Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Yoga Comparing to Amantadine and Commitment Group Therapy on Fatigue and Pain and Life Quality in Patients with Multiple Sclerosis

Protocol summary

Study aim
Determining and Comparing the Impact of Yoga Exercise, Acanthadine Acceptance and Commitment Therapy Group on Pain Control, Reducing Fatigue, and Improving Patients' Living Quality M.S.

Design
Clinical trial of no control group, in parallel, non-random, phase 3 on 90 patients.

Settings and conduct
Semi-experimental study in the form of a post-test test in women aged 15-60 years with MS referred to Neshat Clinic in Hamadan. Non-random division of patients into three groups after matching (age, severity, symptoms, duration of illness). Amantadine 100MG treatment group twice a day for 3 months, yoga exercise group 12 weeks 3 sessions 3 times a week, group therapy based on acceptance and commitment 12 weeks once a week one hour

Participants/Inclusion and exclusion criteria
Definitive diagnosis of the disease, having symptoms of pain and fatigue, lack of satisfaction with the patient's daily functioning, lack of other diseases, failure to receive other drugs, no contraindications to amantadine Not exercising regularly, doing two exercises at the same time, being hospitalized for any reason, dying

Intervention groups
Patients with MSIntervention Group 1: Yoga exercises for three months Intervention Group 2: Acceptance and Commitment-Based Therapy Group for three months Intervention group 3: Use of amantadine for three months

Main outcome variables
Pain, fatigue, quality of life

General information

Reason for update

Acronym
ACT

IRCT registration information
IRCT registration number: **IRCT20200423047176N1**
Registration date: **2020-04-29, 1399/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-29, 1399/02/10**
Update count: **0**

Registration date
2020-04-29, 1399/02/10

Registrant information
Name
raheleh rezaeian langroudi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3821 0047
Email address
r.r1351@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-27, 1399/02/08

Expected recruitment end date
2020-07-25, 1399/05/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effectiveness of Yoga Comparing to Amantadine and Commitment Group Therapy on Fatigue and Pain and Life Quality in Patients with Multiple Sclerosis

Public title
Effectiveness of Yoga Comparing to Amantadine and Commitment Group Therapy in Patients with Multiple Sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis based on neurological examinations and MRI Symptoms of pain and fatigue that have been confirmed by interview and questionnaire Patient dissatisfaction with their daily functioning No other illness Do not take other medications No contraindications to amantadine
Exclusion criteria:
Do not exercise regularly Complications of amantadine Hospitalization for any reason death
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Boroujerd Azad University Ethics Committee
Street address
Yadan Nawab, Yadegar Imam St., Imam Khomeini University Complex Mailbox: 518
City
Boroujerd
Province
Lorestan
Postal code
6915136111
Approval date
2019-12-29, 1398/10/08
Ethics committee reference number
IR.IAU.B.REC.1398.043

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
People whose fatigue rate is determined by the Fatigue Severity Scale (9FSS) to a low to moderate to severe level.
Timepoint
Amantadine 100mg treatment group twice daily for three months.
Method of measurement
Fatigue Severity Scale(FSS-9)

2

Description
People whose pain rate is determined by the NRS (Numeric Pain Rating Scale) are low, medium, and severe.
Timepoint
Yoga Exercise Group 12 weeks 3 sessions per week
Method of measurement
Numeric Pain Rating Scale(NRS)

3

Description
People whose quality of life is determined by the Multiple Sclerosis Impact Scale (MSIS-29)
Timepoint
Acceptance and commitment group therapy group 12 hours a week one hour a week
Method of measurement
Multiple Sclerosis Impact Scale (MSIS-29).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1 Yoga Exercises: For 12 weeks and three sessions each week and each session for 75-60 minutes under the supervision of an experienced instructor. Asana (movement) exercises 40-35 minutes including stretching and softening exercises in all muscles of the body, pranayama exercises (breathing) 10-15 minutes including controlling the ratio of inhalation and exhalation, meditation (release) 15-20 minutes on a regular basis and focusing on a topic Special.

Category

Rehabilitation

2

Description

Intervention Group 2 Acceptance and Commitment Therapy Group for 12 Weeks a week 60-minute session under the supervision of a specialist who has all six components of treatment including admission, fault, self as field, mindfulness, enlightenment values and commitment in The format of metaphors and exercises was taught.

Category

Lifestyle

3

Description

Intervention group 3 Use of amantadine 100mg twice daily for three months (one every 12 hours).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Neshat Clinic

Full name of responsible person
Mahnaz Bastani

Street address
Hamedan, End of Saadieh, above Talented School, Hamedan Branch Cultural and Sports Institute

City
Hamedan

Province
Hamadan

Postal code
6515911111

Phone
+98 81 3821 8650

Fax
+98 81 3821 8650

Email
INFO_HMD@ISAARCSI.IR

Web page address
http://hmd.isaarcsi.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr Abdolreza Moazami Godarzi

Street address
Navab Square, Yadegar Imam St., Imam Khomeini University Complex Mailbox: 518

City
Broujerd

Province
Lorestan

Postal code
6915136111

Phone
+98 66 4251 8000

Email
r.r1351@yahoo.com

Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Raheleh Rezaeian Langroudi

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Masters of Kaj Boulevard Kaj Tower, 3rd floor, unit 6

City
Hamedan

Province
Hamadan

Postal code

6516873597

Phone
+98 81 3821 0047

Fax

Email
r.r1351@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data seems to be as clear as possible

When the data will become available and for how long
Start access three months after printing the results

To whom data/document is available
Researchers working in universities, scientific and medical centers

Under which criteria data/document could be used
In order to be used for the well-being of patients with MS
Conditions: No change of content

From where data/document is obtainable
I am Raheleh Rezaian Langroudi by e-mail r.r1351@yahoo.com or Hamadan Branch of Azad University, Department of Medical Sciences

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

Comments