Author's response to reviews

Title: Nortriptyline in knee osteoarthritis (NortIKA Study): study protocol for a randomised controlled trial.

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Author's response to reviews:

Dear editor,

Thank you for returning the referee’s report on our manuscript. The comments were helpful and we have addressed them as follows.

Major compulsory revisions.

Abstract
1. We have clarified the primary outcome and duration of treatment. (p3)

Background
1. We have removed the assertion that education and weight loss are ineffective (and agree that this was misleading).

Methods
1. We have clarified the question about duloxetine’s funding in New Zealand (p5).
2. Hypothesis 3 – we agree, on reflection, that this is not a testable hypothesis so have removed it. We have retained our intention to assess the tolerability and safety of the study medication as a study aim (p6).
3. We have provided our rationale for choosing the ACR clinical classification criteria (p6-7).
4. We have expanded our description of the WOMAC pain score (in the Methods section on p12). We hope that this will provide an indication of what a score =>20 means.

Minor essential revisions
Abstract
1. We have removed the word “propose”.

Methods
1. We have provided more detail about the way participants’ response to study medication will be assessed during the dose-adjustment period (p10).
2. We recognise that there is overlap between the final assessment section and earlier sections, however in the interest of clarity we would prefer to leave the text as it stands.

Discretionary revisions
Table 1 has been removed as suggested.
We have changed the title “Mechanisms of pain in OA” as suggested (p5).

Editorial requests
1. We have altered the title to conform to the journal style.
2. We have added the date of trial registration at the end of the abstract (p3).
3. We have removed the table altogether.
4. We have expanded our description of obtaining written informed consent in the methods section (p9).

Many thanks.

Ben Hudson.