Reviewer's report

Title: A pragmatic randomised controlled trial of hydrotherapy and land exercises on overall well being and quality of life in rheumatoid arthritis

Version: 3 Date: 10 October 2006

Reviewer: Wilbert van den Hout

Reviewer's report:

General

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

My main concern is with the primary outcome measure. Please address the following issues:
1) The primary outcome measure is (repeatedly) described as "global impression". Global impression of what? How was this labeled to the patient? Global impression of health, well being, illness, treatment effect, …? Please report the precise wording of the question the respondent answered to.
2) Please specify when the measurement "immediately post treatment" took place. Was this on the same day as the last treatment session?
3) The discussion describes why the primary outcome measure was not assessed three months after treatment. However, these reasons are not convincing, because they all equally apply to the secondary outcome measures. It seems very odd to me to discontinue the primary outcome measures when you continue the secondary.
   I am slightly worried that perhaps the results on the primary outcome measure three months after treatment were perhaps undesirable?
4) The primary outcome measure measures "selfreported change", as opposed to the calculated difference between a pre-treatment and a post-treatment measurement. In my experience, such measures are more sensitive to measuring what respondents want to be true, as opposed to what is actually true. This may explain why only your primary outcome shows a difference, since your patients were likely to favor hydrotherapy (otherwise they would not have participated in your trial).
5) Were the participants aware of the fact that your hydrotherapy facility would be closed? If so, can you exclude the possibility that, with their responses, your respondents were trying to save their access to hydrotherapy?
6) You start the discussion by saying that pool-patients were more likely to feel (much) better. I would be more careful and rephrase that they more more likely to report feeling (much) better.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

7) Page 5, end of background: How did you measure "overall well-being"?
Page 19, beginning of conclusions: How did you measure "health gains"?
I assume that both times you mean your primary outcome measure; please be more consistent in how you refer to that main outcome measure
8) Page 6, participants: How many men and women were invited? Please report on the participation rate.

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Discretionary Revisions (which the author can choose to ignore)

9) Page 4: I have no idea what you mean by “makes possible … polyarticular disease”.
10) Page 4: Please report on the findings of references 4 and 5. What was their primary outcome measure?
11) Page 6 “Injections .. within 4 weeks of study entry were not allowed”: by “within” do you mean before or after?
12) Page 6 and 8: by “within 3 months of study entry” do you mean before or after? Was the analysis according intention to treat? Including those defaulting on page 8?
13) Page 7: You exclude “pregnant women and patients with other co-morbid conditions”. Is pregnancy a co-morbid condition?
14) Page 10 and 14, pain VAS: do higher score indicate more pain?
15) Page 12, “Data on the primary outcome was available for 46 and 44 …”: I was initially confused, assuming that the number 44 referred to the other randomization group.
16) Pages 16 and 17: on page 16 you state that the EQ-5D has been shown to be highly responsive to selfreported improvement, yet on page 17 you state that your data underscores concerns about the relevance of measures such as the EQ-5D. Both statements seem contradictory.
17) Page 19, community initiatives: please (also) discuss this issue in the discussion, together with studies on the cost-effectiveness of hydrotherapy.
18) Page 19, end of conclusions: What do you mean by “people with severe disability”?
19) Page 19, end of conclusions: I understand that you would have liked to continue your hydrotherapy facility, but the (nongeneralizable) statement that this option is not now available to your patients should not be the concluding sentence of your paper.
20) You may want to compare your results to the study by Patrick et al (Patrick DL, Ramsey SD, Spencer AC, Kinne S, Belza B, Topolski TD. Economic evaluation of aquatic exercise for persons with osteoarthritis. Medical care 39 (5):413-424, 2001.)
21) Table 2: I think a digit was lost in the footnote (** n=4)
22) Table 2: I think the table would be clearer if you placed the different time points in separate rows, instead of columns.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:

I declare that I have no competing interests