

WITHDRAWN: Yoga Versus Physical Therapy In Multiple Sclerosis: Randomized Controlled Trial

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EDITORIAL NOTE:

The full text of this preprint has been withdrawn by the authors while they make corrections to the work. Therefore, the authors do not wish this work to be cited as a reference. Questions should be directed to the corresponding author.

Abstract

Background. 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 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.

Methods. The patients were randomly assigned to 3 groups (yoga, PT, or waiting list), patients from the waiting list had an opportunity to enter the yoga program after the end of the trial period. After 12 weeks of regular exercises (or absence of them), the effect of yoga and PT on the functional status and quality of life of patients were evaluated. The MS treatment was a part of routine practice, as prescribed by the treating neurologist. The data was collected during the patients' two visits to the study center - before the start of the study and at the end of the 12-week period. The in-person examination included a doctor's assessment of the EDSS, the SF-36 quality of life questionnaire, the fatigue scale, the Berg balance scale, the 6-minute walking test.

Results. A total of 36 patients finished the clinical study: 30 women and 6 men. There was no statistically significant difference between the groups in terms of improvement in MS symptoms as measured by the balance, walking test and fatigue scales. However, in the analysis of the 8 criteria of SF-36 quality-of-life questionnaire the covariation analysis statistically significant differences were found in favor of the yoga group in terms of physical functioning (PF) ($p=0.003$), life activity (VT) ($p<0.001$), mental health (MH) ($p=0.013$), social functioning (SF) ($p=0.028$).

Conclusions. Thus, regular yoga classes under the guidance of qualified staff are a promising method of non-drug rehabilitation of patients with MS with motor disorders. More research is needed to examine the impact of yoga on clinical patient improvement and quality of life indicators.

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Background

Multiple sclerosis (MS) is a progressive, chronic disease of the central nervous system, which manifests itself in various neurological symptoms and their combinations, debuts more often at a young age, and may have different variants of the course. As a result, patients experience temporary or progressive disturbances of movement, walking function, balance, restriction of self-reliance, and a decrease in quality of life. The most common symptoms of multiple sclerosis are muscle weakness and instability in walking, spasticity, pathological fatigue, and other symptoms of CNS lesions may occur at various levels (Scierlo S. 2017). In this regard, MS is one of the frequent reasons for the increased disability length of different age groups of patients. Studies show that more than 65% of patients have trouble moving and up to 85% of patients have gait disorders (Rogers K. 2015). Thus, all MS patients need comprehensive

rehabilitation and for many patients, it is required in the early stages of the disease. There is evidence that physical therapy programs (physical exercises) can improve MS patients' functionality (mobility, walking, endurance) and quality of life (Khan T. 2007, Alphonsus K. 2019, Motl RW. 2020). There is also evidence that more than 60% of patients are willing to use additional approaches to drug treatment, which can include exercise (Miller P. 2017). Among the actively studied methods of physical therapy used in the rehabilitation of patients with MS, there is physical therapy, yoga classes, dance therapy, aerobic exercises, and a combination of these approaches.

The effectiveness of physical therapy has been examined in many studies. A review of 26 randomized trials found a reduction in the risk of aggravation in the group of patients with MS performing exercise compared to the patients without gymnastics (6.3% vs 4.6%), and additionally demonstrated the safety of exercise (Pilutti LA. 2014). Thus, exercises can influence the course of the disease in patients with MS. There is also widely presented in the literature information about the effectiveness of exercise to reduce specific symptoms of MS (Wens I. 2015, Razazian N. 2016). Thus, 45 researches were conducted to study the effects of 69 different types of exercise in 2,250 patients with pathological fatigue in MS (Heine M. 2015). These researches demonstrate the effectiveness of exercise to control the fatigue of patients with multiple sclerosis.

any studies, as well as in the meta-analysis, have obtained data on the effectiveness of yoga in patients with MS on reducing the level of depression, pain, pathological fatigue, bladder dysfunction, postural disorders, and improvement in the quality of life and mobility (Patil N. 2012, Salgado B. 2013, Karbandi S. 2015, Rogers K. 2015, Chobe S. 2016). The safety and efficiency of yoga compared to the non-exercise group of patients are demonstrated in a variety of studies ranging in duration from eight weeks to six months (Cohen E., 2017, Kahraman T. 2018, Nejati S, 2016).

Despite a large number of positive results of using yoga and physical therapy for patients with MS, there are only a limited number of publications, where these methods of non-drug rehabilitation would be compared in a randomized controlled trial (Oken BS. 2004, Razazian N.2016, Garrett M. 2013,).

At the same time, it is obvious that the correct comparison of these methods is of great interest for both researchers and specialists in the rehabilitation of patients with MS. This approach can expand our understanding of the mechanisms of functional disorders during MS and the ways to correct them. As a result, specialists will be able to combine the advantages of different approaches, improving the quality of rehabilitation.

It should also be noted, that contrary to the well-defined physical exercises protocols (Motl RW. 2020, Halabchi F. 2017), in most of the available at the moment studies, there is no detailed description for the performance of yoga protocols, i.e. those complexes of asanas, (special physical exercises), pranayama (breathing exercises) and techniques of mental relaxation, which were offered to patients, as well as the ways of their implementation. We can find an exception only in some articles, where the images and names of poses and the sequence of their performance are given (Guner S. 2015, Kishiyama S. 2002, de Oliveira G 2016, Najafi P. 2017). In other articles, the method of exercise and the use of yoga techniques

are described only in general terms, such as hatha yoga, classical yoga, pranayama, yoga poses, breathing exercises. Typically, the frequency and duration of regular classes, the total number of classes, and the period of research are also specified.

However, our experience of teaching yoga, both in regular classes and for students with specific health problems, including patients with MS shows that for each particular disease or symptom, yoga exercises should be performed according to specially developed techniques. At the same time, each component of this technique: the choice of a set of poses, sequence, duration, and correctness of their performance, plays a crucial role in achieving the goals and is extremely important for ensuring the reproduction, verification, and further practical use of the results.

Therefore, for this study we used B.K.S. Iyengar method of yoga training, which is one of the most recognized, time-tested, and systematic methods of classical hatha yoga (Iyengar B.K.S. 1966.). At the moment, the efficiency of Iyengar yoga has been demonstrated for the treatment of different symptoms, common for patients with MS, such as chronic pain (Crow EM. 2015), depression and anxiety (Scott T. 2019) fatigue (Oken BS. 2004, Bower J. 2012). Our own experience of conducting Iyengar yoga classes for the patients with MS shows, that specially designed complexes of asanas have a beneficial effect on the condition and quality of life of the participants.

In this regard, the main aim of this study is to examine the effect of Iyengar yoga on symptoms (such as walking, balance difficulties) and quality of life in patients with MS, versus physical therapy (exercise therapy) and no exercise.

Methods

Patients.

This study involved adult patients with MS of both genders who had not performed regular physical exercises before. The patients were randomly assigned to 3 groups (yoga, physical therapy, or waiting list), patients from the waiting list had an opportunity to enter the yoga program after the end of the trial period. The observation group (1, 2 or 3) was known to both the patient and the doctor, but it was blinded for the rater. Participants were randomly divided into the yoga, physical therapy, or no exercise group. After 12 weeks of regular exercises (or absence of them), the effect of yoga and physical therapy on the functional status and quality of life of patients were evaluated. The training programs were developed specifically for MS patients. The MS treatment was a part of the routine practice, as prescribed by the treating neurologist. In the event of an exacerbation of MS or for other safety-related reasons (for example, side effects of an exercise), the patients were excluded from the study. The patients signed informed consent and got a patient information leaflet.

Physical methods.

The yoga and exercise classes were held twice a week, for 12 weeks. Each session lasted about 60-75 minutes. The classes were held in a specially equipped hall, using supporting materials, under the guidance of experienced trainers and a trainer assistant. All exercises were performed by the study participants together, in accordance with the detailed instructions of the trainer.

In the exercise group, the class consisted of three parts: 10-15 minutes - a warm-up, which included 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 practiced a special complex consisting of 13 basic and 4 alternative poses described in Appendix 1 and Appendix 2. 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 were also suggested, and basic postures were 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.K.S. Iyengar's book "Clarification of Yoga" by Iyengar.

During the exercises, special attention was paid not only to the time of performance and the correct location of body parts, but also to the correct actions on tension, stretching and relaxation of the muscles of synergists and antagonists, as well as on getting patients' feedback after practicing a posture, increasing awareness and sensitivity of their body and its parts during the exercises. The alteration of activity and rest cycles was also an extremely important condition in the sequence, so that participants did not get tired during the lessons. This is why the sequence involved both more active and more regenerative poses, with alternatives to some postures offered to the participants when fatigue or tension occurred during the main exercise sequences. Throughout the study, the participants were also provided with the illustrated brochures with detailed descriptions and photographic illustrations of the exercises performed (Appendix 2).

Data and statistical analysis.

The data was collected during two visits to the research center: before the study began and at the end of the 12-week follow-up period. The survey on the visits included a doctor's assessment of the EDSS (Expanded Disability Scale Status), the SF-36 quality of life questionnaire, the fatigue scale, the Berg balance scale, the 6-minute walking test.

Descriptive statistics were used to describe demographics and all the data collected in the course of the study. For interval variables, the number of patients for each variable was calculated, the average arithmetic (with a 95% confidence interval on the average, where applicable, and calculating the absolute change relative to the original value), standard deviation, median, minimum and maximum values. For one-order variables, the values of the median, 25- and 75 percent were calculated. For nominal variables, the frequency of categories and confidence intervals for frequencies (95% confidence intervals by the

Klopper-Pearson method) were calculated for each visit in the course of the study. The number of values missed was specified for each variable.

It was planned to use statistical analysis methods, including adjustment with account of the plurality of comparisons. When other methods of statistical analysis were necessary, an additional adjustment to the Bonferroni method was introduced and substantiated.

Statistical analysis was conducted using SPSS/PASW Statistics, SPSS Inc.

Results

The distribution of study participants is presented below (Figure 1). In total, 80 people contacted the organizers of the study. Of these, 61 people were screened and 56 patients with MS were included in the study: 26 in the yoga group, 16 in the PT group and 14 in the waiting list. The remaining 5 people had no neurological symptoms of MS and therefore were not included in the study.

20 patients (11 in the yoga group, 7 in the PT group, and 2 in the waiting list) dropped out before passing the second test (the reasons for dropping out are shown in the table below). The most frequent reasons for dropping out of the yoga group were exacerbation of MS and non-compliance with the protocol, in the PT group – non-compliance with the protocol; 2 patients of the third group dropped out at their own request.

The number and the proportion of patients who successfully participated to the end of the study was 15 (57.7%) in the yoga group, 9 (56.3%) in the PT group and 12 (85.7%) in waiting list ($p=0.157$, Fisher's exact test).

According to the protocol, the endpoint analysis was carried out regarding the patients who had undergone the first and second examination (Per Protocol, PP). The number of the analyzed patients was 36 (15 in the first group, 9 in the second group and 12 in the third group). The results of the scale assessment are presented in the Table 1. Of these, 30 werewomen and 6 were men. The number and proportion (%) of women in the groups was the following: 10/15 (66.7%) in the yoga group, 9/9 (100%) in the PT group and 11/12 (91.7%) in the waiting list. The average age of patients (average \pm standard deviation) was 39 ± 10.4 years in the yoga group, 46.1 ± 11.3 years in the exercise group (PT) and 46.2 ± 10.4 years in the no-exercise group (waiting list); the difference between the averages in the study groups is statistically insignificant (by Student's t-test: (t-test value and df-value) 0,011023 and 40; 0,477188 and 28; 0,010097 and 38). The average MS duration prior to the study was 12.6 ± 8.4 in the yoga group, 18.1 ± 12.3 in the exercise group and 18.5 ± 7.9 in the no exercise group. There were 14 patients with remitting MS, 1 patient with secondary-progressive MS in the yoga group; 6 patients with remitting MS, 2 patients with secondary-progressive MS and 1 patient with primary-progressive MS in the PT group; 7 patients with remitting MS, 5 patients with secondary-progressive MS in the waiting list. At the time of inclusion in the study, 15 (100%) patients in the yoga group, 5 (55.6%) patients in the PT group and 8 (66.7%) patients in the waiting list were taking DMT. The most commonly taken drug was glatyramer

acetate. In second place in frequency was interferon beta-1b. According to the survey on previously done types of exercise, most often, the patients exercised at home or just walked. However, nobody did exercise regularly for rehabilitation purposes. The median of EDSS was 4 points, the same in the yoga and PT groups and 4,5 points in the waiting list group.

Table 1
The results of the scale assessment are presented in the table

	n	Sex (w/m)	Age	RRMS/PMS	MS duration	EDSS, median and min, max
Yoga	15	10/5	39±10.4	14/1	12.6±8.4	4 [2-6]
Exercise	9	9/0	46.1±11.3	6/3	18.1±12.3	4 [2-6, 5]
Waiting list	12	11/1	46.2±10.4	7/5	18.5±7.9	4,5 [2,5-6,0]

There was no statistically significant difference between the groups in terms of improvement in MS symptoms as measured by the balance, walking test and fatigue scales. In the analysis of 8 criteria of SF-36 quality-of-life questionnaire by the covariation analysis (assessment of the influence of the group factor based on time dynamics, Time*Group) statistically significant differences were found in favor of the yoga group in terms of physical functioning (PF) (p=0.003), life activity (VT) (p<0.001), mental health (MH) (p=0.013), social functioning (SF) (p=0.028) (Table 2).

Table 2

In the analysis of 8 criteria of SF-36 quality-of-life questionnaire by the covariation analysis (assessment of the influence of the group factor based on time dynamics, Time*Group) statistically significant differences were found in favor of the yoga group in terms of physical functioning (PF) (p=0.003), life activity (VT) (p<0.001), mental health (MH) (p=0.013), social functioning (SF) (p=0.028)

Outcome measure	Visit	Yoga	Exercise	Waiting list
Berg balance test	Baseline	48,0±8,9	45,9±9,1	46,6±6,8
	12 week	50,5±5,2	46,2±10,7	49,0±6,3
6 minute walking test	Baseline	451,9±119,9	371,2±167,3	379,0±163,0
	12 week	469,5±142,9	392,3±202,1	386,3±158,2
Fatigue scale	Baseline	31,7±6,6	29,0±6,8	29,4±7,6
	12 week	28,4±4,9	27,1±6,2	28,8±4,4
SF-36				
Physical Functioning	Baseline	57,14±25,624	51,67±23,049	57,08±18,885
	12 week	70,00±20,381**	43,33±21,937	51,67±25,346
Role-Physical Functioning	Baseline	28,33±36,433	38,89±43,501	20,83±31,683
	12 week	41,67±37,401	25,00±33,072	25,00±28,204
Role-Emotional Functioning	Baseline	33,333±37,8028	62,956±38,8988	44,442±41,0362
	12 week	55,560±44,8425	62,967±42,3135	44,450±32,8377
Vitality	Baseline	41,43±15,495	45,63±19,353	48,75±20,574
	12 week	61,79±11,866***	49,38±13,479	43,33±17,233
Bodily pain	Baseline	70,833±27,3807	82,500±15,8607	62,292±26,3598
	12 week	75,000±24,3120	80,833±14,0312	56,667±24,9621
General Health	Baseline	45,71±17,744	43,89±8,580	44,17±16,353
	12 week	53,57±11,673	44,44±17,756	46,25±14,790
Social Functioning	Baseline	49,167±21,8899	59,722±22,3413	56,250±16,4282
	12 week	75,833±18,5806*	63,889±26,1041	61,458±23,5116
Mental Health	Baseline	50,00±16,585	60,50±22,162	55,67±21,334
	12 week	68,29±12,982*	59,00±25,545	57,00±14,078

*- p<0.05

**- p<0.01

***- $p < 0.001$

In the course of the study, only 2 patients with UP were registered as having: pain (without clarification) and back pain, both cases in the PT group. There were no side effects during the yoga classes.

Discussion

This study has several unambiguous advantages: the group under research of non-drug rehabilitation (yoga) was compared not only with the control group without exercise, but also with the group treated by the standard method - PT. The sufficient duration of observation (12 weeks) was planned to assess the effect. The focus group may not be fully representative of the general population of patients with MS, but it is close to the population, which is treated by the researched methods (yoga, PT) in routine practice. In addition, there were no demographic restrictions on inclusion in the study. In general, the plan of the study corresponded to its' goals. The main limitations of the plan of this study can be attributed to the relatively small sample size, which reduces the power of the statistical tests. In addition, the planned number of patients (75) was not recruited for organizational reasons, including the introduction of restrictions in connection with the COVID-19 pandemic.

Conclusions

Regular yoga classes under the guidance of qualified staff are a promising method of non-drug rehabilitation of patients with MS with motor disorders. More research is needed to examine the impact of yoga on clinical patient improvement and quality of life indicators.

Abbreviations

CNS: Central nervous system;

DMT: Disease modifying therapy);

EDSS: Expanded Disability Scale Status;

MS: Multiple sclerosis;

PMS: Progressive MS;

PT: Physical therapy;

RRMS: Relapsing remitting MS;

UP: Undesirable phenomenon.

Declarations

Ethics approval and consent to participate

All experimental protocols were approved by a Buyanov City Hospital local ethics committee, (26, Bakinskaya Street, 115516, Moscow; +7 (0)495 322 17 10; gkb12@zdrav.mos.ru), ref: PC-01-18. The date of approval of the study protocol is 19/03/2017.

The informed consent was obtained from all participants of the study.

All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

All participants completed and signed the informed consent form with a consent for publication.

Availability of data and materials

The datasets generated during and/or analysed during the current study are/will be available upon request from Elena Lysogorskaia (kutakovaev@gmail.com).

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

EL performed the neurological examination (blinded rater).

TI was the methodist and PT.

EU was the Methodist and instructor of yoga.

AM and EL made a major contribution to writing the article.

MY and LB managed the project and made a contribution to writing the article.

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Figures

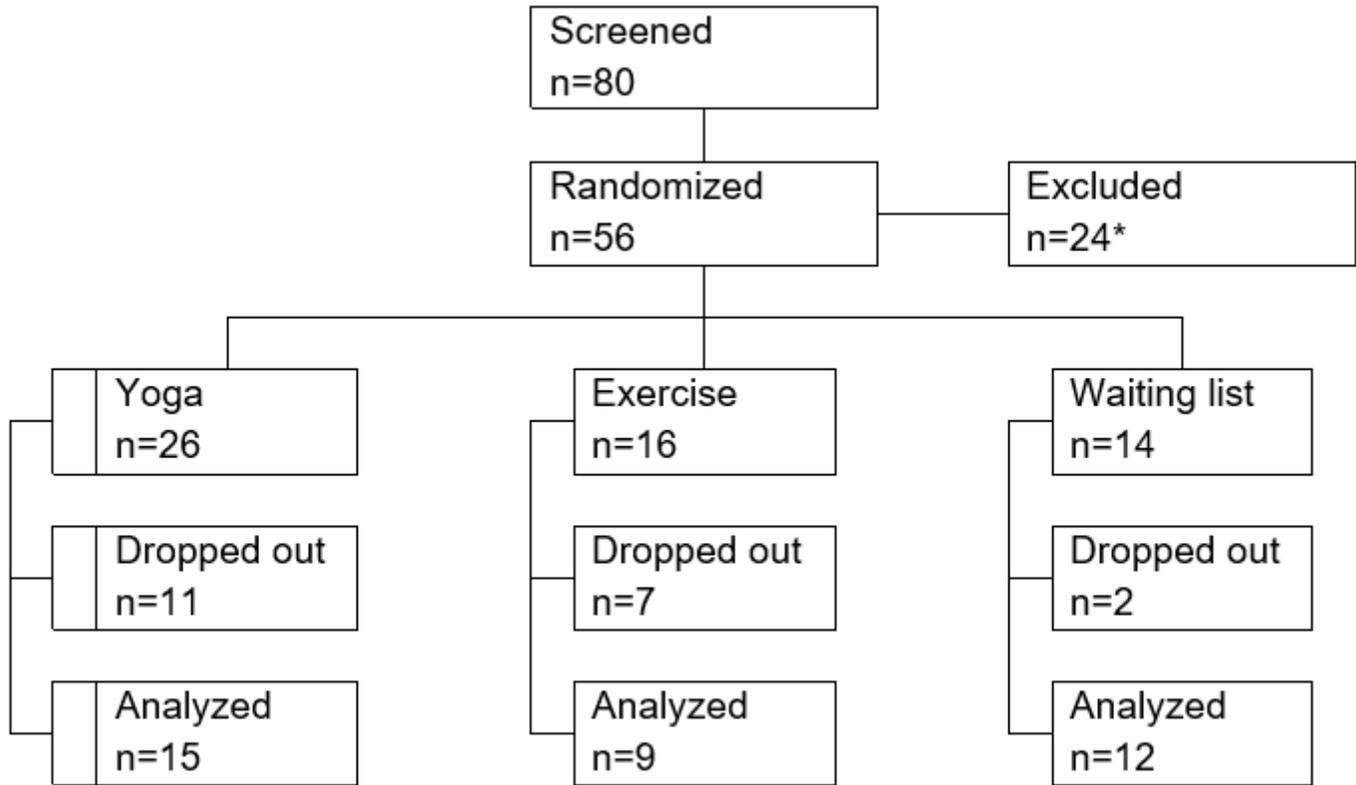


Figure 1

*- 5 patients didn't meet inclusion/exclusion criteria, 12 declined to participate, 7 other reasons.

Supplementary Files

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