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Re: Manuscript ID BMJ.2018.043530.R3

24th July 2018

Dear Dr Loder,

Thank you for providing a further review of our manuscript ID BMJ.2018.043530.R3 entitled "Arthroscopic Hip Surgery compared with Physiotherapy and Activity Modification for the Treatment of Symptomatic Femoroacetabular Impingement: A Multi-Centre Randomised Controlled Trial".

We wish to express concerns over these requested changes as we feel their implementation would harm the integrity of our research. We therefore request that our manuscript is reviewed by an additional independent statistical reviewer with explicit expertise in the conduct, analysis, and reporting of randomised controlled trials.

Our statistical analysis was overseen by Ms Susan Dutton, lead statistician for the Oxford Clinical Trials Research Unit. In response to comments from Prof Riley, we also consulted the wider statistical team at the Oxford Clinical Trials Research Unit and Centre for Statistics in Medicine, University of Oxford.

Areas that cause us particular concern are:

- 1) The request for subgroup analysis beyond those specified in our statistical analysis plan (including interactions between the treatment and continuous variables).
 - i) The requested analyses lie outside our pre-specified analysis plan. As per guidelines for clinical trials, a statistical analysis plan detailing information on all analyses to be performed for the FAIT trial was agreed and signed off before the final data lock for this study. It is best practice that the primary publication is based on this statistical analysis plan only.
 - ii) The subgroup analysis pre-specified by the FAIT team, and included in the original submission, follows standard reporting of RCTs. The FASHION trial, with comparable study populations and interventions, reports an identical subgroup analysis based on dichotomised variables to our statistical analysis plan.
 - iii) The study is not adequately powered for the analyses proposed by Prof Riley and is inappropriate for this sample size. We removed any possible over-emphasis of the results from the subgroup analyses and will emphasise the caveats of the originally proposed exploratory subgroup analysis. We strongly believe that results from the additionally requested subgroup analyses should not be reported in the paper.

- 2) The interpretation of the confidence interval around the treatment effect.

Prof Riley emphasises that we cannot claim benefit of one intervention over the other because the 95% confidence interval includes values that lie below the clinically important difference between groups. Sample size calculations are performed to detect a mean difference between treatment arms. In superiority studies, clinical trials conventionally interpret a difference to be clinically important when the mean difference exceeds the minimum clinically important difference between groups, without taking confidence intervals into account. The FASHION trial used the same interpretation that the statistical reviewer criticises in our manuscript.

- 3) We recognise a potential conflict of interest given Prof Riley works in the same department and recently co-authored a manuscript with the senior author of the FASHION trial.

Your sincerely,



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