

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of emotional freedom technique (EFT) on pain intensity and fatigue in patients with rheumatoid arthritis

Protocol summary

Study aim

Determining the effect of emotional release technique (EFT) on pain intensity and fatigue in patients with rheumatoid arthritis

Design

The sample size is 82 41 intervention people and 41 control people with random block method

Settings and conduct

A randomized controlled clinical trial Rheumatology department of Ahvaz Golestan Hospital or rheumatology clinic or rheumatologist's office Implementation at home or hospital twice a week, 30 minutes each time, during 4 weeks and a total of 8 sessions

Participants/Inclusion and exclusion criteria

Inclusion criteria Not having speech, hearing, and movement disorders Not using other complementary and alternative treatments Absence of injuries and wounds in the desired points of acupuncture Age 18 to 65 years
Exclusion criteria Patient death during the study Failure to complete questionnaires Simultaneous participation in similar educational programs

Intervention groups

In this technique, using the 2 index and middle fingers of the dominant hand on the points including (point ST14 in acupuncture), head (DU20), eyebrow (BL2), side of the eye (GB1), under the eye (ST1), under the nose (GV26) , chin (CV24), lower border of clavicle (KD27), armpit (SP21), margin between thumb and outer corner of nail (LU11), index finger (LI 1), middle finger (PC9), little finger (HT9) And karate point (SI 3) and Gamut point (TH3 acupuncture point located on the back of the hand between the ring finger and the little finger on the metacarpal bone) are hit. This intervention is repeated for 30 minutes. In the control group, no special action will be taken.

Main outcome variables

Reducing the intensity of pain and fatigue in patients with rheumatoid arthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230724058904N1**

Registration date: **2023-07-28, 1402/05/06**

Registration timing: **prospective**

Last update: **2023-07-28, 1402/05/06**

Update count: **0**

Registration date

2023-07-28, 1402/05/06

Registrant information

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sara Faramarzi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of emotional freedom technique (EFT) on pain intensity and fatigue in patients with rheumatoid arthritis	
Public title	The effect of emotional freedom technique (EFT) on pain intensity and fatigue in patients with rheumatoid arthritis
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Not having speech, hearing, and movement disorders Not experiencing severe stress such as the death of relatives and loved ones or divorce in the last 6 months Not having obstructive airway disorders such as apnea and chronic obstructive pulmonary disease Absence of injuries and wounds in the desired points of acupuncture Exclusion criteria: Having mental problems, blindness, deafness or a history of psychological problems Incomplete completion of the demographic information questionnaire Unwillingness and lack of cooperation to participate in the study Alcohol and drug addiction Participation in pain and fatigue coping courses and other complementary courses before entering the study Age less than 18 years or more than 65 years Lack of literacy Musculoskeletal and neurological problems Existence of wound - injury and dressing in the place of the desired points to implement the technique Lack of proficiency in Persian language
Age	From 18 years old to 65 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 82
Randomization (investigator's opinion)	Randomized
Randomization description	In this research, based on the results of previous studies and according to the opinion of the esteemed consultant of statistics and methodology, the number of samples will be 82 people, and random block method will be used for randomization, and people will be randomly divided into two groups (intervention group) and (group control) are placed and blocks of 4 are used. In this way, a card will be awarded to each person who has the conditions to enter the study, in chronological order upon entering the study. Then, by merging the cards together (hitting the cards), one card is removed and its assignment is recorded and a number is assigned to it. And after that card is taken out, it is returned to the pool of other cards. After assigning numbers to each card in the order of choosing the cards, each person and number will be placed in groups A and B respectively. In this way, the first person is placed in group A - the second person is placed in group B - the third person is placed in group A and and this process continues until 82 patients are included in a random list of people. In order to block the samples under the supervision of a statistical consultant
	and based on the random sequence of the cards and according to the number of permutations of 4, random selection process by placing these permutations (6 cards), in the form of cards (AABB), (ABAB), (BABA), (BBAA), (ABBA) and (BAAB)) are considered. In this way, by merging the cards together again (hitting the cards), a card is removed every time until a group of 4 cards is created, which must include two A cards and two B cards. Then each card after being removed is returned to the pool of other cards. Finally, each block is placed in the intervention group and the control group in the chronological order created. Block 1 is the intervention group, Block 2 is the control group, and Block 3 is the intervention group, and this process will continue until 82 patients are allocated treatment. In this way, the samples eligible to enter the study were selected and randomly placed in two intervention groups (41 people) and control (41 people).
	Blinding (investigator's opinion)
	Not blinded
	Blinding description
	Placebo
	Not used
	Assignment
	Parallel
	Other design features
	Secondary Ids
	empty
	Ethics committees
	1
	Ethics committee
	Name of ethics committee
	Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences
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	AHVAZ
	Province
	Khouzestan
	Postal code
	15794- 61357a
	Approval date
	2023-07-24, 1402/05/02
	Ethics committee reference number
	IR.AJUMS.REC.1402.264
	Health conditions studied
	1
	Description of health condition studied
	Rheumatoid Arthritis
	ICD-10 code
	M13.0
	ICD-10 code description

Primary outcomes

1

Description

pain intensity

Timepoint

4 weeks after the intervention

Method of measurement

Brief Pain Questionnaire

2

Description

Fatigue intensity

Timepoint

4 weeks after the intervention

Method of measurement

Multidimensional fatigue measurement questionnaire

Secondary outcomes

1

Description

Pain interference in daily activities

Timepoint

4 weeks after the intervention

Method of measurement

Brief Pain Questionnaire

Intervention groups

1

Description

Intervention group: After coordinating the day and time of the session, the selected samples in the intervention group are gathered in a suitable classroom with communication facilities, and they are asked to maintain the peace of the educational environment as much as possible during the session. The EFT intervention will be done in a group in a quiet room with proper light and temperature, free from environmental stimuli. The participants will be asked to complete a brief pain questionnaire and a multidimensional fatigue measurement questionnaire as a pre-test. Then the researcher will start the emotional release technique session by showing images of the desired areas for stimulation to the people of the intervention group and they will be told how to gently pressurize the desired points using the index and middle fingers, and how to do this, he will show the steps of EFT tapping on the body (face and trunk) and ask the people to tap on their body. The practice continued until everyone learned how to perform EFT and each participant was taught individually. The duration of the training of the experimental group will be 35 minutes on average. This technique will be implemented based on the basic instructions of Gary EFT. In this technique, people are

asked to think about their mental workload, fatigue and pain, check the severity of their problem and give them a score between 1 and 10. Then, using the 2 index and middle fingers of your dominant hand, hit the points around your face and upper body seven times and stimulate these points. At the same time, while hitting the points loudly, say the sentences that indicate his basic problems and the pain and fatigue that the person is experiencing, together with the sentences that indicate the acceptance of these problems. In this stage (adjustment stage), the patient says: 'Although I feel tired and in pain, I accept my body and myself completely and deeply.' He repeats this sentence three times and at the same time, massages the pain point (ST14 point in acupuncture) with a radius of 5 cm. In the recall stage, 13 acupuncture points including the head (DU20), eyebrow (BL2), near the eye (GB1), under the eye (ST1), under the nose (GV26), chin (CV24), below the border of the clavicle (KD27), armpit (SP21), the border between the thumb and the outer corner of the nail (LU11), the index finger (LI 1), the middle finger (PC9), the little finger (HT9) and using the tip of the index finger and the middle finger, hit the karate point (SI 3) hits At the same time, the patient repeats the phrase 'I'm tired and I feel pain', focusing on the fatigue and pain. At Gamut stage 9, tap the Gamut point (the TH3 acupuncture point on the back of the hand between the ring finger and little finger on the metacarpal bone). At the same time, the patient must perform 9 brain stimulation movements. These movements include: closing the eyes, opening the eyes, looking down and right, looking down and left, rotating the eyes clockwise, rotating the eyes counterclockwise, humming the desired song for 2 seconds, counting numbers from 1 to 5 and again humming the desired song for 2 seconds. In the last step, the second step is repeated. This intervention is repeated for 30 minutes. After hitting again, he will check the severity of his problems (fatigue and pain) and give them a score from 1 to 10. This technique will be repeated until the severity of the problems reaches zero. After a visual presentation about the technique, people's questions about EFT will be answered. This training will continue until all patients learn how to apply EFT. Also, each participant will be taught individually how to implement the technique. Practice will continue until all participants learn how to perform the technique. The training of each intervention group lasts an average of 30 minutes. Then the researcher asks the patients to do this technique individually at home or in the hospital twice a week, 30 minutes each time, for 4 weeks and a total of 8 sessions, and explains that to ensure the correct implementation of the technique by the person, reminding them to do EFT twice a week and do their homework, he calls them twice a week and answers them if there are any questions. Also, patients are asked to meet the researcher in person once a week, if possible, so that the correct way of performing the technique can be checked more closely. Then (at the end of 8 sessions), the brief pain questionnaire and the multidimensional fatigue measurement questionnaire will be given to the members of the intervention group in writing and in the presence of the researcher or as an

alternative method in the form of an electronic questionnaire, and the post-test will be taken.

Category

Rehabilitation

2

Description

Control group: Control group: In the control group, no special action will be taken and to prevent these people from contacting the intervention group in order to prevent the effect of the emotional release technique on the patients of the control group, if the patients of the two groups are in the same room, they will be excluded from the study. After the end of the 8 sessions of technique implementation in the intervention group, the people of the control group will also be contacted to complete the brief pain questionnaire and the multi-dimensional fatigue measurement questionnaire as a post-test. And at the end of the study, each of the people in the control group will be taught how to perform EFT.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology department of Ahvaz Golestan Hospital or referred to Rheumatology clinic or rheumatolog

Full name of responsible person

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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?

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

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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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