Reviewer’s report

Title: RCT Examining the Effect of Exercise in People with Rheumatoid Arthritis on Anti-TNFalpha Therapy Medication

Version: 1 Date: 7 April 2010

Reviewer: Arianne Verhagen

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Major compulsory revisions

• Background. The authors do not provide information on why the effect of exercise would be different in patients on anti-TNF-alpha medication compared with the RA patients not on this medication. Why would these patients react differently or why can we not assume that the RA patients on medication react the same as other RA patients?

• Methodology. Hypothesis, page 6. I think the hypothesis should be phrased as a null-hypothesis; stating there will be no difference in effect between the groups. In that case the hypothesis can be falsified and rejected when the difference between groups is statistically significant. The sample size calculation is based on a rejection of the null-hypothesis, so please change the hypothesis here.

• Methodology. Statistical analysis page 13. This section is not complete. Authors should describe when an intention to treat analysis is performed how they will handle missing data. Furthermore more information on multiple regression analysis should be provided. I assume this will be performed using the primary outcome as the dependent variable, but will it be dichotomied? How many and which variables will enter the regression analysis? Etc.

Minor essential revisions

• Methodology. Randomisation page 8. Please state the block size.

• Methodology. Assessment page 9. Please state here that baseline data will be gathered before randomisation.

• Methodology. Assessment page 9. The outcome assessor, when it concerns the primary outcome and some secondary outcome measures, is the patient and the patient is not blinded here. Please specify.

• Methodology. Sample size calculation page 12. In the first para the authors state that 17 people are required per group (for 2 groups that is 34), while in the second para the authors state that 51 patients are required for 2 groups. Please correct the first para, or explain the difference.

• Methodology. Statistical analysis page 13. The correct definition of an intention to treat analysis is that “ALL patients will be analysed in the groups they are allocated to”.