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: 1 Date: 17 May 2019

Reviewer: Ruth Knight

Reviewer's report:

The sample size calculation is incorrect. It allows for approximately 17% loss to follow-up, rather than the 20% stated. An overall sample size of 160 would be required to allow for 20% loss to follow-up. Please update accordingly, either by increasing the sample size or reflecting the true rate of loss to follow-up accounted for.

The analysis population is not defined. Please clarify who will be included in the analysis of the primary outcome.

The planned analysis methods for the primary outcome remain unclear. Will the unadjusted t-test be the primary analysis of the primary outcome, with ANCOVA as a supporting analysis? Given your assertion that a short-coming of a previous trial was the lack of baseline measures would it not be better to have an adjusted analysis as your primary analysis? In addition, will you present an analysis adjusted for your stratification factor (age group)?

In response to a previous reviewer's comment you assert that the primary outcome (OMAS) is only being recorded once; however, it appears this is not the case since you assert the OMAS will also be collected at 'numerous other time points'. I believe the 12 months timepoint is your primary endpoint but you are also collecting the primary outcome at other time points. It is unclear why you do not wish to fit a repeated measures model to take account of all available OMAS data. The estimate provided by this model will be more robust to missing data than using available cases (as you have planned for the primary analysis of the primary outcome). Please consider this as a supporting analysis of the primary outcome, or clarify why this will not be possible.

You have included an additional author on this version of the manuscript, please include their contribution in the relevant section.
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Statistical review
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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