

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of individual psychotherapy based on self-efficacy on quality of life of patients with major thalassemia

Protocol summary

Summary

Objective: to determine the effect of individual psychotherapy based on self-efficacy on quality of life of patients with major thalassemia. Major inclusion criteria include Patients with major thalassemia; Lack of experience the severe stressful events in the past year; Able to read and write Persian language and age above of 15 years old. Major exclusion criteria including experience the severe stressful events during the study; death; unwillingness to continue this research (patient or family) and exacerbation of disease. Design of study: randomized, Population: patients with major thalassemia. Sample size: 50 patients. Intervention: After random allocation of patients to intervention and control groups, individual psychotherapy based on self-efficacy use as intervention for patients in the intervention group. The sessions will be in 8 weeks and every week a session lasted 45 minutes. In these training sessions, the researcher teaches the intervention group about approaches for identifies anxiety, coping with stress, interpersonal coping, methods for controlling anxiety, and optimism. In control group don't perform any intervention. The time and primary outcomes: changing in quality of life and self-efficacy evaluated with quality of life questionnaire and Sherer self-efficacy questionnaire in admission and 1 month after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041627425N1**

Registration date: **2016-05-21, 1395/03/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-21, 1395/03/01

Registrant information

Name

Parigol Taheri

Name of organization / entity

Yasuj University of Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research & technology, Yasuj University of Medical Sciences

Expected recruitment start date

2016-06-14, 1395/03/25

Expected recruitment end date

2017-01-14, 1395/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of individual psychotherapy based on self-efficacy on quality of life of patients with major thalassemia

Public title

Effect of individual psychotherapy based on self-efficacy on quality of life of patients with major thalassemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria include Patients with major thalassemia according to physician`s diagnosis; Lack of experience the severe stressful events such as death, illness, accident and divorce in the past year; Lack of a history about debilitating physical illnesses, severe mental disability and mental illness based on patient records and physician`s diagnosis. Able to read and write Persian language and age above of 15 years old. Exclusion criteria including experience the severe stressful events during the study such as debilitating physical illnesses, severe mental disability and mental illness, severe physical injuries such as fractures; death; unwillingness to continue this research (patient or family) and exacerbation of disease.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yasuj University of Medic Sciences

Street address

Yasuj, Yasuj University of Medical Sciences

City

Gachsaran

Postal code

Iran

Approval date

2016-04-09, 1395/01/21

Ethics committee reference number

ir.yums.REC.1395.1

Health conditions studied

1

Description of health condition studied

Major Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

Quality of life

Timepoint

In admission and then 1 month after admission

Method of measurement

Quality of life questionnaire(SF-36)

Secondary outcomes

1

Description

Self efficacy

Timepoint

In admission and then 1 month ago

Method of measurement

Sherer Self Efficacy Questionnaire

Intervention groups

1

Description

In this study, the individual psychotherapy based on self-efficacy session used as an intervention in the intervention group. The sessions will be in 8 weeks and every week a session lasted 45 minutes. In these training sessions, the researcher teaches the intervention group about approaches for identifies anxiety, coping with stress, interpersonal coping, methods for controlling anxiety, and optimism.

Category

Lifestyle

2

Description

In the control group is not done any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Parigol Taheri
Street address
Gachsaran, Shahid Rajaei Hospital
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasuj University of Medical Sciences
Full name of responsible person
Dr Kheyrollah Noryan
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasuj 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

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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

