Reviewer's report

Title: HAPPi Kneecaps! Protocol for a participant- and assessor-blinded, randomised, parallel group feasibility trial of foot orthoses for adolescents with patellofemoral pain

Version: 0 Date: 30 Jun 2020

Reviewer: Martijn Steultjens

Reviewer's report:

This protocol sets out the study very well. It is clear what the objectives are, and the methods are described in full detail. I have a few discretionary, minor comments which may help improve the paper further:

1) The study is alternately described as a feasibility or a pilot trial. These days those tend to be studies with different methods (feasibility mostly non-randomized). This study has elements of both feasibility study and pilot RCT. My personal preference is for it to then be called a pilot RCT, as that shows it is further advanced down the intervention development pathway, with the objectives and description of the study identifying that it has elements of feasibility as well. This would mean slight changes to the title and text of this protocol.

2) Patellofemoral pain (PFP) in adolescents is more prevalent in girls than boys, and there is also a suggestion that there may be a U-shaped association of PFP risk with level of sports/exercise (i.e. high risk in the very inactive and very active groups). There may be scope to identify this from the pool of eligible volunteers - how does that group compare to the general population for key characteristics including sex, sports activity, and perhaps being pre / in / post growth spurt? This would be important for the population definition of a future full RCT (and by extension, its feasibility).

3) According to the authors there is a 70/30 split in bi- vs unilateral PFP. In a small pilot trial this may lead to imbalance between the groups, which would not be fatal given that between-group comparison is only a secondary objective. However, as in the above point, it would be good to keep an eye on this and identify the actual split in the volunteer pool for this study so that it can inform the design of the full RCT.

4) In the statistical analyses of secondary outcomes, it would be possible to calculate provisional effect sizes for all outcomes, which will be needed for the power analysis and sample size calculation for the full RCT, as well as being helpful for selection of the primary outcome measure for that RCT.

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