Author’s response to reviews

Title: A protocol to prospectively assess risk factors for medial tibial stress syndrome in distance runners

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We thank the reviewers for the constructive feedback they have provided. We believe we have incorporated these recommended changes into our revised manuscript as explained below. All changes made to the original manuscript have been highlighted in yellow in the revised document.

Reviewer 1: With respect to the measures to be taken, given that ultrasound is to be used to obtain muscle cross-sectional area and identify atrophy, the same instrument could also be used to conduct grayscale analysis (Pillen, 2010, Skeletal muscle Ultrasound) for extent of infiltration of fat and fibrous tissue into muscles. This additional analysis could possibly replace the isometric strength testing, where the inclusion of 12 exhorted applications per runner, for a total of 1200 tests, raises the possibility of a muscle strain injury occurring during testing.

Our Response: We appreciate your suggestion of incorporating grayscale analysis into our protocol. We agree that grayscale analysis can be useful to determine fatty infiltration of a muscle. As our participants are experienced runners, we are not expecting fatty infiltration to be a major factor, more so, the relative sizes of the different shank muscles. Furthermore, due to our primary variable being lower leg muscle size measured using B-mode ultrasound, we require the clearest image possible and, therefore, we adjust our settings to achieve this clear image; our settings will not remain constant throughout image collection. As a result, it is not appropriate to have grayscale analysis as a primary outcome variable in this protocol. The inclusion of isometric strength testing has been carefully considered and the protocol has been developed to reduce the likelihood of injury to both the participant and chief investigator.

Reviewer 2: Distance runners still competing tend to be "survivors". Our data suggests MTSS is much more common in novice runners, with less than 3.5 years of running experience and those running around 3 km less than 2x times per week. Targeting a 30 km per week group you may miss the more typical sufferer.
Our Response: We appreciate that novice runners have been found to be at a higher risk of developing MTSS compared to more experienced runners. However, we have chosen runners who are completing more than 30 km per week or those who are training for a half marathon as our cohort in order to reduce the likelihood of running experience being a contributing factor to MTSS development in our study and more likely related to functional and morphological factors. Having more experienced runners will also reduce the likelihood of MTSS development being a result of training errors, which are often associated with novice runners. We appreciate that due to our inclusion criteria, we are likely to have a lower number of runners develop MTSS in our study compared to previous prospective MTSS studies, but we have accounted for this in our sample size calculations.

Reviewer 2: Particularly if you choose a more novice runner group you will need to make account for changes in morphology and other measures that are a positive adaptation of training. Make sure you have a very robust measure of training load (and rest) so that you can give meaningful analysis as to cause and effect of any changes at follow-up.

Our Response: As we are recruiting runners who have been running 30 km per week or those who are training for a half marathon for longer than 6 months our data are less likely to be affected by positive adaptations associated with training. We believe that our measure of tracking all weight bearing activity through daily training logs that are collated monthly will be sufficient to monitor training distance, type, duration, races and any period of time off activity.

Reviewer: Leg girth needs to be normalised to height or shank length otherwise your measure may simply be a proxy of another anthropometric feature.

Our Response: As recommended, leg girth will now be normalised to shank length (see page 10).

Reviewer: I think I understand your "injury" definition- make sure you articulate this a little more clearly in terms of time loss.

Our Response: Please see page 17 for further clarification on what constitutes an injury.

Reviewer 2: Individual Muscle strength with hand-held dynamometer- are you sure this method will work? Some criticism exists of hand held dyno for high power lower limb muscles.

Our Response: We recognise the limitations associated with hand held dynamometer measurements. However, we chose to use a hand held dynamometer because we can use the device to isolate individual lower leg muscle measurements. We have also undertaken extensive pilot testing to ensure measurement reliability when using the hand held dynamometer. In order to elicit reliable measures, particularly from the gastrocnemius and soleus, we will ensure that the plinth and chief investigator are appropriately positioned and securely braced.
Reviewer 2: Surface EMG will be tricky in this area- do you really think you can get independent muscle signals?

Our Response: We appreciate the complexity of surface EMG and the potential for muscle signal cross talk. We will follow surface EMG for a non-invasive assessment of muscles (SENIAM) guidelines and are therefore confident in obtaining EMG signals from independent muscles. We understand the difficulty in capturing an independent muscle signal from the flexor hallucis longus muscle. Current literature supports ultrasound guided placement of a surface EMG sensor to detect EMG activity from the flexor hallucis longus muscle (Peter et al. 2015). However, we feel that the risk of cross talk between the flexor digitorum longus and flexor hallucis longus is too great to reliably isolate this muscle and, as a result, we will describe this sensor and associated EMG activity as the extrinsic toe flexors rather than a specific muscle.

Reviewer 2: If you get enough participants consider some alternatives or additions (train and test approach) to logistic regression - some great freeware around (and some in SPSS) that will enable greater capacity to identify subgroups in your data, with often higher classification accuracy than logistic regression.

Our Response: Thank you for this suggestion. Should we reach the required participant numbers we will undertake additional data analysis as suggested by the reviewer.

References