Author's response to reviews

Title: Development of a theory- and evidence-based intervention to enhance implementation of physical therapy guidelines for the management of low back pain

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Author's response to reviews: see over
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Dear Editor,

Herewith we submit the revised version of the manuscript MS:8314373711058351 entitled “Development of a theory- and evidence-based intervention to enhance implementation of physical therapy guidelines for the management of low back pain”. We thank the reviewers for their effort. It provided us the opportunity to improve our manuscript. Our responses to the reviewers remarks are presented on the next pages of this letter.

Kind regards,

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Response to review (Reviewer 1)

23 November 2013

1) We suggest thus to revise the paper in order to avoid any confusion with a paper presenting the results of a study that would have tested a well-defined hypothesis. It would be better to acknowledge from the start the descriptive, and in some respect, narrative character of your paper. Another option could be to focus the paper on the first step of the intervention program development process: the formative research methods and their findings. It seems indeed that this study phase did include an impressive amount of data collection: 3 + 4 focus groups, a cross-sectional survey and a longitudinal one! And the corresponding results have apparently not been published so far. The comments and suggestions made hereafter do not consider however this last option.

We thank the reviewer for this suggestion. The aim of the paper is indeed to show how the process of intervention mapping can be used to develop an intervention to improve guideline adherence. This process is based on preceding formative research. A paper that reports on this formative research is under development. Therefore we prefer not to further elaborate on the formative research in this paper. However, since reviewer 2 has several questions that relate to the formative research, we decided to add Appendix 1 in which methods and main outcomes of the preceding work are summarised.

Major Compulsory Revisions

2) Please redefine clearly what is the aim of your paper and ensure coherence between the abstract and the background text. In my view, it could possibly be something like “showing how intervention mapping can be used to develop a theory- and evidence-based intervention”.

We adjusted the aim of the paper in the background section and made it coherent with the abstract.

The aim of the study was to demonstrate how the process of Intervention Mapping {Bartholomew, 2011 #935} can be used to develop an intervention, to address the lack of adherence to the national CPG for low back pain by Dutch physical therapists.

We also adjusted the first sentence of the Discussion section: This study demonstrates how the framework of Intervention Mapping can be used to develop interventions that aim to improve guideline adherence based on formative research

2) Explicit for the reader what is the specific scope of this paper with reference to your other published paper (BMC 2013).

To make a more clear distinction between the papers, we added the following lines to the final paragraph of the Background section:
After its development, the intervention was evaluated on its feasibility and potential effectiveness in a pilot test of which the results are reported elsewhere {Rutten, 2013 #945}.

Minor Essential Revisions

3) Explain what is the exact role of the “quality managers” mentioned in the paper. Is this function legally determined in the Dutch health care system? Or is it a particular feature of the physiotherapy departments where the study was conducted? Do these managers have a hierarchical role towards the basic PTs?

To explain the presence of quality managers, we added the following lines to the first paragraph of the Intervention Mapping subsection.

Due to issues of quality control and quality certification by health insurance companies, there is a growing tendency in Dutch physical therapy practices to make one of their colleagues responsible for quality management.

4) As far as a multimodal development process is described, a key information is lacking: no indication is given regarding the duration of each phase or step in the process. This time information would be of great interest when considering the transferability of the described process to other settings or other groups of health professionals.

Intervention mapping is generally rather an iterative than a linear process, in which preparations for the next phase are already made in the previous phase. As a consequence it is difficult to provide an exact timeframe per phase. However, a time indication can be provided per phase of the process. We prefer to let the time investment of the formative research aside, because due to the fact that this was a research project especially this part of the process has been far more extensive as when only the development of a programme would have been at stake.

We added the following lines to the paragraphs of the specific phases.

In the first three months of the Intervention Mapping process, we created matrices of change objectives.

Based on the change objectives, we used the next 3-4 months to match theory-informed intervention methods to the change objectives for therapists and managers and to formulate practical applications.

During the next 4 months, the project team worked with two experienced physical therapy trainers with expertise in quality improvement projects.

5) In the Discussion section, no consideration is given to the intervention related costs. If you conclude (p 19) that “Intervention Mapping can be a valuable framework…”, you should also discuss feasibility aspects.

We added a paragraph to the Discussion section that considers the cost aspect of the process. However, since we did not measure costs of the development of the
intervention, it is difficult to be very specific. Other feasibility issues are raised in the foregoing paragraphs of the Discussion:

Finally, the foregoing issues raised, indicate that thoroughly going through each step of Intervention Mapping may be a time consuming, and therefore costly process. It is indeed our opinion that familiarity and experience with the Intervention Mapping procedure may be a great advantage in this respect. The Intervention Mapping process may further benefit from sound planning based on anticipation on the subsequent steps. This can reduce the likelihood of unforeseen developments and too much backtracking, and consequently of the required time investment.

Discretionary Revisions
6) Abstract (line 2 in results): “Self regulation was appropriate because both…”
Very unclear sentence

We adjusted this sentence:
Self-regulation was appropriate because both the physical therapists and the practice managers needed to monitor current practice and make and implement plans for change.

7) Background (last line p7) : “..adress the lack of adherence to the national CPG…” ref 14 and 15 should be mentioned here.
The references are included.

8) P 10 Intervention mapping : “…two interacting practice levels” : this seem to imply that the work environment is a physiotherapy department in a (or several) hospital, excluding thus private practices. Is this interpretation right?

To avoid this confusion we adjusted the phrase:
The project team focused the intervention on two interacting practice levels: private practice physical therapy and practice quality management.

Response to review (Reviewer 2)

- Major Compulsory Revisions

General response to remarks on subsection Formative Research Methods
These remarks relate to the issue raised by reviewer 1 about the objective of the paper. Based on the recommendation of reviewer 1 we adjusted the phrases about the objective of the paper. Nevertheless, we understand the reviewer's request for more information about the formative research. However, since the objective of the paper is rather to show how the process of intervention mapping can be used to develop an intervention to improve guideline adherence, the focus is on the
We used a multimethod approach to understanding the behavioural and environmental factors that influence guideline adherence {Schoster, 2012 #936}, consisting of two literature reviews and a series of theory-based qualitative and quantitative studies (for detailed information see Appendix 1).

1. Page 8/28, paragraph “Formative Research Methods”: the authors explain that they made 2 literature reviews; I think that additional data is needed regarding the way they were done, the articles that were considered, ....

See Appendix 1

2. Page 8/28, paragraph “Formative Research Methods”: According to me, there is a lack of information regarding the participants to the survey: authors do not describe them at all (age,....) although they could have an influence: one can imagine that the age of the PT might influence the guideline adherence.

See Appendix 1

3. Page 8/28, paragraph “Formative Research Methods”: the authors state “…we aimed to quantify the relation between these cognitive factors and guideline adherence”. However, readers do not understand well how it will be quantify and the results do not really describe the quantification of this relation.

In relatively unexplored research areas such as physical therapists’ guideline adherence, it is a customary approach to start with qualitative research (for instance interviews) and subsequently to use the findings of the qualitative research to develop a questionnaire to execute a survey. Since a questionnaire survey results in quantitative data, it allows the researcher to execute various calculations and analyses that are not possible with qualitative data. The quantification of the relations will be presented in the paper about this subject, but the Appendix 1 provides a more detailed description of the results. We adjusted the sentence:

The subsequent cross sectional survey (n= 472), resulted in quantitative data, which allowed us to assess the strength of the relation between these cognitive factors and guideline adherence.

4. Page 8/28, paragraph "Formative Research Methods": the authors state
“Finally, we conducted a longitudinal survey…”. It is not easy for the reader to understand what are the results of this longitudinal study and when they are presented within the manuscript.

The development of an intervention by means of Intervention Mapping is preferably based on a multi method problem assessment (the formative research). The findings of the formative research presented in this paper are the result of an elaborate process in which the results of qualitative and quantitative cross sectional and longitudinal studies have been used to develop a synthesis. For the main results per method we refer to Appendix 1. We also added a sentence at the start of the ‘formative findings’ subsection:

We used the results of our multi method formative work to develop a synthesis of most important determinants. Subsequently, we organized our findings into a logic model of the problem of lack of guideline adherence highlighting the central roles of therapists and the practice quality managers (See Figure 1). This model was presented to and discussed with the members of the program planning team to check if the model actually covered the most important determinants.

5. Page 9/28, paragraph “Formative findings”: authors state “We found the most important personal influences on physical therapists’ performance were…” It is not easy for the reader to understand which sample was used (n=394?) and how the “PT' performance” was assessed (did you calculate a score?). Do the readers make reference to a previous publication? It is not clear.

Details about the samples are presented in Appendix 1

Indeed we refer to our recently published paper on the evaluation of the intervention. This paper provides a description of the development of the quality indicators to measure PT performance. We adjusted the text to make this more clear. For further adjustments concerning the measurement of PT performance in the text we refer to the answer on remark 7

Based on the guidelines, we described adherence with 12 individual indicators from the guidelines, they are: 1. assessing warning signs of the need for physician referral, 2. making a physician referral if needed 3. applying the ICF, 4. assessing a patient profile, 5. choosing examination objectives based on the profile, 6. creating treatment objectives based on the profile, 7. developing treatment strategies based on the profile; 8. determining maximum number of treatment sessions, 9. providing adequate patient information; 10. measuring outcomes, 11. arranging aftercare, 12. providing a written report to the referring physician {Rutten, 2013 #945}.

6. Page 10/28, paragraph “Environmental influences…”: the authors state that “The CPGs on low back pain were judged by SOME to lack credibility…”. If these are original results of the present publication, results regarding barriers should be described more extensively (e.g. % of citation among the sample).
We agree with the reviewer that this is valuable information. We refer to our answer on remark 4. Detailed information about the results, including means, SD’s and other important values will be written in a separate paper about the formative research. However, Appendix 1 provides more detailed information about the results of the separate methods.

7. Page 15/28: “Evaluation plan”: the authors describe an evaluation plan, about 30 PTs, who were submitted to clinical vignettes to measure adherence to the CPGs … as if this pilot study had been conducted. If it is the case, giving more details about the results and the methodology (were the clinical vignettes original or used in the literature,…?) would be necessary.

We added information about the methods of the evaluation plan. Details about the methods and results of the evaluation study are presented in the paper Rutten et al., BMC Health Services Research 2013, 13;194, which has recently been published. We adjusted the reference to this paper. Given the objective of the current manuscript, we believe that the presentation of the results of the evaluation study would be redundant, because this is a step that goes beyond intervention development.

…fidelity, acceptability and feasibility of the program's implementation in an accompanying process evaluation.

For the effect evaluation, we planned a one-group pre-test/post-test study (N=8 practices, including 30 physical therapists 8 of whom were also the quality managers of the practices). We measured adherence to the CPGs on low back pain with clinical vignettes that addressed the 12 indicators reflecting the guidelines’ main recommendations. These vignettes were based on validated vignettes from a previous study, which showed to have acceptable validity (Spearman’s rs = .31) to measure PTs’ guideline adherence {Cohen, 1988 #17;Rutten, 2006 #113;Vorst, 1997 #16}. Clinical reasoning was measured by assessing the consistency of physical therapists’ choices over three separate quality indicators. Consistency in choices was operationalised as the presence of the conditional argument” (if-then connective) which is an important component of human reasoning {Goel, 2007 #907} (e.g. if the therapist found psychosocial factors that influence the course of recovery, than he should integrate them into the treatment plan). We measured changes in practice quality management with observations, group interviews, and document analyses, with a focus on self-regulation, commitment to quality management, transfer of knowledge to the practice, patient recording, regular deliberation meetings, patient outcome measurement, monitoring systems, and structures for sustainability. Further details as well as the results of the evaluation study are reported elsewhere {Rutten, 2013 #945}.

8. Page 17/28: line 8: I think that additional details should be provided regarding the results of the survey (% of PT incline to follow patient’s preference,…).

We added more detail to this phrase:

For example, from the survey we found that almost 80% of the participating physical therapists were inclined to follow the patient’s preferences.
9. Page 7/28, 2nd paragraph: I think it would be relevant that authors make some distinctions between “acute” and “chronic” low back pain which have different consequences.

In the systematic reviews addressing costs of low back pain, we found no distinction between acute and chronic low back pain. This may be due to the problem of the connection between chronic low back pain and chronic widespread pain (Van Tulder et al. Best Pract Res Clin Rheumatol, 2002, 16(5); 761-75). We added the following sentence to this paragraph:

Although only 2-7% of the patients with acute low back pain develop chronic low back pain, recurrent and chronic low back pain account for 75-85% of total worker’s absenteeism.

10. Page 7/28, 2nd paragraph: regarding the main features of the guidelines, authors make a reference to the paper of Bekkering and state that “restricting manual therapy…” is one of the feature. However, in that paper, one can read only “Manual therapy is not included in these guidelines because these techniques demand specific knowledge and skills”. Is the restriction of manual therapy really present in the recommendations stated by Bekkering?

The main features presented in the manuscript are a combination of the Dutch PT, (reference to Bekkering) and the Dutch MPT (reference to Heijmans) guidelines for low back pain. The paper of Bekkering we refer to, describes the development of the first Dutch PT guideline on low back pain. In the revised version (2005) of this guideline, the original version is not available anymore, the authors refer to the Dutch MPT guideline and do not include any recommendations on MPT for low back pain. The Dutch MPT guideline recognizes the limitations of the strength of the evidence and therefore restricts the application of manipulative therapy to only a limited number of patient profiles. Moreover, these recommendations are not based on highly convincing evidence. For the recommendation to avoid manipulative therapy in patients with acute low back pain with a normal course of recovery the MPT guideline refers to the PT guideline of Bekkering. Findings of recent reviews (Dagenais 2010 and the updated Cochrane review of Rubinstein et al., 2011) confirm the view that the effectiveness of manual therapy for acute low back pain is inconclusive and that for chronic low back pain there is a significant, but small short term effect, of which the clinical relevance is doubtful.

To make the distinction more clear we separated the references and replaced manual therapy with manipulative physical therapy:

To support physical therapists as they manage patients with low back pain, the Royal Dutch Association for Physical Therapy developed a national physical therapy {Bekkering, 2003 #101} and a separate manual therapy CPG {Heijmans, 2003 #53}. The guidelines urge clinical reasoning, assessment and management of psychosocial factors, and documentation including outcome measurement. Their four main features are: applying the International Classification of Functioning, Disability and Health (ICF); identifying and applying patient profiles with duration, course, and psychosocial factors influencing recovery; restricting the
application of manipulative physical therapy and limiting the number of treatment sessions; and focusing on patient behaviour to restore physical activity and social participation.

11. Page 8/28, paragraph “Formative Research Methods”: I think that there is a lack of information regarding the “focus groups”: were they groups of PTs, were they 29-30 participants in each group? Regarding the cross-sectional survey, were the participants in the focus groups included in the group of n=472 or were the participants different in both experiments?

For more detailed information on the focus group interviews we refer to our previous publications and to Appendix 1. The surveys were held among a random sample of the membership record of the Royal Dutch Association of Physical Therapy, so we cannot rule out that some of the respondents were also present in the focus group interviews.

12. Page 10/28, last paragraph: authors state that “…two groups of proposed intervention participants, physical therapists and quality managers,…”. Although p15 3rd paragraph, it seems that physical therapists can also be the quality manager…

This refers to remark 3 of reviewer 1. Based on that remark we added the following lines to the Intervention mapping subsection:

Due to issues of quality control and quality certification by health insurance companies, there is a growing tendency in Dutch physical therapy practices to make one of their colleagues responsible for quality management.

13. Table 2: please improve the layout of the table, check the ATT5d.1, the line regarding the psychosocial factors (check the numbers) and please remind the definition of some abbreviations (GL, UE, RL..)

We thank the reviewer for attending us to these shortcomings. The abbreviations UE and RL were part of a previous version of the Table, but are not relevant for this paper. Therefore, we removed them. The other abbreviations are explained or added to the Table headings. Since this is a selection of the complete matrix the numbers of the change objectives may not be in line for every performance objective.

14. Table 3: I wonder whether it wouldn’t be better that the first column is about “Objective”.

This would indeed be an option, however we think Table 3 has a logical sequence as it is. It was build up as follows: Which theory (column 1) was the source for the selected theoretical method (column 2). Which determinant (column 3) is this method linked with and what is the practical application (column 4) that fits this theoretical method. Finally, which objectives does the practical application aim at (column 5). Therefore, we prefer not to change this Table 3.

15. Page 13/28: “program description”: Does this part correspond to your longitudinal survey (n=394)? It is not clear.
In this subsection we describe the program that, in accordance with the Intervention Mapping framework, is the result of all foregoing steps, which on itself are informed by the complete formative research. We mention this in the first sentence of the Intervention Mapping subsection:

Following the Intervention Mapping framework, we completed the following program development steps based on our formative findings.

We noticed that the headings of the various subsections did not follow logical fonts, therefore we adjusted them in line with the main and sub-steps of Intervention Mapping.

16. Page 17/28: the reference number of Michie is lacking.

We added the reference in the text.

- Discretionary Revisions

17. Figure 1: Is it relevant to include the “indicators of adherence” and the “behaviors of the practice managers” in this figure which is related to “physical therapist’s NON adherence”?

This is due to the fact that Figure 1 reflects the logic model of the problem. The problem is PTs non-adherence to their guidelines. The ‘Indicators of Adherence’ reflect the indicators that were used to measure guideline adherence which result in a view on the extent of (non) adherence. Due to the ecological approach of Intervention Mapping more than one level is assessed in relation to this problem. In this study, next to the PT, we also assessed the behaviour of the quality manager, for as far as it relates to guideline adherence of the PTs in the practice. That is why it is important to include them in this logic model of the problem.

18. Table 3: why didn’t you include the references in the bibliography section and use instead [numbers] to refer to it?

We changed the reference style in Table 3.


We thank the reviewer for this attentiveness. We adjusted the sentence: In order to increase the likelihood of goal attainment, in addition, participants added specific plans (implementation intentions) for carrying out their goals {Gollwitzer, 1997 #329}. 

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