Author’s response to reviews

Title: The German Fibromyalgia Consumer Reports - A cross-sectional survey

Authors:

Winfried Häuser (whaeuser@klinikum-saarbruecken.de)
Eva Jung (eva220979@hotmail.com)
Brigitte Erbslö-Möller (praxis.em@gmx.de)
Mechthild Gesmann (medges@gmx.de)
Hedi Kühn-Becker (hkbe@online.de)
Franz Petermann (fpeterm@uni-bremen.de)
Jost Langhorst (J.Langhorst@kliniken-essen-mitte.de)
Reinhard Thoma (thoma@comcity-online.de)
Thomas Weiss (info@weiss.de)
Andreas Winkelmann (Andreas.Winkelmann@med.uni-muenchen.de)
Frederick Wolfe (fwolfe@arthritiss-research.org)

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Author’s response to reviews: see over
Response letter

Dear editor,

Thank you for giving us the chance to submit a revised manuscript. The manuscript was revised by a native speaker (senior author).
We thank the reviewers for their helpful comments. Please find our point-by-point reply below. The changes in the manuscript are highlighted by the track function of WORD.

Sincerely

Winfried Häuser
Reviewer's 1 report

Title: The German Fibromyalgia Consumer Reports - A cross-sectional survey

Version: 1 Date: 19 January 2012

Reviewer: Juan V. Luciano

Reviewer's report:

This is a clearly-written and succinct article whose main aim is to report the first European fibromyalgia syndrome (FMS) consumer reports on the effectiveness and side effects of FMS-therapies. From my point of view, although the objective of the paper is not ambitious, it might be interesting for European clinicians and researchers that are involved in the study of FMS. The following issues should be addressed by the authors before this paper would be publishable by BMC Musculoskeletal Disorders:

1. Background (page 3). The background is well developed, the length is adequate, it includes recent and relevant studies, and the topic addressed is clearly presented to the reader. Minor essential revision: Reference number 1 and number 7 is identical. Please, correct this mistake.

Reply: Thank you for your attention. We corrected the mistake.


Reply: Please note that this paper reviewed the three existing evidence-based guidelines on the management of FMS which had been cited in INTRODUCTION (reference numbers 11-13 of initial version of the manuscript). Therefore we did not cite the EJP-paper.

3. Methods (pages 3-5)

The study procedure is well exposed and seems correct. I only suggest a minor essential revision:

When the authors say “Participants of the study were recruited by the two largest German FMS-self help organizations and nine clinical institutions. The specialties
of the clinical institutions were pain medicine and psychotherapy (3), rheumatology (2), complementary and alternative medicine (2), physical therapy (1) and pain therapy (1). The settings were outpatient (6), inpatient (2) and day clinic (1). The levels of care were secondary (6) and tertiary care (2) and rehabilitation (1)”, they should have put an “n=” before the numbers, otherwise they seem references at first glance.

Reply: We changed according to your suggestions.

4. Results (pages 5-6)
“There were no data available about how many patients contacted by the self-help organization refused to take part in the study.” This is a serious methodological shortcoming. It is very important to know the response rate in surveys because is an indicator of the generalizability of the results.

Reply: We had written in DISCUSSION/Limitations that a selection bias of patients was possible. We added “The unknown response rate of the participants recruited by self-help organisations limits the generalizability of the results.”

5. Discussion and Conclusions (pages 6-7)
Overall, the conclusions are supported by the data and the limitations are clearly stated.

Minor essential revision: In the section Comparison with other studies, the authors say “NFA-Studie”. Please, correct this mistake.

Reply: We corrected the mistake.

Discretionary revision: The authors might comment on that patients’ opinions are in line with recent meta-analyses concerning the effectiveness of non-pharmacological interventions for FMS (e.g. Häuser W, Bernardy K, Arnold B, Offenbächer M, Schiltenwolf M. Efficacy of multicomponent treatment in fibromyalgia syndrome: A meta-analysis of randomized controlled clinical trials. Arthritis Rheum 2009; 61: 216-224).

Reply: We agree that comments on this topic would be of interest. However, there are numerous systematic reviews on pharmacological and non-pharmacological therapies in FMS available. A comparison of the patients’ opinions with the results of these reviews would have surpassed the topic of the paper.
Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Reviewer's report

Title: The German Fibromyalgia Consumer Reports - A cross-sectional survey

Version: 1 Date: 7 February 2012

Reviewer: Anna Ferguson

Reviewer's report:

1. Minor Essential Amendments
   Are the methods appropriate and well described?
   Yes the authors do appear to be using an appropriate methodology and this is adequately detailed. I did wonder whether the headings used could be more like those seen in usual journals.
   e.g. Methods
   Recruitment (instead of ‘study centres’)
   Procedure (‘Organisation of the study’)

   Reply: We changed according to your suggestions.

   Inclusion and exclusion criteria (seemed appropriate)
   I think specifically in the relation to the questionnaire section the authors should organise this with “Questionnaires” being the main title and then have the title of each questionnaire as a subheading (in italics) with the authors names as well. This may be dependent on how the journal requires the authors to layout their information.
   e.g. Questionnaires
   Benefits and Harms of FMS-Therapies (author)
   With detail of what questionnaire entails under each subheading
   Patient Health Questionnaire-4 (PHQ-4 author)

   Reply: “Questionnaires” had been a heading. We would like to leave the decision to the editorial team, if the names of the questionnaires should be written in italic or underlined. Please note, that is not usual to give the authors of a questionnaire in brackets, but to give the reference as we did.

2. Is the writing acceptable?
   In the main the writing is good however there are a number of typos and the use of some words which don’t appear to be correct. For examples the word ‘valuated’ is used several times – I think the authors mean ‘evaluated’. This may be because the paper has been translated from German into English but these
typing errors should be addressed prior to publication.
Reply: The paper had been revised by a native speaker.

3. Major Essential Amendments:
Is the question posed by the authors well defined?
The abstract is very clear but I think it would be helpful for the authors to state more clearly the research questions/objectives in the introduction as these appear to be much clearer in the abstract. All the authors currently say is that they will do a consumer report which looks at both effectiveness and side effects of FMS therapies – can the research questions be made more explicit or at least expanded upon.
Reply: Thank you for your suggestions. We expanded the last sentence of INTRODUCTION as follows: The limited external validity of RCTs in FMS given, we conducted the first European FMS consumer reports on the effectiveness and side effects of FMS-therapies in routine clinical care.

4. Are the data sound?
a. Hard to tell this as not a statistician but they appear to be. However, from looking more closely at the tables in the back there is clearly missing data – as some of the totals do not add up to the numbers recruited. The authors must highlight how much missing data there is and how it was treated in the analysis. Missing data is often extremely problematic in such postal surveys.
Reply: We added in each table: * Note: The discrepancies between the number of persons included in the study and the number of persons in the following rows are due to missing items.
We added in METHODS/Statistical analysis: Missing values were not substituted.
b. The layout of the numbers in the tables also need to be consistent as on occasions the authors report means/percentages with a decimal point i.e. 4.8 and then in table 2, 3, 4 the means/percentages appear to have commas in them i.e. 56,0. This needs to be corrected.
Reply: We used in decimal point in each table in the revised manuscript.

5. Does the manuscript adhere to the relevant standards for reporting and data deposition?
a. The statistics reported are purely descriptive and so there does not appear to be any sophisticated statistical analysis required. One thing that is clearly not reported in the tables at the back is ethnicity information. The authors should be included if possible.

Reply: We did not assess ethnicity. The participants of the clinical centers were all Caucasians.

b. It would also be important to compare the patient responses from the self-help group to the data from the clinic settings- to see whether the two recruitment populations are different. This should at least be explored prior to publication perhaps using t-tests. As this might indicate that the samples are significantly different from one another and therefore may limit generalisability.

Reply: The comparisons of participants recruited by self-help organisations and by clinical centers is the topic of another paper which had been submitted to a German journal. The participants recruited by the self-help organisation were older and reported a longer duration of chronic pain and time since FMS-diagnosis and less depression than participants recruited by clinical samples. There were no other demographic and clinical differences between the two groups. We believe that the heterogeneity of the sample does not limit but rather ensures the generalisability of the results because of the different recruitment settings.

6. Are the discussion and conclusions well balanced and adequately supported by the data?

The authors only explore the outcomes very briefly and I think the paper would be greatly strengthened by more exploration of the results in the discussion. The authors refer to a previous study in their introduction by Bennett, Jones, Turk, Russell and Matallana (2007) this paper discusses the results in greater detail. I think the authors should refer to this paper to guide them in writing up their findings. I think this would be essential prior to publication.

Reply: We followed your suggestions by adding a table (5) in which we present a comparison of the most frequently used therapies. Please note that a statistical comparison was not possible because the US-survey did not report the response rates for each therapy.

7. Are limitations of the work clearly stated?
The authors do report on the limitations although these appear to be mainly in relation to doing consumer reports generally. I feel the limitations could be more focussed on the current work or at least how the limitations they suggest are demonstrated in the current paper. The report does not focus on the missing data and the limitations of this. The authors should discuss this.

Reply: We had written in DISCUSSION/Limitations: The different modalities of the distribution and recollection of the questionnaires led to the loss of some data. We changed into: “to a relevant number of missing data”. We added: The unknown response rate of the participants recruited by self-help organisations limits the generalizability of the results.

8. General Comments
Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
Yes although there appears to be very little literature carrying out a similar consumer reports prior to this one.
Do the title and abstract accurately convey what has been found?
Yes the abstract appears to be very clear and concise.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I declare that I have no competing interests
Reviewer's report

Title: The German Fibromyalgia Consumer Reports - A cross-sectional survey

Version: 1 Date: 17 February 2012

Reviewer: Nicola Chaloner

Overview

This paper sets out to provide the first European Fibromyalgia Syndrome consumer group report on treatment effectiveness and side effects, which they intend to supplement the findings of broader RCT studies. This is the largest scale consumer review undertaken in Europe to-date and a useful subject for both patients and clinicians alike. The paper also does well to challenge the high recommendation for drug therapies within FMS guidelines which again may have implications for clinical practice.

Whilst the purpose, methods and broad findings of the study are relatively easy to make sense of, there are repeated grammatical, typographical and presentation issues that would need to be addressed in order to aid the reader's comprehension of the study.

In addition, the authors need to give the reader more information on exactly what was being asked of participants as it is impossible to comment fully on the study's design without being able to read a copy of the central questionnaire measure used (alternatively this could be supplied).

The paper would benefit from greater transparency about the study's methodological limitations and the extent to which any firm conclusions can be drawn beyond this, within the discussion. Finally, the paper would benefit from further reflection on the wider theoretical context surrounding the findings, in particular the extent to which key self-reported methods identified as ‘effective’ are reflective of wider evidence related to functional improvements and adjustment.

Major Essential Revisions:

1: Literature Review:

1.1: Whilst I recognise the word limit may be strict this is very brief – it would have been useful to know more about what the key NFA study found in terms of outcome. Equally any reference to the relationships between prior ‘effectiveness’ ratings and wider functioning/quality of life could set the tone for further reflection within the discussion section (see comments below).
Reply: We provided a new table in which the frequencies and effectiveness of therapies used by the NFA- and German consumers were compared. We had not included ratings of quality of life. See reply to 2.2(3)

2: Methodology:

2.1: Without a copy of the questionnaire measure devised it is difficult to fully review the methodology of the study. Specifically, there is no mention of Cognitive Behavioural Therapies within the ‘psychological therapies’ section of the results, despite the fact that this is commented on elsewhere in the paper. As a reader I wanted to know which psychological therapies were being rated and I would have ideally liked a copy of the questionnaire as an appendix.

Reply: A copy of the questionnaire was provided. We added in table 2, that cognitive-behavioral therapies, psychodynamic therapies and couple- and family therapies were included into the category “psychotherapy”.

2.2: Secondly, whilst the authors do well to outline a number of methodological limitations that are clearly beyond the scope of this study to address (limitations of self-report, retrospective design etc), the following areas would benefit from greater discussion and clarification:

2.2(1): Inclusion of individuals with co-morbid inflammatory conditions without commenting on to what extent the results then differed for this subgroup. It would also be useful to know more about what specific diagnoses this group included and whether they were accessing any additional treatments (e.g. specific anti-inflammatory medication) which may have influenced ratings given. A subgroup report would be helpful;

Reply: Within the context of a survey, we did not ask for different inflammatory rheumatic diseases because it can be difficult for some patients to report the exact diagnosis (e.g. in case of two inflammatory rheumatic diseases). Patients were asked in the questionnaire if they suffered from an inflammatory rheumatic disease, “e.g. rheumatoid arthritis, systemic lupus erythematoses, Sjögren-Syndrome, Bechterew’s disease”. One aim of the study was to capture the whole spectrum of patients diagnosed with FMS, that is to say with comorbid inflammatory and rheumatic disorders. Please note that the study of Bennett et al. 2007 did not perform subgroup comparisons too (46% of the participants reported to be affected with arthritis).
Subgroup comparisons of FMS-patients with and without these comorbidities could be the topic of another paper. We added in the last section of RESULTS: “The frequency of use and perceived benefits and harms of some therapies depended on some demographic (e.g. member of self-help group) and some clinical characteristics (e.g. comorbid inflammatory rheumatic disease and probable depressive disorder) which will be detailed in another publication”.

2.2(2): Whilst I recognise that this is the largest scale European consumer review to-date, the results still represent a relatively small sample of the population group and this needs to be better acknowledged and reflected upon. The extent to which ‘lost’ data was a major or minor issue would also be useful for the reader to understand in interpreting the findings.

Reply: We added in DISCUSSION/Limitations:

a. Major methodology limitations of the design of this study are as follows: The different modalities of the distribution and recollection of the questionnaires led to a relevant number of missing data.

b. Whilst this study is the largest scale European consumer review to-date, the results still represent a relatively small sample of the population group.

2.2(3): Whilst recognising that this is a cross-sectional survey, it would have been interesting to include a measure of functioning or quality of life, to provide a broader context for the findings. I do, however, recognise that this is possibly beyond the scope of this study and would be hard to change now. I think this issue could be usefully be flagged up for further thought in the discussion (see interpretative issues below).

Reply: Thank you for the suggestion. We added in CONCLUSIONS: Further FMS-consumer reports should include measures of functioning to provide a broader context for the findings.

2.2(4): Whilst the reviewer recognises that the study set out to provide descriptive statistics on the population sample, it would have been interesting to note whether any relationships existed between participant ratings, demographic variables and self-reported anxiety and depression.

Reply: Please see reply to 2.2(1).
3. Interpretative:
3.1: The reviewer is concerned that initial use of terms such as ‘effectiveness’ and ‘harm’ without clarification, may be misleading for the reader. The use of the term ‘harm’ in particular suggests risk/dangerousness rather than ‘unpleasantness’, which I think this is what you were exploring. This may be a translational issue but these terms need to be clarified earlier on in the paper.
Reply: In the questionnaire “harms” had been explained to be “side effects”. We detailed in METHODS/Questionnaires: effectiveness (relief of symptoms) and harms (side effects). Moreover we added in the heading of table 4 after harms: (side effects)

3.2: Similarly, the reporting of the scale ‘a 0-10 scale, with 10 being most efficacious (harmful)’ took several attempts of reading through to understand – been interesting to view the both sets of mean ratings for each intervention alongside each other.
Reply: We hope that the attached questionnaire will help to overcome potential problems of understanding of the readers. Please note that we mentioned in METHODS/questionnaires that we had conducted a pre-test of understandability with clinicians and patients.

5.3: The organisation of the method section could be made clearer to include inclusion/exclusion criteria after the ‘study centres’ section.
Reply: We changed according to your suggestion.

5.4: Equally it would have helped the flow to provide sub-headings for organisation of the study across self-help arms of the study within the methodology section.
Reply: We provided subheadings for self-help organisations and clinical institutions in METHODS/Procedure

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Needs some language corrections before being published
Statistical review: No, the manuscript does not need to be seen by a
statistician.

Declaration of competing interests:
I have a special interest in acceptance based approaches within pain management and work in this field.