PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A METHODOLOGICAL SURVEY ON REPORTING OF PILOT AND FEASIBILITY TRIALS FOR PHYSIOTHERAPY INTERVENTIONS: A STUDY PROTOCOL
AUTHORS	Scola, Luiz; Moseley, Anne; Thabane, Lehana; Almeida, Matheus; Costa, Lucíola

VERSION 1 – REVIEW

REVIEWER	Salvador Chacón-Moscoso University of Seville (Professor of Methodology), Universidad Autónoma de Chile (Senior Researcher)
REVIEW RETURNED	24-Dec-2017

GENERAL COMMENTS	- Justify the used categories for data extractition (literature review...). - Specify the concrete stages of screening and data collection where Kappa coefficients will be calculated. Specify what to do if adecuate reliability is not found.

REVIEWER	Hector Pardo-Hernandez Iberoamerican Cochrane Centre
REVIEW RETURNED	07-Feb-2018

GENERAL COMMENTS	This is a protocol for a methodological survey that aims to map the existing Physiotherapy pilot or feasibility trials with regards to the feasibility aspects evaluated, the completeness of reporting, and the factors associated with the completeness of reporting. Besides potentially generating guidance for reporting and assessing pilot and feasibility trials in this discipline, this survey may provide methodological parameters to enhance the design of this important type of studies. Below I present some comments and suggestions that should improve the presented protocol. 1. Based on the methodology of the protocol, it may be an overstatement to claim that this survey will evaluate pilot or feasibility trials for the entire discipline of Physiotherapy. The scope of work and of research of the field of Physiotherapy is well established, a fact reflected on the existence of a specific database for this discipline (i.e. PEDro). Nevertheless, the boundaries of what entails to classify an intervention as Physiotherapy may not be clear-cut. As such, there may be pilot or feasibility trials that are not indexed in PEDro and that are therefore not captured by this survey. There is also the issue of protocols published in non-English journals, which are less likely to be indexed in major literature databases, and which would require a handsearching approach. As a result, the statement that the authors will assess

	pilot and feasibility trials for the entire discipline of Physiotherapy should be attenuated. 2. Related to the previous comment, restricting this survey solely to PEDro may potentially miss eligible trials. While focusing on PEDro will lessen the workload by limiting the number of ineligible studies that need to be screened, authors can still implement a specific search strategy in PubMed (at the very least) and CENTRAL. The time of publication restriction is appropriate and properly justified. 3. The introduction is succinct and provides a fitting background to the issue of poor design and reporting of pilot and feasibility trials. However, authors could better explain, towards the end, the specific gap that this study will fill, specifically as it relates to pilot and feasibility trials in the field of Physiotherapy. 4. In the methods, authors should adhere to or at least acknowledge the PRISMA-P checklist, which provides guidance on the reporting of systematic review protocols, as well as the PRISMA checklist, specific for systematic reviews. 5. Authors should clarify how prospective trial registration will be ascertained. Will it be limited to what is reported in the manuscript of eligible studies or will prospective registries be searched? 6. Authors should consider including in this review an assessment of risk of bias using the Cochrane risk of bias assessment tool or a modified version that meets the specific needs of studies eligible for this survey. There is fairly recent evidence (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4498768/) that the PEDro scales score and the Cochrane risk of bias assessment tools may provide diverging quality appraisals, a fact that could be further investigated with the data collected from this study. 7. Under the secondary analysis, authors should clarify what they mean by “trial funded”. It is safe to assume that all trials receive some sort of direct or indirect funding. Perhaps it would be more informative to determine if the funding came from the private or public sector, and if it may be associated with potential conflicts of interest. Reporting of conflicts of interest by study authors could also be collected and assessed. 8. What exactly is meant by “non-Chinese reports”? Is this related to language, affiliation of the first or corresponding author, or type of intervention investigated? 9. What is the hypothesis behind conducting a secondary analysis for number of authors? Would not trial registration, endorsement of CONSORT by journal of publication, impact factor (not included in the protocol), or sample size be more indicative of potential associations? 10. To improve readability, I suggest: - The use of semi-colons throughout the paper should be revised in favor of using commas. The semi-colon should be limited to connecting two full sentences equal in position or rank or to separate lists with items that include commas. - Medical specialties, e.g. Physiotherapy, should be capitalized.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Salvador Chacón-Moscoso

Institution and Country: University of Seville (Professor of Methodology), Universidad Autónoma de Chile (Senior Researcher)
Please state any competing interests: None declared

Justify the used categories for data extraction (literature review...).

Thank you for your comment on this. We have rewritten this topic in order to improve the justification about why we selected these four categories. Please, see below:

Two independent reviewers will classify the reason(s) to conduct a pilot or feasibility for each included trial. There are several reasons for conducting pilot and feasibility studies. These reasons could be grouped under some broad classifications37. A widely known tutorial4 aimed to provide a detailed examination of the key aspects of pilot studies suggested four categories to classify the rationale to conduct a pilot study. The four categories are: 1) process (steps that need to take place as part of the main study), 2) resources (time and budget), 3) management (human and data optimization) or 4) scientific (issues like treatment safety).4 If more than one category is identified for an included trial, we will code for all relevant categories and indicate which category is linked to the primary objective of the trial. The number of subjects randomised and whether the pilot or feasibility trial recommends that a large-scale trial will be conducted will also be recorded.

Specify the concrete stages of screening and data collection where Kappa coefficients will be calculated. Specify what to do if adequate reliability is not found.

Thank you for your comment.

Screening and data extraction will be carried out by two independent reviewers using a customised data extraction form. Any disagreement will be resolved through consensus between the reviewers and by arbitration from the senior authors, if needed (LMC or LT). In order to improve the clarity regarding inclusions and exclusions and to increase accuracy and consistency among the reviewers, between reviewer agreements will be measured using Kappa coefficients using an initial trial run involving 10 articles per reviewer. If adequate reliability will be not achieved, additional training or improvement in the data extraction form will be undertaken.

We have included new information on this paragraph as suggested.

Reviewer: 2
Reviewer Name: Hector Pardo-Hernandez
Institution and Country: Iberoamerican Cochrane Centre
Please state any competing interests: None declared

This is a protocol for a methodological survey that aims to map the existing Physiotherapy pilot or feasibility trials with regards to the feasibility aspects evaluated, the completeness of reporting, and the factors associated with the completeness of reporting. Besides potentially generating guidance for reporting and assessing pilot and feasibility trials in this discipline, this survey may provide methodological parameters to enhance the design of this important type of studies. Below I present some comments and suggestions that should improve the presented protocol.

Based on the methodology of the protocol, it may be an overstatement to claim that this survey will evaluate pilot or feasibility trials for the entire discipline of Physiotherapy. The scope of work and of research of the field of Physiotherapy is well established, a fact reflected on the existence of a specific database for this discipline (i.e. PEDro). Nevertheless, the boundaries of what entails to classify an intervention as Physiotherapy may not be clear-cut. As such, there may be pilot or feasibility trials that

are not indexed in PEDro and that are therefore not captured by this survey. There is also the issue of protocols published in non-English journals, which are less likely to be indexed in major literature databases, and which would require a handsearching approach. As a result, the statement that the authors will assess pilot and feasibility trials for the entire discipline of Physiotherapy should be attenuated.

We would like to thank you for pointing this out. We agree that we are not evaluating pilot or feasibility trials for the entire discipline of physiotherapy. We have attenuated the statement as suggested across the whole manuscript as suggested by you.

Related to the previous comment, restricting this survey solely to PEDro may potentially miss eligible trials. While focusing on PEDro will lessen the workload by limiting the number of ineligible studies that need to be screened, authors can still implement a specific search strategy in PubMed (at the very least) and CENTRAL. The time of publication restriction is appropriate and properly justified.

Thank you for your comment.

The aim of our study is to evaluate the completeness of reporting of pilot and/or feasibility randomized trials that are indexed on PEDro database. We do not aim to systematically review the “entire” literature. The main reasons that we have chosen PEDro as the data source for this study are:
1. Firstly, there is convincing data showing that PEDro is the one of the most comprehensive databases of reports of physiotherapy trials2, 3. These two studies show that PEDro indexes from 92 to 99% of all physiotherapy trials (including non-English trials). Therefore, it is unlikely that the inclusion of trials from a wide range of databases would change the conclusions of our study.
2. Secondly, we have decided to use only PEDro database in order to make the data collection feasible. One of the authors of our study has direct access to the whole PEDro database, including the PDFs from all indexed trials.

Therefore, we would appreciate if you could reconsider your suggestion of searching more trials from a range of different databases.

The introduction is succinct and provides a fitting background to the issue of poor design and reporting of pilot and feasibility trials. However, authors could better explain, towards the end, the specific gap that this study will fill, specifically as it relates to pilot and feasibility trials in the field of Physiotherapy.

Thank you for your suggestion. We have revised this section as suggested. Please, see below:

The number of randomised controlled trials in physiotherapy has grown exponentially over time30. Time and funding are resources that could be saved by conducting high-quality pilot and feasibility studies. To our knowledge, the reporting quality of pilot and feasibility trails of physiotherapy interventions using the new extension of the CONSORT statement for randomised pilot and feasibility trials has not yet been performed, nor the factors associated with better reporting identified.
In the methods, authors should adhere to or at least acknowledge the PRISMA-P checklist, which provides guidance on the reporting of systematic review protocols, as well as the PRISMA checklist, specific for systematic reviews.

Thank you for your comment. We agree that the PRISMA-P should be used to guide the reporting of systematic reviews protocols. However, our study protocol aims to describe the completeness of reporting of pilot of randomized controlled trials indexed on PEDro database, which is the most complete database of randomized controlled trials in the physiotherapy field. The design of our study is a methodological survey and not a systematic review. We recognise that the misinterpretation was

due to the fact that similar articles already published related to this topic have named their study design as “methodological review” and not as a “systematic review”. We have revised the whole manuscript to check whether we have used incorrect words or sentences that could leave to this misinterpretation.

Authors should clarify how prospective trial registration will be ascertained. Will it be limited to what is reported in the manuscript of eligible studies or will prospective registries be searched?

Thank you for your comment. Firstly we will collect if the trial was registered from the trial report from all eligible studies. Secondly, if information on trial registration is missing we will search the International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/).

We have revised the manuscript to clarify this issue.

Authors should consider including in this review an assessment of risk of bias using the Cochrane risk of bias assessment tool or a modified version that meets the specific needs of studies eligible for this survey. There is fairly recent evidence (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4498768/) that the PEDro scales score and the Cochrane risk of bias assessment tools may provide diverging quality appraisals, a fact that could be further investigated with the data collected from this study.

Thank you for your suggestion. We understand that the Risk of Bias tool from the Cochrane Collaboration is a very useful tool. However, as our primary aim is to evaluate pilot and feasibility trials that were indexed on PEDro database; we believe that it would be easer to the readers to interpret the risk of bias assessment that has been already performed by the PEDro database using the PEDro Scale. In addition, risk of bias of the included studies will be downloaded directly from the PEDro server, which have been assessed by 2 well-trained assessors reducing, therefore, the possibility of mistakes. Finally, although the mentioned reference concluded that the PEDro scale score and the Cochrane risk of bias assessment tools may provide diverging quality appraisals, the findings from other studies shows the opposite. For example, there is evidence that PEDro scale has higher reliability for individual ratings and consensus ratings compared to the Cochrane risk of bias4, 5 and also PEDro scale is strongly correlated (r=0.83; 95% CI 0.76 to 0.88) with the Risk of Bias scale from the Cochrane Collaboration6.

Therefore, we believe that using the PEDro scale will not influence the investigation of methodological quality as a predictor of completeness of reporting. We hope that you will find our rationale for keeping PEDro rather than Cochrane risk of bias reasonable.

Under the secondary analysis, authors should clarify what they mean by “trial funded”. It is safe to assume that all trials receive some sort of direct or indirect funding. Perhaps it would be more informative to determine if the funding came from the private or public sector, and if it may be associated with potential conflicts of interest. Reporting of conflicts of interest by study authors could also be collected and assessed.

Thank you for your comment. We agree that collect extra information related to where the funding came from and potential conflicts of interest would improve the description of the included trials and also we could investigate the influence of these variables in the completeness of reporting.

Funding information will be collected throughout the reporting of included studies. The item 16 of the CONSORT extension for pilot and feasibility trials evaluate whether the trials received some source of external funding. Our hypothesis is that trials that have received some source of funding would be better reported than trials that do not received funding.

We have revised this section of the manuscript as suggested by you.

What exactly is meant by “non-Chinese reports”? Is this related to language, affiliation of the first or corresponding author, or type of intervention investigated?

Thank you for your comment on this point. Non-Chinese reports are related to language of publication, i.e. trial written in languages other than Chinese. Previous studies have shown that language of publication does not influence the methodological quality of clinical trials, being the only exception trials published in Chinese languages. Therefore, we have hypothesised that trials written in Chinese could also influence the quality of reporting.

We have revised the manuscript and modified the sentence on “Statistical analysis”. Please, see below:
“7) non-Chinese reports (trials published in languages other than Chinese)”

What is the hypothesis behind conducting a secondary analysis for number of authors? Would not trial registration, endorsement of CONSORT by journal of publication, impact factor (not included in the protocol), or sample size be more indicative of potential associations?

Thank you for this. Previous studies in health-related areas7, 8 reported that a higher number of authors would increase reporting quality of Randomized Controlled Trials. We intend to investigate whether this variable would also increase the reporting quality of pilot and feasibility studies in physiotherapy field. The other variables mentioned by you will be also tested (see methods section for more details).

To improve readability, I suggest:
- The use of semi-colons throughout the paper should be revised in favor of using commas. The semi-colon should be limited to connecting two full sentences equal in position or rank or to separate lists with items that include commas.
- Medical specialties, e.g. Physiotherapy, should be capitalized.

Thank you for your suggestion. We have revised this as suggested.

REFERENCES

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VERSION 2 – REVIEW

REVIEWER	Hector Pardo-Hernandez Iberoamerican Cochrane Centre
REVIEW RETURNED	05-Jun-2018

GENERAL COMMENTS	The authors have addressed most of the concerns raised during the first review. As a result, the protocol has improved substantially. A few aspects remain pending, as follow: 1. It is misleading and inconsistent with current evidence to state that (any kind of) funding is associated with improved reporting quality. There is vast literature pointing that studies funded by the pharmaceutical industry are more prone to dissemination (publication) bias, including failure to report negative results, time-lag bias, and selective outcome reporting. Authors should rephrase the third paragraph in the introduction to reflect this. 2. Regarding the search strategy, I am unaware of how to conduct a search in PEDro. If there are more ways to identify randomised controlled trials besides the term “clinical trial”, authors should consider them as well. 3. Citing only Yamato et al without also citing PMC4498768 – Armijo Olive is misleading to the reader regarding how results based on the PEDro scale compare to the Cochrane Risk of Bias scale. I strongly suggest to cite both and to reword the sentence in page, 10, line 236. 4. Under data extraction, second paragraph, I suppose that reviewers will complete the CONSORT (pilot and feasibility) trials checklist OR the CONSORT (pilot and feasibility) trials abstracts checklist. If this is true, this section should be amended. 5. To improve readability, I suggest: □ The use of semi-colons throughout the paper should be revised. For instance, the use of semi-colons is incorrect in the Abstract/Introduction and under Methods/Data Extraction/fourth paragraph (The items are…). □ Under strengths and limitations – last sentence (page 3 of 21, line 73, findings from this study are restricted…) add “in Physiotherapy”. □ Under Methods/Studies selection, the title could be changed to “Study selection”. The subsequent sentence could be: “Two independent reviewers will screen titles and abstracts to identify references that claim to be a pilot or feasibility trial”.

	□ Add “if available” after journal impact factor (page 11, line 255).

VERSION 2 – AUTHOR RESPONSE

Reviewer: 2
Reviewer Name: Hector Pardo-Hernandez
Institution and Country: Iberoamerican Cochrane Centre
Please state any competing interests: None declared

The authors have addressed most of the concerns raised during the first review. As a result, the protocol has improved substantially. A few aspects remain pending, as follow:
1. It is misleading and inconsistent with current evidence to state that (any kind of) funding is associated with improved reporting quality. There is vast literature pointing that studies funded by the pharmaceutical industry are more prone to dissemination (publication) bias, including failure to report negative results, time-lag bias, and selective outcome reporting. Authors should rephrase the third paragraph in the introduction to reflect this.
Thank you for your comment and we agree with you. We have rephrased the third paragraph as requested. Reference 14 is related physiotherapy trials. All trials from this reference received funding from research funding agencies. This section of the paragraph now reads:

…“receiving grants from research funding agencies”, …

2. Regarding the search strategy, I am unaware of how to conduct a search in PEDro. If there are more ways to identify randomised controlled trials besides the term “clinical trial”, authors should consider them as well.
Thank you for your comment. The term “clinical trial” is the only filter used for searching for randomised controlled trials on PEDro. As this is the only possibility of searching on PEDro, no changes in the manuscript were done.

3. Citing only Yamato et al without also citing PMC4498768 – Armijo Olive is misleading to the reader regarding how results based on the PEDro scale compare to the Cochrane Risk of Bias scale. I strongly suggest to cite both and to reword the sentence in page, 10, line 236.

Thank you for your suggestion. We have cited both references and mentioned the findings of Armijo Olive’s study as suggested. This section now reads:

“There is evidence that PEDro scale has higher reliability for individual ratings and consensus ratings compared to the Cochrane risk of bias[1, 2]. Also, PEDro scale is strongly correlated (r=0.83, 95% CI 0.76

to 0.88) with the Cochrane Risk of Bias scale[3]. On the other hand, a meta-epidemiological study found discrepancies in terms of clinical trial's quality using PEDro and Cochrane Risk of Bias scale [4]."

4. Under data extraction, second paragraph, I suppose that reviewers will complete the CONSORT (pilot and feasibility) trials checklist OR the CONSORT (pilot and feasibility) trials abstracts checklist. If this is true, this section should be amended.

Thank you for you comment. The reviewers will complete both the CONSORT statement trials checklist AND the CONSORT trials abstract checklist. We have clarified this into the manuscript.

5. To improve readability, I suggest:

The use of semi-colons throughout the paper should be revised. For instance, the use of semi-colons is incorrect in the Abstract/Introduction and under Methods/Data Extraction/fourth paragraph (The items are…).

Thank you for your suggestion. The manuscript is now fully revised.

Under strengths and limitations – last sentence (page 3 of 21, line 73, findings from this study are restricted…) add "in Physiotherapy".

Thank you for your comment. We have included "in physiotherapy" as suggested.

Under Methods/Studies selection, the title could be changed to "Study selection". The subsequent sentence could be: "Two independent reviewers will screen titles and abstracts to identify references that claim to be a pilot or feasibility trial".

Thank you. We have revised both the title and the sentence as suggested.

Add "if available" after journal impact factor (page 11, line 255).

Thank you. We have revised this sentence as suggested.

VERSION 3 – REVIEW

REVIEWER	Hector Pardo-Hernandez, PhD Iberoamerican Cochrane Centre
REVIEW RETURNED	30-Nov-2018

GENERAL COMMENTS	The authors have made substantial improvements to this manuscript, which is now ready for publication. The only final suggestion is to add commas to numerals 2) and 3) under Methods/Statistical Analysis, line 287. This change can be made directly on the proofs, right before final publication.