Reviewer's report

Title: The efficacy of physiotherapy upon shoulder function following axillary dissection in breast cancer, a pilot study.

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Reviewer: Adri C Voogd

Reviewer's report:

This is an interesting paper of a small randomized clinical trial on the effectiveness of physiotherapy following axillary lymph node dissection (ALND) as part of breast cancer surgery, a subject which continues to give rise to debate but has been largely neglected as a research topic in the clinical practice of the breast cancer surgeon. It shows remarkably large effects of physiotherapy on shoulder function and pain within 1 year after ALND. The paper has some limitations, such as the small sample size, and should provide more details on methodological issues to increase the credibility of the results. It also needs proper revision by a native English speaker.

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

The authors call their research a pilot study. What is their definition of a pilot study and what are the implications for the strength of the evidence provided by it. Does this explain why a sample size calculation has not been performed?

From the title it should become clear that this is a randomized controlled trial.

The information on page 5 of the methods section is not presented in a logical order. The subdivision in subjects and design seems artificial. It makes more sense to start the methods section with the first sentence under “design” (“The efficacy of physiotherapy was assessed ...”). It is not clear why the patients had to visit the Department of Physiotherapy (concurrent to the first outpatient clinic control). What activities took place during that visit? Randomization? Baseline measurements?

Further details should be provided on the following methodological issues:

- selection process.
  When were the patients informed about the trial and when did the randomization take place? Before surgery or after? The authors write that the study was performed from July 2003 to January 2005. Does this mean that patients were entered in the trial during this period? If so, how many patients underwent ALND during this period in the two participating hospitals?

- randomization
  The randomization procedure is described in such a way that it is not clear if the random allocation was really blinded. Please indicate if there was concealed randomization.

- measurement
  When did the base-line measurement take place? Was any check done to see if the blinding of the researcher doing the assessments was successful?

- treatment
  What exercises were prescribed to prevent lymph edema? Did all patients receive nine sessions of physiotherapy and how many weeks did these nine sessions take? Were there any patients who received more then nine sessions or any additional sessions during the one-year follow-up period? Was there any contamination with physiotherapy in the control group?

- analysis
  Did the authors follow the intention-to-treat principle when analyzing the data?

Any limitations with respect to the above mentioned methodological issues need to be addressed in the
discussion of the paper.

In several places the authors write that all patients under study had a modified radical mastectomy (page 4, last sentence; page 10, last sentence of 3rd paragraph). This is not true, as seven patients with breast-conserving treatment were included.

The information in the discussion (page 10) that 50% of the physiotherapists reported that treatment continuation could be beneficial should be in the results section.

What is the authors' definition of delayed onset exercises (page 11)?

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

page 9: Not only the percentages, but also the absolute numbers should be given.

page 10, Discussion: "The study showed that physiotherapy, starting two weeks after surgery, significantly improved ..."

page 13, reference 6: The authors should look for an alternative reference. Study results of this group, including percentage of patients visiting a physiotherapist, have also been presented in the international literature, for example Br J Surg 2003, Voogd et al.

Discretionary Revisions (which the author can choose to ignore)

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: Not suitable for publication unless extensively edited

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests