

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Mat Pilates and aquatic aerobic exercises for women with fibromyalgia. A protocol for a randomized controlled blind study
AUTHORS	Silva, Hugo Jario de Almeida; Lins, Caio Alano de Almeida; Nobre, Thaiza Teixeira Xavier; de Sousa, Vanessa Patrícia Soares; Caldas, Renata Trajano Jorge; de Souza, Marcelo Cardoso

VERSION 1 – REVIEW

REVIEWER	Stella Peccin Universidade Federal de São Paulo, Brazil
REVIEW RETURNED	19-Mar-2018

GENERAL COMMENTS	The reviewer suggests accepting this paper
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REVIEWER	Neslihan Durutürk Baskent University, Physiotherapy and Rehabilitation Department, Ankara, Turkey
REVIEW RETURNED	20-Mar-2018

GENERAL COMMENTS	<p>General comments: About the manuscript entitled “12-week resistance training using elastic tubing improves muscle strength, exercise capacity and post-exercise creatine kinase clearance in COPD: a randomized control trial” RC-05975</p> <p>The manuscript presents another contribution to the literature about effects of pilates and aquatic exercise training in patients with Fibromyalgia, but some issues have to be raised. The following comments are intended to help the authors improve the quality of the manuscript.</p> <p>Regarding the acceptability, the manuscript needs minor revision. In general it has been planned to compare pilates and aquatic exercises but it is like to compare an apple and pear. Because pilates exercises mostly include strengthening and stretching type exercise but aquatic exercise mostly includes aerobic exercise. And also the effects of aquatic aerobic exercise in FMS has not been improved yet. So you should also include one more control group (also to be a randomised controlled study) and one more combined group.</p> <p>And you should also improve your introduction section by this issue.</p> <p>To improve your outcomes you should also assess the strength of your participants.</p>
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	Your primary outcome measurement is pain severity so you should measure the pain objectively VAS should not be enough to show the pain relief. 6MWT introduction in method section is not enough and please improve and correct this section.
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REVIEWER	Fadime Küçük Okan University-Turkey
REVIEW RETURNED	09-May-2018

GENERAL COMMENTS	It's really well designed and studied article. Congratulations
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REVIEWER	J. Derek Kingsley Kent State University, USA
REVIEW RETURNED	21-Jun-2018

GENERAL COMMENTS	<p>The authors have developed a study that will investigate the effects of Mat Pilates compared to aquatic aerobic exercise, over a period of 12 weeks, on symptoms in women with fibromyalgia. The potential for this study is huge, however a few nuances with this proposed study reduced my enthusiasm.</p> <p>Abstract: If keywords are in the title, adding them here is duplicative. Consider using words that would increase the ability to find them through a search.</p> <p>Page 3, lines 26-32. The authors sometimes use 'Pilates', sometimes 'Mat Pilates', and here on this page and line number use 'mat pilates.' Consistency is key. In this section the authors also use 'FM patients.' However, at this point in time 'FM' has not been defined. Also, I would urge the authors to use the phrase, 'women with FM' and defining them by their disease 'FM patients' labels people by their disease, which I completely disagree with. Please check manuscript throughout for 'FM patients' and fix accordingly.</p> <p>Background</p> <p>-Page 3, line 41. 'FM' is defined in the first sentence, but then the authors use 'fibromyalgia' after this point, which is confusing. Abbreviate the word at the first showing and then use the abbreviation throughout the document. Please address this throughout the manuscript.</p> <p>-Page 5, line 16. Please define what muscles are involved in 'core' strength.</p> <p>Methods</p> <p>-Why was the initial diagnostic criteria used (Wolfe et al. 1990) and not the revised criteria (Wolfe et al. 2010)? It took 20 years to adopt a new, more refined diagnostic criteria, and the research, 18 years later, needs to utilize it.</p> <p>-How do the authors plan to assess reliability and validity of the physician diagnosing the FM? This is why the new criteria are important and why they were revised, as the tender point exam, the old criteria, generates a lot of error bias.</p> <p>-Page 8, line 2-5. Will other known concomitant diseases or conditions be controlled for in this study? Primarily Systemic Exertion Intolerance Disease (formerly chronic fatigue syndrome)? Thyroid issues? Obesity?</p>
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	<p>-If using the old criteria, why were the tender points, and tender point sensitivity, not utilized as dependent variables?</p> <p>-Page 13-Secondary outcome measures. None of these were included in the hypothesis. Therefore, I am confused as to why there were included. None of them are included in the 'Background' section. All of them seem like an afterthought. There must be justification and a purpose for all variables, and that has not been done for any of these.</p> <p>-Table 3. If all of these are addressed at every data collection point, is this Table necessary? I don't feel that it adds anything.</p> <p>Discussion</p> <p>-None of the secondary variables are addressed here either.</p> <p>-Page 18, lines 22-30. This exact same sentence was found earlier in the manuscript. Please revise.</p> <p>Page 18, line 35. 'Adherence to treatment....for chronic musculoskeletal disorders.' However, in the 'Background' section the authors spend a paragraph discussing how the unknown etiology stems from a central nervous system dysfunction (page 4, lines 6-12). There has been no mention of this being a musculoskeletal disease until now. How can the authors justify this?</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewers' Comments to Author:

Reviewer: 1

Reviewer Name: Stella Peccin

Institution and Country: Universidade Federal de São Paulo, Brazil

Competing Interests: None declared

The reviewer suggests accepting this paper

Reviewer: 2

Reviewer Name: Neslihan Durutürk

Institution and Country: Baskent University, Physiotherapy and Rehabilitation Department, Ankara, Turkey

Competing Interests: none

General comments:

About the manuscript entitled "12-week resistance training using elastic tubing improves muscle strength, exercise capacity and post-exercise creatine kinase clearance in COPD: a randomized control trial" RC-05975

We believe the reviewer was wrong about the study title. This is not a title.

The manuscript presents another contribution to the literature about effects of pilates and aquatic exercise training in patients with Fibromyalgia, but some issues have to be raised. The following comments are intended to help the authors improve the quality of the manuscript.

Regarding the acceptability, the manuscript needs minor revision.

In general it has been planned to compare pilates and aquatic exercises but it is like to compare an apple and pear. Because pilates exercises mostly include strengthening and stretching type exercise but aquatic exercise mostly includes aerobic exercise. And also the effects of aquatic aerobic exercise in FMS has not been improved yet. So you should also include one more control group (also to be a randomised controlled study) and one more combined group.

And you should also improve your introduction section by this issue.

To improve your outcomes you should also assess the strength of your participants.

Your primary outcome measurement is pain severity so you should measure the pain objectively VAS should not be enough to show the pain relief.

6MWT introduction in method section is not enough and please improve and correct this section.

Dear reviewer, we appreciate your comments to improve our study.

It is different to compare pilates and aerobic aquatic exercise, it does not look like apple and pear. As you yourself mentioned, the pilates exercises mostly include strengthening and stretching type exercise but aquatic exercise mostly includes aerobic exercise.

This is the proposal of this protocol, comparing two modalities of exercises, one that focuses on strengthening / stretching with another that focuses only on the aerobic. Some references show us that aqua aerobic exercise is good for fibromyalgia (Assis MR, Silva LE, Alves AM, Pessanha AP, Valim V, Feldman D, et al. A randomized controlled trial of deep water running: clinical effectiveness of aquatic exercise to treat fibromyalgia. *Arthritis Rheum.* 2006 Feb 15;55(1):57-65.)

We chose not to assess the strength of the study participants, since the water exercise group will not perform any specific strength training, however we believe it may improve because of water resistance, but this is not an important clinical outcome in isolation.

We agree that VAS is not the most reliable measure of pain, but unfortunately we are not in a position (money) to have an algometry device that objectively assesses pain.

The 6MWT introduction in method section has been corrected.

Reviewer: 3

Reviewer Name: fadime küçük

Institution and Country: Okan University-Turkey

Competing Interests: None declared

It's really well designed and studied article. Congratulations

Reviewer: 4

Reviewer Name: J. Derek Kingsley

Institution and Country: Kent State University, USA

Competing Interests: None declared

The authors have developed a study that will investigate the effects of Mat Pilates compared to aquatic aerobic exercise, over a period of 12 weeks, on symptoms in women with fibromyalgia. The potential for this study is huge, however a few nuances with this proposed study reduced my enthusiasm.

Abstract: If keywords are in the title, adding them here is duplicative. Consider using words that would increase the ability to find them through a search.

The words have been changed to improve the search.

Page 3, lines 26-32. The authors sometimes use 'Pilates', sometimes 'Mat Pilates', and here on this page and line number use 'mat pilates.' Consistency is key. In this section the authors also use 'FM patients.' However, at this point in time 'FM' has not been defined. Also, I would urge the authors to use the phrase, 'women with FM' and defining them by their disease 'FM patients' labels people by

their disease, which I completely disagree with. Please check manuscript throughout for 'FM patients' and fix accordingly.

It was standardized throughout the text "women with FM 'as suggested by the reviewer. The term "mat pilates" has been standardized throughout the text.

Background

-Page 3, line 41. 'FM' is defined in the first sentence, but then the authors use 'fibromyalgia' after this point, which is confusing. Abbreviate the word at the first showing and then use the abbreviation throughout the document. Please address this throughout the manuscript.

The abbreviation FM was used throughout the document.

-Page 5, line 16. Please define what muscles are involved in 'core' strength.

Add in the manuscript

Methods

-Why was the initial diagnostic criteria used (Wolfe et al. 1990) and not the revised criteria (Wolfe et al. 2010)? It took 20 years to adopt a new, more refined diagnostic criteria, and the research, 18 years later, needs to utilize it.

-How do the authors plan to assess reliability and validity of the physician diagnosing the FM? This is why the new criteria are important and why they were revised, as the tender point exam, the old criteria, generates a lot of error bias.

We agreed with the reviewer, we talked to the rheumatologist in our city, and they will apply the ACR 2010 method. In the study design we had put the 1990 criteria because they made the sample more homogeneous and still be used in scientific studies. The new 2010 criteria are important criteria in CLINICAL PRACTICE but not always the most reliable when it comes to scientific research. But understanding this, rheumatologist doctors will use the 2010 criteria and the reference has been changed.

-Page 8, line 2-5. Will other known concomitant diseases or conditions be controlled for in this study? Primarily Systemic Exertion Intolerance Disease (formerly chronic fatigue syndrome)? Thyroid issues? Obesity?

Participants will perform a medical evaluation with a rheumatologist who specializes in soft tissue rheumatism. However, if they present such diseases they will be excluded from the study. These diseases were added to the exclusion criteria. Thanks for your suggestion.

-If using the old criteria, why were the tender points, and tender point sensitivity, not utilized as dependent variables?

The 2010 criteria will be used.

-Page 13-Secondary outcome measures. None of these were included in the hypothesis. Therefore, I am confused as to why there were included. None of them are included in the 'Background' section. All of them seem like an afterthought. There must be justification and a purpose for all variables, and that has not been done for any of these.

All of these secondary outcomes are used in fibromyalgia studies. In the introduction only the primary endpoint was erroneously placed. As requested by the reviewer, we added the secondary outcome measures in the introduction.

-Table 3. If all of these are addressed at every data collection point, is this Table necessary? I don't feel that it adds anything.

The table presents a summary of the data that will be collected, presented in a summarized and didactic way. Other protocol studies present the same table, in other articles in the journal itself. We would kindly request that the table be maintained.

Discussion

-None of the secondary variables are addressed here either.
Add in the manuscript

-Page 18, lines 22-30. This exact same sentence was found earlier in the manuscript. Please revise. This is the justification and high point that serves as the basis for developing our protocol, to make it clear to the reader why we have decided to do the study. Pilates in soil is very well known and recommended but there is almost no study on the subject.

Page 18, line 35. 'Adherence to treatment...for chronic musculoskeletal disorders.' However, in the 'Background' section the authors spend a paragraph discussing how the unknown etiology stems from a central nervous system dysfunction (page 4, lines 6-12). There has been no mention of this being a musculoskeletal disease until now. How can the authors justify this?
Although fibromyalgia involves the central nervous system, the patient presents with symptoms of generalized and chronic musculoskeletal pain, so it is also considered a rheumatic disorder with origin not yet fully elucidated but with changes in the pain system.

VERSION 2 – REVIEW

REVIEWER	Neslihan Durutürk Baskent University, Turkey
REVIEW RETURNED	26-Jul-2018

GENERAL COMMENTS	The manuscript is acceptable in this form
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REVIEWER	J. Derek Kingsley Kent State University, USA
REVIEW RETURNED	24-Jul-2018

GENERAL COMMENTS	<p>This revised manuscript is an improvement over the original, and the authors should be proud of their work. However, I have a few suggestions, that will further strengthen this manuscript.</p> <p>-Page 32, lines 7, and 21. Here the authors just use 'FM'. Again, 'women with FM' although may sound redundant, it is important as these women are more than just their disease, correct?</p> <p>-Page 32. First paragraph. Here is where including literature on sleep and women with FM needs to be discussed in order to setup the hypothesis.</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewers' Comments to Author:

Reviewer: 2

Reviewer Name: Neslihan Durutürk

Institution and Country: Baskent University, Turkey

Please state any competing interests or state 'None declared': None

The manuscript is acceptable in this form

Answer: Thank you.

Reviewer: 4

Reviewer Name: J. Derek Kingsley

Institution and Country: Kent State University, USA

Please state any competing interests or state 'None declared': None declared

This revised manuscript is an improvement over the original, and the authors should be proud of their work. However, I have a few suggestions, that will further strengthen this manuscript.

-Page 32, lines 7, and 21. Here the authors just use 'FM'. Again, 'women with FM' although may sound redundant, it is important as these women are more than just their disease, correct?

Answer: This has been adjusted in the text.

-Page 32. First paragraph. Here is where including literature on sleep and women with FM needs to be discussed in order to setup the hypothesis.

Answer: Our hypothesis is that the Mat Pilates method can also bring benefits for improving pain in women with FM, similar to aquatic aerobic exercise. The secondary objectives of the study are to compare the impact of disease, functionality and performance, sleep quality and quality of life in women with FM who perform two different exercise modalities. We believe that a discussion of secondary goals will be more important when we get the results of the study.