# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Examining the Effect of Benson’s Relaxation Technique on Anxiety and Aggression Patients with Thalassemia Major

## Protocol summary

**Study aim**
Determining and comparing the mean score of anxiety and aggression in patients with thalassemia major; Before and after performing Benson relaxation technique in two groups of intervention and control

**Design**
The clinical trial has two groups of intervention and control, which are randomly identified by a card and performed on 60 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, Aggression, Physical Aggression, Verbal Aggression, Anger, Hostility

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200918048750N1**
Registration date: **2020-12-15, 1399/09/25**
Registration timing: **prospective**

Last update: **2020-12-15, 1399/09/25**
Update count: **0**

**Registration date**
2020-12-15, 1399/09/25

**Registrant information**

**Name**
Mahnaz Ghaljeh

**Name of organization / entity**

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-12-20, 1399/09/30

**Expected recruitment end date**
2021-03-14, 1399/12/24

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Examining the Effect of Benson’s Relaxation Technique on Anxiety and Aggression Patients with Thalassemia Major

**Public title**
The effect of Benson relaxation technique on anxiety and aggression in patients with thalassemia major
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age over 18 years Ability to communicate in Persian No hearing / heart or lung problems Lack of known neurological problems such as multiple sclerosis and Parkinson's (due to lack of technical ability) 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 6 weeks Having a cell phone in person or in the family or having a landline at home Have a minimum literacy level of reading and writing Resident of Zahedan Anxiety score above 43 and aggression score above 48
**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: **60**
**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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Sistan-va-Balouchestan
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9816743463
**Approval date**
2020-10-11, 1399/07/20
**Ethics committee reference number**
IR.ZAUMS.REC.1399.372

## Health conditions studied

### 1

**Description of health condition studied**
The effect of Benson relaxation technique on anxiety and aggression in 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 intervention and two 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**

The patient scores the Bass and Perry Aggression Questionnaire in the range of 145-29.

**Timepoint**

It is before the intervention and two months after the end of the intervention

**Method of measurement**

This questionnaire has 29 questions and evaluates four aspects of aggression. Questions 1,5,9,13,17,21,24,26,28 related to physical aggression and questions 6,2,10,14,18 related to verbal aggression, questions 3, 7,11,15,19,22, 29 related They show hostility to anger and questions 4,8,12,16,20,23,25,27. Scoring: For each question, there are five options to answer as follows: It is completely contrary to my characteristics (score 1); Is somewhat contrary to my characteristics (score 2); Only slightly expresses my characteristics (score 3); It is somewhat indicative of my characteristics (score 4); It is quite telling of my characteristics (score 5) that the score of questions 24 and 29 is inverse. The scores of the subscales are obtained by summing the scores of the questions of that subscale. The total score is the sum of the total scores of the questions and its range is from 29 to 145. Higher scores are a sign of more aggression.

**3**

**Description**

Physical aggression score that is measured by Bass and Perry aggression questionnaire and its score range is 9-45

**Timepoint**

It is before the intervention and two months after the end of the

**Method of measurement**

The Bass and Perry Aggression Questionnaire is a 29-item questionnaire that includes 4 domains. The domain of physical aggression includes questions (1-5-9-13-17-21-24-26-28) and its score range is 9-45.

**4**

**Description**

Verbal aggression score that is measured by the Bass and Perry Aggression Questionnaire and its score range is 5-25.

**Timepoint**

It is before the intervention and two months after the end of the

**Method of measurement**

The Bass and Perry Aggression Questionnaire is a 29-item questionnaire that includes 4 areas. The area of verbal aggression includes questions (2-6-10-14-18) and its score range is 5-25.

**5**

**Description**

Anger score that is measured by Bass and Perry Aggression Questionnaire and its score range is 7-35.

**Timepoint**

It is before the intervention and two months after the end of the

**Method of measurement**

The Bass and Perry Aggression Questionnaire is a 29-item questionnaire that includes 4 areas, the anger area includes questions (3-7-11-15-19-22-29) and its score range is 7-35.

**6**

**Description**

The hostility score is measured by the Bass and Perry Aggression Questionnaire and its score range is 8-40.

**Timepoint**

It is before the intervention and two months after the end of the

**Method of measurement**

Bass and Perry Aggression Questionnaire is a 29-item questionnaire that includes 4 areas, the area of hostility includes questions (4-8-12-16-20-23-25-27) and its score range is 8-40.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention description: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 aggression, 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 8 weeks, the researcher completes a questionnaire, anxiety and aggression for patients in the intervention group.

**Category**

Rehabilitation

**2**

**Description**

Control group:If the patient is assigned to the control group, the demographic information questionnaire, anxiety and aggression questionnaire are completed by the researcher to start the pre-test, and this group does not receive any intervention except for routine care. After 8 weeks, the Anxiety and Aggression Questionnaire will be completed again by the researcher at the same time as the intervention group. Finally, the control group is given a CD of Benson relaxation technique

**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**

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## Sponsors / Funding sources

**1**

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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**

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**Position**
Faculty member Assistant University

**Latest degree**
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**Other areas of specialty/work**
Nursery

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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