Author's response to reviews

Title: The effect of nursing instruction in patients receiving steroid pulse therapy for the treatment of autoimmune diseases

Authors:

Yu-Chu Pai (ycpai@vghtpe.gov.tw)

Version: 2 Date: 1 March 2010

Author's response to reviews: see over
March 1, 2010

John Kerr  
Assistant Editor  
BioMed Central  
BMC Musculoskeletal Disease

Re: MS: 6662347482988180, titled, Nursing instruction improves outcomes for lupus and rheumatoid arthritis patients receiving steroid pulse therapy

Dear Mr Kerr:

Thank you for your interest in our manuscript and for the valuable comments of the reviewers. We have read their comments and revised the manuscript accordingly. Additionally, as requested below we have provided our point-by-point responses to the comments.

Thank you again for your support of our work, and we look forward to your continued correspondence.

Sincerely,

Yu-Chu Pai, MSN  
Nursing Department  
Taipei Veterans General Hospital  
Taipei 11217, Taiwan

**Author’s point-by-point responses to reviewer comments**

***Competing interests - Please include a 'Competing interests' section between the Conclusions and Authors' contributions. If there are none to declare, please write 'The authors declare that they have no competing interests'.

**Author Response:** We have included the statement as requested: The authors declare that they have no competing interests'.

***Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include their source(s) of funding. Please also acknowledge anyone who contributed materials essential for the study.
Acknowledgements

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Please list the source(s) of funding for the study, for each author, and for the manuscript preparation in the acknowledgements section. Authors must describe the role of the funding body, if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

NOTE: In particular we would suggest including an acknowledgement for the medical writer who aided in the copyediting of the manuscript.

Author Response: This study was supported by a grant from Taipei Veteran General Hospital (No. 367-11). We have included this information in the Acknowledgement section. Also, please see our response above.

***Ethics - Experimental research that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/e/policy/b3.htm), and any experimental research on animals must follow internationally recognized guidelines. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

Author Response: This study was conducted in accordance with Good Clinical Practice and the Declaration of Helsinki and its amendments. The protocol was approved by the Institutional Review Board of Taipei Veterans General Hospital. Written informed consent was obtained from each patient. We have included this paragraph in the Methods section of the manuscript.

Reviewer's report

The theme is very interesting. There are some viewpoints which are important to clarify.

1. Is the question posed by the authors well defined?

The aim of the study was to provide a basis for the formulation of nursing guidelines for pulse therapy patients. What are the research questions? The
authors could clarify them.

**Author Response:** The research questions is, “What are the needs of nursing instructions for patients receiving steroid pulse therapy in order to improve patient cognitions related to their diseases and treatments?” We have clarified this in the Introduction section.

2. Are the methods appropriate and well described?
The study is descriptive, comparative research. What kind is exactly the study design? The figure about the design would be very illustrative.

**Author Response:** The flow chart of study design is shown below, and has been included in the manuscript.
3. Are the data sound?
The data were appropriate.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
The manuscript is written according scientific guidelines.
I was missing some viewpoints about theoretical background.
**Author Response:** Nursing instruction should be patient-centered and coupled with a patient’s knowledge and education level in order to provide the appropriate information to improve their self-care ability as well as cognitive level. We have clarified this in the introduction.
5. Are the discussion and conclusions well balanced and adequately supported by the data? The discussion part is needed more critical discussion about limitations. Also discussion about ethical aspects is missing. 

**Author Response:** A limitation of the study is that data were only collected from a single medical center. Another major limitation is that the study was not a randomized control trial. Subjects were recruited in 6 months. Patients could not be divided into control and nursing instruction groups, because all patients should receive appropriate nursing instructions. To not provide all patients with the best instruction possible would not be ethical. Another limitation is that some subjects were lost to follow-up, and this may have introduced bias into the results. However, 90% of the subjects finished the study, thus we believe that the results were not significantly affected by the number lost to follow-up. We have included this information in the manuscript.

6. Are limitations of the work clearly stated? 

**Author Response:** Please see our response above.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? 

There are some references concerning this study.

8. Do the title and abstract accurately convey what has been found? 

The title and abstract are appropriate.

9. Is the writing acceptable? 

The writing is acceptable with minor revisions.

**Reviewer's report**

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- Minor Essential Revisions

1. What is the theoretical background and what kind of are theoretical assumptions? 

**Author Response:** Nursing instruction should be patient-centered and coupled with a patient’s knowledge and education level in order to provide the appropriate information to improve their self-care ability as well as cognitive level. We have clarified this in the introduction.

2. Formulation of research questions. 

**Author Response:** The research questions is, “What are the needs of nursing instructions for patients receiving steroid pulse therapy in order to improve patient
cognitions related to their diseases and treatments?” We have clarified this in the Introduction section.

3. What kind of is study design? (Figure)

**Author Response:** A flow chart has been added to the manuscript. Please see the flow diagram above.

4. Especially discussion part is important to clarify: limitations and ethical aspects

**Author Response:** A limitation of the study is that data were only collected from a single medical center. Another major limitation is that the study was not a randomized control trial. Subjects were recruited in 6 months. Patients could not be divided into control and nursing instruction groups, because all patients should receive appropriate nursing instructions. To not provide all patients with the best instruction possible would not be ethical. Another limitation is that some subjects were lost to follow-up, and this may have introduced bias into the results. However, 90% of the subjects finished the study, thus we believe that the results were not potentially affected by the number lost to follow-up. We have included this information in the manuscript.

**Reviewer's report**

**Title:** Nursing instruction improves outcomes for lupus and rheumatoid arthritis patients receiving steroid pulse therapy

**Version:** 1 Date: 17 November 2009

**Reviewer:** Sarah Hewlett

**Reviewer's report:**

Thank you for asking me to review this interesting observational study of an educational intervention by nurses for patients receiving steroid therapy by injection.

**Major Compulsory revisions**

1) The English needs attention throughout, as currently it is difficult to understand the methods and hence also the results.

**Author Response:** The manuscript has been edited by a native English speaking medical / scientific writer.

2) Title - this is not a randomized controlled trial, therefore we cannot be sure that it was the nursing intervention and not the steroid that improved outcomes, unless you are talking about knowledge outcome.

**Author Response:** We have revised the title to: The effect of nursing instruction in patients receiving steroid pulse therapy for the treatment of autoimmune diseases

3) Abstract - 'need for nursing instruction' needs to be clarified, what exactly does this mean? In addition, the level of the difference (ie the results) rather than just the level of significance should be reported.
Author Response: “The need for nursing instruction” described the need for nursing instruction so that the patient can understand the diseases and therapy procedures, effects and side effects of drugs, management of side effects, diet restrictions, significance of each test, daily care, and methods of emergency medical treatment.
The level of the difference indicates the extent of difference in outcome (ie. results); the level of significance indicates the level of confidence ($\alpha=0.05$) when testing the hypothesis. For the need for nursing instruction among the 4 time points, the level of significance should be the proper way to do it. No outcome is involved.

4) Methods - Was ethics approval obtained?
Author Response: This study was conducted in accordance with Good Clinical Practice and the Declaration of Helsinki and its amendments. The protocol was approved by the Institutional Review Board of Taipei Veterans General Hospital. Written informed consent was obtained from each patient. We have included this paragraph in the Methods section of the manuscript.

5) 'the need for nursing instruction' survey - please clarify what you asked by giving the question. Was it how distressed patients were for each of the 9 categories, or whether they wanted more information?
Author Response: The question asked whether the patient required instruction with respect to the cardio-pulmonary, endocrine, musculoskeletal, digestive, nervous, optic, integument, immune, and reproductive systems. We have clarified this in the manuscript.

6) 'to evaluate cognitive level'. Do you mean knowledge level? Is this a separate questionnaire?
Author Response: It should be “knowledge level”. The text has been revised accordingly.

7) Who delivered the nursing intervention, was it one nurse, or several nurses?
Author Response: Nursing intervention was administered by the senior nurses in the Divisions of Allergy, Immunology, and Rheumatology.

What was the intervention exactly?
Author Response: Nursing instruction regarding the disease, treatment, and effects.

Had it been standardized, or was it just the nurses' usual practice?
Author Response: It has been standardized.

Was it written or verbal?
Author Response: Both written and verbal.
Was it individualized?

**Author Response:** Yes, it was individualized.

How long did the intervention last - it was given over 2 days but was that for 10 minutes each day, or 6 hours?

**Author Response:** At least 10 minutes each day.

8) How do you know this was a sufficient number of patients? Was there a sample size calculation?

**Author Response:** The sample size has been calculated.

The sample size calculation was performed thorough a sample size calculator by Rasoft, Inc. (http://www.raosoft.com/samplesize.html)

Basic Information: In terms of the numbers you select, the sample size $n$ and margin of error $E$ are given by

$$
\begin{align*}
    n &= \frac{N x (N-1) E^2 + x}{N} \\
    E &= \sqrt{\left(\frac{N - n}{n(N-1)}\right) x}
\end{align*}
$$

where $N$ is the population size, $r$ is the fraction of responses that you are interested in, and $Z(c/100)$ is the critical value for the confidence level $c$.

In this study, we set the margin of error to 5%, confidence level to 95%, assumed a population size of 75, and a response rate of 50%; thus, recommended sample size is 63. The above information has been included in the manuscript.

9) Results - 63 patients participated, but how many declined and were they any different to those who consented?

**Author Response:** The initial number of patients was 70, but 7 patients withdrew because they did not meet the inclusion criteria or refused to participate.

10) Was the weight change an increase or decrease?

**Author Response:** The weight change was an increase.

11) Paragraph 2, what was the level of symptom distress? It wasn't possible to understand from the methods section how this was measured. It would be helpful if you could use the same phrases in both sections

**Author Response:** “The level of symptom distress” was a self report-type questionnaire with a Likert 5 point scale. “Symptom distress” was the level of concern over symptoms related to the particular category. We have clarified this term in the manuscript. A higher score reflected a greater level of symptom distress, i.e., concern regarding symptoms.
12) Which timepoint are the data in Table 3?

**Author Response:** Before intervention. We have clarified this in the table.

13) Patients had either RA or SLE - did you analyze them separately and were they different in their education needs?

**Author Response:** Among the 63 subjects, there were 43 diagnosed with systemic lupus erythematosus (SLE). Among those patients, 4 were complicated with RA and 6 were complicated with sicca syndrome. Therefore, we categorized those 43 patients into a “SLE group”. The other 20 patients had systemic sclerosis. We have clarified this in the manuscript.

14) Discussion - It is stated that patients needed information about all the 9 categories at all 4 timepoints - but if your intervention has been successful, shouldn't the need have reduced by the end?

**Response:** The change in the need of nurse instruction has been added in Table 4. (See the overall.) According to the comparison for overall, the overall need of nurse instruction decreased after pulse therapy as compared with before therapy.

15) Limitations need to be discussed. In particular this was not a randomized controlled trial therefore we do not know whether patients would have gained this knowledge anyway during standard nursing care? We cannot be sure that it was the nursing intervention that made the difference.

**Author Response:** A limitation of the study is that data were only collected from a single medical center. Another major limitation is that the study was not a randomized control trial. Subjects were recruited in 6 months. Patients could not be divided into control and nursing instruction groups, because all patients should receive appropriate nursing instructions. We have included that in our Discussion section. It is possible that patients gained his knowledge from the self-care of nursing instruction. However, because our subjects only received our nursing instruction after entering the investigation, the difference observed during the study period should be considered as the effect of nursing instruction.