Reviewer’s report

Title: Effectiveness, costs and cost-effectiveness of chiropractic care and physiotherapy compared with information and advice in the treatment of non-specific chronic low back pain - study protocol for a randomized controlled trial

Version: 0 Date: 29 Aug 2017

Reviewer: Sarah Paganini

Reviewer’s report:

The present study aims to evaluate the effectiveness and cost-effectiveness of chiropractic care and/or physiotherapy with information and advice and information and advice only. This can help to reveal if one of the treatments is superior and results might be helpful in decision making processes. However, the importance and rationale of this trial should be discussed and highlighted more. Furthermore the cost-effectiveness analysis should be described in more detail. Because of these aspects and as well because of linguistic aspects the present manuscript needs some revision.

Major comments:

Title:

1) One aim of the study is to evaluate the cost-effectiveness: This should be mentioned in the title (not only "costs")

Abstract:

1) In "Methods" it is not clear, that "information and advice" is present in all groups.

Background:

1) 84-94: More aspects of CLBP and its consequences should be discussed (more detailed).

2) 89: How high are the costs for this disorder? Examples would be helpful.

3) 102: "Physiotherapists typically also use different types of training and exercise, which is less frequently used by chiropractors." The meaning of this and the following sentence is very broad. The authors should specify these statements and refer to literature.

4) 108-110: The authors should specify their statement. Main results of the cited reviews should be summarized/reported.
5) 117: "costs within and outside the health care system" should be specified.

6) 123: "QALYs" are no type of analysis. The analysis is the cost-effectiveness- (or cost-utility-) analysis.

7) 131: High internal and external validity is mentioned. However, it should also be mentioned the limitation, that the study is not powered for an economic evaluation (maybe under "Methods").

8) There should be a more detailed rationale for the aim of this study. Why is it important to compare these treatments? Why is there a comparison to "only information and advice"? Is the hypothesis that information and advice might be enough and the other treatments could be used less often?

Methods:

1) Aim and research questions should be in the section before

2) The research questions should be formulated more precisely. The group with "only information and advice" is "missing" in this research question. Why are there two research questions for QALYs/costs and cost-effectiveness? By conducting a cost-effectiveness-analysis the parameters of question 2 are included and can be discussed.

3) 181: "Each participant's treatment is at the discretion of the individual chiropractor and/or physiotherapist." Are there (official) guidelines existing, that define what those treatments typically include or how many sessions are standard?

4) 204: This exclusion criteria should be specified: „patients with specific pathology or who in any other way are unsuited for the study treatments."

5) 230: What is the block size?

6) To increase quality of the trial, it should be conducted and reported according to the CONSORT statement (guidelines for reporting parallel group randomised trials).

7) 350: It should be described more detailed how quality of life values are generated with the mentioned instrument/question (SRH). The given reference is about the EQ5D.

8) 366: A societal perspective usually includes absenteeism and presenteeism costs. Do you also collect data, like days not worked because of sick leave or how productive they are at work?

9) Is there a guidline or recommendation of an article for the calculation of indirect costs/value of production conducted in this trial?
10) How are the direct and indirect costs assessed exactly? Are participants asked for it or is a questionnaire used?

11) There is no description of the statistical analysis for the cost-effectiveness analysis. This is only described under "Exploratory outcome measures". According to this section, only ICERs are calculated (no bootstrapping, acceptability curves, cost-effectiveness diagram). Is that right? If a cost-effectiveness paper is planned, the CHEERS guidelines should be followed (Husereau et al., 2013. Consolidated Health Economic Evaluation Reporting Standards (CHEERS)—Explanation and Elaboration: A Report of the ISPOR Health Economic Evaluation Publication Guidelines Good Reporting Practices Task Force).

12) According to the SPIRIT-Checklist there are some aspects missing (e.g. aspects of the section „Monitoring“)

Discussion

1) In the discussion there is a strong focus on the recruitment. Some parts would better fit into the section "Methods". It should be more highlighted what the strengths and limitations of this trial are. There is only one sentence about the impact of results. This should be discussed more detailed.

At times, some of the phrasing was a bit unclear or difficult to follow. Syntax/grammar/spelling should be checked and I think that the manuscript could benefit from proof reading by a native English speaker.

Minor Comments:

1) 127: A better alternative to „an economic evaluation is integrated in a RCT“ is „an economic evaluation was conducted alongside a RCT"

2) 254-257 and 258: The explanation of „information and advice“ is given twice

3) Missing references: 86-89, 105 (there should be the reference instead of the publication year), 111-112, 125, 320 (reference of the questionnaires)

4) 446: The authors of the studies should be written down (instead of only the reference numbers 39 and 40)

5) The order could be modified in some sections, e.g.: 182: A "similar RCT" is mentioned here. Results of this study could be better implemented and discussed in the background section, 320: Outcome measures could be described first (then data collection and timeline); 404: The information, that missing data will be imputed should be mentioned and described earlier, when the use of ITT analysis is described (right now it is in 440),
The calculation of the sample size should be mentioned earlier (according to the SPIRIT in „Methods: Participants, interventions, and outcomes“)

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