 14 to 18 years
Minimum elementary education

Exclusion criteria:

Unwillingness to participate in the study
Other chronic comorbidities
Passing similar courses of hope therapy

Age

From **14 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of the samples to the study groups will be based on days of visit to the clinic (couple and individual) and on a lottery basis.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyst will be unaware of the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad School of Nursing

Street address

Ibn Sina St ., Doctora's intersection ., Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2019-07-10, 1398/04/19

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.034

Health conditions studied

1

Description of health condition studied

تبعیت از درمان در نوجوانان مبتلا تالاسمی و امید در نوجوانان مبتلا به تالاسمی

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Adherence to treatment

Timepoint

Before, immediately and one month after the intervention

Method of measurement

Score obtained from Modanloo treatment adherence questionnaire

2

Description

Hope

Timepoint

Before, immediately and one month after the intervention

Method of measurement

Score obtained from Snyder Hope Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

For adolescents in the intervention group, the Hope Therapy program will be conducted in 8 sessions of 60 minutes (two sessions per week) based on Snyder studies and each session will consist of 4 sections. In the first part, about 10 minutes will be discussed of Clients activities and assignments In the last week and encourage people to help each other with problems related to those assignments. In the second part, they will learn about 10 minutes of mental training and hope-related skills that fall into three areas of crossroads and operating goals. The third part, which will take about 30 minutes, will discuss how to apply these skills in one's daily life, and will encourage clients to objectively and

explicitly help one another with the use of hope skills, To solve them. In the final 10 minutes of the session, participants will be given an assignment on the topic of the same session, and in the next session before the session begins, the assignments will be reviewed and with the participation of the group members will be discuss about assignments.

Category

Lifestyle

2

Description

Control group: Only routine actions will be provided for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized server polyclinic

Full name of responsible person

Dr. Zahra Badie

Street address

North Shahrivar 17th Street 8., Between 17 Shahrivar Square and Panj rah

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Sheikh.Hos@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

University Street- Opposite University Street-
Mashhad University of Medical Sciences- Vice-
Chancellor for Research & Technology

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Province

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vcresearch @ mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Saeedeh Ilkhani

Position

Postgraduate student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Postgraduate student

Latest degree

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Person responsible for updating data

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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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available