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: 20 May 2019

Reviewer: Susan Dutton

Reviewer's report:

Thank you for revising your manuscript. There are a few further clarifications required.

Please clarify the sample size estimation. allowing 20% loss to follow-up would require 160 participants rather than the 154 quoted.

You are stratifying on young/old assuming a 3:1 ratio, and using opaque envelopes for the randomisation. What will you do if the patients presenting are in a different ratio? Will you be adjusting for age in the primary outcome analysis?

OMAS is being collected at multiple time-points. It would therefore be beneficial to undertake a mixed effects regression model taking all of these into account. This method is reasonably robust to missing at random data. The 12 month time-point can be taken from the complete model and all available data is included. Looking at change over time by assessing the slope of the linear regression line assumes that recovery trajectory is linear. This is unlikely to be the case.

The primary outcome should also adjust for the stratifying factor of age group as well as the baseline OMAS score.
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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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