

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effect of acupuncture and exercise training on anxiety level of generalized anxiety disorder (GAD) patients

Protocol summary

Study aim

Comparison of the effect of acupuncture and exercise training on the level of anxiety in patients with generalized anxiety disorder (GAD)

Design

A randomized controlled clinical trial with parallel groups, no blinding, randomized

Settings and conduct

120 female with GAD that referred by a psychiatrist according to DSM5 diagnostic criteria and Sung Anxiety Questionnaire (S.A.S). Patients were selected from referrals to Mostafavian and Tooba specialty clinics 1 and 2 and Zareei hospital and Sari private offices.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. People who have been diagnosed with GAD according to DSM5 criteria by a psychiatrist. 2. The degree of anxiety of patients less than severe 3. Female gender 4. Informed consent to participate in the study 5. Literacy of reading and writing 6. Age 18-60 years 7. Patients should not use opiates, stimulants, and other psychiatric drugs since 6 weeks prior to study. 8. No history of chronic physical illness Exclusion criteria 1. Dissatisfaction with continuing to participate in the study 2. Past history of suicide 3. Hematoma complication as a result of acupuncture and exacerbation of musculoskeletal diseases with exercise therapy. 4. Pregnant women 5. Absence for more than 3 sessions

Intervention groups

1. Medication 2. Medication + acupuncture 3. Medication + exercise

Main outcome variables

Anxiety level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140708018409N1**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Gholamreza Partovi

Name of organization / entity

Mazandaran University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 6552

Email address

ghpartovi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-19, 1399/01/31

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of acupuncture and exercise training on anxiety level of generalized anxiety disorder (GAD) patients

Public title

The effect of acupuncture and exercise on GAD patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People who have been diagnosed with GAD according to the DSM 5 criteria by a psychiatrist. Patients' anxiety levels are less than severe. Patients have informed consent to participate in the study. Patients with literacy (at least third grade of elementary school to read and write Persian correctly). Patients did not have any opiate, stimulants, and other psychiatric medications from the 6 weeks before beginning of the study until after completing the last Anxiety Questionnaire. Patients do not have a history of chronic physical illness. Patients have female gender. Patients age 60-18 years.

Exclusion criteria:

Patients have a history of suicide. Pregnant women Hematoma as a result of acupuncture and exacerbation of musculoskeletal diseases with exercise therapy Patients were not happy to continue the study Absent more than 3 sessions

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Three cards containing the treatment groups are in the container and the patient selects one. Then the card enters the container and the next patient selects another card.

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 Mazandaran University of Medical Sciences

Street address

Moalem Street. Moalem Square. Vice chancellor for

research, Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2019-10-01, 1398/07/09

Ethics committee reference number

IR.MAZUMS.REC.1398.901

Health conditions studied

1

Description of health condition studied

Generalized Anxiety Disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

S.A.S questionnaire anxiety score

Timepoint

0,6,10 week

Method of measurement

S.A.S questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pharmacotherapy and acupuncture. Acupuncture, two sessions per week with needle number 25 * 0.25 in areas Li4, Du20, PC6, SP6, HT7 and LU7 according to the theory of managers for 20 minutes by sport medicine resident

Category

Treatment - Other

2

Description

Intervention group: Drug therapy and exercise therapy. Exercise training including Shrug, Crunch, Hip abduction, Heel raise, 3 sets daily with 15 repetitions and 20 minutes daily aerobic exercise (100 steps per minute)

Category

Treatment - Other

3

Description

Control group: Pharmacotherapy. Pharmacotherapy under the supervision of plan psychiatrist

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafavian Clinic

Full name of responsible person

Dr. Gholamreza Partovi

Street address

Razi 3

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 6552

Email

ghpartovi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

Moalem

City

Sari

Province

Mazandaran

Postal code

4471848178

Phone

+98 11 3325 7230

Email

pajhooheshi@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Partovi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

Razi 3

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 6552

Email

ghpartovi@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Gholamreza Partovi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

Amir Mazandarani Ave., Emam Khomeyni Hospital

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 6552

Fax

+98 11 3336 3754

Email

ghpartovi@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Partovi

Position

Assistant Professor

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Results of statistical analysis and its analysis

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Health researchers

Under which criteria data/document could be used

View data

From where data/document is obtainable

corresponding author

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

About 1 month

Comments