

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Applying Life Skills on Quality of Life in Major Thalassemic Adolescents

#### Protocol summary

##### Study aim

Determining the Effect of Dexterity Life on Quality of Life in Adolescents with Thalassemia Major

##### Design

The research units will be selected through easy and available sampling from these adolescents. Subjects will then be divided into two groups of intervention (42) and the control group (42). Detection in each of the two groups is randomly based on The lottery is then followed by both groups of pre-test questionnaires. This study is a clinical trial with a control group, community based and pragmatic, non-blind.

##### Settings and conduct

The training intervention will be conducted by the researcher in six sessions for 2 sessions. The training material will be performed in each two-skill training session and reviewing the previous skills. The last session of the review will be all the material being told. At each meeting ... people are present. Meetings are held at the conference hall of the Baghaee Hospital 2.

##### Participants/Inclusion and exclusion criteria

The teenager tends to attend educational sessions. The person has not previously participated in life skills training courses. Not having simultaneous chronic illnesses and other treatments (known).

##### Intervention groups

In this study, the samples were divided into intervention and control groups. The control group receives ten life skills, but the control group does not receive intervention. At the end, the effectiveness of applying these skills and its impact on the quality of life of the control group is measured and compared with the control group

##### Main outcome variables

Physical dimension of quality of life, physical dimension, psychological dimension, dimension of school environment, self-perception, social acceptance and relationship with peers, financial resources, autonomy, creativity and excitement

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181202041825N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **retrospective**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

##### Registration date

2019-03-09, 1397/12/18

##### Registrant information

##### Name

Hadis Zamanifar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4322 4819

##### Email address

zamanifar.h@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-06, 1397/08/15

##### Expected recruitment end date

2018-11-13, 1397/08/22

##### Actual recruitment start date

2018-11-06, 1397/08/15

##### Actual recruitment end date

2018-11-13, 1397/08/22

##### Trial completion date

empty

##### Scientific title

The Effect of Applying Life Skills on Quality of Life in Major Thalassaemic Adolescents

## Public title

The Effect of Applying Life Skills on Quality of Life in Thalassaemic Adolescents

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Willing to participate in the study. Not known to have any other illness (known) The person has not participated in life skills training courses before

### Exclusion criteria:

Do not attend life skills classes.

## Age

From **13 years** old to **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **84**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The method of assigning intervention to individuals is randomized and random blocked blocks with block size 4 (using the table for random permutations) by statistician.

## 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

The Ethics Committee of the University of Ahvaz  
Jundishapur University of Medical Sciences

##### Street address

No. 7, West Golestan Ave., Golestan Blvd.,  
AhvazTown

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6193673111

## Approval date

2018-11-05, 1397/08/14

## Ethics committee reference number

IR.AJUMS.REC.1397.572

## Health conditions studied

### 1

#### Description of health condition studied

Major Talasemi

#### ICD-10 code

D56.1

#### ICD-10 code description

Beta thalassemia

## Primary outcomes

### 1

#### Description

Quality of Life Score in Kidascrine's Questionnaire 52

#### Timepoint

At the beginning of the study and 3 months after it began

#### Method of measurement

Quality of life questionnaire for adolescents in Kidascrine 52

## Secondary outcomes

### 1

#### Description

quality of life

#### Timepoint

Before starting the study. 2months after teaching life skills, quality of life is measured

#### Method of measurement

According to the Quality of life questionnaire for adolescents in Kidascrine 52

## Intervention groups

### 1

#### Description

Intervention group: Pretest is taken. Next, intervention is the teaching of ten life skills (skills provided by the World Health Organization) in the form of classroom classes, questions and answers, the use of visual audiovisual equipment, instructional manuals, etc. 2 months later, the post-test is taken.

#### Category

Behavior

### 2

#### Description

Control group: This group is taken out of the pre-test. They will not receive the training. 2 months later, the post-test is taken

**Category**  
Behavior

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Baghaee2 Hospital  
**Full name of responsible person**  
Hooshang Alijani Renani  
**Street address**  
Baghaee2 Hospital.,Golestan Blvd., Ahvaz Town  
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alijani-h@ajums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Alijanirenani Hoshang  
**Street address**  
Golestan Highway, Ahvaz University of Medical Sciences, Nursing Midwifery Faculty  
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alijani-h@ajums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ahvaz 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

2

### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammad Badvi  
**Street address**  
No. 7, West Golestan Ave., GolestanBlvd., AhvazTown  
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hadiszamanifar69@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ahvaz 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**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Alijanirenani Hoshang  
**Position**  
University professor  
**Latest degree**  
Master  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
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Zamanifar Hadis  
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Student  
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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

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

En Information on the primary outcome and the secondary outcome is shared.

### When the data will become available and for how long

Start the access period, 6 months after printing the results

### To whom data/document is available

En Data is only available to researchers working in universities

### Under which criteria data/document could be used

It is applicable to life skills and adolescents of thalassemia

### From where data/document is obtainable

It is available to assess the knowledge and performance of families.

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

The application must first be sent to the Ahvaz University of Medical Sciences. After being examined by the Vice-Chancellor, the application will be sent to the Nursing Midwifery Faculty, and will be sent to the Nursing Midwifery Library after being submitted to the library.

### Comments