Reviewer's report

Title: Effects of aerobic exercise on pain and disability in patients with non-specific chronic low back pain: a systematic review protocol

Version: 0 Date: 22 Nov 2018

Reviewer: Sofie Rygård

Reviewer's report:

I am pleased to get the opportunity to read and comment on this protocol. This is an interesting subject and very important to elucidate the existing knowledge on the field by a systematic review.

I have some comments and suggestions before finalization of the protocol.

TITLE: Are you not assessing the effect instead of the efficacy?

INTRODUCTION: consider rephrasing: "the most commonly prevalent..." to "the most prevalent...". In the last paragraph on the first page, your state the rationale for, why aerobic exercise can improve outcome among patients with chronic back pain. This paragraph could be more precise in stating, what do we know from other cohorts, what is the effect and why should this work on the patient group that you are examining?

METHODS:

PICO: Why are you planning to exclude studies with inadequate randomization process - this is not common practice. Instead, you would classify these studies as having a high risk of bias and base your primary analysis on the trials with overall low risk of bias.

Why are you only interested in mixed gender trials? You may describe the heterogeneity of studies and limit the conclusions because of heterogeneity of the patients. You may risk excluding valuable knowledge.

Do you plan to include cross-over studies - and if so, what will an required "wash-out" period be as minimum?
Regarding the outcomes: how are pain intensity and disability going to be defined? Would you consider only one primary outcome? Maybe QoL is more important to the patients - as it may contain pain and disability. …

Search: you should consider also include studies regardless of the publication status, and then perform searches in trial registries and conference proceedings, to find unpublished trial results. Publication bias is one of the most important bias in systematic reviews. If only published material is included, there is a risk of overestimating the intervention effect. Therefore, attempts to limit the publication bias should be achieved.

Consider having two reviewers for both screening phases.

Data extraction: consider specifying exactly what characteristics (patients and interventions) you would like to extract.

Risk of bias assessment: I am not familiar with the PEDro score, but the domains seems very appropriate and sufficient to be used instead of the Cochrane Handbook's tool for risk of bias assessment. Though, I have a major concern, that you will use other's assessments and not uniformly apply your own assessment and judgement for all included trials. Moreover, I am very concerned, that a cut off at 6 points is far to optimistic. In the Cochrane's tool, only when all domains are judged as being of low risk of bias, the overall judgement will be low - and ONLY these trials, will be of low risk of bias. As you mentioned in you preface, one limitation (important) to your review and meta-analysis is, that it can only be as good, as the included studies. By judging not-low-risk-of-bias-trials, as being low, you will introduce bias to your own review and results. It is far better to be completely transparent, and plan to perform your primary analysis on the trials with overall low risk of bias. If no trials are of overall low (score 10), then it is obvious, that this area needs more good clinical trials, and you can still perform secondary analyses, on all trials despite risk of bias. Alternatively, of you expect none to be of low risk of bias, you can in the protocol specify a category of overall "lower" risk of bias. Then you should specify, which items you would accept as not being met (getting a "no" answer). In this area, blinding is obviously impossible, and then these items could be allowed to have a "no", but you would still require the outcome assessors to be blinded.

Statistics: If you plan to use two primary outcomes, you should adjust for statistical significance level to account for multiple testing and the chance of a type I error.

Have considered included subgroup analyses (with test of interaction) - on e.g. overall low versus overall high risk of bias studies?
You should also consider including a sequential method (e.g. Trial Sequential Analysis) to account for random errors due to small sample sizes and multiple testing (i.e. the imprecision in the GRADE evaluation). Attempts to decrease bias and decrease random errors will improve your accuracy. Please see the proposed reference articles.1-3


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Were you mentored through this peer review?

No