PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Dislocated distal radial fractures in adult patients: Four weeks versus Six weeks of cast immobilisation following reduction, a multicenter randomised controlled trial, study protocol
AUTHORS	van Delft, Eva A.K.; Bloemers, Frank; Sosef, Nico L; Bonjer, H.J. (Jaap); Schep, Niels W.L.; Vermeulen, Jefrey

VERSION 1 – REVIEW

REVIEWER	Reviewer name: Andrea M Bruder Institution and Country: Andrea M Bruder (PhD),La Trobe University, School of Allied Health, Melbourne, Australia Competing interests: None declared
REVIEW RETURNED	01-Nov-2018

GENERAL COMMENTS	This protocol plans to explore length of immobilisation after distal radius fracture on patient outcomes. This is an important study given preliminary evidence suggests reduced immobilisation does not negatively effect patient outcomes after non-to- minimally displace distal radius fracture (Bentohami et al 2018). There are some typographical errors and the protocol should be consistently written with reference to what you will do (e.g. future tense). Page 7: Please use inclusive disability language and amend the sentence…. Patients with a displaced distal radius fracture suffer from long-term functional restrictions… Page 7: Please include references at the end of the following sentence: “Two prospective studies of patients with distal radial fractures showed that a shorter immobilization period was safe…” Page 7: Grammatical error. Please amend the following sentence: “Obviously, the ultimate treatment of reduced distal radial fractures is short, safe and leads to an early return of function.” Page 7: Line 29. Amend ‘is’ to will be (conducted). Page 9: Line 7: change ‘is’ to will be (compared to). Page 9: Line 45: change ‘adequately’ to adequate. Method: Please outline the course of additional Physiotherapy both groups will receive and when this will commence (e.g. immediately after removal of cast). Although Physiotherapy is not the intervention being examined, if there is variability in the Physiotherapy provided it may confound interpretability of results regarding 4 weeks versus 6 weeks of cast immobilisation. Bruder et al (2016) and (2017) may be useful studies to guide you through these decisions. If Physiotherapy will not be provided in a systematic/controlled way, please consider more rigorous methods to monitor adherence to Physiotherapy and prescribed exercise programs, including number of Physiotherapy sessions, the content of these sessions and duration of these sessions.

	Outcome Measures: Will the work and recreational modules of the QuickDASH be used? It seems like they may not, but I would encourage the authors to consider those modules to gain a broader understanding of meaningful occupations and long-term outcomes for patients after DRF. Please provide description about wrist range of motion that will be measured and the standardised procedures that will be followed. Will the assessor be blinded? If so, state this. What is the experience of the assessor assessing range of motion? Given that a shorter immobilisation period will hopefully result in patients being able to actively move their wrist and recommence earlier use, have you considered monitoring activity levels perhaps in the first 6 weeks after cast removal? It would be interesting to look at any possible relationship between activity levels and outcomes. Although you may not have capacity to include in your study design, follow up earlier than 3 months may reveal differences between the two groups that may be lost at 3 month follow up. For example, does the group with the shorter cast immobilisation regain function quicker than the group in the delayed immobilisation group? I commend the authors on their ambitions to conduct this study and attempt to challenge typical length immobilisation periods.

REVIEWER	Reviewer name: MANUEL BAYON- CALATAYUD, MD, PhD Institution and Country: PHYSICAL AND REHABILITATION MEDICINE DEPARTMENT. COMPLEJO HOSPITALARIO DE TOLEDO-SESCAM. TOLEDO-SPAIN Competing interests: NONE DECLARED
REVIEW RETURNED	05-Nov-2018

GENERAL COMMENTS	Congratulations to authors, The design of this protrocol is right. However I may find some objections: Regarding exclusion criteria " pre-existing abnormalities or functional deficits of the fractured wrist" it seems to me that provided information is insufficient. In example, Hipotiroidism, pre-existing osteoporosis, specially among elderly, some kind of medications (antiepileptic drugs, corticosteroids) may influence bone mineral density and delay bone consolidation leading to a longer period of inmobilisation.. Are these patients excluded? In addition to inmobilisation, Rehabilitation following wrist fracture may influence long term functional outcomes and reduce pain. I am not able to find enough information about which kind of rehabilitation was provided to study participants. Patients followed the same Rehabilitation protocol after inmobilitasion ?, wich kind of therapies, intensity, dutration?, rehabilitation specialist also participated in assessment and follow-up? Please consider these suggestions only to optimise the protocol.

VERSION 1 – AUTHOR RESPONSE

Reviewers comments reviewer: 1, Reviewer Name: Andrea M Bruder, PhD

4. Please state any competing interests or state 'None declared': None declared

None declared

5. This protocol plans to explore length of immobilisation after distal radius fracture on patient outcomes. This is an important study given preliminary evidence suggests reduced immobilisation does not negatively affect patient outcomes after non-to- minimally displace distal radius fracture (Bentohami et al 2018).There are some typographical errors and the protocol should be consistently written with reference to what you will do (e.g. future tense).

Thank you for your notification. We made substantial changes to the manuscript. E.g. page 4, line 15, 16, 18, 29; page 5, line 3-4, 14; page 6, line 21; page 7, line 2, 6, 7; page 9, line 5.

6. Page 7: Please use inclusive disability language and amend the sentence…. Patients with a displaced distal radius fracture suffer from long-term functional restrictions…

You might meant page 4 instead of page 7, on page 7 no such notifications were made.

We included the disabilities of the long-term functional restrictions on page 4, line 5-6.

7. Page 7: Please include references at the end of the following sentence: "Two prospective studies of patients with distal radial fractures showed that a shorter immobilization period was safe…"

See point 6, changes were made on page 4, line 12-13.

8. Page 7: Grammatical error. Please amend the following sentence: "Obviously, the ultimate treatment of reduced distal radial fractures is short, safe and leads to an early return of function."

Corrections were mage on page 4, line 15-16.

9. Page 7: Line 29. Amend 'is' to will be (conducted).

We would like to refer to point 5, Corrections were mage on page 4, line 29.

10. Page 9: Line 7: change 'is' to will be (compared to).

We would like to refer to point 5, Corrections were mage on page 5, line 3-4.

11. Page 9: Line 45: change 'adequately' to adequate.

Corrections were mage on page 4, line 26, 28, as well as on page 2, line 14.

12. Method: Please outline the course of additional Physiotherapy both groups will receive and when this will commence (e.g. immediately after removal of cast). Although Physiotherapy is not the intervention being examined, if there is variability in the Physiotherapy provided it may confound interpretability of results regarding 4 weeks versus 6 weeks of cast immobilisation. Bruder et al (2016) and (2017) may be useful studies to guide you through these decisions. If Physiotherapy will not be provided in a systematic/controlled way, please consider more rigorous methods to monitor adherence to Physiotherapy and prescribed exercise programs, including number of Physiotherapy sessions, the content of these sessions and duration of these sessions.

We outlined the course in which additional physiotherapy is advised to the patients, also we added your recommendation to the text, see page 5, line 6-8 and reference 15.

13. Outcome Measures: Will the work and recreational modules of the QuickDASH be used? It seems like they may not, but I would encourage the authors to consider those modules to gain a broader understanding of meaningful occupations and long-term outcomes for patients after DRF.

Thank you for this recommendation. In the standard part of the QuickDash there are two questions, one on amount of complaints during leisure activities (eg. Playing tennis, golf, rebuilding) and one on restrictions during work. Those two questions are validated and could be transformed to an objective score using the QuickDASH score. The work and recreational modules, however, are difficult to use for an objective rating of the amount of complaints, as for example, a construction worker will experience more complaints of his distal radial fracture than a school teacher. It will be impossible to stratify the outcomes for different types of work or sport/instrument, and therefore we chose not to use this modules.

14. Please provide description about wrist range of motion that will be measured and the standardised procedures that will be followed. Will the assessor be blinded? If so, state this. What is the experience of the assessor assessing range of motion?

The assessor will not be blinded, however investigator will be. Range of motion will be measured according to the references of the American Academy of Orthopedic Surgeons. As it is known that inter and intra observer variety of assessors using a goniometer is high, the assessors are trained and advise to measure the ROM three times and use the mean value of the range of motion for this study. Changes were made on page 7, line 23-25 and reference number 18.

15. Given that a shorter immobilisation period will hopefully result in patients being able to actively move their wrist and recommence earlier use, have you considered monitoring activity levels perhaps in the first 6 weeks after cast removal? It would be interesting to look at any possible relationship between activity levels and outcomes.

It will be very interesting to examine patients in the first six weeks after cast removal. In previous studies, it has been suggested that patients suffer from long-term functional restrictions following conservative treatment. A shorter period of immobilisation might reduce these kind of complaints, however, no evidence based literature existed so far. Therefor we developed this study. The main goal of this study is to evaluate the long term outcome of displaced and reduced distal radial fractures that are treated by a shorter period of immobilisation. To get insight in the function earlier in follow up, patients will also be examined three and six months after the initial trauma. These results will be published as secondary outcomes. Hopefully these results will give insight in complaints shortly after removal of the cast in distal radial fractures. After examining the long-term results, future studies are planned to focus on short term outcome.

16. Although you may not have capacity to include in your study design, follow up earlier than 3 months may reveal differences between the two groups that may be lost at 3 month follow up. For example, does the group with the shorter cast immobilisation regain function quicker than the group in the delayed immobilisation group?

We would like to refer to point 15. Hopefully this study will provide information that will help in the development of future studies on short term outcome.

Reviewers comments reviewer: 2, Reviewer Name: Manuel Bayon-Calatayud, MD, PhD

17. Please state any competing interests or state ‘None declared’: NONE DECLARED

None declared

18. Regarding exclusion criteria " pre-existing abnormalities or functional deficits of the fractured wrist" it seems to me that provided information is insufficient.

In example, Hipotiroidism, pre-existing osteoporosis, specially among elderly, some kind of medications (antiepileptic drugs, corticosteroids) may influence bone mineral density and delay bone consolidation leading to a longer period of inmobilisation.. Are these patients excluded?

Thank you for this point of feedback. Patient with for example, severe rheumatoid arthritis, will suffer from pre-existent complaints of pain, decreased range of motion and therefore increased outcome of PRWE and QuickDASH questionnaire. As the primary outcome of this study is the PRWE score after one year after a distal radial fracture, we decided to exclude patients with underlying diseases that will influence the pre-existent patient rated function of the wrist. As bone mineral density and delayed bone consolidation are no primary outcomes we decided to not exclude these patients from the study. We emphasized this in the study protocol on page 5, line 24-25.

19. In addition to inmobilisation, Rehabilitation following wrist fracture may influence long term functional outcomes and reduce pain. I am not able to find enough information about which kind of rehabilitation was provided to study participants. Patients followed the same Rehabilitation protocol after inmobilitasion ?, wich kind of therapies, intensity, dutration?, rehabilitation specialist also participated in assessment and follow-up?

We would like to refer to the method session on page 5, line 2-10 and point 12 (see above). In the Netherlands physiotherapy after distal radial fractures is based on specified guidelines.

Formatting amendments (if any)

20. Please provide better qualities figures, ensuring the figures are not pixelated when zoomed in on.

Figures can be supplied in TIFF or JPG format (figures in DOCUMENT, EXCEL or POWERPOINT format will not be accepted), we also request that they have a resolution of at least 300 dpi and 90mm x 90mm of width.

We edited all the figures to JPG format of 300 dpi.

VERSION 2 – REVIEW

REVIEWER	Reviewer name: Andrea M Bruder PhD Institution and Country: La Trobe University, Australia Competing interests: None declared
REVIEW RETURNED	05-Dec-2018

GENERAL COMMENTS	The authors should be congratulated on addressing the comments made. Most of these have been responded to appropriately however my concern still lies with the Method and justification for the provision and monitoring of Physiotherapy. Thank you for consulting the manuscripts suggested, however the findings from the pilot RCT (Bruder et al 2016) suggest that progressive exercise provided no additional benefit to structure advice delivered by a Physiotherapist. If I'm not mistaken your interpretation, or at least the way in which you have stated these findings in your protocol suggest that structured advice won't be provided in addition to exercise as they did not provide any additional benefit. Both groups received the same advice program in this RCT so advice cannot be evaluated. Even though Physiotherapy is not the intervention being examined (length of immobilisation is), the detail of the intervention to allow future study replication is important.

	For example, include the number of sessions per week patients will receive after cast removal, number of weeks, when will Physiotherapy be stopped etc. A comma should also be inserted after 'immobilisation' in the sentence that begins with "Following immobilisation ....." on Page 5. The following study may help with description of the Physiotherapy intervention: Hoffmann Tammy C, Glasziou Paul P, Boutron Isabelle, Milne Ruairidh, Perera Rafael, Moher David et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide BMJ 2014; 348 :g1687

VERSION 2 – AUTHOR RESPONSE

Reviewers comments reviewer: 1, Reviewer Name: Andrea M Bruder, PhD

1. Physiotherapy

Thank you for your notification. It is very important that interventions are clearly described to allow future study replication. Therefore we made changes to the manuscript. In this study, physiotherapy is after cast removal is advised and exercises to train the wrist function will be given to the patients. A structured advice programme was not generally prescribed. However, to examine the influence of physiotherapy on the outcome of this study, patients will be asked about physiotherapy during follow up visits. They will be asked if they received physiotherapy, and if this was the case they will be asked about the number of sessions per week and total number of weeks they received the physiotherapy. We will evaluate these details, to make sure that the amount of physiotherapy in both groups was equal and will not provide any bias in the study result. We outlined this in the manuscript, page 5, line 9-11.

2. A comma should also be inserted after 'immobilisation' in the sentence that begins with "Following immobilisation ....." on Page 5.

Corrections were mage on page 5, line 5.

3. The following study may help with description of the Physiotherapy intervention: Hoffmann Tammy C, Glasziou Paul P, Boutron Isabelle, Milne Ruairidh, Perera Rafael, Moher David et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide BMJ 2014; 348 :g1687

Thank you for this recommendation. We used this study to formulate the changes in the manuscript on the part on physiotherapy, described above at point 1.