Author's response to reviews

Title: Evaluation of a tailored, multi-component intervention for implementation of evidence-based clinical practice guidelines in primary care physical therapy: a non-randomized controlled study

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Date: 4 December 2013

Author's response to reviews: see over
Dear editor (s):

Thank you very much for inviting us to submit another revision of our manuscript “Evaluation of a tailored, multi-component intervention for implementation of evidence-based clinical practice guidelines in primary care physical therapy: a non-randomized controlled trial” (MS: 1250914102102607).

We thank Reviewer 1 for accepting the previous version of the manuscript and Reviewer 2 for her additional comments, thorough review, and many constructive suggestions for our manuscript. We have carefully considered all comments and suggestions, have revised the manuscript on relevant points and have addressed them point-by-point in this response letter. We are somewhat reluctant to comply with some suggestions for additions, in view of the manuscript already being long (and the reviewer simultaneously suggesting to shorten it), as well as the other reviewer being satisfied with our previous revision.

We acknowledge that the manuscript is still long, but believe that it is important to describe and discuss interventions in sufficient detail to enhance transparency.

Details of our revision are provided below.

We thank you in advance for your continued consideration of this manuscript for publication in BMC Health Services Research and hope that the current version will be accepted for publication.

Sincerely,

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Reviewer's report

Version: 2 Date: 6 November 2013

Reviewer: Henna Hasson

Reviewer's report:

Comments to the authors

Major Compulsory Revisions

My main concern is still the fact that the study design is too weak for investigating effects of implementation strategies. The authors answered to my previous comment (number 1) with “…. compare different implementation strategies, to see which one are most effective in implementing the intervention….”. I totally agree with this definition. Thus, the comparison of different strategies is missing in this study. Perhaps the aim of the study should be rephrased to for instance following: …To analyze implementation outcomes after receiving a multi-component implementation intervention, compared with those receiving no intervention (control group). This would imply not using the wording effects which would have consequences for the presentation of the results and the discussion part.

Thank you for raising this concern and allowing us to clarify. We consider this to be an intervention study rather than an implementation study, as there was a concerted effort to influence the behaviors of healthcare providers and other process outcomes. Intervention studies can focus on patients, populations, healthcare providers, etc. The intervention involved education, and effectiveness was measured primarily in terms of various aspects of guideline use. We compared an intervention to a control group that, as you say, received no intervention but continued usual practice. We have attempted to rephrase the aim to further clarify this, and changed the word “effects” to “effectiveness” and replaced “usual practice” with “no intervention” (revised consistently throughout the manuscript). However, our somewhat different perspectives on implementation research (implementation study vs intervention study) have led us to understand why you earlier wanted us to change “process outcomes” to “implementation outcomes”. We now feel that “process outcomes” is indeed the more suitable term for intervention studies; it is the term that we see used quite consistently in the literature in this field. We also think it is important to distinguish process outcomes from patient health outcomes, and it is a limitation of our study that we only measured process outcomes. We have clarified this in the Methodological considerations section (p. 23). We are therefore proposing to change back to this term and have done so in the manuscript. Should this be a major problem for acceptance of the paper we would of course be willing to reconsider.

Please note that the only difference between our study and the strongest research design, RCT, is that we did not perform a randomization. However, we allocated physiotherapists to the intervention or control group based on geographical region. All physiotherapy practices within these regions were invited to participate in the study, so selection bias is likely to be small. Also, baseline data did not differ significantly, and differences between the groups are likely to be effects of the intervention (see our discussion under Methodological considerations, p. 23).

It is stated that the intervention was based on a theoretical model. This model is not presented in the paper. I’m not sure that the reference (number 17) includes any theories. Or perhaps the
authors mean a conceptual model or framework rather than a theory? Perhaps there is a different understanding for what consist of a theory and the authors should clarify what they mean with a theory in this case. The basic components of that theory should be presented in the paper. This part should be clarified and the entire paper referring to the theory should be revised in accordance.

Thank you for these suggestions. The intervention was based on the 5-step implementation model by Grol et al, which is presented in Figure 3 (along with how it was adapted/applied to our study). We have revised the manuscript to clarify this (p. 9). Grol et al’s model is an implementation model based on theories, but in a rather implicit way. Reference no. 17 is a comprehensive textbook in implementation science, written by Grol et al. The book includes a considerable number of theories for behavioral change, e.g. cognitive, educational, social, communication, and marketing theories (Ch. 2, pp 15). The implementation model that we used is based on a comprehensive overview of theories for behavioral change and integrates several of these theories (Ch. 3, pp 41). We used the model as a framework, and selected it because it is based on several theories and constitutes a synthesis of these, as stated in the manuscript (p. 9). We feel that defining and describing theories is outside the scope of this paper, and would require considerable space. We have downplayed the role of theory by changing “theory-based” to “theory-informed” in the Introduction (p. 6), Discussion (p. 15) and in the Conclusion (p. 26). We have changed “theoretical model” to “implementation model” (Discussion, p.15).

It is suggested that a rational for the choice of these intervention components should be more developed. The table 4 presents the findings of the prior survey and the activities provided in the intervention. It seems that most of these aspects deals with knowledge of guidelines rather than for instance facilitation of actual work with guidelines at work practices. Is it possible that the survey lacks relevant items and thus the intervention also lacks some important components?

Thank you for this suggestion. We agree that it is important to describe the rationale for the choice of the intervention components, but feel that we have done so sufficiently already. It is described both under Implementation strategy development and in more detail in Figure 4. The figure presents barriers and facilitators identified in the survey and how they were addressed, either in the guideline development or in the guideline implementation intervention. Only three of these 12 variables (awareness of the existence of guidelines, knowledge where to find them, and knowledge how to integrate patient preferences with guidelines) fall within the knowledge domain. As you point out, it is possible that the survey and the intervention lacked some components. Still, we believe the ones we addressed, such as awareness of, knowledge where to find, and easy access to guidelines indeed facilitates working with guidelines at practices, compared with not knowing and having to search high and low for them, as was the case before our intervention.

The prior studies that are currently presented in the paper are mostly used to motivate the current intervention components (for instance “educational material (e.g., guidelines) [22], interactive education [23] and reminders [24]” p. 5). The extensive review by Grimshaw et al (2013) also present other intervention activities that the authors could have used. Thus, a rational is needed for the choice of for instance a seminar. What was the main function of this activity? Or is the choice of intervention components based on the theory of the intervention? We agree that there are many different intervention activities that could potentially be chosen. However, it should be noted that our intervention was planned in 2010 and carried out in 2011 – one year before the Grimshaw review (2012) was published. We developed our implementation intervention based on the literature available in 2010 plus the identified barriers and facilitators that were specific to this context and target group. The seminar was
structured as an interactive education session since the literature showed this to be effective. The main function of the seminar was information and education. We have added a brief discussion on other possible intervention components under Implementation Strategy in the Discussion section (p. 23).

The paper could benefit from at least two things: 1) rational and discussion of other possible implementation strategies (which was also suggested by the reviewer Ilona Autti-Rämmö) and 2) a program logic thinking i.e. providing a description of core intervention components together with a short description of expected immediate, short and long term outcomes. This should then also be discussed in the discussion part in terms of what parts of the multi-component intervention were possible affecting the outcomes. In addition, the reviewer Ilona Autti-Rämmö raised a concern about alternative strategies (comment 5). It is suggested that the authors take some more time on considering this comment. The choice of the primary outcomes should be motivated. Are these relevant measures taken into consideration the logic model suggested above? The authors could discuss the outcomes in relation to Proctor’s implementation outcomes and provide a rational for the choice of the outcomes.

Thank you for these suggestions. We agree that using a program logic model (“program theory”), could be useful in this type of study, particularly when interventions are multi-component and complex, and that it could have facilitated making explicit the assumed causal mechanisms of such programs, i.e. essentially specifying the theory of change. However, this seems somewhat less relevant when using an intervention which is primarily based on “cognitive assumptions”, i.e. change requires changes in awareness, knowledge, attitudes, etc., as described in numerous social cognitive theories which are based on similar assumptions of how behaviour change occurs. In other words: the logic models of these theories/models is sort of inherent in the theories/models. Also, since we have used the Grol model, we find it difficult to apply another model/concept a posteriori, and this would also entail a risk of the paper becoming too long. We have added the rationale for the choice of primary outcomes (p. 11-12).

As regards the rationale for the implementation strategy, this is built up in the paper from the Introduction (p. 5, second half, and p. 6) and in the section Implementation strategy development (p. 8). We have revised the first paragraph in the aforementioned section to present the rationale for the strategies more clearly (p. 9). We have added a discussion on other implementation strategies, in the Implementation strategy section (p. 22-23) and in the Implications for research section (p. 25). Other possible educational strategies, as per the suggestion by the other reviewer, are already discussed in the Implications for practice section (p. 24).

It is stated that ”This study showed that a tailored, multi-component guideline implementation intervention, based on a theoretical model as well as current evidence, can affect the frequency of guideline use, as well as several determinants of guideline use, among PTs in primary care.” However, the results of the study showed that the intervention group had significantly higher proportion of PTs that reported being aware of guidelines, knowing where to find guidelines and having easy access to guidelines. The use of guidelines between the intervention and control group was only significant when analyzing the sub-groups of the intervention group. Thus, the results showed that the PTs who participated in the implementation seminar reported frequent use of guidelines to significantly greater extent than those in the control group. Would this imply that the seminar (a single intervention components rather than multi-component interventions) had significant effect on guideline use? A program logic (as suggested above) could help to make sense of this.

Yes, we believe the implementation seminar was the core intervention component and that this
had a significant effect on guideline use. This also justifies performing separate analysis of those who participated in the seminar, as we have done. We also believe that of the other components, particularly the website was an important component since it addressed the other primary outcomes (awareness, knowledge, access).

The first paragraph in the discussion section states that knowledge of guidelines is important for use of guidelines. Knowledge is one component, but later research on implementation has clearly showed that knowledge is not enough for using guidelines/methods (for instance several publications from Michie et al). It is suggested that the authors do not emphasize the knowledge items this much. In addition, more recent references to this part should be used. Many of the references are old and not totally in line with current research. Rather, the discussion should be more balanced in terms of recognizing the limitation of these findings. In fact, even the knowledge increased among intervention participants they still did not use the guidelines to any higher extent.

Thank you for this suggestion. We agree with your comments. We have nuanced this first paragraph to be more balanced and not emphasize the knowledge domain outcomes, by adding text on guideline use, with recent references (Ref. 49-51), and also adding attitudes to the introductory summary of findings in the paragraph (p. 15). Guideline use (behavior) is also already discussed to a larger extent later in the Discussion section, which further balances the discussion. The fact that knowledge increased but not use of guidelines to the same extent is also already discussed in Implications for practice. Most of our references are articles published between 2005 and 2013. The ones that are older are classical works that we consider relevant.

Minor Essential Revisions

The discussion section is still lengthy and needs to be sharpened. Instead of comparing to several prior studies separately (section Comparison to previous studies) perhaps the studies could be grouped in a meaningful way. This would shorten this part which is necessary. In addition, some of the text under heading "Possible explanations of the results" are more methodological discussion points. Perhaps these could be organized under a heading methodological discussion. The heading limitation could be removed in that case. We have shortened the discussion under Comparison to previous studies and rearranged the section so that the PT studies now are grouped together in a more meaningful way, before we discuss implementation effects in other healthcare areas. Since there are so few studies done on guideline implementation in physical therapy, we feel it is important and relevant to discuss them in some detail (e.g., intervention components) in the way we do. We added a sentence at the end of this section to further explain why baseline rates were high (p. 21). We have changed the heading “Limitations” to “Methodological considerations” and moved two paragraphs from Possible explanations of the results.

A short discussion about when to measure different implementation outcomes would be fruitful. Is this correct time frame to measure for instance knowledge and use. Should use be measured after knowledge? Kirkpatrick’s model of evaluation might guide this discussion. Thank you for the interesting suggestion to use Kirkpatrick’s model, which has stood the test of time as a framework (essentially a logic model) for evaluating courses, education, etc. We completely agree that implementation science could benefit from this type of model to support logic chains and time frames. However, as robust as Kirkpatrick’s model is, it has a rather narrow focus on knowledge and education (a “cognitive revolution” product). Therefore, we do not think it is fully appropriate for this study. We didn’t aim for or measure outcomes at the 4 levels in the Kirkpatrick model, particularly not the first and last. Although the core
component of our intervention, the seminar, included a learning component, learning and increased knowledge was not the main goal of the intervention. The knowledge items we measured were awareness and knowledge about the existence of guidelines, not the content of the guidelines. Time frame is discussed under Methodological considerations as well as Implications for practice. We have elaborated on the time frame, citing the Pathman model, which is guideline-specific and, like Kirkpatrick, supports a logic and sequential thinking (p. 24).

The discussion section still lacks a discussion of the most important implication of this study, especially for implementation and intervention research. We have added an important implication related to our use of the Grol model, in the Implementation Strategy section (p. 20) and in Implications for Practice (p. 25). We believe we have already discussed several other important implications.

Comments concerning the “Implications for research” “Measuring the effect of implementation interventions as well as guideline use is very complex, but very important.” seem not to add anything to the paper. Could be omitted.

We believe that measuring guideline use and the effectiveness of implementation interventions is very important in this day and age when an abundance of guidelines are being developed but it is rare that their use is being measured and that their implementation is evaluated, particularly in physiotherapy. We therefore want to emphasize this.

The suggestion that a passive dissemination of guidelines should be evaluated in future studies seems strange. Wouldn’t it be more valuable to evaluate for instance two active interventions with a manipulation on different intervention components based on prior studies and relevant theories? The main suggestion should perhaps be the comparison of active interventions rather than having intervention versus control? This would be in line with Hybrid design type of studies. We have revised the sentence as per your suggestion (p. 25).

Please clarify what “Data should be collected so that individual changes from baseline to follow-up can be analyzed.” implies. This sentence was added in our previous revision in response to the other reviewer, who was satisfied with it. We hope this is clear so that we do not need to further revise the paper on this issue. (The main implication is that it would allow for more sophisticated statistical methods than the rather simple proportion analyses we have performed).

Many of the suggestions for future research are important but not in the main scope of implementation researchers (effect on patient outcomes, cost-effectiveness, qualitative studies). It would be more interesting to hear the authors more thorough analysis of need for future research based on the learning from this specific study. What is the next step for multi-component, tailored implementation studies?

We believe that implementation science (i.e. implementation research with a focus on implementing evidence-based practices in health care) is at an early stage of development. We think the field needs further development and this is occurring as we speak. Hence, we believe that studying patient outcomes, cost-effectiveness and performing qualitative studies are indeed within the main scope of implementation research, particularly as it relates to the sub-field of guideline implementation. These are already issues that are being discussed at international conferences in the field. Specific suggestions based on the learning from our study have already been stated in the beginning of the section Implications for research, and further with the present revision of points above.