Reviewer's report

Title: Medial Malleolus: Operative Or Non-operative (MOON) Trial Protocol'A prospective randomised controlled trial of operative versus non-operative management of associated medial malleolus fractures in unstable fracture dislocations of the ankle'

Version: 0 Date: 28 Feb 2019

Reviewer: Susan Dutton

Reviewer's report:

This is a well written and structured protocol paper.

I have a few comments that would improve the paper and therefore make it suitable for publication:

There is no mention of blinding in the article. There is mention of the allocation sticker being added to the consent form on randomisation. Would the patient be aware of this. As the primary outcome is a patient reported outcome it is important for this to be described. If blinding is not possible, then please state this.

Sample size is appropriate.

statistical analysis outline: one of the criticisms you make of an earlier RCT is that the sample size was small and that baseline patient reported outcome scores were not recorded. Are you collecting these in your study, it is not clear from the description. If you are collecting them the appropriate statistical analysis would be Analysis of covariance adjusting for the baseline PROM. Please could you clarify. Are you planning on adjusting for the stratification factors used in the randomisation?

There is no discussion about what you will do with missing data. The primary outcome is being collected at multiple time points. Is all the available data going to be used in the analysis, such as using a mixed level model taking all time-points into account Please expand the statistical analysis section with more details about the primary and supporting analysis for the primary outcome as a minimu. I would recommend that you ask the statistician who will be analysing the data to review and update this section.

Limitations: the authors describe the main limitations of the study: intra-operative randomisation. have you thought how this can be mitigated in that the envelope /sticker could include the time that the envelope was opened and this could be compared to the timing of the operation to see if the envelope was open at the correct time.
single centre - although the authors have discussed this, I still think it is a potential quitting a large limitation for this pragmatic trial in that the results may not be generalisable outside the centre. Expanding the study to more centres would provide a shorter time scale for completion and also improve the generalisability.

AS the primary outcome is a patient reported outcome, I would recommend the authors to report following the relevant extension to the CONSORT statement for patient reported outcomes.

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Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.
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