Reviewer's report

**Title:** Study protocol: Non-dislocated distal radial fractures in adult patients: Three weeks vs. five weeks of cast immobilization. A randomized controlled trial.

**Version:** 2  **Date:** 30 June 2013

**Reviewer:** Gertraud Gradl

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Summary: This paper is a protocol for a prospective, randomized comparison of three versus five weeks of immobilization for non-displaced fractures of the distal radius.

Comments: The topic is of potential relevance to BMC readership given the frequency of distal radius fractures and the variety in treatment protocols. However, there are several serious issues that need to be addressed.

**Major Compulsory Revisions**

1. **Title and throughout the whole manuscript:** In the title, as well as in the manuscript, the terms dislocated and displaced are used interchangeably. Since there is an important difference between dislocation and displacement, please clarify.

2. **Background:** “The variety of fracture classification systems, with associated issues of reliability and validity further complicates this area.”
   
   This sentence is unclear. Please clarify what “area” you mean.

3. **Rationale for the trial:** “A randomized clinical trial with sufficient power is needed to provide scientific support for a preferred treatment strategy for nondislocated intra- and extra- distal radial fractures.”

4. **Rationale for the trial:** Please clarify what you mean by “nondislocated intra- and extra- distal”.

5. **Rationale for the trial:** “This trial will provide level-1 evidence for the comparison of consolidation and functional outcome between two treatment options for dislocated distal radial fractures.”

6. **Rationale for the trial:** According to your inclusion criteria, you are planning to evaluate non-displaced distal radius fractures. Please clarify!

7. **Methods:** Please provide a detailed description of the treatment strategy. Are you using casts or splints? Long- or shortarm. Will it be plaster or fiberglass? Will patients receive physiotherapy and when will this be started.

8. **Study design:** Since your study is lacking a control group, this is a randomized
trial, not a randomized controlled trial.

9. Study design: “Block size will be four”. I assume you mean that you are allocating subjects to four blocks (table 1). Block size, however, refers to the number of subjects in each block. Please explain.

10. Study design: What do you mean by fracture type? Classification? Intra- or extraarticular? Flexion or extension?

9. Blinding: Please explain the use of the Lidström score, which is not a commonly used score.

11. Bias prevention: I am not sure I understand, apart from medical reasons, why you are planning to evaluate patients, not included in the trial and what you are planning to do with the data obtained. Please explain how this will reduce bias.

12. Study population: You claim that subjects should be able to independently perform ADL. How are you going to control for this? A validated instrument such as the Barthel Scale, Katz ADL scale, Lawton IADL scale or Bristol Activities of Daily Living Scale should be used.

13. Inclusion criteria: Are you planning to include both intra- and extraarticular fractures and are you treating them as separate entities? Intraarticular fractures are usually higher energy injuries and are associated with higher complication rates and worse outcome, especially in terms of degenerative changes.

14. Outcome measures: Please explain why you are planning to assess the left and right elbow.

15. Study procedures: “At each visit from six weeks onwards, the ROM of the wrist will be measured using a goniometer by a doctor blinded for the treatment of the dislocation.” Please explain what you mean by treatment of the dislocation.

16. Study procedures: How are you going to grade degenerative joint changes and more important, how are you planning to account for differences in fracture type (intra- vs. extraarticular) and preexisting degenerative changes. You do not mention evaluation of degenerative changes at the time of injury. Please explain “this is common practice in this type of patient”. Is it common practice at your institution or common practice in the Netherlands? What do you mean by this type of patient?

17. Study procedures: I have strong concerns about you applying the intention to treat principle, especially since you are planning to evaluate two specific treatment methods and it is likely that there will be drop out, crossover or even complete change of protocol, i.e. operative intervention.

18. Sample size: The minimal detectable change at the 95% confidence level (MDC95) was calculated for the QuickDASH across three different study populations and ranged from 16 to 20 QuickDASH points (with a mean of 18). A
recent prospective trial reported a MCID of 14 points. Please explain why you think that a much lower difference will be clinically important.

19. Sample size: As for your sample size calculation, your estimation seems to be based on a low standard deviation of QuickDASH scores in each group and a large effect size. Considering the reported outcomes for various treatment strategies with only marginal differences between groups, your study will very likely not have enough power to detect clinically relevant differences. Please consider increasing the sample size.

20. Withdrawal: Are you planning to analyze already obtained data of patients that drop out?

Minor Essential Revisions
21. There are several spelling and grammatical mistakes (e.g. patient instead of patients in the abstract, immobilisation). Please run a spell check.

Level of interest: An article of importance in its field

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

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests