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A study of the impact of yoga and physical therapy on symptoms and quality of life in patients with multiple sclerosis

Submission date
24/01/2021

Recruitment status
No longer recruiting

Registration date
12/05/2021

Overall study status
Completed

Last Edited
12/04/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Yoga originated in the territory of modern India more than 3000 years ago and uses techniques for working with the musculoskeletal system, cardiorespiratory system and attention. Currently, the effectiveness and safety of yoga in patients with various neurological disorders, including multiple sclerosis (MS), is of interest to many scientists and clinicians. The main aim of this study is to examine the effect of yoga on symptoms and quality of life in patients with MS versus physical therapy (exercise therapy) and no exercise.

Who can participate?
Patients aged 18 and over with MS in remission phase

What does the study involve?
Participants are randomly allocated to yoga, physical therapy, or no exercise. Qualified instructors will teach yoga and exercise therapy. Yoga classes will be held at yoga practice centers. Exercise therapy classes will be held at the research center. The training program is tailored specifically for MS patients. MS treatment will continue as part of routine practice, as prescribed by the treating neurologist. In the event of an exacerbation of MS or other safety-related reasons (for example, side effects of exercise), the patient will be excluded from the study. Data collection will take place during the patient's two visits to the study center - before the start of the study and at the end of the 12-week period.

What are the possible benefits and risks of participating?
The main benefit for the patient is to be involved in a 12-week structured outpatient exercise programme that is otherwise not a part of routine care. The study doesn't have any additional risks for the patient, except those related to the physical activities during classes (i.e. exertion).

Where is the study run from?
1. The April Rehabilitation Center (Russia)
2. V.M. Buyanov's Hospital (Russia)

When is the study starting and how long is it expected to run for?
March 2018 to May 2020

Who is funding the study?
Federation “Yoga Practika” (Russia)

Who is the main contact?
Lev Brylev
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PC-01-18

Study information

Scientific Title
A study of the impact of yoga and physical therapy on symptoms and quality of life in patients with multiple sclerosis

Study objectives
The main objective of the study was to examine the effect of yoga compared to physical therapy and lack of exercise on symptoms and quality of life in patients with multiple sclerosis (MS).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 19/03/2017, Buyanov City Hospital local ethics committee, (26, Bakiskaya Street, 115516, Moscow; +7 (0)495 322 17 10; gkb12@zdrav.mos.ru), ref: PC-01-18

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple sclerosis (MS)

Interventions
Current intervention as of 08/07/2021:
A pre-prepared list of randomization numbers is used, in which the randomization number corresponds to the observation group, using a random number generator. The observation group (1, 2 or 3) is known to both the patient and the doctor, but it was blinded for the rater. Participants are randomised to yoga, physical therapy, or no exercise depending on the group. Yoga and exercise classes are held twice a week for 12 weeks. Each session lasts about 60-75 minutes.

In the exercise group, the class consisted of three parts: 10-15 minutes - a warm-up, which includes exercises on stretching of the main muscle groups, flexibility, in combination with breathing training; 25-35 minutes - endurance training, muscle strength, coordination and balance exercises, aerobic exercises; 10-15 minutes - relaxing techniques in combination with breathing exercises.

The yoga group use a yoga complex consisting of 13 basic and 4 alternative poses. The complex is basic, universal for patients with MS and is designed to ensure safety, but at the same time give practitioners the opportunity to progress and improve their condition. Alternative, lighter versions of those poses that may cause difficulties are also suggested, and basic postures are performed using additional materials to ensure comfortable exercise. The names of poses and the basic principles of their implementation correspond to the classification given in B.C.S. Iyengar's book "Clarification of Yoga" by Iyengar.

All patients continue their MS therapy according to routine practice. Participation in the study lasts up to 14 weeks, including the preliminary examination (up to 1 week), the period of exercises (12 weeks) and the final assessment (up to 1 week after the last exercise).

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Previous intervention:
A pre-prepared list of randomization numbers is used, in which the randomization number corresponds to the observation group, using a random number generator. The observation group (1, 2 or 3) is known to both the patient and the doctor. Participants are randomised to yoga, physical therapy, or no exercise depending on the group. Yoga and exercise classes are held twice a week for 12 weeks. Each session lasts about 60-75 minutes.

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Intervention Type
Behavioural

Primary outcome(s)
Balancing ability measured using mean Berg Balance Scale score after 14 weeks of exercises and observation

Key secondary outcome(s)
1. Tolerance of physical activity measured using the 6-minute walk test result (m) after 14 weeks of exercises and observation
2. General well-being measured using the SF-36 questionnaire after 14 weeks of exercises and observation
3. Fatigue measured using Fatigue Assessment Scale after 14 weeks of exercises and observation
4. Proportion of patients who successfully complete the study measured using attendance records at baseline and 12 weeks
5. Adverse events related to physical activity appeared during the study measured using interview at baseline and 12 weeks

Completion date
12/05/2020

Eligibility

Key inclusion criteria
1. Written informed consent form
2. Age 18 years old and above
3. A diagnosis of remitting MS or secondary progressive MS
4. Presence of the walking, balance impairment or pathological fatigue
5. A patient has no previous regular physical exercises for MS treatment
6. EDSS score from 2.0 to 6.0
7. Agreement and ability to do regular exercise during the study
8. Agreement and ability to comply with the protocol (performing tests, completing questionnaires)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
56

Key exclusion criteria
Exacerbation of MS within 30 days before the study and during the study

Date of first enrolment
07/04/2018

Date of final enrolment
14/03/2019

Locations

Countries of recruitment
Russian Federation

Study participating centre
V.M. Buyanov's Hospital
26, Bakinskaya Street
Moscow
Russian Federation
115516

Study participating centre
April Rehabilitation Center
32, building 4, Nizhegorodskaya Street
Moscow
Russian Federation
109029

Sponsor information

Organisation
Russian regional sports public organization “Federation Yoga Practika”

Funder(s)

Funder type
Other

Funder Name
Federation “Yoga Practika”

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Lev Brylev (lbrylev@aprel-clinic.ru).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		27/12/2021	12/04/2022	No	No