PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Effects of a mindfulness- and acceptance-based group-programme followed by physical activity for patients with fibromyalgia: a randomised controlled trial
AUTHORS	Haugmark, Trond; Hagen, Kåre; Provan, Sella; Smedslund, Geir; Zangi, Heidi

VERSION 1 – REVIEW

REVIEWER	Paolucci, Teresa Università G D'Annunzio di Chieti
REVIEW RETURNED	22-Dec-2020

GENERAL COMMENTS	no comments

REVIEWER	Larsson, Anette University of Gothenburg, Department of health and rehablitation, Physiotherapy
REVIEW RETURNED	24-Jan-2021

GENERAL COMMENTS	This is an RCT study, well conducted and following the Guidelines in Consort statement.The authors are to be congratulated with an interesting trial investigating the effects of a mindulness- and acceptance based group programme followed by physical activity for patients with recently diagnosed fibromyalgia. The paper is interesting for the readers of the journal. However I have a few concerns: 1. What is treatment as usual? Since we do not know what that is or what this group recieved, it might be better to refer to that the control group recieved "no treatment or any other treatment". 2. It is not clear if there was only counselling about physical activity or if the patients had supervised physical activity. In the abtract it says supervised physical exercise, in the aim it is physical activity counselling, and in procedure it is unclear what the patients actually recieved. Please clarify. 3. In results: the intervention group had a significantly higher age and symptom duration, not slightly. Please add p-values. 4. 32 patients attended the physical activity intervention. Did these patients differ in any baseline characteristics or outcome variables compared to the group that did not attend? How many patients actually completed the intervention? How does the fact that so few actually recieved the intended physical activity intervention affect your results? Why is it that so few attended the physical activity

	intervention? This needs to be discussed in more detail in the discussion section. 5. Twelve of the patients that attended the physical activity intervention reported adverse effects. Do you have any knowledge about what the patients recieved during their physical activity intervention, or about the level of pre-understanding in how to adjust physical activity for patients with musculoskeletal pain among the health care providers that delivered the intervention? There are several earlier studies showing that individually adjusted exercise is beneficial for patients with FM. Would the results in your study be different if the patients had recieved individually adjusted physical activity delivered by healtcare professionals with knowledge about FM? 7: Did you make adjustments for multiple comparisons?

REVIEWER	De Silvestri, Annalisa Foundation IRCCS Polyclinic San Matteo
REVIEW RETURNED	07-Apr-2021

GENERAL COMMENTS	This is an interesting paper but some points need to be clarified why randomization list are separately created for each site instead a unique list stratified by centers? How balancement between treatments is maintained in presence of differential enrolment between centers? Authors declare an ITT analyses of all the randomized paper (85 per group) but they analysed only 76 and 77 patients at 12 months Please report median PGIC at 3 and 12 months in the two groups to improve reasibility how differences in age and disease duration between groups could have affected the results?

VERSION 1 – AUTHOR RESPONSE

1. What is treatment as usual? Since we do not know what that is or what this group received, it might be better to refer to that the control group received "no treatment or any other treatment".	Thank you for this suggestion. We agree that “treatment as usual” might be misleading if not explained. We did not monitor any other treatments than physical activity and realise that the control group might have initiated other treatments as well. We have therefore added an explanation in the abstract and in the	P. 2, line 32,33 P. 5, line 106

	manuscript; «The control group received treatment as usual, i.e. no treatment or any other treatment of their choice”.	

2. It is not clear if there was only counselling about physical activity or if the patients had supervised physical activity. In the abstract it says supervised physical exercise, in the aim it is physical activity counselling, and in procedure it is unclear what the patients actually received. Please clarify.	Thank you for this comment. We agree that we have been unclear in our description and realise that we have been using these terms inconsequently. We have therefore changed to “physical activity counselling” throughout the text in accordance with the term we used in our study protocol. All patients were offered physical activity counselling by a physiotherapist at three time points during the 12-weeks; before the start-up, after 6 weeks and at the end of week 12. The aim was to set individual goals and plan the activity and participation level in mutual collaboration between the patient and the physiotherapist. The Healthy life centres typically offer individual and group physical activity indoors or outdoors, and what the patients actually received varied. A limitation in our study is that we did not receive a complete report on what type of physical activity the patients actually performed. We have added a sentence about this in the Discussion section.	P. 2, line 32 P. 7, line 145 P. 17, line 323 P. 21, line 438 P. 18, line 368
3. In results: the intervention group had a significantly higher age and symptom duration, not slightly. Please add p-values.	Thank you for this observation. We have changed this sentence to “significantly higher” and added the p-values.	P. 12, line 259, 260
4. 32 patients attended the physical activity intervention. Did these patients differ in any baseline characteristics or outcome variables compared to the group that did not attend? How many patients actually completed the intervention? How does the fact that so few actually received the intended physical activity intervention affect your results? Why is it that so few attended the physical activity intervention? This needs to be discussed in more detail in the discussion section.	Thank you for this comment In our study protocol, we did not pre-define how many times the patients needed to attend a physical activity session at the HLC. As mentioned in comment number 2, a limitation in our study is that we did not receive a complete report on how many times each patient attended the HLC and what type of physical activity they actually performed. Some patients attended a few hours with counselling and then continued the activities on their own. Of the 32 patients, only 14 participated 12 times or more during the 12-week period. We have now specified the number of participants who participated more than 12 times in the text. Because the 32 patients attended the HLC different number of times and implemented various types of activities, we consider that it will be of uncertain	P. 13, line 270, 271

	value to compare baseline characteristics or outcome variables between this group and the patients who did not attend. It is possible that low adherence to the physical activity intervention have had an impact on the results. This is now discussed in more detail in the Discussion section.	P. 18, line 364
5. Twelve of the patients that attended the physical activity intervention reported adverse effects. Do you have any knowledge about what the patients received during their physical activity intervention, or about the level of preunderstanding in how to adjust physical activity for patients with musculoskeletal pain among the health care providers that delivered the intervention? There are several earlier studies showing that individually adjusted exercise is beneficial for patients with FM. Would the results in your study be different if the patients had received individually adjusted physical activity delivered by healthcare professionals with knowledge about FM?	Thank you for this comment. As mentioned in comment 2 and 4, the report on what type of physical activity the patients attended was incomplete and varied greatly, we do not know the specific type of physical activity the patients received during the physical activity intervention. All included patients attended a 3-hour patient education programme where graded physical activity was one of the topics. In addition, we visited each HLC and provided the physiotherapists with information about the intervention and the importance of individually adjusted physical exercises for patients with FM. Thus, patients and physiotherapists received the same information regarding physical activity before study start. We do not monitor if and how they followed the advice and how compliant they were during the study period. We have added a paragraph about this issue in the Discussion section.	P. 18, line 363-371
(No 6) 7: Did you make adjustments for multiple comparisons?	We have not adjusted for multiple comparisons. We have included this as a limitation in the Discussion section.	P. 21, line 434
Reviewer: 3		
This is an interesting paper, but some points need to be clarified why randomization list are separately created for each site instead a unique list stratified by centres? How balancement between treatments is maintained in presence of differential enrolment between centres?	Thank you for this comment. We agree that randomization could have been performed as you suggest. We did not perform randomization by centre, but in two geographical areas. We conducted the RCT in Oslo and Øvre Romerike, including both urban and rural communities. The VTP courses were held in parallel with each other in central locations in the two geographical areas. The reason for this organization was that patients should have access to VTP in their immediate area and avoid traveling longer than necessary.	

	The recruitment strategy was equal in both areas and the distribution of the patients from the two areas was balanced towards the end of the recruitment.	
Authors declare an ITT analyses of all the randomized paper (85 per group) but they analysed only 76 and 77 patients at 12 months Please report median PGIC at 3 and 12 months in the two groups to improve reasibility how differences in age and disease duration between groups could have affected the results?	Thank you for this comment. All 170 patients; 85 in each arm was included in the ITT analyses and retained their randomization group throughout the study period. The reason for the numbers 76 and 77 is that 9 patients in the intervention group and 8 patients in the control group dropped out and did not respond to the questionnaires at 12 months follow-up. The flow-chart, figure 1. included in the manuscript further explains the patients' flow throughout the study. We have now added the median at 3 and 12 months in both groups. We cannot rule out the possibility that a higher median age and a longer symptoms duration in the intervention group compared to controls may have affected the results. In accordance with our study protocol, we did not perform any sub-group analyses to further explore this.	P. 14, line 280, 281

VERSION 2 – REVIEW

REVIEWER	Larsson, Anette University of Gothenburg, Department of health and rehablitation, Physiotherapy
REVIEW RETURNED	15-Jun-2021

GENERAL COMMENTS	The authors have adressed all suggested points made in the first revision. I have no further comments. Thank you for an interesting and well written manuscript that will add to the knowledge of how to treat fibromyalgia.

REVIEWER	De Silvestri, Annalisa Foundation IRCCS Polyclinic San Matteo
REVIEW RETURNED	08-Jun-2021

GENERAL COMMENTS	The manuscript is now fine for me