Author’s response to reviews

Title: Which aspects of health differ between working and nonworking women with fibromyalgia? - A cross-sectional study of work status and health

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Author’s response to reviews:

We would like to thank the editor and the reviewers for giving us the opportunity to revise our manuscript. The revisions are highlighted in yellow in the manuscript.

We would like to thank reviewer 1 for valuable comments

Comments from reviewer 1:

1. Abstract (Background) & Background (of body text): It is stated that “there is no line of division that defines when subjective health problems develop into obstacles for activity and work participation”, suggesting that the current study might clear this issue. However, as indicated in the Discussion and by other researchers (e.g., Reisine et al., 2008), a cross-sectional study investigating health between working and non-working patients could not distinguish between ‘cause and effect’.

Response: The wording of this sentence is now changed in the Abstract and in the Background (page 4) to: “However, it is difficult to define to which extent symptom severity can be compatible with work.”

2. Measures: In addition to the ‘personal factors’, there were 23 dependent variables which might differ between the 129 patients. A p-value of .05 and also .01 is too large to avoid type I errors. So, effort should be undertaken to improve the power of this study by either increasing the sample size or a further reduction of the p-value.

Response: The number of analyses has been reduced due to suggestions from reviewer 3 to exclude subgroup analyses from the study.

The calculation of risk of possible type 1 errors has been added to the section “statistics” on page 8: “To control possible Type I errors, the upper limit of expected number of false significances for the analyses was calculated by the following formula: #/1– # × (number of tests – number of significant tests), where
The result of the type 1 error calculation has been added in the Results section on page 9: "Type I error. The between-group analyses comprised a total of 33 statistical analyses, with 11 significant values at significance level 0.01, and the upper level of number of false significances was 0.2, which indicates that 0-1 significances found might be false."

3. Statistical analysis: The Mann-Whitney U test should only be used to test differences between groups of variables with a non-normal distribution. It should be mentioned which variables had a non-normal distribution and in these cases medians instead of means should be reported in the Tables 1 and 2.

To my opinion, the univariate binary logistic regression analyses are not necessary here as group differences for each of the variables are already examined with other tests (with some more appropriate because of a non-normal distribution).

Response: When planning statistical method for group comparisons, one has to choose between parametric or non-parametric methods. T-test is the most powerful test, while the Mann Whitney U test is more robust and almost as powerful. However, we regard Mann Whitney as a more safe method, and prefer to use it. We tested the variables for normality, and found that for 6 of the total of 33 variables the hypothesis of normality was not rejected. This doesn’t mean that we know that the distribution of the variables is normally distributed. If the distribution of the variables are not normally distributed we can’t trust the p-values from the t-test. We performed the t-test on the normally distributed variables and the results showed exactly the same significance value as the results from the Mann Whitney U test in these variables. Therefore, calculation with the t-test in these variables would not add any new information, why we choose to present the Mann Whitney U test for all variables as previously, being consistent throughout our analyses.

Medians and ranges are now added for all variables applicable in Table 1 and 2.

Thank you for pointing out the unnecessary presentation of the univariate logistic regression analysis. It has now been omitted from the manuscript and the Table 3 has been removed from the manuscript. The results from the stepwise multiple logistic regression analysis is presented in text on page 10: "Stepwise multiple logistic regression analyses. Variables displaying a significant difference (p<0.010) between WW with FM (n=53) and NWW with FM (n= 76) were included in stepwise multiple logistic regression analysis. FIQ pain (n=128) was the only statistically significant variable to independently explain work (OR 0.95, CI 0.93- 0.98), p<0.001, (AUC 0.75, CI 0.66- 0.83)."

4. Discussion: The discussion contains new findings of the current study, which should be avoided. In addition, only a selection of the findings is discussed and no attempt is taken to integrate the findings.

Furthermore, the discussion of the findings and of the implications of the findings
is very superficial. A paragraph on the limitations of the study is lacking.

Response: We are aware that we mentioned the difference in 6 minute walk test in meters, between full-time and part-time workers, as the latter showed a better capacity, however this result is omitted from the text since subgroup analyses are removed from the manuscript according to reviewer 3 suggestions.

We have focused Discussion on key results. We have now omitted following parts: parts of the discussion relating to subgroup results and the section relating to physical activity due to reviewer 3 suggestions. The discussion is therefore condensed to some extent, while effort has been taken to deepen the discussion to include more findings, integrate findings and implications of the findings. The following developments have been made:

Page 11: “The main finding in this study was that working women (WW) with FM displayed better ratings than nonworking women (NWW) with FM in terms of pain, fatigue, stiffness, depression, disease specific health status and physical health related quality of life, which represent body functions and overall health status.”

Page 11: “Physical capacity did not differ significantly between WW and NWW in terms of performance-based tests (see Table 2) where both groups presented lower capacity than the average population [22, 23]. This supports earlier studies showing impaired body function in women with FM [4, 31]. However, the physical work demands might influence the work ability in persons who have an impaired physical capacity. Earlier studies have reported the importance of the work environment in women with FM [8, 32-36] and in other rheumatic diseases [37].”

Page 11: “The number of pain localizations was significantly lower in WW than in NWW and global pain (FIQ pain) was significantly milder in WW than in NWW (see Table 2).”

Page 12: “Some women appear to be able to work despite severe pain, which raises the question if there are workplace related factors that support their ability to work [36, 40].”

Page 12: “Global fatigue (FIQ fatigue) was found to be significantly lower in WW than in NWW as well as physical fatigue (MFI-20), reduced activity (MFI-20), and mental fatigue (MFI-20) (see Table 2).”

Page 12: Depression was rated significantly lower in WW than in NWW in the HADS, assessing depression. This supports the results of an earlier study on work disability in FM reporting the negative impact of depression symptoms on work ability [41].

Page 12: “WW displayed a significantly better disease specific health status (FIQ total, eight-item) than NWW (see Table 2). This supports the results from an earlier study on work disability in FM where the FIQ total score was found to predict work disability [6].”

We have included a paragraph about limitations on page 13: “A limitation of this study is the cross sectional design which does not allow analyses of cause and effect. Also, the specific demands in work were not reported in the study and need further investigation.”
1. The introduction starts with the 1990 ACR criteria for fibromyalgia. However, new criteria have been published in 1990, see Wolfe et al. in Arthritis Care Res 62;600-610.

Response: Yes, we use ACR 1990 criteria for recruitment of patients. New criteria suggested by Wolfe at 2010 were not available when the patients were examined.

2. Abstract (Conclusion) & Discussion (of body text): These sections contain new findings of the current study, which are not described in the Results section. This should be avoided.

Response: We have now included reference to Tables where results are presented in Results and Discussion, to help the reader to find the results discussed.

3. Methods, Participants: ‘Working full-time’ and ‘working part-time’ are not defined and neither is described what reasons people had to work part-time or not at all, although it is stated that “part-time workers and non-workers received disability benefits”. However, there might also be people who do not want work and therefore do not receive disability benefits, for example, in order to take care of the children.

Response: We have once more scrutinized our data, and clarified the definitions of the categories of work is now included on Page 5: “The study population was divided into two groups according to work status; WW (25-100%) and NWW (0%). The WW included 13 full-time workers (80-100%), 13 part-time workers working less than 50% (25-49%), 17 part-time workers working 50%, and 10 part-time workers working 50% or more (50-75%). Thirty-seven part-time working women received disability benefits while three did not. All NWW received disability benefits.”

4. Methods, Measures: The descriptions are a bit chaotic since the measures themselves and the order of the measures are not consistent across the text and tables. Other remarks about Table 1 and Table 2:

Response: The order of the measures is restructured to be consistent in methods and Tables. Also, in addition to the headings of categorization of measures, we have referred to the Table where the results are presented.

The FIQ subscales are clarified and presented in the measures section according to ICF (International Classification of Function, Disability and Health) to be consistent with Tables 1 and 2. On page 6: “The Fibromyalgia Impact Questionnaire (FIQ) is disease specific and comprises ten subscales of disabilities and symptoms ranging from 0 to 100. A higher score indicates a lower health status [29]. The subscale FIQ feel good is presented as a personal factor according to the ICF [26].”

On page 7: “The Fibromyalgia Impact Questionnaire (FIQ) is disease specific and
The Fibromyalgia Impact Questionnaire (FIQ) is disease specific and comprises ten subscales of disabilities and symptoms ranging from 0 to 100. A higher score indicates a lower health status [29]. The subscales FIQ pain, FIQ fatigue, FIQ morning tired, FIQ stiffness, FIQ anxiety, and FIQ depression are presented as factors of body function according to the ICF [26].

On page 7-8:

“The Fibromyalgia Impact Questionnaire (FIQ) is disease specific and comprises ten subscales of disabilities and symptoms ranging from 0 to 100. A higher score indicates a lower health status [29]. The subscale FIQ physical function is presented as a factor of activity and participation according to the ICF [26].”

a. Table 1: according to the title, this table includes ‘contextual factors, but according to the first line it includes ‘personal factors’; in addition, it does not contain ‘environmental factors’, although announced in the text; the ‘FIQ feel good’ score is a bit strange in this table; it is unclear why educational level is divided into # 9 years and 10-12 years and the percentages for this variable do not count up to 100%; there is no information on household income, as was announced in the text.

Response: The term “contextual factors” involves both personal and environmental factors, according to the ICF classification system. However, to clarify the categorization of data for the reader, the term “contextual” is removed and replaced with “personal- and environmental factors”.

The layout of Table 1 and 2 has now been modified so that it fits into one single page, which is anticipated to clarify its contents to the reader.

Considering FIQ feel good, the FIQ has previously been analyzed according to the ICF classification system [19] and the subscales are presented accordingly.

b. Table 2: there is no information on social support, although announced in the text; there are only 7 FIQ subscales in the table instead of the 8 announced in the text; it is unclear why ‘MFI reduced activity’ is not classified in the ‘Activity and participation’ category; it is unclear why subscales of the SF-36 are not used.

Response: Social support (MOS-SSS) is presented in Table 1 as it is an environmental factor according to the ICF.

The eighth subscale is FIQ feel good, which is presented in Table 1 as a personal factor.

MFI20 has earlier been analyzed according to the ICF classification system [19], where MFI20 mainly involved measures of body function. We have followed this categorization. Please see page 7.

We chose to only use the component scores for SF36, which is a generic questionnaire, giving an index for physical and mental quality of life. Subscales of SF36 are not used due to an excess of variables.

c. Tables 1 & 2: the significance of the difference between group 1 and 2 is lacking, but interesting; differences between groups should be corrected for
differences (at least) in age between the three subgroups!
Response: All subgroup analyses are now omitted, due to suggestions from reviewer 3. Please see Table 1 and 2.
Differences between groups are not corrected for differences in age between the groups since there were no differences in age between the groups.

d. Tables 1 & 2: I recommend removing the combined scores of the working group and showing exact p-values here and not in the text.
Response: To clarify the main analysis of the study, we have omitted the subgroups and subgroup analyses in text and Tables, due to suggestions from reviewer 3.
Table 1 and Table 2 now display exact p-values for all variables.
e. Tables 1 & 2: all abbreviations (thus also ‘yrs’, ‘m’, ‘N’, ‘nr’, etcetera) should be explained below the tables.
Response: Abbreviations are now clarified in the Tables.

5. Results, Study population: The number of tender points and the pain threshold for the three groups are not reported as are the statistics regarding the group differences for these variables.
Response: Tender points and pain threshold were regarded as demographic data to describe the group, and not chosen for outcome variables.

6. Results, Body function: The results are a bit chaotic since the order of the measures is not consistent across the text and tables. In addition, some results are lacking in the text (e.g., FIQ morning tired), whereas others are lacking in the table (e.g., FIQ depression).
Response: Effort has been taken to clarify the results. All the results are presented in Tables. In the text we have summarized the significant differences, see Result section on page 9-11.

a. Background: Ref 8 and Ref 9 are identical.
Response: Thank you for noticing this. Identical references are now corrected.

b. Methods, Participants: an error occurred since 154-22-12-18=102 and 102+65=167 instead of 168 participants in the study.
Response: Thank you for noticing this. The numbers have been scrutinized and the error has been corrected. The section has also been condensed for clarification of patient flow on page 4-5: “Women with FM were recruited to an experimental study [15] from three primary health-care centres in West Sweden by systematic search of patient journals and by consecutive recruitment. The inclusion criteria were women who were 18-60 years of age and suffered FM according to the American College of Rheumatology (ACR) criteria for FM [1]. The search patient journals found 298 potentially eligible women who were
contacted by post (n = 55) or telephone (n = 243) for further screening. Forty-eight women could not be contacted, 55 did not meet inclusion criteria at telephone screening, and 61 declined to participate in the study, while 134 agreed to participate in an examination. Twenty-three of them did not meet inclusion criteria at examination, 17 were excluded due to; treatment in progress (n = 3), severe disorders (n = 9) or unemployment (n=5) and 18 declined to participate. At the same time, 93 women were consecutively recruited to the study. Fifty-three of them fulfilled inclusion criteria and agreed to participate in the study. A total of 129 women with FM formed the study population.”

We would like to thank reviewer 2 for valuable comments

Comments from reviewer 2:
1. Page 4, line 19. Please define the abbreviation CWP
   Reply: Thank you for noticing this. The section on participants on page 4-5 has now been condensed for clarification purposes and the term CWP has been omitted from the text: “Women with FM were recruited to an experimental study [15] from three primary health-care centres in West Sweden by systematic search of patient journals and by consecutive recruitment.”
2. Page 5, line 8.
   Please clarify the statement "women who were unemployed in terms of being available for work" - Were these women who were willing and able to work, but had not been able to find an employment position for other reasons?
   Response: Your interpretation is correct and we have chosen to simplify the statement and describe it as “unemployment”. Also the sentence has been modified and included among the exclusion reasons on page 4: “Twenty-three of them did not meet inclusion criteria at examination, 17 were excluded due to; treatment in progress (n = 3), severe disorders (n = 9) or unemployment (n=5) and 18 declined to participate”
3. Page 5, line 11.
   Please explain "part-time" in terms of how many days or hours per week worked.
   Response: Thank you for this suggestion. A paragraph on work status in terms of percentage of work is now included on page 5: “The study population was divided into two groups according to work status; WW (25-100%) and NWW (0%). The WW included 13 full-time workers (80-100%), 13 part-time workers working less than 50% (25-49%), 17 part-time workers working 50%, and 10 part-time workers working 50% or more (50-75%). Thirty-seven part-time working women received disability benefits while three did not. All NWW received disability benefits.”
4. Page 6, line 20. Please define "ICF"
   Response: Thank you for noticing this fault. ICF is now defined on page 5, in the section Data collection: “Aspects of health are presented according to the International Classification of Function, Disability and Health (ICF) [17].”
5. Page 8, line 19. Please consider adding "mean" to the phrase describing tender point count and pain threshold if that is what the values represent.

Response: Thank you for noticing this. "mean" is now added on page 9, in the Results section, Study population paragraph.

1. Do you have any comment or theory as to why non-working subjects had a higher level of self-reported limitation to their physical function than working subjects, although there was no difference between these groups when measured with objective tests of physical capacity?

Response: Thank you for this very interesting point of suggestion. However, this part of the result is excluded since the level of significance for the result is too high (p=0.013), as suggested from reviewer 3.

We would like to thank reviewer 3 for valuable comments.

Comments from reviewer 3:

a. The purpose of the study was to investigate which aspects of health differ between working and nonworking women with fibromyalgia. With this rationale, why the authors divided the sample in three groups? Perhaps, it would be preferable to group working patients in a single category. This would clarify the results and would facilitate the statistical analysis. If the authors have considered the working conditions as important, it would be specified not only the time of dedication at work (full-time or partial-time), but also, the specific demands in job. This limitation has to be considered.

Response: This is correct, the main objective of this study is to analyze differences between two groups, namely the working and the non-working women. To clarify this, we have chosen to omit the subgroups and the subgroup analyses as you suggest. The study now only includes working and non-working women.

A paragraph on limitations has been added on page 13: “A limitation of this study is the cross sectional design which does not allow analyses of cause and effect. Also, the specific demands in work were not reported in the study and needs further investigation.”

b. I have supposed that the level of significance of p<0.01 has been considered with the purpose to reduce the probability of type I errors. Nevertheless, in tables 1 and 2, p<0.05 were presented. The authors have to correct this point.

Also, using the cut-off criteria of p<0.01, the p-value of p=0.013 would not be significant (see in Results the paragraph “activity and participation”).

Response: Exact p-values are now displayed for all variables in Table 1 and Table 2 and p-values <0.01 are shown in bold type. The results of activity limitations as significant are removed and the section on page 10 changed: “Activity and participation, Table 2. No significant differences were found between working and nonworking women in activity limitations in daily life (FIQ
physical function) or leisure time physical activity (LTPA).

c. Inclusion and exclusion criteria were not specified. Also, the authors did not clarify if FM patients were suffering another concomitant chronic pain condition.

Response: Inclusion and exclusion criteria are now clarified on page 4: “The inclusion criteria were women who were 18-60 years of age and suffered FM according to the American College of Rheumatology (ACR) criteria for FM [1].” Exclusion criteria are described on page 5: “12 were excluded due to treatment in progress (n = 3), severe disorders (n = 9) or unemployment (n=5) and 18 declined to participate.” No patient suffered from other concomitant chronic pain conditions.

d. The paragraph "Participants" is confusing. Apparently the authors excluded some different groups of participants in different moments and with different reasons (v.gr. “…35 did not meet inclusion criteria, and 61 declined to participate in the study, while 154 agreed to participate in an examination. Twenty-two of them did not meet inclusion criteria. …”).

Response: There were two parallel recruitment methods, a journal search and consecutive recruitment, and potential women were first screened by telephone interview where some were excluded. In the next stage, women were invited to an examination, and some were excluded at this phase. Due to the parallel recruitment and different stages of inclusion it can seem confusing. A clarification has been made on page 4-5, paragraph “Participants”:

“A systematic search of patient journals found 298 potentially eligible women who were contacted by post (n = 55) or telephone (n = 243) for further screening. Forty-eight women could not be contacted, 55 did not meet inclusion criteria at telephone screening, and 61 declined to participate in the study, while 134 agreed to participate in an examination. Twenty-three of them did not meet inclusion criteria at examination, 17 were excluded due to; treatment in progress (n = 3), severe disorders (n = 9) or unemployment (n=5) and 18 declined to participate. At the same time, 93 women were consecutively recruited to the study. Fifty-three of them fulfilled inclusion criteria and agreed to participate in the study.”

e. Limitations of the work have to be considered in the text. Some of them are consequences of the commented above. Other possible limitations would be related with coping, the relative limitation of the sample or the influence of the demands of family work in health status.

Response: A paragraph on limitations has been added on page 13: “A limitation of this study is the cross sectional design which does not allow analyses of cause and effect. Also, the specific demands in work were not reported in the study and needs further investigation.”

a. Abbreviations are to be defined. What means CWP or ICF? (International classification of functioning, disability and health?).
Response: Thank you for noticing this. The abbreviation CWP has been omitted from the text due to condensation of the paragraph “Participants” on page 4-5: “Women with FM were recruited to an experimental study [15] from three primary health-care centres in West Sweden by systematic search of patient journals and by consecutive recruitment.”

ICF is now defined on page 5: “Aspects of health are presented according to the International Classification of Function, Disability and Health (ICF) [17].”

b. The references that justified the use of the clinically significant differences for the 6MWT are not specified.
Response: This part of the results is omitted from the manuscript since we have chosen not to include subgroup analyses of part-time and full-time working women.

c. In the paragraph "References", articles 8 and 9 are identical.
Response: Thank you for noticing this. The references are now corrected

d. Perhaps an abbreviation for “working women” and for “non working women” would facilitate the lecture of the original.
Response: Thank you for this suggestion. We agree that an abbreviation would facilitate the reading of the article and changes are made according to your suggestion, working women (WW) and nonworking women (NWW).

We would like to thank the Editor for valuable comments.

Comments from the Editor:

(1) Authors' Contribution: Please include an Authors' Contributions section after Competing interests. Please check the instructions for authors on the journal website for the correct format to use for Authors' Contributions.
Response: A paragraph on author contribution has been added on page 14:

“Authors’ contributions. AP participated in the design of the study, performed the statistical analysis and drafted the manuscript. JB participated in the design of the study and helped to draft the manuscript. KM conceived of the study, and participated in its design and helped to draft the manuscript. All authors read and approved the final manuscript.”

(2) Competing interests: Manuscripts should include a ?Competing interests? section. This should be placed after the Conclusions/Abbreviations. If there are none to declare, please write 'The authors declare that they have no competing interests'. For more information please visit the instructions for authors on the journal website.
Response: A section on competing interests is added on page 14:
Competing interests. The authors declare that they have no competing interests.