

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the Effectiveness of a Course of Yoga Exercises on Depression and Anxiety, Balance and Attention in Patients with MS.

Protocol summary

Study aim

Determining the effectiveness of a course of yoga exercises on depression and anxiety, balance and attention in patients with MS.

Design

This research has followed the Small Sample method and the study has been implemented in ABAB phases. So that phase A represents the baseline condition, and phase B represents the intervention status. The test has been conducted on 4 examinees, and during the research period, relevant tests are administered and recorded every 4 days to finally check the effectiveness of yoga exercises in the baseline and intervention phases.

Settings and conduct

In the baseline phase, the examinees are recording the desired tests every 4 days for a duration of 16 days without receiving any yoga exercises. In the intervention phase, for 24 days, the examinees are participating in 10 yoga training sessions, and the tests are being administered and recorded every 4 days. This process will be repeated two consecutive times.

Participants/Inclusion and exclusion criteria

Inclusion criteria: not having the experience of practicing yoga or at least 6 months passed since last yoga course; having the possibility to attend yoga classes. Non-inclusion criteria: Inability to Participate in Face-to-Face Yoga Classes

Intervention groups

In this research, the effectiveness of a course of yoga exercises on depression and anxiety, balance and attention of patients with MS is being investigated. According to the ABAB plan, in each phase B or intervention, 10 sessions, examinees are being provided with 10 sessions of 90 minutes yoga exercises.

Main outcome variables

Depression; Anxiety; Balance; Attention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230508058119N1**

Registration date: **2023-07-12, 1402/04/21**

Registration timing: **retrospective**

Last update: **2023-07-12, 1402/04/21**

Update count: **0**

Registration date

2023-07-12, 1402/04/21

Registrant information

Name

Faezeh AliBakhshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4244 4225

Email address

faezehalibakhshi97@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-03-14, 1401/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Effectiveness of a Course of Yoga Exercises on Depression and Anxiety, Balance and Attention in Patients with MS.

IR.IAU.B.REC.1402.030

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

d2 test score to measure the level of attention

Timepoint

Every 4 days since the beginning of the research

Method of measurement

d2 Attention test

2

Description

Berg and Bess test score to measure balance

Timepoint

Every 4 days since the beginning of the research

Method of measurement

Berg and Bess balance test

3

Description

GHQ mental health test score to measure the level of depression and anxiety

Timepoint

Every 4 days since the beginning of the research

Method of measurement

GHQ mental health test

Secondary outcomes

empty

Intervention groups

1

Description

In the present study, the Small Sample method is used for community experimentation. In this method, each participant acts as a unit of analysis and serves as their own control group. The method involves serial observations of the sample population, both individually and in groups, before, during, and after the intervention period. The basic design of this classification is based on the ABAB structure, where "A" refers to the baseline phase and "B" indicates the intervention phase. In the first baseline phase (A), participants do not receive any

Public title

The Effect of Yoga on the Complications of MS.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The examinee does not have the experience of practicing yoga or at least 6 months have passed since her last yoga course The examinee has the possibility to attend yoga classes

Exclusion criteria:

Inability to Participate in Face-to-Face Yoga Classes

Age

From **30 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **4**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Borujerd

Street address

No. 36, Pirasteh Alley, North Modares St , Nakhi Crossroad

City

Borujerd

Province

Lorestan

Postal code

6919753935

Approval date

2023-05-01, 1402/02/11

Ethics committee reference number

yoga exercises for a duration of 18 days. On the first, fourth, eighth, twelfth, and sixteenth days, predetermined tests are conducted and recorded. Generally, these tests are repeated five times during this phase. In the first intervention phase (B), participants engage in 10 yoga training sessions over a period of 24 days, with each session lasting 90 minutes. Tests are administered and recorded every four days. Typically, these tests are repeated six times during this phase. In the second baseline phase (A), participants do not receive any yoga exercises for a duration of 18 days. Tests are conducted and recorded every four days. Generally, these tests are repeated four times during this phase. In the second intervention phase (B), participants participate in 10 yoga training sessions over a period of 24 days, with each session lasting 90 minutes. Tests are administered and recorded every four days. Typically, these tests are repeated six times during this phase. Throughout all stages (a total of 21 tests), measurements are repeatedly taken and recorded. The data obtained from the conducted tests are transformed into graphical representations, and visual analysis is employed to examine the data within and between phases.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Association of Special Diseases of Borujerd

Full name of responsible person

Fatemeh Yarahmadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ali Ariapour

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Imam Khomeini University Complex; Yadgar Imam St; Nawab Sq

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6915136111

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name@domain.com

Grant name

Grant code / Reference number

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

No

Title of funding source

The financial resources of the research were provided privately.

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Faezeh AliBakhshi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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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

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

Title and more details about the data/document

After removing confidential information, participants' data files can be made available to future researchers.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers of scientific and academic institutions and related students

Under which criteria data/document could be used

Currently, no specific conditions have been determined.

From where data/document is obtainable

To access the data, refer to the email address below.
faezehalibakhshi97@gmail.com

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

Currently, no specific conditions have been determined. If necessary, the researcher can contact the email address provided and the details of her/ him service will be provided

Comments