Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Benson relaxation technique on anxiety and quality of life in patients with thalassemia major

Protocol summary

Study aim
Determining and comparing the mean score of anxiety and quality of life in patients with thalassemia major; Before, one and three months after performing Benson relaxation technique in both intervention and control groups

Design
The clinical trial has two groups of intervention and control, which are randomly identified by a card and performed on 80 patients.

Settings and conduct
The above project is performed in the thalassemia ward of Hazrat Ali Asghar Hospital in Zahedan, and the Benson relaxation technique will be performed individually by the researcher in the intervention group in the training class located in the hospital.

Participants/Inclusion and exclusion criteria
People over 18 years old referred to the thalassemia ward of the relevant hospital who have thalassemia major and live in Zahedan, also have a minimum of educational literacy and are willing to participate in the study are considered as inclusion criteria; And people who do not want to participate in the study and are other than the stated cases are considered as exclusion criteria

Intervention groups
If the patient is in the intervention group, the researcher first completes a questionnaire of personal characteristics, anxiety and aggression for patients in the intervention group. Then, Benson relaxation technique is taught individually in 2 face-to-face sessions of 30 to 45 minutes with an interval of 2 to 3 days in Ali Asghar Clinic, the time of which is determined in coordination with the patient, by the researcher. The intervention group is asked to do relaxation exercises twice a day for 6 weeks according to the schedule set at home. Take about 15 to 20 minutes at a time.

Main outcome variables
Anxiety,quality of life, physical health, mental health, social relationships, environmental health،Quality of life and general health

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200926048842N2**
Registration date: **2022-01-25, 1400/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-25, 1400/11/05**
Update count: **0**

Registration date
2022-01-25, 1400/11/05

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-18, 1400/10/28
Expected recruitment end date
2022-04-17, 1401/01/28
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Benson relaxation technique on anxiety and quality of life in patients with thalassemia major

Public title
The effect of Benson relaxation technique on anxiety and quality of life in patients with thalassemia major

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years No problems such as mental retardation, behavioral and mental disorders, hearing, speech according to medical records No hearing / heart or lung problems Ability to communicate in Persian Having an anxiety score above 43 (above average) Lack of known neurological problems such as multiple sclerosis and Parkinson's (due to the ability of the technique) No substance abuse No history of participating in training courses and not attending similar courses (before and during research) No disorders of the musculoskeletal system Do not take anti-anxiety drugs Ability to access and control the patient during 3 months Resident of Zahedan Having a cell phone in person or in the family or having a landline at home Not participating in similar training courses Have a minimum literacy Get a quality of life score less than 50 from the WHOQOL-BREF quality of life questionnaire

Exclusion criteria:
Withdrawal from study during research for any reason Incidence of severe physical complications from the disease

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done by available methods. Then the selected patients are randomly divided into two groups of intervention and control. In this way, first, an envelope containing the group name is prepared for the total number of people studied and randomly arranged, and with the gradual referral and selection of individuals, one of the cards will be assigned to them, respectively; Which will determine the individual group in the intervention or control group. Due to random sampling, the samples will have an equal chance of being selected in both intervention and control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
After selection, in order to standardize the research conditions for both intervention and control groups, the random allocation method will be used. If the patient is in the intervention group, the Benson relaxation technique will be performed, but no intervention will be performed for the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences-Baluchistan Blvd- Dr. Hesabi Square

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Zahedan

Province
Sistan-va-Balouchestan

Postal code
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Approval date
2022-01-16, 1400/10/26

Ethics committee reference number
IR.ZAUMS.REC.1400.357

Health conditions studied

1

Description of health condition studied
The effect of Benson relaxation technique on the psychology and quality of life of patients with thalassemia major

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
The patient scores on the Spielberger Anxiety Inventory in the range of 160-40.

Timepoint
It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The questionnaire has 40 items with the lowest and highest scores equal to 40 and 160, respectively. At the Anxiety Scale, the main goal is to measure anxiety from low to high. That is, low scores indicate calmness, moderate scores indicate moderate levels of stress and anxiety, and high scores reflect intense fear, close to panic. In response to these substances, subjects show the intensity of their emotion on a 4-point scale (basically, somewhat, moderately, and very much) at a specific time. In response to the anxiety trait, subjects on a 4-point scale (never, sometimes, often, and always) show how they generally feel

2

Description

Quality of life score, which is measured by the World Health Organization quality of life questionnaire and its score range is from 26-130

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales. And the difference between the two is 28; Mental Health Sub-Scale: The sum of the scores of questions 5-6-7-11-19-26 in the questionnaire The range of scores of this subscale will be between 6 and 30 and the difference between the two is 24; Social Interface Sub-Scale: The sum of the scores of questions 20-21-22 in the questionnaire The range of scores of this sub-scale will be between 3 and 15 and the difference between the two is 12; Environmental Health Sub-Scale: The sum of the scores of the questions 8-9- 12-13- 14-23-24-25 25 in the questionnaire The range of scores of this subscale will be between 8 and 40 and the difference between the two is 32; Quality of life and general health: The sum of the scores of questions 1 and 2 in the questionnaire The range of scores of this subscale will be between 2 to 10 and the difference between the two is 8

3

Description

Physical health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 7-35

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales. Physical Health Sub-Scale: The sum of the scores of the questions 3- 4- 10- 15-16-17-18 in the questionnaire. The range of scores of this subscale will be between 7 and 35. ; And the difference between the two is 28

4

Description

Mental health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 6-30

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The World Health Organization Quality of Life Questionnaire, a 26-item questionnaire that includes four subscales of mental health subscale: Total scores of questions in the questionnaire 5- 6 -7 -11- 19- 26 subscale scores range between 6 to 30 will be the difference These two are 24

5

Description

Social relations health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 3-15

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales; Social Relations Sub-Scale: The sum of the scores of the questions 20-21-22 in the questionnaire The range of scores of this sub-scale will be between 3 and 15 and the difference between the two is 12

6

Description

Environmental health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 8-40

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales, Environmental Health Sub-Scale: Total scores of questions 8-9- 12-13-14-23-24-25 in the range of scores of this subscale between 8 Will be 40 and the difference between the two is 32

7

Description

Quality of life and general health score that is measured by the World Health Organization quality of life questionnaire and its score range is from 2-10

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention

Method of measurement

The World Health Organization Quality of Life Questionnaire, which is a 26-item questionnaire and includes 4 subscales; Quality of life and general health: The sum of the scores of questions 1 and 2 in the

questionnaire The range of scores of this subscale will be between 2 and 10 and the difference between the two is 8

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Prior to his intervention, the researcher will undergo theoretical and practical training in relaxation techniques in several stages under the full supervision of a psychologist. First, the researcher will provide patients with a questionnaire, which includes a questionnaire of demographic characteristics, anxiety and quality of life , and after completing the questionnaire; Benson relaxation technique is taught individually by the researcher in 2 face-to-face sessions of 30 to 45 minutes with an interval of 2 to 3 days in Ali Asghar Clinic, the time of which is determined in coordination with the patient. The first session is training in the technique and the second session is training with questions from the patient and answers to questions that arise for him during the practice of the Benson technique at home. A CD containing Benson's step-by-step relaxation instruction is provided to the intervention group. The intervention group is asked to do relaxation exercises twice a day for 6 weeks according to the schedule set at home. Take about 15 to 20 minutes at a time. The technique is performed as follows: first before performing the relaxation technique; The patient removes all additional items such as watches, bracelets, rings and all items that can be detached and puts them next to him, and then Benson relaxation steps are taught to patients as follows: 1) Gently in position Comfortable. 2) Close your eyes slowly. 3) Relax all the muscles of the body deeply. Start from the soles of your feet and gradually move towards the face. This will keep people calm. 4) At the same time, Breathe through the nose. Be aware of your breathing and while exhaling slowly, repeat soothing words such as (God, love, rain, rainbow and the like) under your lips and start breathing deeply and regularly and do it with your nose and tail. Then exhale with your mouth and repeat the word in your mind. 5) Continue this for 15 to 20 minutes and try to relax all your muscles from the tips of the toes to the upper body muscles so that all the muscles of the body reach full expansion. After 15-20 minutes, slowly open your eyes and do not get up for a few minutes. 6) Do not worry about reaching a deep level of relaxation or not; Let the relaxation happen with his own song. When annoying thoughts occur, try to ignore them. During 6 weeks, to ensure that the relaxation technique is performed on the prescribed days, a checklist is provided to the samples until the day , The time and duration of the technique and if not, record the cause. In addition, a technique training CD will be provided to the patient. Also, in order to solve possible problems in the field of technique implementation, during the research period, the researcher has made a phone call with the research samples two days a week to ensure the process of technique implementation and completion of the checklist. It will also hold a training session for patients' families and ask them to monitor the patient's performance of the technique at home and to notify the researcher in the event of a problem. Finally, after one and three month, the researcher completes a questionnaire, anxiety and quality of life for patients in the intervention group.

Category

Rehabilitation

2

Description

Control group: In cases where the patient was assigned to the control group, the demographic information questionnaire, test questionnaire and quality of life questionnaire were completed first to begin the pre-test, and this group does not intervene except for routine care. After one and three months with the intervention group, the health and quality of life questionnaire is completed again by the researcher. At the end, the control group is given a Benson relaxation training CD

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences, Hazrat Ali Asghar Hospital

Full name of responsible person

Mahnaz Ghaljeh

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No. 19, Alley 12, Shohada Lebanon, Tehran St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Mahnaz Ghaljeh

Position
University faculty member, assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Position
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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

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